

Chapter 3

Ministry of Health and Long-Term Care

Section 3.08

Health Laboratory Services

Background

Medical laboratories perform tests and analysis of patient samples to assist in the diagnosis, prevention, and treatment of disease. Most laboratories also own and operate one or more specimen-collection centres to gather the samples. As of March 2005, there were 191 hospital laboratories, 45 private laboratories, and 341 specimen-collection centres operating in Ontario. In addition, the Ministry was operating 12 public-health laboratories that tested human samples for various communicable diseases and private well-water samples for bacterial contamination.

The Ministry of Health and Long-Term Care's Laboratories Branch is responsible for developing and managing all areas of medical laboratory services in Ontario (this includes hospital and private laboratories, as well as specimen-collection centres) and for operating the province's public-health laboratories. Under the *Laboratory and Specimen Collection Centre Licensing Act*, the Ministry licenses and regulates Ontario's hospital and private medical laboratories, including these laboratories' specimen-collection centres. In addition, the Ministry has a contract with the Ontario Medical Association (OMA) to operate a quality-management

program to monitor and improve the proficiency of licensed laboratories. This quality-management program for laboratory services provides a number of services, including the evaluation of the quality of testing performed in all licensed medical laboratories in Ontario, as well as laboratory accreditation. The Ministry is also responsible for payments for laboratory services, which are made under the *Health Insurance Act* to private laboratories.

During the 2003/04 fiscal year, the Ministry spent \$1.3 billion on laboratory services. Hospital laboratory expenditures accounted for \$730 million; \$541 million was paid to private-sector laboratories, with three companies receiving over 90% of these payments; and \$3.7 million was paid to the OMA to operate its quality-management program for laboratory services on the Ministry's behalf.

Audit Objective and Scope

The objective of our audit was to assess whether the Ministry:

- had adequate processes in place to ensure that private-sector and hospital laboratories and specimen-collection centres were complying with applicable legislation and established

policies and procedures, that test results were appropriately reported, and that private-sector laboratories were funded in a cost-effective manner; and

- had adequate policies and procedures to ensure that public-health laboratories were reporting well-water test results on a timely basis.

In conducting our audit, we reviewed relevant files and administrative policies and procedures, interviewed appropriate ministry staff, reviewed relevant literature, and researched the delivery of laboratory services in other jurisdictions. While our audit focused on the Ministry, we also met with representatives of the OMA with regard to its quality-management program for laboratory services. In addition, we followed up on the status of recommendations made in our last audit of private and hospital laboratories and specimen-collection centres, conducted in 1995. We also reviewed and, where warranted, relied on work completed by the Ministry's Internal Audit Services.

At the time of our audit, the Ministry was undertaking an operational review to identify and define core testing services of its 12 public-health laboratories and the mechanisms required for these testing services; determine the enhancements required to ensure that the public-health laboratory system performs at an optimum level; and develop a model for reconfiguring the public-health laboratory system as an agency. The Ministry anticipated that the review would be completed in August 2005. Given this review, we excluded the operations of the public-health laboratories from our audit, with the exception of the reporting of well-water testing results.

Our audit was conducted in accordance with the standards for assurance engagements, encompassing value for money and compliance, established by the Canadian Institute of Chartered Accountants and accordingly included such tests and other procedures as we considered necessary in the circumstances, except as explained in the Scope Limitation

section that follows. The criteria used to conclude on our audit objective were discussed with and agreed to by senior ministry management.

SCOPE LIMITATION

On November 1, 2004, sections of the *Quality of Care Information Protection Act, 2004* and related regulations came into force that prohibit the disclosure of information prepared for or by a designated quality-of-care committee unless the committee considers the disclosure necessary to maintain or improve the quality of health care. Similarly, anyone to whom such a committee discloses information may share the information only if it is considered necessary to maintain or improve the quality of health care. We understand that this legislation was designed to encourage health professionals to share information to improve patient care without fear that the information would be used against them.

The *Quality of Care Information Protection Act, 2004* prevails over all other Ontario statutes, including the *Auditor General Act*, unless specifically exempted. Because the OMA is designated as a quality-of-care committee with respect to its activities under the *Laboratory and Specimen Collection Centre Licensing Act*, during this audit our access to information relating to the OMA's quality-management program for laboratory services was limited. Specifically, we were prohibited from examining the OMA's quality-management program, or the Ministry's monitoring of this program, after October 31, 2004, because the *Quality of Care Information Protection Act, 2004* came into force on November 1, 2004. Finally, any issues arising from the audit work that we had conducted prior to the scope limitation becoming effective could not be followed up on once the legislation came into force. We were therefore unable to determine whether the quality-management program for laboratory services was functioning as intended.

