Ministry of Health and Long-Term Care

Laboratory Services in the Health Sector

1.0 Summary

Laboratory services involve the collection, testing and analysis of a patient's specimen (such as blood, urine or stool) for health-care professionals to make decisions on the diagnosis and treatment of their patients. Various studies note that laboratory tests inform and guide over 70% of medical decisions.

Ontario has about 540 specimen collection centres (collection centres) where specimens are collected from patients, and about 200 laboratories where the collected specimens are analyzed. In 2015/16, the Ministry of Health and Long-Term Care (Ministry) spent about $2 billion funding 260 million tests performed by four types of laboratory service providers, including:

1. community laboratories (operated by private companies);
2. hospital laboratories;
3. authorized health-care professionals (mainly physicians) who perform tests in their own offices; and
4. Public Health Ontario laboratories.

Health-care professionals are responsible for ordering laboratory tests for their patients.

Depending on the type of test ordered and the location of the health-care professional (within a hospital or in a community), specimens needed for testing are obtained from patients in different ways. Generally:

- Patients seen by authorized health-care professionals practising in their communities can go to any collection centre operated by community laboratory service providers.
- Patients seen by their health-care professionals practising in a hospital (hospital out-patients) go to the hospital collection centre.
- Patients staying in hospitals (in-patients) will have their specimens collected directly from their rooms.
- Patients seen by authorized health-care professionals who have the ability to perform simple tests (such as urine dipstick analysis to detect pregnancy and drugs) can have their specimens collected directly in their health-care professionals' offices.

Once the specimens are collected from patients, they are sent to a laboratory for analysis. In addition to community and hospital laboratories, Public Health Ontario laboratories also perform testing for infectious diseases (such as HIV and hepatitis), either to identify the presence of a disease or to confirm test results for community or hospital laboratories by re-testing specimens. Regardless of the type of laboratory that performs the test, the laboratory sends the test results back to the health-care professionals who ordered the tests, who will make diagnostic and treatment decisions for their patients.

All community, hospital and Public Health Ontario laboratories operate under the *Laboratory and Specimen Collection Centre Licensing Act*, which requires all laboratories and collection centres to be licensed by the Ministry. To be licensed, all laboratories and collection centres must participate in the quality management program operated by the Institute for Quality Management in Healthcare (Institute), which is a subsidiary of the Ontario Medical Association (OMA). The Ministry funds the Institute (about $4.7 million annually) to deliver the quality management program, which involves two main components: accreditation (to ensure that laboratories have good procedures and processes in place), and proficiency testing (to ensure that laboratory processes provide accurate test results).

Our audit found that laboratory services are generally provided to Ontarians safely, and accurate laboratory tests results are generally provided to health-care professionals in a timely manner. Despite these successes, several areas relating to cost-effectiveness, accessibility, and performance measurement and reporting of laboratory services need improvement.

Our audit also found that the Ministry has managed Ontario's laboratory sector in a fragmented manner with funding, planning and oversight functions taking place in several departments and at varying levels across the Ministry, depending on the type of laboratory service provider. The following are some of our significant observations.

One important set of issues relates generally to cost to the Ministry and to patients.

- **Outdated laboratory test price list resulted in overpayments to community laboratory service providers.** While technological advancements have led to significant automation and cost reduction for many tests, the Ministry has not made any major updates to its price list (which defines the type and price of each test that the Ministry pays community laboratories to perform) since 1999. It only plans to implement a new price list in 2017/18. We found that if the new price list had been in effect in 2015/16, the Ministry would have paid community laboratory service providers about $39 million less than it actually paid in that year alone. A 2015 report by a stakeholder group (composed of some smaller community laboratory service providers, non-profit organizations, physicians and patient groups) also estimated that the government may have overpaid certain community laboratory service providers over the past 15 years as a result of the price list not accurately reflecting the actual costs of these service providers.
- **Price list not updated using all relevant cost data.** In 2016, the Ministry hired a consulting firm to help review and update its community laboratory test price list. The consulting firm obtained data from various laboratory service providers, including laboratory service providers in the United States and one community laboratory service provider in Ontario that accounted for less than one-third of the provincial community laboratory test volume. The data used by the consulting firm did not include cost information from the two largest community laboratory service providers in Ontario as they chose not to provide this information to the Ministry. These community laboratory service providers receive the majority of the Ministry's total funding to community laboratories. Without collecting cost data from these large community laboratories, which can achieve economies of scale and lower overall costs per test by performing a large volume of tests, the Ministry does not know if the consulting firm did a reasonable analysis of expected profit margins and cost information in updating the price list.
- **Medically necessary tests remain uninsured.** In 2015/16, health-care professionals in Ontario ordered about 1.1 million laboratory tests that were not funded by the Ministry. Patients generally had to pay

community laboratory service providers for these uninsured tests out-of-pocket or through their private insurance. The Ministry has not regularly evaluated whether currently uninsured tests should be funded, even though many of these tests have become more widely accepted as medically necessary and are often funded by other provinces. In 2016, however, the Ministry did engage a consulting firm that identified 16 uninsured tests (such as a test that is used to measure the amount of protein cancer antigen 125 in a patient's blood) that it recommended the Ministry start funding. The Ministry did not implement this recommendation and has no timetable to do so. We noted that many of these 16 tests are insured in other provinces.

- **More action needed to reduce unnecessary testing.** Unnecessary testing results in the overuse of laboratory services, wasting patients' time and health-care costs. We found that the Ministry's actions to reduce unnecessary testing, especially relating to vitamin D testing and aspartate aminotransferase (AST) testing (usually used to identify liver damage), did not result in effective or sustainable long-term reductions in testing. Ontario studies found that both of these tests were being ordered in situations where the result was not useful in improving the health of a patient. In 2010, the Ministry restricted unnecessary vitamin D testing at community laboratories, which dropped initially (from about 760,000 tests in 2009/10 to 173,000 tests in 2011/12) but increased again, more than doubling between 2011/12 and 2015/16 (to about 385,000 tests), while all other types of tests increased only about 1%. In 2013, the Ministry implemented eligibility criteria to reduce unnecessary AST testing; however, a few years after implementation, a group representing several community laboratory service providers submitted a report to the Ministry suggesting that almost 1.5 million AST tests (costing about $3.8 million) conducted between April 2014 and March 2015 potentially provided no clinical value.

We also noted issues related to the cost of genetic testing and regional inequities in the availability of laboratory services.

- **Inadequate strategy for genetic testing results in costly out-of-country testing.** The Ministry's approach to deal with the growing demand for genetic testing (used to examine a person's genetic material such as DNA) has not been cost-effective. While physicians can apply on behalf of their patients for the Ministry's out-of-country program for genetic testing, the associated costs are significant. Between 2011/12 and 2015/16, out-of-country genetic tests almost doubled and the associated costs increased by about 80%. During this period, Ontario paid over US$120 million related to over 54,000 specimens that were sent out of the country. While the Ministry's cost to perform some genetic tests would be cheaper if these tests were brought in-province, the Ministry's current strategy to increase the number of tests done in-province is still preliminary. In some cases, the Ministry has licensed community laboratories to perform these tests, but allows them to perform the tests only for non-Ontarians. The Ministry informed us that this arrangement is being reconsidered as it further develops its genetic strategy.
- **More effort needed to identify and improve underserved areas of laboratory services.** The Ministry has not set a provincial target number of collection centres and has not regularly collected sufficient information (such as the number of patients served—a number that British Columbia's Ministry of Health collects in that province) to assess if the current number and size of community collection centres across the province is appropriate and sufficient to meet patient needs.

Another set of concerns relates to the lack of oversight and controls over Ontario's laboratory services and the laboratories' performance.

- **Limited investigation of large in-office laboratory test volumes and billings by physicians.** In 2015/16, physicians who billed OHIP performed about 10.6 million in-office laboratory tests, which accounted for about $83 million (or 4%) of the Ministry's funding for laboratory services. We noted that among these physicians, 120 family and general practice physicians were responsible for almost half of all laboratory testing performed by physicians in their own offices. Among this group, the 15 physicians with the highest billings for in-office tests each performed between about 75,000 and 182,000 tests, and billed between about $600,000 and $1.4 million in 2015/16. In contrast, the average family and general practice physician who billed OHIP for in-office laboratory testing performed about 660 tests and billed approximately $4,700 in 2015/16. The Ministry has only performed a limited number of reviews (on eight of the 120 family and general practice physicians) to verify the accuracy of these billings.
- **No licensing and quality management of physicians' in-office laboratory testing.** Unlike hospital and community laboratories, physicians still do not require a licence to perform in-office laboratory testing and are not required to participate in the Province's quality management program. This has been raised as a concern repeatedly in our 1995 and 2005 audits, as well as external studies, but has remained unresolved over the past two decades because the Ministry has not taken any action to address this concern.
- **Lack of regional co-ordination and integration of hospital laboratories.** While some hospitals have worked together to develop regional laboratory networks that resulted in cost savings (through buying equipment and supplies in bulk, developing policies and procedures jointly and centralizing tests at certain laboratories), this has not been widely adopted across the province. In Ontario, regional laboratory networks exist in only six of the 14 Local Health Integration Networks (LHINs); but even in these six LHINs, not all hospitals participate in their networks. In contrast, as of April 2017, Quebec's Ministry of Health and Social Services moved all its laboratory services to regional networks. It estimated that this will result in an annual cost savings of up to 20% of its spending on laboratory services (excluding spending on specimen collection centres and genetic testing).
- **No oversight of billing practices by hospital laboratories.** Hospitals can send laboratory testing to other hospitals if their equipment is down or if they find that it is not cost-effective to do the tests themselves. However, the Ministry has not provided any guidelines and has not collected any information on this practice to ensure consistency and prevent hospitals from taking advantage by overcharging other hospitals. We identified cases where the prices that certain hospitals charged other hospitals for the same test differed significantly, with price differences ranging from 31% to 176%.
- **No consistent performance measurement and reporting of laboratory services.** The Ministry has not set provincial performance targets or collected performance information to measure, monitor and determine if all laboratory services have been provided efficiently, and in a consistent and timely manner across Ontario. As a result, the extent of performance measurement and reporting varies, depending on the type of laboratory service provider. Overall, there has been very limited public reporting on the performance of laboratory services. We found significant variations in performance, even within the same type of laboratory service provider. For example, the specimen rejection rate

(percentage of times that a test cannot be done due to a mistake made while collecting or handling specimens) in 2016/17 ranged from 0% to 4.4% within a sample of hospital laboratories in Ontario.

- **No provincial target, data collection and monitoring of wait times for laboratory services.** Laboratory service providers set their own wait-time targets for specimen collection. For example, while one community laboratory service provider targets serving 90% of patients at its collection centres within 30 minutes, another targets serving 90% of its patients within 40 minutes. For hospital collection centres, wait-time targets ranged from 20 minutes to 45 minutes. Unlike Ontario, hospital and community laboratories in Alberta must submit wait-time information to Alberta Health Services, which shares the information with all laboratories in Alberta to let each one gauge its performance relative to its peers. The Ministry planned to collect wait-time data from community laboratories by making $8.5 million of its funding dependent on whether they developed and implemented a consistent wait-time definition they could use to capture and report data. However, it abruptly discontinued its data collection to save costs as part of a broader Ministry-wide cost-savings initiative.
- **No assessment of the effectiveness and efficiency of laboratory service providers by Ministry.** We identified cases where certain tests could be performed more effectively and efficiently by one type of laboratory service provider than another. The Ministry can save money and ensure better patient care if certain laboratory service providers perform tests currently done by other providers. For example, one hospital was expected to save about $120,000 annually by performing *Clostridium difficile* testing itself instead of sending specimens to a regional Public Health Ontario laboratory for testing. Savings came from getting test results faster (in less than five hours as opposed to 24 to 72 hours), which enabled the hospital to diagnose diseases and discharge patients more quickly from an isolated room and use the room for other patients.
- **Inadequate oversight of quality management program.** The Ministry has relied on the Institute for Quality Management in Healthcare's (Institute's) quality management program to assess whether laboratories are providing accurate test results, but it has not collected enough useful information to assess the results of the program on an ongoing basis and identify where the quality of laboratory services needs improvement. For example, while overall, laboratories have implemented the policies and processes required under the quality management program, we noted regional variation in the number of non-conformances (such as not documenting test procedures or not having evidence on ongoing training of laboratory staff) that potentially warranted further investigation by the Ministry. Between 2013 and 2016, the average number of non-conformances per the Institute's assessment visit among the LHINs for accreditation purposes ranged from eight to 28.

Overall Conclusion

Overall, the Ministry has systems, procedures and controls to ensure that laboratory services are provided to Ontarians in a safe manner that complies with applicable legislation, policies and standards, and accurate laboratory tests results are provided to health-care professionals in a timely manner based on specific test standards. The quality management program, which has assessed the quality of all licensed laboratories in Ontario using strict criteria, has had satisfactory assessment results.

However, the Ministry has not ensured that laboratory services are provided to Ontarians

cost-effectively. This is mainly due to the lack of regular assessment of the funding and services provided by different types of laboratory service providers as well as inadequate oversight of laboratory billing practices. As well, the Ministry has not ensured that laboratory services are equally accessible to Ontarians, mainly because no regular assessment has been done to identify and improve underserved areas. In addition, the Ministry has not ensured that accurate and complete data on the efficiency and effectiveness of laboratory services is collected, assessed, used for performance management and service improvement, and publicly reported. This is largely due to the absence of provincial targets and measures, which has led to variations in measurement and reporting standards across Ontario.

This report contains 12 recommendations, consisting of 25 actions, to address our audit findings.

OVERALL MINISTRY RESPONSE

The Ministry of Health and Long-Term Care (Ministry) welcomes the Auditor General's report on Ontario's laboratory services system. We believe the report's recommendations align with, and will further enhance, the Ministry's ongoing work to modernize Ontario's laboratory sector.

The Ministry established the Laboratories and Genetics Branch in 2015 as the focal point for laboratory and genetic services in Ontario, and work is underway on several strategies. The Ministry's Community Laboratory Modernization Strategy is updating the funding model for community laboratories by improving value, access, accountability and quality of service. Under Schedule 3 of Bill 87, the *Protecting Patients Act, 2017*, amendments to three statutes have passed that support the Ministry's goal of modernization. The Ministry is making progress on updating the regulatory frameworks that govern laboratory service delivery.

The Ministry has made significant progress on achieving value for money in the community laboratory sector: (1) it has developed a new funding model for community laboratories; (2) it has introduced updates to the Schedule of Benefits for Laboratory Services following a systematic, evidence-based review of fee codes; and (3) it is bringing greater accountability and capacity to monitor and manage system performance of community laboratories by paying community laboratories through an accountability agreement starting in 2017/18. To ensure patients have better access to community laboratory services, consultations are under way to develop a Northern and Rural Laboratory Services Strategy, and enhanced specimen collection funding has been introduced to support improved laboratory services in traditionally hard-to-serve areas.

Recognizing the exponential growth in demand for genetic services and the need for focused leadership to drive genetic system improvements, the Ministry is currently consulting and collaborating with genetics experts and health system partners through several advisory groups and committees that were implemented in 2016/17 (for example, Consultation and Advisory Group for Genetics in Ontario; Ontario Genetics Advisory Committee at Health Quality Ontario) to address the immediate needs for genetic services across the province. This work will support the introduction of the comprehensive Genetics System Framework, a holistic approach to delivering genetic services that continues to build on the Ministry's efforts to increase capacity and capability across the health-care system for new genetic tests and services.

2.0 Background

2.1 Process Used for Laboratory Services

Health-care professionals order and use laboratory tests for various purposes, which include identifying changes in their patients' health (such as vitamin/mineral deficiencies or viral infections), diagnosing diseases (such as diabetes and cancer) in their patients, planning treatments, evaluating treatment results, and monitoring health conditions or diseases over time for their patients. In 2015/16, health-care professionals ordered over 700 different types of laboratory tests in Ontario.

Figure 1 shows that a patient's experience with laboratory services involves four steps. These vary depending on the location of the patient's health-care professional, the type of test ordered and the type of laboratory service provider (see **Section 2.2**). Generally, the process starts with a health-care professional (usually a physician) signing and providing a patient with a test requisition form, which indicates the type of laboratory test requested. Once the patient's specimen is collected and tested by the appropriate laboratory, the test results are sent back to the health-care professional who requested the tests (by fax, mail or electronically) to be used to help treat or monitor their patient's conditions.

2.2 Types of Laboratories

Ontario has four main types of laboratory service providers. Each performs different types of tests and has different sources of funding (see **Figure 2**).

2.2.1 Community Laboratories

Community laboratories are generally responsible for performing more routine laboratory tests for people who live in their communities (as opposed to people who are treated in hospitals). The majority of tests done by community laboratories are used to evaluate the overall health of an individual by measuring blood cell counts and the level of different hormones, proteins and minerals to detect a range of disorders (such as anemia, diabetes and liver disease).

Community laboratory tests are primarily performed on specimens collected from community specimen collection centres (collection centres). As of March 31, 2017, Ontario had 356 community collection centres and 18 community laboratories operated by seven privately owned companies. **Figure 3** shows the breakdown of the Ministry's funding to each of the seven companies that operate community laboratories.

