



**Provincial Plan for Integrated
Laboratory Services in Alberta**

February 2017

Table of Contents

FOREWORD	1
EXECUTIVE SUMMARY	2
INTRODUCTION	14
METHODS	16
STAKEHOLDER ENGAGEMENT	16
BEST PRACTICE ENVIRONMENTAL SCAN	19
FINDINGS	21
CURRENT LABORATORY SYSTEM OVERVIEW	21
MANAGING THE BUSINESS OF THE LABORATORY	38
BEST PRACTICE ENVIRONMENTAL SCAN	52
OTHER FEEDBACK.....	61
ANALYSIS, RECOMMENDATION AND REQUIRED ACTIONS.....	70
ANALYSIS.....	70
RECOMMENDATION: SERVICE DELIVERY MODEL.....	82
REQUIRED ACTIONS	82
LABORATORY INFORMATION SYSTEM	82
INVESTMENT IN INNOVATION AND TECHNOLOGY.....	83
ORGANIZATION OF LABORATORY SERVICE DELIVERY	83
DIAGNOSTIC TEST MENU	84
STANDARDIZATION	87
OPTIMIZING LOGISTICS	88
OPTIMIZING FACILITY INFRASTRUCTURE.....	89
ENSURING ACCESS TO SKILLED LABORATORY PROFESSIONALS	89
ACCREDITATION	90
TRANSLATIONAL RESEARCH, INNOVATION AND ECONOMIC DEVELOPMENT.....	90
APPENDIX A – STAKEHOLDERS.....	92
APPENDIX B – PROVINCIAL RESOURCE GROUP - MEMBERSHIP LIST	94
APPENDIX C – BIBLIOGRAPHY	96
APPENDIX D – CPSA LABORATORY ACCREDITATION	102
APPENDIX E – LABORATORY ORGANIZATIONS CONSULTED IN BEST PRACTICE REVIEW	112
APPENDIX F - TRANSLATIONAL RESEARCH WORKSHOP	122
APPENDIX G – CALGARY LABORATORY SERVICES - SERVICE DELIVERY MODEL	133
APPENDIX H – COST / TEST COMPARISON	139
LIST OF FIGURES.....	142
LIST OF TABLES	142

GLOSSARY OF ACRONYMS	143
REFERENCE LIST	146

Foreword

Lab services are one of the most critical and sometimes underappreciated areas of our healthcare system. Every day patients and providers across Alberta make important decisions about care based on the results of laboratory diagnostics. Thousands of laboratory physicians, scientists, technologists and other staff work to serve the needs of Albertans in a timely way.

Hundreds of these individuals took the time to talk to us as we developed a *Provincial Plan for Integrated Laboratory Services in Alberta*. Their dedication and commitment to both patients and high-quality laboratory services was obvious in all of their engagement with the project team. Staff, medical and scientific professionals, and senior managers from Alberta Health Services, Calgary Laboratory Services, *DynaLIFE*, Covenant Health, Lamont Health Care, and Medicine Hat Diagnostic Laboratory generously gave their time, energy and forthright input to a multitude of discussions about how we could better meet the needs of Albertans in this important area of healthcare.

Others outside the service delivery sphere also shared their thoughts and suggestions with us including non-laboratory clinical groups, regulatory colleges, training and research institutions, patient advisory councils, professional associations and unions in the laboratory sector, and staff from Alberta Health and other ministries and agencies across the Government of Alberta. Over the last eight months we also talked with senior leaders of leading laboratory service organizations across the world, learning about their challenges and experiences – we are very appreciative of the time and effort they contributed to this project.

We would like to thank the Provincial Steering Committee, chaired by the Deputy Minister of Health, who provided us guidance and clear direction during this work and the Alberta Health Services executive sponsors of the Provincial Laboratory Services Project, who enabled our work. We also want to extend a sincere thank you to Penny Ballem, MD, FRCP, FCAHS, who served as the project lead and principle author of this report.

The unique business of laboratory services is the fastest changing area of healthcare. Our review of the current status and suggestions for moving ahead are grounded in the need to adapt quickly to the many challenges and to ensure laboratory services in Alberta are a sustainable, integrated, and high quality sector in our public healthcare system.

Executive Summary

The laboratory diagnostic sector is unique in the health system. Accounting for just 3.5 per cent of the total health budget, the results of laboratory diagnostics inform and impact over 70 per cent of healthcare decisions. The timely delivery of laboratory services is vital in sustaining patient care on a daily basis and in enabling the health system to function efficiently. Whether it is testing prior to initiating weekly chemotherapy, before a patient can be discharged from hospital, or adjusting anticoagulants for a patient in the community, an effective and efficient laboratory diagnostic sector is essential to optimal patient outcomes and a high functioning and high quality healthcare system.

The laboratory sector is changing rapidly and the last 15 years have been particularly remarkable with molecular diagnostics transforming many of the sub-disciplines of laboratory medicine. However, the cost of meeting volume pressures, an aging population, new testing demands, and needed investment in rapidly evolving diagnostic and information technology is a significant challenge for diagnostic laboratories everywhere. Given these challenges, many jurisdictions and providers of laboratory services are focusing on innovative models for service delivery to support ongoing transformation of the laboratory sector to ensure the financial sustainability of high quality and accessible laboratory services.

Beyond the provision of service, research and innovation in the diagnostic laboratory sector can also be an important economic driver. In Alberta, there are untapped opportunities for economic benefits through the translation of diagnostic laboratory innovations developed in the local research community for application in the care of patients here and around the world.

In May 2016, the Minister of Health released the report by the Health Quality Council of Alberta (HQCA) on laboratory services in Alberta. The report, *Moving Ahead on Transformation of Laboratory Services in Alberta*,¹ made a number of recommendations. In response, the Minister directed that a project team be established under a Steering Committee of senior officials and that work proceed in an expedited manner on four major themes:

1. A provincial plan for integrated laboratory services in Alberta
2. One laboratory information system for the province
3. Planning for new laboratory infrastructure to meet the urgent needs in Edmonton
4. A robust stakeholder engagement process to support these processes

The Provincial Laboratory Services Project Steering Committee, whose members include the Deputy Minister of Health (Chair), the Deputy Ministers of Alberta Infrastructure, Advanced Education and Finance, the CEO of Alberta Health Services (AHS), and the CEO of the HQCA was established by the Minister of Health to provide oversight and direction to the Project Team.

Significant progress has been made on the four themes of the Provincial Laboratory Services Project since May 2016:

- In 2016, the Government of Alberta committed capital funds toward a new province-wide clinical information system (CIS) for AHS. A new laboratory information system (LIS) is part

of that project. Procurement of the LIS, as part of the CIS project, is well underway with a final decision targeted for September 2017.

- The 2016 Government of Alberta capital budget also committed planning funds for a new, state of the art hub laboratory facility in Edmonton, to address urgent facility issues referenced in the HQCA report. Development of the business case for the hub laboratory is underway and is targeted for completion in April 2017.
- In September 2016, as part of assuring continuity of laboratory services in the Edmonton zone, pending the construction of the new hub laboratory, AHS reached an agreement for the extension of the *DynaLIFE* laboratory services contract to 2022. At that time services currently provided by *DynaLIFE* will be consolidated into the new facility.

This report responds to the request by the Minister for a provincial plan for integrated laboratory services in Alberta. In support of the report, an extensive engagement process was undertaken with stakeholders in the laboratory sector; involving over 1,400 individuals from around the province. Various mechanisms were made available to ensure engagement of the diverse stakeholders, working groups, and committees in and around the laboratory sector. The process provided opportunities to share specialized knowledge and innovative ideas, experience with the current laboratory system, identification of successful initiatives and areas where improvement is needed in the laboratory sector. A Provincial Resource Group was created which provided an important forum where representatives of all the key constituencies were able to come together in one place to discuss and provide input to the different elements of the provincial laboratory project.

In addition to the engagement process, a review of the literature and of 10 leading laboratory service organizations around the world was undertaken with a clear focus on large organizations in the public or non-profit sector who are responsible for providing integrated laboratory diagnostic services across multiple facilities. Discussions with these organizations focused on their current strategies and experiences in meeting the significant challenges of delivering high quality laboratory services to their constituents. Key challenges were identified across all jurisdictions:

- Increasing demand from an increase in volume due to population growth and aging, and the demand for new innovative tests by patients and clinicians;
- The need to introduce new game-changing technologies and tests and remove older diagnostic tests which are no longer best practice;
- Static or shrinking resources and in some jurisdictions the need for payment reform;
- Resistance to change from within the laboratory service organization and from healthcare providers;
- Broad diversity across ‘customers’ (e.g., large complex academic and regional healthcare centres, small rural sites, diverse individual community healthcare providers) and challenging geography in some jurisdictions; and
- Multiplicity of information systems.

Since 2008, AHS has had overall accountability for laboratory diagnostic services which are delivered by six different organizations in the province. Of the six delivery organizations, three (AHS, Calgary Laboratory Services (CLS) and *DynaLIFE*) account for 95 per cent of the laboratory testing and 96 per cent of the budget for laboratory services in the province. Covenant Health, Lamont Health Care Centre and Medicine Hat Diagnostics, together, deliver the other 5 per cent of services.

Key metrics which summarize the laboratory sector in Alberta include:

- 2.3 million unique patients served per year
- 2.9 million patient encounters with laboratory services; two-thirds in the community and one-third in AHS facilities
- 75 million tests performed annually; over 200,000 tests performed daily
- 133 laboratory facilities
- approximately 5,000 staff
- 6 organizations delivering laboratory services
- approximately \$700 million annual budget

These metrics are significant in that the volume of activity far exceeds any other operational area in AHS. In addition, laboratory services is also responsible for providing service to patients and providers in the community sector, where the majority of patient encounters with laboratory diagnostic services occur.

Based on a review of reports on transforming laboratory services from Canada and other jurisdictions, the scientific literature, and interviews with 10 leading organizations, the following key elements which are critical to the provision of sustainable, high quality integrated services in this unique area of healthcare were identified:

1. **A robust strategic plan.**
2. **Clear leadership structure with transparent decision-making processes.**
3. **One LIS across the organization.**
4. **Regular investment in innovation and new technology.**
5. **Strategic organization of the delivery of services:**
 - **Optimal integration and consolidation of the system.**
 - **Tiering of the scope of services by site based on size, function and location**, while ensuring structured support from medical, scientific and technology leaders in regional and academic centers through a hub and spoke model.
 - **Hub laboratories** to support economies of scale and opportunity for technological innovation.

- **Point of care testing** to support better, more convenient and cost effective access to laboratory services.
 - **Sophisticated and patient-centred pre-analytical logistics.**
 - **Standardization** of equipment and testing menus across the organization to leverage economies of scale and ensure equity of access for patients.
6. **Comprehensive quality programs across the laboratory system.**
 7. **Academic partnerships to support the integration of research into practice.**
 8. **Capacity and strategies to enhance performance** (efficiency, value for money and the ability to introduce game-changing diagnostic programs) on an ongoing basis supported by:
 - **Processes for nimble decision-making.**
 - **Appropriate programs and support for appropriate utilization management.**
 - **Structures for ongoing engagement of medical and scientific leadership.**
 - **Robust analysis of evidence, business and clinical metrics to support decisions and evaluate their impact over time.**
 - **Change management and business process redesign skills** across the organization.

In assessing the current state of laboratory services and reviewing the engagement feedback in relation to the elements for success cited above, there was strong consensus from across the province that the laboratory sector in Alberta is at a key milestone, a tipping point where change is needed in order to provide sustainable and high quality laboratory services to Albertans. The status quo was not seen as viable.

A key issue identified was the complexity of accountability and decision-making structures in AHS with no single point of accountability for laboratory services. This has resulted in prolonged processes and long delays for decision-making, uneven implementation of decisions, and a resulting lack of nimbleness in the ability to respond to the needs of the laboratory sector. There are four vice-presidents with accountability for laboratory services in the AHS organization and this fragmented accountability structure, combined with six different organizations providing diagnostic laboratory services, is at the root of these issues. The impact of this has permeated many different areas of activity including the quality program, decisions related to the introduction of new tests or technology (including point of care testing), the ability to move ahead and optimize the advantages of standardization, consolidation of testing, and the move to one laboratory information system. Even the move to a single test requisition form for laboratory services across AHS has been under discussion for over three years without resolution.

The lack of sufficient investment in equipment and technology and the lack of resources for supporting laboratory information systems, both of which are the lifeblood of a high quality laboratory sector, was a universal concern brought forward from the stakeholder engagement. The aging laboratory equipment in AHS and CLS and the lack of an appropriate clinical platform for molecular diagnostics to serve the province were concerns expressed by all during the engagement process. Many of the medical and scientific staff and leaders expressed their grave concern that the

ability to provide patient care was being compromised because of these issues and Alberta was falling behind its peers.

The LIS is the foundation for laboratory operations, and is the information highway to and from ordering physicians and their patients. The day-to-day operating environment of the laboratory requires constant changes to the LIS. Delays in resources to make those changes compromises implementation of quality initiatives, access to the operating system by new staff, ability to standardize or change reference ranges, or add new tests or changed methodologies into the system. The chronic lack of information technology resources available to support laboratory operations was another important theme from the engagement process.

The recent decision by the Government of Alberta to provide resources for a new CIS for AHS will include a new LIS. This announcement was welcomed by laboratory leaders as an important step forward in optimizing the integration, quality and safety of laboratory services. The roll out of a new CIS is currently projected to take 10 years. The hub and spoke system for laboratory service delivery which is evolving in the province means that patient specimens are moving by the thousands on a daily basis across information system boundaries. This requires the implementation plan for the LIS be carefully planned and rolled out over a much shorter timeframe to mitigate lapses in the flow of vital information to providers in support of patient care decisions. In addition, the LIS will also be implemented across the community sector which constitutes a much broader scope of coverage than the rest of the CIS. There was significant concern expressed from the stakeholders that the resources for the rollout of the LIS would not be adequate to ensure that different parts of the province were not compromised during implementation.

The physical state of laboratory facilities in Edmonton has long been a topic of concern with the majority of investment in laboratory facilities in the last 15 years occurring in the Calgary region. At the time of the release of the HQCA report in May 2016, this was a significant concern. The commitment by the government for funding for planning, and the initiation of the planning process in November 2016 for a new hub laboratory in Edmonton, has been very well received by the stakeholder community.

During the engagement process the voice of the many small rural sites in the laboratory network was heard. Laboratory staff from rural sites understood the need for change, felt they were part of the network of laboratories across the province, and were included in different discussions. However, they also expressed that there was often not an adequate appreciation of the challenges they face, particularly their capacity for and the pace of ongoing change. Some also expressed the fragility of the professional/scientific support systems and the lack of a clear and explicit structure delineating roles and responsibilities of both regional and hub laboratories for supporting their activities. Finally, while they understood the best practice of a hub and spoke model, the need for robust logistics and information systems to support the flow of specimens and information in support of this model was critical, and in some situations lacking.

Providing diagnostic laboratory services is a unique business in healthcare. The complexity and sheer daily volume of laboratory diagnostics, high rate of change and innovation, critical dependence on information from the diagnostic laboratory for daily patient care decision-making, financial sustainability challenges, along with growing volume demands and requests for new tests,

have pushed many healthcare organizations (both public and non-profit) to look for more effective ways to deliver laboratory services. Delivery organizations for laboratories are unique in that unlike any other part of healthcare, the patient can stay in one place but their specimen can travel long distances for testing. This has allowed the laboratory sector to take advantage of significant economies of scale, consolidation, and standardization in a way that is unique in the health sector. It also requires significant logistical systems to ensure appropriate tracking and movement of specimens around the network.

As public and non-profit health service delivery organizations have been merged and consolidated into larger and significantly more complex organizations, it is becoming more difficult to sustain a focus on the fast paced, sophisticated, technology dependent laboratory operation in an environment of the day-to-day stresses and competing priorities characteristic of these comprehensive health service organizations. Gradually, there has been a trend in Canada and in other jurisdictions toward the establishment of stand-alone public and non-profit laboratory service organizations with the responsibility of providing financially sustainable, high quality, integrated laboratory diagnostic services to the health system. Of the 10 leading laboratory organizations reviewed, seven were stand-alone laboratory service providers. They were either an agency of the local Ministry of Health or a wholly owned subsidiary of a public sector or non-profit comprehensive health service delivery organization(s). One laboratory service delivery organization, in the United Kingdom, is a joint venture between two major National Health Service Hospital Trusts and a private sector laboratory.

The following key attributes were cited as contributing to the success of a stand-alone laboratory service organization:

- an ability to focus exclusively on the dynamic and fast paced laboratory operations providing high quality services to patients;
- a skilled Board, which includes laboratory expertise to optimize the performance of the organization;
- nimbleness to move quickly and effectively leverage economies of scale, consolidation opportunities, standardization, utilization management and other strategies to remain financially sustainable;
- enhanced engagement and alignment of pathologists and other laboratory professionals to the goals of the core business and their role in enhancing patient care;
- increased financial flexibility with the ability to reinvest savings, from efficiencies and external revenue streams, back into the operation for further enhancements;
- increased opportunities for strategic partnerships with the private sector, academia, and other health service delivery organizations to achieve strategic objectives; and
- the opportunity to create receptor capacity for innovation and translational, or applied research, which can benefit patients and leverage economic benefits.

The current state analysis of laboratory services in Alberta and feedback from extensive stakeholder engagement strongly suggests that laboratory services, as currently structured in the

province, are not sustainable and are unable to achieve the goals of a high quality integrated system serving the needs of patients in Alberta. Serious consideration should be given to moving to a more strategic organizational model to address the significant issues and restore the confidence of the stakeholders in the laboratory sector. Furthermore, based on the assessment conducted by Boston Consulting Group for AHS in 2013, a high functioning laboratory organization with engaged professionals and a comprehensive utilization management program will be able to achieve significant financial reductions over the next 10 years from the current cost trajectory.

An important consideration for moving to a stand-alone organizational model is that there is precedent in Alberta for this approach to delivering laboratory services. CLS is a stand-alone agency, originally a joint venture of the Calgary Health Region and two private laboratories, and now a wholly owned subsidiary of AHS. In a careful review of CLS and through discussions with both retired and current leaders and staff, it is clear that many of the attributes described by stand-alone laboratory organizations across the world were fundamental to the achievements of CLS over the years. Many jurisdictions in the best practice review reference the leadership model of CLS in laboratory service delivery. By 2008, when AHS was founded, CLS had already established a consolidated hub and spoke model serving 13 hospitals, the community sector and 3 health centres in the Calgary region. In 1996, CLS moved to a single LIS for its network of laboratories and built the first hub laboratory in the public sector in Canada in 2003 and, according to stakeholders, CLS was consistently the first in Alberta with new diagnostics for patients in the Calgary region. Under its founding governance model, CLS was encouraged and successful in attracting external revenues from clinical trials and other external service contracts; generating net revenue which was systematically reinvested in diagnostic technology and in-house research. This local case study in the public sector of a stand-alone model of laboratory service delivery was ahead of its time, and it provides important learnings and reassurance as to the robustness of the model and its feasibility in Alberta.

Over the next few months the significant initiatives which are already underway regarding the future of the laboratory will require strategic guidance and decisions. These include the planning for a new state of the art hub laboratory in Edmonton; the procurement of a new LIS and the detailed planning for implementation; and the planning for the transition of *DynaLIFE* staff and services in 2022 into the new provincial laboratory model. In addition, there are a number of strategic initiatives and opportunities related to advancing the translational research agenda for laboratory diagnostics which are coalescing at this point. These include the completion, in January 2017, of the Alberta Precision Health Prospectus which maps the key opportunities across Alberta in this exciting area of healthcare and identifies laboratory diagnostics as a key area of involvement; the Genome Canada 2017 Large-Scale Applied Research Project Competition in Genomics and Precision Health; and the ongoing planning for a new CLS molecular diagnostic laboratory at the new Calgary Cancer Centre. An expedited decision in regard to the future governance of laboratory services for the province would enable both better management of risk and enhanced leverage of opportunities which are currently in play.

The following recommendation and required actions are designed to lay the foundation for addressing the significant issues which face the laboratory sector in Alberta today. The primary recommendation relates to the need for a new, more responsive organizational structure to address

the unique dynamics of a clinical service which is critical to all patients, no matter what their health problem. The required actions that follow address issues which need urgent attention to support a new service delivery model with the goal of achieving a high quality integrated laboratory service for all Albertans.

Recommendation: Service delivery model

Create a Public Agency (Health Board) under the *Regional Health Authorities Act* with the mandate to govern, oversee, and deliver globally competitive, high quality integrated laboratory services across the province.

Required actions

In addition to the model of service delivery, the following required actions would be a high priority for the Public Agency.

Laboratory information system

1. On an expedited basis, commence development of a strategic plan for the implementation of the LIS, pending selection and finalization of the contract with the new LIS/CIS vendor by AHS.
2. Ensure the availability of appropriate information technology resources within the laboratory organization to support day-to-day operations, the needs of clinicians, and effective utilization management.

Investment in innovation and technology

1. Develop a menu of appropriate funding mechanisms and related policies to enable and support regular capital investment in equipment and technology.
2. Develop a plan based on the use of the various funding mechanisms to support an annual allocation of 2.5 - 3.5 per cent of operating revenue (based on the industry benchmark) for investment in equipment and technology.
3. Develop an asset management plan for laboratory equipment and technology aligned with best practice, as a roadmap for investment.
4. Standardization of equipment should be the default policy with consideration of ongoing opportunities for consolidation of testing platforms at the time of major capital investment.

Organization of laboratory service delivery

1. Continue to evolve and optimize the tiered hub and spoke model for the delivery of laboratory services across the province.
2. Expedite the planning, design and, pending approval by government, construction of a new state of the art hub laboratory in the Edmonton zone. The hub laboratory will consolidate community services currently delivered by *DynaLIFE*, public health and genetics laboratories; all services from the Edmonton hospitals (other than rapid response requirements); and specialized testing for regional and small hospitals in adjacent zones.

3. Develop a multi-pronged best practice strategy to ensure an ongoing effective interface with non-laboratory clinicians in Edmonton hospitals impacted by the consolidation of services in the new hub facility.
4. Ensure appropriate infrastructure for digital pathology in the new hub laboratory.
5. Strengthen, clarify and formalize the relationship between small rural sites across all AHS zones, and the regional and hub laboratories to ensure small rural sites have structured and reliable access to the expertise needed to sustain high quality service for patients and clinicians.
6. Establish a formal Provincial Rural Program reporting to the executive leadership of the agency with a specific mandate to work with small rural sites to optimize their role and more effectively address their issues.
7. Work with Covenant Health and Lamont Health Care Centre to develop a delegated management services agreement or a contract for delivery of services to their facilities to enable enhanced integration and quality of service delivery to patients and clinicians.

Diagnostic test menu

1. Finalize and implement on an expedited basis a streamlined and evidence based process for review and approval of the addition, removal, or limitation of use of diagnostic tests:
 - a. Build on the proposed framework illustrated in Figure 18.
 - b. Establish a provincial formulary for laboratory diagnostic tests.
2. Work with Alberta Health on a principle-based approach for funding of new diagnostic tests. Consider a tiered/cost shared approach based on the concept of materiality to implement new diagnostics:
 - a. Level 1 Materiality: < \$200,000 annualized cost. Laboratory services absorbs the cost through savings related to consolidation, standardization, efficiencies, utilization management, and removal of outdated tests.
 - b. Level 2 Materiality: \$200,000 - \$2 million annualized cost. Cost sharing between laboratory services envelope and AHS global budget.
 - c. Level 3 Materiality: >\$2 million annual cost. Cost sharing between laboratory services envelope, broader AHS global budget, and Alberta Health.

(Note: these levels of materiality are proposed only and require further discussion)

3. Review on a regular basis the business case for repatriation of tests currently referred out of province to assess if “in-house” testing would be more cost effective. Net savings could be applied to the implementation of new diagnostics (budget for referred out diagnostics in 2015/16 was \$5 million). Continue to actively triage referred out tests to ensure appropriateness.
4. Establish point of care testing (POCT) as a fully accredited provincial program under laboratory services:

- a. Utilize a co-director model for program leadership – a laboratory clinician leader and a non-laboratory clinical leader.
- b. Integrate the review of new POCT tests into the test review process outlined above.
- c. Develop a transparent methodology for funding the POCT program and any new POCT diagnostics. The funding methodology should recognise any non-laboratory system savings and efficiencies and ensure they are helping support the funding of new POCT diagnostics.

Standardization

1. Create an organizational policy on standardization.
2. Formalize the criteria informing a decision to standardize. Criteria could include the following:
 - a. Impact on patient safety and patient outcomes.
 - b. Feasibility of moving to the standard and ability to sustain the standard.
 - c. Risk identification and adequate risk mitigation plans.
 - d. Opportunity for innovation.
 - e. Cost impact (total cost) up front and over the life of the asset, process, or policy.
3. Formalize the process to manage requests for exceptions by clarifying the criteria and decision-making process.

Optimizing logistics

1. Establish one provincial program responsible for logistics supporting the provincial integrated laboratory system.
2. Address current gaps in performance with rural sites as a priority.
3. Engage global expertise in logistics management through strategic partnerships and personnel recruitment.

Optimizing facility infrastructure

1. Review consolidation opportunities in the hub laboratories in Calgary and Edmonton, or, in the five regional hub laboratories at the time of planning for any new laboratory facility or any significant renovation of an existing facility.
 - a. Drivers for these decisions would include changing clinical practice and patient needs; the transformational impact of new technology (including POCT); digital pathology initiatives; staffing and medical/professional capacity; the need to address recruitment challenges; and capacity for enhanced logistics support.
2. Planning for any new facility should ensure best practice design that offers maximum flexibility over time given rapidly changing technology which impacts the look, size, and design of clinical diagnostic laboratories of the future.

Ensuring access to skilled laboratory professionals

Technologists

1. Establish one consolidated provincial platform to work with the three training institutions to ensure effective leverage of the full scope of clinical placements available across an integrated provincial laboratory system.
2. Examine the feasibility of a new simulation laboratory to support ongoing training needs for students in the south of the province.
3. Establish regular discussions with the licensing bodies to ensure they leverage their statutory powers under the *Health Professions Act* to ensure the required competencies align with the needs of the provincial system, while not compromising their obligations under the inter-provincial Internal Trade Agreements.

Pathologists

1. Develop a provincial strategy with the Departments of Laboratory Medicine and Pathology at the University of Calgary and University of Alberta to address the shortage of general pathologists who are key to the regional laboratories and their support of small rural sites in Alberta.

Accreditation

1. Continue to support the move to a program of individual certificates of accreditation by site versus one certificate for all laboratories in each delivery organization. Anticipate and work with the CPSA to address the challenges of accrediting the different activities consolidated in the hub laboratories in the network.
2. Continue to support the work toward a western accreditation program across Manitoba, Saskatchewan, Alberta, and British Columbia.

Translational research innovation and economic development

1. Establish an effective program of translational research (TR) which will support the Alberta Precision Health initiative and allow the integration of innovative and value add technologies and diagnostics into patient care and the delivery of healthcare, while contributing to economic growth and diversification.
2. Include translational research space in the business case and functional program underway for the new hub laboratory in Edmonton.
3. Finalize a province-wide governance structure for TR which will be accountable for optimizing the results of the new TR program through direction setting, oversight and reporting.
4. Develop a business case for the provision of core funding for TR with targets based on published benchmarks for leverage from the investment.
 - a. Clarify priorities for first five years based on current assets in the province including initiatives and strategies related to the Provincial Precision Medicine Initiative.

- b. Formalize partnerships with key stakeholders (Universities, AHS, Alberta Innovates, Institute of Health Economics, Government of Alberta, industry) to optimize program support.
- c. Create key metrics and targets for assessing success in terms of both health and health system outcomes and economic benefits.
- d. Identify and pursue key external revenue opportunities.

Introduction

In May 2016, the Minister of Health released the report by the Health Quality Council of Alberta (HQCA) on laboratory services in Alberta. The report, *Moving Ahead on Transformation of Laboratory Services in Alberta*,¹ made a number of recommendations. In response, the Minister directed that a project team be established under a Steering Committee of senior officials and that work proceed in an expedited manner on four major themes:

1. A provincial plan for integrated laboratory services in Alberta
2. One laboratory information system for the province
3. Planning for new laboratory infrastructure to meet the urgent needs in Edmonton
4. A robust stakeholder engagement process to support these processes

The Provincial Laboratory Services Project Steering Committee was established by the Minister of Health to provide oversight and expedited decision-making to the Project Team. The Committee is chaired by the Deputy Minister of Health and the members include: the provincial Deputy Ministers of Advanced Education, Finance, and Alberta Infrastructure; and the Chief Executive Officers of Alberta Health Services (AHS) and the HQCA. The Project Team provide ongoing support to the Steering Committee.

In addition to the development of a provincial plan and the related engagement process, which is the subject of this report, significant progress has been made on other elements of the project.

Laboratory information system (LIS)

- AHS clinical information system (CIS) project - financing has been approved by the Government of Alberta for a new CIS for AHS and the LIS will be a key module of the CIS. Phase One of procurement (identifying the shortlisted proponents) for the CIS is complete; Phase Two is now under way, and will identify the preferred CIS and evaluate whether the laboratory module of the accepted CIS is acceptable, or if procurement of a best of breed LIS is necessary. Completion of Phase Two is currently targeted for May 2017.
- Provincial patient health portal - a project is underway to enable the public to access key laboratory data through the portal. Results on approximately 50 of the most highly utilized laboratory tests will be made available to patients across Alberta. *New laboratory infrastructure for Edmonton*
- Business continuity in the Edmonton zone - from May 2016 to September 2016, negotiations took place between *DynaLIFE* and AHS regarding the possibility of extending the *DynaLIFE* contract beyond the end date of March 31, 2017. On September 30, 2016, an agreement was reached extending the service contract term for five years to 2022. End of contract terms support the development of a plan for a seamless transition of services currently provided by *DynaLIFE*, including the transition to AHS of staff, diagnostic and other assets and infrastructure which support the operations.
- Funding for planning of a new hub laboratory in Edmonton was included in the 2016 capital budget for Alberta Infrastructure (AI). In June and July of 2016, the Steering Committee

reviewed a long list of potential sites for a new laboratory against a decision-making framework developed by AI.

- o A short list of sites was confirmed by the Steering Committee in July 2016.
- o A consultant team was hired in September 2016 to develop the business case and make recommendations on the final site.
- o Technical user groups providing input to the business case commenced discussions at the end of November 2016.
- o The business case is targeted for completion in April 2017.

The work which has been completed to date on the Provincial Laboratory Services Project has set the stage for completing the provincial plan for integrated laboratory services in Alberta. The plan has been developed based on extensive engagement of stakeholders across the province, review of best practice organizations and analysis of key metrics from laboratory services in Alberta.

Laboratory services are an integral component of healthcare impacting the majority of healthcare decisions. Appropriate use of diagnostic laboratory testing is essential for achieving safe, effective and efficient care for patients.^{2, 3, 4} The laboratory sector is unique in the health system. No other part of healthcare is as technology intense, with such a rapid cycle of innovation resulting in a steady demand for new diagnostic tests as well as opportunities for transforming laboratory operations.^{5, 6} The last 15 years have been particularly remarkable with molecular diagnostics transforming many of the sub-disciplines of laboratory medicine.^{7, 8, 9} However, the cost of meeting both volume and new testing demands is a significant challenge for diagnostic laboratories everywhere. Given these challenges, many jurisdictions and providers of laboratory services are focusing on innovative models for service delivery to transform the laboratory sector to ensure the financial sustainability of high quality and accessible laboratory services.

Beyond the provision of service, research and innovation in the diagnostic laboratory sector is an important economic driver.^{10, 11, 12} In Alberta, there has been significant investment in discovery research and, in the area of laboratory diagnostics, there are untapped opportunities for further economic benefits through the transfer of diagnostic laboratory innovations developed in Alberta into care for patients here and around the world.

Change is happening quickly in the unique business of laboratory diagnostics.^{13, 14} This report provides an overview of the current status and structure of laboratory service delivery, insight into areas where Alberta is falling behind peers, identifies opportunities which are waiting to be leveraged in the province, and finally outlines key steps which need to be taken to ensure the laboratory diagnostic sector is effectively integrated, providing high quality services to patients, financially sustainable and contributing to the economic objectives of the government.

Methods

Stakeholder engagement

In accepting the recommendations from the Health Quality Council of Alberta's (HQCA) report, the Minister was very clear that wide and comprehensive stakeholder engagement was essential to ensure the success of the project moving forward. The engagement process was designed to engage numerous stakeholders representing all facets of laboratory services and to build on the extensive discussions and consultations undertaken as part of the Alberta Health Services (AHS) request for proposal for laboratory services which took place in 2014 and 2015.

Many stakeholders are involved in delivering laboratory services across the province; others are customers or clients of laboratory services. Post-secondary institutions train the staff who work in the laboratory sector; other organizations in the province are responsible for accrediting and regulating laboratory facilities and the health professionals who work in them. There is also a broad academic community who are involved in research related to laboratory medicine. Various mechanisms were made available to ensure engagement of these diverse groups, providing them opportunities to share specialized knowledge and innovative ideas, identify initiatives which have been successful, and areas where improvement is needed in the laboratory sector.

Between May 2016 and December 2016, 1,400 stakeholders from across the province contributed to the discussions, through teleconferences, videoconferences, in-person meetings, town hall meetings, and site visits. In addition, presentations were made to various stakeholder committees and networks which are part of the ongoing operations of the laboratory sector (Figure 1 and Figure 2) (see Appendix A – for the list of stakeholders).

Figure 1: Consultation activities May to December 2016

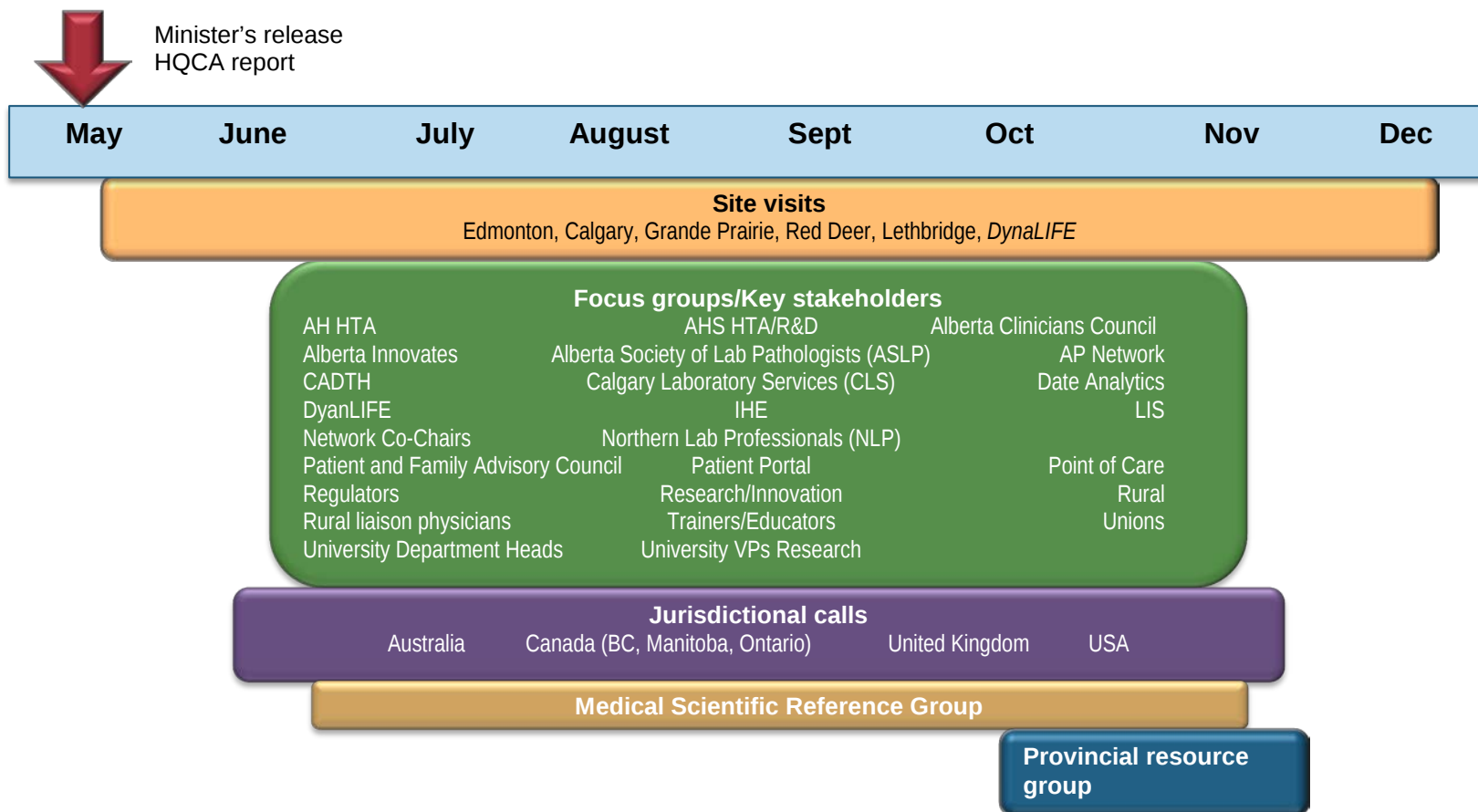
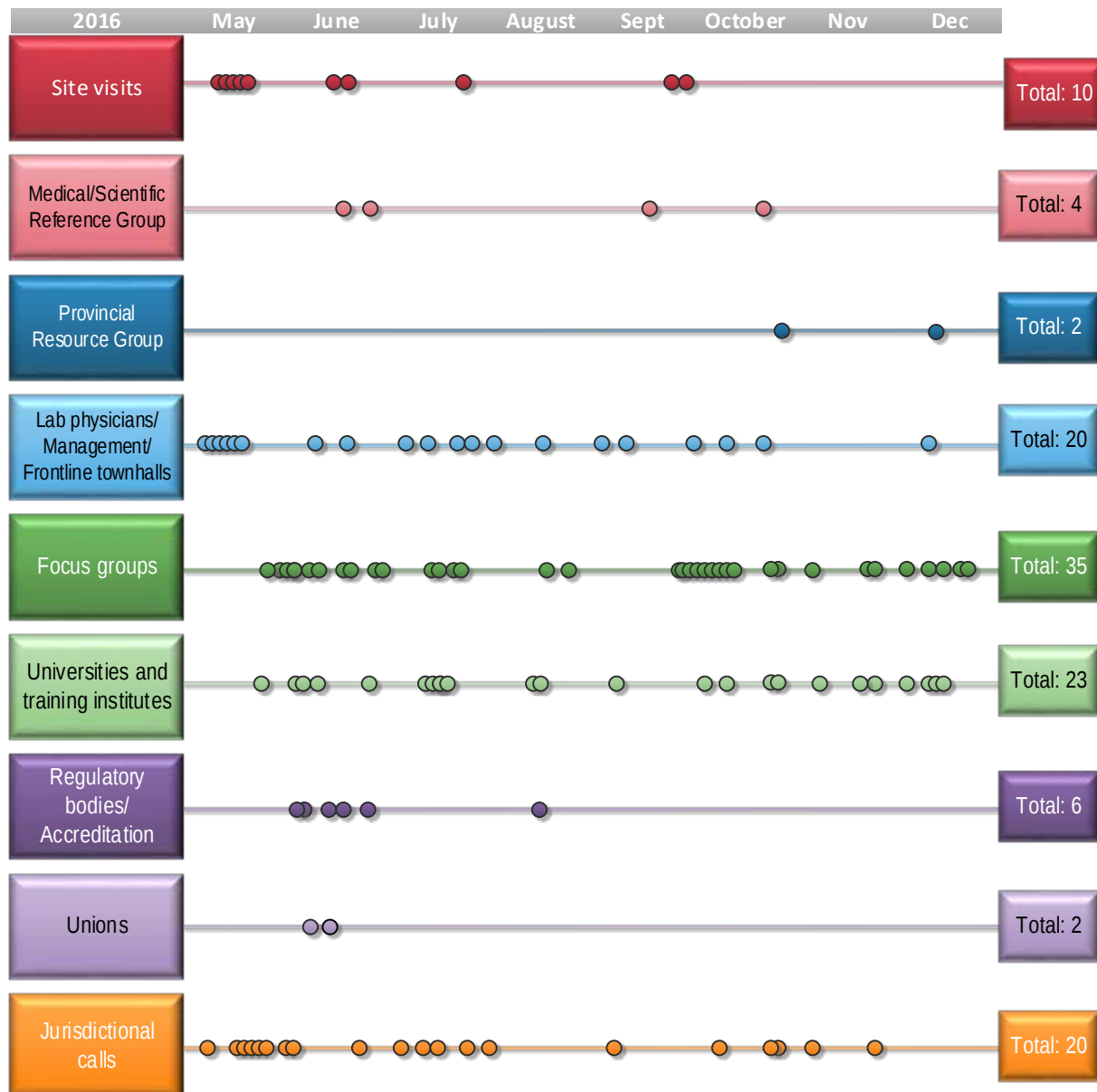


Figure 2: Consultation frequency



The discussion topics ranged from organizational structure and processes related to laboratory services to highly technical discussions about point of care testing, laboratory information systems, translational research, standardization and others. Special attention through the process was paid to the issues faced by rural sites in the province. Overall, the process endeavoured to access the vast expertise of both individuals and groups with an interest and commitment to sustainable high quality laboratory services.