Our concerns with the scope limitation imposed by the *Quality of Care Information Protection Act, 2004* date back to December 2003, when the Act was introduced for first reading in the Legislature. We explained the problem and proposed a solution in a January 15, 2004 letter to the Ministry and again in a presentation to the Standing Committee on General Government on January 28, 2004. No relevant action was taken during the subsequent three months, so we expressed our concerns yet again in a letter to the Minister in April 2004. In November, the *Quality of Care Information Protection Act, 2004* passed without any changes having been made with respect to our access to information. We have continued to seek a remedy to this situation and again communicated our concerns and our proposed remedial action in a letter to the Minister in February 2005 and followed up with a letter to the Ministry in March 2005.

Summary

Due to the scope limitation already noted, we were unable to fully assess whether the Ministry had adequate processes in place to ensure that private-sector and hospital laboratories were complying with applicable legislation and established policies and procedures. However, we were able to determine that, for the most part, the Ministry had adequate procedures to ensure that specimen-collection centres were complying.

Laboratory testing provides up to 80% of the information that physicians use to make medical decisions. It is therefore essential that test results be accurate and reliable. Since our 1995 audit of private and hospital laboratories and specimen-collection centres, the Ministry has increasingly delegated responsibility to the OMA for assessing the quality of laboratory services. It is therefore more important than ever that the Ministry obtain

adequate information to assess whether the OMA is fulfilling its responsibilities to the degree needed to ensure quality patient care. In this regard, we found that the Ministry was obtaining more information from the OMA than when we audited this program in 1995. For instance, the Ministry was now being informed when the OMA sent a laboratory a letter of concern or a letter regarding an on-site consultation, and the Ministry generally was receiving reports resulting from on-site consultations. However, it was still not obtaining sufficient and timely information on laboratories that performed poorly and did not ensure that timely corrective action was always being taken. Our specific concerns in this regard, as well as our other concerns about laboratories, included:

- Although laboratories were being notified in advance that a specimen sample being submitted was part of the OMA's quality-management program to test laboratory performance, the number of significant errors being made when testing those samples had increased (significant errors are those with the potential to cause mis-treatment or misdiagnosis).
- The Ministry was not normally notified that a laboratory was producing inaccurate or questionable test results (that is, significant and lesser errors) for certain types of tests until the laboratory had been performing poorly on its external quality-assessment tests for between two and four years. In one case, a laboratory that had been experiencing ongoing problems with certain tests since 1981 and performed poorly on related external quality assessments since at least 1999 was allowed to continue performing these tests until 2003.
- As noted in our *1995 Audit Report, the Laboratory and Specimen Collection Centre Licensing Act* (Act) allows laboratories in physicians' offices to conduct *simple* laboratory procedures, whereas a regulation under the Act effectively allows physicians to conduct *all* laboratory tests. At the

time of our current audit, this inconsistency was still unresolved, as was our concern that laboratories in physicians' offices are not subject to the quality-assurance provisions that other laboratories are required to participate in.

We also noted that 75% of payments made to laboratories in physicians' offices in the 2003/04 fiscal year were for tests not defined as simple procedures. The Ministry paid \$22.6 million for these tests. In spring 2005, changes to the Act and related regulations were tabled that, if passed, would permit physicians to conduct any type of laboratory procedure for their patients. They would also continue to be exempt from participating in any ministry or OMA quality-monitoring activities. With respect to this last concern, ministry staff advised us that no external quality-assurance process was required as physicians' laboratories were under the jurisdiction of the College of Physicians and Surgeons of Ontario. Our discussion with the College indicated that they do not monitor or regularly review physicians' offices' laboratories to assess the testing performed.

- No integrated system was in place to make laboratory test results accessible to all health-care providers. For example, the results of laboratory tests performed prior to a patient being admitted to hospital were generally not accessible by the hospital, which could result in duplicate testing and delays in patient treatment. According to the Ministry, the implementation of the Ontario Laboratory Information System in the 2005/06 fiscal year will address this issue.
- The Ministry had not periodically reviewed or studied on an overall basis whether laboratory tests that were conducted were appropriate or necessary, even though other jurisdictions had noted concerns in these areas and had found that their best-practice guidelines were shown to significantly improve laboratory utilization.

- The Ministry had not analyzed the underlying actual costs of providing laboratory services so that this information could be utilized in negotiating the fees to be paid for private laboratory services. This is of concern given the province's significant expenditures on private laboratory services: an inter-provincial study estimated that Ontario's per-capita spending on all laboratory services in the 2001/02 fiscal year was about \$90.41—the second highest in Canada—while the Canadian average was \$77.49.

Furthermore, the Ministry's policies and procedures to ensure that well-water testing is completed and results are reported to well owners on a timely basis should address the following issues:

- The report of the results of well-water testing issued to well owners does not clearly state that well water that is reported to have no significant evidence of bacterial contamination may still be unsafe to drink due to chemical and other contaminants.
- The Ministry's policy of not testing well-water samples when the accompanying submission form is missing any required information, such as a postal code or phone number, even though individuals can access their results through an automated telephone service, could potentially result in individuals continuing to drink unsafe water until another sample, with complete information, is submitted for testing.