The Ministry has established a community laboratory test price list, which identifies the amount the community laboratory service providers can bill the Ontario Health Insurance Plan (OHIP) for each

Figure 1: Process Used for Laboratory Services in Ontario
Prepared by the Office of the Auditor General of Ontario

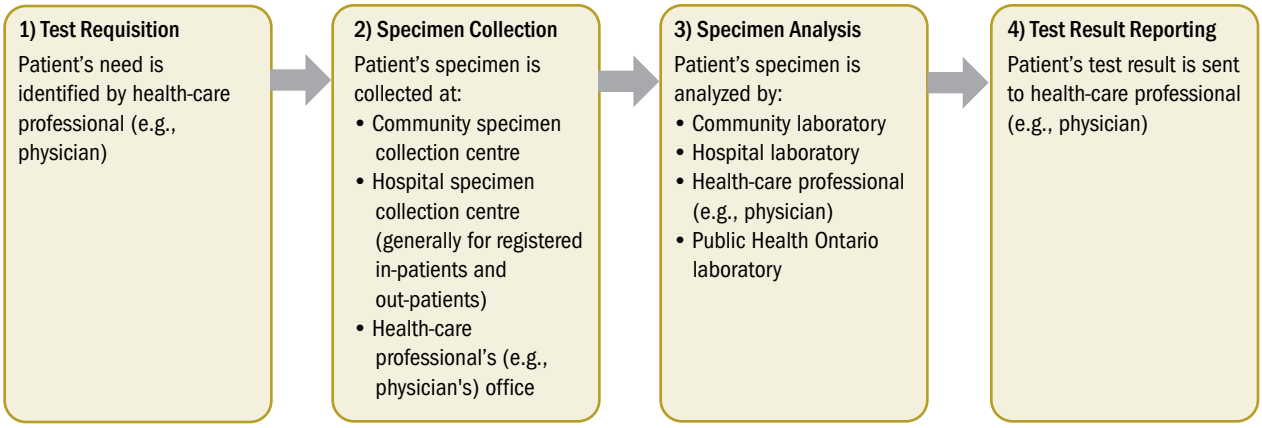


Figure 2: Main Laboratory Service Providers in Ontario

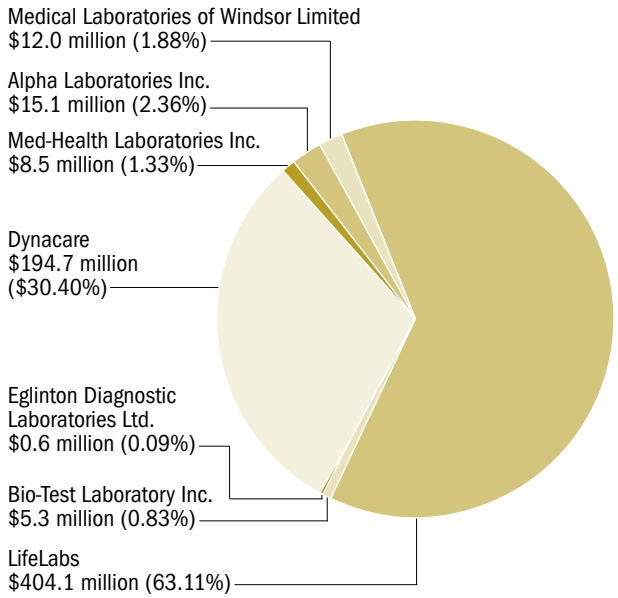
Prepared by the Office of the Auditor General of Ontario

Type of Laboratory Service Provider	Types and Examples of Testing Performed	Funding Source	# of Specimen Collection Centres [1]	# of Laboratories[1]	Cost per Test (2015/16)[2] ($)
1. Community laboratory	• Less urgent testing and screening (e.g., blood tests to identify vitamin, electrolyte and mineral levels, blood-cell count) for people living in the community	• Insured tests: Ministry (through OHIP) • Uninsured tests: Patients pay out-of-pocket or through private insurance	356[3]	18[3]	5.29
2. Hospital laboratory	• Almost all types of testing performed by community laboratories for registered in-patients and out-patients • More urgent/complex testing (e.g., blood tests to identify stroke or heart attack) in emergency departments	• Ministry (through hospital's global budget)	182	169	9.02
Hospital laboratory: genetic testing	• More complex testing to diagnose or identify an individual's risk of developing a certain disease or condition through analyzing DNA	• Ministry (primarily through hospital's global budget)	—[4]	14[5]	410.26
3. Health-care professional (in-office)	• Primarily point-of-care testing that can be performed easily to determine diagnosis and treatment (e.g., urine tests to detect pregnancy or drugs)	• Ministry (through OHIP)	11,202[6]	11,202[6]	7.80[6]
4. Public Health Ontario laboratory	• More specialized testing to identify the presence of infectious diseases (e.g., HIV, hepatitis) • Confirmatory testing to verify positive test results for infectious diseases identified by a community or hospital laboratory	• Ministry (through funding to Public Health Ontario)	—[4]	11	18.34

1. Information is as of March 31, 2017.
2. Cost per test was calculated as Ministry expenditure on the laboratory sector in 2015/16 divided by the total volume of tests performed by that sector in 2015/16. Hospitals and Public Health Ontario allocated part of the global budgets they received from the Ministry to provide laboratory services. Part of Public Health Ontario's funding allocation to laboratory services relates to items not directly related to performing laboratory tests on patients, such as funding for communicable disease surveillance, outbreak response, research and other services.
3. There are seven privately owned companies that operate community collection centres and laboratories.
4. Specimens for hospital laboratory genetic testing are generally collected in hospital collection centres. Specimens for Public Health Ontario laboratory testing are generally collected by community or hospital collection centres.
5. Fourteen hospital laboratories are licensed to perform genetic testing in Ontario.
6. These physicians performed all or some of the laboratory tests in 2015/16 on a fee-for-service basis, whereby they billed OHIP for each test performed. Other physicians may have performed laboratory testing in 2015/16 that was not billed through OHIP on a fee-for-service basis.

Figure 3: Ministry Funding to Community Laboratory Service Providers, 2015/16

Source of data: Ministry of Health and Long-Term Care



Note:

- 2015/16 funding to community laboratory service providers has not been finalized at the time of this audit.
- Community laboratory service providers operating in Ontario are private corporations.
- An eighth community laboratory service provider (Reese Nuclear Medicine Laboratory) last billed the Ministry in 2015/16 for approximately $7,800. It was not included in the above breakdown.

test they perform. Since 1993/94, the Ministry has capped the total funding to the community laboratory sector as a whole (called an "industry cap"). In 1996/97, the Ministry also began to cap the amount of funding it gives to each individual community laboratory service provider (called a "corporate cap"). The cap system has enabled the Ministry to contain its overall costs. **Figure 4** shows the total billings and payments made by the Ministry to community laboratory service providers under the "industry cap" between 2006/07 and 2015/16.

In 2015/16, community laboratory service providers performed more than 121 million tests, for which they received about $640 million in funding from the Ministry. Of this amount, $606 million was paid to the service providers based on the tests they billed OHIP. The remaining $34 million was paid primarily for the performance of two tests under separate funding agreements: prostate specific antigen (which is used to diagnose prostate cancer) and fecal occult blood test (which is used to screen for colorectal cancer).

2.2.2 Hospital Laboratories

Hospital laboratories generally provide laboratory services to hospital in-patients and out-patients. While hospital laboratories perform the same type of routine tests as community laboratories, they also perform more urgent and complex tests (such as a blood test to determine if a patient in an emergency department has had a stroke or heart attack) that community laboratories are not licensed to perform. As of March 31, 2017, there were 182 hospital specimen collection sites and 169 hospital laboratories (as some hospitals have multiple collection sites).

Each hospital funds its laboratory or laboratories independently, primarily through the global budgets the Ministry provides hospitals through the 14 Local Health Integration Networks (LHINs). In 2015/16, hospitals spent about $1.1 billion to perform about 123 million laboratory tests.

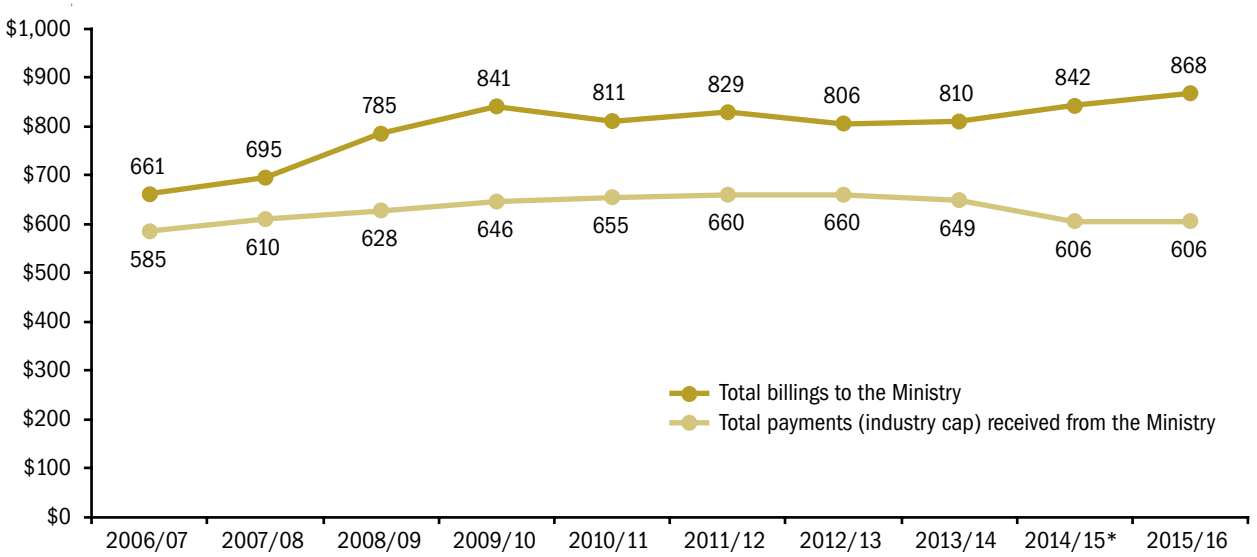
2.2.3 Hospital Laboratories: Genetic Testing

Genetic testing is a type of laboratory test that involves the examination of an individual's genetic material, such as strands of DNA. The results of a genetic test can help confirm or rule out a suspected genetic condition or help determine the chance that a patient will develop or pass on a genetic disorder. The majority of genetic testing performed each year in Ontario is for the diagnosis and treatment of cancers as well as to identify fetuses that have or are likely to have a genetic disorder.

Most genetic testing is done by hospital laboratories and is paid out of hospitals' global budgets. In 2015/16, Ontario hospitals spent about $64 million on 157,000 genetic tests that they performed. In addition, the Ministry also spent about US$31 million on about 15,300 specimens sent outside of the country for genetic testing in 2015/16.

Figure 4: Community Laboratory Service Sector Total Billings to the Ministry and Total Payments Received from the Ministry, 2006/07–2015/16 ($ million)

Source of data: Ministry of Health and Long-Term Care



Note: This figure represents community laboratory service provider billings and payments related to tests identified in the Ministry's price list. In each year identified, total payments to the providers matched the Ministry's industry cap. The community laboratory service providers also receive funding from the Ministry related to other items (primarily for performing a laboratory test related to diagnosing prostate cancer and another test that is used to screen for colorectal cancer). In 2015/16, the Ministry paid community laboratory service providers $34 million for these items outside of the industry cap.

* The decrease in the industry cap in 2014/15 primarily relates to funding that was removed from the industry cap that community laboratory service providers received as funding under a separate agreement. This separate agreement was then cancelled in 2015/16 to meet cost-reduction goals as part of the government's 2015 Budget.

2.2.4 Health-Care Professionals' In-Office Testing

Authorized health-care professionals such as physicians can perform certain tests directly on their patients and bill the Ministry through OHIP for the tests they perform. Most of these tests, known as point-of-care tests, can be performed relatively easily compared to other laboratory tests, as they do not require sophisticated equipment to perform the analysis. Examples of point-of-care tests are blood glucose testing, drug abuse screening, urine strips testing, pregnancy testing and cholesterol screening.

In 2015/16, over 11,200 physicians in Ontario billed OHIP about $83 million related to about 10.6 million point-of-care tests they performed on patients in their own offices. These were primarily urinalysis (to detect and manage conditions such as urinary tract infections, kidney disease and diabetes) and tests to detect drugs of abuse.

2.2.5 Public Health Ontario Laboratories

Public Health Ontario is a government agency responsible for providing scientific and technical advice and support to the government, health-care workers and related sectors. Public Health Ontario was created in 2007 as a result of several public health events, including the outbreak of *E. coli* infections at Walkerton in 2000 and the outbreak of severe acute respiratory syndrome (SARS) in 2003.

One of Public Health Ontario's responsibilities is to provide laboratory services to health-care professionals across Ontario. These laboratory services were performed by the Ministry prior to Public Health Ontario's establishment. Public Health Ontario operates 11 laboratories that primarily

test for infectious diseases to diagnose a patient or to confirm a positive test result that a hospital or community laboratory has identified. Public Health Ontario laboratories are also responsible for performing tests for rare diseases (such as Zika), regional outbreaks (such as measles), bacteria in food and water, and laboratory-based infectious disease surveillance.

In 2015/16, Public Health Ontario received $151 million in funding from the Ministry and spent about two-thirds (or $101 million) of this to perform about 5.5 million laboratory tests. This includes about 300,000 tests related to testing food and water for the presence of pathogens.

2.3 Volume of Laboratory Services and Ministry Expenditures

In 2015/16, approximately 260 million laboratory tests were performed in Ontario, the majority of them by hospital and community laboratories. **Figure 5** provides the breakdown of tests performed by each type of laboratory service provider. Between 2011/12 and 2015/16, the overall volume of laboratory tests in Ontario increased by about 4%.

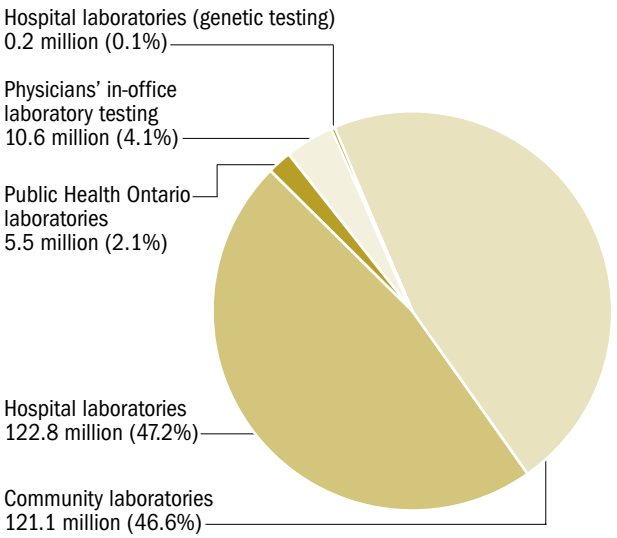
In 2015/16, the Ministry spent about $2 billion on laboratory services. **Figure 6** provides the breakdown of spending on laboratory tests performed by each type of laboratory service provider. Between 2011/12 and 2015/16, the Ministry's spending on laboratory services increased by about 2%.

2.4 Licensing and Quality Management of Laboratory Services

Under the *Laboratory and Specimen Collection Centre Licensing Act*, all medical community, hospital and Public Health Ontario laboratories, as well as specimen collection centres, must be licensed by the Ministry's Laboratories and Genetics Branch. The Ministry has the ability to perform unannounced inspections at laboratory service providers' facilities.

Figure 5: Test Volume by Type of Laboratory Service Provider, 2015/16

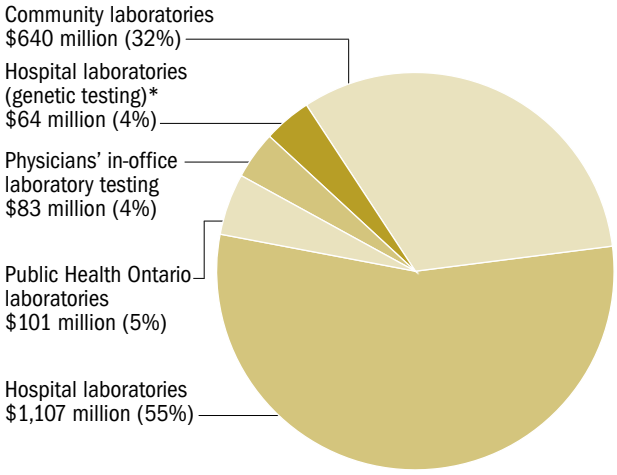
Source of data: Ministry of Health and Long-Term Care



Note: At the time of our audit, 2015/16 data was the latest data available. The Ministry also had not finalized volume information for community laboratories. We included the Ministry's best information available at the time of our audit.

Figure 6: Ministry Funding by Type of Laboratory Service Provider, 2015/16

Source of data: Ministry of Health and Long-Term Care



* Funding for genetic testing did not include about US $31 million spent on out-of-country genetic tests.

To remain licensed, laboratories and collection centres must participate in the quality management program operated by the Institute for Quality

Management in Healthcare (Institute). The quality management program began operating under the Ontario Medical Association (OMA) in 1974 and was transferred to the Institute (a subsidiary of the OMA) in 2015. The Institute receives about $4.7 million annually from the Ministry to carry out its quality management program on laboratory service providers in Ontario. The Institute's quality management program involves two main components—accreditation and proficiency testing—which are summarized in **Figure 7**.

3.0 Audit Objective and Scope

Our audit objective was to assess the systems, procedures and controls of the Ministry of Health and Long-Term Care (Ministry) to ensure that:

- laboratory services are accessible to Ontarians;
- accurate laboratory test results are provided to health-care professionals in a timely manner based on specific test standards;
- laboratory services provided to Ontarians are cost-effective;
- laboratory services provided to Ontarians are safe and comply with applicable legislation, policies and standards; and
- accurate and complete data on the efficiency and effectiveness of laboratory services is collected, assessed, used for performance management and service improvement, and publicly reported, for the benefit of Ontarians.

Before starting our work, we identified the audit criteria we would use to address our audit objective. We based these criteria on a review of applicable legislation, policies and procedures, and internal and external studies. Senior management at the Ministry reviewed and agreed with our objective and associated criteria as listed in **Appendix 1**.

We conducted our audit work primarily at the Ministry's Laboratories and Genetics Branch in Toronto from December 2016 to June 2017. We obtained written representation from the Ministry that, effective November 3, 2017, it has provided us with all the information it is aware of that could significantly affect the findings of this report. We also met with key personnel at the Ministry involved in the oversight of laboratory services and reviewed related documentation and data.

In addition:

- We met or spoke with staff at laboratories and their specimen collection centres across the province, which included the three largest community laboratories (LifeLabs, Dynacare and Alpha Laboratories); 13 hospital laboratories (Children's Hospital of Eastern Ontario, Credit Valley Hospital, Headwaters Health Care Centre, Health Sciences North, Juravinski Hospital, North Bay Regional Health Centre, North York General Hospital, Pembroke Regional Hospital, St. Joseph's Healthcare Hamilton, Sunnybrook Hospital, The Ottawa

Figure 7: Summary of Quality Management Program for Licensed Laboratory Service Providers in Ontario
Source of data: Institute for Quality Management in Healthcare

	Accreditation	Proficiency Testing
Purpose	To ensure that processes at laboratories are *in place*.	To ensure that processes at laboratories are *effective*.
Method	• Performing an on-site assessment every four years to review and determine if the laboratories' policies and procedures conform to the program's requirements and standards. • Reviewing a self-assessment performed by laboratories two years after the previous on-site assessment.	• Sending sample specimens to laboratories for testing and requiring them to report the test results back to the Institute for Quality Management in Healthcare, which analyzes and verifies the accuracy of testing.

Hospital, Thunder Bay Regional Health Sciences Centre, and Timmins and District Hospital) in eight Local Health Integration Networks (LHINs); and two regional Public Health Ontario laboratories (in Toronto and Ottawa). We also examined data and documentation provided by these laboratories.