Provincial Resource Group (PRG)

This group was created at the specific request of the Minister and was designed to ensure that representatives of all the key constituencies were able to come together to discuss and provide

input to the different elements of the provincial laboratory project (see Appendix B – for membership). The membership of the PRG included representatives from the following groups:

- Patients
- Health profession regulators
- Accrediting agencies
- Primary care and medical specialist providers
- Healthcare delivery organizations – nursing, administration, physicians (including Covenant Health)
- Laboratory medicine providers – medical, scientific and technical, including front-line staff
- Public health and Genetics laboratory leaders
- Unions and health professional associations
- AHS and Calgary Laboratory Services (CLS) management and laboratory leaders
- Universities, Southern Alberta Institute of Technology and Northern Alberta Institute of Technology – Vice Presidents’ Research; Deans; Heads of laboratory medicine and pathology
- Alberta Health

Many members of the PRG were involved in other aspects of the stakeholder engagement process; however, by bringing them together it provided an opportunity for the members to collectively share their perspectives, ideas, and concerns which resulted in a more robust and enriched discussion.

Medical Scientific Reference Group

This committee included key medical and scientific leaders in Laboratory Medicine, Pathology and Genetics in Alberta. Specifically, the Department Heads of Pathology and Laboratory Medicine from the University of Alberta and University of Calgary (who also serve as Edmonton and Calgary zone Laboratory Medical Directors respectively); the Provincial Medical Director for Laboratory Services; the zone Laboratory Medical Directors from the North, Central and South zones; the Directors of Genetic Laboratory Services and Public Health Laboratories; and the heads of the Alberta Medical Association (AMA) Section of Laboratory Physicians and the Northern Laboratory Physicians. This group provided input, advice and served as a sounding board throughout the development of the provincial plan.

Best practice environmental scan

A comprehensive literature review on laboratory system transformation was undertaken with support from a medical librarian (see Appendix C for the bibliography). In addition, the networks of both the HQCA and senior laboratory leaders in Canada were leveraged to enable discussions with both national and international best practice health organizations (Table 1) who deliver integrated laboratory services to large numbers of patients through a geographic network of facilities.

Table 1: National and international best practice organizations

Canada	Manitoba – Diagnostics Services Manitoba
	Ontario – Eastern Ontario Regional Laboratory Association (EORLA)
	British Columbia – BC Agency for Pathology and Laboratory Medicine (BCAPLM)
USA	Kaiser Permanente
	Intermountain Healthcare
	Health Partners
	Mayo Medical Laboratories
	ARUP Laboratories (University of Utah)
UK	Health Services Laboratory (University College London Hospitals/Royal Free London/Doctor's Laboratory)
Australia	New South Wales Pathology

By design, the engagement process ensured that the plan builds on the experiences of others facing similar challenges in the publicly funded or non-profit laboratory services sector, embeds key elements of the literature, while integrating the extensive stakeholder feedback.

Findings

Current laboratory system overview

Scope of laboratory services

Table 2: Scope of laboratory services in Alberta

• 2.3M patients served per year
• 2.9M encounters with Lab
• 75M tests performed
• 133 laboratory facilities
• ~5,000 staff
• 6 organizations delivering laboratory services
• ~\$700M annual budget

The scope of laboratory diagnostic services in Alberta is illustrated in Table 2. Alberta Health Services (AHS) is responsible for the overall laboratory system, overseeing six laboratory service delivery partners across the province. 2.3 million patients are served annually; representing a total of 2.9 million encounters with the laboratory. About two-thirds of the laboratory encounters are in the community with the rest in healthcare facilities (e.g., emergency departments, hospitals, long term care facilities) (Table 3). Seventy-five million tests are performed across 133 laboratory facilities in the province. This laboratory structure is the largest in Canada, and compares with the larger laboratory service organizations around the world.

Table 3: Patient encounters with laboratory services by AHS zone and setting

Zone	Community	Emerg/Out patient	Inpatient	LTC	Total
North	188,588	74,028	27,023	669	290,308
Edmonton	662,838	218,894	97,643	19,683	999,058
Central	209,895	62,861	29,551	2,165	304,472
Calgary	737,838	283,955	117,183	17,279	1,156,255
South*	96,217	40,081	20,813	410	157,521
Total	1,895,376	679,819	292,213	40,206	2,907,614

*MHDLC community collection centres in Medicine Hat and Brooks are not included in the South zone data

Phases of laboratory testing

The actual process of performing a laboratory test is only one of three components that make up the total end-to-end testing process: pre-analytical, analytical and post analytical services.

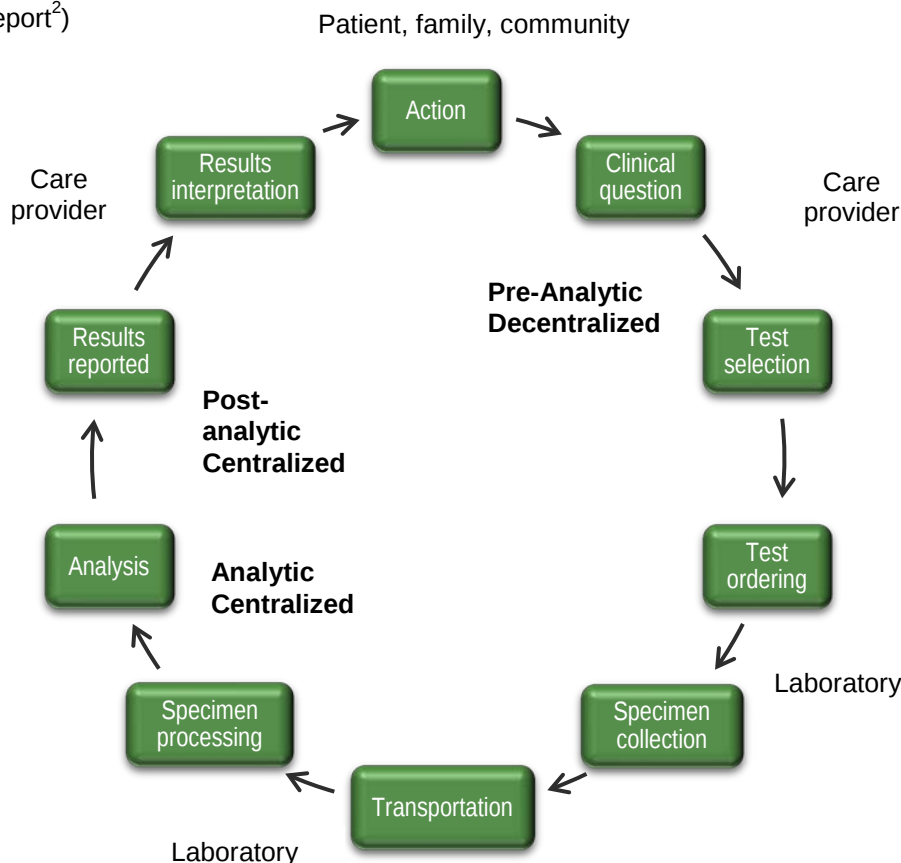
Pre-analytic: activities (clinical test selection, test ordering, specimen collection, and specimen transport) that involve the patient and the healthcare provider interacting in a variety of settings (e.g., physician offices, patient homes, community collection centres, long term care, acute care hospitals and other facilities).

Analytic: activities that involve specimen processing, specimen testing, result review, and quality control measures. If the turnaround time for a test result is non-urgent, the analytical process can be distanced from the patient, allowing it to be centralized to take advantage of economies of scope and scale. This is a unique feature of delivering laboratory services. Urgent (or ‘STAT’) testing usually needs to be done closer to the patient.

Post-analytic: involves result reporting, specimen storage, clinical interpretation, call centres and laboratory consultation services. As a general rule, post-analytic activities flow from analytic activities, and therefore lend themselves to significant consolidation.

As demonstrated in Figure 3, the laboratory testing process involves the patient, the care provider and the laboratory at different points throughout the process. There is also a clear delineation between which services must be located in close proximity to the patient to ensure appropriate access, and what processes can be centralized to enhance productivity and efficiency improving value and quality in the process.

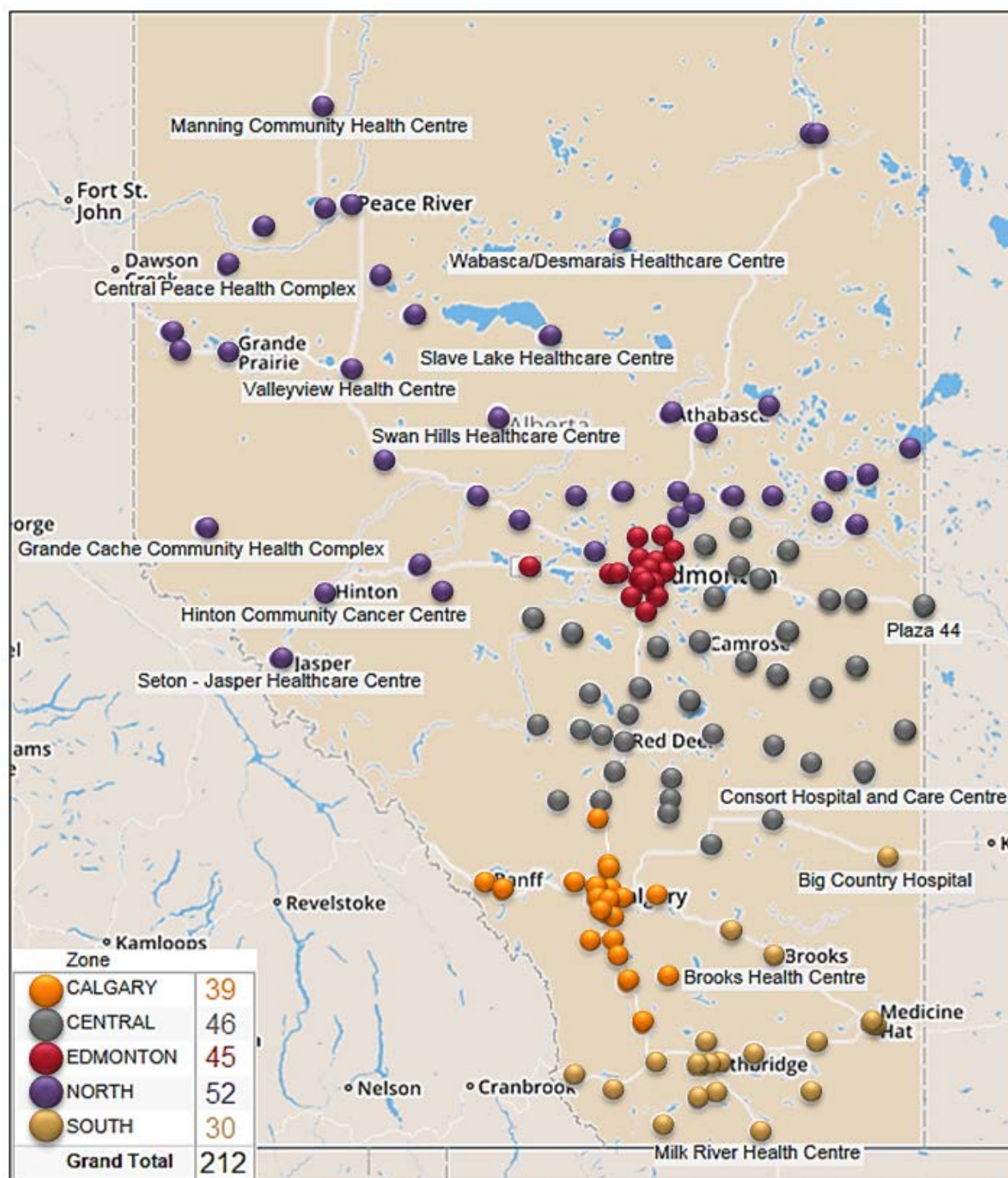
Figure 3: Phases of the laboratory testing process (adapted from Laboratory Medicine: A National Status Report²)



Specimen collection and logistics

There are currently 212 specimen collection locations across the province (see Figure 4). This provincial collection network is comprised of the following:

Figure 4: Specimen collection locations in Alberta



Community collection centres

- These are standalone patient service centres (PSCs) in the community performing blood and urine collection, electrocardiograms (ECG) and other specialty laboratory collections. They are located in Calgary (CLS), Edmonton (DL), Red Deer (DL), Lethbridge (AHS), Medicine Hat (MHDL), Fort McMurray (DL), Grand Prairie (AHS), Camrose (DL), and Lloydminster (DL).
- Hospital laboratory outpatient collection centres augment standalone PSCs in the urban centres and serve as the primary collection service in rural and remote areas.
- Patient appointment booking is offered in select locations only including Calgary (CLS), Edmonton (DL), Red Deer and surrounding area (AHS and DL), Fort McMurray (DL), Camrose (DL), Lloydminster (DL), Lethbridge (AHS), and Medicine Hat (MHDL).

(Note: CLS - Calgary Lab Services, DL - *DynaLIFE*, AHS - Alberta Health Services, MHDL - Medicine Hat Diagnostic Laboratory)

Home and mobile collections

- Regularly scheduled visits to long term care facilities
- Home based collections for qualifying patients

Logistics

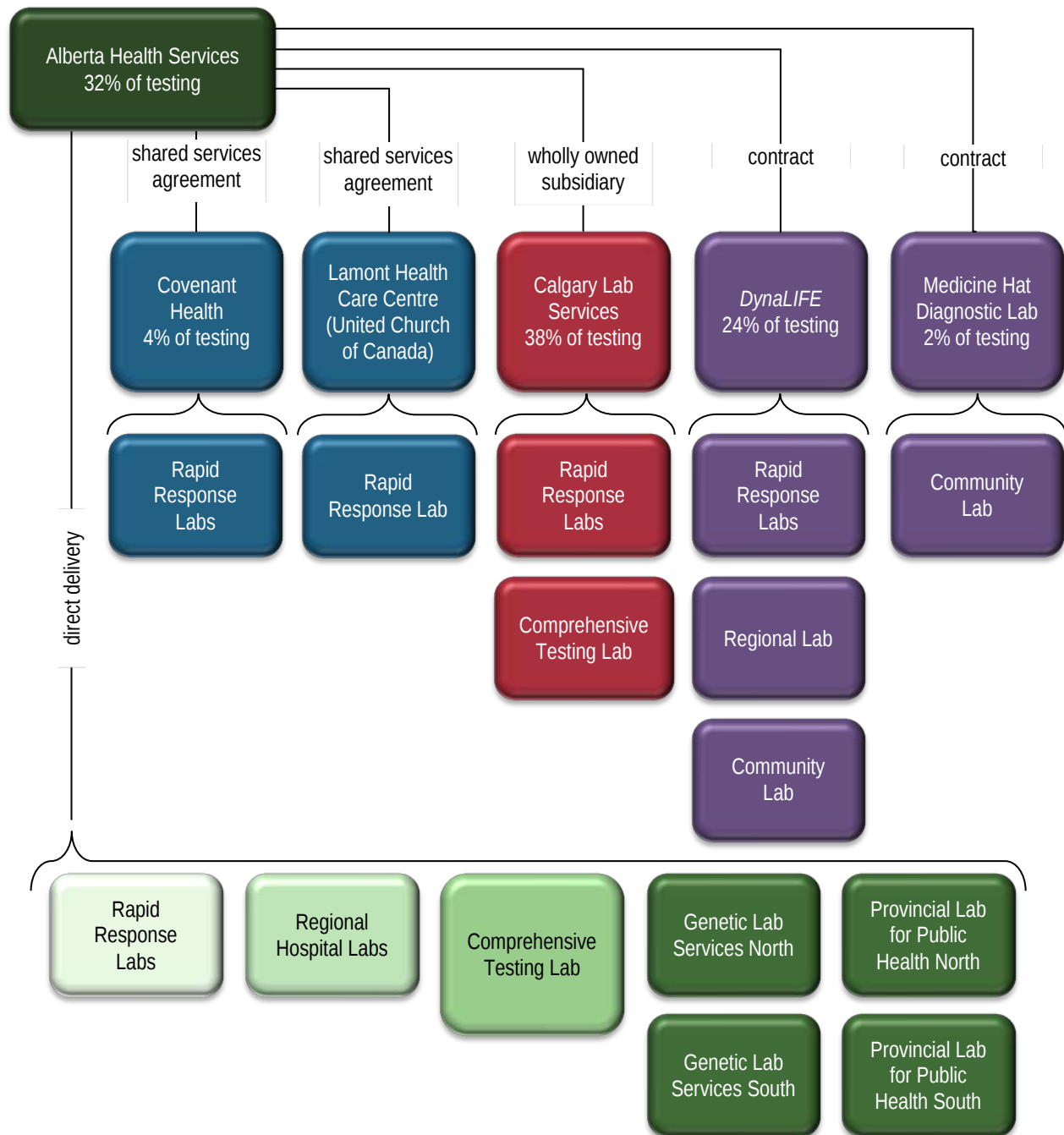
- Transportation network connecting physician offices, patient service centres, hospital and hub laboratories.
- Specimen pickup and supply delivery to physician offices and patient services centres; delivery of paper reports to physician offices.
- Specimen routing and delivery between hospitals and central testing facilities.

Logistics programs are operated by in house staff and fleets at *DynaLIFE* in Edmonton and CLS in Calgary. AHS Central, South and North zones utilize contracted couriers for specimen delivery within a zone and for transport of specimens to Edmonton or Calgary.

Laboratory services providers

The delivery of laboratory diagnostic services is complex in the province. As noted in Figure 5 there are six providers of laboratory services, of varying sizes.

Figure 5: Laboratory service providers in Alberta



These six providers operate the 133 accredited laboratory facilities in the province. They are organized by provider and AHS zone in Table 4 below.

Table 4: Laboratory testing facilities by AHS zone and service provider

Zone	AHS	Covenant Health	CLS	<i>DynaLIFE</i>	MHDL	Lamont Health Care Centre	Total
North	32	1	-	4	-	-	37
Edmonton	15	2	-	3	-	-	20
Central	29	5	-	2	-	1	37
Calgary	3	1	17	-	-	-	21
South	16	-	-	-	2	-	18
Total	95	9	17	9	2	1	133

AHS is directly accountable for laboratory service delivery in Alberta, and through shared service agreements and service contracts co-ordinates the delivery of laboratory services across the province by the six partners. In the provincial network of laboratory service providers:

- CLS is based in Calgary and is a wholly owned subsidiary of AHS providing laboratory services in Calgary and southern Alberta.
- Covenant Health and Lamont Health Care Centre are faith based, not for profit organizations that deliver laboratory services for the acute care hospitals they operate across the province. A shared services agreement with AHS provides quality management, information systems, and purchasing and supply chain services.
- *DynaLIFE* is a contracted private service provider based in Edmonton providing laboratory services primarily for northern Alberta. The contract between AHS and *DynaLIFE* expires March 31, 2022.
- MHDL is a contracted private service provider based in Medicine Hat providing community laboratory services to Medicine Hat and the surrounding area. The contract between AHS and MHDL is in its final term. In 2017, laboratory services will transition to AHS and will be consolidated with the Medicine Hat Regional Hospital laboratory.

Table 5 shows the budgets, test volumes, facilities, and staffing (both physicians and non-physicians) for each of the six laboratory service providers. AHS, CLS and *DynaLIFE* together account for over 90 per cent of the testing laboratories, 95 per cent of the testing performed in the province, and 96 per cent of the budget.

Table 5: Snapshot of laboratory services by provider, Alberta 2015/16

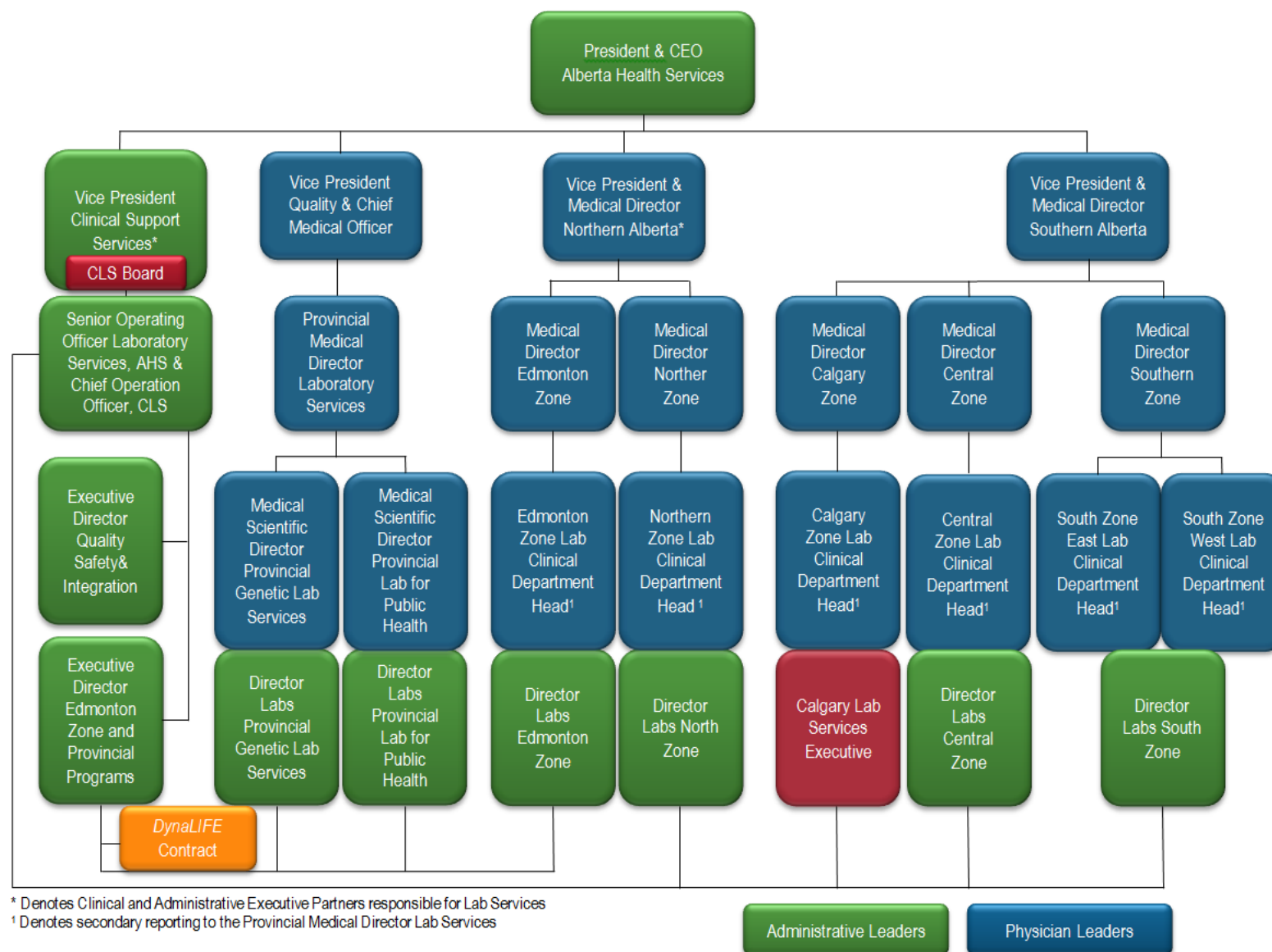
	Public				Private			Total
	AHS	Covenant Health	CLS	Total Public	<i>DynaLIFE</i>	MHDL	Total Private	
No. Tests	24.7M	3.0M	28.8M	56.5M	17.8M	1.2M	19.0M	75.5M
	32.7%	4%	38.1%	74.8%	23.6%	1.6%	25.2%	
No. Testing Labs	95	9	18	123*	8	2	10	133
	71.5%	7%	13.5%	95%	6%	1.5%	5%	
Staff (FTE)	1,855	158	1,440	3,453	1,212	55	1,267	4,720
	39.3%	3.4%	30.5%	73.2%	25.7%	1.1%	26.8%	
Medical Staff (head count)	118	Included in AHS count and budget	90	208	31	1	32	240
	49%		38%	87%	12.9%	0.1%	13%	
Annual Budget	\$282.6M	\$21M	\$245.3M	\$548.9M	\$133.4M	\$7.9M	\$141.3M	\$690.2M
	41%	3%	35.5%	79.5%	19.3%	1.2%	20.5%	

*this total includes the Lamont Health Care Centre

Organizational structure for laboratory services

The accountability and governance structure for laboratory services in AHS (Figure 6) is complex, with multiple reporting lines to members of the senior executive team.

Figure 6: Organizational structure of laboratory services in AHS (2016)



In AHS, there are four vice-presidents on the executive team with direct accountability for laboratory services. These include the Vice President Quality and Chief Medical Officer, the Vice President Clinical Support Services, one Vice President and Medical Director for Northern Alberta, and a second for Central and Southern Alberta. This structure effectively separates the alignment and accountability into four different portfolios. All non-medical staff report up through the Senior Operating Officer for Laboratories to the Vice President of Clinical Support Services. Physician laboratory leaders report through one of the three other vice-president portfolios. The Provincial Medical Director for Laboratory Services has limited operational authority over laboratory operations across the province.

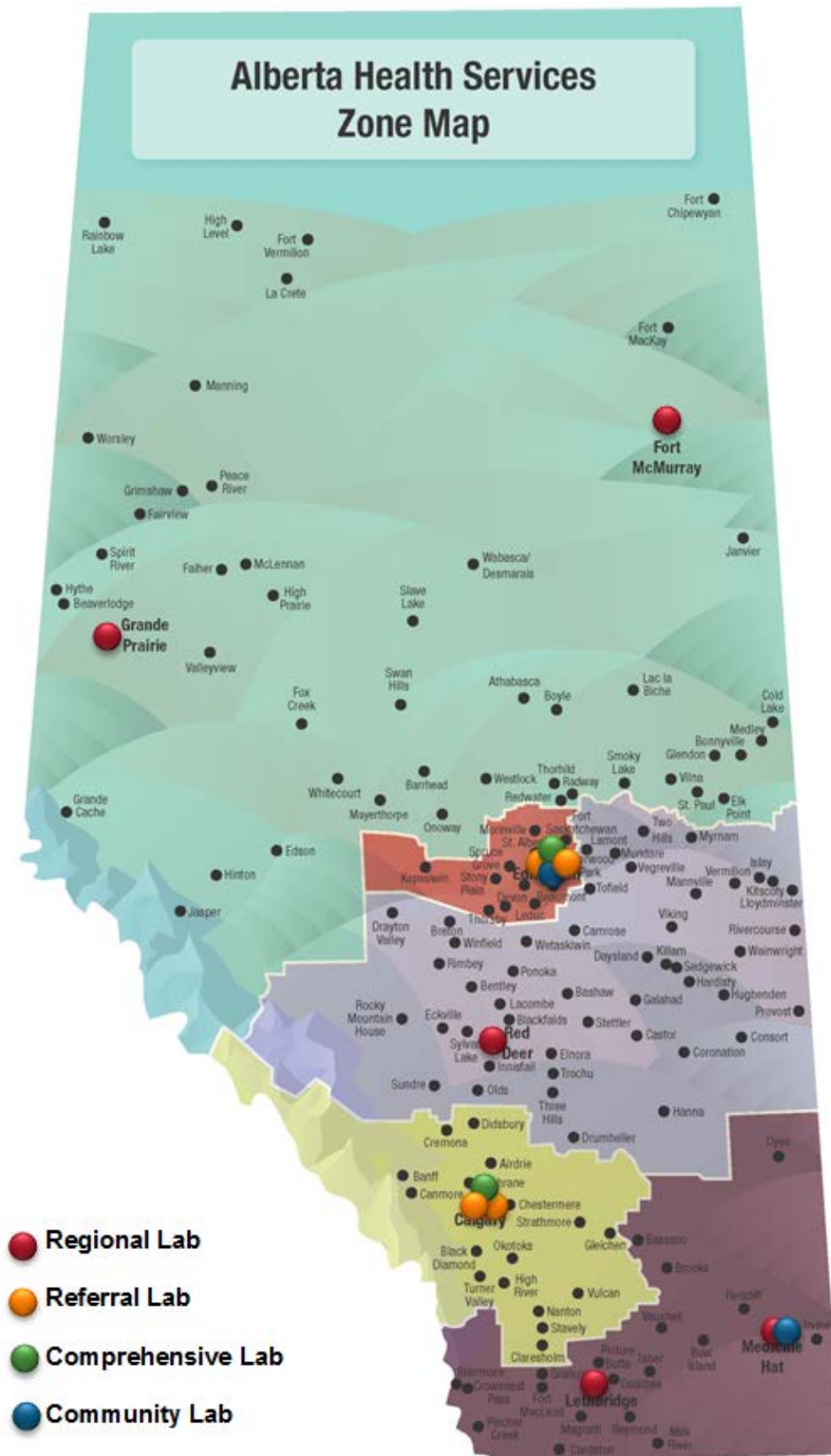
Further complicating the reporting mechanisms, the five other organizations deliver laboratory services through agreements with AHS and are accountable as follows:

- CLS - the Senior Operating Officer for Laboratory Services at AHS serves as the Chief Operating Officer of CLS and reports to the AHS Vice President Clinical Support Services; the Medical Director for CLS is accountable through the Central and Southern Alberta Vice President and Medical Director.
- *DynaLIFE* – the operating staff and the Senior Medical Officer at *DynaLIFE* report to the *DynaLIFE* CEO who is accountable to the Board of *DynaLIFE*. Accountability to AHS is through the service contract between AHS and *DynaLIFE*; with day-to-day issues managed through the AHS Senior Operating Officer for Laboratories. There is no relationship of medical staff at *DynaLIFE* to the Laboratory Zone Clinical Department Heads or the Provincial Medical Director Laboratory Services at AHS.
- Covenant Health, Lamont Health Care Centre and MHDL organizations are accountable through their senior administration to their respective Boards; their agreements with AHS are managed at the AHS zone level.

Organization of laboratory diagnostic facilities

Laboratory testing facilities are located throughout Alberta (Figure 7), are tiered based on size and function, and are categorized as follows:

Figure 7: Tiering of laboratory services in Alberta



Rapid response laboratory (RRL): these laboratories operate in acute care hospital sites and provide collection services for inpatients and outpatients as well as limited on-site laboratory testing in chemistry, hematology, transfusion medicine, and, in some cases, anatomic pathology. The RRL coordinates transfer of the majority of microbiology specimens, anatomic pathology and non-urgent and specialized samples to the nearest hub or regional laboratory for testing. There are 120 RRLs across the province including all rural hospitals as well as large community hospitals in Edmonton and Calgary. Rapid response laboratories are operated by AHS in the South zone; AHS, Covenant Health and Lamont Health Care Centre in Central zone; AHS and Covenant Health in the Edmonton zone; Calgary Laboratory Services and Covenant Health in the Calgary zone; and AHS, Covenant Health and *DynaLIFE* in the North zone.

Regional laboratory: these laboratories operate in regional hospitals serving the hospital and community, and provide a hub-like service to surrounding rural laboratories. There are five regional laboratories in Alberta located in Red Deer (AHS), Lethbridge (AHS), Medicine Hat (AHS), Grand Prairie (AHS), and Fort McMurray (DL). These full service laboratories offer inpatient and outpatient collection services as well as comprehensive on-site test procedures in chemistry, hematology, transfusion medicine, microbiology, and anatomic pathology. Regional laboratories coordinate the transfer of specimens for specialized diagnostic testing to Edmonton or Calgary.

Community laboratory: these laboratories are operated by the private sector and provide laboratory testing for community physicians and, in Edmonton, hub-like services to Edmonton community hospitals and small rural hospitals in northern Alberta. Operated by *DynaLIFE* in Edmonton and Medicine Hat Diagnostics Laboratory in Medicine Hat, the two community laboratories in Alberta operate laboratory facilities outside of the hospital and are responsible for the standalone community patient service centers and logistic networks in their catchment areas. Community laboratories are designed to manage low complexity high volume testing; referring more complex and specialty testing to the comprehensive and reference laboratories located in Edmonton and Calgary.

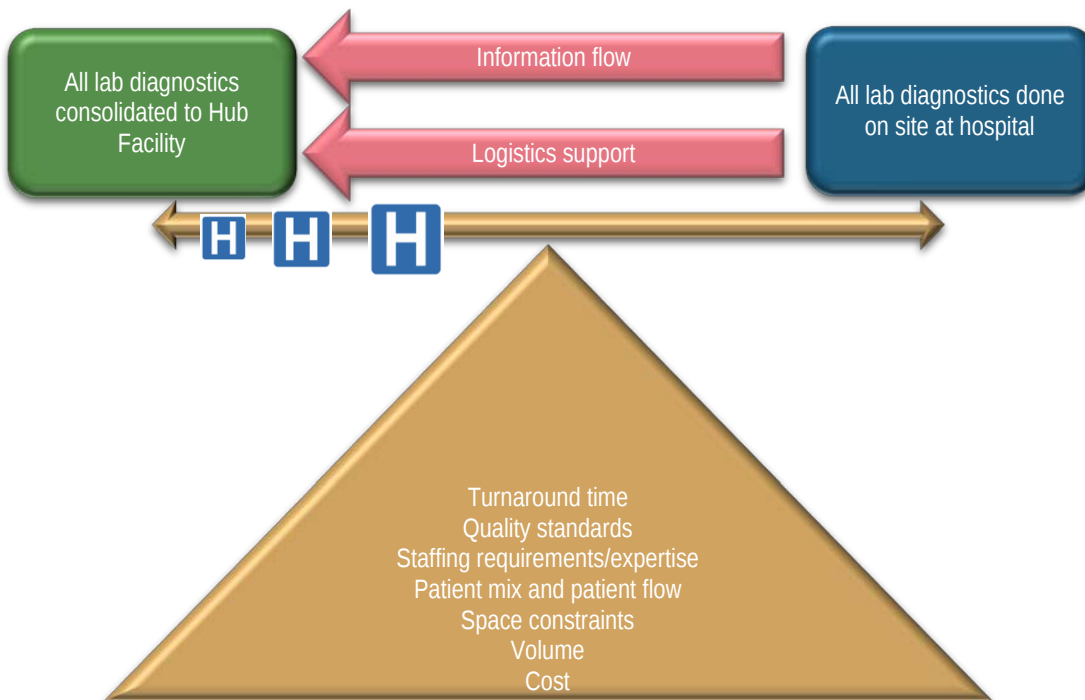
Comprehensive laboratory: these laboratories support all levels of testing including general and specialized testing in chemistry, hematology, transfusion medicine, microbiology, anatomic pathology, molecular pathology, and histocompatibility. Comprehensive laboratories provide centralized specialty testing and receive samples from all categories of laboratories in the province. There are two comprehensive laboratories in Alberta. The first is located at the University of Alberta Hospital (AHS) in Edmonton and the second at the hub Diagnostic and Scientific Centre (CLS) in Calgary (CLS also provides laboratory services to the community as well as the hospital sector in the Calgary zone). Both laboratories are closely affiliated with and support the academic and research mission of the University of Alberta and the University of Calgary respectively.