Detailed Audit Observations

MEDICAL LABORATORIES

Monitoring of Private and Hospital Laboratories

Historically, the Ministry has monitored medical laboratories and specimen-collection centres through its own licensing and inspection activities

and through a contract with the OMA, which is paid to operate a quality-management program for laboratory services. The OMA's quality-management program includes an accreditation program and an external quality-assessment program. All of these monitoring activities are established to help the Ministry determine if laboratories and specimen-collection centres are complying with the *Laboratory and Specimen Collection Centre Licensing Act* (Act) and related regulations, which include requirements for meeting generally accepted standards of proficiency to help ensure that laboratory test results are accurate.

Licensing

Private and hospital laboratories and specimen-collection centres in Ontario must be licensed. Licences are renewed annually upon payment of specified fees and receipt of the licence application form, which is to include details on a laboratory's staff number, staff qualifications, and laboratory equipment. No new laboratory licences have been issued in the last 10 years—primarily, we were informed, due to ministry funding restrictions.

The Ministry reviews the licence application form and follows up on any significant changes that may have an impact on compliance with the Act. Under the Act, a licence may be revoked or its renewal refused if specimen collections or laboratory tests are incompetently carried out, or the owner/operator does not comply with the Act and related regulations. We examined the Ministry's licence renewal process and found that laboratory and specimen-collection centres were licensed on a timely basis and that, in accordance with the Act, the correct fees were paid to the Ministry.

Inspections and Accreditation

In September 2000, the Ministry contracted with the OMA to create and implement a mandatory medical laboratory accreditation program that

would assess and rate licensed laboratories in accordance with established criteria. The accreditation program that was developed is based on international standards and includes criteria for assessing laboratories on such matters as organization structure, quality-management system, physical facilities, equipment, and analytical process. The OMA began phasing in its accreditation program in 2003 and expected it to be fully implemented within five years.

As of October 31, 2004, 30 of the 236 laboratories had been accredited. Laboratories are generally to be accredited every five years. Once a laboratory is accredited, the Ministry will cease its regular laboratory inspections. However, we were informed that ministry inspectors will continue to inspect all specimen-collection centres and, if necessary, laboratories that are experiencing difficulties.

At the time of our audit, the Ministry was inspecting medical laboratories and specimen-collection centres that had yet to be accredited by the OMA's accreditation program about every 18 and 24 months, respectively, to ensure that these organizations are in compliance with the Act. We were informed that all ministry inspectors were members of the College of Medical Laboratory Technologists of Ontario. We reviewed a sample of inspections and found that inspections of specimen-collection centres were performed consistently and on a timely basis in accordance with the Ministry's established procedures. For laboratories, we noted that the Ministry's inspection process was performed on a timely basis but that the inspections to ensure compliance with the Act were not always consistently performed. For example:

- Legislation requires that laboratories have an adequate number of qualified staff to test samples. However, the Ministry has no criteria for determining what is adequate staffing and informed us that staffing standards existed for only one type of laboratory test. While all the inspections we reviewed indicated that staffing

was adequate, in some cases, a subsequent review by the OMA's quality-management program recommended that the laboratory hire additional staff to address deficiencies. The Ministry informed us that the OMA would be reviewing staffing as part of the accreditation process.

- Inspectors did not consistently determine each laboratory's turnaround time from the receipt of a sample to the reporting of the results to a physician. Some inspectors examined laboratory records to determine turnaround times, while other inspectors just asked laboratory staff and did not examine supporting documentation to verify that the verbal responses were accurate.
- Inspectors were not required to request and review the results of the laboratory's tests from the OMA's quality-management program to obtain information on any higher-risk areas. We did note that, while they were not required to do so, at least some inspectors had reviewed these results as part of their inspection process.

Following an inspection, the laboratory receives a report listing any deficiencies noted during the inspection. We found that laboratories generally reported their corrective action to the Ministry within ministry-established time frames. In addition, we noted that the deficiencies generally were not noted on a subsequent inspection.

External Quality Assessment

The Ministry receives an annual report from the OMA on the overall results of the OMA's quality-management program for laboratory services. According to its 2003 report, laboratory testing provides up to 80% of the information that physicians use to make medical decisions; therefore, it is important to determine the frequency of laboratory mistakes and the most effective way of minimizing their occurrence and impact. In addition, the *2004 Canadian Adverse Events Study*, by an interjurisdictional research group, found that a significant number of adverse events in hospitals (such as inju-

ries, deaths, and prolonged stays) were due to inadequate health-care management, which includes diagnostic errors like laboratory-related errors.