- We met with senior management and staff as well as reviewed data and documentation at the Institute for Quality Management in Healthcare (Institute) to understand the quality management program that all licensed community, hospital and Public Health Ontario laboratories and specimen collection centres must follow in Ontario.
- We spoke with representatives from the College of Physicians and Surgeons of Ontario and the Ontario Medical Association to understand the oversight of physicians' in-office laboratory testing and physicians' thoughts on Ontario's laboratory system.
- We met or spoke with representatives of various laboratory stakeholder groups, including the Ontario Association of Medical Laboratories (an association representing six community laboratories, including the two largest community laboratories in Ontario), In-Common Laboratories (a not-for-profit organization that helps health-care professionals and laboratories who are unable or choose not to perform tests themselves find other laboratories to do so), the Eastern Ontario Regional Laboratory Association (a not-for-profit organization composed of 16 hospital laboratories in the Champlain LHIN), and Choosing Wisely Canada (a campaign that engages clinicians and patients in conversations about unnecessary tests and treatment, including laboratory tests).
- We spoke to the provincial bodies responsible for oversight of laboratory services in British Columbia, Alberta, Saskatchewan, Manitoba and Quebec to identify best practices and understand oversight of laboratory services in other jurisdictions across Canada.
- We reviewed and followed up on the relevant audit issues raised in our 2005 audit of Health Laboratory Services and a 2015 review of Ontario's community laboratory sector by the Laboratory Services Expert Panel (Expert Panel) commissioned by the Ministry. **Appendix 2** provides a summary of the implementation status of recommendations from the Expert Panel's report.

Furthermore, we engaged an independent adviser with expertise in the field of laboratory services to assist us on this audit.

4.0 Detailed Audit Observations

4.1 Overpayments to Community Laboratories

The Ministry has not significantly updated its price list that sets the amount it pays community laboratories to perform each laboratory test since 1999. We estimate that the Ministry overpaid community laboratory service providers, which perform nearly 50% of the laboratory tests in Ontario (see **Figure 5**), by at least $39 million in 2015/16. Although the Ministry plans to implement a new price list in 2017/18, this list is not based on the actual costs of all community laboratory service providers in Ontario.

4.1.1 Outdated Price List Resulted in Overpayments to Community Laboratories

Seven community laboratory service providers currently operate in Ontario (see **Figure 3**). These providers are primarily paid through a fee-for-service arrangement with the Ministry by billing the Ontario Health Insurance Plan (OHIP) based on a price list that defines the types and prices of laboratory tests. The amount paid to each community laboratory service provider is based on each test's price multiplied by the volume of each

test, subject to a cap that limits the total amount each provider can receive from the Ministry (see **Section 2.2.1**). Once they have reached their caps, community laboratory service providers continue providing services and submitting bills that account for their services performed; between 2011/12 and 2015/16, they collectively billed over 30% more than they received from the Ministry under the cap funding system.

The Ministry is responsible for reviewing and updating the price list; however, it had no process in place at the time of our audit to regularly do so. As a result, it has not made any significant changes to the price list since 1999. The current price list is outdated and does not reflect changes in testing methods and technological advancements in laboratory testing, which have led to significant automation and cost reduction in performing many routine tests.

The Ministry started the process of reviewing and updating the current price list in 2013 but put this on hold because this review only developed prices for a limited number of tests and the Ministry wanted to develop a more cohesive strategy to modernize the community laboratory sector, including modifying the fee-for-service funding arrangement with community laboratory service providers.

In 2015, the Ministry commissioned an expert panel to review Ontario's community laboratory sector. The expert panel recommended that the Ministry update the price list. Consequently, the Ministry engaged a consulting firm in 2016 to perform a review of the price list, and used the review results to draft the new price list.

Based on our review of the current price list and the draft new price list for 2017/18, we noted that the prices of some common tests have fallen significantly, meaning that the Ministry has been overpaying the community laboratory service providers for these tests. **Figure 8** provides examples of common tests with significant price differences (ranging from 41% to 77%) between the current price list and the draft new price list.

Price Cap Has Not Resolved Overpayments

While the current cap funding system has enabled the Ministry to stabilize and contain the overall cost of community laboratory services by limiting the amount each community laboratory service provider can receive from the Ministry, the current price list has still resulted in overpayments. These could have been avoided or reduced if the Ministry had reviewed and updated its price list on a more frequent basis.

Based on the 2015/16 volume of each test performed by community laboratories, we calculated that the Ministry would have paid community

Figure 8: Examples of Significant Test Price Differences between the Ministry's Current and Draft New Price List for Common Laboratory Tests, 2015/16

Source of data: Ministry of Health and Long-Term Care

Type of Test	Most Common Purpose of Test	Test Volume (2015/16) (million)	Price on Current Price List ($)	Price on Draft Price List ($)*	Price Difference (%)
25-hydroxyvitamin D	To determine vitamin D levels	0.38	51.70/test	11.66/test	77
Thyroid stimulating hormone	To identify thyroid disorders	5.40	9.82/test	3.58/test	64
Prothrombin time	To check if medicine to prevent blood clots is working	1.72	6.20/test	2.66/test	57
Glucose	To screen, diagnose and monitor diabetes	6.42	2.59/test	1.28/test	51
Complete blood count	To look for anemia, nutrition status, infections and certain cancers	8.27	6.72/test	3.98/test	41

* Based on prices included in the Ministry's draft price list as of June 30, 2017.

laboratory service providers about $39 million less if it had implemented the draft new price list in 2015/16 as opposed to using the current price list from 1999. To illustrate, while community laboratory service providers billed the Ministry about $868 million in 2015/16 for tests they performed based on the current price list, the actual amount the Ministry paid to these providers for performing these tests was capped at about $606 million (see **Figure 4**). If the draft new price list had been in effect in 2015/16, these service providers would have billed the Ministry about $567 million and would have been paid that much only. This is $39 million lower than the $606 million that was paid to these providers in 2015/16 for performing these tests under the cap funding system.

Planned Mitigation Fund Will Delay Ministry Savings

Although implementing the new price list would result in immediate savings, the Ministry did not plan to fully realize such savings. Instead, it proposed to use the savings to set up a three-year mitigation fund (at a total cost of over $95 million) in order to help community laboratory service providers, which will initially receive less Ministry funding each year as a result of the new price list that has lower test prices. In other words, the Ministry will provide community laboratory service providers with additional funding during the first three years when the new price list is in effect to compensate community laboratory service providers that earn less under the new price list. Consequently, the Ministry will not fully benefit from reducing payments to community laboratory service providers until the fourth year after implementing the new price list.

Other studies of Ontario's community laboratory sector also raised concerns about the current price list, which has resulted in payments made to community laboratory service providers that were well above their costs. For example:

- According to a report by the Laboratory Services Expert Panel (Expert Panel) commissioned by the Ministry in 2015, an earlier review of Ontario's community laboratory service sector conducted by a consulting firm for the Ministry in 2012 noted that "the pricing of laboratory services outlined in Ontario's current [price list] appears to be generous and provides a significant profit margin to community laboratory service providers."
- A 2015 report by a stakeholder group (composed of some smaller community laboratory service providers, non-profit organizations, physicians and patient groups) estimated that the government may have overpaid certain community laboratory service providers over the past 15 years as a result of the community price list not accurately reflecting the actual costs of community laboratory service providers.

As previously mentioned, we calculated that the Ministry would have spent about $39 million less in 2015/16 if it had implemented its draft new price list in that year. However, our estimate of $39 million only represents overpayment for 2015/16 alone rather than the overall potential overpayment for prior years. We are unable to estimate the overall overpayment because it is not clear what test prices would have been in prior years if the Ministry had updated the price list more regularly since 1999.

4.1.2 Price List Update Was Not Based on All Relevant Data

While the Ministry plans to update its price list for 2017/18, the draft new price list is not based on actual cost data from all community laboratory service providers in Ontario. This is because the Ministry does not have access to any financial information (such as costs of performing laboratory testing or profit margins) from community laboratory service providers under the fee-for-service arrangement currently in place with these providers.

In 2016, the Ministry engaged a consulting firm to conduct a review of the price list that has been in place since 1999. Updated prices on the Ministry's

draft new price list are largely based on prices proposed by the consulting firm, with some adjustments based on input from community laboratory service providers and advice from an expert with community laboratory experience contracted by the Ministry.

The consulting firm used price lists from other Canadian jurisdictions along with cost information from hospitals in Ontario, public health laboratories, laboratory service providers in the United States and one community laboratory service provider in Ontario that accounted for less than one-third of the provincial community laboratory test volume to determine the base price (cost) for each test. The consulting firm then added a 30% corporate overhead cost (to cover costs such as administration and rent for specimen collection centres and laboratories) and a 20% profit margin to arrive at the final recommended prices on the draft price list.

However, we question the appropriateness and relevance of the information used in determining the new price list for community laboratory service providers, because full cost data from the two largest community laboratory service providers in Ontario (accounting for the majority of the Ministry's funding to community laboratory service providers) was not made available to the consulting firm. These community laboratory service providers informed us that they did not share cost or other financial information with the Ministry or the consulting firm. Since these two largest community laboratory service providers process a larger volume of certain tests than many hospitals and smaller community laboratory service providers, they can achieve economies of scale and lower overall costs per test. In addition, without financial information from these community laboratory service providers, the Ministry did not know if the corporate overhead cost and profit margin used by the consulting firm in developing the price list were reasonable.

The Ministry was also unsuccessful in its earlier attempt to determine community laboratories' costs. In response to our 2007 follow-up to our 2005 audit on Health Laboratory Services, the Ministry stated that it was planning a two-stage review that would allow it to determine the actual costs of community laboratories in Ontario by 2008/09. However, changes in the Ministry's branch or division responsible for overseeing community laboratory services resulted in it not completing the review. Since 2008/09, the Ministry has changed its oversight of community laboratory services four times. For most years between 2008/09 and 2015/16, the Ministry did not have a dedicated director solely responsible for overseeing community laboratory services. This meant that there has not been a consistent person or group in the Ministry responsible for overseeing the community laboratory sector for most years since 2008/09.

RECOMMENDATION 1

To ensure that payments made to community laboratory service providers are reasonable, we recommend that the Ministry of Health and Long-Term Care (Ministry):

- establish a process to regularly assess and update the price list for community laboratory services based on actual community laboratory cost data and input from industry experts; and
- regularly collect and assess cost information from community laboratory service providers to ensure the amount paid by the Ministry is based on relevant information.

MINISTRY RESPONSE

The Ministry agrees with this recommendation. The Ministry supports establishing a process to regularly update prices in the Schedule of Benefits for Laboratory Services (SOB-LS), a key component of the Ministry's Community Laboratory Modernization Strategy. The Ministry is developing plans to establish a test review and utilization committee, composed of industry experts, to address this commitment. This work

is anticipated to commence late in the 2017/18 fiscal year.

The Ministry supports obtaining the lowest possible pricing for tests and will use all available information, including laboratory costs, where feasible, in order to establish the payment for laboratory testing (note that private corporations are not obligated to provide costing information to the Ministry).

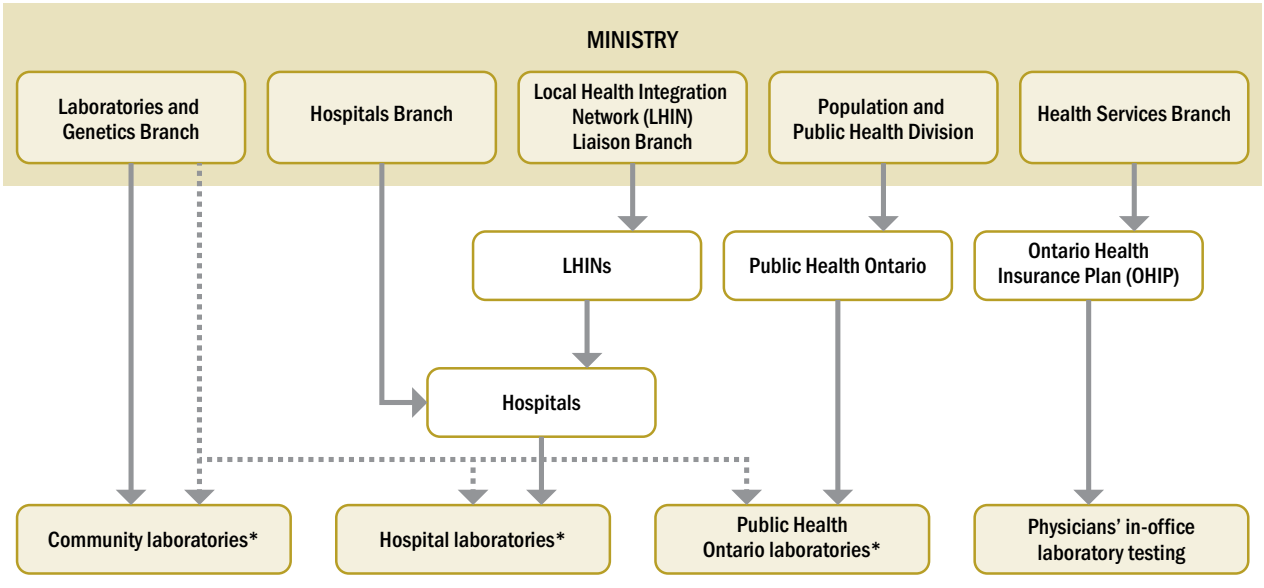
In 2017/18, the Ministry will implement an updated SOB-LS based on costing data from various laboratories, which will reduce test prices. These lower test prices result from economies of scale and advances in testing technology/automation. The Ministry has taken action to limit the possibility of overpayments by having a financial cap system in place that limits payments to the community laboratory service providers. While it is difficult to quantify historical overpayments, the Ministry has mitigated the risk by flatlining and reducing funding in recent years, in recognition of the lower costs for many laboratory tests.

4.2 Fragmented Management of Laboratory Sector

The Ministry's fragmented management of the laboratory sector has prevented an assessment of the appropriateness of funding to different laboratory service providers, as well as the effectiveness and efficiency of laboratory services performed by each provider. While the Ministry's Laboratories and Genetics Branch is responsible for licensing laboratories in Ontario, other functions (such as funding, planning, operation and oversight) of Ontario's laboratory sector fall under various branches and divisions across the Ministry, depending on the type of laboratory service provider (see **Figure 9**). Specifically:

- community laboratories are operated by community laboratory service providers, which are overseen by the Ministry's Laboratories and Genetics Branch;
- hospital laboratories are operated by individual hospitals, which are accountable to the Ministry's Hospitals Branch and the Local Health Integration Networks (LHINs)

Figure 9: Key Ministry Departments and Other Entities Involved in Managing Ontario's Laboratory Sector
Prepared by the Office of the Auditor General of Ontario



* Particpate in the Institute for Quality Management in Healthcare's quality-management program (see **Section 2.4** for more details).

that are overseen by the Ministry's LHIN Liaison Branch;

- Public Health Ontario laboratories are operated by Public Health Ontario, which is overseen by the Ministry's Population and Public Health Division; and
- physicians' in-office laboratory testing is overseen by the Ministry's Health Services Branch.

4.2.1 No Assessment on Appropriateness of Funding to Different Types of Laboratories

The Ministry has not done any analysis to determine whether funding has been appropriately allocated to different types of laboratory service providers.

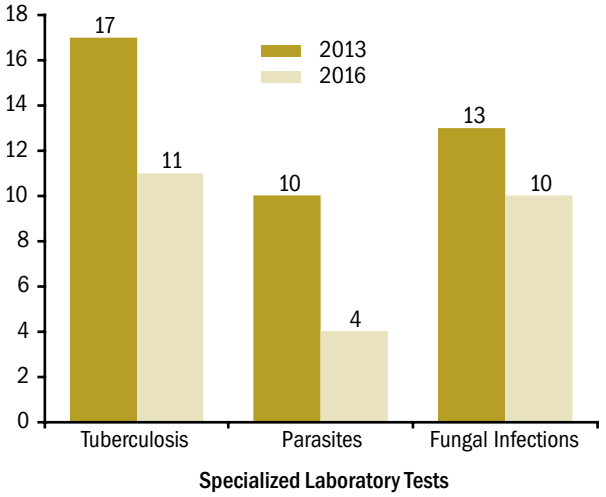
Based on our review of data between 2011/12 and 2015/16, the Ministry's base funding to hospitals increased by over $250 million while hospital laboratory expenses alone increased by $63 million, meaning that about 25% of the increase in hospital funding was spent on covering the increase in laboratory expenditures. We noted cases where, to deal with funding pressures and higher laboratory expenditures, hospitals reduced their on-site laboratory services, which in turn increased test volumes at Public Health Ontario laboratories and community laboratories.

Hospital Laboratories Passing Tests to Public Health Ontario Laboratories

Between 2011/12 and 2015/16, the number of certain specialized laboratory tests performed by Public Health Ontario laboratories (such as tests to detect tuberculosis, parasites and fungal infections) increased by 7% (from about 350,000 tests to about 375,000 tests). Public Health Ontario indicated that this increase was mainly because fewer hospital and community laboratories were performing specialized tests themselves, but instead were requesting Public Health Ontario laboratories to perform them. **Figure 10** shows the number of hospital and community laboratories performing selected specialized laboratory tests in 2013 and 2016. One of the hospitals also informed us that in order to save costs, it has been asking a Public Health Ontario laboratory to perform hepatitis testing on its behalf, because the cost of testing was paid out of Public Health Ontario's budget.

Figure 10: Number of Hospital and Community Laboratories Performing Selected Specialized Laboratory Tests, 2013 and 2016

Source of data: Public Health Ontario



Between 2012/13 and 2016/17, the number of tests performed by Public Health Ontario laboratories increased by 13% (from 4.7 million to 5.3 million tests), partly due to the growing number of test requests from the hospitals. Public Health Ontario informed us that it raised this as a concern with the Ministry in 2016/17, because additional requests from hospitals have made it challenging for its laboratories to perform all requested tests within the time frames expected by physicians to meet patient needs. The Ministry is still considering what action to take to address Public Health Ontario's concern.

Hospital Laboratories Passing Tests to Community Laboratories

Some hospitals used to provide laboratory services to community patients (those who are not registered in-patients or out-patients with these hospitals), but they have stopped doing so to contain costs as a result of funding pressure. While

the hospitals have reduced the laboratory services they provide, there has been no adjustment to the amount of funding the hospital receives. The reduction in laboratory services by hospitals for community patients has increased the amount of testing that community laboratories perform. For example:

- One hospital used to collect specimens from community patients and pay other community and hospital laboratories to do the laboratory testing on its behalf. To save costs, since 2016 this hospital has stopped collecting specimens from community patients for tests that it does not perform on-site and that are available through a nearby community laboratory service provider. As a result, this hospital has seen about 12,000 fewer community patients (about 33,000 in 2012/13 compared to about 21,000 in 2016/17), which in turn increased patient volume at a community laboratory service provider (located four kilometres away from this hospital) by over 30% (from about 85 to 115 patients per day).
- Another hospital has stopped offering laboratory services to community patients since 2015, which in turn increased patient volume at a community laboratory service provider (located less than one kilometre away from this hospital) by about 50% (from about 110 to 170 patients per day).

4.2.2 No Assessment on Effectiveness and Efficiency of Different Types of Laboratories

Some interrelationships exist between the different types of laboratory service providers—for example, hospital laboratories may refer complex tests for infectious diseases to Public Health Ontario laboratories. Nevertheless, the Ministry has not done any analysis to determine whether laboratory services are being provided to Ontarians efficiently and effectively, in a cohesive manner, to meet patient needs and to save overall health system costs.