Reference Laboratory: these laboratories are distinct in that they provide complex testing in very specialized areas. In Alberta, the Provincial Laboratory for Public Health (ProvLab) is an AHS operated laboratory located on two campuses in Edmonton and Calgary. The ProvLab provides microbiology testing to support public health surveillance and immediate public health threats to the population. Genetic laboratory services, also operated by AHS, provides complex genetic testing in laboratories located in Edmonton and Calgary. Similar to the comprehensive laboratories, there

is a critical mass of expertise and technology linked to a strong academic and research base at the University of Alberta and University of Calgary.

Test menus defining the scope of service in each of the 133 laboratory sites have evolved over time and continue to gradually change in response to various factors as illustrated in Figure 8.

Figure 8: Criteria for test menu by site



Deciding on local test menus and related scope of testing for each site include the following considerations:

- time to turn around a result (TAT) to support quality patient care
- quality standards
- ability to access skilled staff
- mix of patients at a facility
- space constraints
- overall volume and cost of providing on-site services

Discipline specific areas of laboratory diagnostics

Testing in laboratory medicine occurs within a number of discipline specific areas. These areas require special expertise and varied diagnostic technology and methodologies, but all inform medical and care decisions for individual patients. Listed below are the major laboratory disciplines and examples of the most common tests ordered:

- Hematology - hemoglobin, white blood cell and platelet counts

- o Coagulation – a subspecialty area of hematology assessing patients for bleeding disorders or monitoring the prothrombin time for patients on anticoagulants
- Chemistry - liver and kidney function tests, hemoglobin A1C for diabetes patients
- Microbiology and virology - urine culture for bladder infection, throat swab for strep throat
- Transfusion medicine - cross match for provision of a blood transfusion
- HLA (human leukocyte antigen) - testing for transplantation compatibility of donors and recipients
- Anatomic pathology - analysis of a skin biopsy taken in a family physician's office, analysis of a cancerous growth removed by a surgeon in an operating room
 - o Cytopathology (a sub-specialty area of anatomic pathology) - pap smear, needle biopsy of a lung tumor taken by a radiologist in the radiology department
- Genetics – testing high risk women for the breast cancer gene, chromosomal analysis on a baby with developmental abnormalities
- Toxicology – testing done on a drug overdose patient

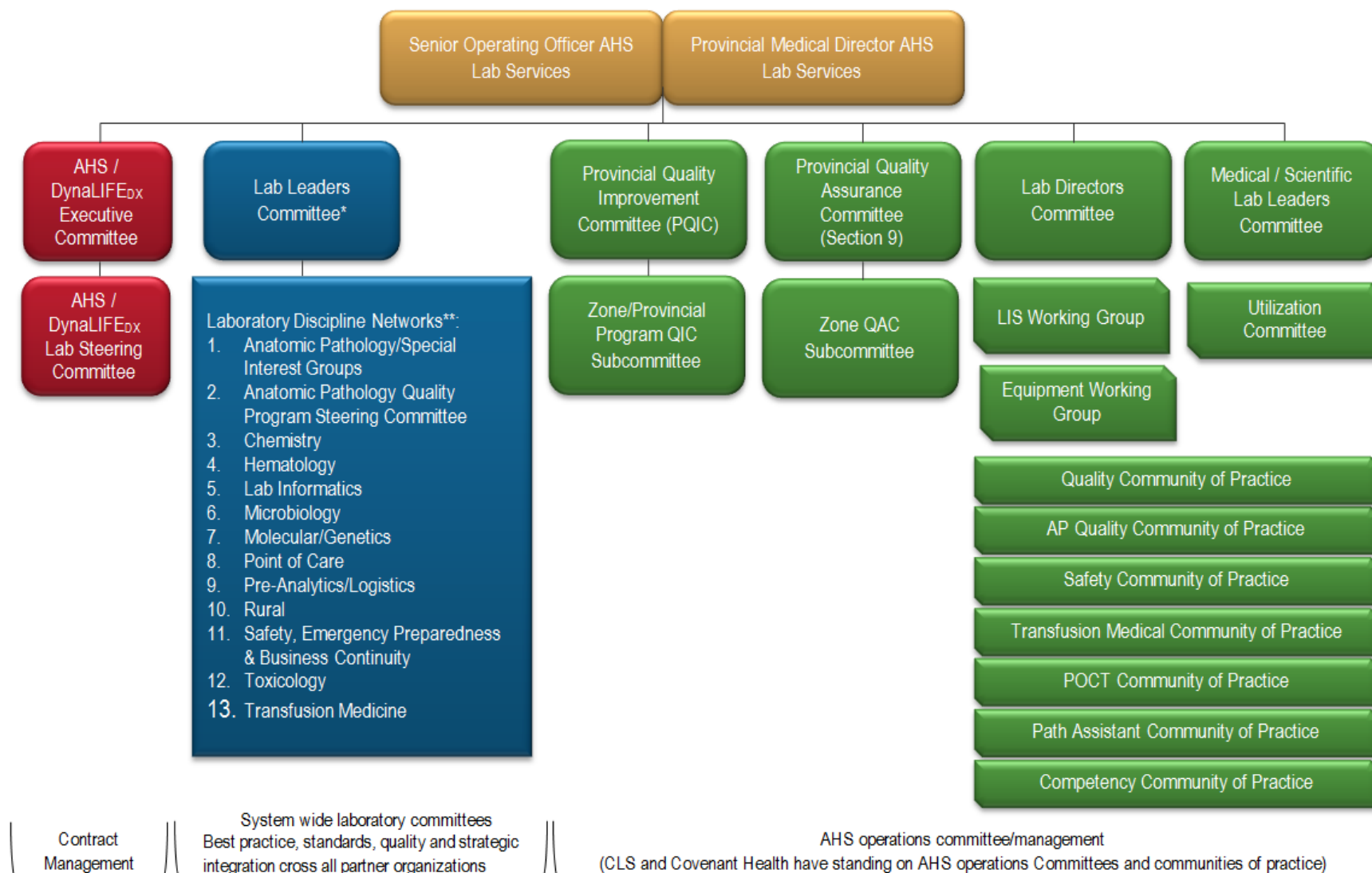
Quality management

Ensuring ongoing and rigorous quality management is a foundational activity in diagnostic laboratories.^{2, 4, 15, 16, 17} Rigorous quality control is essential in all phases of diagnostic testing including the pre-analytical phase (getting the specimen properly collected, documented and transferred for testing), analytical phase (conducting the test), and post-analytical phase (reporting the results, storing specimens, etc.). Sustaining a consistent and high level of quality management across all phases, all six providers of laboratory services, five geographic zones, 133 laboratory sites, thousands of pieces of analytical equipment, and approximately 5,000 staff presents a significant challenge for AHS. The complexity of the various laboratory information systems across the province adds to this challenge.

There are two major mechanisms for quality management of laboratory services in Alberta:

- Internal quality programs and structures within each of the six laboratory service provider organizations.
- External accreditation of all laboratory diagnostic facilities in the province by the College of Physicians and Surgeons of Alberta (CPSA) (Appendix D).

Figure 9: AHS laboratory services quality management structure



*AHS and CLS representatives

**AHS, CLS, Covenant Health, DynaLIFE_{Dx} and MHDL representatives

The structure is complex and somewhat duplicative due to the multiple organizations delivering laboratory services and the complex accountability structure within AHS. The Laboratory Discipline Networks bring together representatives from across the six service delivery organizations by laboratory specialty area to work together on various quality initiatives. However, legal accountability for quality management rests with the individual organizations delivering laboratory services (AHS, CLS, *DynaLIFE*, Covenant Health, Lamont Health Care Centre, MDHL), and the implementation of quality initiatives is variable across the partners.

Within AHS itself, the Provincial Quality Improvement Council (PQIC) for laboratory services establishes key performance indicators (KPIs). In addition, as can be seen in Figure 9, there are a number of committees, working groups and communities of practice providing opportunities for discussion of quality issues, tracking and responding to KPIs results, and managing change. Suggested changes and improvements which flow from the Provincial Medical Director and Senior Operating Officer may not be supported by the zone leadership, resulting in uneven implementation of quality initiatives within AHS.

Quality performance metrics

In AHS, laboratory KPIs and related metrics from all sites and zones are internally reported regularly on a web-based dashboard. They are monitored at both the provincial and local zone level through the AHS quality management structure. AHS laboratory services routinely monitors metrics that assess: (1) access to laboratory services; (2) timeliness of reporting laboratory results; (3) accuracy and quality of laboratory testing; and (4) staff safety. Table 6 lists the current quality metrics and associated performance targets.

Table 6: Laboratory key performance Indicators

Dimension	Metric	Definition	Target
Access	Patient wait time	Amount of time a patient waits for blood collection after arriving at the laboratory. Literature suggests that patients correlate a short wait time with high quality of service, and a long wait time with poor quality of service. Patient wait time begins when the patient enters the laboratory area. For patients with a booked appointment, patient wait time begins with the booked appointment time or the patient arrival time, whichever is later. Patient wait time ends when the blood sample is collected from the patient.	80% of patients will be served within 30 minutes of arrival at the collection site.
Timeliness	Turnaround time (TAT)	Turnaround time is the amount of time it takes the laboratory to report out a test result. This metric is measured from the time a specimen is collected to the time the result is verified and released by the laboratory. A proxy list of tests is used to monitor overall TAT performance.	<u>Urgent Request:</u> Emergency department: 90 min Inpatient: 120 min Outpatient: 4 hrs Community: 8 hrs <u>Non Urgent Request:</u> Emergency department: Not Applicable Inpatient: 4 hrs Outpatient: 12 hrs Community: 24 hrs
Accuracy and Quality	External proficiency testing (PT)	Proficiency testing is the use of inter-laboratory comparisons to determine the performance of individual laboratories for specific tests or measurements and to monitor a laboratory's overall performance. The metric provides a rate of the number of acceptable proficiency testing results over the total number of proficiency testing results.	95% acceptable
	User satisfaction	Standardized quantitative user satisfaction surveys are performed annually alternating between Patient Satisfaction (year 1) and Healthcare Provider Satisfaction (year 2).	80% Satisfied or Extremely Satisfied
	Blood culture contamination	A rate of the number of contaminated blood cultures over the total number of blood cultures collected	<3% contamination
	Specimen adequacy	The percentage of specimens rejected is monitored for trends and quality improvement opportunities	N/A
	Laboratory occurrences, complaints and critical incidents	A system to monitor non-conforming events, complaints and incidents causing serious physical or psychological harm or other material impacts to patient care.	N/A
Safety	Safety improvement plan	A system to monitor and audit safety performance in the laboratory. Includes workplace inspection, hazard assessments, safety culture and training, incident reporting and injury investigation.	N/A

All six service providers report on these metrics to AHS through the Provincial Quality Improvement Committee (AHS and CLS) or through contract management mechanisms (*DynaLIFE* and *MHDL*), but ultimate responsibility for managing quality issues remains within each of the separate organizations.

Alberta has developed a standardized Anatomic Pathology Quality Assurance (APQA) Plan with a focus on surgical pathology, one of the most difficult areas of quality management in the laboratory. The APQA Plan flowed from several national high profile patient safety incidents in anatomical pathology. The APQA now encompasses all service providers and sites in the province and is unprecedented in Canada in scope and comprehensiveness.¹⁸ Elements of this approach are being reviewed to enhance the effectiveness of quality management in other areas of laboratory services.

Accreditation

The CPSA is responsible for accreditation of all diagnostic laboratory facilities in Alberta. Accreditation by the CPSA follows a four year cycle (see Appendix D for a detailed description of the process). The CPSA is a leader in Canada in establishing accreditation standards for laboratories. In May 2014, the International Society for Quality in Healthcare (ISQua) accredited the CPSA's Diagnostic Laboratory Standards, making them among the highest laboratory standards in the world. These standards ensure Alberta's laboratories meet or exceed safety and quality standards for performance of laboratory services.

In addition, through their related Alberta Laboratory Quality Enhancement Program (ALQEP), the CPSA provides an ongoing external quality assessment program through the circulation of survey samples sent to patient service laboratories for analysis and report back. When testing proficiency is found to be deficient, ALQEP has a structured process to work with the laboratory and management to correct the deficiencies.

In addition to the CPSA, the American Association of Blood Banks (AABB), the Canadian College of Medical Geneticists (CCMG), the College of American Pathologists (CAP), the American Society for Histocompatibility and Immunogenetics (ASHI), and the Canadian Association for Laboratory Accreditation (CALA) also contribute to accreditation of different laboratories in the provincial system.

Over the years, the sophisticated technology in laboratory diagnostics has significantly changed the nature of quality assurance. Major diagnostic platforms come with complex quality assurance programs built into the technology software which is then integrated with the laboratory information system. Today, laboratory errors most commonly occur in the pre-analytical phases and are due to human or process error, particularly in specimen labelling and accessioning of samples and specimens.¹⁵ Over the past five years, laboratory providers have taken steps and invested in automation in this area of diagnostic laboratory services. A good example being the introduction of the Vantage system which uses bar code technology to track and process specimens as they reach the lab. Vantage is now in use across all six providers of laboratory services reducing the potential for labeling errors by almost 93 per cent. Vantage was first initiated in the *DynaLIFE* system, then CLS, and more recently across the rest of the system.

Managing the business of the laboratory

Ongoing business transformation in the laboratory sector is a necessary activity in order to successfully manage demand and deliver quality services in the setting of constrained resources a situation facing all providers of laboratory diagnostics^{2, 13, 19, 20, 21,22, 23}

Globally, laboratory test volumes are rising on average at approximately 6 per cent per year – growth varies across diagnostic areas with more expensive and complex diagnostics (genetics, anatomic pathology, microbiology) rising at a faster rate than high volume low complexity areas (hematology and chemistry).^{24,25} Rising demand for laboratory diagnostics can be attributed to:

- Population growth – the Alberta population is expected to grow from the present population of 4.1 million to six million over the next 25 years (47 per cent increase).
- A demographic shift toward an older population with 36 per cent of the population over the age of 65 by 2041.
 - o People over 65 years of age undergo approximately five times as many laboratory tests per year as those under the age of 65.²⁵
 - o An increasingly elderly population will have a higher prevalence of chronic disease. Chronic disease accounts for roughly 50 per cent of laboratory activity.¹³
- Emphasis on early detection and prevention of disease – new population health screening programs (such as the fecal immunochemical test (FIT) for colon cancer), are designed to identify health issues at an early stage to enhance the opportunity for intervention and cure.
- The development of novel diagnostics emanating from new technologies and innovative research are seen as a gateway for enhanced health outcomes delivered through precision medicine.
- Inappropriate utilization of laboratory diagnostics – a recent report by the Canadian Agency for Drugs and Technologies in Health (CADTH) suggests that approximately 20 per cent to 50 per cent of laboratory testing may not be appropriate, highlighting the importance of robust utilization management programs in laboratory services.^{26, 27, 28}

The key enablers of successful business transformation in the laboratory are the laboratory information system, robust business analytics, technology innovation, facility infrastructure, and the human skills and capacity for managing and implementing ongoing change.

Laboratory information systems

For a large laboratory service network spread out over multiple locations, a high functioning and integrated laboratory information system is crucial to linking patients and providers to test results; improving the appropriateness of testing for patients; maximizing efficiency in the laboratory; adapting to growing needs for service; maintaining quality; and enhancing integration of the various professional disciplines involved in patient care both inside and outside the laboratory.^{19, 29}

The current system in Alberta is complex with eight separate laboratory information systems (LIS) supported by three different vendors (Table 7). The systems are not standardized nor do they communicate directly with each other. The complexity of these systems results in significant

duplication and error potential as samples move around the province in the tiered hub and spoke system of diagnostic facilities. As seen in Table 7, the complexity of the LIS environment remains a significant barrier to integrated laboratory services across the province.

Table 7: LIS environment in Alberta

	System	Sites	Order Entry	Results to CIS	Results to NetCare	Results to POSs
North Zone	Meditech–AHR	23	Meditech-AHR	Meditech-AHR	Yes	Multiple
	Meditech-PCH	16	Meditech-PCH	Meditech-PCH	Yes	Multiple
	Sunquest/Copath (Edmonton zone Instance)	4	None	Meditech-NLR	Yes	Multiple
Edmonton zone	Sunquest/Copath	20	None	Tandem, Vax, Aria, E-clinician, EDIS, OTTR, E-Critical	Yes	Multiple
	Histo Trac	1	None	Tandem, Vax, Eclinician	Yes	None
Central zone	Meditech-DTH	23	Meditech-DTH	Meditech-DTH	Yes	Multiple
	Meditech-ECH	17	Meditech-ECH	Meditech-ECH	Yes	Multiple
Calgary zone	Cerner Millennium	17	SCM	SCM, Aria, PARIS, E-Critical	Yes	Multiple
	Pathnet Classic (converting to Histo Trac)	1	SCM	SCM	Yes	Multiple
South zone	Meditech-CHR	11	Meditech-CHR	Meditech-CHR	Yes	Multiple
	Meditech-PHR	5	Meditech-PHR	Meditech-PHR	Yes	Multiple
	Fusion (retired 2017)	2	None	None	Yes	Multiple
Prov Laboratory	Cerner Millennium (Calgary Zone instance)	2	SCM – Calgary only	SCM, Tandem, Vax, Aria, e-Critical, PARIS,	Yes	Multiple
Genetic Laboratory Services	Specimen Gate	1	None	None	None	None
	Fox Pro	1			None	None
	Shire	2			None	None
	Sunquest/Copath	1			Yes	Multiple

Beyond the complexity of the systems themselves, standards are evolving quickly. For example, physician order entry and access for patients to their results is now a best practice standard enhancing quality and safety and responsiveness to patients. Currently, all Edmonton hospitals, including the University of Alberta Hospital, and the community sector are paper-based. In addition, patients in Alberta are not yet able to access their laboratory results on-line.

Provincial government information technology (IT) initiatives

Fortunately, in the last few months, the Government of Alberta has announced two major initiatives which will address the need to move to one high functioning LIS across laboratory services in Alberta as well as enhance access for patients to laboratory test results.

Provincial CIS/LIS project: In September 2016, following approval of funding by the Government of Alberta, the first phase of procurement for a new Clinical Information System (CIS) for AHS was initiated. This project will include a new LIS for the province. The CIS project has a ten-year rollout; however, based on discussion at the Provincial Laboratory Services Project Steering Committee, the LIS has been highlighted as the priority for the first phase of the rollout. One of the unique features of the LIS, in contrast to the CIS, is that its scope includes healthcare facilities and the whole community sector. This sector generates two-thirds of patient encounters with the laboratory.

Patient access to laboratory results: A central focus of patient-centred care, still outstanding in Alberta, is the ability of patients to access their own laboratory results on-line. This is standard in many health systems around the world including the National Health Service in the United Kingdom,³⁰ many large health delivery organizations in the United States,³¹ and in British Columbia and parts of Ontario through the LifeLabs Excelleris system.³² Alberta Health and AHS have been working together on creating a single repository for standardized laboratory data in the province – a necessary step for patient access to laboratory results. Currently, it is targeted that patients will be able to access their laboratory results through the Patient Health Portal by June 2017.

The move to one LIS across the province is a foundational step toward integrated laboratory services in the province. Ensuring that the LIS is appropriately supported on an ongoing basis is also essential to smooth and efficient operations. The sheer volume of business in laboratory services provides context for the intensity of demands on IT services and for the critical need to move to a unifying, high functioning LIS. As can be seen in Table 8, when compared to other areas within AHS, the laboratory is exponentially more patient and data intense. The daily requirements of supporting laboratory services in AHS alone generates on average over 1,200 requests for LIS adjustments to the corporate IT shared services every month.

Table 8: AHS key business metrics - annualized figures (2015)

Hospital discharges	404,513
Total hospital days	2,811,727
Emergency department visits	2,134,954
Health Link calls	755,334
Main operating room activity	281,312
MRI exams	195,419
CT exams	391,600
General X-rays	1,874,879
Laboratory tests	75,513,093
EMS events	517,640
Cancer patient visits	616,237
Seasonal flu immunizations	1,146,549

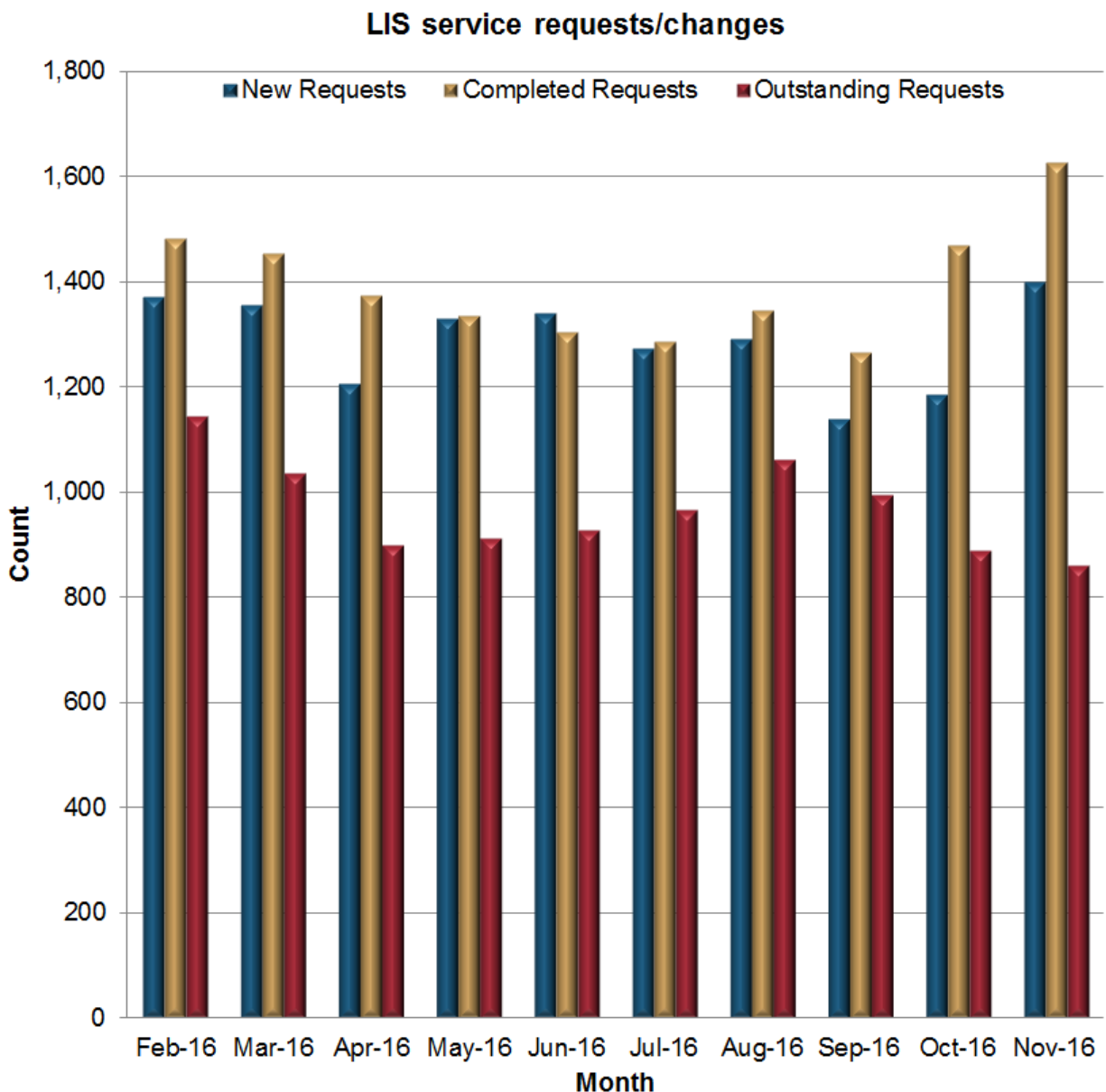
Source: AHS Quick Facts – Provincial Dashboard 2015/16 Total

The need for LIS IT support on a daily basis reflects a variety of operational requirements including:

- Ongoing standardization/harmonization initiatives e.g., moving to a standard reference range for tests across the system
- Programing of system rules targeting appropriate utilization of laboratory tests by ordering clinicians
- Bringing new laboratory instruments online
- Specimen and test changes
- Deployment of staff and workload allocation
- Quality assurance
- Adapting and enhancing laboratory processes, i.e., voice recognition software for pathologist dictation
- Day to day database adjustments e.g., sign-on of new physicians, physician locums, new users
- Fixing system interruptions across the many systems and interfaces

A review of the LIS IT laboratory status dashboard (Figure 10) shows the challenge of the day-to-day requirements of supporting laboratory services. In spite of a significant level of service, hundreds of service requests remain outstanding on an ongoing basis. Both CLS and *DynaLIFE*, have benefited from operational and developmental IT resources embedded closely with day-to-day operations in the laboratory. This results in significantly more capacity and agility for ongoing business transformation, creative ways to streamline operations, implementing initiatives related to quality programs, and general support of day-to-day operations.

Figure 10: LIS service requests 2016 (source: AHS Lab Status Dashboard, December 2016, Provincial Support Services)



Business analytics

Key to business transformation in laboratory diagnostics is the ability to access, translate and then use the large amounts of data available through the LIS to understand the business and make evidence informed decisions to enhance operations.^{3, 19, 33} Historically, CLS created a business analytics unit to support its ongoing business transformation needs. Over the last 20 years, this unit has supported the work of CLS as it evolved its hub and spoke model of laboratory services in the Calgary zone and more recently into southern Alberta. Laboratory medicine leaders at CLS and the University of Calgary are globally recognized for health system research enabled by this unit.

Over the last three years, in part to support the development of a standardized central repository for laboratory data from across the province, investments have been made in the CLS business analytics unit which has allowed it to provide more analytics support to the provincial network.

Capital investment - equipment

Laboratory services are technology intense; between AHS and CLS (which together account for over 70 per cent of all testing in the province) there are 4,600 pieces of equipment which are used every day. The rate of technological innovation in laboratory diagnostics is high, the most rapid innovation cycle in the health sector.^{3, 5, 6, 19} The introduction of new technology in the laboratory is driven by two major objectives:

- Enhancing patient outcomes through the introduction of new methodologies which are more accurate, more sensitive, or as in the case of precision medicine, allow individual patients to be identified who will respond to a new precision drug or other intervention.
- Impacting the business of the laboratory through technology which makes business processes in the laboratory more streamlined and efficient.

The ability to sustain an appropriate ongoing investment in technology is fundamental to providing high quality patient care and to creating a financially sustainable business model.⁵ However, a review of the financial data related to investment in technology (Figure 11, Table 9) reveals that in both AHS and CLS, technology has not been replaced or refreshed at an appropriate rate given the vital role it plays in the delivery of laboratory services. Seventy-six per cent of AHS laboratory equipment and nearly 60 per cent of CLS equipment is at end of life (100 per cent amortized on a 10 year amortization cycle). This is in contrast with diagnostic imaging equipment in AHS, where only a third is at end of life (Figure 12, Table 10). In Table 11, standardized data related to capital investment in technology by AHS, CLS, and *DynaLIFE* show the significant difference in investment between the public and private sector laboratories providing services in Alberta in the four years from 2012/13 to 2015/16.

Figure 11: Equipment amortization status AHS and CLS – 10 year amortization cycle

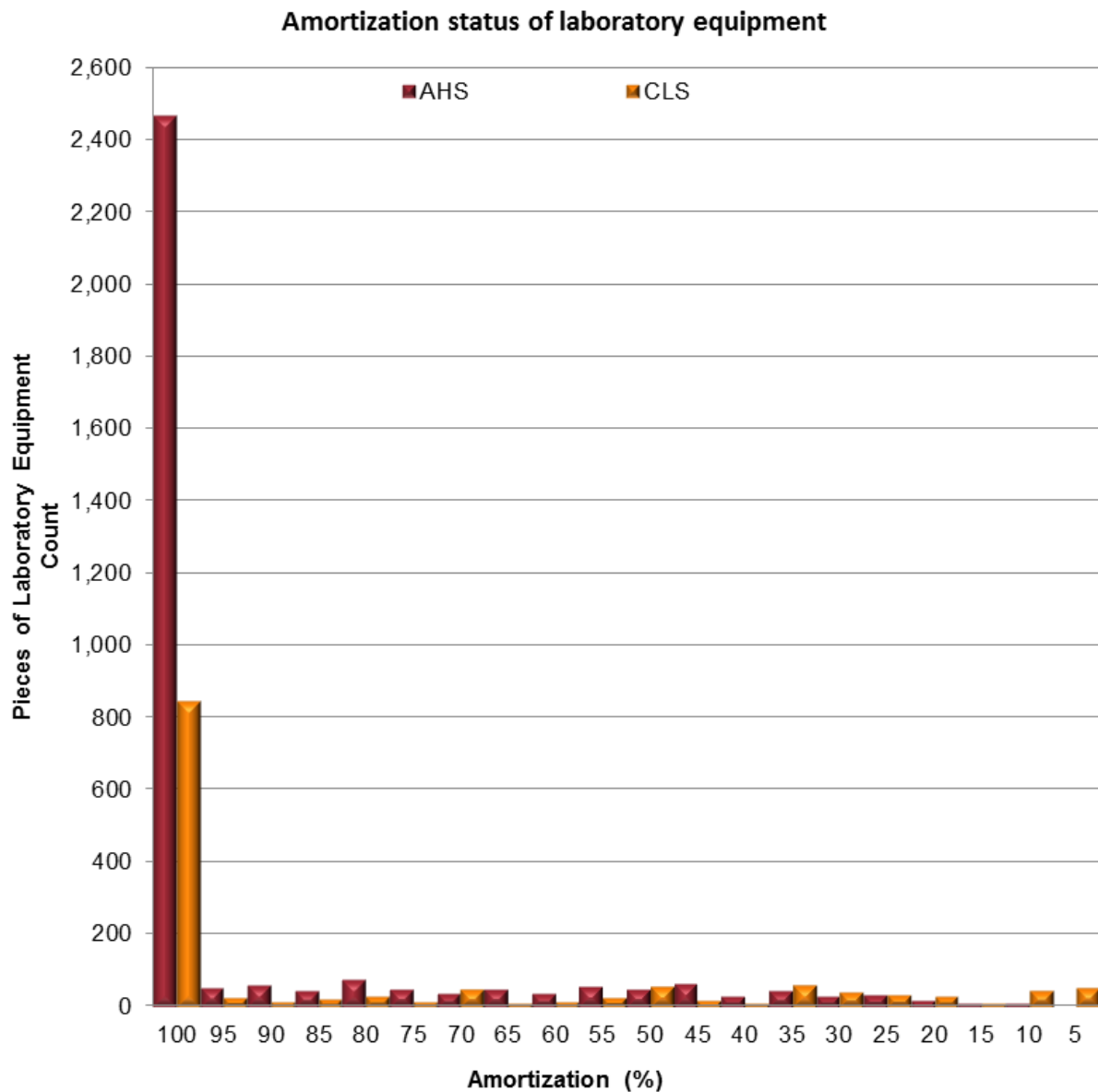


Table 9: Percentage of laboratory equipment fully amortized – AHS and CLS

	Total pieces of equipment	% past useful life
Alberta Health Services	3,235	76%
Calgary Laboratory Services	1,417	59%
Total	4,652	71%

Figure 12: Amortization status of laboratory (AHS and CLS) and diagnostic radiology equipment (AHS) – 10 year amortization schedule

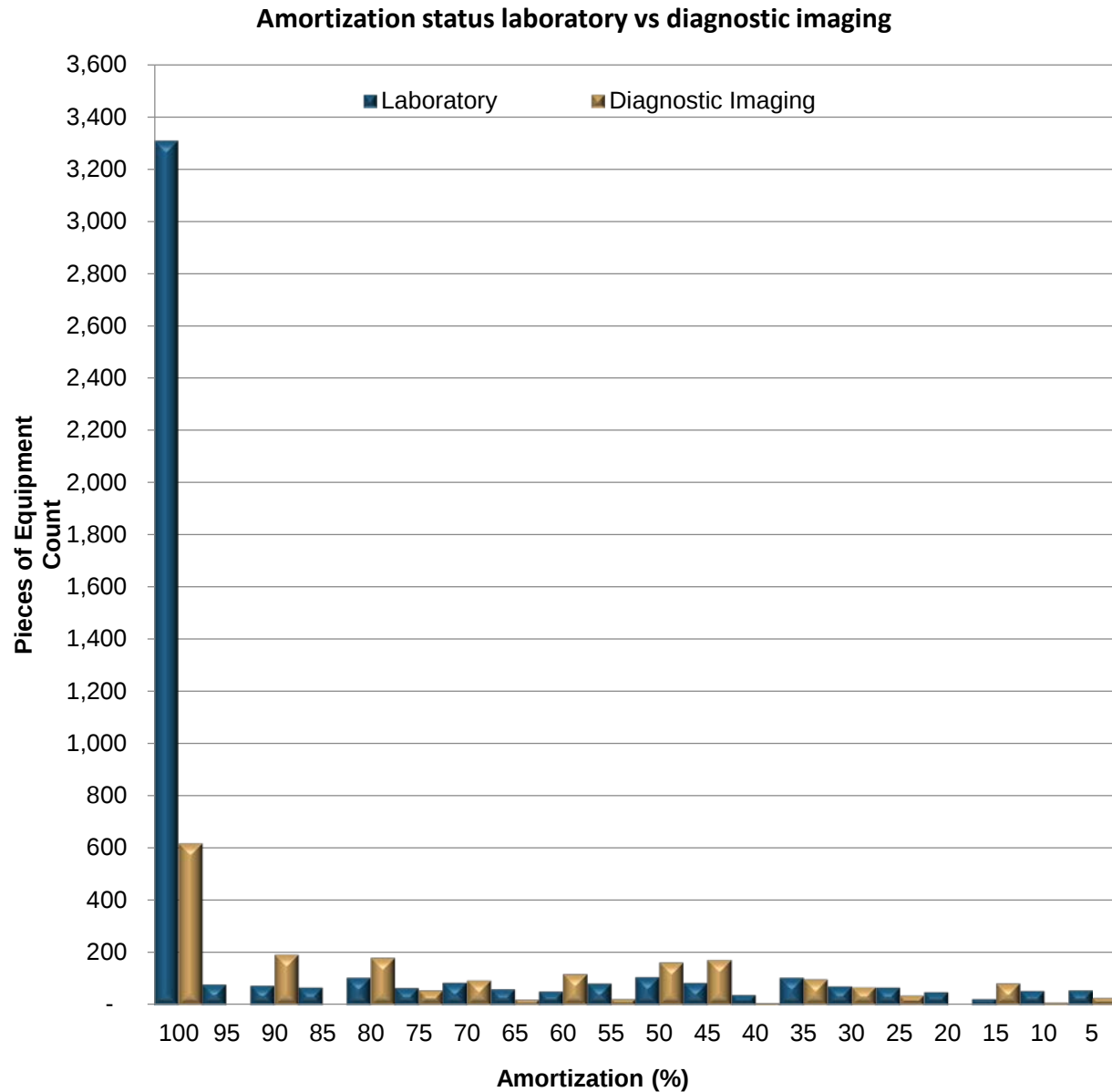


Table 10: Percentage of laboratory (AHS and CLS) and diagnostic radiology (AHS) equipment fully amortized

	Total pieces of equipment	% past useful life
Laboratory	4,652	71%
Diagnostic Imaging	1,983	31%

Table 11: Relative investment in capital across three large service providers in Alberta – by dollars per test performed

Fiscal Year	AHS/Covenant Health		CLS		DyanLIFE		Provincial Total
	Capital \$	\$/test	Capital \$	\$/test	Capital \$	\$/test	
2015/2016	\$2.2M	\$0.08	\$1.2M	\$0.04	\$5.1M	\$0.29	\$8.5M
2014/2015	\$1.0M	\$0.04	\$0.6M	\$0.02	\$4.9M	\$0.28	\$6.5M
2013/2014	\$1.7M	\$0.06	\$0.08M	\$0.03	\$4.7M	\$0.26	\$7.2M
2012/2013	\$2.4M	\$0.09	\$1.2M	\$0.04	\$4.4M	\$0.25	\$8.0M

2015/16 Test volumes used to calculate \$/tests for all years

Properly planned and implemented, the ongoing capital needs for refreshing and replacing diagnostic equipment in laboratories based on an appropriate asset management plan are in fact quite modest, particularly given the critical role of laboratory diagnostics in clinical care. Based on the historical experience of CLS, *DynaLIFE*, and discussions with best practice organizations, the equipment allocation for the diagnostic laboratory would amount to approximately 2.5 - 3.5 per cent of the operating budget. Furthermore, the ability to introduce innovation through new technology often results in a significant return on investment offsetting the capital cost.^{3, 5, 6, 16}

Capital investment - Facilities

The majority of laboratories in Alberta are situated in hospital space that is constrained with little to no room to expand or modernize. Key enhancements in the last 15 years have included:

- 2002 – opening of the *DynaLIFE* hub laboratory in downtown Edmonton
- 2003 – opening of the CLS Diagnostic and Scientific Centre on the University of Calgary campus
- 2012 – a new CLS laboratory in the South Health Campus facility in Calgary allowing expansion of microbiology services in CLS
- 2015 – a new CLS laboratory in the Foothills Hospital McCaig Tower (2015)
- 2016 – the new Edson Healthcare Centre including laboratory facilities
- Currently under construction, the new Grande Prairie Hospital will have a new laboratory facility
- Planning is underway for the Calgary Cancer Centre which will have a state of the art CLS molecular diagnostics laboratory

Edmonton laboratory facilities have fallen behind in terms of facility investments. In 2007, a space assessment of Edmonton laboratories concluded existing space at the University of Alberta Hospital, Royal Alexandra and Provincial Laboratory in Edmonton was oversubscribed and poorly

designed.³⁴ Recommendations included relocation and major renovation and expansion. Other high priority facilities with capacity and safety issues include:

- The Genetics Laboratory in Edmonton
- The Provincial Laboratory in Calgary

Skilled laboratory workforce

Employees are laboratory services most valuable asset. AHS allocates close to 70 per cent of their laboratory expense budget to personnel costs. The age profile of the current laboratory workforce (approximately 41 per cent at 45 years of age and older) cannot sustain services in their present form for the long term. Based on AHS internal human resources data on current trends and projections, only 47 per cent of eligible retirees could be replaced by the current pool of graduating laboratory technologist students.