The OMA's quality-management program includes an External Quality Assessment program that sends out test specimens to licensed laboratories (for selected tests, which are determined each year). The OMA analyzes the results of laboratory analysis and provides the laboratory with information on its performance. In 2004, all licensed laboratories performing the tests that were subject to the OMA's quality assessment that year participated in this program.

Test results that do not meet accepted standards are evaluated by the External Quality Assessment program's scientific committees, which assess errors based on their clinical significance. Errors fall into two categories. "Significant errors" are those that have the potential to cause mistreatment or misdiagnosis, while "lesser errors" exceed acceptable limits but are unlikely to impact clinical decisions.

We noted that the Ministry did not request or receive the total errors for Ontario's licensed laboratories. In fact, the OMA's annual report to the Ministry contained only summary information on all of its quality-management activities, which included laboratories in other jurisdictions as well as Ontario. Nevertheless, the report indicated that approximately 97% of its quality testing related to licensed laboratories in Ontario. Results from the past three years are outlined in Figure 1.

Although laboratories are notified in advance that the test sample is part of the OMA's quality-management program (and this is consistent with other jurisdictions), laboratories are expected to test the sample in the same way as patients' samples. However, we believe that it is reasonable to assume that laboratories would test these samples with extra care. We were informed that the OMA considered the advanced warning necessary for a number of reasons, including ensuring that

its specimen samples did not cause laboratories to unnecessarily alarm public-health officials when they identified the results.

Notwithstanding the advance notice that laboratories are given, the OMA's annual report noted that errors still occur, and in 2004 the number of significant errors increased (see Figure 1). We were informed that this increase was due in part to a change in how significant errors were assessed in 2004 for one class of tests. However, even after adjusting for this change, significant errors still rose by 23% from 2003 to 2004. The OMA's annual report cited a number of reasons for errors, including a lack of awareness or understanding in the laboratory, problems associated with automated systems, a lack of attention to procedures, inadequate handling of samples, and clerical errors in transcribing results.

In cases where errors have occurred, the scientific committees request that the laboratory explain what caused the problem and what corrective action has been taken. Further communication with the laboratory or an on-site consultation may take place if a laboratory's performance does not improve. If these and other remedial steps still do not improve a laboratory's performance, the scientific committee may submit a report to the Conjoint Committee, which comprises ministry and OMA representatives. The Conjoint Committee can recommend to the Ministry that a laboratory be designated non-proficient for certain tests, which means that the laboratory will no longer be allowed to perform these tests. In 2003, one laboratory was made non-proficient in a particular class of tests, while no laboratories were made non-proficient in 2004.

The Ministry relies on the OMA's quality-management program to assess whether laboratories are providing accurate test results and, where they are not, to ensure that appropriate and timely corrective action occurs. In our *1995 Annual Report*, we recommended that the Ministry be advised as soon as possible of any laboratory that did not

Figure 1: Errors Identified by the OMA's Quality Management Program, 2002–04

Source of data: Quality Management Program – Laboratory Services annual reports

	2002	2003	2004
significant errors	519	515	825
lesser errors	859	467	310
Total errors	1,378	982	1,135
labs made non-proficient for certain tests	0	1	0

meet accepted standards, as well as of remedial action being taken by staff of the Laboratory Proficiency Testing Program—now the OMA's quality-management program for laboratory services.

At the time of our current audit, the Ministry did not receive information on the number of significant and lesser errors that had been identified for each licensed laboratory in Ontario and was therefore not aware when or which laboratories performed poorly. Rather, the Ministry was only being informed when the OMA sent the laboratory a letter regarding an on-site consultation or a letter of concern. We noted that this generally occurred after the laboratory had been experiencing problems for some time based on assessments by the External Quality Assessment program. Our review of files noted the following examples:

- From 2000 to 2001, one private laboratory had four significant and seven lesser errors for one class of laboratory proficiency tests. Three prior on-site consultations dating as far back as 1981 had been held at this laboratory concerning the same class of tests. A letter of concern was sent in December 2001, and another on-site consultation took place in April 2002, which indicated that the laboratory's error rate was the highest of all participating laboratories over the past two years. An additional on-site consultation was held, and in April 2003, the laboratory's licence was amended to exclude this class of tests, meaning that the laboratory could no longer perform or bill for these tests. The Ministry indicated that

the OMA's quality-management program for laboratory services had worked with the laboratory throughout to attempt to improve its performance. We further noted that the same laboratory also performed poorly on proficiency testing in other classes of tests from 1998 to 2003 and had related on-site consultations for one of these classes of tests in November 2002 and again in April 2004.