We identified cases where certain tests could be performed more effectively and efficiently by one type of laboratory service provider than another. This includes examples where hospitals or community laboratories may be a better choice to perform tests than Public Health Ontario laboratories.

Health-Care Efficiency Could Be Improved with Some Increased In-Hospital Testing

Hospitals can have *Clostridium difficile* (*C. difficile*) testing done by Public Health Ontario laboratories at no cost to the hospitals. Public Health Ontario laboratories provide *C. difficile* testing services for over 35,000 specimens from across the province. Five thousand of these originate from hospitals, and some hospitals may benefit from testing for *C. difficile* in their laboratories.

One hospital informed us that it has been conducting its own *C. difficile* tests since 2013, even though it is less than one kilometre away from a regional Public Health Ontario laboratory. In 2012, the hospital sent about 1,700 *C. difficile* tests to the nearby Public Health Ontario laboratory. Our review of the estimates done by a consultant for this hospital has found that the hospital potentially saves about $120,000 a year by doing *C. difficile* tests itself because of shorter turnaround times for test results—less than five hours, as opposed to 24 to 72 hours in waiting for the results from Public Health Ontario laboratories as these laboratories do not perform this testing on a daily basis. This lets the hospital diagnose diseases faster and discharge patients who were incorrectly suspected of having *C. difficile* more quickly from an isolated room, and use the room for other patients.

For similar reasons, it may be more appropriate for some hospitals to perform influenza testing than for hospitals to send specimens to Public Health Ontario laboratories for testing. One hospital we spoke with is planning to purchase new equipment in 2017/18 to conduct its own influenza testing because of shorter turnaround times, even though it is only three kilometres from a regional Public Health Ontario laboratory.

In 2016/17, Public Health Ontario laboratories conducted over 35,000 tests related to detecting *C. difficile* and over 70,000 tests related to detecting influenza for hospital and community patients. The Ministry has not done any analysis to determine the extent of savings for the overall health-care system if more of these tests were performed by hospital laboratories.

Community Laboratories Could Perform Additional Tests but Are Not Allowed to

Community laboratories have the capability to perform certain tests but are not allowed to do so by the Ministry. For example:

- HIV diagnosis, treatment, support and surveillance is an integral component of the public health response to the HIV epidemic. The Ministry has assigned Public Health Ontario laboratories to serve as the sole provider of diagnostic testing for HIV, which includes performing additional tests and capturing enhanced epidemiological information in support of the treatment of HIV-positive patients. Public Health Ontario also uses information from these test results to inform its other public health programs. Between 2012/13 and 2016/17, the number of HIV tests performed by Public Health Ontario laboratories increased by over 14% (from about 691,000 tests to 789,000 tests). Nevertheless, one of the largest community laboratory service providers operating in Ontario informed us that its laboratories are able to perform HIV testing and have been doing so for some Ontarians (as when employers require their employees to be tested); however, they are not allowed to perform HIV testing for diagnostic purposes even though they are still the ones who collect and transport the specimens to Public Health Ontario laboratories for testing. The Ministry has not performed any analysis to determine potential cost savings or other impacts on HIV care of transferring HIV testing to community laboratories.
- As part of the Ministry's Maternal Serum Screening Program (Program), seven hospitals in the province receive funding to perform prenatal laboratory tests for pregnant women to detect genetic disorders such as Down syndrome. Hospital laboratories performed more than 80,000 of these tests in 2015/16. Community laboratories are also able to perform these tests, but only when they are ordered separately and not part of the Ministry's Program. The Ministry informed us that, historically, the hospitals that were part of the Program have been providing educational materials and counselling services to parents based on the test results. Patients who are being tested under this Program can have their blood drawn at community collection centres, which then have to transport the specimens to the designated hospitals for testing. These designated hospitals are often located further away than the community laboratory associated with the collection centre where the specimen was collected. As a result, the longer time needed to transport specimens to the designated laboratory can delay how quickly the testing can be performed.

RECOMMENDATION 2

To ensure that laboratory services are appropriately funded and performed effectively and efficiently to meet patient needs, we recommend that the Ministry of Health and Long-Term Care analyze the capabilities and responsibilities of different types of laboratory service providers (community, hospital and Public Health Ontario) to determine if any changes are needed with respect to the types of tests each provider performs and, accordingly, the amount of funding each provider receives.

MINISTRY RESPONSE

The Ministry supports this recommendation. The Ministry is currently working to modernize

community laboratory services. The Ministry intends to conduct a review of hospitals and public health laboratories starting in 2018/19, using the broader sector recommendations of the Laboratory Services Expert Panel's 2015 report.

4.3 No Regular Review of Medically Necessary Tests

The Ministry currently has no process in place to regularly evaluate and determine whether it should be paying for some laboratory tests in the community setting that have become more widely accepted as medically necessary. Some of these tests, such as cancer antigen 125 or CA 125 (used to measure the amount of protein cancer antigen 125 in a patient's blood) and Carbon-13 Urea Breath test (used to identify infections caused by *Helicobacter pylori*) are paid for by other provinces. While the Ministry licenses community laboratory service providers to perform uninsured tests ordered by health-care professionals, it has not set or monitored the prices that these providers charge their patients (who generally have to pay out-of-pocket or through private insurance) for these tests.

4.3.1 Medically Necessary Tests Remain Uninsured

In 2015/16, community laboratories performed about 1.1 million laboratory tests (relating to over 45 types of tests) that were not paid for by the Ministry. These uninsured tests were largely for patients who were seeking health care outside of a hospital. They still require a health-care professional's requisition for the tests to be performed, but are generally paid for by a patient out-of-pocket or through private insurance.

In 2016, the Ministry engaged a consulting firm to review the current price list for community laboratory services (see **Section 4.1.2**). As part of this review, the consulting firm identified 16 medically necessary tests not funded by the Ministry that it recommended adding to the new price list for 2017/18. However, we noted that the Ministry did not include any of these tests in its draft new price list. The Ministry informed us that it may consider reviewing whether any currently uninsured tests should be insured at a later time; however, it has not established a timeline for this review.

Based on our analysis of 2015/16 test volumes and cost data from laboratory service providers, we estimated that if the Ministry had funded these 16 uninsured tests, the additional cost would have been less than $5 million to perform the same volume of tests. This additional cost would be more than offset by the savings of about $39 million to be realized from updating the price list (see **Section 4.1.1**). In fact, we noted that the majority of the 16 tests recommended by the consulting firm are insured in other provinces such as British Columbia and Alberta (see **Figure 11**).

4.3.2 Lack of Information on Fees Charged to Patients for Uninsured Tests

The Ministry licenses community laboratories to perform uninsured tests on patients that are ordered by a health-care professional. While patients generally must pay out-of-pocket (or through private insurance) for these tests, the Ministry has not set or monitored the prices that community laboratory service providers charge their patients. Although the Ministry has the authority to set the fee that community laboratory service providers bill for tests that the Ministry insures through OHIP, it does not have the authority to set the fees charged by service providers for uninsured tests.

Since community laboratory service providers' annual billings to the Ministry are capped under the current fee-for-service arrangement (see **Section 4.1.1**), performing uninsured tests and charging patients has provided a way for community laboratory service providers to increase their revenues. Without oversight by the Ministry, the fairness of the prices community laboratory service providers charge their patients is unclear.

We analyzed a sample of uninsured tests that patients may pay community laboratory service providers in Ontario to have performed, and found that the price charged to patients for the same test varied from one laboratory to another. We also collected information from a community laboratory service provider in British Columbia and identified examples of uninsured tests where the price it charged for each of these tests was often less than the price charged by community laboratory service

Figure 11: Comparison of Insured Status of 16 Laboratory Tests in Ontario, British Columbia and Alberta, as of June 30, 2017

Source of data: Alberta Health Services, British Columbia's Ministry of Health and Ministry of Health and Long-Term Care

		Insured Test		
Type of Test	Most Common Purpose of Test	Ontario[1]	British Columbia[2]	Alberta
1. Allergen specific IgE	To diagnose an allergy to specific substances in a person who presents with acute or chronic allergy-like symptoms	×	✓	✓
2. Anti-gliadin IgG	To evaluate celiac disease	×	×	✓
3. Apolipoproteins A and B	To measure cholesterol levels	×	✓	✓
4. Bioavailable testosterone	To evaluate a variety of medical conditions such as infertility in men	×	✓	×
5. Beta-2 microglobulin	To identify the amount of cancer present to inform the blood cell cancer prognosis	×	✓	✓
6. CA 125	To measure the amount of the protein cancer antigen 125 in a patient's blood	×	✓	✓
7. CA 15-3	To monitor a patient's response to breast cancer treatment and recurrence of breast cancer	×	✓	✓
8. CA 19-9	To diagnose and monitor pancreatic cancer	×	✓	✓
9. Cyclic citrullinated peptide antibody	To diagnose and assess a form of arthritis	×	✓	✓
10. Free light chains	To detect, diagnose and monitor plasma cell disorders (a type of white blood cell)	×	✓	✓
11. HER2/neu	To determine how much HER2 (a protein) a tumour makes for the purpose of informing breast cancer treatment	×[3]	✓	✓
12. IGF – 1	To identify growth hormone deficiency	×	✓	✓
13. Sex hormone binding globulin	To evaluate men for low testosterone and women for excess testosterone production, typically for reproductive purposes	×	✓	✓
14. Urease production by *H. pylori*	To diagnose infection due to *H. pylori* bacteria and effectiveness of treatment	×	✓[4]	✓
15. Vitamin B1	To detect a patient's vitamin B1 levels	×	✓	✓
16. Vitamin E	To detect a patient's vitamin E levels	×	✓	✓

Note: These tests are insured by the hospital for hospital patients. This comparison refers to the insurability of the tests as performed for community patients (those seeking health care outside of a hospital).

1. While the Ministry's consulting firm recommended that all 16 of these tests should be insured in Ontario, in some cases it recommended that there be ordering guidelines and/or eligibility criteria for some of these tests.
2. British Columbia's price list of insured tests for community patients was last revised on July 31, 2017. Certain tests are covered in British Columbia only if eligibility criteria are met.
3. A community laboratory service provider in Ontario currently provides this test at no cost to community patients. However, this community laboratory does not receive Ministry funding for this test. The service provider informed us that if it does not receive Ministry funding for this test going forward, it may stop performing the test.
4. Different laboratory tests can be used to detect *H. pylori*. British Columbia covers tests for *H. pylori* that analyze breath and stool specimens provided by patients. One community laboratory service provider in Ontario provides uninsured testing for *H. pylori* using breath samples.

Figure 12: Comparison of a Sample of Uninsured Test[1] Prices Charged by Community Laboratory Service Providers in Ontario and British Columbia

Source of data: Select community laboratory service providers

		Price per Test ($)			
Type of Test	Most Common Purpose of Test	Community Laboratory Service Provider #1 (Ontario)	Community Laboratory Service Provider #2 (Ontario)	Community Laboratory Service Provider #3 (British Columbia)[2]	Difference between Lowest and Highest Price (%)
C-telopeptide	To diagnose patients with osteoporosis	75	20	65	275
Galectin-3	To identify patients with chronic heart failure	85	150	78	92
Cyclic citrullinated peptide antibody	To diagnose and assess a form of arthritis	55	30	30	83
Apolipoprotein B-100	To measure cholesterol levels	35	35	28	25
Herpes simplex type 1 and 2	To diagnose active herpes (a sexually transmitted disease and/or cold sores)	160	140	130	23

1. Community laboratory service providers are not licensed to perform some of these tests. In those cases, the community laboratory service provider will collect the specimen from the patient, charge the patient, and send the specimen out to a different laboratory for testing.
2. Some of these tests are covered in British Columbia only when specific criteria are met. Community laboratory service providers charge patients when they do not meet the eligibility criteria.

providers in Ontario. **Figure 12** shows a comparison of a sample of uninsured test prices charged by two community laboratory service providers in Ontario and a community laboratory service provider in British Columbia.

RECOMMENDATION 3

To ensure that Ontarians are able to access and pay fair prices for the medically necessary laboratory tests they require, we recommend that the Ministry of Health and Long-Term Care analyze the current list of uninsured tests in Ontario (particularly those identified by the consulting firm it engaged) to determine the medical appropriateness of these tests and how these tests are funded in other jurisdictions, and to formally decide whether to fund any of these tests and at what prices.

MINISTRY RESPONSE

The Ministry agrees that the current list of uninsured tests should be reviewed to determine if any of these tests have clinical validity and utility in the community setting. A new test review and utilization committee, which is anticipated to begin work in the 2017/18 fiscal year, will conduct a further review of uninsured tests and develop a process to evaluate uninsured tests in the future.

4.4 More Action Needed to Reduce Unnecessary Testing

The Ministry has not taken adequate actions to reduce unnecessary laboratory tests ordered by physicians for their patients. According to a review (conducted by researchers affiliated with Harvard Medical School in 2013) of various studies on laboratory testing performed around the world, globally the average over-utilization rate (the rate

of unnecessary laboratory tests out of all laboratory tests reviewed by these studies) was over 20%. The Ministry has no process in place to proactively assess and determine the extent of overuse of laboratory tests and its funding of unnecessary testing. It has largely relied on Health Quality Ontario (HQO) to perform research and develop guidelines around overused laboratory tests. HQO is a government agency that reviews many aspects of the Province's health-care system but does not have a focus on laboratory testing specifically.

Unnecessary testing can be defined as tests ordered that do not have evidence to indicate the test is clinically useful for the medical treatment of a patient for a given condition. For example, the Canadian Association of Pathologists identified that it is not necessary to perform repetitive (daily) complete blood counts on a hospitalized patient who is in a stable condition. This does not mean this test is not useful for any patient (for example, such a test may be appropriate for a hospitalized patient who is not in a stable condition).

Unnecessary testing not only wastes health-care resources, but certain tests can potentially lead to medical complications, physical discomfort and emotional stress. For these reasons, eliminating or reducing unnecessary testing is important to improve the quality of patient care and to control the growth of health-care costs.

While the Ministry plays a role in reducing unnecessary testing by setting guidelines over the conditions when a laboratory test can be ordered by an authorized health-care professional, it is up to health-care professionals and community laboratory service providers to follow those guidelines.

Over the last five years, the Ministry has made some changes to reduce unnecessary testing for community patients by restricting the insurance conditions under OHIP for coverage of certain tests, such as only insuring tests when ordered by certain physicians or when assessing patients with certain conditions. However, the Ministry's actions to reduce unnecessary testing, especially vitamin D testing and aspartate aminotransferase (AST) testing (usually used to identify liver damage), did not result in effective or sustainable long-term reductions in testing.

4.4.1 Ineffective Action Taken to Sustain Long-Term Reduction of Unnecessary Vitamin D Testing

During the early 2000s, a multitude of international studies associated vitamin D with the prevention of illnesses such as cancer and cardiovascular diseases. These studies likely contributed to the significant increase in vitamin D testing in Ontario. Between 2004/05 and 2009/10, the frequency of vitamin D testing increased about 19 times (from approximately 40,000 tests to 760,000 tests).

In June 2010, a medical expert group (which became part of HQO when it was formed in 2011) reported that there was insufficient evidence to support the conclusion that vitamin D testing improves non-bone-related health outcomes for conditions such as various types of cancer and cardiovascular diseases. The group therefore recommended against routine vitamin D testing for the general population as it does not add clinical value to improve patient health outcomes. In response to this recommendation, in December 2010, the Ministry stopped funding vitamin D testing for the general population. Vitamin D tests became insured only for patients who are taking drugs that can affect their metabolism of vitamin D as well as those with certain medical conditions, such as bone-health-related medical conditions like osteoporosis and rickets, as well as renal disease.

Although the Ministry acted quickly to restrict unnecessary vitamin D testing in response to HQO's recommendation, and insured testing dropped initially by about 77% (from about 760,000 tests in 2009/10 to 173,000 tests in 2011/12), vitamin D testing at community laboratories has again increased in recent years. Between 2011/12 and 2015/16, the number of insured vitamin D tests more than doubled (from about 173,000 to 385,000 tests), while all other laboratory tests performed

by community laboratories increased only by about 1% on average (from about 119 million to 121 million tests). While this trend could be an indication that the Ministry's restriction has been ineffective in sustaining a long-term reduction in unnecessary vitamin D testing, the Ministry has not investigated the reason for the recent increase in vitamin D testing and has not taken further action to enforce its implementation of the restriction.

4.4.2 Ineffective Action Taken to Reduce Unnecessary Aspartate Aminotransferase (AST) Testing

In 2011/12, 69% of AST testing in community laboratories was ordered by family and general practice physicians, usually to identify liver damage. In August 2012, HQO consulted experts to provide advice on the appropriate use of AST testing in community laboratories. HQO noted that AST testing has limited value in a community setting because it is a relatively non-specific test that may not distinguish liver damage from damage in other tissues, such as heart and muscle cells. Other tests, such as alanine aminotransferase (ALT) testing, are more useful for identifying liver disease. Therefore, HQO recommended that AST testing be ordered only by physicians with expertise in treating liver disorders or on the advice of those physicians. In January 2013, the Ministry implemented this recommendation by insuring AST tests under OHIP only when they are ordered under these eligibility criteria. When the physician indicates the patient's medical condition does not meet the eligibility criteria, the patient has to pay for the test out-of-pocket or through private insurance.

In the year after the Ministry put its restriction in place, the volume of AST testing decreased by 17% (from about 1.97 million tests in 2012/13 to 1.63 million in 2013/14). However, in April 2016, about three years after the Ministry's guideline came into effect, a stakeholder group submitted a study to the Ministry. The study suggested that almost 1.5 million AST tests conducted between April 2014 and March 2015 potentially provided no clinical value to the physicians and patients. These tests were worth about $3.8 million, assuming the current price list for community laboratory services. As a result of this study, the Ministry has asked HQO to further review this situation.

4.4.3 Inadequate Effort to Encourage Reduction of Unnecessary Testing

Many health-care organizations have demonstrated greater interest and success in reducing unnecessary laboratory testing ordered by health-care professionals. Despite successful examples of implementing test-ordering guidelines or initiatives, the Ministry and LHINs have not required hospitals to implement similar guidelines or initiatives to ensure that hospital funding is used to perform only necessary laboratory tests.

One of the successful initiatives to reduce unnecessary laboratory testing is Choosing Wisely Canada, a national campaign organized by leading Canadian physicians that engages clinicians and patients collaboratively to promote the appropriate use of tests and treatment in health care, including laboratory tests. In June 2014, a hospital in Toronto adopted the principles of Choosing Wisely Canada. In September 2014, it implemented an initiative to improve the use of laboratory testing in its emergency department. It has since experienced a reduction in unnecessary laboratory tests:

- In the second year after implementing the initiative, the number of laboratory tests ordered by its emergency department fell by over 15%, even though emergency department visits increased by over 5% during the same period.
- In the first year after implementing the initiative, this hospital's emergency department reduced the volume of 10 common laboratory tests it requested (such as glucose tests and complete blood count), resulting in a reduction of about $157,000 in direct costs associated with performing these tests.