This critical future gap of qualified laboratory personnel combined with the increasing demand for services is a major driver behind the need for a streamlined, integrated laboratory service network. Further consolidation, investments in automation and new technology, optimized skill mix, and strategic deployment of staff are required to maintain quality service into the future.

Automation is becoming an increasing necessity in the constantly evolving field of laboratory diagnostics. Information systems, specimen handling, high throughput chemistry and hematology analyzers, and robotic specimen storage are commonly available and rapidly expanding into the traditionally manual areas such as microbiology and anatomic pathology. Investment in automation is necessary to conserve and redeploy manpower, and offers additional benefits such as more rapid results, tighter quality control, and a lower unit cost per test. Point of care testing (POCT) is becoming a viable alternative in a number of settings providing on-site results and options which can positively impact care and health system utilization. Point of care testing involves a broader group of providers from outside the laboratory, creating significant oversight responsibilities in the laboratory for quality assurance, training, and integrating the appropriate information into the LIS.^{19, 35}

Training of technology staff is becoming more complex and challenging. Based on national requirements and given the broad range of practice settings in Canada from the large number of small rural laboratories to large consolidated and highly automated hub labs in urban settings, medical laboratory technologists must be trained in both manual and automated diagnostic technology. Rural communities face particular challenges recruiting and retaining appropriately trained staff due to the more limited scope of testing in their facilities.

Currently, there are approximately 5,000 staff across the six laboratory service delivery providers. These staff are comprised of physicians (pathologists, medical microbiologists, hematopathologists, medical geneticists), scientists in various disciplines (PhDs); medical laboratory technologists; pathology assistants; combined laboratory and diagnostic X-ray technologists (CLXT); and medical laboratory assistants. Other staff include non-technical staff that support laboratory services such as logistics, transportation, IT, data analysis, finance, supply chain and human resources.

Three unions (AUPE, HSAA, CUPE) and a sub-section of the Alberta Medical Association represent staff and physicians respectively across the laboratory diagnostic sector.

National and provincial regulatory colleges and associations are involved in credentialing and licensing the technical staff and physicians. A number of regulatory agencies credential staff in the laboratory sector including:

- Canadian Society for Medical Laboratory Science
- College of Medical Laboratory Technologists of Alberta
- Alberta College of Combined Laboratory and X-ray Technologists
- College of Physicians & Surgeons of Alberta
- Royal College of Physicians and Surgeons of Canada
- Canadian College of Microbiologists
- Canadian Academy of Clinical Biochemistry (CACB)
- Canadian College of Medical Geneticists (CCMG)

There are six training institutions in the province providing a wide array of training programs for laboratory professionals as shown in Table 12.

Table 12: Training institutions for laboratory professionals in Alberta and number of graduates

Program	Annual Total	Institution (Degree and Annual # of Graduates)					
		U of Alberta	NAIT	U of Calgary	SAIT	Red Deer College	Alberta Business and Education Services
Medical laboratory technologist	111	BSC 30	Diploma 32		Diploma 49		
Pathology assistants	8	MSc 2		MSc 6			
Medical laboratory assistant	202		54		64	24	60
Cytotechnology	6		6 every other year				
Combined laboratory and x-ray technologist (CLXT)	40		40				
Pathologists		FRCP		FRCP			
General	3-4	1-2		2			
Anatomic	6-8	3-4		3-4			
Neuro	1			1			
Medical micro	3-4	2-3		1			
Hem	1-2	1-2					
Fellows	6-10	2-4		4-6			
Total pathologist trainees	20-29	9-15		11-14			

Trainees across all disciplines receive their clinical training opportunities in a variety of diagnostic facilities across the province.

The University of Alberta Medical Laboratory Science Program and AHS provide a jointly managed simulation laboratory located at Edmonton General Hospital which provides another setting for trainees to gain clinical experience. No other simulation facility exists in the province.

Pathology residents in the University of Alberta and the University of Calgary programs work in various sites across the province, with the majority of their training taking place in Edmonton hospitals, CLS sites in Calgary, and occasionally the Red Deer Regional Hospital. Given the complexity of laboratory medicine and the rapid pace of change, training programs are working hard to keep up with both the changing competencies required as part of national certification, and with the need for clinical practicums which provide appropriate experience for the changing workplace.

The University of Alberta, Medical Laboratory Science Program, in an effort to address system needs, is proposing the creation of graduate level training programs in four areas:

- Bioinformatics and molecular diagnostics
- Laboratory leadership
- Research and development
- Laboratory utilization and applied statistics

These courses will be offered on-line to allow professionals to remain in the work force; certificates for each course would be a stand-alone credential or part of a ladder to a Master's degree.

Staff working in the laboratory sector are managing change on an ongoing basis. Access to ongoing professional development and support is essential; the large laboratory service providers in Alberta take varied approaches to this support. Onboarding programs are provided by all for orienting new staff. Calgary Laboratory Services has invested heavily over the years in training many staff in process excellence (LEAN and Six Sigma business processes) and AHS supports leadership development and a Change Management Network across all sites to support staff in developing resilience and skills related to a changing work environment. Approximately 100+ senior technologists and pathologists across the province work as part of the training network ensuring clinical practicums for students are adequately supported.

Sustainable financing of laboratory services

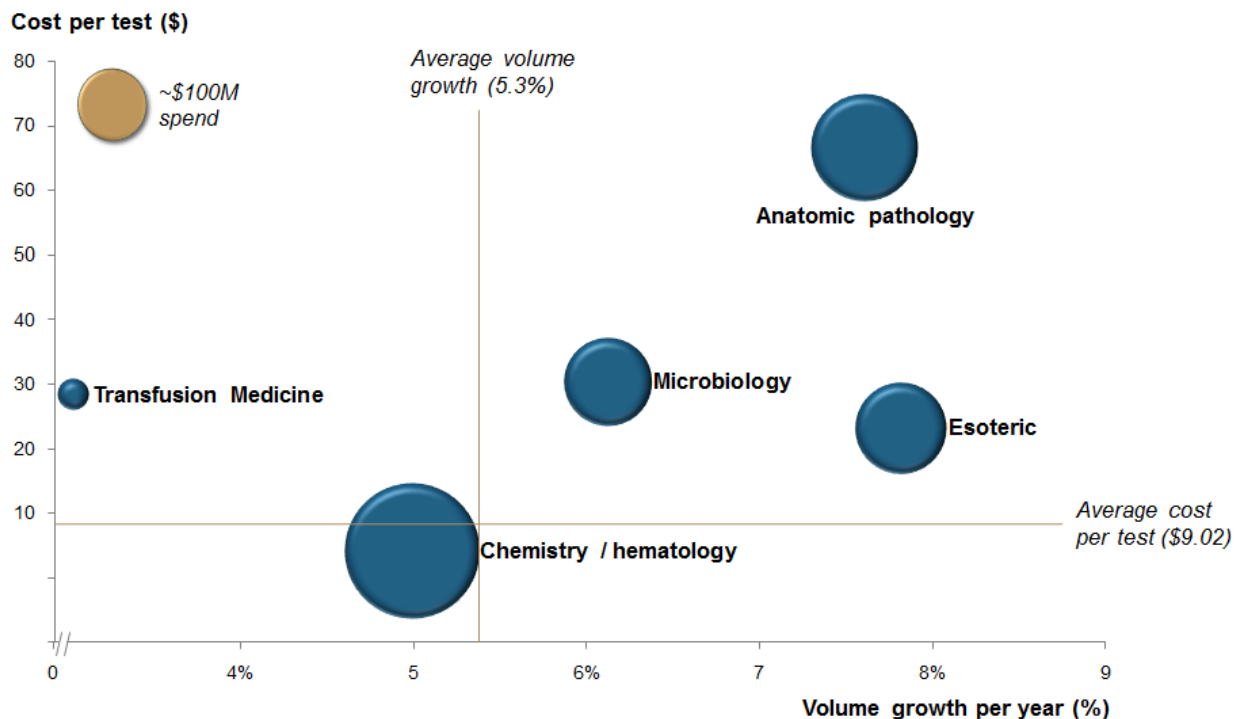
As noted in Table 5, the overall provincial budget for laboratory services for 2015/16 was approximately \$700 million. Laboratory services represent a small proportion of health spending at approximately 3.5 per cent of the overall budget for health and 5 per cent of the overall budget of AHS. However, laboratory diagnostics plays a critical function in informing and supporting the vast majority of patient care decisions and enabling the smooth functioning of the healthcare system.

Demand for laboratory services outstrips available funds. This is a common dynamic across all diagnostic laboratory providers (public, non-profit and private) and it is a trend which will continue, requiring active management. AHS data shows historical volume growth of 6 per cent

annually in the laboratory, with the last four years of data showing an average 3.8 per cent rise in costs annually.

In 2013, the Boston Consulting Group (BCG) provided projections (during the work on the AHS laboratory request for proposal for Edmonton and Northern Alberta) for both laboratory volume and cost increases for AHS out to 2025.²⁴ The BCG estimates showed differential growth in both volume and costs in different areas of the laboratory with chemistry and hematology, the highest volume and most automated areas of the laboratory, projected to have the lowest volume growth at 5 per cent per year. More complex areas such as anatomic pathology, microbiology and the more esoteric areas of testing, which are more resource intense due to their complexity, were projected to grow at approximately 8 per cent per year (Figure 13). The BCG further estimated that in a *business as usual* scenario, overall test volume would rise at 5.3 per cent annually and associated cost would rise at 5.8 per cent annually over the next 13 years.¹⁹ Given the last three years since these projections, the growth rate in the cost of laboratory services has been reduced from 5.8 per cent to an average of 3.8 per cent. Looking ahead, funding constraints will continue and the capacity to enable ongoing transformation of service delivery will be necessary to deliver quality services while working within available financial resources.

Figure 13: Projections of cost per test and volume growth for Edmonton and Northern Alberta 2013 to 2025 (Boston Consulting Group¹⁹)



Research and development

Strong academic links and ongoing research and development in the clinical laboratory are critical to the success of a high quality laboratory service. CLS and AHS through their respective affiliation agreements with the University of Calgary and the University of Alberta support academic time for

research, and teaching by pathologists and laboratory scientists who are University faculty. The scope of research by members of the Departments of Laboratory Medicine and Pathology cross the four research pillars – basic research, clinical trials, health systems, and population health research. Basic science research currently encompasses developing the capability to implement a new diagnostic test as a standard of care in an accredited laboratory, e.g., the assessment of companion diagnostics which must accompany new precision medicines in cancer care. An example of this is the recent work in laboratory services which was undertaken to compare two genetic biomarker assays (Prosigna and Oncotype Dx); either of which would be used to distinguish women who would qualify for adjuvant therapy for invasive breast cancer. Other important research activities include involving the clinical laboratory as a site for beta testing new technology allowing early experience with new, evolving technology platforms.

Across universities and different faculties, there is growing Alberta research expertise in the areas of nanotechnology, proteomics, and metabolomics.³⁶ This has been fostered by significant investment in discovery research over the last decade and is driving the development of novel diagnostics by researchers across a variety of university faculties. The growing field of precision medicine has major implications on the laboratory, as a diagnostic test is often the gateway to a targeted intervention which can provide dramatic results for patients. Such opportunities are growing in number and there is currently a lack of clarity over how such diagnostic tests are reviewed and ultimately implemented in the province. Another very significant opportunity for Alberta in the area of clinical laboratory services is the ability to provide a platform for translational research (applied research), where new discovery is moved from research to the bedside.^{37, 38, 39, 40, 41} This is an area still underdeveloped in Alberta laboratory services. Both of these issues are discussed later in the report.

Best practice environmental scan

Laboratory reform in the public sector, aimed at providing accessible integrated high quality laboratory diagnostic services over the long term, has been studied in detail within Canada and internationally.^{1, 5, 13, 20, 42, 43, 44, 45, 46, 47} Bayne, in her report on laboratory system change in British Columbia in 2003, highlighted the following attributes needed to support successful integration across the province: (1) the need for a provincial policy forum with clear leadership from the laboratory medicine physicians; (2) an integrated approach to management of laboratory facilities; (3) one LIS; (4) robust financial and utilization analytics; (5) a provincial approach to standardization and quality management; (6) rationalization of levels of services with special attention to small sites in sparsely populated regions; and (7) coordinated human resource planning. Terret⁴⁶ concluded that an integrated laboratory model provides benefits such as: single point accountability; operating economies of scale and standardization; the ability to assure equality of service in remote areas; standardization of testing; effective utilization management; homogenous quality management; and enhanced response to emergency due to coordinated redundancy. What is clear from the literature and the significant number of reports written on the topic is that change is slow, and systems around the world are still working toward many of these shared goals.

The private sector is a significant player in laboratory diagnostics in Canada and around the world and in terms of innovation, strategic investment in technology and business transformation, they are leaders. In North America, *IBISWorld* reports the private diagnostic medical laboratory sector employs nearly 300,000 staff and generates annual revenues of \$56 billion.⁴⁸ Across many jurisdictions, the private laboratory sector provides public services through a number of arrangements. In some cases, private sector laboratories are contracted by public health authorities to provide specific services (such as the *DynaLIFE* contract); in other situations, they are licensed and permitted to compete for fee for service business from public payors. Generally, there are two challenges for public payors in their relationship with private laboratories.^{5, 45, 49} The first challenge is ensuring that private providers are aligned with the policy goals and expectations of the public system, which almost universally include the key parameters of access, quality, accountability, transparency, and value. Aligning private sector providers with these outcomes requires skilled performance management of comprehensive service contracts which contain appropriate deliverables, metrics, reporting requirements and processes for scope change as patient needs evolve over time. This level of performance management is often lacking in the public sector. The second challenge is that public sector payment or compensation structures for private laboratory services are unable to keep up with changes in cost structure related to the private sector's capacity for rapid business transformation and innovation. Consequently, the efficiency savings enjoyed by industry are not generally shared with the public payor.⁴⁹

In the launch of this project, the Minister provided clear direction that the planning, governance and oversight of the laboratory sector in Alberta are the responsibility of the government and the public sector. Involvement of the private sector in delivering laboratory service was not precluded; however, it would be based on an assessment of value for the taxpayer. Based on this direction, the best practice review focused on public sector and non-profit sector laboratory networks who had the accountability for the delivery of laboratory services, with a clear focus on large organizations serving multiple facilities of diverse sizes, and in most cases across dispersed geographic regions.

Four of the organizations (Table 13) are public sector in Canada and Australia, five are non-profit healthcare entities in the United States, and one (Health Laboratory Services in the UK) is a joint venture of two public sector National Health Service hospital trusts and a private sector lab. A brief summary of each organization is provided in Appendix E.

Table 13: Laboratory organizations consulted in best practice review

Discussion with other jurisdictions

Canada	Manitoba – Diagnostics Services Manitoba
	Ontario – Ontario: Eastern Ontario Regional Laboratory Association (EORLA)
	British Columbia – BC Agency for Pathology and Laboratory Medicine (BCAPLM)
USA	Kaiser Permanente
	Intermountain Healthcare
	Health Partners
	Mayo Medical Laboratories
	ARUP Laboratories (University of Utah)
UK	Health Services Laboratory (University College London Hospitals/Royal Free London/ Doctor's Laboratory
Australia	New South Wales Pathology

Discussions with these best practice organizations focused on their current strategies and past experiences in meeting the significant challenges of delivering high quality laboratory services to their constituents. Key challenges are common across the world:

- Increasing demand – both sheer volume due to population growth and aging of the population, and demand for new innovative tests by patients and clinicians.
- The need to introduce new game-changing technologies and tests and remove older diagnostic tests which are no longer best practice.
- Static or shrinking resources and in some jurisdictions the need for payment reform.
- Resistance to change in laboratory service organizations from within the laboratory as well as from healthcare providers.
- Broad diversity across ‘customers’ (e.g., large complex academic centres, regional centres, small sites, very diverse individual community healthcare providers) and challenging geography in some jurisdictions.
- Multiplicity of information systems.

These challenges drive the key elements which are the foundation for a successful integrated laboratory organization or network. Throughout the literature and based on multiple discussions with best practice organizations, there was strong agreement on the following key elements.

Elements of success for high quality integrated laboratory services organization

1. **A robust strategic plan.**
2. **Clear leadership structure with transparent decision-making processes.**
3. **One LIS across the organization** with enhanced level of support for clinicians.
4. **Regular investment in innovation and new technology.**

5. **Strategic organization of the delivery of services:**
 - a. **Optimal integration and consolidation of the system.**
 - b. **Tiering of the scope of services by site based on size, function and location**, while ensuring a structured system of support from medical, scientific and technology leaders in regional and academic centers.
 - c. **Hub laboratories** to support economies of scale and opportunity for technological innovation.
 - d. **Point of care testing** to support better, more convenient and cost effective access to healthcare.
 - e. **Sophisticated and patient-centred pre-analytical logistics.**
 - f. **Standardization** of equipment and testing menus across the organization to leverage economies of scale and ensure equity of access for patients.
6. **Comprehensive quality programs across the laboratory system.**
7. **Academic partnerships to support the integration of research into practice.**
8. **Capacity and strategies to enhance performance** (efficiency, value for money and the ability to introduce game-changing diagnostic programs) on an ongoing basis supported by:
 - a. **Processes for nimble decision-making.**
 - b. **Appropriate programs and support for appropriate utilization management.**
 - c. Structures for ongoing **engagement of medical and scientific leadership.**
 - d. **Robust analysis** of evidence, business and clinical metrics to support decisions and evaluate their impact over time.
 - e. **Change management and business process redesign skills** across the organization.

Local engagement summary

The stakeholder engagement process included a variety of interactions with over 1,400 participants from May to December 2016 (Appendix A). Site visits, in person meetings, on-line meetings, teleconferences, town halls, and discussions with existing networks, committees and working groups were used to dialogue and receive input and feedback on the state and future of laboratory services in Alberta. Providers and staff from practically every organization involved in laboratory services in Alberta participated.

To help summarize the many issues discussed and shared, the local feedback was organized under the elements for success of a high quality integrated laboratory sector as outlined above. The feedback is presented in a manner that, as closely as possible, reflects the many voices heard.

1. **A robust strategic plan**

- There is currently no formal provincial strategic plan for laboratory services in Alberta. A strategic plan would provide a roadmap moving forward and improve the priority setting process.
- A strategic plan would help illustrate the critical role diagnostic laboratory services plays in medical decision-making for patients and would help change the perception of laboratories as just a support service like laundry or security services.

2. **Clear leadership structure with transparent decision-making processes**

- The Provincial Medical Director for laboratories has little authority over laboratory operations. Zone Clinical Department Heads report to zone Medical Leadership while administrative Laboratory Directors report to the Senior Operating Officer. Mixed reporting relationships lead to confusion and inconsistent management.
- Decision making is very slow and it is unclear who is finally accountable for making specific decisions:
 - o often provincial level decisions are not ultimately reflected at the zone laboratory operations level
 - o it is not clear how services and supporting budgets transfer between AHS and Covenant Health
- Making decisions on new diagnostics and the introduction of new technology is particularly problematic; taking months to years to make decisions. The funding methodology for new diagnostics is unclear and is a stumbling block to their introduction.
- Decisions addressing quality issues made by the provincial program are not consistently implemented across all zones. Accountability for implementation is unclear.
- Too many individuals across the system appear to have veto power. Evidence based decisions by laboratory leaders, following an inclusive process by committee structures, don't proceed due to vetoes by physicians inside and/or outside the laboratory.
- The point of care testing program is drifting and urgently needs governance structure and clear mechanisms for decision making and funding.
- Lack of support and very slow decision-making regarding integration of research with clinical service activities.
- Some decision making is made at unnecessary high levels and is too centralized without a sufficient level of local flexibility.

3. **One LIS across the organization**

- Generally, the concept of one LIS is supported as the right course of action, although acknowledged as difficult and arduous to implement. It was identified that a strategic implementation plan is needed given all the risks.
- Paper based systems are seen as creating risks to patients and inefficient.
- At this time, many would prioritize replacing aged and out of date diagnostic equipment versus spending the money to move to one LIS.
- There is a severe lack of IT resources across the laboratory program which impacts daily operations, quality and safety, and interferes with implementing any level of change. There is a high level of frustration and concern in this area.
- The last CLS upgrade of their LIS (Cerner Millennium) was cited as painful, but helpful in optimizing information flow and analytics; however, it was identified that the change process could have been better.
- Alberta is behind in the ability to provide sophisticated support for clinicians and patients such as interfaces with mobile devices, critical result reporting, decision support, standing order management for doctors, and web enabled patient access to results.
- More and broad-based access to data analytics is required for optimizing laboratory operations across the province.
- It was identified that appropriate and secure access to data needs to be enabled for researchers; currently it is very difficult to access data for research purposes.

4. **Regular investment in innovation and new technology**

- This is the issue of highest concern across the province in the laboratory sector (note this was not the perception of *DynaLIFE* staff).
- CLS past processes allowed flexible financial tools to ensure organization was keeping up with investment needs; this has been very constrained since consolidation under AHS.
- Intense frustration around the province was voiced regarding the state of laboratory equipment and lack of investment in new technologies.
- Procurement and purchasing, renovation, and IT services which are provided corporately are completely uncoordinated and disconnected adding time and barriers to equipment installation.
- Young pathology recruits, from other jurisdictions, expressed concern that Alberta is far behind in investment in technology platforms which impacts job satisfaction and ability to keep up their skills.
- Some technologies are research based and there is no process for integrating these into the clinical laboratory.

5. Strategic organization of the delivery of services

Tiering of services by site

- Generally tiering of services is supported.
- General support for hub and spoke model, although uncertainty regarding change and impact at individual staff level.
- Better support needed in small sites in specific areas e.g., transfusion medicine, utilization management.
- Delayed sign off by central decision-makers on day-to-day business needs is delayed and creates operational and relationship issues with vendors leading to operational issues in regional and rural facilities.
- Small laboratory service providers (Covenant Health, Lamont Health Care Centre) have significant needs which can't be adequately supported by their organizations; a different model for management of these laboratories is needed.
- AHS sets provincial standards through the Chief Medical Director for Laboratories and the Senior Operating Officer; however, there is no consistent alignment and accountability with different service providers and different zones causing uncertainty regarding "who is in charge" and delays in implementation of agreed upon standards.
- Small rural laboratories often feel their medical and scientific support is too dependent on personal relationships and not properly structured.
- Recruitment is an issue and retention of staff can be an issue in small sites; more support is required to strategically manage this issue.
- There are often issues with non-laboratory clinicians (including locums) who don't support or understand changes in laboratory services. This is difficult for laboratory staff to deal with; enhanced outreach and change management strategies are needed.

Hub labs and consolidation of services

- Most staff generally understood and supported consolidation and the hub and spoke model as a best practice for sustainable laboratory services, but small rural and regional sites do have concerns about consolidation and impact on services and personnel.
- Laboratory networks have worked hard to develop a test matrix to guide appropriate on-site test menus and tests that need to be referred out.
- With consolidation of service in a hub or regional laboratory, ongoing assurance of expected turnaround time is needed where testing is done off site.
- Some hospital based pathologists voiced concern about how to ensure support to non-laboratory clinicians in hospitals with a move to a hub laboratory. Others see opportunities to enhance their ability to provide subspecialty expertise in a hub laboratory environment.

- Digital pathology, rotating on site pathology services, and other strategies were seen as important to sustain support and connection with clinicians.
- Expression of frustration at Calgary/Edmonton competition (referred to as the “arms race”) which leads to unnecessary duplication and strong message that this needs to be fixed.

Sophisticated and patient-centred pre-analytical logistics

- This is seen as a critical area particularly in a tiered hub and spoke model. Some gaps were identified, particularly in the North zone and small sites, where logistics are less structured and reliable. This poses a risk for quality and safety.
- Central management of CLS logistics works well for their network of large and small institutions.
- *DynaLIFE* has a tightly managed logistics portfolio.
- Quality problems in the logistics area, particularly those related to turn around times, need expedited resolution.

Standardization of equipment and testing menus

- Standardization is understood and generally supported; some worry that there is insufficient redundancy in the system to protect against product failure.
- Rural concerns are heard but don’t seem to be integrated into decision-making.
- Need expressed to allow for some local flexibility if there is no material impact.
- Capital equipment budgets are insufficient and create a piecemeal approach to standardization which is counterproductive.
- Decisions related to standardization are difficult to implement across the different providers and zones due to mixed accountability and fragmented decision-making.

6. Comprehensive and accountable quality management program

- Generally strong support for current inclusive approach in structure of program.
- Anatomic pathology quality assurance program cited as leading edge and could be used as model for other laboratory areas.
- Need for coherent, mandated provincial approach for whole system versus distinct approaches by the various providers and zones - need for an expedited issue escalation and resolution process.
- Concerns raised regarding the very slow pace of decision-making. Problems were expressed with the implementation of provincially mandated quality initiatives due to mixed accountability of zones and other partners in the system which raises safety and risk issues.

- Other issues raised such as the need to move to common reference ranges and methodologies across province (particularly if patients will have access to their own results), one general laboratory test requisition form for whole province (three years already spent trying to achieve this).

7. **Academic partnerships to support the integration of research into practice**

- Appreciation for the importance of being part of the research and teaching enterprise associated with both the University of Calgary and University of Alberta.
- Frustration associated with the lack of nimbleness in AHS and the universities in enabling laboratory services to participate in supporting research.
- Strong sense of the opportunity to be leveraged in the area of translational research but need a governance mechanism that transcends the current competition between Calgary and Edmonton.

8. **Capacity and strategies to enhance performance**

Nimble decision-making

- This is lacking in the current organizational structure – decision-making is slow and endless process.
- Deep frustration across the province that this is interfering with the ability of the laboratory sector to meet the need for innovation and ultimately be financially sustainable.
- Urgent situation regarding companion diagnostics as to who pays; who chooses the assay; current system not working.
- Significant issue with point of care testing program.

Appropriate programs and support to clinicians for appropriate utilization management

- Strong desire to move ahead with this – seen at every level to be difficult in current construct.
- Vitamin D decision seen as a success; fetal fibronectin process seen as an example of how difficult it is to make evidence based decisions in current structure.
- Too many vetoes across AHS organization – both within the laboratory and outside of laboratory – no accountability for outcomes for those who veto.
- New AHS system-wide committee has been established, but very broad mandate that includes all health services; laboratory services need to move faster.

Engagement of medical and scientific leadership

- Generally, there are good structures in the laboratory networks for medical and scientific leadership to work with each other and provide input.

- Discussion regarding whether there should be an AHS Laboratory Strategic Clinical Network or whether laboratory professionals should be invited to participate on other SCNs. At present, there is concern that neither is happening and there is a need for enhancement of dialogue between laboratory leaders and clinical leaders from outside the laboratory.

Robust analysis of evidence, business and clinical metrics

- CLS seen to have established a successful and robust analytics group – this capacity supports the province but more capacity needed to support whole provincial laboratory network.
- Seen as critical function for success of diagnostic services, business transformation and research.
- Move to one LIS will enhance overall understanding of laboratory operations.
- Need better ways to support data access for research.

Change management and business process redesign skills

- CLS seen as a leader through their training of staff in Process Excellence over the years.
- Change management training and Change Network seen as a good step; educators see this as a priority in training of technologists.
- Investment is key – concerns that professional development funds have been severely cut back in AHS and little opportunity to learn new skills.

Other Feedback

During the local engagement process, many discussions were held with subject matter experts and specific working groups related to other specific areas of laboratory services that were not reflected above. The summaries below provide more detail on feedback received in a few specific areas critical to a successful laboratory sector.

Public health

There are two public health laboratories in Alberta; one in Calgary and one in Edmonton. Public health laboratories have a unique role, providing vital laboratory services in support of the legislative responsibilities of the Chief Medical Officer of Health (CMOH) in the Ministry of Health and other Medical Officers of Health in AHS. The public health laboratories have several areas of activity including:

- surveillance for a variety of public health risks such as influenza, sexually transmitted diseases, hepatitis, etc.;
- response to and monitoring of emerging issues (e.g., SARS, H5NI outbreaks, food related outbreaks of E Coli 0157, outbreaks of tuberculosis, water contamination and others);
- reference testing; and
- training and education.

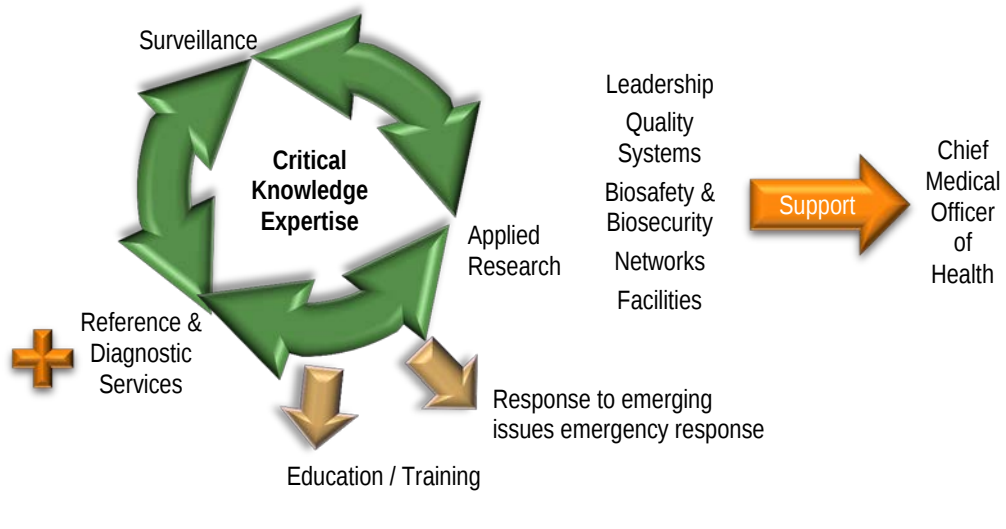
The public health laboratory has a dual reporting relationship to both the CMOH in the Ministry of Health and the Provincial Medical Director and Senior Operating Officer for Laboratories in AHS. During the engagement process, leaders of the Public Health Laboratory as well as senior representatives of the Office of CMOH stressed the importance of ensuring a clear understanding, in any new integrated structure, of the unique role and specific needs of the public health laboratory (Figure 14).

The feedback received indicated that the Public Health Laboratory does not need to perform all the testing involved in its surveillance program; however, the flow of information and the standardization of tests used in the surveillance program is critical. Examples were shared of gaps in both of these areas leading to risk and compromise of the public health function. Another issue raised was the importance, in the event of a public health emergency such as the SARS outbreak or the 2015 MERS (Middle East Respiratory Syndrome) outbreak, that the public health laboratory have sufficient technical expertise and technical capacity to oversee the required surveillance testing, and, if necessary, develop and oversee a novel testing regime to manage the epidemic.

Figure 14: Alberta public health laboratory activities

Emerging & Emergency issues

SARS/MERS CoV
Bioterrorism
Influenza (pH1N1, H5N1)
Listeria
E. coli 0157
West Nile Virus
Lyme Disease
Antimicrobial Resistance (AMR)
Legionella
Enterovirus D-68
Ebola
Zika Virus



Genetics laboratory services (GLS)

The use of genetic testing and the inclusion of patient's DNA information in directing healthcare decisions about diagnosis and management is called genomic medicine. GLS plays a key role in supporting the vision of the Alberta Genomic Health Program.⁵⁰ GLS currently has two laboratory sites in each of the academic centers in Alberta (Calgary and Edmonton). Genomic medicine has the capacity to improve patient care at a lower cost by supporting early and accurate diagnosis and individualized treatment, avoiding unnecessary and often invasive diagnostic testing, harmful and ineffective interventions, and healthcare resources costs. The feedback received indicated a sense amongst stakeholders that Alberta is falling behind regarding capacity for supporting state of the art genomics testing.

Key priorities identified by GLS which would begin to address this situation and allow appropriate support for an overall genomic health program include:

- Expedited procurement of the appropriate clinical technology (e.g., next generation DNA sequencer) to support repatriation of specimens referred out-of-province for testing.
 - o In 2015, projected cost savings following repatriation of genetic testing currently sent out of province was estimated at \$350,000 in year 1, and \$2.5 million in year 2.
- Expansion of microarray testing to meet national standards.
- Expansion of biochemical genetic testing to address critical clinical shortfalls.
- Expansion and strengthening of pharmacogenomic research and clinical services.
- Enhancement of cancer genomic biomarker testing.
- Enhanced bioinformatic capacity to respond to the interpretive complexities of next generation sequencing

Point of care testing (POCT)

Although not a new concept, there has been a dramatic rise in the opportunities for POCT in the last few years related to advances in technology.^{2, 5, 13, 19, 51} The benefits of POCT include:

- Expedited assessment of patients – for example, the ability to rule out a heart attack immediately in a patient with chest pain in the emergency department using a POC rapid troponin assay when the facility does not have access to a rapid turnaround time for a troponin test performed in the laboratory.
- Supporting critical patient care decisions – POCT for rapid HIV diagnosis is used in specific circumstances to ensure clinical interventions are appropriate based on HIV status.
- Health system efficiencies – enabling rapid access to critical laboratory diagnostic testing in small sites after hours to avoid repeated call-back of staff and delays in assessment and treatment of patients.

POCT is both convenient, and yet complex to implement, because testing is performed in clinical areas outside the laboratory and often by health professionals who are not laboratory professionals. Approximately 12 million POC patient tests were performed in 2014/15 across the province. POCT is being utilized in clinical areas ranging from pre- and post-natal clinics, the emergency department, intensive care units, and across the healthcare system for many patients with diabetes. Key issues arising from this include:

- POCT is performed using laboratory diagnostic technology and must undergo regular and rigorous quality control to ensure accuracy and reproducibility of results.
- Laboratory professionals are trained specifically in the area of diagnostic testing and rigorous quality control while other health professionals, who are administering POCT, have no formal training in these areas.

- POCT results and related quality metrics need to be integrated into the laboratory information system, a technical challenge given the complex IT systems in the province and the diverse clinical areas using POCT.

Currently, there is a POCT network charged with overseeing this area of diagnostics. In the 2014/15 POCT Network Annual Report,⁵² and during the stakeholder engagement process, the Chair and other clinical experts in the network expressed the urgent need to bring the governance of POCT into compliance with international best practice standards,⁵³ and into conformance with applicable accreditation standards from Accreditation Canada, the College of Physicians and Surgeons of Alberta, and the International Organization for Standardization (ISO).

The other issue raised by the POCT Network was the absence of a funding methodology for the implementation of new tests. POCT often creates savings in a non-laboratory clinical area (e.g., emergency department) while the technology and program costs are borne by the laboratory. The lack of formal and accountable governance for POCT, and the lack of clarity related to funding is resulting in instances where clinical areas are planning to implement POCT without oversight, appropriate quality control, or linkage with laboratory information systems posing significant risks and further fragmentation to the system.

Introduction of new diagnostic tests and methodologies

Discussions with a number of groups identified the lack of clear process and timely decisions for the introduction of new diagnostics to be one of the most significant gaps currently in the laboratory sector.

The drive to introduce new diagnostics is intense. There are many new diagnostic tests in development across many areas of clinical medicine (prenatal screening, population health screening for cancer, new diagnostics to manage public health threats, medical genetics and others). Not all of these new tests will bring real change or value to patients or the healthcare system; however, the ability to introduce the new tests and associated technology which are game changers, is critical.^{2, 3, 54, 55, 56} The scope of new diagnostics ranges from minor changes in a panel of markers used in the laboratory to determine the aggressiveness of a specific cancer, to tests which will determine access to a new precision cancer drug.

Removing or exiting an existing test from the test menu or restricting access to a specific test (by patient diagnosis or specific medical disciplines), is as hard or harder to achieve as adding a new one. Feedback indicated that there is a need to ensure decisions about removing unnecessary or obsolete tests are subject to the same processes as those used for adding a new test. Furthermore, both locally and in the literature, there was a strong sense that success in implementing changes to the test menu, whether adding or removing a test requires robust analysis, effective outreach, change management, and strategic decision-making tools to help support non-laboratory clinicians in evidence based practice.⁵⁷

Feedback was gathered from various experts from the following organizations who are currently providing input into decisions related to adding new laboratory diagnostics:

- CADTH
- Alberta Health HTA Assessment Program (and external partners)
- AHS HTA Assessment Branch
- Institute of Health Economics
- AHS Appropriateness of Care Committee
- Senior Laboratory Management
- AHS Laboratory Networks
- AHS Strategic Clinical Networks
- AHS zone Medical Leaders
- Alberta Medical Association, Choosing Wisely

In summary, there was agreement that the journey to a decision about a new diagnostic is complex, often takes many months to several years to reach a conclusion, and it is not clear who and where the final decisions are made related to making the test available, paying for it and determining where it will be implemented. This was a major source of frustration for laboratory providers and clinicians external to the laboratory.