- Another laboratory received a letter of concern in 2001 and a letter regarding an on-site consultation in July 2002 due to practices for one class of tests that “may lead to erroneous or misleading reports being issued to the clinician and potentially compromising patient care.” Of further concern was that this laboratory was a regional hospital reference laboratory, which performs testing on samples for a number of hospitals and private laboratories in the region. In fact, we found that the Ministry had no evidence to show that the hospitals and laboratories involved were informed that they may have relied on inaccurate test results from the reference laboratory. In November 2002, the laboratory in question voluntarily ceased performing certain tests in this class of tests.

An on-site consultation generally results in recommendations to assist a laboratory in improving its performance. Laboratories report their corrective action to the OMA, which usually conducts a follow-up on-site consultation within one year to one and a half years. We reviewed the follow-up on-site consultation reports and noted that the majority of the laboratories had in fact not addressed all of the original recommendations in full, even though they reported that corrective action had been taken.

RECOMMENDATION

To help ensure that laboratories comply with the *Laboratory and Specimen Collection Centre Licensing Act* and can be relied upon to produce accurate test results, the Ministry should:

- enhance its oversight of the Ontario Medical Association's (OMA's) quality-management activities, including obtaining sufficient information on the results of the OMA's accreditation process, as well as significant and lesser errors found in laboratory test results and evidence that corrective action has been taken on a timely basis; and
- until such time as it ceases its regular inspections, conduct them consistently.

MINISTRY RESPONSE

The Ministry regularly receives copies of letters of concern and on-site reports from the Ontario Medical Association's (OMA's) quality-management program for laboratory services and is kept apprised of quality issues through the joint Ministry–OMA Conjoint Committee. According to recent data obtained from the OMA, while the number of significant errors has increased, in part due to a new method of tracking discrepancies, the percentage of significant errors assigned after review by the Quality Management Program—Laboratory Services' scientific committees has remained relatively constant (1.1% for all disciplines in 2003 and 1.2% in 2004).

The Ministry has recently requested the OMA to advise the Ministry on the resolution of all letters of concern along with the time frames for resolving the issues (from the identification of a concern to its resolution). In addition, the Ministry will review its oversight of the quality-management program for laboratory services,

including ensuring that the Ministry is receiving sufficient information, and will discuss possible enhancements with the OMA.

While individual inspectors have different information collection styles, ministry inspectors perform all aspects of their inspections. The Ministry will review the application of the checklists during inspections to ensure that they are applied consistently.

Monitoring of Physicians' Offices' Laboratories

As we noted at the time of our 1995 audit, under the *Laboratory and Specimen Collection Centre Licensing Act* (Act), physicians did not require a licence to collect specimens and conduct simple laboratory procedures for the purpose of diagnosing and treating their own patients (simple procedures are prescribed by regulation and include, for instance, immunologic pregnancy tests of urine and blood glucose determination). We also noted at that time that a regulation under the Act exempted physicians from the section that referred to simple procedures, thereby permitting physicians to perform *all* laboratory tests on their patients. At that time, the Ministry agreed that it should determine what laboratory procedures physicians could conduct for their own patients and resolve the inconsistency between the Act and its regulation. However, at the time of our current audit, this inconsistency still existed.

According to ministry records, for the 2003/04 fiscal year, the Ministry paid a total of \$30.8 million to over 750 physicians for laboratory tests for their patients. Of that amount, \$22.6 million (or about 75%) was paid for laboratory tests that were not listed as simple procedures. Besides the inconsistency between the Act and the regulation that allowed for these procedures and related billings, senior ministry management informed us that the

regulation listing simple procedures was outdated and that other procedures could be performed in physicians' offices. In this regard, in spring 2005, changes to the Act and related regulation were tabled that, if passed, would make the legislation and regulations consistent and permit physicians to conduct any type of laboratory procedure for their patients. In addition, physicians would also continue to be exempt from participating in ministry inspections or the OMA's quality-management program that other laboratories are subject to for the same tests.

We noted in our *1995 Audit Report* that the Ministry's Laboratory Service Review Committee had recommended in 1994 that laboratories and specimen-collection centres in physicians' offices be licensed to bring them under the quality-assurance provisions of inspection and proficiency testing. The Ministry agreed with this recommendation at that time, but we noted during our current audit that no action had been taken in this regard. Ministry staff informed us that physicians' offices' laboratories were still not subject to the quality-assurance provisions because they were under the jurisdiction of the College of Physicians and Surgeons of Ontario, but the College informed us that it does not monitor or regularly review physicians' offices' laboratories to assess the quality of testing performed.

We noted that in the United States, federal legislation requires that all physicians' offices participate in a quality-assurance program if they perform moderate or complex laboratory testing. Given the proposed changes in Ontario to resolve the legislative inconsistency and permit physicians to conduct any laboratory test in their offices, we believe that it is important to patient safety that the quality of this testing be periodically evaluated.

RECOMMENDATION

To help ensure that laboratory tests conducted in physicians' offices are properly performed and produce accurate results, the Ministry should assess whether the quality-assurance processes required for other medical laboratories should apply to laboratories operated by physicians.