RECOMMENDATION 4

To ensure that the use of unnecessary tests is effectively managed, we recommend that the Ministry of Health and Long-Term Care:

- implement a process to regularly identify potential unnecessary laboratory testing by monitoring test volume increases, requesting unusual test ordering patterns from laboratory service providers, and reviewing academic research studies available in the field;
- establish a process to regularly revise and improve the existing test ordering guidelines and restrictions to eliminate or reduce unnecessary tests; and
- work with Local Health Integration Networks to encourage hospitals to adopt consistent laboratory test ordering guidelines.

MINISTRY RESPONSE

The Ministry agrees with this recommendation. Various ordering guidelines have already been established for community physicians through other established industry standards. In addition, the Ministry's use of a financial cap on community laboratories' funding has protected against increases in utilization by removing the financial incentives for community laboratories to perform more tests than is necessary. A process to regularly review guidelines to reduce unnecessary tests will be established by the test review and utilization committee. This work will also require the co-operation of the Ontario Medical Association.

The Ministry will consult with the Local Health Integration Networks and other stakeholders to consider adopting consistent laboratory test ordering guidelines for hospitals.

4.5 Inadequate Strategy for Genetic Testing Results in Costly Out-of-Country Testing

The Ministry has not kept up with the growing demand for genetic testing. A complex form of laboratory testing, genetic testing involves the examination of an individual's DNA to confirm or rule out a suspected genetic condition or help determine the risk of developing or passing on a genetic disorder. Ontario's medical system has lagged in investment, infrastructure and development of expertise in this area. As a result, many genetic tests have been sent out-of-country, at a significant expense to the Ministry. While the Ministry created the Laboratories and Genetics Branch in September 2015 to address this and other issues, this Branch is still developing its strategy for genetic testing.

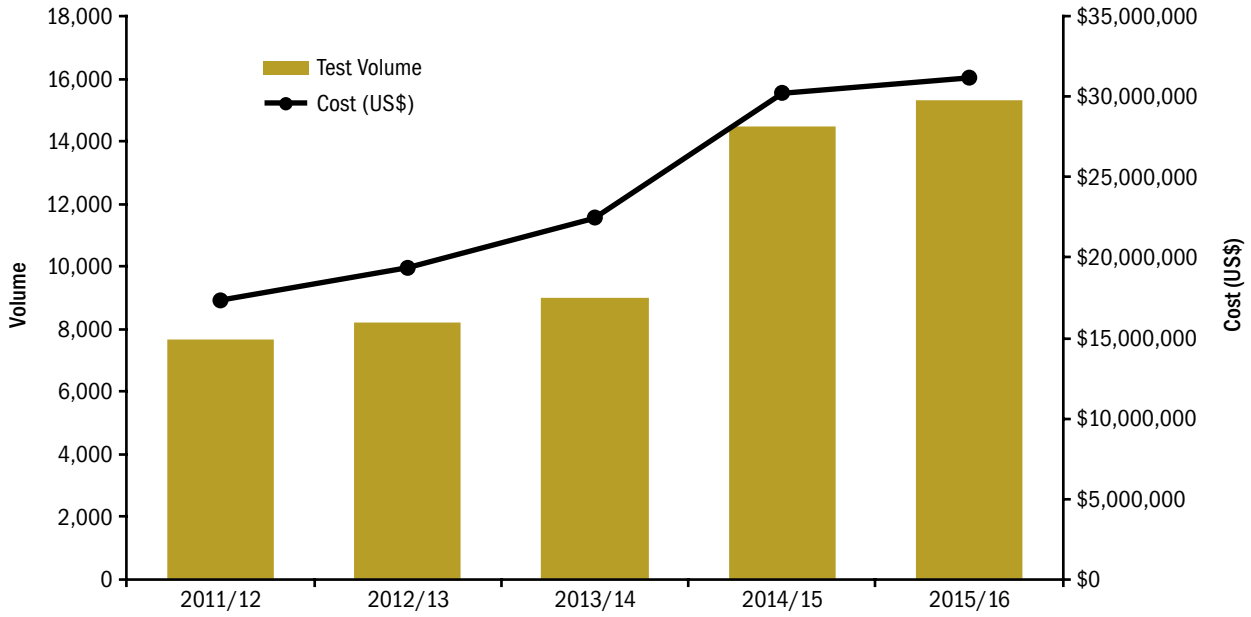
4.5.1 Plan to Increase In-Province Genetic Testing Still Preliminary

Increasing the amount of genetic testing done in Ontario rather than relying on out-of-country genetic testing could reduce the price the Ministry pays to have these tests performed. Ontario has taken some steps in this direction; however, the Ministry's strategy to reduce its reliance on out-of-country testing is still under development.

While physicians can apply to the Ministry's out-of-country program to send specimens outside of Ontario for genetic testing that is not performed within the province, the associated costs to the Province are significant. Between 2011/12 and 2015/16, the number of specimens Ontario paid to send out-of-country yearly almost doubled (from 7,700 to 15,300), and the associated annual costs increased by about 80% (from US$17 million to US$31 million). During this period, Ontario paid total costs of over US$120 million related to over 54,000 specimens that were sent outside the country. **Figure 13** shows the volumes and costs of out-of-country genetic tests between 2011/12 and 2015/16.

Figure 13: Out-of-Country Genetic Test Volume and Cost (US$), 2011/12–2015/16

Source of data: Ministry of Health and Long-Term Care



Note: Test volumes relate to the year a genetic test was paid for, which may not match the year the genetic specimen was sent out-of-country for testing.

Both Alberta and Ontario have been sending specimens to the same provider in the United States to perform a specific type of genetic testing that helps physicians determine treatments to prevent breast cancer recurrence. In 2015/16, Alberta paid about $1 million while Ontario spent almost $10 million out-of-country on this genetic testing (due to the larger number of tests Ontario requested). Alberta informed us that it plans to bring an alternative genetic test into the province instead of sending specimens to the United States for testing.

Alberta estimates that performing this alternative genetic test in the province will achieve an annual savings of at least $500,000 for subsequent years (or 50% of the current total cost of sending tests out-of-country). If Ontario could also achieve similar cost savings, it would save at least US$5 million annually by performing this alternative genetic test in-province instead of sending specimens out-of-country for testing. Despite these potential savings, the Ministry informed us that it has no current plans to perform this test in Ontario and will continue to send specimens for out-of-country testing.

The Ministry has taken some actions to reduce its reliance on out-of-country genetic testing. Between 2014/15 and 2015/16, it provided additional funding to hospitals to perform 46 genetic tests that were previously done outside of Ontario. However, in November 2015, the Laboratory Services Expert Panel indicated that the Ministry had achieved only "modest" overall results in its efforts to bring genetic testing into Ontario.

For example, in 2015, the Ministry started funding specific laboratories to perform non-invasive prenatal testing on pregnant women who met certain risk factors (such as being 40 years old or above). Before then, the Ministry was sending specimens outside of Ontario for these tests. While the test cost about $950 when it was sent out-of-country in 2016/17, the Ministry now pays $395 to laboratories (or savings of almost 60%) to have it performed in Ontario. The Ministry estimated that it saved almost $4.5 million by having this test performed in Ontario in 2016/17 over 8,000 times.

Apart from a few cases, the Ministry has no immediate plans to bring additional genetic tests into the province because it wants to develop a

more comprehensive genetic strategy first, which would include an improved process to identify and bring new genetic tests to Ontario. At the time of our audit, there was still a significant amount of genetic testing being performed out-of-country; between April 1, 2016, and March 31, 2017, the Ministry paid approximately $34 million related to about 10,000 genetic tests performed outside of Canada.

While Ontario has a system in place to co-ordinate access and delivery of genetic testing in the province, the Ministry acknowledged that it has been facing challenges. For example:

- The current system for genetic testing was developed 15 years ago and has not evolved much, resulting in the demand for genetic testing outpacing resources.
- The Ministry's slow response to the growing demand for genetic testing resulted in an increased use of out-of-country genetic testing to meet patient needs.
- Different branches in the Ministry have managed delivery of genetic services, resulting in a lack of co-ordination and weak oversight, such as insufficient policies and quality assurance processes for genetic testing.
- There is no clear pathway for evaluating, approving and funding new genetic tests, which has resulted in difficulties in adopting new technology to benefit both patients and the overall health-care system.

The Ministry informed us that, to address these challenges, it was in the process of developing a new provincial strategy for genetic testing at the time of our audit.

4.5.2 Community Laboratories Restricted from Performing Genetic Testing for Ontarians

Community laboratory service providers informed us that, while they are capable of performing genetic testing, the Ministry has prohibited them from performing these tests, except for three specific cases: non-invasive prenatal testing, tuberous sclerosis testing and retinoblastoma testing (to detect a form of eye cancer).

The Ministry licenses community laboratories to perform over 30 additional genetic tests; however, it allows community laboratories to perform these tests only for non-Ontarians. For example, one community laboratory service provider performs testing related to albinism (a genetic disorder characterized by a lack of pigment), but only for patients referred, for example, through other provincial governments or academic institutions.

We noted instances where community laboratory service providers charge less to perform genetic testing than what the Ministry spends on sending specimens out-of-country for an equivalent test. For example, one community laboratory service provider operating in Ontario is able to perform the previously mentioned genetic test that Alberta brought in-province (see **Section 4.5.1**). This community laboratory service provider charges $4,200 to perform the test in its British Columbia laboratory, which is about 20% less than the Ministry spends ($5,400 at the time of this audit) to have the similar test performed out-of-country. This community laboratory service provider informed us that it could offer this genetic test in Ontario, but it has not been approved to do so.

The Ministry informed us that it has licensed community laboratories to perform genetic testing for non-Ontarians so that community laboratories can develop their genetic testing capabilities without impacting existing hospital funding and testing volumes. The Ministry also indicated that the hospitals may lose the expertise and skill to accurately perform genetic testing if their genetic test volumes are shifted to community laboratories. However, the Ministry does not appear to have considered the consequences of restricting these tests to hospitals that may lack the capability to meet the needs of Ontarians.

4.5.3 Delays in Processing Time of Out-of-Country Applications for Genetic Testing

The amount of time the Ministry took to approve out-of-country genetic testing applications was longer than its target at the time of our audit. This could delay how quickly the results of these tests are available for making decisions related to clinical interventions and treatments.

In January 2017, the Ministry transferred its oversight of the out-of-country genetic testing from the Health Services Branch to the Laboratories and Genetics Branch (Branch), which targets reviewing and processing the out-of-country applications within 14 business days from receipt of an application. The Branch has been able to process urgent applications for genetic testing (such as genetic tests for cancer treatment) within four business days. However, it was unable to meet its 14 business-day target for all other types of out-of-country genetic testing requests, which could delay clinical interventions and treatments.

At the time of our audit in June 2017, the Branch took on average 48 business days to process most out-of-country applications for genetic testing, significantly longer than its target. Following our audit fieldwork in July 2017, the Ministry eliminated this backlog by hiring additional staff and streamlining its process. As a result, the Branch has been able to process out-of-country genetic testing applications within its 14 business-day target.

4.5.4 Long Wait Times to Obtain Counselling Services for Genetic Testing

The Ministry has not measured and monitored if patients have access to counselling services for genetic testing on a timely basis.

Genetic counsellors are medical professionals who are specially trained to help patients understand their genetic test results and recommend actions to ensure that patients have the best possible health outcome. Based on their experience with genetic testing, genetic counsellors are generally better suited than health-care professionals to educate patients on genetic conditions.

As a result of the growing demand for genetic testing, patients have experienced long wait times to see genetic counsellors. The longer a patient waits to see a genetic counsellor for initial consultation or to learn about test results, the longer the patient may also have to wait to start any necessary treatment. Such delays can result in the worsening of the patient's condition.

While there is no provincial wait-time target for patients to see genetic counsellors, guidelines published by the Human Genetics Society of Australasia (comprising Australia and New Zealand) indicated that non-urgent patient referrals should be seen by a genetic counsellor or clinical geneticist (a physician who evaluates patients for genetic conditions) within 12 weeks. However, the wait time in Ontario can be significantly longer than this guideline. Our review of wait-time information and our discussions with genetic counsellors at four hospitals found, for example:

- For cancer inquiries, the wait time to see a genetic counsellor at one hospital was about six months.
- For pediatric inquiries (such as parents seeking diagnosis for their child's developmental delay), the wait time to see a clinical geneticist at a different hospital was about 14 months.

RECOMMENDATION 5

To ensure that genetic testing is provided to Ontarians appropriately and cost-effectively in a timely manner, we recommend that the Ministry of Health and Long-Term Care:

- evaluate the existing provincial capacity and funding for genetic testing to determine if they are sufficient to meet the growing demand for genetic testing and genetic counsellors;
- analyze the costs and benefits of current genetic testing providers to determine the most appropriate provider of each genetic test for Ontarians;

- continue to process out-of-country genetic testing applications within turnaround-time targets to prevent recurrence of a backlog; and
- work with Local Health Integration Networks and hospitals to develop provincial wait-time targets for genetic counsellor services, regularly measure actual wait times against these targets, and take corrective action if the targets are not met.

MINISTRY RESPONSE

The Ministry welcomes this recommendation. As part of the Genetic Services Framework Strategy, the Ministry plans to analyze the costs and benefits of existing genetics funding and current genetic testing providers to develop an updated funding and genetics service delivery model that meets future needs, including services provided by genetic counsellors.

The Ministry will evaluate all current genetic testing providers—hospitals, community and non-Ontario laboratories—to determine the best sourcing of genetic testing that ensures quality, meets service delivery needs, and maximizes value to the system. Enabling these activities will require the co-operation of Ontario genetics laboratories and clinics to share operational, resourcing and costing information with the Ministry for evaluation of existing provincial capacity and genetic services funding. The Ministry will also continue to process out-of-country genetic test requests within a turnaround-time target.

The Ministry agrees that any future service delivery model should have appropriate performance measures (such as wait-time targets) with mechanisms in place for corrective action if targets are not met. The Ministry will work with Local Health Integration Networks, hospitals and the broader genetics sector to streamline and evolve genetic services, including the development of performance standards that make sense, are achievable, and help to move the system forward.

4.6 More Effort Needed to Improve Underserved Areas of Community Laboratory Services

The Ministry has not regularly performed any detailed analysis to identify areas of the province underserved by community laboratory service providers' collection centres, and has not taken effective action to improve the accessibility, availability and capacity of these services throughout the province.

4.6.1 Limited Data Collection and Analysis on Availability of Community Laboratory Services

The Ministry has not established a provincial target for the availability of collection centres across the province, but only set a target for rural areas: 90% of rural Ontarians are to be within a 30-minute drive of a collection centre. Although the Ministry met this target for rural areas, it did not consider the differences in capacity (such as operating hours or the number of blood-drawing chairs) that could affect how many patients the collection centres can serve. For example:

- One of the community laboratory service providers has one of its collection centres in North York open an average of 10 hours for six days each week with six blood-drawing chairs on-site, while another collection centre in Stayner (Simcoe County) is only open four hours a day for three days each week with two blood-drawing chairs on-site.
- Five collection centres (all operated by one community laboratory) in St. Catharines have different total operating hours per week (ranging from 25 hours to about 45 hours per week), and only one of them operates on Saturdays.
- Six collection centres (all operated by one community laboratory) in Guelph have different total operating hours per week (ranging from 40 hours to 47.5 hours per week), and only one location operates on Saturdays.

The Ministry has not collected sufficient information to assess the capacity and use of community collection centres. Although it collects operating hours from each community collection centre on an annual basis, it has not used this information to assess differences in total operating hours of community collection centres in each region of the province. Also, community laboratory service providers only report to the Ministry the total number of laboratory tests performed annually, but currently do not report the number of patients served or specimens collected by each of their collection centres. Without this information, the Ministry cannot assess if the current capacity of community collection centres is sufficient to meet patient needs across the province.

Under their fee-for-service arrangement with the Ministry, community laboratory service providers have full discretion to determine where they operate their collection centres. The Ministry has not conducted any regular reviews to assess the availability of collection centres across the province and determine where additional ones needed to be opened to meet patient needs.

In Ontario, when the Ministry receives a request from a community laboratory service provider to open a new collection centre, the Ministry does not consider whether there are other community collection centres in the area. It only assesses if the proposed new collection centre location is within two kilometres of an existing hospital laboratory. In those cases, the Ministry asks the hospital if it has concerns that the proposed new collection centre will potentially reduce its own testing, as laboratories need to perform sufficient tests to maintain their expertise.

We noted that the Ministry could have learned and applied practices from other jurisdictions and similar programs in Ontario to assess the availability of laboratory services. For example:

- British Columbia's Ministry of Health requires each collection centre to report its operating hours and number of blood-drawing chairs annually as part of the province's laboratory licensing requirements. This information, along with data on the number of patient visits to each collection centre, is used to assess laboratories' requests for opening new collection centres and determine if there is a need for more collection centres in specific areas. In contrast, Ontario only collects operating hours from each community collection centre on an annual basis, but does not use the information to assess the needs and locations of new collection centres.
- Laboratories and independent health facilities (which provide diagnostic services such as x-rays and ultrasounds) are very similar in terms of services and operations. In order to identify areas underserved and overserved by independent health facilities, the Ministry calculated the number of services billed per capita by hospital out-patients and by independent health facilities in various areas. Then it compared these numbers to the provincial average. In 2014, the Ministry also implemented a facility relocation policy to enable independent health facilities to move from adequately served or overserved areas to underserved areas.