A specific concern was raised related to precision medicine drugs and related companion diagnostics. There is a robust process involving CADTH, with final decisions by Alberta Health, to determine whether precision medicine drugs will be publicly funded. However, there is no process for evaluating or making decisions on accompanying diagnostic tests (the companion diagnostic) which identifies the patients who will respond to the drug. This is a significant concern given the 30 plus precision cancer drugs (each of which will require a companion diagnostic) currently under review at CADTH.

As shown in Table 14, other provinces are managing these issues (both adding a new test and removing obsolete tests or restricting their use) in a more streamlined fashion.

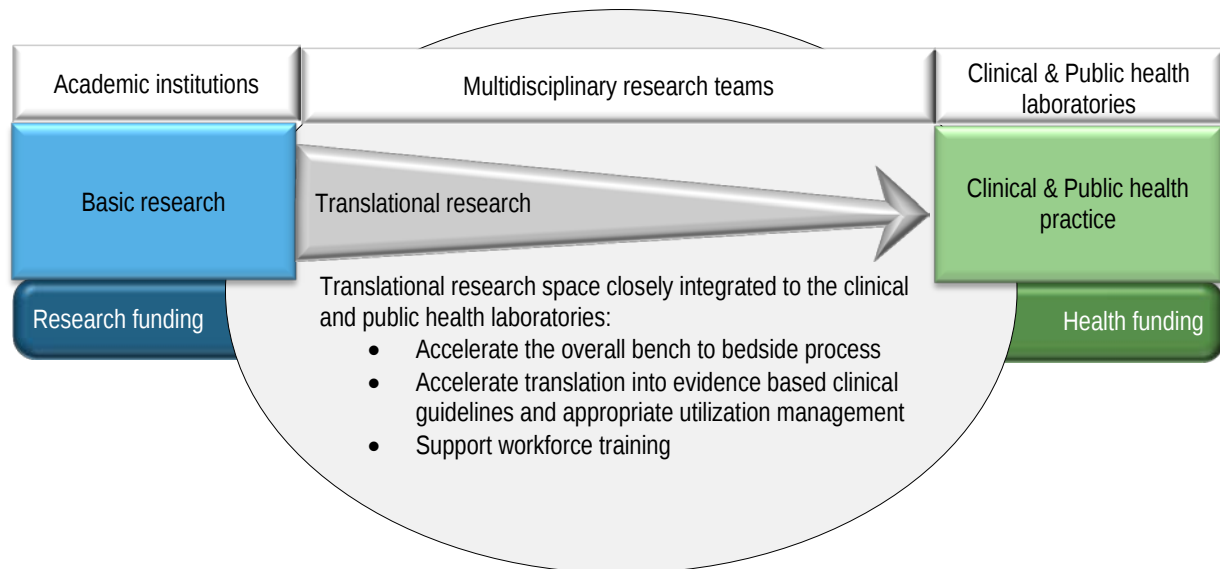
Table 14: Mechanisms to review new laboratory diagnostics across Canada

British Columbia Agency for Pathology and Laboratory Medicine/Ministry of Health	Test Review Committee^{58, 59} • Standing operational unit reporting to the Laboratory Agency • Recommending body • Introduction, replacement and elimination of publicly-funded tests • Stringent evaluation criteria, expert consultation and economic considerations • Recommendations through the Laboratory Agency to the Ministry of Health for final decision Genomic Testing for Cancer Care⁶⁰ • Standing Committee with BC Cancer Agency/ PHSA reporting to the Laboratory Agency • Recommending body
Diagnostic Services Manitoba/Ministry of Health	• Test Menu Add Process⁶¹ • Provincial Genomics Testing Advisory Committee
Province of Ontario	Laboratory Services Expert Panel⁴⁵ • Recommendation 6: Establish a provincial process to formally evaluate new laboratory tests, recommend or not recommend such tests, and retire obsolete testing with a regularly updated Schedule of Benefits

Translational research

Translational research (TR) is designed to take fundamental and innovative basic science, clinical or population health discoveries and move them to the real world of providing care for patients (Figure 15). The significant investment in discovery research over the last decade, by the Government of Alberta and others, has positioned Alberta researchers in nanotechnology, proteomics, metabolomics and genomics on the international stage of precision diagnostics. This expertise, when aligned with the shift of industry diagnostic development models from in-house development to academic partnering, presents a significant opportunity for Alberta. An effective integrated and responsive provincial laboratory sector with the support of enabling government platforms, such as Alberta Health, the Ministry of Economic Development and Trade, Alberta Innovates, InnoTech Alberta, Tech Edmonton, the Edmonton Health Innovation Strategy, the Institute of Health Economics and others, has set the stage for an unprecedented opportunity for translational research and implementation science in laboratory diagnostics. Capitalizing on this opportunity will help realize the full potential of Alberta's academic research programs for the benefit of Albertans, foster greater and continued industry investment into the province, and ultimately maximize knowledge transfer, commercial opportunities, and adoption of new innovations in Alberta's health system in the evolving era of precision health.

Figure 15: Translational research in laboratory diagnostics – interface with academia and clinical laboratories



The engagement process, on the specific topic of TR, included a workshop hosted by the HQCA (see Appendix F) which brought together over 40 key stakeholders from across the province. Other discussions involved the Deans of Medicine and VPs/Associate VPs of Research from the University of Calgary and University of Alberta, the VP of Research at the University of Lethbridge, and other scientists in laboratory medicine and pathology as well as other departments and faculties.

Stakeholders shared the frequent experiences of Alberta researchers developing novel technology and diagnostic tests who either abandoned their projects or took their prototype at the developmental stage to other countries for commercialization and integration into clinical care. This situation reflects the current lack of a structured TR program in the area of laboratory diagnostics in Alberta and causes loss of innovation value created locally through government investments. The main barrier and gap identified was the lack of a seamlessly integrated TR facility with a focus on precision diagnostics enabling implementation science under real world conditions.

Reviewing the literature revealed that over the last decade, Canada and other jurisdictions including the United States, the United Kingdom, and the European Union have committed to significant investments in establishing infrastructure to support translational research.^{22,}

^{39, 62, 63, 64, 65, 66, 67, 68, 69} Laboratory diagnostics is recognized as the pivotal and essential translational research interface in advancing precision health into clinical reality. The elements below were identified in the literature and through the engagement process as necessary for a successful TR program in the area of laboratory diagnostics:

- Dedicated laboratory (space, equipment and processes) adjacent to and seamlessly integrated with the clinical laboratory. The TR space must be accredited by the CPSA and/or the CALA to ISO standards depending on the TR opportunity.
- Access for researchers to strategic expertise and advice in the areas of:
 - o all elements of quality control and process improvement for laboratory diagnostics,

- o clinically appropriate and accredited technology platforms,
- o bioinformatics expertise, and
- o expertise and support in health ethics, health economics, and health technology assessment.
- Access to specimens which can be used for setting reference ranges and testing the specificity and sensitivity boundaries of a novel diagnostic test.
- Access to laboratory utilization data (appropriately anonymized and secure) and health economic evaluation expertise.
- Ability to protect proprietary information and technology.
- Funding to support a core TR team with specific expertise who can coordinate the involvement of existing clinical laboratory staff, clinicians and researchers, and enable the successful procurement of research funding from provincial, national, and industry sources to support the program.
- Other enabling supports specifically for commercialization of novel diagnostics (which could be leveraged through other provincial partners such as Alberta Innovates, the Ministry of Economic Development and Trade and others) include:
 - o procurement advice,
 - o marketing expertise,
 - o economics expertise, and
 - o access to venture capital.

The best practice research indicated real economic benefits associated with TR.^{11, 12} For example, an economic impact analysis of the University of Florida Clinical Translational Science Institute (CTSI), funded by a federal government grant, demonstrated that for every one dollar of investment for support for the TR program, eleven dollars of economic value was generated in the local economy.¹¹

Based on feedback during the engagement on this topic, it was the consensus that the demands on a structured translational research program and facility, as described above, will likely be significant given the current scope of innovation research in the area of laboratory diagnostics which is ongoing in the academic institutions across Alberta. In discussions with stakeholders, and particularly the academic Department Heads for Laboratory Medicine and Pathology at both the University of Calgary and the University of Alberta, there was conceptual agreement on the need for a governance framework to oversee an evolving TR program to ensure that it was provincial in nature, integrated with both the Provincial Plan for the laboratory sector and the Alberta Precision Health Initiative. Given the strategic role of TR in enhancing clinical service delivery, there was agreement that the oversight or governance structure would reside in the organization delivering laboratory services for Alberta, would reflect a provincial approach, and would involve the following responsibilities:

- Defining, monitoring and evaluating performance standards for translational research.

- Strategic planning and direction setting for the program based on the following principles:
 - Research must be aligned with patient needs.
 - Emphasis should be on research activities which will significantly enhance outcomes – both patient and health system outcomes.
 - When a diagnostic innovation is determined to be appropriate for addition onto the provincial test menu, the TR process should provide objective input on where the test should be done, utilization guidelines and appropriate post implementation evaluation.
- Capacity assessment:
 - Expertise needed for the program.
 - Training needs.
 - Planning strategies for accessing necessary skills and people.
- Resources:
 - Determining a strategy for obtaining and allocating a core investment in the TR program.
 - Determining the strategy for leverage of the core investment based on international benchmarks.

Analysis, recommendation and required actions

Analysis

The Minister's request for a *Provincial Plan for Integrated Laboratory Services* is timely. The laboratory sector accounts for just 3.5 per cent of the overall health budget (approximately 5 per cent of the AHS budget). However, diagnostic laboratory services are a key point of leverage given their role in informing the vast majority of healthcare decisions for patients. In addition, timely delivery of laboratory services is vital in enabling the health system to function efficiently. Whether it is testing prior to initiating weekly chemotherapy, before a patient can be discharged from hospital, or adjusting anticoagulants for a patient in the community, an effective and efficient laboratory diagnostic sector is essential to a high functioning and high quality healthcare system. Therefore, it is critical that this area of service be positioned to be nimble, integrated, high quality, and financially sustainable. The best practice review and engagement process revealed that more needs to be done to ensure Albertans have access to high quality, sustainable laboratory services and emphasized the importance of aligning organizational structure with the unique dynamics and needs of laboratory services was clear.

In addition to ensuring that the laboratory sector can provide high quality care to all patients across the province, there are other important contributions which the sector can make. Alberta has made a significant investment in discovery research over the last decade, building centres of expertise across numerous research disciplines, all directly applicable to laboratory diagnostics (nanotechnology, proteomics, metabolomics, genomics). Harnessing this local expertise to bring change and innovation to the healthcare system is the process of translational research. A more integrated, streamlined and nimble clinical laboratory services sector could enable Alberta to take a global leadership role in translational research in laboratory diagnostics. The sheer size of the laboratory enterprise, the diverse population and geography it serves, the unique datasets available in Alberta, and the presence of two strong medical research universities present an unparalleled opportunity for innovation and associated economic activity while enhancing outcomes for patients. In other Canadian jurisdictions, the United States, the United Kingdom and Europe, partnerships are being developed to pursue these economic and health outcomes opportunities. The Alberta advantage is recognized by laboratory leaders around the world as was evident during the best practice consultation.

Vision and goals for a high quality integrated laboratory sector

Articulating a vision and goals for an integrated provincial laboratory sector was an important point of discussion during the engagement. The following vision and goals were broadly supported by all stakeholders.

Vision

With patients as the focus, Alberta will create a globally competitive, high quality, fully integrated, innovative, and sustainable laboratory system to enable patients and providers to achieve the best health outcomes.

Goals

- **Patient centered.**
- **Safe and high quality** in all its dimensions and locations.
- **Accessible** for patients across the continuum of health services and across the geography of the province.
- **Achieves enhanced patient care and outcomes** through engaged medical and scientific laboratory professionals.
- **Nimble and transparent** in its response to technologic and other advances designed to significantly enhance patient outcomes or achieve significant business efficiencies or both.
- **Innovative and resilient** in its clinical and business approaches.
- **Linked to research and training** through strong academic links.
- **Fosters a healthy progressive workplace** for all staff.
- **Cost effective and financially sustainable.**
- **Globally competitive and contributing to a diversified Alberta economy.**

The above goals would form the basis for future performance management of the integrated laboratory system in the province.

Delivery model options for a high quality integrated laboratory sector

The HQCA made the following recommendation in their report released in May 2016:

Develop options for the creation of a single public sector platform for the delivery of laboratory services through an integrated provincial plan. This platform would align with the needs of the health system, but be structurally separate and include appropriate transparency, accountability requirements, and improved clinical and business metrics; while enhancing safety, quality and overall service to patients.

Following the release of the HQCA report the Minister directed that options be brought forward that aligned with this recommendation.

Providing diagnostic laboratory services is a unique business in healthcare. The complexity and sheer volume of laboratory diagnostics, high rate of change and innovation, criticality of the laboratory's impact on patient care, and the challenges to financial sustainability with growing volume demands and requests for new tests have pushed many jurisdictions and healthcare organizations (both public and non-profit) to look for more effective ways to deliver laboratory services. In addition to this, there is a growing desire to tap into the opportunity for clinical laboratories to work with technology and health data innovators to enable enhancements to patient care as well as drive economic opportunities through translational or applied research.^{66, 67, 68, 69}

In the best practice review, service delivery models of ten leading organizations in laboratory diagnostics were studied (Table 15). There is a clear trend toward the establishment of stand-alone

laboratory service organizations that are separate from comprehensive health services delivery organizations.

Of the 10 laboratory organizations reviewed, seven were stand-alone laboratory service providers. They were agencies of the Ministry of Health of the local jurisdiction (BC Agency for Pathology and Laboratory Medicine, Diagnostic Services Manitoba, New South Wales Pathology), or a wholly owned subsidiary of a comprehensive health service delivery organization(s) (EORLA in Ontario, ARUP Laboratories in Utah, Mayo Medical Laboratories in Minnesota). Health Services Laboratories is a joint venture between two major National Health Service Hospital Trusts (Royal Free and University College London Hospital) and the Doctor's Laboratory, a private sector laboratory.

The remaining three organizations studied operated their laboratory services as a division within their large comprehensive health delivery organization (Kaiser Permanente, Intermountain Health, and Health Partners).

Table 15: Leading health service delivery organizations – laboratory service delivery model

Organization	Key information	Agency under the Health Ministry	Subsidiary under the Health Authority(s)	Part of HA/Hlth Organization
Public sector				
Agency for Pathology and Laboratory Medicine, BC	Laboratory Services Act, October 2015, agency under development, budget \$730M	√		
Diagnostic Services Manitoba	79 labs, budget \$250M, 1,700 FTE, 28M tests/year	√		
Eastern Ontario Regional Laboratory Association (EORLA)	16 Hospitals – a member-based Not for Profit Corporation 18 Labs, budget \$113M, 1,000 FTE, 13M tests/year		√	
New South Wales Pathology	Legislated agency by State government 200 Labs, budget \$600M, 4,500 FTE, 61M tests/year	√		
Health Services Laboratory	Public Private Joint Venture University College London, Royal Free and the Doctor's Laboratory 1 hub lab; several hospital response labs; in development – no metrics		√	
Non-Profit Sector				
ARUP Laboratories	Subsidiary of U of Utah		√	
Mayo Medical Laboratories	Subsidiary of Mayo Clinic 3 hub labs; 24M tests/year		√	
Kaiser Permanente	Seven autonomous regions – moving to integrated Lab system; 38 hospital labs; 150M tests/year			√
Intermountain Healthcare	22 labs, 1,100 FTE, 46M lab tests/year			√
Health Partners	1 central lab, 6 hospital labs plus remote clinic labs; 9.1M tests/year			√

The rationale and merits of a stand-alone dedicated organization for laboratory diagnostics were consistent across the seven organizations identified:

- Focus – laboratories are a fast moving and competitive business with a sustainability challenge; an organization dedicated to the laboratory business allows a focus on supporting patient care and on the business of laboratories while managing the rapid pace of innovation and change.
- Governance – this model allows experts in the business of laboratories as well as other skilled board members to drive performance, rigorous planning, service to clients, and risk management.
- Nimbleness and leverage – processes are simpler (fewer priorities compared to comprehensive health delivery organizations); there is an ability to expedite decisions and leverage opportunities such as the move to one LIS; standardization; consolidation; and optimizing skills of the laboratory workforce to meet changing needs – all of which contribute to financial sustainability.
- Engagement and alignment of the expert laboratory community – enables alignment of pathologists and other laboratory professionals to the needs of both patients, the non-laboratory clinician, and smaller sites; an ability to invest and focus on evidence-based utilization management strategies; and support providers in evidence-based practice.
- Financial flexibility – allows a focus on strategic investment in new diagnostics, innovative technology, and patient and client focused IT programs in part through reinvestment of savings generated by automation, more cost-effective methodologies / technology, consolidation and standardization.
- Partnerships – enhanced agility to develop strategic partnerships to access global expertise and networks (e.g., academic, private sector, other health service organizations) and develop external revenue streams to support reinvestment in organization.
- Research and Innovation – significantly enhanced capacity for building receptor capacity for innovation and translational research and leveraging related economic benefits.

In Canada, the model of stand-alone public sector agencies providing core high quality public services while pursuing economic opportunities (both at home and abroad) has matured over the years, particularly in the transportation and public utility sectors. EPCOR Utilities Inc. is a good example of this in Alberta. EPCOR is an agency of local government, the City of Edmonton, with an independent board appointed by City Council. Over the years, EPCOR has successfully functioned as a local utility serving the residents of Edmonton, but has also broadened its scope developing expertise and delivering regulated utility services to municipalities across western Canada and in the US. Key to its success has been the clarity of their mandate, their highly skilled and consistent governance, clarity of their funding model and fiscal tools, in depth annual planning, a skilled senior leadership team with strong operational expertise in the sector, and highly skilled finance and risk management leaders.⁷⁰

Calgary Laboratory Services (CLS)

Importantly, the Alberta health system has its own long-standing experience with a stand-alone organization in the public sector providing laboratory diagnostic services to both the community sector and a network of health facilities (15 hospitals, 3 health centres) in Calgary and the South zones. CLS was founded in 1996 as a joint venture between the Calgary Health Region and two private sector laboratories. The Board had membership from the University of Calgary, the Health Region, and the private sector partners. CLS has delivered high quality laboratory services to both community providers and hospitals through an evolving hub and spoke model over the last 20 years and received significant external recognition for their work which was evident during the international best practice review (for details of the service model of CLS see Appendix G).

Since 2009, CLS has operated as a wholly owned subsidiary of AHS following the exit of the private sector partners. Following the transition to AHS ownership, the CLS Board was replaced by one member of the AHS senior management team.

Over the years and particularly in the first 12 years of operation (1996-2008) CLS in the Calgary region, in contrast to other parts of the province, was able to implement many of the leading practices identified in the literature and from the best practice review:

- an early move to one LIS across its network of laboratories (1996) which has continued to be updated;
- a consolidated hub and spoke network of laboratory facilities in the Calgary region;
- standardization and consolidation of services across the network of 18 hospital/health centre laboratories in the Calgary and surrounding area;
- Development of a hub diagnostic facility in 2003 on the campus of the University of Calgary (Calgary Diagnostic and Scientific Centre) where 60 per cent of the testing across the network is performed;
- a robust analytics function which is now serving the entire province;
- significant nimbleness particularly in their first 10 years of operation in the procurement and implementation of new technology and diagnostic tests relative to the rest of the province;
- strategic investment in the training of staff in process excellence (LEAN and Six Sigma);
- cost effectiveness – detailed financial analysis on 2015/16 data, standardized to ensure a comparable scope of diagnostic testing, reveals that CLS operations are more cost effective than comparable AHS operations in the Edmonton zone (Appendix H);
- strong academic links and research activities particularly in health system research with international recognition; and
- active business development function bringing external revenue opportunities with net proceeds invested in capital and research/innovation.

Following the creation of AHS, CLS, whose mandate for the first 12 years was serving the Calgary region, has struggled with the concept of a provincial view. However, over the last three years CLS

has moved to provide more support for regional and small sites in the South zone; has participated in the provincial laboratory discipline networks (Figure 9); has undertaken outreach to non-laboratory clinicians in the area of utilization management; and their robust analytics unit has been an invaluable resource in supporting a better view of laboratory operations across the province.

Many laboratory stakeholders, from within and external to CLS, and many laboratory leaders in other jurisdictions shared their perspectives of CLS. Below is a summary of this feedback and the results of the analysis of CLS operations. Overall, CLS has been a successful organization and a recognized leader in laboratory services delivery.

Perspectives on CLS from the engagement;

Positive

- 1996 – moved to one LIS (Cerner) across all facilities – first step of partnership
- 2006 – Hub laboratory investment of University of Calgary campus
- Alignment of Laboratory Medicine physicians – all pathologists part of one organization from the beginning
- Consolidation: Over the years drove consolidation of services with hub and spoke model; international recognition for service delivery model; strong endorsement of service from hospitals in region
- Operations benchmarked against NA competitors
- Nimble, able to introduce new technology and testing, expertise in logistics; procurement
- Robust business analytics unit, IT, procurement
- Research – slow start – last 10 years significant progress; good relationship with U of C
- More cost competitive than Edmonton zone

Negative

- Too nimble – got out ahead of rest of province
- Since AHS – no provincial view – still operating as “Calgary”/CLS focused
- Not always a team player
- Duplication resources; dysfunctional competition between UAH and CLS

From perspective of CLS staff:

- Board capacity and skills lost with transition to AHS governance;
- Support for nimbleness lost; very slow decision-making
- Way behind on equipment/technology investment and ability to move to new diagnostics
- Third party revenue opportunities more difficult to enable since 2008

Options considered

Based on extensive feedback and analysis of the current state of laboratory services in Alberta as outlined in the first half of this report, the status quo is not compatible with achieving the goals of a high quality integrated laboratory sector. The daily demands and competing priorities and the complex organizational structure of AHS are not conducive to the unique needs of a high quality laboratory sector.

However, there is a significant opportunity to build on the experience of other organizations and jurisdictions, as well as Alberta's experience with CLS, and move to a stand-alone laboratory services agency.

There are two conceptual options for a public sector stand-alone organization with the mandate to deliver laboratory services. Both would be established under the legislative framework of the *Regional Health Authorities Act*. Either entity could be established by regulation.

Option 1: Public agency of the Government of Alberta

A public agency in Alberta, as defined under the *Alberta Public Agencies Governance Act (APAGA)*, is a board, commission, tribunal or other organization which is:

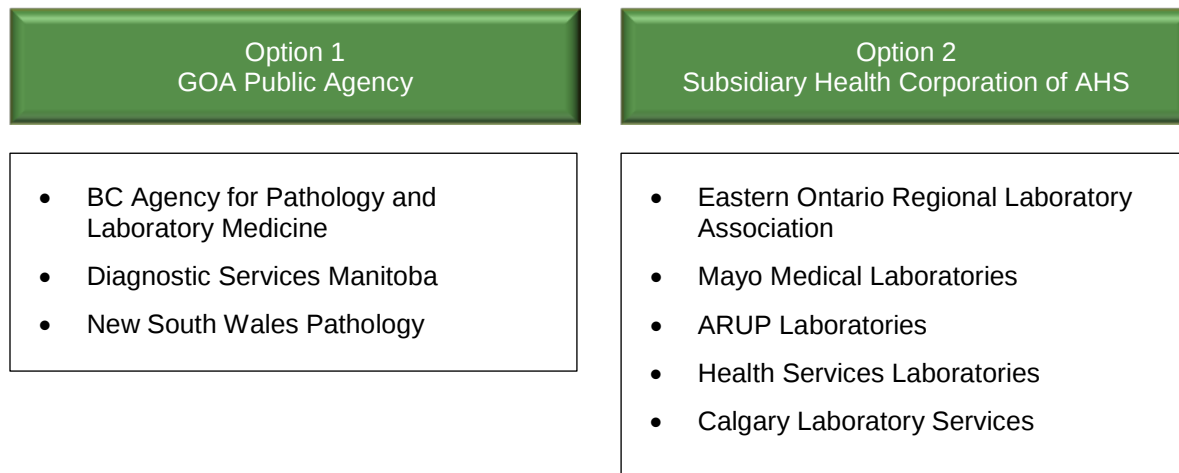
- established by government but not part of a government department;
- that has been given responsibility to perform a public function;
- that is accountable to government;
- that has some degree of autonomy from government; and
- for which the government holds the primary power of appointment.

A public agency delivering laboratory services could readily be established by regulation as a Provincial Health Board under section 17(1)a(ii) of the *Regional Health Authorities Act* which refers specifically to a Provincial Health Board delivering health services, diagnostic services or treatment services.

Option 2: Subsidiary health corporation of Alberta Health Services

Under the *Regional Health Authorities Act* a subsidiary health corporation is a corporation that is a subsidiary or is controlled by a regional health authority which, in this situation, would be Alberta Health Services. Figure 16 illustrates the two options and the alignment of each option with the seven stand-alone organizations from the best practice review.

Figure 16: Options for a stand-alone entity for the delivery of laboratory services.



Planning assumptions for a public stand-alone laboratory services organization

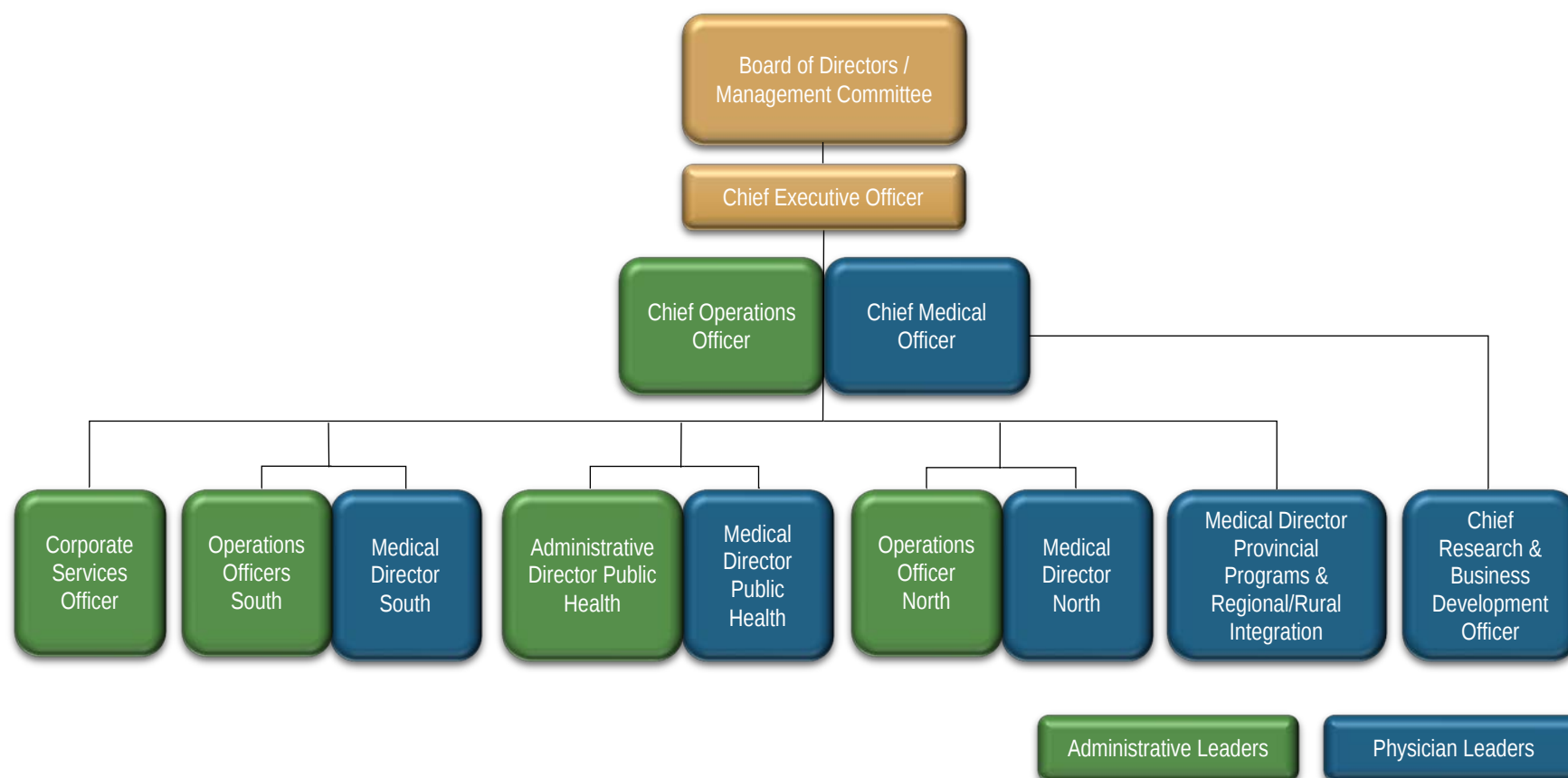
Fundamental to the success of an organization under either option 1 or 2 would include the following key assumptions:

- **Mandate** – high quality laboratory services delivered in clear alignment with the needs of patients, AHS and community providers.
- **Governance** – a Board appointed by the shareholder which includes experts in laboratory medicine from both operations and academia, the CMOH (Alberta Health), a representative from the Board or senior management of AHS. Other Board members would bring the perspective of patients and a variety of necessary skills from the broader community and business community. A proposed organizational structure is illustrated in Figure 17.
- **Operational scope** – all laboratory operations and services currently provided by:
 - o AHS (all zones, Provincial Lab for Public Health and Genetic Lab Services)
 - o CLS
 - o *DynaLIFE* (integration of *DynaLIFE* staff would align with terms negotiated in the contract extension)
 - o Covenant Health and Lamont Health Care Centre (this would require discussion and negotiation with these organizations)
- **Staff** – staff from AHS, CLS and *DynaLIFE* will be transitioned into the organization through a plan developed in consultation with labour unions and consistent with obligations under existing labour agreements. Serious consideration should be given to transitioning all staff into the Alberta Local Authorities Pension Plan (AHS has already committed to this for the *DynaLIFE* staff transition with the result that two thirds of laboratory staff would be in the ALAPP). The incremental investment to align the CLS staff is estimated at \$6 million. Discussions with Covenant Health and Lamont Health Care Centre will need to be undertaken as to options for their staff.

- Physicians – physicians would transfer into the organization either through an employment agreement or on a contractual basis. Compensation would be aligned with the current terms and conditions of the Alberta Laboratory Physicians Agreement. Financial support provided by CLS and AHS for university appointed tenured faculty would continue in the new organization and be reflected in University Affiliation Agreements.
- Funding:
 - o Start-up - transfer of the existing AHS budget for laboratory services for the province (operating, capital, accrued surplus in CLS, along with a reasonable reallocation of current resources from AHS shared services).
 - o Going forward - a model based on the *DynaLIFE* contract methodology (and the proposed Sonic contract) which includes: a global contract for a defined basket of services; a methodology for an annual inflator; and other adjustments based on untoward changes in the consumer price index or volume increases, changes to the basket of services, or compensation settlements negotiated on a provincial basis.
 - o Financial policies to enable capital investment will permit external financing for capital investment within government approved policy guidelines and the use of net revenue from appropriate external business opportunities within and outside of the province of Alberta.
 - o Assuming a transfer to the stand-alone organization of all currently funded resources in the *DynaLIFE* and CLS organizations, there would be no requirement for new government funding for the organization.
- Dividend for shareholder – under either option 1 or 2, an agreement for sharing of net income from third party revenues would be appropriate; the laboratory organization would commit to reinvesting their share into capital investments to support the ongoing delivery of high quality public services.
- Support services – the organization would be responsible for its own information systems and technology, business analytics, as well as other corporate services (e.g., finance, legal, human resources, facilities, logistics, supply chain and contract management, customer relations). On an ongoing basis, the potential of shared service arrangements with AHS or other public sector partners should be pursued if considered beneficial to the organization by the Board.
- Partnerships are critical to sustained success – The field of diagnostic laboratory services is highly competitive and expertise contributing to the rapid pace of change in the sector is now coming from a wide range of scientific and business disciplines.
 - o Academic partnerships – affiliation agreements with universities and other post-secondary institutions will be negotiated to:
 - ensure successful training of laboratory workforce and their transition into the workplace; and

- support a robust translational research agenda focused on improving healthcare and health outcomes for Albertans, on contributing to economic diversification in Alberta, and positioning Alberta as a global competitor in this area of research.
- o Private sector and other partnerships – the organization will have the flexibility to develop partnerships with the private sector to achieve explicit objectives while ensuring that such partnerships are appropriately managed through a best practice results-oriented agreement.^{71, 72} Fundamental to any partnership is that control of the organization and its activities rests with the public sector and serves the public interest.

Figure 17: Proposed organizational structure



Differentiating between options 1 and 2

There are many similarities but some important distinctions between options 1 and 2 should be considered.

Governance

For the Public Agency (Health Board) described in option 1, the Government of Alberta would appoint the Board. The government has a structured approach and a dedicated secretariat in place to support Board appointments and other governance needs of a large number of public agencies, ensuring they are clear on their accountability to deliver on expectations of government.⁷³

Under option 2, a subsidiary health corporation, Alberta Health Services would be responsible for Board appointments. Currently, Alberta Health Services has three subsidiary health corporations – two are organizations providing continuing care (Carewest, CapitalCare Group), and the third is Calgary Laboratory Services. The Boards of all three organizations consist largely of senior staff of AHS. In the case of CLS, the Board consists of one AHS vice-president. The ambitious mandate of the laboratory organization requires a skilled board which can be appointed quickly and will be able to leverage the significant opportunities and manage the challenges outlined in the report.

Accountability

Under the *Regional Health Authorities Act* the Minister has more direct authority to proactively set the mandate and accountability for a Public Agency (Health Board) under option 1. This is a significant factor if the government wishes to set a secondary mandate for economic growth and diversification through a robust translational research program.

Under option 2 (a subsidiary health corporation of AHS) ministerial authority is more responsive and is limited to the ability to require an audit, inspection or reporting on specific issues.

Mandate

Economic diversification and innovation – a laboratory agency will have as its first and core mandate the delivery of high quality integrated laboratory services. Under option 1, a Public Agency of the Government of Alberta, the Government can set other mandates which align with their broad public policy agenda and can be supported through the expertise across government. The innovation and economic diversification agenda through the translational research activities would be a likely secondary mandate under option 1.

Under option 2, the alignment of this secondary innovation and economic diversification mandate would be less well supported given the major focus and alignment of AHS on health service delivery versus economic development and diversification.

Alignment of scope

Two-thirds of encounters with patients in laboratory services occur in the community. These are initiated by community providers; particularly primary care physicians. Alberta Health has overall responsibility for the full scope of health services to Albertans, including primary care. The major focus and mandate of AHS relates to providers working in the many facilities in their organization

with significantly less interaction with community based providers. Option 1 supports a better alignment of scope with the shareholder.

Existing entity

Alberta Health Services currently has a stand-alone laboratory service organization as a subsidiary health corporation (CLS). Utilizing this entity as the existing platform on which to build a provincial laboratory agency under option 2 would be an efficient use of time and could allow an expedited move to one stand-alone organization for laboratory services.

Recommendation: Service delivery model

Create a Public Agency (Health Board) under the *Regional Health Authorities Act* with the mandate to deliver globally competitive, high quality integrated laboratory services across the province. Constitute the organization based on the planning assumptions for a stand-alone organization discussed previously.

Required actions

In addition to the model of service delivery, the following required actions would be a high priority for the Public Agency.

Laboratory information system

A single comprehensive integrated laboratory information system is essential for quality clinical care and sustainable laboratory operations. Complex technology, a broad array of tests, and the stringent quality control required has driven the laboratory sector to comprehensive information systems well in advance of other areas of healthcare. Throughout the engagement process, one of the most consistently mentioned frustrations expressed by laboratory leaders and staff across the province were the complexity of the existing patchwork of laboratory information systems and the lack of adequate IT resources to support the day-to-day operational needs of the laboratory.

The decision has been made by the Government of Alberta and AHS to fund the procurement of a new clinical information system for AHS. In reviewing best practice, the elements of a modern LIS go well beyond its historic function. The need for an effective user interface with all clients; the ability for patients to seamlessly access their own laboratory results; online ordering capacity for providers; secure interfaces with mobile devices with critical results reporting and physician alerts; modules to support clinical decisions and utilization management are all examples of enhancements which are becoming an expected standard for an LIS.

The roll out of the AHS CIS is anticipated to take approximately 10 years. The timeframe for the implementation of the LIS will have to be much shorter and broader in scope in order to avoid creating breaks in the flow of information critical to laboratory operations and supporting the care of patients, AHS facilities and the community.

Actions:

1. On an expedited basis, commence development of a strategic plan for the implementation of the LIS, pending selection and finalization of the contract with the new LIS/CIS vendor by AHS.
2. Ensure the availability of appropriate information technology resources within the laboratory organization to support day-to-day operations, the needs of clinicians, and effective utilization management.

Investment in innovation and technology

The inability to replace aging equipment and to keep up with innovation was the most significant issue and the greatest frustration and source of anxiety brought forward through the stakeholder engagement process.

Based on discussions with other organizations, the amount of capital required on an annual basis to maintain a quality laboratory service (approximately 2.5 - 3.5 per cent of operating budget) is small relative to the overall annual capital expense of most public health systems in Canada and elsewhere. Furthermore, compensating for the need for ongoing investment in the laboratory, new technology will often pay for itself over a relatively short timeframe.

Actions:

1. Develop a menu of appropriate funding mechanisms and related policies to enable and support regular capital investment in equipment and technology.
2. Develop a plan based on the use of the funding mechanisms to support an annual allocation of 2.5 - 3.5 per cent of operating revenue (based on the industry benchmark) for investment in equipment and technology.
3. Develop an asset management plan for laboratory equipment and technology aligned with best practice as a roadmap for investment.⁷⁴
4. Standardization of equipment should be the default policy with consideration of ongoing opportunities for consolidation of testing platforms at the time of major capital investment.