MINISTRY RESPONSE

Whether laboratory tests are appropriate or necessary is a medical decision based on an authorized practitioner's clinical assessment of the patient. The Ministry will initiate further discussions with the College of Physicians and Surgeons of Ontario (CPSO) regarding the provisions within the *Laboratory and Specimen Collection Centre Licensing Act* and regulations that relate to physicians performing tests on their own patients to determine whether the Act and regulations need to be modified. It is the responsibility of the CPSO to monitor the physician's scope of practice. The Ministry will follow up with the CPSO on this matter.

Management and Reporting of Laboratory Tests

At the time of our audit, there was no central system in place to integrate and store laboratory test results for a patient, and thereby allow for test results to be accessible to all health-care providers and laboratory service providers. Rather, private laboratories, hospital laboratories, public-health laboratories, and other laboratories in Ontario were using different reporting systems and different methods of tracking and maintaining laboratory data.

The lack of an integrated system may lead to duplicate testing and delayed treatment for

patients. For example, when a patient has been admitted to hospital, the results of any laboratory tests performed prior to their being admitted generally would not be accessible by the hospital, and duplicate testing may have to be done by the hospital. While some repeat testing is necessary in the treatment and monitoring of patients, a 2003 research study in Eastern Ontario of eight laboratory tests found that potentially redundant duplicate tests constituted up to about 16% of annual expenditures. The 2003 BC Laboratory Services Review noted that studies from other jurisdictions have found test duplication rates as high as 30%.

We also noted that the Ministry did not periodically review or study, on an overall basis, whether laboratory tests that were conducted were necessary or appropriate. In our review of ministry files, we found that one laboratory's personnel expressed the concern that certain physicians tended to order an excessive number of tests or wide-ranging tests that did not appear necessary. The Ministry indicated to us that it did not review laboratory testing because it was a medical decision.

Notwithstanding, many research studies conducted in other jurisdictions have found that tests are often ordered inappropriately. In particular, one international study, which reviewed various other studies, estimated that 33% of laboratory tests were ordered inappropriately. In addition, it noted that following best-practice guidelines has been shown to significantly improve laboratory utilization in some jurisdictions, such as in British Columbia. We noted that the Ministry, in conjunction with other organizations, such as the OMA, has issued a few best-practice guidelines for physicians, and the Ministry informed us that another guideline was under development. However, the Ministry has not monitored the adoption or impact of these guidelines. We believe that the introduction of additional guidelines, especially for frequently performed tests, combined with education and periodic monitoring to encourage the adoption of

all guidelines, could result in significant savings to the Ministry.

The February 1994 report of the Ministry's Laboratory Service Review Committee outlined a number of recommendations, including the establishment of a centralized interactive database with electronic communications links for laboratory service requesters and providers. The Ministry is now developing the Ontario Laboratories Information System, which is expected to enable laboratory test information on individual patients to be accessed by all health-care and laboratory service providers directly involved with the patient. In addition, the system is expected to build a comprehensive information base to help manage and plan for laboratory service delivery, improve fiscal management of laboratory services, and provide timely utilization data to help develop best-practice guidelines for laboratory tests. The Ministry anticipates that this system will be operational in late 2005, will be fully implemented by April 2007, and will cost about \$84 million. We will follow up on the implementation of this system during our next audit of Health Laboratory Services.

Payments to Private Laboratories

In the early 1990s, the Ministry and the Ontario Association of Medical Laboratories negotiated an industry cap on laboratory funding to control the rising costs of private laboratory services. A cap was applied to the entire industry beginning in the 1993/94 fiscal year based on payments made to laboratories in the 1992/93 fiscal year. Further, caps on payments to individual laboratories were implemented in the 1996/97 fiscal year. Since then, negotiated increases have been applied to the caps to reflect additional costs, resulting from, for instance, an increase in laboratory tests being ordered. In the 2003/04 fiscal year, \$541 million was paid to private laboratories, with three companies receiving over 90% of these payments.

According to the 2003 BC Laboratory Services Review, the cost of providing laboratory tests has declined dramatically in the past 20 years due to improvements in laboratory technology. In addition, an inter-provincial comparison included in the review estimates that Ontario spent \$90.41 per capita on laboratory services in the 2001/02 fiscal year, while the Canadian average was \$77.49 per capita. Ontario had the second highest per-capita spending of all the provinces. For this study, data for hospitals, including those in Ontario, excluded overhead costs. While there may be some differences in the way jurisdictions reported their costs, Ontario's high cost per capita nevertheless highlights the need to evaluate the underlying cost of laboratory services.

The Ministry informed us that it did not know when the last comprehensive evaluation of the cost of laboratory services occurred, but stated that it was at least 10 years ago. Without sufficiently detailed information on the underlying costs of laboratory services, which may have significantly declined due to technological advances, the Ministry is unable to demonstrate that it is acquiring private laboratory services in an economical manner.