4.6.2 More Action Required to Identify and Improve Availability of Community Laboratory Services

The Ministry does not currently collect useful information on collection centre capacity throughout the province. Without this information, it is not clear whether the Ministry's actions have resulted in the appropriate availability of community laboratory services across the province, especially in underserved areas. For example:

- In 2013/14, the Ministry established a fund to "increase access while maintaining existing laboratory services" in order to tie some of its funding to community laboratory service providers to an increase in collection centres' operating hours. However, the Ministry did

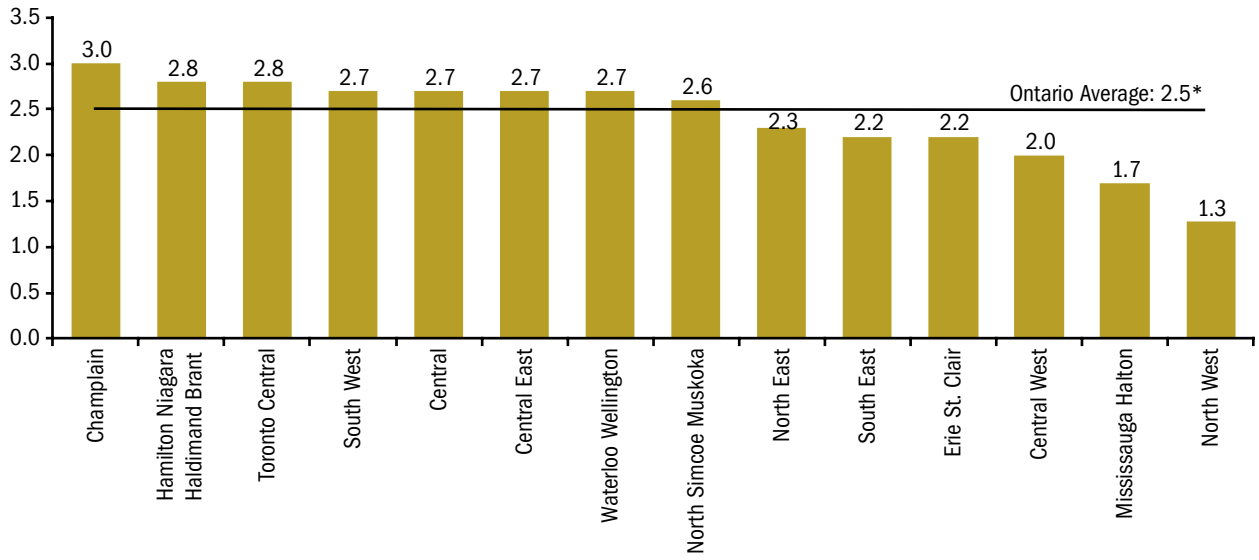
not require that the increase in operating hours had to be in underserved areas. For example, a laboratory could receive funding for keeping its collection centres open for two more hours in the evening, even if the collection centre was in a well-served part of the province and no one actually went to the collection centres during these hours. In 2015/16, the Ministry cancelled this fund to meet cost-reduction goals as part of the government's 2015 Budget. The Laboratory Services Expert Panel's 2015 review supported this funding cancellation as it identified that the fund was "an inadequate tool" to generate sufficient access and performance improvement.

- Under the short-term (three-year) transfer payment agreements that the Ministry plans to enter into with community laboratory service providers in 2017/18 (see **Section 4.7.1**), providers that operate collection centres in northern or rural parts of Ontario will receive more money than those in other parts of the province ($12.76 per patient served in a rural area; $14.26 per patient served in a rural and remote northern area; and $10.76 per patient served in an urban area). The Ministry expects this change will give more incentive to community laboratory service providers to maintain or increase the number of their collection centres in underserved areas. However, we question the effectiveness of this change in improving the availability of laboratory services, because the underserved areas are not necessarily located in rural and remote northern areas, based on our analysis of the ratio of community collection centres by LHIN (see **Figure 14**). For example, Mississauga Halton LHIN (an urban area) has the province's second-lowest ratio of community collection centres, which is actually worse than rural and northern areas such as the North East LHIN and the North Simcoe Muskoka LHIN. To more fully understand which parts of the province are underserved, the Ministry needs to collect and analyze information on the capacity of collection centres across the province.

We also noted that Ontario has relatively fewer specimen collection centres than other provinces. The collection centre rate (including both hospital and community collection centres) per 100,000

Figure 14: Number of Community Specimen Collection Centres per 100,000 People by Local Health Integration Network (LHIN), 2017

Source of data: Ministry of Health and Long-Term Care



* The provincial average for community specimen collection centres per 100,000 people is 2.5, while the provincial average for all specimen collection centres (including both hospital and community) per 100,000 people is 4.0.

people in Ontario has been low in comparison with other jurisdictions. According to a study in 2012 by a consultant for British Columbia's Ministry of Health, Ontario's collection centre rate per 100,000 people was four, which was lower than Alberta (five), British Columbia (six), Quebec (six) and Manitoba (15). We obtained 2017 data and repeated the calculation based on the study's methodology. We found that the collection centre rate per 100,000 people has remained at about four in Ontario, indicating no significant improvement since 2012. While this analysis did not consider the capacity of collection centres in each province, it supports that there is a need for the Ministry to gather more information on the capacity to determine if all areas of the province have reasonable access to collection centres.

RECOMMENDATION 6

To ensure that Ontarians have timely access to community laboratory services, we recommend that the Ministry of Health and Long-Term Care:

- establish regional targets to monitor and assess the availability and accessibility of community specimen collection centres;
- collect and analyze the operating hours, locations and distribution of community specimen collection centres on a regular basis (such as annually); and
- identify underserved areas for community specimen collection centres and take corrective action.

MINISTRY RESPONSE

The Ministry agrees with this recommendation. Access continues to be an important focus for the Ministry. In the past, the Ministry has worked with stakeholders to restore access in areas where services were previously withdrawn and to increase hours of operation across the province. Access to community laboratory services will be addressed by the Ministry's Community Laboratory Modernization Strategy.

The Ministry has established an access measure through a drive-time target for Ontario residents for specimen collection for all types of collection services. The licensing process already collects logistical information regarding specimen collection centres, and this will be further enhanced within the new transfer payment agreements with providers that are being implemented in 2017/18.

Underserviced northern rural areas are currently being identified and reviewed as part of the Northern and Rural Laboratory Services Strategy, a key component of the Community Laboratory Modernization Strategy. This strategy will begin with a focus on laboratory services in the communities within the North East and North West Local Health Integration Networks. In the future, the Ministry plans to consider community laboratory services in other rural parts of Ontario.

4.7 Inadequate Oversight of Community Laboratory Services

The Ministry has not consistently tied its payments to community laboratory service providers to their performance because the Ministry has not established and tracked useful performance measures to monitor the community laboratory sector. The Ministry also has not verified if community laboratory service providers have been billing OHIP accurately for tests actually performed.

4.7.1 Comprehensive Performance-Based Contracts with Community Laboratory Service Providers Needed

While the lack of regular performance measurement and reporting on community laboratory service providers has been a concern in Ontario for more than 20 years, the Ministry has done little to address this concern until 2017/18. Specifically:

- In 1994, an external advisory committee commissioned by the Ministry released its

Laboratory Services Review report, which indicated that to effectively oversee the laboratory sector, the Ministry needed "mechanisms to monitor and evaluate outcomes" related to the performance of laboratory service providers.

- In 2015, the Ministry commissioned the Laboratory Services Expert Panel (Expert Panel), which noted two significant concerns: absence of formal performance-based contracts between the Ministry and each community laboratory service provider to clearly identify each party's role and responsibilities; and lack of measurable performance standards and indicators for the Ministry to assess the performance of community laboratory service providers.
- In 2016, the Ministry's submission to Cabinet on modernizing the community laboratory sector noted that "for the past 18 years the funding model has been provider-centric and volume-driven, instead of patient outcomes-based service delivery. Service quality for patients has been defined by the supplier."

The Expert Panel recommended the Ministry establish long-term (seven to 10 years) performance-based contracts with community laboratory service providers to ensure stability in the delivery of laboratory services. Despite this, the Ministry plans to enter into short-term (three-year) contracts with these providers instead.

The Ministry informed us that it is pursuing short-term contracts with the community laboratory service providers to allow for changes to happen more quickly in the community laboratory service sector without restricting the Ministry's ability to change contract terms in the future. As part of the short-term contracts, the Ministry will modify the cap that limits the total amount of funding each community laboratory service provider can receive from its total billings each year. However, senior staff at some community laboratory service providers expressed to us the concern that the short-term contracts proposed by the Ministry do not give them the incentive to focus on providing high-quality laboratory services, because:

- Short-term contracts will reallocate funding based on community laboratory test volumes every year, which will encourage community laboratory service providers to focus on competing in large population areas in order to seize market share from each other. This will not improve accessibility for patients in underserved areas, but will further disadvantage remote rural locations that are already not adequately served.
- Short-term contracts will discourage community laboratory service providers from investing in new equipment, which is generally expected to be used for five to seven years. Staff at community laboratory service providers informed us that they feel less comfortable investing in new equipment and technologies given the increased uncertainties over their funding and profitability under short-term agreements.

4.7.2 No Regular Review of Inappropriate Billings by Community Laboratory Service Providers

The Ministry pays community laboratory service providers based on the amount and type of tests they perform according to a price list. However, the Ministry has not taken sufficient action to verify that community laboratory service providers have been billing accurately for tests actually performed.

The Ministry used to conduct audits of community laboratories to verify that the tests they performed and billed were supported by signed physicians' requisitions. It stopped conducting these audits in 2013. Under the current fee-for-service arrangement, the Ministry primarily funds community laboratory service providers based on a price list for each test performed, up to a cap or maximum amount for each provider. Between 2011/12 and 2015/16, community laboratory service providers collectively billed over 30% more

than the cap, meaning that they were receiving their maximum payments allowed (see **Section 4.1.1**). Consequently, the risk of paying community laboratory service providers for erroneous or fraudulent billings has been relatively low.

However, the risk of inappropriate billings by community laboratory service providers may increase once the Ministry implements changes to the community laboratory sector in 2017/18. First, the Ministry plans to introduce a new price list in 2017/18, which will reduce prices for many tests that community laboratories perform (see **Section 4.1**). Second, the Ministry plans to enter into new transfer payment agreements with community laboratory service providers, under which the funding cap of each community laboratory service provider will be revised annually, and funding to each one will increase or decrease based on changes in its test volumes over the past two years compared to other community laboratory service providers (see **Section 4.7.1**). These changes will increase the incentive for community laboratory service providers to overstate the number of tests they perform in order to maximize their total billings.

Even under the current system where billings are capped and laboratories have nothing to gain by overbilling, the Ministry's prior years' audits of community laboratories have identified instances where some providers have billed the Ministry for tests that they could not prove to be legitimate. For example, in the Ministry's final audit of a community laboratory service provider in 2013, the Ministry concluded that the provider may have overbilled it by over $25 million between 2009/10 and 2012/13. The Ministry based its conclusion on its inability to obtain appropriate evidence that a sample of the tests it reviewed as part of the audit had actually been ordered by an authorized healthcare professional.

The Ministry informed us that, as part of the new transfer payment agreements with community laboratory service providers, it plans to reinstate an audit function by setting up an audit group that will review specific incidents or concerns relating to the community laboratory sector. However, it does not plan to perform regular reviews to identify or investigate inappropriate billings from community laboratory service providers, unless specific issues are brought to its attention.

RECOMMENDATION 7

To ensure that community laboratory service providers operate effectively and efficiently and bill accurately for tests actually performed, we recommend that the Ministry of Health and Long-Term Care:

- assess the costs and benefits of short-term versus long-term (recommended by the Laboratory Services Expert Panel in 2015) performance-based contracts with community laboratory service providers; and
- reinstate periodic reviews of community laboratory service providers to verify that the laboratory tests they billed were actually performed.

MINISTRY RESPONSE

The Ministry agrees with this recommendation. As part of the Community Laboratory Modernization Strategy, transfer payment agreements with community laboratories are currently under development and the term of these agreements has been carefully considered. The need to change the length of these contracts will be reconsidered after the initial contract's expiry. Audit provisions included in the transfer payment agreements will support periodic reviews of community laboratories.

4.8 Inadequate Oversight of Physicians' In-Office Laboratory Testing

The Ministry has not verified that all physicians who perform in-office laboratory testing have been billing accurately for tests actually performed, and it has continued to exempt these physicians from

licensing and quality management requirements that other laboratory service providers (including community, hospital and Public Health Ontario laboratories) must follow.

4.8.1 Limited Investigation of Large In-Office Laboratory Test Volumes and Billings by Physicians

Physicians can perform point-of-care tests that are generally simple to do, such as urine dipstick tests that detect pregnancy, drugs of abuse, and disorders like urinary tract infections, kidney disease and diabetes. However, the Ministry did not check the accuracy of all physicians' billings related to performing these tests, including those who billed much higher than the average physician for in-office laboratory testing.

Based on our review of 2015/16 OHIP data provided by the Ministry, over 11,200 physicians billed the Ministry approximately $83 million for performing about 10.6 million in-office laboratory tests on a fee-for-service basis. Of those, 120 family and general practice physicians accounted for half of all billings and tests performed by physicians who billed OHIP for in-office laboratory testing (or $42.2 million for 5.1 million tests performed). We further noted that 15 of those 120 physicians were responsible for about 15% of all billings and tests performed by physicians who billed OHIP for in-office laboratory testing (or $12.4 million for 1.57 million tests performed).

Figure 15 provides a summary of these 15 family and general practice physicians. Each one performed between about 75,000 and 182,000 tests per year, which was about 114 times to 275 times higher than the average test volume (about 660 tests) of a typical family and general practice physician who billed OHIP for in-office laboratory testing. They each billed the Ministry about $600,000 to $1.4 million per year, ranging from 128 times to almost 300 times higher than the average billings (about $4,700) of a typical family and general practice physician for in-office testing.

Figure 15: Fifteen Family and General Practice Physicians with Highest Test Volume and Billing Amount for Laboratory Testing Performed, 2015/16

Source of data: Ministry of Health and Long-Term Care

Physician	Test Volume	Billing Amount ($)
1	181,736	1,402,755
2	124,559	985,295
3	121,946	940,796
4	113,621	920,368
5	104,864	845,697
6	103,986	826,731
7	102,239	816,828
8	101,507	790,920
9	93,445	789,613
10	98,613	756,291
11	95,031	729,875
12	91,810	712,065
13	81,457	674,049
14	75,036	614,991
15	75,454	597,092
Average*	**662**	**4,721**

* The averages were calculated using data from all family and general practice physicians who billed OHIP for laboratory tests performed in their offices on a fee-for-service basis, excluding these 15 top-billing physicians.

The Ministry indicated that most of these top-billing physicians provided addiction medicine treatment for their patients. Therefore, the Ministry expects these physicians to perform more tests related to identifying and monitoring the level of drugs in a patient's body than other physicians. Between 2011/12 and 2015/16, the Ministry only reviewed the billings related to eight of the 120 family and general practice physicians identified above. Only one of these reviews related to the 15 top-billing family and general practice physicians noted above. While the Ministry collected some information during these reviews to understand the size of the physicians' practices, in the vast majority of cases the Ministry has not collected details on the size of top-billing physicians' practices to determine if they accurately billed for laboratory testing provided to their patients or if

they billed the Ministry fraudulently for laboratory testing not performed.

4.8.2 Physicians' In-Office Laboratory Testing Exempt from Licensing and Quality Management Requirements

All licensed laboratories (community, hospital and Public Health Ontario laboratories) and specimen collection centres in Ontario must participate in a quality management program operated by the Institute for Quality Management in Healthcare (Institute), which is a subsidiary of the Ontario Medical Association (OMA). As reported in our 1995 and 2005 audits on laboratory services, we noted during our current audit that physicians are still not required to be licensed by the Ministry to perform laboratory services. They continue to be exempt from participating in the quality management program, even though in 2015/16, physicians who bill OHIP performed 10.6 million in-office tests.

The Ministry allows physicians to collect certain patient specimens and perform generally simple point-of-care tests in their offices so they can diagnose and treat their own patients in their offices without sending specimens to a laboratory for analysis. While point-of-care tests can provide faster results to physicians to help them treat their patients faster, there can be concerns with how accurately these tests are performed. Point-of-care testing is often performed by clinical staff, such as a nurse, as opposed to other laboratory tests that are performed by laboratory staff with specialized training. Unlike physicians who do in-office testing, when hospital and community laboratories (or staff such as nurses who are associated with these laboratories) perform point-of-care tests, they must meet certain licensing and quality assurance requirements. For example:

- they must develop standards and processes for how point-of-care testing should be done;
- staff competence to perform the tests needs to be regularly assessed; and
- staff require retraining or recertification and continuing education to perform the tests.

Every four years, the Institute examines whether hospital and community laboratories comply with these requirements. Between 2012 and 2016, the Institute most commonly found issues at licensed laboratories with point-of-care testing (accounting for about 17% of total issues identified by the Institute). This raises concerns about the performance of point-of-care testing done by physicians, who are not subject to the Institute's quality management program.

Previous expert reviews and our audits have repeatedly identified physicians' exemption both from the licensing requirement and from participation in Ontario's quality management program as a concern. Nevertheless, we noted that this matter has remained unresolved over the last 20 years because the Ministry has not taken any action to address this matter. Specifically:

- Our 1995 audit noted that the Ministry's Laboratory Service Review Committee had recommended in 1994 that laboratories in physicians' offices be licensed to bring them under the quality assurance provisions of inspection and proficiency testing. Although the Ministry agreed with this recommendation, we noted during our 2005 value-for-money audit that no action had been taken in this regard.
- Our 2005 audit recommended the Ministry assess whether the quality assurance process for licensed laboratories should be applied to laboratory services performed at physicians' offices. The Ministry agreed with the recommendation and indicated that it would initiate discussions with the College of Physicians and Surgeons of Ontario (College) on this matter. However, we have found that the Ministry has made no further progress.
- The 2015 Laboratory Services Expert Panel recommended that "the current physician exemption from the Licensing Act should be rescinded."

The Ministry informed us that testing in physicians' offices is not licensed or subject to the Province's quality management program because physician practice is under the jurisdiction of the College. However, the College informed us that it does not measure or regularly review the proficiency of physicians' offices in performing laboratory testing. The College indicated that physicians are expected to take continuing professional development courses and that its Peer and Practice Assessment Program (Program) would review whether physicians appropriately ordered a test and properly interpreted test results. Although participation in the Program is required under legislation, only a small portion of physicians (approximately 2,600) are selected each year to participate in it. (In 2015/16, over 30,000 physicians billed OHIP.) Therefore, despite the existence of the Program, the point-of-care testing done by many physicians is not regularly assessed. The College informed us that there could be benefit in having an independent and objective quality assessment program (like the one done by the Institute) for physicians who perform point-of-care tests.

RECOMMENDATION 8

To ensure that billings by physicians for their in-office testing are accurate and physicians are performing these tests properly, we recommend that the Ministry of Health and Long-Term Care:

- identify and collect information on physicians' practices with high volumes of in-office testing and high billing amounts related to these tests, on an ongoing and timely basis;
- investigate physicians whose billings related to in-office testing are not supported by the information collected; and
- implement quality assurance requirements for laboratory tests done in physicians' offices.

MINISTRY RESPONSE

The Ministry welcomes this recommendation. Although the Ministry does audit physicians who have a pattern of high billings for certain services, the Ministry will identify potential changes to existing payment accountability processes in an effort to increase efficiency and effectiveness. It is important to note that certain specialized practices will appropriately bill high volumes of certain laboratory services (for example, addiction medicine).

The Ministry agrees and supports that a quality program should be provided for in-office physician laboratory testing. The Ministry will engage and consult with both the Ontario Medical Association and the College of Physicians and Surgeons of Ontario in order to introduce this change.

4.9 Inadequate Oversight of Laboratory Services Provided by Hospital Laboratories

Hospitals fund their laboratory services through global budgets from their respective Local Health Integration Networks (LHINs), which are overseen by the Ministry's LHIN Liaison Branch. We noted that, in spite of the involvement of these co-ordinating bodies, hospital laboratory services were generally not provided to Ontarians in a co-ordinated and consistent manner.