Organization of laboratory service delivery

Currently, laboratory service delivery in Alberta is based on a consolidated model with a tiered hub and spoke approach. This approach is well aligned with best practice and should be continued. A new Edmonton hub laboratory facility will significantly strengthen the hub and spoke system through consolidation and reduction of duplication. In addition, it will improve the ability to develop needed subspecialty pathology expertise, provide a state of the art training facility, and leverage the opportunities for translational research. The shift to a hub laboratory service model will require thoughtful planning for the ongoing support of non-laboratory clinicians in the Edmonton hospitals.^{75, 76, 77}

As part of the further strengthening and integrating the system of service delivery small rural sites require more structured support, enabled by both the regional and hub laboratories.

Actions:

1. Continue to evolve and optimize the tiered hub and spoke model for the delivery of laboratory services across the province.
2. Expedite the planning, design and, pending approval by government, construction of a new state of the art hub laboratory in the Edmonton zone. The hub laboratory will consolidate community services currently delivered by *DynaLIFE*, public health and genetics laboratories, all services from the Edmonton hospitals (other than rapid response requirements); and specialized testing for regional and small hospitals in adjacent zones.
3. Develop a multi-pronged best practice strategy to ensure an ongoing effective interface with non-laboratory clinicians in Edmonton hospitals impacted by the consolidation of services in the new hub facility.
4. Ensure appropriate infrastructure for digital pathology in the new hub laboratory.
5. Strengthen, clarify and formalize the relationship between small rural sites across all AHS zones, and the regional and hub laboratories to ensure small rural sites have structured and reliable access to the expertise needed to sustain high quality service for patients and clinicians.
6. Establish a formal Provincial Rural Program reporting to the executive leadership of the agency with a specific mandate to work with small rural sites to optimize their role and more effectively address their issues.
7. Work with Covenant Health and Lamont Health Care Centre to develop a delegated management services agreement or a contract for delivery of services to their facilities to enable enhanced integration and quality of service delivery to patients and clinicians.

Diagnostic test menu

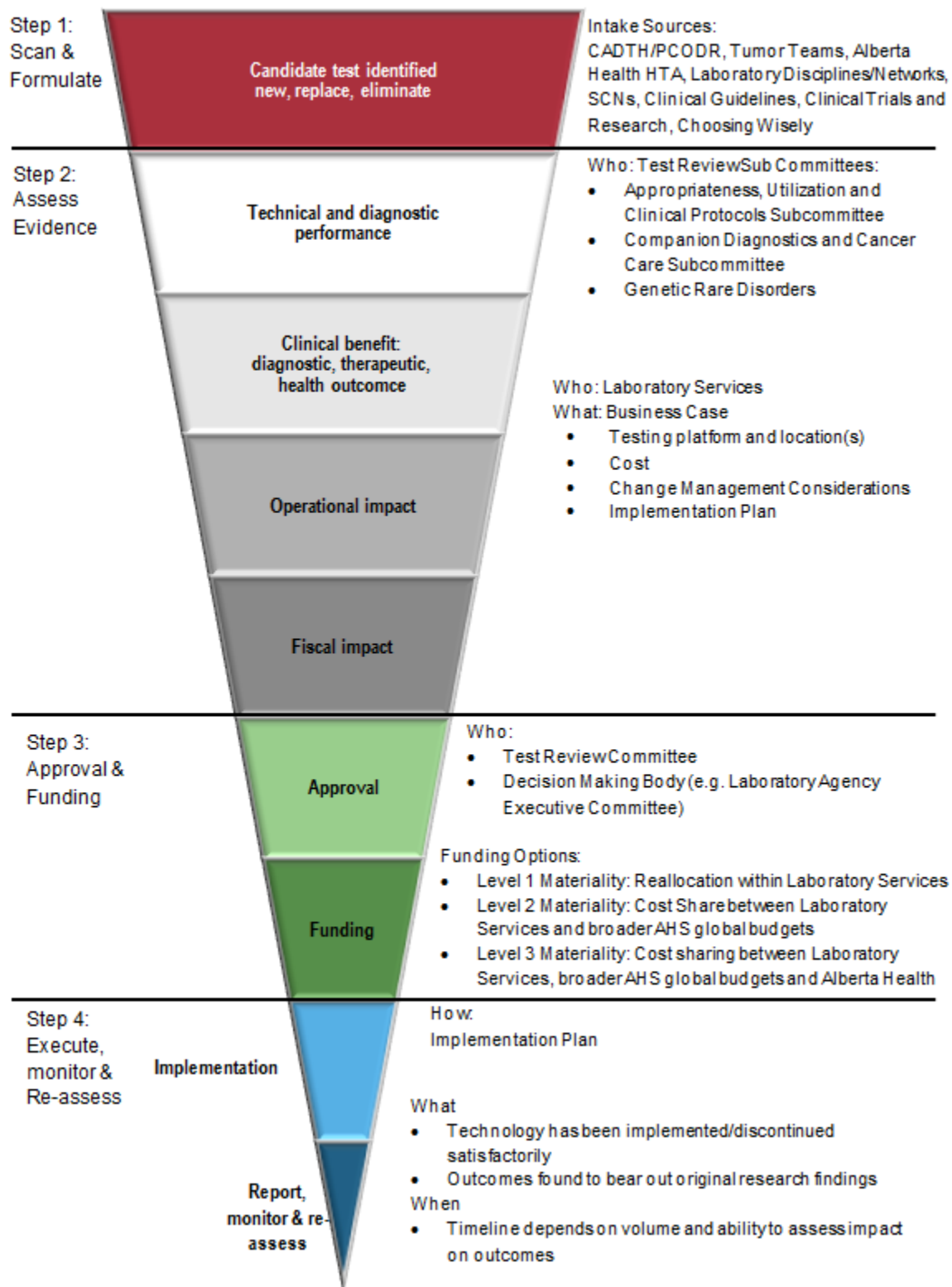
A high profile issue identified in the engagement process impacting quality of services was difficulty with the introduction of new diagnostics (including point of care testing) and the managed exit of low value tests. A clear, robust and expedited process needs to be in place to expedite these decisions, capture savings from removal of unneeded diagnostic tests, and identify funding mechanisms for new diagnostics.

During the engagement on this issue which involved discussions with Alberta Health, AHS, Institute of Health Economics (IHE), CADTH, and health technology assessment experts from the University of Alberta, a draft test review decision-making framework was developed and discussed with a number of stakeholders. Based on this framework, a structured approach should be put in place to make recommendations for the addition and removal of diagnostic laboratory tests, accountable to the senior provincial medical leader for laboratory services.

As illustrated in steps 1 and 2 in Figure 18, the process would ensure the appropriate expertise and input from expert partners such as CADTH, the Institute of Health Economics, and Alberta Health's Health Technology Assessment unit. A comprehensive review would entail a proper assessment of effectiveness, health economics review, operational feasibility, and a recommendation for location of testing. Step 4 includes a post-listing evaluation of effectiveness, something that is infrequently done.

The outstanding issue for all involved, related to step 3 in Figure 18, is who makes the final decision and how and by whom does a new diagnostic test get funded. The answer to this can build on the experience of other jurisdictions where an inclusive and rigorous process, as outlined in step 2, results in a committee making a recommendation. The recommendation goes to the senior laboratory agency leaders for approval, followed by the final decision by the Ministry of Health to approve and identify the source of funding. The process for the final stage of step 3 (funding options) would require further discussion.

Figure 18: Proposed framework for test review decision-making



Actions:

1. Finalize and implement on an expedited basis a streamlined and evidence based process for review and approval of the addition, removal, or limitation of use of diagnostic tests:
 - a. Build on the proposed framework illustrated in Figure 18.
 - b. Establish a provincial formulary for laboratory diagnostic tests.
2. Work with Alberta Health on a principle-based approach for funding of new diagnostic tests. Consider a tiered/cost shared approach based on the concept of materiality to implement new diagnostics:
 - a. Level 1 Materiality: < \$200,000 annualized cost. Laboratory services absorbs the cost through savings related to consolidation, standardization, efficiencies, utilization management, and removal of outdated tests.
 - b. Level 2 Materiality: \$200,000 - \$2 million annualized cost. Cost sharing between laboratory services envelope and AHS global budget.
 - c. Level 3 Materiality: >\$2 million annual cost. Cost sharing between laboratory services envelope, broader AHS global budget, and Alberta Health.

(Note: these levels of materiality are proposed only and require further discussion)
3. Review on a regular basis the business case for repatriation of tests currently referred out of province to assess if “in-house” testing would be more cost effective. Net savings could be applied to the implementation of new diagnostics (budget for referred out diagnostics in 2015/16 was \$5 million). Continue to actively triage referred out tests to ensure appropriateness.^{78, 79}
4. Establish point of care testing (POCT) as a fully accredited provincial program under laboratory services:
 - a. Utilize a co-director model for program leadership – a laboratory clinician leader and a non-laboratory clinical leader.
 - b. Integrate the review of new POCT tests into the test review process outlined above.
 - c. Develop a transparent methodology for funding the POCT program and any new POCT diagnostics. The funding methodology should recognise any non-laboratory system savings and efficiencies and ensure they are helping support the funding of new POCT diagnostics.

Standardization

Across all best practice organizations and the literature review there was an overwhelming trend to standardization whenever possible. Standardization applies to multiple areas of activity in an integrated system - policy, equipment, methodologies, test parameters, test menus, etc. Standardization provides many advantages such as enhanced safety and quality; ease of patient

access to laboratory results and the move to one LIS; ability to leverage significant economies of scale and the procurement, installation, commissioning and maintenance of new equipment; reduction in the number of standard operating protocols; more mobility for staff across the tiered hub and spoke system; and more efficient training and orientation of new staff and ongoing training of existing staff.

In the best practice review, standardization was reflected as organizational policy. Involvement of local laboratory subject matter experts, and when appropriate non-laboratory clinicians, is important in the development of the standard.

Actions:

1. Create an organizational policy on standardization.
2. Formalize the criteria informing a decision to standardize. Criteria could include the following:
 - a. Impact on patient safety and patient outcomes.
 - b. Feasibility of moving to the standard and ability to sustain the standard.
 - c. Risk identification and adequate risk mitigation plans.
 - d. Opportunity for innovation.
 - e. Cost impact (total cost) up front and over the life of the asset, process, or policy.
3. Formalize the process to manage requests for exceptions by clarifying the criteria and decision-making process.

Optimizing logistics

A consolidated and integrated laboratory sector for Alberta, based on a tiered hub and spoke model requires sophisticated logistical support to enable the accurate tracking and movement of patient specimens from hundreds of collection sites across the province to the appropriate diagnostic facilities. Ensuring the appropriate collection processes, environmental conditions during transport and applicable timeframes are met for each specimen, and a clinically acceptable turnaround time for the results are all part of the parameters of a quality laboratory service. Currently, significant expertise and capacity for this activity resides in the *DynaLIFE* and CLS organizations, both of whom run high volume hub and spoke systems serving urban and rural sites.

Actions:

1. Establish one provincial program responsible for logistics supporting the provincial integrated laboratory system.
2. Address current gaps in performance with rural sites as a priority.
3. Engage global expertise in logistics management through strategic partnerships and personnel recruitment.

Optimizing facility infrastructure

Similar to investing in technology, ensuring laboratory facilities are able to meet the needs of an integrated fast changing laboratory system is important.

In Edmonton, investment in facilities is overdue and delivery of services, in contrast to Calgary, is more fragmented and less consolidated. The completion of the hub laboratory will effectively transform service delivery in the north of the province, complementing the work done in Calgary and the South zone over the last decade.

Given the 133 sites in the province delivering laboratory services, there will be an ongoing need to invest in laboratory facilities. It will be critical to maintain focus on the evolving integrated system.

Actions:

1. Review consolidation opportunities in the hub laboratories in Calgary and Edmonton, or, in the five regional hub laboratories at the time of planning for any new laboratory facility or any significant renovation of an existing facility.
 - a. Drivers for these decisions would include changing clinical practice and patient needs; the transformational impact of new technology (including POCT); digital pathology initiatives; staffing and medical/professional capacity; the need to address recruitment challenges; and capacity for enhanced logistics support.
2. Planning for any new facility should ensure best practice design that offers maximum flexibility over time given rapidly changing technology which impacts the look, size, and design of clinical diagnostic laboratories of the future.

Ensuring access to skilled laboratory professionals

Technologists

There is generally good alignment of technologist training programs with system need in Alberta, as well as partnerships with laboratory leaders to anticipate evolving skill sets required in the sector. A number of issues will require attention:

- The ability to find clinical placements for trainees during their formal training.
- The need to optimize the mobility of staff across the evolving scope of the hub and spoke system.
- The ability to recruit and retain staff with appropriate skills in smaller centres.
- The need for strategies to enhance the acquisition of new skills by current laboratory staff in key areas such as bioinformatics, molecular diagnostics, POCT and others.

Actions:

1. Establish one consolidated provincial platform to work with the three training institutions to ensure effective leverage of the full scope of clinical placements available across an integrated provincial laboratory system.

2. Examine the feasibility of a new simulation laboratory to support ongoing training needs for students in the south of the province.
3. Establish regular discussions with the licensing bodies to ensure they leverage their statutory powers under the *Health Professions Act* to ensure the required competencies align with the needs of the provincial system, while not compromising their obligations under the inter-provincial Internal Trade Agreements.

Pathologists

The training of pathologists is complex and highly regulated by the Royal College of Physicians and Surgeons of Canada. The scope of this report did not include an in-depth review of this area. However, there are some key system issues which need to be addressed in support of the tiered hub and spoke service delivery model.

Action:

1. Develop a provincial strategy with the Departments of Laboratory Medicine and Pathology at University of Calgary and University of Alberta to address the shortage of general pathologists who are key to the regional laboratories and their support of small rural sites in Alberta.

Accreditation

As services are integrated, particularly in a new hub laboratory, there will be a need for laboratory leaders to continue to work with CPSA to support and help refine their evolving approach to accrediting laboratory facilities. Part of this work includes an initiative which has been underway for over a decade to create a shared platform for laboratory accreditation across the western provinces. This would be a step forward, assuming the benchmark standards of CPSA are adopted.

Actions:

1. Continue to support the move to a program of individual certificates of accreditation by site versus one certificate for all laboratories in each delivery organization. Anticipate and work with the CPSA to address the challenges of accrediting the different activities consolidated in the hub laboratories in the network.
2. Continue to support the work toward a western accreditation program across Manitoba, Saskatchewan, Alberta and British Columbia.

Translational research, innovation and economic development

With the move toward an integrated provincial laboratory sector and ongoing planning for a new hub laboratory in Edmonton, there is a significant opportunity for developing and implementing a robust laboratory medicine translational research (TR) program for the province. The Edmonton hub laboratory would contain the first purpose built space for this provincial program and would be available for researchers from academia and industry from across the province. During the engagement on this topic, there was good initial discussions among academic leaders from across the province on a potential governance model for this activity.

Actions:

1. Establish an effective program of translational research which will allow the integration of innovative and value add technologies and diagnostics into patient care and the delivery of healthcare, while contributing to economic growth and diversification.
2. Include translational research space in the business case and functional program underway for the new hub laboratory in Edmonton.
3. Finalize a province-wide governance structure for TR which will be accountable for optimizing the results of the new TR program through direction setting, oversight and reporting.
4. Develop a business case for the provision of core funding for TR with targets based on published benchmarks for leverage from the investment.
 - a. Clarify priorities for first five years based on current assets in the province including initiatives and strategies related to the Provincial Precision Medicine Initiative.
 - b. Formalize partnerships with key stakeholders (Universities, AHS, Alberta Innovates, Institute of Health Economics, Government of Alberta, industry) to optimize program support.
 - c. Create key metrics and targets for assessing success in terms of both health and health system outcomes and economic benefits.
 - d. Identify and pursue key external revenue opportunities.

Appendix A – Stakeholders

During the engagement process, the Project Team spoke to stakeholders across the system – more than 1,400 – from many organizations. These discussions were with formal committees or working groups, small groups of experts on various themes, and large town halls which the project team attended in person, by videoconference or teleconference. Some individuals were involved in more than one discussion.

Laboratory Service providers (1,082 stakeholders)

- Alberta Health Services
- Calgary Laboratory Services
- *DynaLIFE*
- Covenant Health

Advisory groups (101 stakeholders)

- Calgary Laboratory Services Patient Advisory Group
- Greater Edmonton Health Advisory Council
- Patient and Family Advisory Council
- Provincial Resource Group

Professional provider groups (56 stakeholders)

- Alberta Clinician Council
- Alberta Association of Clinical Laboratory Doctoral Scientists (AACLDS)
- Alberta Society of Lab Pathologists
- AHS/AMA Joint Venture Council (PCN)
- Medical and Scientific Reference Group
- Northern Lab Professionals

Unions: (4 stakeholders)

- Alberta Union of Provincial Employees (AUPE)
- Health Sciences Association of Alberta (HSAA)

Government and related agencies (70 stakeholders)

- Government of Alberta, Alberta Health
- Government of Alberta, Alberta Infrastructure
- Government of Alberta, Advanced Education
- Government of Alberta, Economic Development and Trade
- Alberta Innovates
- Canadian Agency for Drugs and Technologies in Health (CADTH)
- Health Quality Council of Alberta
- Institute of Health Economics (IHE)

Regulators (8 stakeholders)

- Alberta College of Combined Laboratory and X-Ray Technologists (ACCLXT)
- College of Medical Laboratory Technologist of Alberta (CMLTA)
- College of Physicians & Surgeons of Alberta

Other jurisdictions (62 stakeholders)

- ARUP Laboratories
- Diagnostic Laboratory of Oklahoma, USA
- Diagnostic Services Manitoba
- Eastern Ontario Regional Laboratory Association (EORLA)
- Government of British Columbia, Ministry of Health
- Government of Ontario, Ministry of Health and Long Term Care
- Government of Manitoba, Ministry of Health and Long Term Care
- Grattan Institute, Australia
- Health Partners, USA
- Health Services Laboratory, UK
- Intermountain Health, USA
- Kaiser Permanente, USA
- Maskwacis Health Service
- Mayo Medical Labs, USA
- New South Wales Health Pathology, Australia
- Northwell Health, USA
- Quinte Healthcare, Ontario
- Royal Free Hospital London, UK
- University College Hospitals London, UK

Academic institutions (66 stakeholders)

- Northern Alberta Institute of Technology (NAIT)
- Southern Alberta Institute of Technology (SAIT)
- University of Alberta
- University of Calgary
- University of Lethbridge

Appendix B – Provincial Resource Group - Membership list

Stakeholder Group	Invited Member
Laboratory Providers	
Alberta Health Services	Dr. Carolyn O'Hara, Provincial Medical Director Dr. Graham Tipples, Director Provincial Lab for Public Health Dr. Lakshmi Puttagunta, Pathologist at the University of Alberta Hospital Lyn Morrison - Lab Assistant II, University of Alberta Hospital Shawna Gawreluck - Lab Technologist at the Royal Alexandra Hospital Keith Kirkland, Lab Manager, Red Deer Regional Hospital Dr. Kaila Topping, Pathologist Royal Alexandra Hospital and Misericordia Community Hospital Tamara Trotter, Anatomic Pathology Quality Coordinator
Calgary Lab Services	Paula Hall, Former Calgary Lab Services COO (retired) Brenda Strange, Manager Community Services
Covenant Health	Dr. George Wood, Pathologist Joan Card - Lab Technician at the Misericordia Community Hospital
Laboratory Consumers	
Patients	Lawrence Tymko, Greater Edmonton Health Advisory Council Bobbie Sparrow, Member Calgary Lab Services Patient Advisory Council
Physicians	Dr. Shelley Duggan (Nephrology Edmonton President Edmonton Medical Staff Association) Dr. Francois Bernier (Calgary – Chair of Medical Genetics, research, genomics, innovation) Dr. Neil Hagen, Tom Baker Cancer Centre (cancer control representative – Task force on AP Quality Assurance Plan) alternate - Dr. Matthew Parliament, Cross Cancer Institute (cancer control representative)
Health Centres	Dr. Owen Heisler, Chief Medical Officer Covenant Health Shelly Pusch, Chief Zone Officer, North zone Dr. Jack Regehr, South zone Medical Director Randy Littlechild, Executive Director Maskwacis Health Services
Public Health	Dr. Karen Grimsrud, Chief Medical Officer of Health, Alberta Health

Post-Secondary Institutions

Laboratory Medicine and Pathology Department Chairs	Dr. Hallgrimur Benediktsson, Acting Chair Dept Pathology and Lab Medicine University of Calgary Dr. Michael Mengel, Chair Dept Lab Medicine and Pathology University of Alberta
Research	Dr. Randy Goebels, Associate Vice-President (Research) and Associate Vice-President (Academic), University of Alberta Dr. Ed McCauley, Vice-President Research, University of Calgary
Technical Institutes	Denise MacIver, Associate Dean, School of Health Sciences, NAIT Dr. Judith McGillivray, Interim Dean, School of Health and Public Safety, SAIT

Labour

Unions and Professional Associations	Dan MacLennan, Former President Alberta Union of Provincial Employees Elisabeth Ballermann, President Health Sciences Association of Alberta Guy Smith, President Alberta Union of Provincial Employees Marle Roberts, CUPE Alberta President Dr. Andrew Schell, President Alberta Society of Laboratory Physicians Dr. Mark Lee, Lead Northern Laboratory Professionals, Royal Alexandra Hospital
Quality and Regulatory	Liz McBride, CPSA Accreditation Dr. Jan Davies (Former Blue Ribbon Group, HQCA consultant) Lori Kmet, Executive Director, College of Medical Laboratory Technologists of Alberta Lyndsay Arndt, Executive Director/ Registrar, Alberta College of Combined Laboratory and X-ray Technologists

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Appendix D – CPSA Laboratory Accreditation

Purpose of Accreditation

Accreditation is defined as the public recognition of quality achievement by a healthcare organization, as demonstrated through an independent external peer comparison of the organization's performance against current best practices.

The College of Physicians and Surgeons of Alberta (CPSA) diagnostic accreditation programs:

- assist facilities with a process of ensuring accuracy and reliability of examination/services
- provide standards of practice and assess compliance to these standards
- identify deficiencies that affect the quality of examination/services, and impact patient and/or staff safety
- evaluate a facility's quality system's ability to identify and mitigate risk and variability in system processes
- gives formal recognition that a facility's provision of quality diagnostic services
- encourage and facilitate peer review
- provide educational opportunities for both the facility being accredited and the assessment team
- promote uniformity in practice provincially, where variations in practice are counter-productive for the province
- maintain a comprehensive data repository for scope of service/levels of testing and resources
- promote standardization and educational initiatives across Canada through inter-provincial collaboration
- promote and encourage dialogue amongst stakeholders on best-practices and best ways to incorporate them into the workflow
- ensure effective medical direction over medical practices so that business interests do not determine the standards of care

Accreditation Program History

In 1965, the College of Physicians and Surgeons of Alberta, upon recommendation from the Alberta Society of Pathologists, took steps to set up a program for accreditation for diagnostic medical laboratories. The Advisory Committee on Laboratory Medicine, which then reported to Council of the College of Physicians and Surgeons of Alberta, was formed. The mandate of the Committee was to monitor and improve the quality of clinical laboratory services in Alberta. In order to meet this mandate, the Committee developed a process for accreditation that included requirements for on-site assessments of medical laboratories and a proposal for a proficiency-testing program to monitor testing performed.

The first assessments for accreditation took place in 1968 and included only non-hospital-based laboratories. In 1970 the Alberta Department of Health entered into a contract with the CPSA to accredit hospital-based laboratories on their behalf and to make recommendations to them pertaining to accreditation.

Since that time, the CPSA has remained the accreditor of all public and private diagnostic laboratories in the province of Alberta.

Authority and Oversight

The College of Physicians and Surgeons of Alberta is constituted under the *Health Professions Act* (Schedule 21) with a mandate to regulate medical practitioners and medical practice in the best interests of the public of Alberta. Authority to accredit specified medical services and facilities is one aspect of that mandate.

Pursuant to section 8.4 of Schedule 21 of the Health Professions Act, and the Bylaws of the College, facility staff are required to cooperate fully with any assessment, which shall include:

- a) permitting the assessment team to enter the laboratory facility and assess the premises and all diagnostic equipment located therein;
- b) permitting the assessment team to assess all records pertaining to the provision of diagnostic laboratory services, and providing copies of the same if so requested;
- c) providing to the assessment team, information requested by them in respect of the provision of diagnostic laboratory services, in the facility;
- d) providing the information described in clause (c) in the form requested by the assessment team;
- e) providing requested samples or copies of any material, specimen, or product originating from the diagnostic laboratory services, provided by the facility;
- f) answering questions posed by the assessment team as to procedures or standards of performance and if requested, providing copies of records relating to procedures followed and standards of performance applied in the diagnostic laboratory facility;
- g) providing requested copies of all documents and information relating to business arrangements involving the practice conducted in the diagnostic laboratory facility.

Although the CPSA's statutory authority does not extend to health services in approved hospitals or healthcare facilities operated by the Government of Canada or the Government of Alberta (*Health Professions Act* Schedule 21 - 8.1(1)), the value of practice uniformity between the private and public sectors and the credibility of the CPSA's programs have long been acknowledged by practitioners and government (48 years). This ensures that the public sector facilities are held to the same high standards as the private sector facilities. Other accreditation programs (eg. Accreditation Canada) and systems are less robust and provide only a high level oversight of laboratory services. For example, Accreditation Canada's laboratory accreditation program does not have discipline specific standards for Anatomic Pathology, Chemistry, Hematology and Microbiology, Molecular Diagnostics & Genetics etc. Consequently, four of the CPSA's accreditation programs (laboratory medicine, diagnostic imaging, pulmonary function and neurophysiology) are under contract with government agencies (AHS) to provide accreditation of public sector facilities.

The CPSA's accreditation programs are overseen by a standing committee, the Medical Facility Accreditation Committee (MFAC), with members appointed by the Council from diverse disciplines in clinical and diagnostic medicine. MFAC conducts a secondary review of practice standards developed by the accreditation advisory committees, hears argument on all changes to accreditation standards and reviews all facility accreditation and physician approval statuses. A member of the MFAC also attends a full meeting of the individual accreditation advisory committees each year to report on the diligence and objectivity of the work conducted.

The 5 standing advisory committees are composed of peer professionals (both physician/technical) who identify the needs and realities of Alberta stakeholders based on local practice. The Advisory Committee on Laboratory Medicine includes participation by an external pathologist consultant expert. The consultant expert's role is to observe and report to AHS on the objectivity of the CPSA's accreditation decisions in regard to AHS medical laboratories.

Overview of Laboratory Accreditation Program

The CPSA administers accreditation programs for those services that Council determines deserve explicit standards and verification of compliance with those standards, whether pertaining to the qualifications of physicians who provide them or the safety of those services to the public.

Accreditation looks at compliance, emphasizing continuous quality improvement and promoting optimum performance. More specifically, the CPSA's accreditation program looks closely at policies, processes and procedures to assess the safety and reliability of the service being provided, as well as the performance of the people involved and the product produced.

The Laboratory Accreditation Program examines all aspects of laboratory quality and operations including:

- organization, management and personnel
- quality management systems
- physical facilities
- equipment, reagent and supplies
- laboratory information systems
- pre-examination, examination and post-examination activities
- quality assurance activities
- safety
- point-of-care testing

The Laboratory Accreditation Program is a peer review process with a goal to improve laboratory performance through objective evaluation. Assessors evaluate a laboratory's compliance with the specific requirements of a standard based on objective observation and assessment. All accreditation assessment findings are vetted by the Advisory Committee on Laboratory Medicine to eliminate any potential personal assessor bias, ensure consistent and thorough approach for all facilities, and to review standards for applicability to current best practice.

Benefits of CPSA Laboratory Accreditation Program

- Assists facilities with the process of ensuring accuracy and reliability of testing/services
- Provides standards of practice and assesses compliance to the standards
- Identifies deficiencies that affect the quality of testing/services, as well as patient and staff safety
- Provides educational opportunities for both the facility being accredited and the inspection team
- Promotes uniformity in practice provincially – where variations in practice are counter-productive for the province.
- Promotes standardization and educational initiatives across Canada through interprovincial collaboration
- Maintains a comprehensive data repository for scope of service/modalities/levels of testing and resources within the province
- Promotes and ensures dialogue amongst providers and administrators on best practices and best ways to incorporate them into the workflow.
- Encourages and facilitates peer review.
- Ensures effective medical direction over medical practices so that business interests do not determine the standards of care.

Frequency and Selection of Laboratories to be Assessed

Diagnostic laboratories are assessed initially when opened, subsequently on a four year rotation and if they relocate their laboratory to a different physical facility. This does not preclude an interim assessment that may be required as a result of expansion of services or unsatisfactory performance of tests that are monitored by the Alberta Laboratory Quality Enhancement Program.

Assessments are conducted by geographical zone areas ensuring that all laboratories within the designated zone are assessed in the same calendar year. At the beginning of the year, all facilities in the area due to be assessed are identified and the Assessment Coordinator and Team Leader are assigned. All facilities, both public and private, performing laboratory examination for patient management, with the exception of physicians doing basic testing, are required to undergo an assessment. The CPSA does not register or accredit Physician Office Laboratories.

After a new facility is registered and initially accredited, it will then be added in to the regular zone geographical 4-year cycle. If the timing of this next 4-year cycle is very close to when the new facility was accredited, the CPSA may choose not to re-assess the facility.

On-going Self-Assessment

The CPSA laboratory accreditation process does not have a requirement for self-assessment. However, the CPSA laboratory accreditation General Standards requires facilities to conduct formal internal audits of all system elements, both managerial and technical, at a frequency defined in their quality management system. The CPSA accreditation standard tools are a significant resource for self-audits as they promote a constant state-of-readiness. Laboratories are able to customize the standards tools by:

- tailoring to scope of testing
- documenting/embedding links to policies, processes, procedures, records, forms and labels beside the relevant standard
- utilizing the tool for the performance of comprehensive or targeted audits in between the 4-year CPSA assessments

Standards Overview

The Standards are the basis for accreditation decisions and are compiled by CPSA and stakeholder experts, reviewed and are reviewed and approved by the Advisory Committee on Laboratory Medicine, with final vetting and approval by the Medical Facility Accreditation Committee.

The Standards are evidence based and reference accepted best practices, Provincial and Canadian legislation, relevant International Organization for Standardization (ISO) standards, and other recognized provincial, national and international standards (e.g. College of American Pathologists, CLSI, ASTM, Canadian Standards Association). Each accreditation standard has an accompanying reference citation(s).

All standards included in the documents are mandatory requirements for accreditation.

The Standards are process-based and incorporate a quality management system approach. The language, terms and organization of the documents are consistent with ISO 15189 (Medical laboratories – Requirements for quality and competence).

A review of accreditation standards occurs on an ongoing basis, considering and incorporating stakeholder feedback. Comprehensive formal review occurs on an annual basis.

The CPSA Laboratory Accreditation program currently maintains the following standards documents for the assessment of diagnostic laboratory facilities:

- General (also includes LIS, Safety and POCT)
- Anatomic Pathology
- Chemistry (also includes Urinalysis and Toxicology)
- Fertility Assessment – Semen Analysis
- Flow Cytometry
- Hematology
- Microbiology
- Molecular Diagnostics and Genetics
- Transfusion Medicine

- Histocompatibility (HC) Testing – NOTE: Current protocol accepts certification/accreditation by American Society for Histocompatibility & Immunogenetics (ASHI) or the College of American Pathologists (CAP). CPSA accreditation standards apply to the general sections of the TT/HC laboratory (Physical Facility, Safety LIS etc.).

- There is only one customizable standard set for ALL facility types regardless of scope (High Complexity – High Volume, High Complexity – Medium Volume, Moderate Complexity – Medium Volume, Moderate Complexity – Low Volume, Basic Complexity – Low Volume, Specialized Complexity – High Volume, Specialized Complexity – Low-Medium Volume).

All accredited Alberta facilities receive a complete standards document set. CPSA accredited laboratories and other approved users may access, print or make a copy of the standards for their non-commercial personal use. Any other reproduction in whole or in part requires written permission from the CPSA and the material must be credited to the CPSA.

Prior to each assessment customized standards documents, tailored to the scope of testing of a facility, will be made available to:

- facilities for self-assessment and/or to prepare for an on-site CPSA assessment.
- CPSA assessors in preparation for on-site assessments and to record objective evidence/ observations while performing on-site assessments.

Format of New Laboratory Accreditation Standards

The new standards are process-based and incorporate a quality management system approach. The language, terms and organization of the documents are consistent with ISO 15189.

All standards documents are consistently organized in the following order (as applicable in each document):

- Organization, Management & Personnel
- Quality Management System
- Physical Facilities
- Equipment, Reagents & Supplies
- LIS
- Pre-examination policies, processes and procedures
- Examination policies, processes and procedures
- Quality Assurance of examination procedures
- Post-examination policies, processes and procedures
- Safety
- POCT

The 'General Standards' document includes ALL standards common to ALL disciplines. To eliminate redundancy, the discipline-specific standards include ONLY those standards specific and relevant to each discipline. For example, general quality control, proficiency testing, calibration, validation, and procedure manual standards are not repeated in each discipline specific standard.

Standards Review and Revision

A comprehensive review of references occurs annually to ensure they are compliant with current standard references and best practices. Supporting references and any new references are reviewed, updated and their impact (if any) on the wording of the requirement is assessed.

Any stakeholder may offer suggestions for standards revision at any time.

Revision submissions are considered by the CPSA ONLY if they meet the following conditions:

- submitted using the Stakeholder Standards Review Form.
- identification of specific standard or section if applicable to multiple standards
- supported by detailed rationale/justification AND verifiable references (link or attachment must be included)
- applicable to all diagnostic laboratory facilities across the province and are not limited to organization specific practice
- contact information included for use by the CPSA if clarification of submission is required

New Laboratory Accreditation Standards: Development and Revision Timelines

Task	Timeline
Draft sentinel standards documents completed and formatted (General, Anatomic Pathology, Chemistry, Fertility Assessment, Flow Cytometry, Hematology, Microbiology and Transfusion Medicine).	2010/2011
High-level content review of above standards documents by discipline-specific Focus Groups	2011
Reviewing/collating submissions/editing the standards documents based on Focus Group feedback.	June 11-29, 2012
Distribute revised versions of standards for public stakeholder comment	July 10 – August 21, 2012
Collate/ incorporate stakeholder feedback from public comment period; determine questions/issues requiring Committee Consultation	September – November 2012
Pilot revised standards and process with Zone 5 – North assessment (in parallel with current standards and processes)	October 24-26, 2012
Consider any changes to standards and or processes based on pilot and prepare dossier for standards review meeting	November-December 2012
Develop assessor/AC/TL training tools and programs; Develop educational documents/tools for facilities	November 2012 – March 2013
Conduct extraordinary Lab Accreditation Advisory Committee meeting to review revised standards/process and address issues resulting from consultations	January 2013
Revised standards to be presented to Medical Facility Accreditation Committee for approval	February 2013
Revised standards to be presented CPSA Council for final approval	March 2013
Initiate roll-out of revised accreditation standards, processes and tools in conjunction with the 2013 assessments (Central Zone)	Spring 2013
Developed Molecular Diagnostics and Genetics (following same stakeholder consultation and approval process)	2013
Pursue ISQua accreditation of new laboratory standards	2013/2014
Revision and publication of 2014 standards	2014/2015
Revision and publication of 2015 standards	2015/2016

International Accreditation of CPSA Diagnostic Laboratory Standards

The CPSA received International Society for Quality in Healthcare international accreditation of its standards in May 2014. The CPSA was commended for its comprehensive laboratory standards; its demonstrated commitment to quality and patient care and identifying standards that directly apply to staff and patient safety.

Standards Review and Distribution

- A comprehensive review of reference documents occurs annually.
- Supporting references are reviewed, updated and their impact (if any) on the wording of the requirements is assessed.
- There is a formal process for the submission of stakeholder requests for revisions to current standards.

Accreditation Canada

In follow-up to the previous 4 year Memorandum of Understanding (MOU), a subsequent MOU (5 years) was signed in 2016 between CPSA and Accreditation Canada which continues to outline the jurisdiction of each organization in the provision of laboratory accreditation services and promotes collaboration with regards to program outcomes and coordination of accreditation visits.

Western Canada Diagnostic Accreditation Alliance (WCDAA)

The Western Canada Diagnostic Accreditation Alliance (WCDAA) group was formed as a result of a recommendation from the Health Quality Council of Alberta (HQCA) regarding laboratory accreditation program and the need to deal with real or perceived conflicts of AHS employees performing assessments. There was also a need in the other provinces for accreditation standards and assessor resources.