The Ministry pays private laboratories on a monthly basis for tests performed and specimens collected based on billings submitted to the Ontario Health Insurance Program (OHIP) and within the limits dictated by the laboratories' payment caps. As a condition of payment, each laboratory enters into a verification agreement with the Ministry, which allows the Ministry to examine laboratory records to ensure that laboratory services were actually performed, were authorized by a medical practitioner, and were billed correctly. The Ministry can recover any overpayments that occurred before the 1996/97 fiscal year. Subsequent to that date, any incorrect billings to OHIP—where a laboratory has overbilled for services—can only be recovered if the amount in error is greater than the difference

between the total amount billed and the payment cap.

The Ministry has found billing errors, including laboratory tests that were billed without evidence that the test was either requested or performed. However, no recoveries have been made subsequent to the 1996/97 fiscal year, which is consistent with the verification agreement, because the errors found in the ministry reviews have amounted, on a yearly basis, to less than the difference between the laboratory's total billings and its payment cap.

RECOMMENDATION

To help ensure that private laboratory services are acquired in an economical manner, the Ministry should periodically determine the actual cost of providing these services and utilize this information when negotiating payments for laboratory services.

MINISTRY RESPONSE

The Ministry uses a variety of approaches to ensure that the funding agreement for private laboratory services provides both productivity improvements and value for money. These approaches include a review of the level of payments and an analysis of factors (such as population growth) that contribute to increased testing being performed by private laboratories. As well, the cost of performing roughly the same types and total overall number of tests in hospitals is used as a benchmark.

The Ministry notes that the estimated Canadian average cost per capita as reported is based on data from several provinces that exclude overhead expenditures from their costing, while Ontario's estimate includes overhead for private laboratories. This inconsistency in data collection understates the estimated average cost per capita and makes inter-provincial comparisons difficult.

The Ministry recognizes that an actual costing of laboratory services has not been conducted recently and would add an additional element of certainty to the assessment of the resources required.

WELL-WATER TESTING

The Ministry operates the province's 12 public-health laboratories, which, among other things, test well-water samples submitted by individuals in Ontario. In 2004, all of these public-health laboratories were accredited by the Standards Council of Canada based on recommendations resulting from the Canadian Association of Environmental Analytical Laboratories' assessments. The accreditation process included ensuring that certain technical requirements are met. These requirements cover such areas as quality control, testing and method validation, and management requirements like organizational structure and document controls.

There are about 500,000 private wells in Ontario. Private well owners in Ontario are responsible for maintaining the quality of their own water. According to ministry staff, the most common problem with well water is contamination from pathogens. Pathogens are organisms that can make people sick and include certain forms of bacteria (for example, *E. coli*), protozoa (tiny parasites), and viruses (for example, Norwalk). Each of these organisms can lead to different illnesses, some of which are very serious. Common symptoms of exposure to pathogens generally include diarrhea, nausea, abdominal cramps, and low-grade fevers.

To help ensure that well water is free of pathogens, individuals may submit samples of their well water for testing at the Ministry's public-health laboratories. This testing is provided free of charge and is usually completed within three days. All well-water test results are posted on the Ministry's interactive voice response system, which allows

individuals to obtain their results by phoning in. In addition, individuals may choose to pick up their test results report or have it sent to them through the mail. According to ministry staff, public-health officials phone individuals whose water is found unsafe to drink. In addition, we were informed that public-health officials determine whether to notify neighbouring well owners if problems are detected in a water sample tested.

In 2004, the Ministry hired a consultant whose work included determining what it was costing the Ministry for each well-water test. Based on information in the consultant's report, we estimated that the Ministry spent about \$3.7 million testing about 290,000 well-water samples, or about \$13 per test.

Test Results Reporting

As shown in Figure 2, when a public-health laboratory tests well water for pathogens, the results are reported to the submitter as either:

- No significant evidence of bacterial contamination;
- Significant evidence of bacterial contamination. May be unsafe to drink; or
- Unsafe to drink. Evidence of sewage contamination.

The Ministry only tests well water for bacterial contamination, and although a well-water sample may not have evidence of such contaminants, the water may still be unsafe to drink due to chemical or other contamination (for instance, nitrates found in fertilizers). A 1992 study of 1,300 Ontario farm wells that was sponsored by the federal Department of Agriculture and Agri-Food Canada in partnership with the Ontario ministries of the Environment and Agriculture and Food indicated that about 15% of the wells tested contained nitrates in concentrations above the provincial drinking-water standards that existed at that time. In this regard, we noted that the Ministry's one-page report to well owners on the results of a well-water test does not advise

Figure 2: Interpretation Section of Ministry's Form for Bacteriological Analysis of Citizens' Drinking Water, Identifying Three Possible Results

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

For Laboratory Use Only/Réservé à l'usage du laboratoire
Interpretation for this water sample/Interprétation de cet échantillon d'eau
 This water sample was only tested for the presence of both Total Coliform and *E.coli* bacterial indicators of contamination, by Membrane Filtration. / Cet échantillon d'eau n'a été analysé que pour déceler la présence des coliformes totaux et des bactéries colibacillaires, indicateurs de contamination par filtration sur membrane.