4.9.1 Lack of Regional Co-ordination and Integration of Hospital Laboratories

While some hospitals have worked together to develop regional laboratory networks that resulted in cost savings, this practice has not been widely adopted across Ontario.

Each hospital is responsible for determining what laboratory services to offer its patients. In some regions of the province, hospitals have worked together to create regional networks for

laboratory services. Regional networks for laboratory services have various benefits, which include:

- buying equipment and supplies in bulk to obtain volume discounts and achieve cost savings;
- developing policies and procedures jointly to ensure best practices are followed as well as ensure the uniformity of operations and test results; and
- centralizing tests at certain laboratories to maximize the use of equipment and minimize the need to buy and maintain equipment and supplies at multiple hospital sites.

Other provinces have been moving toward setting up regional networks for laboratory services. For example, as of April 1, 2017, 123 laboratories in Quebec's Ministry of Health and Social Services formed 11 regional clusters. It estimated that it will spend about 15% to 20% less on laboratory testing annually (excluding specimen collection centre and genetic testing costs, which were not included in the cost estimate) as a result of obtaining discounts from bulk purchasing equipment and supplies as well as reducing staff and equipment through centralizing laboratory tests within each regional cluster.

In Ontario, regional laboratory networks exist in only six of the 14 LHINs; but even in these six LHINs, not all hospitals participate in their respective regional networks. Examples of the existing regional networks include the Eastern Ontario Regional Laboratory Association (EORLA) in the Champlain LHIN, CoLabs in the Hamilton Niagara Haldimand Brant LHIN, and Northeastern Ontario hospitals in the North East LHIN.

- EORLA is the most fully formed and integrated regional network. It is a not-for-profit organization established in 2012 that has formal agreements with 16 hospitals in the Champlain LHIN. EORLA bulk buys equipment and supplies on behalf of its member hospitals, creates uniform laboratory operating policies and procedures, centralizes some laboratory tests in the region to only one laboratory, and has the ability to transfer laboratory staff working for EORLA throughout the region to any laboratory. In 2015/16, EORLA consolidated testing to identify diseases caused by bacteria, fungi, parasites and viruses from seven regional laboratories into one laboratory. By becoming a regional laboratory network, and consolidating testing and improving efficiencies, EORLA was able to decrease its annual staffing expenditure by about $1 million from 2012/13 to 2016/17.
- CoLabs is a laboratory network similar to EORLA. CoLabs was formed in 2012 as a partnership by eight hospitals in the Hamilton Niagara Haldimand Brant LHIN. The hospitals work together collaboratively to streamline and standardize processes through joint development of operating policies and procedures, and centralization of some laboratory tests in the region. In 2016, CoLabs made a first attempt to do a single bulk purchase of all equipment and supplies for testing blood disorders, resulting in about $400,000 in savings for the hospitals in the network. At the time of our audit, the second bulk-buy initiative was under way to purchase equipment for testing blood transfusions, which CoLabs estimated will save $200,000 per year for the hospitals in the network.
- In Northeastern Ontario, 10 hospitals have worked together since 2005 to create joint standards and centralize some laboratory tests to examine tissue samples at one hospital laboratory. Staff at one of the hospitals involved in the network informed us that they do not calculate accumulated savings among all the hospitals, but estimated that a joint procurement of laboratory supplies resulted in about $150,000 in savings (or 5% of total laboratory expenditures) in 2015/16.

4.9.2 No Oversight of Billing Practices by Hospital Laboratories

Hospitals can send laboratory testing to other hospitals if their equipment is down or if they find that it is not cost-effective to do the tests themselves. However, the Ministry has not provided any guidelines and has not collected any information (such as test volumes done by one hospital on behalf of others or fees charged by one hospital to others) to ensure fair and reasonable prices are being charged to other hospitals.

Without guidelines from the Ministry, hospitals have been using inconsistent billing practices when providing laboratory services on behalf of other hospitals. Hospital staff expressed frustration to us over the lack of provincial guidelines in this area. Without information on test volumes and funding flow between hospitals for tests hospitals perform for each other, the Ministry does not know the actual costs of operating hospital laboratories and cannot allocate funding to hospitals appropriately. This lack of oversight can also result in hospitals taking advantage of other hospitals to generate revenues for themselves.

We reviewed information provided by some hospitals that charge other hospitals to do laboratory testing on their behalf, and found that they were inconsistent in their billing practices. For example:

- Two hospitals performed tests on behalf of other hospitals and charged other hospitals a percentage of the prices based on the Ministry's price list for community laboratory services (one charging 70%, and another charging either 100% or 80%, depending on the tests).
- Another hospital that performed tests for other hospitals charged prices based on its direct costs to perform the tests plus a 30% margin to cover its fixed costs.
- One hospital found itself in puzzling situations, first when another hospital referred a patient to one of its specialty programs and then when it referred a patient to another hospital's specialty program. It found it had to pay the costs of the patient's tests in both cases, regardless of whether it was the referring hospital or the receiving hospital.

Figure 16 provides examples of different prices that three hospitals charged for performing the same test on behalf of other hospitals. (We show results for five tests.) The difference between the lowest and highest price charged by each hospital was significant, ranging from 31% to 176%.

RECOMMENDATION 9

To ensure that best practices are shared between hospital laboratories to improve the co-ordination and consistency of hospital laboratory services, we recommend that the Ministry of Health and Long-Term Care work

Figure 16: Differences in Prices Charged by a Sample of Hospitals for the Same Test

Source of data: Select hospitals

Type of Test	Hospital 1 ($)	Hospital 2 ($)	Hospital 3 ($)	Difference Between Lowest and Highest Price ($)	Difference Between Lowest and Highest Price (%)
Potassium	1.81	2.07	5.00	3.19	176
Vitamin B12	10.13	11.58	15.00	4.87	48
Partial thromboplastin time (used to check for bleeding problems in a patient)	5.07	5.79	7.20	2.13	42
Ammonia (used to detect an elevated level of the byproduct that can be caused by liver disease or kidney disease)	14.11	16.13	12.00	4.13	34
Thyroid stimulating hormone	6.88	7.86	9.00	2.12	31

with Local Health Integration Networks and laboratory service providers to:

- conduct an analysis of the costs and benefits of moving toward a regional laboratory system; and
- establish guidelines for hospitals to determine the test prices they charge to each other.

MINISTRY RESPONSE

The Ministry supports this recommendation. Each Local Health Integration Network (LHIN) that does not have a hospital laboratory network already in place will be asked to consider the feasibility of doing so.

The Ministry will consult with the LHINs and other stakeholders regarding the feasibility of adopting consistent laboratory referral guidelines for hospitals.

4.10 No Consistent Performance Monitoring of Laboratory Service Providers

The Ministry has not set provincial performance targets or collected performance information to measure, monitor and determine if laboratory services have been provided efficiently, and in a consistent and timely manner across Ontario.

4.10.1 No Consistent Performance Measurement and Reporting of Laboratory Services

With no provincial performance targets and measures in place, the extent of performance measurement and reporting varies across Ontario, depending on the type of laboratory service provider. Overall, there has been very limited public reporting on the performance of laboratory services. While Public Health Ontario publicly reports on a number of performance measures related to its laboratory services, the Ministry does not collect or report on key performance indicators related to other laboratory service providers. **Figure 17** identifies the differences in performance measurement and public reporting related to each laboratory sector.

According to a 2015 review conducted by the Laboratory Services Expert Panel, Alberta is the only province that has used performance targets and measures to oversee laboratory service providers. Key metrics that are tracked for hospital and community laboratory service providers in Alberta include patient wait times, test turnaround times, and patient/health-care provider satisfaction. In contrast, the Ministry has not established any key performance targets and measures in Ontario. Each laboratory sets its own targets to assess its own performance, but the Ministry does not collect this information.

Our review of performance measures used by a sample of different laboratory service providers (community, hospital and Public Health Ontario) found significant variations in their performance, even within the same type of laboratory service provider (see **Appendix 3**). For example:

- The specimen rejection rate (percentage of times that a test cannot be done due to a mistake made while collecting or handling a specimen) ranged from 0% to 4.4% among hospital laboratories in Ontario.
- The blood culture contamination rate (percentage of times when a blood culture is contaminated with bacteria or other organisms as a result of using an improper specimen collection or handling technique) ranged from 0% at a community laboratory to 6.7% at one hospital laboratory.

4.10.2 No Data Collection and Monitoring of Wait Times for Laboratory Services

The Ministry has not set wait-time targets and has not collected wait-time information to measure and monitor the length of time that patients have to wait to have their specimens collected at hospital

Figure 17: Performance Measures and Public Reporting of Performance by Laboratory Service Providers
Prepared by the Office of the Auditor General of Ontario

Type of Laboratory Service Provider	Performance Measures	Public Reporting
Community laboratory	Under current fee-for-service arrangement: • Test volume Under new transfer payment agreement*: • Performance measures under development at the time of our audit	×
Hospital laboratory	• Test volume • Laboratory expenditure • Laboratory workload units (the amount of time spent on laboratory testing by staff)	×
Public Health Ontario laboratory	A variety of performance indicators, such as: • Test volume • Percentage of certain laboratory tests completed within target turnaround time (from receiving specimens to reporting test results) • Number of complaints received related to Public Health Ontario's products and services	✓
Physician (in-office)	• Test volume	×

* The Ministry plans to enter into short-term (three-year) transfer payment agreements with community laboratory service providers in 2017/18.

or community collection centres. Therefore, the Ministry does not know if the laboratories collected specimens from Ontarians within a reasonable amount of time.

While the Ministry does not collect or monitor wait times for specimen collection, many laboratories measure their own wait times against targets they set themselves. Based on our analysis of data provided by hospital and community collection centres, we identified differences in wait-time targets and actual wait times for specimen collection. For example, while one community laboratory service provider targets serving 90% of its patients within 30 minutes of their arrival at a collection centre, another targets serving 90% of its patients within 40 minutes of their arrival. For hospital collection centres, wait-time targets also varied, ranging from 20 minutes to 45 minutes. **Figure 18** shows various wait-time targets and actual wait times from a sample of hospitals and community laboratory service providers for 2016/17.

We noted that, unlike Ontario, hospitals and community laboratory service providers in Alberta must submit wait-time information to Alberta Health Services, which targets serving patients within 30 minutes of their arrival at a collection centre. Alberta Health Services also shares wait-time information with all laboratories in Alberta to enable each laboratory to gauge its performance relative to its peers.

The Ministry could have better met the needs of patients if it had focused on tracking and improving wait times across Ontario. Surveys of both physicians and patients indicated that wait times for specimen collection need improvement. For example:

- According to a 2013 survey conducted by a laboratory services stakeholder organization, the specific area needing improvement most frequently mentioned by patients (in 30% of the patient responses that identified areas for improvement) was wait times for specimen collection.
- According to a 2015 survey conducted by the Ministry, 84% of physicians indicated that an appropriate wait time for a patient to see a technician at a community collection centre is between five and 20 minutes, which is shorter than the current wait-time targets (30 minutes and 40 minutes) set by the community

Figure 18: Examples of Wait-Time Targets and Actual Wait Times for Specimen Collection at Selected Hospital and Community Laboratory Service Providers, 2016/17

Source of data: Select community laboratory service providers and hospital laboratory service providers

Type of Laboratory Service Provider	Specimen Collection Wait-Time Target[1] (minutes)	Avg. Wait Time for Specimen Collection[1] (minutes)	Specimens Collected within Wait-Time Target (%)
Community Laboratory 1	30	14	87
Community Laboratory 2	40	17	89
Hospital Laboratory 1	30	10	92
Hospital Laboratory 2	n/a[2]	n/a[2]	n/a[2]
Hospital Laboratory 3	20	15	70
Hospital Laboratory 4	30	30	56
Hospital Laboratory 5	20	12	83
Group Hospital Laboratory 1[3]	45	n/a[2]	n/a[2]
Group Hospital Laboratory 2[3]		10	100
Group Hospital Laboratory 3[3]		15	100

1. Some laboratory service providers' wait-time targets are designed to capture the average wait for most, but not all, patients. For example, some community laboratory service providers aim to serve 90% of patients within their stated wait-time targets.
2. N/A refers to the fact that a laboratory either does not have an on-site collection centre or that it does not collect wait-time information related to its collection centre.
3. These are individual hospital results provided by a single regional laboratory network, which includes 18 hospital laboratories associated with 16 hospitals. The network sets wait-time targets and monitors wait times on behalf of its member hospitals. **Appendix 3** provides results of all 18 hospital laboratories within this network.

laboratory service providers in our samples. Based on our review of data from 2016/17 provided by these providers, they were on average serving patients in less than 20 minutes of their arrival at collection centres (see **Figure 18**).

- The Ministry at one time planned to collect wait-time information by providing community laboratory service providers with funding to develop a method for tracking and reporting this information accurately. In 2013/14 and 2014/15, the Ministry entered into an agreement with seven of the eight community laboratory service providers, making $8.5 million of funding dependent on whether these providers were able to develop and implement a consistent wait-time definition they could use to capture and report data to the Ministry. Although the service providers successfully completed this task and received funding in full, the Ministry abruptly discontinued its wait-time data collection to save costs as part of a broader Ministry-wide cost-savings initiative. The Laboratory Services Expert Panel identified in its 2015 report that this funding process was "an inadequate tool" to generate sufficient access and performance improvement. It suggested that "an overall redesign to the process of contracting and managing laboratory services is required to maximize value."

RECOMMENDATION 10

To ensure that the laboratory sector in Ontario is operating effectively and efficiently as well as providing value and timely services to Ontarians, we recommend that the Ministry of Health and Long-Term Care:

- establish standard performance targets and measures for community and hospital laboratories, collect and analyze performance information from laboratories, and take corrective action if targets are not met; and

- set wait-time targets for specimen collection in hospitals (for out-patients) and community specimen collection centres, regularly collect and assess wait times, and take corrective action if targets are not met.

MINISTRY RESPONSE

The Ministry fully supports establishing and collecting/analyzing performance measures for community laboratories and for establishing wait-time targets for community specimen collection centres. The Ministry has collected measures in the past and is proposing to build on this work by introducing a number of key performance indicators in the new transfer payment agreements with the community laboratories. These indicators will allow the Ministry to measure and manage performance of the community laboratory system over several domains. These domains include patient access, quality of service, availability of services, patient and provider experience, and reporting.

The Ministry will review the feasibility of wait-time targets for specimen collection with the Local Health Integration Networks and hospitals to determine if these targets are feasible.

4.11 Inadequate Oversight of Quality Management Program

The Ministry has not collected useful information to assess the results of the Institute for Quality Management in Healthcare's (Institute's) quality management program on an ongoing basis and identify where the quality of laboratory services needs improvement across the province.

4.11.1 Ministry Collected Limited Information on Quality Management Program

The Ministry has been relying on the Institute's quality management program to assess whether laboratories are providing accurate test results and, when they are not, to ensure that appropriate and timely corrective action is taken. The Ministry routinely obtains quarterly and annual reports from the Institute that contains information on the quality management program. The Ministry also receives reporting whenever a more significant deficiency is identified by the Institute. However, we noted that the Ministry did not request or receive enough sufficient information to assess the performance of laboratories participating in the Institute's quality management program on an ongoing basis.

The Institute's quarterly and annual reports to the Ministry contain limited, high-level summary information on the Institute's quality management activities (such as the number of site assessment visits done by the Institute) as opposed to detailed information on how individual laboratories are performing (such as the number of issues the Institute found during assessment visits of laboratories or proficiency testing). Since the Ministry does not require public disclosure and reporting, the Institute does not disclose any details of the results of its laboratory assessments to the public.

Both our 1995 and 2005 audits of Health Laboratory Services raised the concern that the Ministry did not have sufficient information on the quality management activities conducted by external parties. In our 1995 audit, we recommended that the Ministry be advised as soon as possible of any laboratory that did not meet accepted standards, and of remedial action being taken by staff of the quality management program. In our 2005 audit, we found that the Ministry did not receive information on the number of errors that had been identified for each licensed laboratory; therefore, it was not aware when laboratories performed poorly or which ones they were. Even though this matter has been raised repeatedly, we noted that it has remained mostly unresolved over the last 20 years.

4.11.2 Ministry Has Not Collected Accreditation On-Site Assessment Results

The Ministry has not collected sufficient data from the Institute to identify and determine if there were regional differences in the quality of laboratory services that warranted corrective actions.

The Institute performs an on-site assessment at each of the licensed laboratories every four years to review and determine if each laboratory's policies and procedures conform to its requirements. The Institute considers any instance where a laboratory's policies and procedures do not conform to these requirements as a non-conformance (such as not documenting test procedures or not having evidence of ongoing training of laboratory staff).

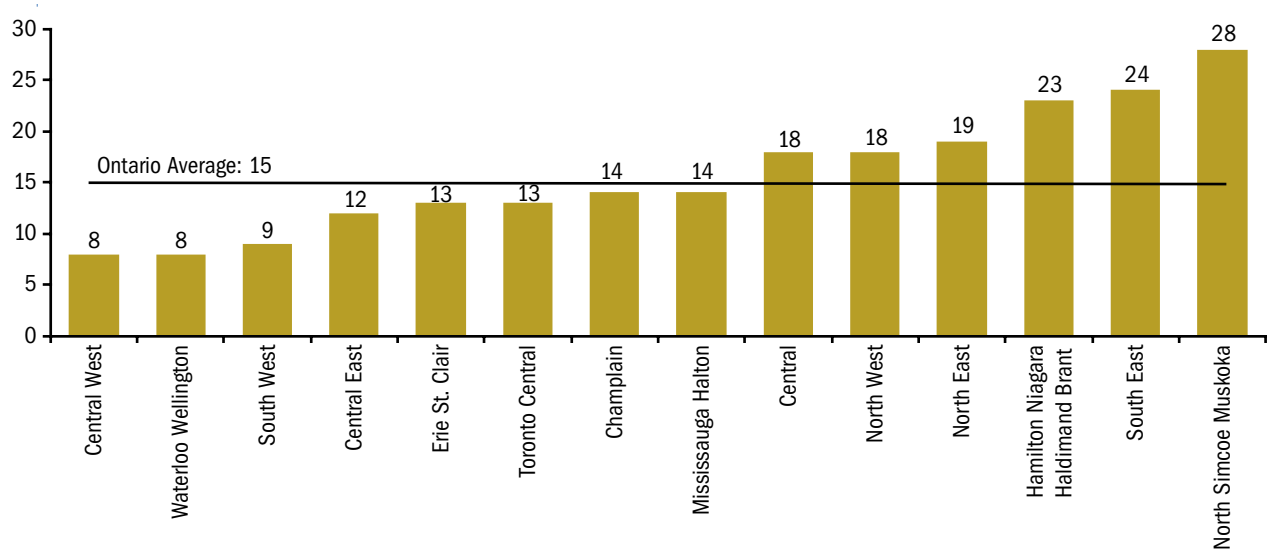
Between 2012 and 2016, the total number of non-conformances was about 800 per year, on average. During this period, on average, the overall conformance rate was about 97%, which the Institute considered as high and an indication that laboratories generally had effective processes in place, given that they had to comply with over 400 individual requirements. (This assumes they were licensed for all laboratory tests, as some requirements do not apply if a laboratory does not perform every type of test.)