WCDAA Timeline:

March 2013	WCDAA was formed
	Workshop held between BC, AB, SK, and MB at the CPSA
	Agreement reached by all jurisdictions to collaborate on a common set of standards
May 2013	Standards from AB, BC, and SK were compared and discussed using an agreed upon matrix
	Agreement was made to use AB standards as the common set of standards
December 2013	Meeting of the WCDAA was held and a decision was made to review AB standards for applicability in the other jurisdictions; province specific directives were relocated to province specific appendices
May 2014	Meeting to review findings from December 2013
June 2015	Memorandum of Agreement drafted and sent to all provincial member organizations for comment; document was agreed upon and finalized; the draft MOA included detail on the control, protection and distribution of CPSA standards, standards revision management, assessor resource management, licensure and funding model
	BC formally opted out of WCDAA; indicated their wish to be kept informed of group activities
	Signed MOA received from SK
	MB indicate their intent to sign; however, require government approval
	Secure SharePoint site setup specifically for the WCDAA members which facilitates access to province specific and general information, tools, and templates
September 2015	SK shadowed CPSA on an assessment
January 2016	SK attended CPSA Advisory Committee meetings to provide stakeholder feedback on proposed standard revisions and further shadowed CPSA accreditation processes
April/September 2016	SK successfully piloted standards and processes in multiple health regions
June 2016	MB advised funding in place to participate; MOA with CPSM legal council
June/September 2016	Collaboration with SK provided CPSA with enhanced access to out-of-province assessor resources (South Zone assessments – all out-of-province assessors were from SK)
2017	SK to assess a further four health regions using WCDAA standards and processes

Cross-jurisdictional assessor sharing - each WCDAA member province is committed to actively promoting the WCDAA to its provincial stakeholders and encouraging participation in cross-jurisdictional assessments. The CPSA has committed to sharing its assessor training and competency assessment tools and resources with other member provinces. Recent experiences from 2016 CPSA assessments, where the majority of the external assessors were from Saskatchewan, indicate that both the Alberta and Saskatchewan team members found it a very valuable and productive experience, especially now that Saskatchewan is using the same standards and model.

Value of External Assessors

- Cross-trained on standards to assess in other WCDA participating provinces
- Consistency in assessing to standards
- Provides a broader range of knowledge of best practices
- Alleviates perception of conflict of interest
- Use of Alberta assessors provides sharing and standardization across the province
- Is expensive due to flights etc.
- Use of a percentage of the in-province assessors and out-of-province assessors on assessment alleviates some of the cons and promotes the positive benefits.
- Use of 100% external assessors would be detrimental because we would lose the benefit of Alberta assessors sharing practices across the province and initiating standardization activities
- Current Alberta assessors are more familiar with provincial practices and able to do a more efficient assessment
- CPSA's assessment model, including reporting and oversight, has numerous steps/checks and balances to mitigate any potential assessor bias
- Internationally, the use of peer assessor for accreditation assessments is the gold standard in healthcare

Appendix E – Laboratory Organizations Consulted in Best Practice Review

Diagnostic Services Manitoba

Diagnostic Services Manitoba is Manitoba's public sector diagnostic healthcare service provider (under the *Regional Health Authorities Act*) with responsibility for providing high quality laboratory tests and diagnostic imaging services to Manitobans. It provides 80 per cent of laboratory services in Manitoba with the private sector providing the other 20 per cent through provision of a portion of community laboratory diagnostic services. DSM is not-for-profit corporation accountable to the Minister of Health, with a Board of Directors appointed by the Minister of Health. DSM is also responsible for rural diagnostic imaging services.

DSM was created to position Manitoba's public laboratory services and rural imaging services to meet the challenges that the industry was facing. It has a major focus on advancing the areas of standardization, implementation of new technology and innovation, enhancing quality as well as optimizing education, training and recruitment in order to maintain a skilled workforce of technical, medical and scientific staff in the face of a growing national industry shortage.

DSM has an annual strategic planning session and a published five year rolling strategic plan (2016-2021). It has a staff of 1,700, a budget of ~ \$250M, it manages and staffs 79 laboratory facilities across the province and is responsible for 29 million laboratory tests per year. At this time, the Manitoba Public Health Laboratory remains under the management of the Ministry of Health. Laboratory Medicine physicians (pathologists) are accountable to DSM through a system of contracted services. Many of these physicians also have a dual appointment at the University of Manitoba and are involved in academic activities. The senior pathologist for DSM is appointed in a joint process with the Department of Pathology in the Faculty of Medicine at the University of Manitoba.

Recent accomplishments and strategies:

- Standardized report formats, turnaround times, referral patterns for specialty pathology work for whole province
- First province-wide digital pathology program in Canada, 2015
- Liquid based cytology screening for cervical cancer province-wide, 2014
- First province in Canada to achieve system wide accreditation of pathology services by College of American Pathologists (CAP)
- Moving to one LIS – currently 80 per cent of the total test volume is on one LIS
- Hub laboratory – currently in the process of planning a new consolidated hub laboratory

Eastern Ontario Regional Laboratory Association (EORLA)

EORLA is an integrated member based non-profit entity created by and to deliver laboratory services to 16 acute care hospitals in the Champlain Local Health Integration Network in Ontario. It is responsible for delivering services over nearly 18,000 square kilometers, revenues of \$113M per year, serves a population of 1.3 million residents in 18 different laboratory facilities, performing 13 million tests per year as well as participating in academic and research activities with its university partners in the area of laboratory medicine. It delivers its services in both French and English. It is the single employer of laboratory staff and physicians with 900 medical laboratory technologists and medical laboratory assistants, 82 medical and scientific staff and 24 medical residents and fellows. EORLA provides comprehensive hospital based diagnostic laboratory testing.

The Board of EORLA has six members appointed by member organizations, four competency based independent directors, and one university appointed member. The By-laws of the organization are approved by the government. The role of the board is to approve goals and strategic plan and directions, establish a framework for performance oversight, oversee programs and quality, oversee financial conditions and assets, enterprise risk management, supervision of the CEO, and, stakeholder relations and management of the board's own governance.

Through a series of contractual agreements with member organizations, EORLA is delegated the authority to deliver services, occupy premises in member hospitals, lease hospital equipment, and manage and integrate staff resources. They currently manage 11 collective agreements.

Activities currently out of their scope include ownership of hospital based laboratory information systems; point of care testing (EORLA maintains QA and compliance); ownership of laboratory licenses (EORLA operator status; hereditary genetic testing (CHEO) and newborn screening and better outcomes registry and network (BORN)).

Key areas of activity include: enhancing quality, access, cost reductions, sustainability, enhanced information system connectivity, optimizing the regional laboratory model through consolidation, integration, and stabilization, and laboratory utilization/clinical decision support.

Significant enhancements achieved in a short timeframe through a stand-alone laboratory organization were highlighted:

- Very strong and coherent medical and scientific leadership through one integrated team, all part of the Agency
- Standardization of quality metrics introduced and implemented in 2014 across all labs
- Financial gains from streamlining and efficiencies for the overall system
- Successful networking, consolidation and integration of all anatomic pathology
- Development for the first time of a regional transfusion medicine structure and utilization management function
- Standardized equipment platforms across all disciplines and all sites
- Automation and integration of microbiology

- Business intelligence tools developed and applied across all sites
- Development of a regional utilization management capacity for all sites

BC Agency for Pathology and Laboratory Medicine (BCAPLM)

In October 2015, the *Laboratory Services Act* was enacted in British Columbia. The Act was the result of ongoing reform of the clinical laboratory system in BC over the last decades. The new legislation enables BC to strengthen clinical laboratory patient services and to ensure that clinical laboratory resources are deployed efficiently and where they are most needed for the best patient care possible.

BCAPLM is in its early stages. It is an agency embedded in the Clinical Services Division of the larger BC Clinical and Support Services (BCCSS) Society which is a not-for-profit society created by the Ministry of Health to promote health in British Columbia by coordinating, managing and/or providing clinical, diagnostic and support services to British Columbia's healthcare system.

The legislation provides the BC Agency for Pathology and Laboratory Medicine the authority to better administer and coordinate inpatient and outpatient clinical laboratory service delivery systems throughout the province's six health authorities (five geographic regional and one provincial authority). It also enables British Columbia to enter into agreements with third party service providers for greater certainty regarding short-term costs and services and long-term sustainability of the entire system. Under the new legislation the Agency is responsible for strategic oversight of clinical laboratory services, funding (\$730M), efficiency and effectiveness, quality, human resources and education.

Early activities in BCAPLM's first year of operation include:

- Establishment of a framework and process for approving clinical laboratory tests for residents of British Columbia: A provincial Test Review Committee (TRC) is responsible for reviewing, evaluating and making evidence-based recommendations regarding the introduction, replacement or elimination of publicly-funded clinical laboratory tests (including inpatient, outpatient, out-of-province). The test review process entails a stringent evaluation criteria, expert consultation, value for payment economic considerations and with medical and scientific input from experts at the forefront of clinical academic medicine. Underlining this formal framework is the TRC's goal to ensure fair and transparent laboratory test review and adjudication processes. The TRC's recommendations are reported to the Agency, which then forwards the recommendations to the Ministry of Health for final decision. The current structure of the TRC includes six standing voting members, the Chair and two ex-officio members — all who have expertise in clinical laboratory medicine.
 - o In the first year of activity 120 laboratory tests have been delisted from the fee for service test menu including aspartate aminotransferase; hemoglobin A1c has been recosted; one test has been repatriated to be performed in province, and several tests have moved to full funding status from provisional status.

- A subcommittee established with the BC Cancer Agency for review of genomic testing for cancer patients: In September 2016, the Ministry approved the availability of clinical tests that can detect multiple different mutations in several genes simultaneously associated with solid or blood-based cancers, respectively. These were the first gene panels to be available province-wide and as part of standard cancer care in Canada for acquired cancers. Tests of this kind are only available at the top few cancer care institutions in the world.
- Establishment of the Laboratory Operational Committee (LOC). Bringing together representatives of major stakeholders in the laboratory services sector, including laboratory medicine physicians, referring practitioners, medical laboratory technologists, health authorities, publicly-funded laboratory facilities, and the general public, the 10-member LOC is mandated to provide the Ministry with advice and guidance on laboratory operational issues, including but not limited to:
 - o Approvals (and cancellations) regarding the provision of benefits, fees, testing technology;
 - o Approvals of new and changes to existing laboratory requisitions;
 - o The development and implementation of laboratory protocols and guidelines;
 - o Policy issues that may impact the quality of services, care of patients and/or the delivery of laboratory services in the province;
 - o Other initiatives that may optimize the efficiency and effectiveness of various aspects of the laboratory system;
 - o Appoint sub-committees or working groups of the LOC, at the discretion of the Chair in consultation with the Ministry, if required to support the LOC in achieving its mandate; and,
 - o Any other matter which the Ministry may refer to the LOC from time to time.

Kaiser Permanente (KP)

Kaiser Permanente is one of the largest not-for-profit health organizations in the US, serving more than 11.6 million members across nine states and headquartered in Oakland California. There are three organizational groups which comprise KP – the Kaiser Foundation Hospitals and their subsidiaries, the Kaiser Foundation Health Plan and the Permanente Medical Groups. Annual operating revenues for KP totals \$60 billion. KP is well known for their integrated patient centred primary care services. In 2015, Kaiser Permanente announced plans to open a new medical school that will redesign physician education. The Kaiser Permanente School of Medicine will focus on training physicians to provide high-quality care beyond traditional medical settings, emphasizing teamwork to inform treatment decisions, and addressing disparities in health.

KP provides 150M diagnostic tests per year across 38 hospitals and 628 medical facilities across their network. Their laboratory services are part of their comprehensive organization. They have over 200,000 employees and employ nearly 20,000 physicians. They have several consolidated laboratories and continue to drive consolidation and automation. In California they recently opened

a new LEED Gold laboratory, which was formerly an abandoned retail furniture warehouse – this highly automated laboratory which builds on innovative design is one of two hub laboratories in southern California and encompasses 160,000 square feet and will process 60,000 samples per day. They are moving toward one LIS. Their primary focus is on a high quality efficient laboratory service, providing optimal service and a full scope testing menu to patients and to their health networks. Research and innovation in laboratory diagnostics is not a key focus at this time.

Intermountain Healthcare

Intermountain Healthcare is a not for profit health system based in Salt Lake City, Utah. Laboratory services are provided as part of their comprehensive health organization which includes 22 hospitals, more than 185 clinics, 1,500 physicians and other care-givers and 37,000 employees overall.

Their laboratory services division has 1,100 employees, working out of a tiered hub and spoke structure with hospital based laboratories and one hub laboratory, performing 46 million laboratory tests annually across the system.

Highlights:

- Move to one LIS – key benefits – mobility of staff, reduced time and efforts on multiple SOPs, procurement savings
- Progress in standardization of equipment, IT, anatomic pathology processes
- Inclusive decision-making using a clear “decision rights” process for key clinical decisions
- They invest \$3-4M per year in capital and have a separate budget process for large diagnostic platforms

Health Partners

Health Partners is an integrated nonprofit healthcare provider located in Bloomington, Minnesota serving 1.5 million members. Health Partners provides care through a network of seven hospitals and 55 clinics throughout Minnesota and Wisconsin. More than 1,700 physicians work across the organization.

Laboratory services provide diagnostic testing in 35 labs across their system performing 9.2 million tests per year. They are moving to one LIS (decision imminent and project a two year rollout) and are continuing to try and standardize IT support across network as well as other areas which require standardization. Consolidation of microbiology is well underway and esoteric testing is done on one site. Health Partners is working to minimize laboratory testing at clinic sites and moving to consolidate clinic testing activity in one central lab. This is a service provider with no research and innovation focus. Reference testing is provided by three different labs as part of their merged organization – they are currently putting out an RFP for reference laboratory services.

Mayo Medical Laboratories (MML)

Mayo Medical Laboratories operates as a subsidiary within the Department of Laboratory Medicine and Pathology in the Mayo Clinic, a non-profit healthcare provider. The organization provides laboratory testing to support health care systems, hospitals, specialty clinics and other clinical laboratories in 60 countries around the world. Mayo Medical Laboratories operate three hub laboratories across three states (Minnesota, Arizona, Florida) serving 70 hospitals in their local regional networks while serving a total of 4.5 million patients worldwide; they employ 165 physicians and scientists including 90+ subspecialty pathologists. MML performs 23 million tests annually and offers a test menu of 3,000+ diagnostic tests.

Key highlights:

- Move to one LIS, essential to standardization and coherence across all areas of laboratory to ensure financial sustainability; it took two years for professionals in their system to see and appreciate the advantages of one LIS.
- Extensive proprietary digital services to clients across the world for online order entry and reporting, utilization management support, business analytics, decision support to providers.
- Leading edge molecular diagnostic platforms as part of reference laboratory services.
- Specialty Council – provides input and advice on quality, innovation and operational issues.
- Physician extender program – special program which trains technologists in areas of special expertise to enhance flow of work and enhance turnaround times, particularly in anatomic pathology.
- Contact/Call Centre – Mayo Medical Laboratories’ customer service center has been certified as a Center of Excellence by BenchmarkPortal for the third straight year. The Center of Excellence recognition is one of the most prestigious awards in the customer service and support industry.
- Multiple organizational awards for “best employer” status.
- Translational research and innovation agenda, introducing 150 new tests into clinical care annually. MML professionals publish 560 peer-reviewed articles annually.
- Recognized for their consultation services providing advice and oversight to other facilities as they work to become self-sufficient – they do not provide services through these arrangements –strongly committed to laboratory excellence.

ARUP Laboratories (Associated Regional and University Pathologists Inc.)

ARUP Laboratories is an American national reference laboratory and a nonprofit enterprise of the University of Utah, and it’s Department of Pathology. Located in the University of Utah Research Park in Salt Lake City, Utah, United States, ARUP provides medical laboratory testing services for clients and their patients throughout the United States. ARUP’s diagnostic-testing and disease-management menu encompasses all areas of clinical medicine, including allergy and immunology,

clinical chemistry, cytogenetics and molecular genetics, endocrinology, obstetrics, neonatology and pediatrics, hematology, infectious diseases, neurology, oncology, preventive medicine, and anatomic pathology.

ARUP's 3,000 clients across the USA include university teaching hospitals and children's hospitals, regional hospital networks, major commercial laboratories and clinics, group-purchasing organizations, and military and government facilities. ARUP does not compete for physician-office business but supports its clients' existing test menus by providing referral tests and consultative support.

ARUP Laboratories has nearly 3,000 employees and the laboratories are housed in a single 300,000-square-foot (28,000 m²) hub laboratory facility in the University of Utah Research Park in Salt Lake City, where more than 30,000–35,000 specimens of blood, fluid, and tissue samples are processed each day. The laboratory runs 24/7. ARUP's test menu includes over 3,000 diagnostic assays. Faculty from the University of Utah's School of Medicine, including the Department of Pathology, serve as medical directors for each ARUP laboratory department, as consultants on diagnosis and patient-management questions, as researchers into new diagnostic laboratory technology and disease mechanisms, and as educators.

ARUP is heavily involved in training providing educational offerings, training and internships for undergraduate medical technologists, genetic-counselor training, and residency and fellowship programs in pathology and related disciplines. ARUP also provides phlebotomy services for the University of Utah Health Care system.

Key Highlights:

- Excellence in automation – ARUP has sophisticated proprietary automation systems developed over the last 30 years which position it as one of the most efficient reference laboratories in the nation; some examples include:
 - o A 1,100-foot (340 m) transport and sorting system with a capacity of 5,000 specimens per hour.
 - o An automated storage sorter that can sort 4,000 finished specimens per hour into storage trays. The machine supplements two 1,000-per-hour storage sorters that were at full capacity.
 - o The trays of finished specimens are loaded into a two-story automated storage and retrieval system (AS/RS) housed in the world's largest clinical laboratory freezer. The fully automated system has a capacity greater than 2.3 million specimens and individual specimens can be retrieved in 2.5 minutes.
 - o The world's first automated thawing and mixing work-cells that thaw and then mix frozen specimens at a rate of more than 1,000 per hour each, reducing pre-analytical preparation and turnaround time while improving testing quality.
- Leadership in integrated information services - key examples:
 - o 5-10 per cent of revenues spent on IT including bioinformatics support of NGS; need embedded and substantial IT team.

- o One LIS; suite of other digital support services - ARUP Connect; ARUP Consult; ARUP Gateway, ATOP provide analytics, advice, education, utilization management information to clients.
- o AUP Connect: sophisticated proprietary web enabled program for client interface with ARUP Laboratory.
- o UM+ - Comprehensive Utilization Management solution - highly sophisticated digital platform for supporting comprehensive utilization management, benchmarking, decision-support and other analytics for clients of ARUP.
- Change Management re Utilization Management – significant investment in change management; Chief Value Officers work with hospitals in regard to best practice – change management expert physicians, spend time engaging clinicians re best practice, educating them; ATOP(program which analyzes test ordering patterns) provides data and used by Chief Value Officers to change practice.
- Academic leadership: ARUP Laboratories professionals are international leaders in pathology and laboratory medicine. A recent award to Dr. Karl Voelkerding is an example - awarded the CAP Distinguished Service Award for Developing next generation sequencing (NGS) Proficiency Testing program for CAP.
- Molecular diagnostics – databases: the University of Utah Department of Pathology and ARUP Laboratories hosts a growing number of human gene variant-disease database collections. Each database relies on both medical and molecular expertise, and uniquely displays sequence variation and clinical information together.
- Innovation and Translational Research - the ARUP Institute for Clinical and Experimental Pathology® since its inception in 1996 has developed approximately 620 tests that ARUP now performs in-house. Of these 620 tests, more than 400 were developed by institute scientists, while more than 200 others were improved and validated so that ARUP could perform them in-house rather than continue to refer them out.
 - o Spoke about impact of impending regulation of laboratory developed tests by FDA; stressed accreditation of their laboratory by CLEA and CAP as essential to managing this evolving regulatory environment.
 - o ARUP research scientists have published more than 1,700 original peer-reviewed research publications in leading journals.

Health Services Laboratories

Health Services Laboratories is a recent joint venture between two public sector NHS Hospital Trusts (University College London Hospitals Trust and the Royal Free London Hospital Trust) and the Doctor's Laboratory (a private sector laboratory) in London, England. The organization was the result of a longstanding relationship between the Doctor's Laboratory and the University College Hospital Laboratory. The Doctors Laboratory is the largest independent provider of laboratory diagnostic services in the UK, with two hub laboratories in London and Manchester supporting a

national network of laboratories across the UK. HSL was created to deliver medically-led diagnostics, innovation, value and long-term investment for the three partners. The joint venture combines The Doctors Laboratory's long standing, specialist pathology expertise with the Royal Free London and UCLH's internationally recognized heritage of continual research, development and academic excellence. The organization is committed to rigorously high standards of quality, while also delivering efficiencies to healthcare through careful workforce planning, pioneering technology, and significant investment in infrastructure and IT.

HSL is building a new hub laboratory in the heart of London's globally renowned life sciences hub, 'Medcity' reflecting the goal of outstanding and transformational pathology service. The hub facility will be state of the art with sophisticated proprietary automation systems to optimize performance and efficiency. The hub laboratory will support rapid response laboratories in acute care facilities belonging to the partners and through service contracts with other community hospitals. The hub laboratory will cover 11 floors with five split-level basements, be home to more than 1,000 staff working within a connected suite of laboratories spanning more than 100,000 square feet. The Halo will also have dedicated clinical and non-clinical cores for vertical connectivity. The pioneering work conducted at Halo will be seamlessly linked to the Doctor's Laboratory national network of hub and spoke laboratories throughout the UK.

The HSL Board is chaired by Lord Carter of Coles, author of the laboratory reform report for the NHS published in 2008, and contains both appointees from the member organizations as well as senior members of the HSL management team. The joint venture is founded on a shared equity and risk agreement, sophisticated agreements and processes for addressing any conflicts amongst partners, and a strong commitment to alignment of medical staff to the overall goals of the organization while maintaining their alignment with academic responsibilities and research interests.

New South Wales Health: Pathology (NSWHP)

NSWP is Australia's largest public sector laboratory service organization. In August 2011, a NSW Health report titled *Future Arrangements for the Governance of NSW Health* identified the potential value of creating an integrated, state-wide public pathology service to support public hospitals and health services. In November 2012, the Director-General endorsed a state-wide model that brought together four previously separate pathology networks – Pathology North, Pathology West, South Eastern Area Laboratory Services, and Sydney South West Pathology Service – to form NSW Health Pathology. In December 2012, the Director-General endorsed the merger of Forensic Medicine services across the state with the former Division of Analytical Laboratories at Lidcombe to create a fifth NSW Health Pathology network – the Forensic and Analytical Science Service. NSWHP is responsible for a \$600M budget, nearly 5,000 staff, operates more than 70 laboratories and performs 61 million laboratory diagnostic tests across five health networks in the state, serving a total of 200 hospital sites which include large urban academic sites, regional hospitals and small rural facilities. Their activity is largely limited to hospital laboratories with a small amount of community services. The private sector in NSW does most of the high volume low acuity community laboratory diagnostic work.

NSW Health Pathology is responsible for the strategic leadership and decision-making to ensure the people of NSW have access to the public pathology, forensic and analytical science services. A NSW Health Pathology executive team works with the networks to deliver state-wide strategies and benefits, foster greater collaboration and improve the long-term sustainability of services across NSW.

Included in their scope of services is forensic pathology, public health testing including environmental analytical laboratory services, Point of Care Testing in hospitals across the state, genomics, research and training through partnerships with 15 different universities. Their Board provides strategic advice and support to the organization in the implementation of their strategic plan (New South Wales Health Pathology Strategic Plan 2014-2018).

Key Highlights:

- POCT – rolled out one of the largest POCT programs in the world across 175 rural and regional hospitals
- Operates the largest central stem cell processing laboratory in NSW
- Established the first nationally accredited cancer genomics laboratory in Australia
- Responsible for the World Health Organization National Influenza Centre
- Provide a 24/7 laboratory support service for hemophiliacs across the state
- Significant public health activities both nationally and internationally including: partnering with WHO in surveillance of various communicable diseases (including Ebola testing), one of two national hospital based entomology labs providing advice and testing in regard to insect borne diseases, comprehensive analytical testing for trace elements providing a national service
- Statewide procurement policies and processes delivering efficiencies and economies of scale
- Statewide automation initiatives including toxicology and microbiology
- Work has begun on a \$12 million biobanking facility that will house Australia's first large-scale automated storage facility for biological samples used in medical research
- Three year strategic plan being implemented for a statewide genomics service
- Created a national campaign designed to educate Australians about how pathology contributes to our personal health
- Building a new \$91M state of the art forensic pathology facility serving all of NSW
- Strategy to extend hours of laboratory services to better serve patients

Appendix F - Translational Research Workshop

Invitees	Title	Organization
Andrew Neuner	Chief Executive Officer	Health Quality Council of Alberta
Charlene McBrien-Morrison	Executive Director	Health Quality Council of Alberta
Chris Le	Professor, Laboratory Medicine & Pathology	University of Alberta
Christie Lutsiak	Director, Health Research Policy and Partnerships Unit	Ministry of Health
Dan Rizzoli	Assistant Deputy Minister, Strategic and Corporate Services Division	Advanced Education
Deborah James	Executive Director/Innovation, Faculty of Medicine and Dentistry	University of Alberta
Denise Perret	Assistant Deputy Minister, Strategic Planning and Policy Development	Ministry of Health
Don Juzwishin	Director HTAI Research Innovation Analytics	Alberta Health Services
Dr. Carolyn O'Hara	Interim Medical Director, Laboratory Services, Pathology, General	Alberta Health Services
Dr. Chris Naugler	Calgary zone Clinical Department Head, Pathology & Laboratory Medicine, Medical Director	Calgary Laboratory Services
Dr. Francois Belanger	Vice President, Quality and Chief Medical Officer	Alberta Health Services
Dr. Hubert Eng	Senior Director, Life Sciences Industries	Ministry of Economic Development and Trade
Dr. Lawrence Richer	Associate Professor/Neurology, Pediatrics	University of Alberta
Dr. Marvin Fritzler	Mitogen Advanced Diagnostics Laboratory	University of Calgary
Francois Bernier	Associate Professor, Department Head, Medical Genetics	University of Calgary

Graham Tipples	Medical-Scientific Director, Provincial Laboratory for Public Health (ProvLab)	Alberta Health Services
Jason Pincock	Chief Executive Officer	<i>DynaLIFE</i>
John Ferguson	Director, Capital Planning and Grant Management Branch	Ministry of Advanced Education
Jonathan Meddings	Professor, Department of Medicine Vice-Dean, Faculty of Medicine	University of Calgary
Kristina Watkins	Executive Assistant to the CEO	Health Quality Council of Alberta
Marcello Tonelli	Associate Vice President - Research(Health), Professor, Medicine	University of Calgary
Martin Somerville	Professor & Director, Genetic Lab Services, Medical Genetics	Alberta Health Services
Mauro Chies	Vice President, Clinical Support Services	Alberta Health Services
Michael Mengel	Chair and Professor, Laboratory Medicine & Pathology	University of Alberta
Norman Neuman	Professor, School of Public Health	University of Alberta
Penny Ballem	Facilitator	
Randy Goebel	Assoc VP (Acad)/Assoc VP (Res), Provost and Vice-President (Acad)	University of Alberta
Reg Joseph	Vice President, Health	Alberta Innovates (formerly Alberta Innovates – Health Solutions)
Rod Skura	Deputy Minister	Ministry of Advanced Education
Steven Lewis	Facilitator	
Tammy Hofer	Senior Operating Officer, Laboratory Services	Alberta Health Services
Tim Murphy	Vice President, Provincial Platforms & Alberta Strategy for Patient-Oriented Research (SPOR) SUPPORT Unit	Alberta Innovates (formerly Alberta Innovates – Health Solutions)

TRANSLATIONAL RESEARCH WORKSHOP

Monday, November 21, 2016

**Alberta Health Services, Seventh Street Plaza
10030 – 107 Street NW, Edmonton, AB T5J 3E4
Main Floor, Board Room A
2:00 p.m. – 5:00 p.m.**

1. Welcome and opening remarks	Andrew Neuner, CEO, HQCA Denise Perret, Assistant Deputy Minister, Strategic Planning & Policy Development, Alberta Health
Opening remarks on the history and purpose of the Provincial Laboratory Services Project; to create an integrated plan for provincial laboratory services. Articulated the goals of this session which are to: ▪ Better define what translational research is, ▪ Provide advice to the Provincial Laboratory Services Project team on how it should consider this area of research as it relates to the laboratory services sector, and ▪ Identify Alberta's competitive advantage in this area.	
2. Roundtable introductions	All
Completed.	
3. Introduction to Provincial Laboratory Project and Translational Research Initiative	▪ Dr. Penny Ballem, Provincial Lead, Provincial Laboratory Services Project ▪ Dr. Michael Mengel, Chair of the Department for Laboratory Medicine & Pathology, University of Alberta ▪ Dr. Christopher Naugler, Head of the Department of Pathology & Laboratory Medicine, University of Calgary
Dr. Ballem offered a history of the Laboratory Services Project and highlighted the objectives the project team has been tasked with:	

1. Developing a strategic plan for provincial integrated laboratory services;
2. Working toward one provincial laboratory information system (LIS), with the knowledge that the provincial clinical information system (CIS) is moving forward;
3. Addressing the immediate, critical laboratory services facility needs of Edmonton; and
4. Undertaking a comprehensive engagement of stakeholders in the laboratory sector

The Laboratory Services Steering Committee is currently overseeing moving this agenda forward. To do that, the steering committee needs to consider how translational research fits within the laboratory services sector

Dr. Mengel delivered presentation entitled 'Translational Research in the Era of Precision Medicine' (attached).

Dr. Naugler delivered presentation entitled 'Southern Alberta Genomic Services: Southern Alberta Experience Moving to a Provincial Strategy' (attached).

Both Dr. Mengel and Dr. Naugler emphasized the importance of adopting new technologies and actively pursuing some of the integrated work mentioned in their presentations. Both feel that laboratory services are a foundational part of precision public health. Enthusiasm was also expressed over the common LIS. Both shared a commitment to a provincial approach to governance of a program for translational research in the laboratory diagnostics sector.

Both identified the opportunity of future new facilities (Calgary Cancer Centre and Edmonton hub laboratory – both in the planning stage) as enabling of this opportunity.

4. Question & answer period

All

- **Data access issues.** Multiple questions posed regarding access to data - notably concerns about the difficulty of accessing databases that have been generated using public funding, resulting in an underused asset.

Robust discussion held around issues created by data siloes. Many expressed a need to inventory current databases and determine how they could be made more accessible and linkable. Comment was made that data is readily available and that collaborative research agreements can help with some of the articulated access issues. This led to further discussion around access difficulties. During this conversation, frustration was also expressed regarding the resources required to clean up and monitor data quality to ensure data usefulness.

- **Economics.** Questions posed and discussion held around the perceived and possible economic benefits to Alberta in expanding the translational research agenda. Discussion raised questions of scope and if return on investment is defined in terms of improved health outcomes in Alberta or is there also an expectation of broader economic return from expanded research activities funded by external agencies as well as activities associated with commercializing and licensing technology (nationally and/or internationally). Given this is an information gathering workshop and no decisions have been made, these questions have been captured for consideration and did not receive a definitive response.

In discussing the potential economic benefits, the point was raised that any necessary investment in creating a foundation to support translational research will in the foreseeable future take place in a constrained financial environment. This will place a premium on activities and initiatives that will benefit the cost curve of the health system, help achieve better outcomes without increasing costs. Expanding translational research can only be done by developing a divestment strategy in

conjunction with the innovation strategy.

- **Nimbleness.** Question posed on how translational research can be more nimble. Currently the Alberta health system is not seen as enabling in this area. Expressed the importance of investing and divesting quickly with the fast-paced reality of translational research timelines. For example, in the field of genomics, an innovation cycle happens in 6 – 12 months. Often there isn't time for a long-term plan and proposal; sometimes a researcher may only have 10 weeks to capitalize on an opportunity.
- **Goal of expanding translational research.** Question posed about approach to a proposal to expand translational research in Alberta. Comment made that if the goal is diversification of the economy, Alberta will need a balanced portfolio of adoption and creation. Based on best practice, research and development (R&D) seed funding (to be leveraged by external funding) is necessary.
 - o Comment made in response that a functional laboratory will have an R&D budget and that current beta testing sites are not nimble enough to be responsive; this is why a significant amount of innovation work is taken out of province.
 - o Tying this to an overall provincial strategy makes a lot of sense given precision medicine is expanding and needs a broader agenda. Some participants supported the idea of moving a lot of the research happening at the universities into dedicated translational laboratory space in new facilities being built.
- **Two hub model.** Commitment to including translational research in Edmonton hub laboratory and request for the project team to think carefully about how to do it in Calgary, given current plans for the Calgary Cancer Centre (CCC). Will the CCC be focused exclusively on cancer-related technologies or can its mandate be expanded to include a broader translational agenda?
- **Type of translational research.** Discussion held around clarifying what types of translational research (i.e. where on the T1-T4 spectrum) Alberta is interested in pursuing. Initial conversations have pointed to T3-T4 focus, however comment was made that doing some work across the whole T1-T4 spectrum is important. Given the zero-sum budget reality Alberta is facing, need to gain clarity on the research focus, how to use the existing tools and facilities, recognize that expensive technologies cannot be adopted at this time unless there is a clear business case, and accompanying management of divestment of clinical activities and diagnostic testing practices that do not provide value.

5. Discussion 1 – Translational research: Opportunities related to laboratory medicine and pathology

- What are the goals and outcomes we wish to achieve in a program of translational research in this sector in Alberta?
- What are the measures of success (at 5 years)?
- What are the enablers of translational research in this sector?
- What is Alberta's competitive advantage?

Facilitator: Steven Lewis, President, Access Consulting Ltd. and Adjunct Professor of Health Policy, Simon Fraser University

The attendees were split into four working groups to consider the questions articulated in the agenda item above. Below are some aggregated highlights by question.

What are the goals and outcomes we wish to achieve in a program of translational research in this sector in Alberta?

- Alignment of research to support health system needs
 - o Provide the most effective outcomes for Albertans
 - o Intent to prevent disease versus intent to treat; disease prevention would offer significant value to the system
 - o Corollary impact on economic growth if successful
- Governance structure that ensures that health needs drive the priorities and activities
 - o Define accountability around use and stewardship
 - o Provincial approach to ensure maximum leverage
- Improved data access
 - o Multiple groups expressed frustration that data access is limited and can hinder translational research work significantly
- Must be value driven
 - o Strategic investment and divestment (i.e., ensure that obsolete technologies and processes cease once superior options have been implemented)
 - o Can the value proposition actually offer results?
- Create an integrated ecosystem (people/process)
 - o Consider soft and hard systems methodology
 - o Governance structure important to fully leverage resources across the province
 - o Consider innovative platforms
- Collaborative culture
- Multi-faceted goals for health improvement and return on investment:
 - o Implementation science behind managed exit
 - o Evaluation science for assessing tests
 - o Develop a framework for introducing new tests
 - o Policy underpinning the points above
- Clearly align data sources
 - o Achieving this can drive secondary analysis and tertiary use of data
- Evidence-informed process for the evaluation of new biomarkers (of notable importance to companion drug testing)
- Deliberate strategy articulated to build research and development (R&D)
- Novel data analytics and visualization
- Pursue way forward expeditiously

Comment was made by multiple groups that commercialization may be a positive outcome achieved by pursuing the translational research agenda; however, commercialization cannot be the sole driving factor for pursuing work in this area given the lack of guarantee of discovery and the highly competitive (and often well-funded) international environment.

What are the measures of success (at 5 years)?

- Better health outcomes
- Better value for Alberta's health system
 - o Economic model established
 - Is the single-integrated model the right model?
 - Would a translational laboratory have an impact in making front-line laboratory service delivery more effective? More efficient?
 - Can this work be commercialized?
 - Is there a way to create incentives?
 - Establish the minimum evidence required to inform policy change

What are the enablers of translational research in this sector?

- An integrated LIS/CIS
- Collaboration
- Implementation sciences
- Policy
- Opportunity of new physical space – Calgary Cancer Centre molecular diagnostics laboratory and new Edmonton hub laboratory both in planning stage
- Access to comprehensive data sets
- Willingness to develop a de-innovation pipeline
 - o Address zero-sum economic reality
- Single point of entry for proposals
- Scale and scope (leverage Alberta Health Services)
 - o Alberta's single health authority structure makes it easier to design projects, gather data, and implement solutions

What is Alberta's competitive advantage?

- Leverage of implementation sciences which already exist in academic institutions
- One system to transition theoretical to reality
- Ability to attract investment
- PACEOMICS – Personalized, accessible, cost-effective applications of 'Omics technologies
- Clinical trial infrastructure
- Pragmatic trials
- Research and development; adoption of Alberta Laboratory for Medical Diagnostics (ALMDx) model

6. Discussion 2 – Top 3 priorities for translational research in Alberta	Facilitator: Steven Lewis
Instead of the asset mapping exercise as articulated on the draft agenda, the four groups were asked to instead articulate the top three priorities the Provincial team should consider with respect to translational research as they continue to elaborate the four objectives articulated under agenda item 3. Below is an aggregated summary of the suggestions from the small group discussions: ▪ Articulate the return on investment (ROI) for pursuing translational research work within the provincial laboratory services agenda - o Define value; consider the link between precision medicine and public health - o Establish economic model ▪ Define the function - o What kind of research is being conducted? - o Who is doing this research? - o What human resources are required to support this research? ▪ Define the required space for the new hub laboratory facility and in addition consider use of existing - o Physical - o Virtual - o Data access required ▪ Develop translational laboratory program that introduces precision diagnostics as quickly as they're validated and shown to be cost-effective and replace traditional testing. - o Divestments of obsolete diagnostic programs could help pay for new initiatives ▪ Pick three high volume, high cost clinical areas to start based on where Alberta is in a position to move quickly. - o Include change and behavior management strategies as core elements of proposals as implementation and scale-up are always difficult. - o Expertise to inform this are in the oncology space (Edmonton, Calgary), microbiology space (Edmonton, Calgary), public health space, Strategic Pipeline to Accelerate Research into Care (SPARC; Alberta Innovates) ▪ Bend the cost-curve; laboratory testing is a gate keeper to dowing the right thing, for the right patient, at the right time. ▪ Commit to and invest in precision medicine - o When diagnostics are efficient, external customers will follow; resulting in commercial benefit	
7. Next steps and closing remarks	Dr. Penny Ballem / Steven Lewis
Summarized some recurring themes that included: ▪ Recognition of the importance of this work given the potential positive public, clinical health and economic implications	

- The importance of data access in support of this activity
- Precision medicine is a field that will continue to grow and Alberta needs to decide the role it wants to play in this area
- Broad interest in aligning the Hub Lab with the translational research opportunity, the needs of the system; given the economic constraints
 - o Desire to take a hard look at what diagnostics could be divested to help fund this and make this happen

Regarding next steps, reiterated that today's workshop was the first broader consultation on the topic of translational research and as the project team has more formalized suggestions ready for feedback, the team will reach out to solicit more input/feedback.