The Ministry did not regularly request the results of the Institute's assessment visits for further review and analysis. Based on our review of data from the Institute for the assessment visits between 2013 and 2016, we noted some common types of non-conformances and regional patterns in non-conformances that may warrant further investigation by the Ministry. For example:

- The most common type of non-conformances were related to point-of-care testing (17% of all non-conformances), laboratory systems for tracking issues with testing (16%) and laboratory equipment and supplies (12%).
- The average number of non-conformances was 15 for the province, but varied from one LHIN to another, ranging from eight non-conformances at some LHINs (Central West LHIN and Waterloo Wellington LHIN) to 24 or more non-conformances at other LHINs (North Simcoe Muskoka LHIN and South East LHIN). **Figure 19** shows the average number of non-conformances per assessment visit by LHIN.

Figure 19: Average Number of Non-conformances Noted During the Institute for Quality Management in Healthcare's (IQMH's) Assessment Visits, by Local Health Integration Network (LHIN), 2013–2016

Source of data: Institute for Quality Management in Healthcare



Note: A non-conformance is any instance where a laboratory's policies and procedures do not conform to the IQMH quality-management program's requirements.

4.11.3 Ministry Has Not Collected Proficiency Testing Results

The Ministry requires all licensed laboratories to participate in the proficiency testing program. The Institute defines proficiency testing as the determination of a laboratory's performance by means of inter-laboratory comparisons. The Institute conducts proficiency testing by sending out proficiency testing materials several times throughout the year to licensed laboratories and having them report test results back to the Institute, which then identifies test results that do not meet its standards for specimen handling or test analysis/reporting. The Institute considers any instance where a laboratory's test result does not meet its specimen-handling or test-analysis/reporting standards as an error.

Between 2011/12 and 2015/16, the average proficiency testing error rate was below 1%, which the Institute considered low or satisfactory. While there is no consistent target error rate associated with proficiency testing across Canada, Alberta targets its laboratories to achieve a 5% or lower error rate from its proficiency testing program.

The Ministry did not regularly receive the results of the Institute's proficiency testing for further review and analysis. Based on our review of proficiency testing error rates between 2011/12 and 2015/16, we noted that even though the overall error rate was below 1%, the error rate for different type of tests varied, and that this might warrant further investigation by the Ministry. For example, in 2015/16, error rates ranged from 0.04% for pathology (tests related to disease diagnosis) to 1.8% for bacteriology (tests to detect bacterial infections).

RECOMMENDATION 11

To ensure that the quality management program provides useful information to identify where the quality of laboratory services needs improvement across the province, we recommend that the Ministry of Health and Long-Term Care obtain and analyze appropriate accreditation and proficiency test results from the Institute for Quality Management in Healthcare on a regular basis and evaluate if any additional corrective action is warranted.

MINISTRY RESPONSE

The Ministry supports the recommendation and agrees to appropriately enhance the quality management program reporting for licensed laboratories and specimen collection centres currently provided by the Institute for Quality Management in Healthcare (Institute). This reporting is necessary to ensure accountability of licensed laboratories and specimen collection centres to regulatory requirements and accountability of the Institute for the Ministry funding it receives. The Ministry is currently engaged in this work as it negotiates a new agreement with the Institute, which is expected to take effect in 2018/19.

4.12 Areas of Improvement for Quality Management Program

While Ontario has a quality management program in place, improvements can be made. These include moving to a more rigorous accreditation standard and performing unannounced site visits.

4.12.1 More Rigorous Standard Is Available for On-Site Assessment Visits

The Institute performs an on-site assessment of all licensed laboratories every four years, whose purpose is to provide accreditation to the laboratories. The Institute's accreditation is based on standards such as those developed by the International Organization for Standards (ISO), like ISO 15189, which requires standardized processes and procedures at laboratories for both quality system and technical requirements.

The Institute offers a more rigorous program, called ISO 15189 Plus, which is a standard recognized worldwide that requires a more frequent visit (known as a surveillance visit) every two years

between the regular accreditation assessment visits. Licensed laboratories in Ontario perform a self-assessment to show their compliance with the Institute's requirements instead of having the Institute perform a surveillance visit. More frequent visits can be advantageous as they allow for the faster identification and resolution of issues at the laboratories. While not all provinces require laboratories to follow a program similar to this more rigorous program, New Brunswick as well as Newfoundland and Labrador require all laboratories in their provinces to be accredited using ISO 15189 Plus standards.

As of July 2017, 58 (17 community laboratories and 41 hospital laboratories) of the 198 laboratories in Ontario voluntarily paid and received accreditation for the ISO 15189 Plus from the Institute to further ensure that they followed the more rigorous program standards.

4.12.2 On-Site Assessment Visits Announced in Advance

The Institute gives advance notice to laboratories regarding when it will perform an assessment visit during its regular four-year cycle. The next visit is tentatively scheduled as soon as an assessment visit is done, and it is then confirmed approximately 90 days before the visit.

We identified two separate laboratory accreditation programs that conduct unannounced visits, the College of American Pathologists (CAP) and the Joint Commission. One of the programs identifies a three-month window when its inspection will occur, and the other program may perform an unannounced visit with no notice between 18 and 36 months following its previous visit. The CAP indicated that unannounced visits both require and ensure that laboratories are in continuous compliance with all requirements.

RECOMMENDATION 12

To ensure that Ontario's quality management program continues to operate effectively in assessing the quality and accuracy of laboratory services provided by all licensed laboratories and specimen collection centres in Ontario, we recommend that the Ministry of Health and Long-Term Care conduct an analysis of similar programs in other jurisdictions to identify best practices that can be implemented in Ontario (such as implementing more rigorous accreditation standards and performing unannounced accreditation assessment site visits).

MINISTRY RESPONSE

The Ministry supports the recommendation and agrees to conduct an analysis of quality management programs in other jurisdictions. A cost-benefit analysis will support the Ministry's decision-making about potential changes to Ontario's program. The Ministry anticipates that it will initiate a jurisdictional analysis in 2018/19.

Appendix 1: Audit Criteria

Prepared by the Office of the Auditor General of Ontario

1.	Processes are in place to ensure that funding and resources are allocated appropriately to laboratories to meet the needs of Ontarians, used for the purposes intended, administered with due regard for economy and efficiency, and reviewed on a timely basis for reasonableness.
2.	Procedures are in place to ensure that laboratory services are performed accurately on a timely basis, consistently across the Province, and in accordance with applicable legislation, policies, standards and best practices to meet the needs of Ontarians.
3.	Processes are in place to ensure that the costs of providing laboratory services are managed properly and monitored on a timely basis.
4.	Performance measures and targets are established, monitored and compared against actual results to ensure that the intended outcomes are achieved and that corrective actions are taken on a timely basis when issues are identified.
5.	Accurate, timely and complete financial and operational information is regularly collected from the laboratories to assess their performance, effectiveness and efficiency, and results are publicly reported.

Appendix 2: Implementation Status of Recommendations from 2015 Laboratory Services Expert Panel Report

Sources of data: Ministry of Health and Long-Term Care

	Recommendation	Implementation Status (as of June 30, 2017)
1.	Negotiate long-term performance-based contracts (approximately seven to 10 years, with reopeners) directly with individual labs, with price discounts from present levels with a deadline (six months) to come to agreement, failing which an RFP will be initiated	**In the process of being implemented:** The Ministry is developing Transfer Payment Agreements (TPAs) for implementation in 2017/18 as part of its Community Laboratory Modernization Strategy. See **Section 4.7.1**.
2.	Discontinue the Utilization Discount Modifier and Access and Performance Fund	**In the process of being implemented:** The Ministry plans to discontinue the Utilization Discount Modifier in 2017/18. (The modifier reduced the amount community laboratories received for performing testing for health-care professionals who ordered tests that exceeded a set threshold.) **Implemented:** The Ministry cancelled the Access and Performance Fund (which tied some of the Ministry's funding to community laboratories to achieving various performance targets) in 2015/16. The Ministry is re-establishing performance measures as part of TPAs that are expected to be in place with community laboratory service providers in 2017/18.
3.	Move to a single core funding envelope with test schedule, combining existing segregated funding envelopes as market saturation occurs	**In the process of being implemented:** The TPAs that the Ministry plans to establish with community laboratory service providers streamlines all Ministry funding to community laboratory service providers into the single agreement, where possible.
4.	Establish New Technology Testing Fund via RFPs open to new market entrants	**In the process of being implemented:** The Ministry plans to introduce a New Tests and Technology Fund in 2018/19 to help community laboratory service providers adopt new tests and technologies that improve patient outcomes and the patient experience.
5.	Create a Small Labs Opportunity Fund to establish a level playing field for performance measurement and reporting	**In the process of being implemented:** The Ministry plans to implement a three-year Mitigation Fund in 2017/18 for small and large community laboratory services providers. The Ministry expects that this Fund will allow community laboratory service providers to transition to the new funding model. See **Section 4.1.1**.
6.	Establish a provincial process to formally evaluate new laboratory tests, recommend or not recommend such tests, and retire obsolete testing within a regularly updated Schedule of Benefits	**In the process of being implemented:** The Ministry does not currently have a process to regularly evaluate and determine whether newly developed tests are medically necessary and should be funded. The Ministry plans to establish a test review and utilization committee by late 2017/18 to regularly evaluate the price list.

	Recommendation	Implementation Status (as of June 30, 2017)
7.	Require public reporting of laboratory performance and accreditation results	**Not implemented (under consideration):** The Ministry plans to include performance measures as part of the TPAs it plans to enter into with community laboratory service providers in 2017/18. The accreditation status of each laboratory continues to be posted on the Institute for Quality Management in Healthcare's (IQMH's) website. The Ministry is still considering additional public reporting of accreditation results in the future. See **Sections 4.10** and **4.11**.
8.	Develop and deploy a Province-wide appropriateness/ utilization program with supporting tools (e.g., electronic order entry prompts)	**In the process of being implemented:** The Ministry expects to establish a test review and utilization committee in late 2017/18 to address the issues related to appropriate utilization of laboratory tests and funding for unnecessary tests.
9.	Establish a focal point for Laboratory Program leadership within government and strengthen capacity in contract negotiation and contract and relationship management, supported by robust analytics and an appropriate audit/inspection regime	**Partially implemented:** The Ministry established the Laboratories and Genetics Branch in September 2015 to fund and oversee community laboratories. As part of the TPAs with individual community laboratory service providers, the Ministry has proposed inspection and audit provisions that would strengthen accountability. See **Section 4.7.2**.
10.	Modernize and streamline licensing requirements and processes	**In the process of being implemented:** The Ministry has required all licensed specimen collection centres to be accredited in addition to the laboratories; and has updated its licensing system to allow licensed laboratory service providers to electronically renew licenses online throughout the year. The Ministry is reviewing the licensing requirements and process to further modernize and streamline the licensing system.
11.	Establish independence of the Institute for Quality Management in Healthcare and develop a cost recovery model for accreditation	**Not implemented (under consideration):** The Ministry is still considering the most suitable governance structure and mechanism of payment for the Province's quality management program and plans to conduct a jurisdictional review to better understand other models both within and outside of Canada.
12.	Remove impediments to e-ordering/e-signature and expedite implementation with appropriate safeguards	**In the process of being implemented:** The Ministry is currently in the policy development and early design stage for e-ordering/e-signature.
13.	Review policy on point-of-care testing and home and community collection to ensure equity and consistency	**In the process of being implemented:** The Ministry is reviewing and considering extending its existing quality management framework to alternate settings such as point-of-care testing sites. Under the TPAs that the Ministry plans to enter into with community laboratory service providers, the Ministry plans to collect information on home specimen collections.
14.	Introduce independent and regular patient satisfaction surveys for laboratory services, with sufficient breadth and depth to inform regional service adjustments	**In the process of being implemented:** The TPAs that the Ministry plans to establish with community laboratories in 2017/18 is expected to include patient satisfaction as a performance measure.

	Recommendation	Implementation Status (as of June 30, 2017)
15.	Conduct detailed assessment and develop recommendations on the approach to optimizing value across the broader laboratory system as a next phase of study to cover: a. Strategically position genetic testing services to meet current and future needs b. Champion the role and contribution of Ontario's research-intensive hospitals in experimental test development as part of the formal process to assess and approve new health technologies in Ontario c. Identify opportunities to balance hospital out-patient testing and community laboratory testing, where appropriate and more convenient for patients and providers d. Conduct a reference, full cost accounting study across the broader laboratory sector (community, hospital and public health) to inform rationalization of test menu across sectors e. Provide quality oversight and develop comparable payment for physician in-office testing in relation to community laboratory testing f. Expedite OLIS for remaining hospitals, community laboratories and physicians conducting in-office testing, and facilitate interoperability with local information systems g. Local Health Integration Network (LHIN) to take leadership in rationalization and optimization of hospital laboratory capacity in geographically proximal areas h. Explore opportunities to allow routine public health testing to be conducted by community labs	**Not implemented:** The Ministry is currently working on the modernization of community laboratory services. The Ministry plans to conduct a review of hospitals and public health laboratories starting in 2018/19 and the broader sector recommendations of the Laboratory Services Expert Panel.

Appendix 3: Performance Measurement by Laboratory Service Provider, 2016/17

Sources of data: Community laboratory service providers, hospital laboratory service providers, Public Health Ontario and Ministry of Health and Long-Term Care

Community Laboratory Service Provider	Specimen Rejection Rate[1] (%)	Blood Culture Contamination Rate[2] (%)	Avg. Ministry Payment Per Test ($)[3]	Routine Blood and Chemistry Tests Completed within Target Turnaround Time[4] (%)	Wait Time at Specimen Collection Centres		
					Wait-Time Target (minutes)[5]	Avg. Wait Time (minutes)	Specimens Collected within Wait-Time Target (%)
1	0.9	0.0	5.45	94	30	14	87
2	0.2	0.6	5.31	99	40	17	89

Hospital Laboratory Service Provider	Specimen Rejection Rate[1] (%)	Blood Culture Contamination Rate[2] (%)	Avg. Cost Per Test ($)[3]	Avg. Turnaround Time of Urgent Blood Test to Measure Overall Health[6] (minutes)	Wait Time at Specimen Collection Centres		
					Wait-Time Target (minutes)[5]	Avg. Wait Time (minutes)	Specimens Collected within Wait-Time Target (%)
1	0.8	0.3	12.92	6	30	10	92
2	4.4	2.5	11.79	15	n/a[7]	n/a[7]	n/a[7]
3	0.3	0.8	10.33	17	20	15	70
4	1.4	1.6	10.77	15	30	30	56
5	0.6	0.7	7.34	22	20	12	83
6	n/a[7]	0.6	12.82	60	n/a[7]	n/a[7]	n/a[7]
7	0.0	1.1	7.75	10	n/a[7]	n/a[7]	n/a[7]
8	0.0	4.0		n/a[7]	n/a[7]	n/a[7]	n/a[7]
9	0.0	3.9		n/a[7]	n/a[7]	n/a[7]	n/a[7]
10	0.1	n/a[7]	11.40[8]	n/a[7]	n/a[7]	n/a[7]	n/a[7]
11	0.1	4.6		n/a[7]	n/a[7]	n/a[7]	n/a[7]
12	0.1	6.7		n/a[7]	n/a[7]	n/a[7]	n/a[7]
Group Hospital Laboratory[9]							
1	0.3		29.52	11		n/a[7]	n/a[7]
2	0.4		12.88	18		10	100
3	0.0		21.96	14		15	100
4	0.4		12.37	10		n/a[7]	n/a[7]
5	1.2		34.83	12		21	100
6	0.7		15.46	17		n/a[7]	n/a[7]
7	0.1		18.63	10		22	100
8	0.0		14.02	15		9	100
9	0.9	not individually tracked	10.77	6	not individually tracked	n/a[7]	n/a[7]
10	0.1		14.74	19		20	100
11	0.8		13.31	9		16	100
12	0.4		9.58	10		15	100
13	1.0		7.14	10		16	100
14	0.0		12.08	43		8	100
15	1.4			20		21	100
16	1.1		6.88[8]	26		30	77
17	1.3			24		28	100
18	2.5		15.49	25		6	100
Group result		**2.5**			**45**		

Public Health Ontario Laboratory[10]	Specimen Rejection Rate[1] (%)	Avg. Cost Per Test ($)[3]	Tests Completed within Target Turnaround Time (%)		
			Manual Tests[11]	Semi-Automated Tests[11]	Automated Tests[11]
1	1.6	18.34	99.1	95.5	99.5

1. Specimen rejection rate is the percentage of specimens collected that could not be tested (due to a mistake made while collecting or handling the specimen) divided by total specimens collected.
2. Blood culture contamination rate is generally calculated as the percentage of blood cultures contaminated with bacteria (as a result of using an improper collection or specimen handling technique) divided by all blood cultures collected or tested.
3. Note 2 in **Figure 2** identifies how payment/cost per test is calculated based on 2015/16 data.
4. Community laboratory service providers target providing test results for routine blood and chemistry (analysis of bodily fluids) within 24 hours after the specimen was picked up and transferred to a laboratory for testing. In 2015/16, this type of test accounted for about 75% of the testing that these service providers performed. Some laboratory service providers include other types of testing in this measure, which represents less than 1% of the total tests those laboratories included in this measure.
5. See **Figure 18** for additional details on laboratory wait-time targets.
6. This test measures blood characteristics to detect a wide range of disorders, including anemia, infection and leukemia; it is most commonly ordered on an urgent basis when done for a patient being treated in an emergency department. Turnaround time is the amount of time it takes to perform this test.
7. N/A refers to the fact that the laboratory either does not perform what the associated metric covers or does not track information on the performance of this activity.
8. Some costs and volumes related to these hospitals are tracked in aggregate, as they all relate to the separate laboratories/sites of one hospital or a hospital group.
9. Group Hospital Laboratory represents 18 hospital laboratories associated with 16 hospitals. These hospital laboratories are operated by a not-for-profit organization that is responsible for performance monitoring for these hospital laboratories. Some performance measures are done at an individual hospital level and some are done at the organizational level, where the individual performance of each hospital laboratory is not separately tracked.
10. Public Health Ontario Laboratory data is an aggregate of all 11 Public Health Ontario Laboratories.
11. Public Health Ontario tracks the percentage of times it performs a test within its target turnaround time (from the time a specimen is received by Public Health Ontario until the test has been performed and the test result reported back to the ordering health-care professional). Three individual tests are used as proxies for the three main ways that laboratory tests can be performed, and are specifically monitored: (1) manual tests that require a laboratory professional to analyze a specimen; (2) automated tests that are performed by laboratory equipment with minimal intervention by a laboratory professional; and (3) semi-automated tests that require laboratory equipment and analysis by a laboratory professional.