Translational Research Workshop – November 21, 2016

Background

The Minister has tasked the Provincial Laboratory Services Project team to:

- Develop a strategic plan for provincial integrated laboratory services;
- Work toward one provincial laboratory information system (LIS), with the knowledge that the provincial clinical information system (CIS) is moving forward;
- Address the immediate, critical laboratory services facility needs of Edmonton; and
- Consider a precision medicine strategy.

The Laboratory Services Project Steering Committee is currently overseeing moving this agenda forward. To do that, the steering committee needs to consider how translational research fits within the laboratory services sector.

As a member and on behalf of the Laboratory Services Project Steering Committee, the Health Quality Council of Alberta (HQCA) hosted a half-day workshop on November 21, 2016 to obtain advice and input to inform the strategy for integrating translational research activities into the overall laboratory strategy and into any new laboratory infrastructure.

The goals of this half-day workshop were to:

- Better define what translational research is,
- Provide advice to the Provincial Laboratory Services Project team on how it should consider this area of research as it relates to the laboratory services sector, and
- Identify Alberta's competitive advantage in this area.

Summary of Themes: Top Priorities to Consider

The attendees were broken out into four groups and asked the following questions:

- What are the goals and outcomes we wish to achieve in a program of translational research in this sector in Alberta?
- What are the measures of success (at 5 years)?
- What are the enablers of translational research in this sector?
- What is Alberta's competitive advantage?

After discussing these questions, the four groups were asked to use the answers generated during the discussion to identify their top three priorities for the way forward for the translational research strategy in Alberta. Below is an aggregated summary of the suggested priorities from the small group discussions for the Steering Committee and Project team to consider further:

- Articulate the return on investment (ROI) for pursuing translational research work within the provincial laboratory services agenda

- o Define value; consider the link between precision medicine and public health
- o Establish economic model
- Define the function
 - o What kind of research is being conducted?
 - o Who is doing this research?
 - o What human resources are required to support this research?
- Define the required space and consider use of existing
 - o Physical
 - o Virtual
 - o Data access required
- Develop translational laboratory program that introduces precision diagnostics as quickly as they're validated and shown to be cost-effective and replace traditional testing.
 - o Divestments pay for new initiatives
- Pick three high volume, high cost clinical areas to start based on where Alberta is in a position to move quickly.
 - o Include change and behavior management strategies as core elements of proposals as implementation and scale-up are always difficult.
 - o Assets to inform this are in the oncology space (Edmonton, Calgary), microbiology space (Edmonton, Calgary), Strategic Pipeline to Accelerate Research into Care (SPARC; Alberta Innovates)
- Surveillance
 - o Review the data for disease prevention and inform policy
- Bend the cost-curve; laboratory testing is a gate keeper to doing the right thing, for the right patient, at the right time.
- Commit to and invest in precision medicine
 - o When diagnostics are efficient, external customers will follow; resulting in commercial benefit

Closing Comments and Next Steps

The workshop attendees agreed the importance of this work given the potential positive public and clinical health implications for Alberta. Precision medicine is a field that will continue to grow and Alberta needs to decide the role it wants to play in this area. There was a broad interest in aligning the Hub Lab with the needs of the system and, given the current economic constraints, a willingness to take a hard look at what could be divested to make this happen.

Regarding next steps, the project team intends to reach out to this cohort to solicit more input/feedback as plans become more concretely developed.

Appendix G – Calgary Laboratory Services - Service Delivery Model



Calgary Laboratory Services

SERVICE DELIVERY MODEL

Calgary Laboratory Services (CLS) was formed in November 1996 as a partnership between the Calgary Health Region (CHR) and private company to provide medical laboratory testing to the Calgary area. CLS became a wholly owned subsidiary of Alberta Health Services (AHS) in 2009. Since its inception, CLS has streamlined, consolidated and standardized testing to improve quality, efficiency and cost effectiveness in the provisions of laboratory tests. CLS operates nineteen patient collection centres (PSC), a community mobile collection service, six outpatient collection sites, and provides testing services at the Diagnostic and Scientific Centre (DSC), the Rapid Response Laboratories (RRL) in the acute care sites and at the Health Centres in Calgary with essentially all Community EKG's in Calgary are performed by CLS. CLS provides support to AHS through management and medical oversight for the rural laboratories in Calgary Zone as well as consultative medical and logistical support to Southern Alberta, a provincially focused data analytics team and utilization office.

A regional Laboratory Information System (LIS) provides a single platform for the ordering, testing and reporting of laboratory results to our clients. Utilizing a patient centric model, a patient's electronic record is a comprehensive record of their laboratory results wherever they accessed service, in the acute care site, community or long term care. This reduces duplication of testing as health care providers are able to access laboratory results across the continuum of care. This large volume of results (29 million tests per year in 2015) provides a valuable data base useful for epidemiology, academic and research purposes.

Diagnostic and Scientific Centre (DSC) is situated in the University Research Park close to University of Calgary, Foothills Medical Centre and the Alberta Children's Hospital. The DSC provides laboratory testing support for community patients. In addition, centralized testing departments such as Cytopathology, Dermatopathology, Microbiology, Immunochemistry, Molecular Hematology, Tissue Typing, Special Coagulation and Analytical Toxicology are located at this site. Over sixty percent of the testing performed by CLS occurs at the DSC.

Support departments such as Administration, Quality, Finance, Human Resources, Environmental Health & Safety, Occupational Health & Wellness and Information Technology are also located at the DSC.

Rapid Response Laboratories provide phlebotomy and on site testing service in Chemistry, Hematology and Transfusion Medicine testing as well as Anatomic Pathology for both inpatients and outpatients in the acute care setting. The RRL also plays an active role in the sample collection and shipment of specimens from patients enrolled in Clinical Trials.

Operational Services provides phlebotomy, patient registration and sample processing for Inpatients and Outpatients to the Rapid Response Laboratories at the acute care facilities. Operational Services also provides accessioning services at the Diagnostic and Scientific Centre (DSC) facility, in addition to supporting External referrals for all areas in CLS.

Health Centre Testing Laboratories (HCTLs) located at South Calgary Health Centre (SCHC), Sheldon M. Chumir Health Centre (SMCHC), Airdrie Community Health Centre (ACHC) and Cochrane Community Health Centre (CCHC) provide STAT testing for patients seen in the Urgent Care Centres, Outpatient Clinics as well as handling Community Paramedic samples.

Genomics testing is performed by CLS for Calgary and Southern Alberta as well as providing consultative services for Alberta, parts of British Columbia and Saskatchewan. Over 20,000 tests per year are performed by 5 testing labs within CLS. There has been significant investment recently in advanced diagnostic platforms within the organization to further expand and promote this area of testing.

Microbiology provides comprehensive diagnostic infectious disease services in all areas of testing (Bacteriology, Mycology, Parasitology, Virology, and HIV Viral Load Testing). The department has been fully consolidated to the DSC Molecular Microbiology provides molecular investigation into the epidemiology of infectious disease and the development of antimicrobial resistance.

Clinical Biochemistry provides blood and urine testing at all acute care sites, HCTLs, CRLs and the DSC. The scope of testing is very broad and includes the analysis of general and specialized chemistry tests such as proteins, hormone and thyroid levels, basic chemistry analysis and protein electrophoresis.

Analytical Toxicology tests blood and urine specimens for the presence of therapeutic and toxic drugs for acute care and community patients as well as the addiction programs in the area. The department also provides testing for immunosuppressive drug analysis to support organ/tissue transplants.

Immunochemistry performs autoimmune testing, allergy testing, vitamin D, serum tumor markers, hormone levels and first and second trimester maternal serum prenatal screening.

Hematology provides testing of blood and urine specimens for patients from all acute care sites and the community.

Special Hematology (SH) receives and processes bone marrow samples from all adult acute care hospitals. The department also screens for abnormal hereditary hemoglobin diseases for patients from Calgary and Southern Alberta.

Molecular Hematology provides molecular analysis for the diagnosis and monitoring of patients in the bone marrow transplant program. It also provides support for the diagnosis of inherited disorders such as hemophilia or for the risk factors implicated in excessive blood clotting.

Special Coagulation performs specialized testing to determine hereditary predisposition to clotting or bleeding disorders such as those in Hemophilia. SC also assists in the diagnosis of acquired bleeding problems and helps identify the most effective treatment for the condition.

Tissue Typing (TT) is responsible for Human Leukocyte Antigen (HLA) and antibody investigations necessary for kidney and bone marrow transplantation. The department types and screens both donors and patients regularly before transplantation and monitors the patients after surgery to assess the success of the procedure and the risk of organ rejection. This program currently supports the bone marrow program for the province of Alberta and solid organ kidney pancreas transplant program for Southern Alberta. The Tissue Typing Department has accreditation from the American Society of Histocompatibility and Immunogenetics (ASHI).

Transfusion Medicine (TM) Transfusion Medicine performs pretransfusion testing and is responsible for the distribution of blood and blood products. Testing also includes investigating blood group incompatibilities between mother and baby, complex antibody investigations and computer assisted cross matches. Transfusion Medicine is also responsible for the Hematopoietic Progenitor Cell Processing Program, which provides bone marrow processing, storage, and preparation for transplantation.

Anatomic Pathology (AP) The division offers Frozen Section Diagnosis, Surgical Pathology, Dermatopathology, Autopsy Pathology, Cytogenetics and Molecular Pathology service and consultative services.

Cytopathology (CP) involves the interpretation of cells that spontaneously exfoliate or are removed from tissues by abrasion or fine needle aspiration, such as specimens from the cervix, breast, thyroid, lymph node, liver etc.

Flow Cytometry (FC) is a regional laboratory servicing southern and central Alberta, as well as southeastern BC, and offers the largest scope of clinical applications in Canada. This department aids in the diagnosis of leukemia and lymphomas, immunodeficiency disorders, and in the monitoring of patients with HIV. It is also an integral part of the bone marrow/stem cells in stem cells samples from both donors and patients. It serves as a reference lab for other facilities across Canada (Vancouver to Newfoundland) and has been involved in many research projects.

Client Services is comprised of several operational support areas: Data Maintenance, Medical Records, Optical Scanning, Mailroom, Client Interface Team (CIT), Laboratory Information Centre (LIC) and Patient Appointment Line (PAL).

- LIC is an integral link in the delivery of health care services. The team is responsible for the communication of 9,500 critical and 9,900 stat test results each month. The staff responds to inquiries for test results, specimen requirements, and collection procedures test preparations for health care providers and patients.
- CIT is the primary point of contact for physicians and health care providers with concerns. They investigate and resolve reporting problems meeting the needs of external and internal customers.

- **PAL** supports CLS' commitment to provide the best service possible by providing appointments for all CLS Patient Service Centres. (PSC) Appointments can be made through the PAL call centre or can be booked on line. PAL books 80,000 patients appointments each month.

Research department coordinates external and internal research activities. The administrative office is located at the DSC and is responsible for the overall administrative coordination and supervision of research including research data requests, summer studentship and research competitions.

Quality division supports the organization through the development, implementation, maintenance, and monitoring of the CLS Quality System. The CLS system is based on the Clinical and Laboratory Standards Institute (CLSI) consensus standards and is comprised of 15 Quality System Essentials (QSEs) that outline key elements needed to consistently provide cost-effective and excellent service. Operating within a Quality System ensures that CLS meets or exceeds regulatory and accreditation requirements, promotes patient safety and provides quality service and satisfaction to our clients.

Point of Care Testing (POCT) division provides quality assurance support for point of care testing performed by non laboratory health care personnel such as Respiratory Therapists or nursing staff in the acute care sites as well as in the community and long term care facilities.

Mobile Collection Service (MCS) provides blood collection to Long Term Care and Assisted Living Facilities, group homes, and hospices. CLS MCS staff also travels to the private homes of disabled, elderly, terminally ill, immobilized and housebound patients who are facing significant medical challenges that prevent them from accessing CLS Patient Service Centres (PSCs). MCS service area includes Calgary, Airdrie, Cochrane as well as the county of Rockyview.

Clinical Education supports CLS's commitment to ensuring a stable workforce in order to meet the increasing testing demands, as well as compensate for our aging workforce. Through our partnership with the educational institutions of U of C, NAIT, SAIT and ABES (Alberta Business and Education Services), students are being trained as Pathology Assistant, Cytotechnologists, Medical Laboratory Technologist and Medical Laboratory Assistants. CLS also provides support to the University of Calgary Cummings School of Medicine by training residents in four Pathology Training Programs and also provide the largest Fellowship Training Program in Canada.

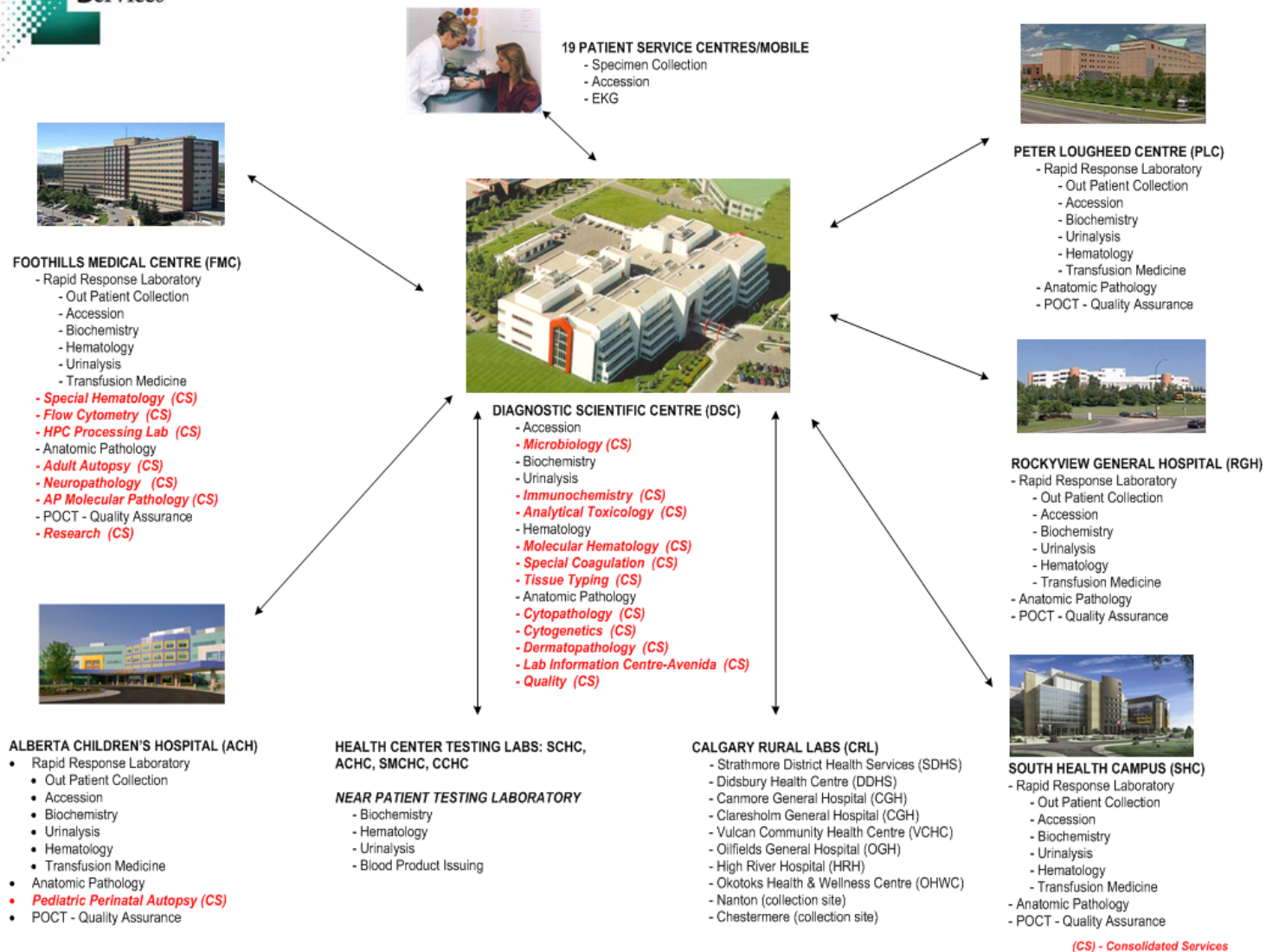
Community Services – Patient Service Centres: Community Services offer a variety of specimen collection services including EKG and Drug Screen testing through 19 Patient Service Centres in and around the Calgary area.

Calgary Rural Labs (CRL) management was transferred to CLS in March 2012. This includes hospital sites with a 24 hour Emergency Department at Strathmore District Health Services (SDHS), Didsbury Health Centre (DDHS), Canmore General Hospital (CGH), Claresholm General Hospital (CGH), Vulcan Community Health Centre (VCHC), Oilfields General Hospital (OGH) and High River Hospital (HRH). Also included are lab operations at Okotoks Health and Wellness

Centre (OHWC) and collection sites at Nanton and Chestermere. All sites provide basic laboratory services for community Out Patients, as well as a smaller In Patient population and Long Term Care located within the hospitals.

The CLS Courier Department provides both routine and Stat sample transport service seven days a week 24 hours a day. Its main function is the efficient transport of specimens, reports, biohazardous waste, and limited supplies for the Diagnostic & Scientific Centre (DSC), Rapid Response Labs (RRL), Patient Service Centres (PSC), Health Centre Testing Labs (HCTL), Extended Care Facilities and Physician Offices throughout the communities of Calgary, Airdrie and Cochrane. CLS also provides sample transport support for the communities of Lethbridge, Medicine Hat, Brooks and Bassano.

CURRENT SERVICE DELIVERY MODEL 2016



Appendix H – Cost / test comparison

Figure 19: High level comparison of cost per test in Edmonton zone and Calgary zone

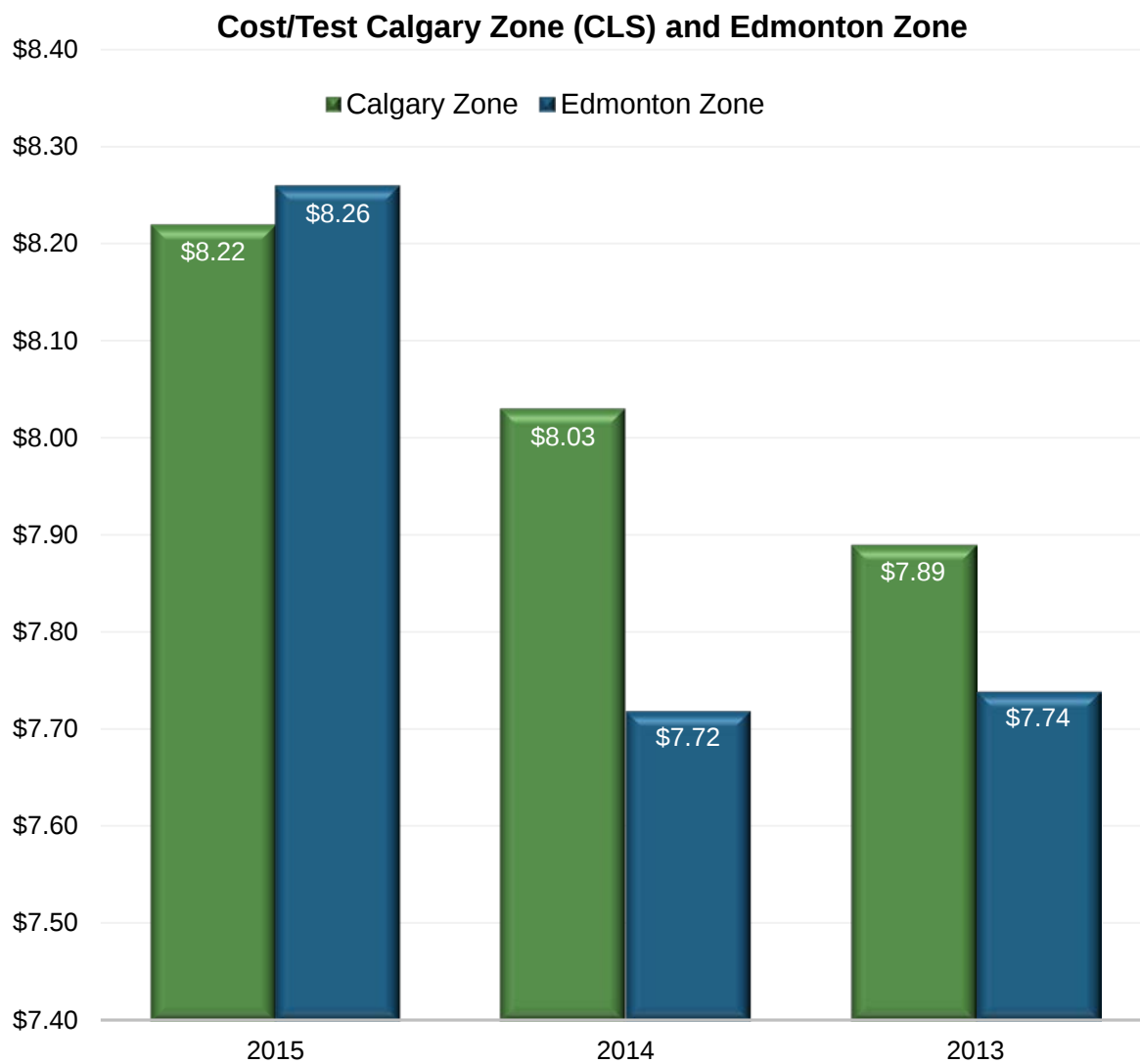


Figure 20: Adjusted cost per test Edmonton zone and Calgary zone: hub laboratory (CLS and *DynaLIFE*) and complex testing (University of Alberta Hospital and CLS)

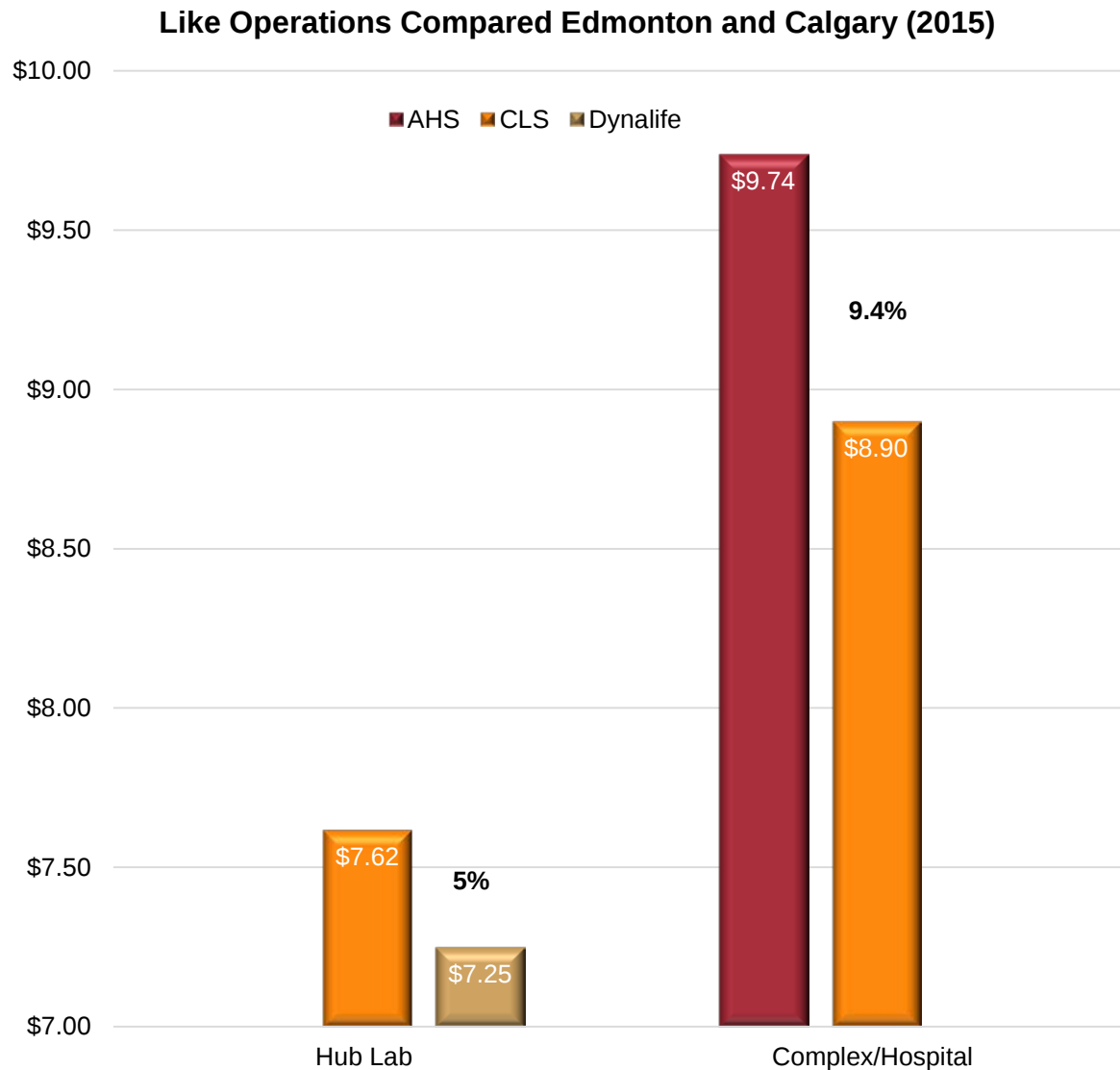


Figure 21: Breakdown of cost per test by provider in Edmonton zone; no adjustment for complexity

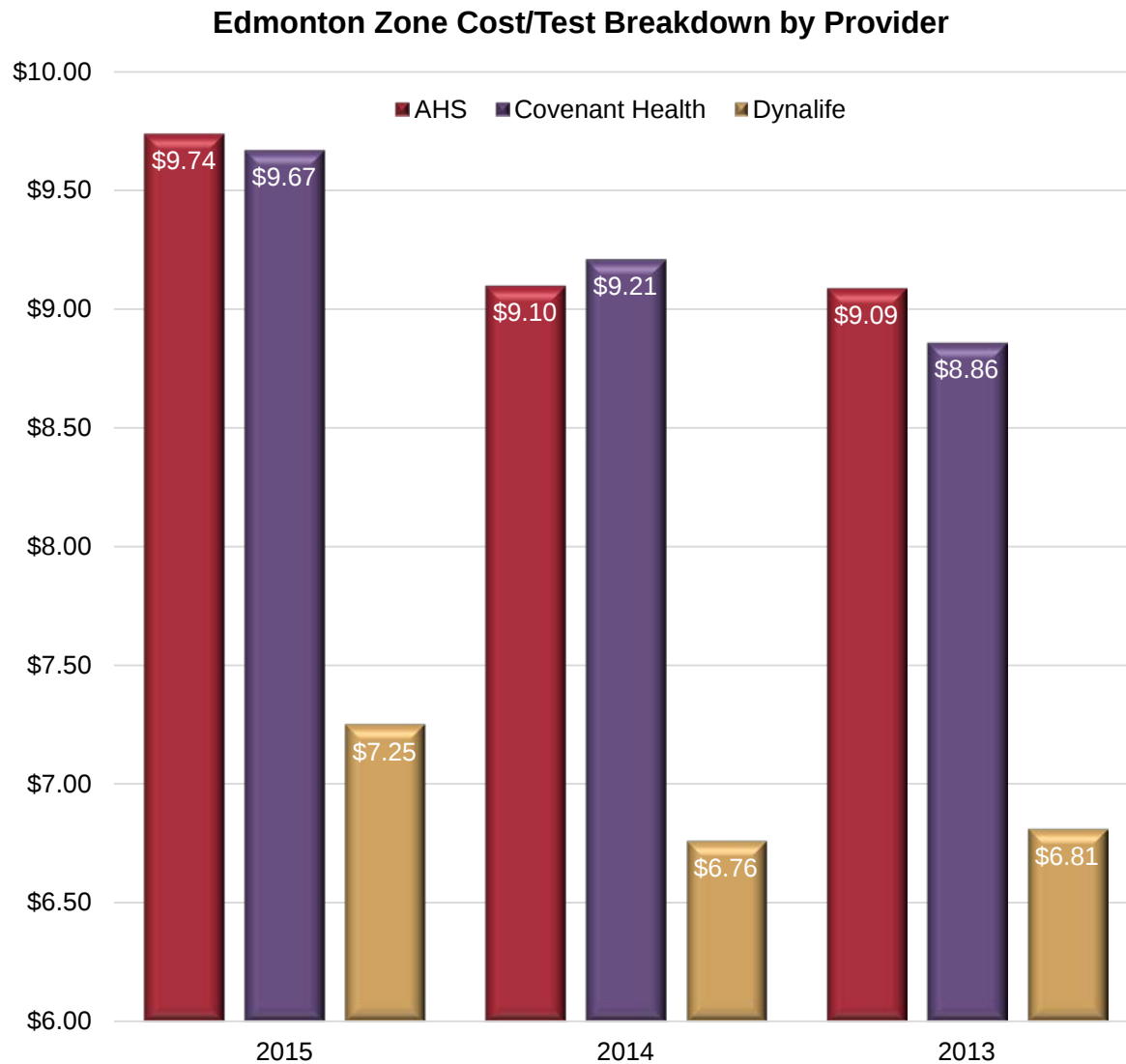


Table 16: High level comparison of number of tests by provider and location in Calgary and Edmonton zones

	Calgary Zone	Edmonton Zone
Hospital laboratories	CLS	AHS, Covenant Health
Hub laboratory	CLS	<i>DynaLIFE</i>
Number of hospital and complex test (2015)	10.6M	9.1M (AHS) 1.9M (Covenant Health)
Number of hub laboratory tests (2015)	17.8M	16M

List of Figures

FIGURE 1: CONSULTATION ACTIVITIES MAY TO DECEMBER 2016.....	17
FIGURE 2: CONSULTATION FREQUENCY	18
FIGURE 3: PHASES OF THE LABORATORY TESTING PROCESS (ADAPTED FROM LABORATORY MEDICINE: A NATIONAL STATUS REPORT ²)	22
FIGURE 4: SPECIMEN COLLECTION LOCATIONS IN ALBERTA.....	23
FIGURE 5: LABORATORY SERVICE PROVIDERS IN ALBERTA.....	25
FIGURE 6: ORGANIZATIONAL STRUCTURE OF LABORATORY SERVICES IN AHS (2016)	28
FIGURE 7: TIERING OF LABORATORY SERVICES IN ALBERTA	30
FIGURE 8: CRITERIA FOR TEST MENU BY SITE	32
FIGURE 9: AHS LABORATORY SERVICES QUALITY MANAGEMENT STRUCTURE	34
FIGURE 10: LIS SERVICE REQUESTS 2016 (SOURCE: AHS LAB STATUS DASHBOARD, DECEMBER 2016, PROVINCIAL SUPPORT SERVICES).....	42
FIGURE 11: EQUIPMENT AMORTIZATION STATUS AHS AND CLS – 10 YEAR AMORTIZATION CYCLE	44
FIGURE 12: AMORTIZATION STATUS OF LABORATORY (AHS AND CLS) AND DIAGNOSTIC RADIOLOGY EQUIPMENT (AHS) – 10 YEAR AMORTIZATION SCHEDULE	45
FIGURE 13: PROJECTIONS OF COST PER TEST AND VOLUME GROWTH FOR EDMONTON AND NORTHERN ALBERTA 2013 TO 2025 (BOSTON CONSULTING GROUP ¹⁹)	51
FIGURE 14: ALBERTA PUBLIC HEALTH LABORATORY ACTIVITIES.....	62
FIGURE 15: TRANSLATIONAL RESEARCH IN LABORATORY DIAGNOSTICS – INTERFACE WITH ACADEMIA AND CLINICAL LABORATORIES.....	67
FIGURE 16: OPTIONS FOR A STAND-ALONE ENTITY FOR THE DELIVERY OF LABORATORY SERVICES.	77
FIGURE 17: PROPOSED ORGANIZATIONAL STRUCTURE	80
FIGURE 18: PROPOSED FRAMEWORK FOR TEST REVIEW DECISION-MAKING	86
FIGURE 19: HIGH LEVEL COMPARISON OF COST PER TEST IN EDMONTON ZONE AND CALGARY ZONE.....	139
FIGURE 20: ADJUSTED COST PER TEST EDMONTON ZONE AND CALGARY ZONE: HUB LABORATORY (CLS AND <i>DYNALIFE</i>) AND COMPLEX TESTING (UNIVERSITY OF ALBERTA HOSPITAL AND CLS).....	140
FIGURE 21: BREAKDOWN OF COST PER TEST BY PROVIDER IN EDMONTON ZONE; NO ADJUSTMENT FOR COMPLEXITY	141

List of Tables

TABLE 1: NATIONAL AND INTERNATIONAL BEST PRACTICE ORGANIZATIONS	20
TABLE 2: SCOPE OF LABORATORY SERVICES IN ALBERTA.....	21
TABLE 3: PATIENT ENCOUNTERS WITH LABORATORY SERVICES BY AHS ZONE AND SETTING	21
TABLE 4: LABORATORY TESTING FACILITIES BY AHS ZONE AND SERVICE PROVIDER	26
TABLE 5: SNAPSHOT OF LABORATORY SERVICES BY PROVIDER, ALBERTA 2015/16	27
TABLE 6: LABORATORY KEY PERFORMANCE INDICATORS	36
TABLE 7: LIS ENVIRONMENT IN ALBERTA.....	39
TABLE 8: AHS KEY BUSINESS METRICS - ANNUALIZED FIGURES (2015)	41
TABLE 9: PERCENTAGE OF LABORATORY EQUIPMENT FULLY AMORTIZED – AHS AND CLS	44
TABLE 10: PERCENTAGE OF LABORATORY (AHS AND CLS) AND DIAGNOSTIC RADIOLOGY (AHS) EQUIPMENT FULLY AMORTIZED	45
TABLE 11: RELATIVE INVESTMENT IN CAPITAL ACROSS THREE LARGE SERVICE PROVIDERS IN ALBERTA – BY DOLLARS PER TEST PERFORMED.....	46
TABLE 12: TRAINING INSTITUTIONS FOR LABORATORY PROFESSIONALS IN ALBERTA AND NUMBER OF GRADUATES.....	49
TABLE 13: LABORATORY ORGANIZATIONS CONSULTED IN BEST PRACTICE REVIEW.....	54
TABLE 14: MECHANISMS TO REVIEW NEW LABORATORY DIAGNOSTICS ACROSS CANADA.....	66
TABLE 15: LEADING HEALTH SERVICE DELIVERY ORGANIZATIONS – LABORATORY SERVICE DELIVERY MODEL	72
TABLE 16: HIGH LEVEL COMPARISON OF NUMBER OF TESTS BY PROVIDER AND LOCATION IN CALGARY AND EDMONTON ZONES.....	141

Glossary of acronyms

AABB	American Association of Blood Banks
AHS	Alberta Health Services
AI	Alberta Infrastructure
ALAPP	Alberta Local Authorities Pension Plan
ALQEP	Alberta Laboratory Quality Enhancement Program
AMA	Alberta Medical Association
APAGA	Alberta Public Agencies Governance Act
APQA	Anatomic Pathology Quality Assurance
ARUP Laboratories	Associated Regional and University Pathologists Inc.
AS/RS	automated storage and retrieval system
ASHI	American Society for Histocompatibility and Immunogenetics
AUPE	Alberta Union of Provincial Employees
BCAPLM	BC Agency for Pathology and Laboratory Medicine
BCCSS	BC Clinical and Support Services
BCG	Boston Consulting Group
BORN	Better Outcomes Registry and Network
CACB	Canadian Academy of Clinical Biochemistry
CADTH	Canadian Agency for Drugs and Technologies in Health
CALA	Canadian Association for Laboratory Accreditation
CAP	College of American Pathologists
CCC	Calgary Cancer Centre
CCMG	Canadian College of Medical Geneticists
CHEO	Children's Hospital of Eastern Ontario
CHR	Calgary Health Region

CIS	clinical information system
CLS	Calgary Laboratory Services
CLXT	Combined laboratory and x-ray technologist
CMOH	Chief Medical Officer of Health
CPSA	College of Physicians & Surgeons of Alberta
CTSI	University of Florida Clinical Translational Science Institute
CUPE	Canadian Union of Public Employees
DL	<i>DynaLIFE</i>
ECG	electrocardiograms
FIT	the fecal immunochemical test
EORLA	Eastern Ontario Regional Laboratory Association
GLS	Genetics laboratory services
HLA	Human Leukocyte Antigen
HSAA	Health Sciences Association of Alberta
HTA	Health Technology Assessment
ISO	International Organization for Standardization
ISQua	International Society for Quality in Healthcare
KP	Kaiser Permanente
KPIs	key performance indicators
LIS	laboratory information system
LOC	Laboratory Operational Committee
MHDL	Medicine Hat Diagnostic Laboratory
MML	Mayo Medical Laboratories
NGS	next generation sequencing
NLP	Northern Lab Professionals

NSWHP	New South Wales Health: Pathology
PCN	Primary Care Network
PQIC	Provincial Quality Improvement Council
PRG	Provincial Resource Group
ProvLab	Provincial Laboratory for Public Health
PSCs	patient service centres
PT	proficiency testing
R&D	research and development
ROI	return on investment
RRL	Rapid response laboratory
SPARC	Strategic Pipeline to Accelerate Research into Care
TAT	time to turn around a result
TM	Transfusion Medicine
TRC	Test Review Committee
UAH	University of Alberta Hospital

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