NO SIGNIFICANT EVIDENCE OF BACTERIAL CONTAMINATION
 3 consecutive samples, taken 1 to 3 weeks apart, with this designation are needed to determine the stability of the water supply).
AUCUNE PREUVE DE CONTAMINATION BACTÉRIENNE SIGNIFICATIVE
 (cette désignation doit être affectée à 3 échantillons consécutifs, dont le prélèvement aura été espacé de 1 à 3 semaines, pour que la source d'approvisionnement en eau soit jugée stable).

SIGNIFICANT EVIDENCE OF BACTERIAL CONTAMINATION May be unsafe to drink. (Consult local health unit for information as soon as possible).
PREUVE DE CONTAMINATION BACTÉRIENNE SIGNIFICATIVE
 Peut être non potable. (Consultez le bureau de santé local le plus tôt possible pour plus de détails).

UNSAFE TO DRINK Evidence of sewage contamination. Consult local health unit for appropriate action as soon as possible.
EAU NON POTABLE Preuve de contamination par les égouts. Consultez le bureau de santé local le plus tôt possible pour de plus amples renseignements sur les mesures à prendre.

Date Reported Stamp/
Date du rapport

the well owner that the water was not tested for chemical and other contaminants that may affect water quality, nor where the well owner can have such tests performed. We believe that there is a risk that individuals may assume that their water is safe to drink, when in fact it may not be. Since the form includes the category “unsafe to drink,” individuals may incorrectly assume that the reverse is true when notified that their water contains “no significant evidence of bacterial contamination.”

RECOMMENDATION

To help ensure that individuals are aware of all potential contaminants in their well water, the Ministry should:

- indicate that the water was not tested for other contaminants, including chemical contaminants, and therefore may be unsafe to drink even when there is no significant evidence of bacterial contamination; and
- indicate on the test results report where individuals can obtain information on having their water tested for other contaminants.

MINISTRY RESPONSE

Although the Ministry believes that the current instructions in the private-water test-collection kit and the wording of the final test report clearly state that the tests performed only relate to the presence of bacterial contamination, the Ministry will review the current information supplied with the test kit to determine if it is necessary to add an additional statement to the report advising well owners to consult their local health units if they have concerns about possible chemical contamination of their well.

Rejection of Test Samples

To have their well water tested, individuals must complete a form to accompany the well-water samples they are submitting. The form includes instructions on how to collect and submit the water samples, as well as a section the submitter must complete with basic information such as name and address, location of the water’s source, and a day-time telephone number. The form specifies that all required information must be completed in full or the laboratory will not test the sample.

In 2004, the Ministry rejected about 4% or 11,900 of the well-water samples submitted because the form was not completed in full by the submitter. Water samples would not be tested if, for example, the form was missing a submitter’s telephone number or postal code. Ministry management informed us that they were concerned about increasing the Ministry’s exposure to liability in cases where they test well water, find it unsafe to drink, and cannot readily notify the sample’s submitter. Therefore, the Ministry does not test well-water samples if the form is missing any information.

Nevertheless, the Ministry mails notices to submitters that indicate their water sample cannot be tested due to the form missing a postal code, and doing so involves the Ministry looking up the postal code in order to send the notice. Furthermore, we were informed that the Ministry would test a water sample if the submitter indicated on the form that they did not have a telephone.

Given that submitters can access their results by phone, we question the practice of rejecting samples with missing telephone numbers or postal codes. Furthermore, the delays stemming from this practice could result in people drinking unsafe water until another sample, with complete information, is submitted for testing. In fact, we noted one incident where a well-water sample was rejected due to a missing postal code, and the subsequent submission of a new sample revealed that the water contained significant evidence of bacterial contamination.

RECOMMENDATION

To better assist Ontarians in the timely identification of well water that is unsafe to drink, the Ministry should re-examine its policy of rejecting and not testing water samples due to missing postal codes and/or telephone numbers.

MINISTRY RESPONSE

Ministry staff work to ensure that the important services provided for private well-water testing are done accurately and efficiently to protect public health. An important component of the testing and reporting process involves staff having accurate information that will allow them to quickly notify submitters of adverse test results and to track and follow up with local health units and others where needed.

To fulfill these obligations, submitters, who are best placed to know their own personal information and private well location, are asked to do their part by following proper water collection procedures and completing the water requisition form accurately and completely, in accordance with the form's instructions. It clearly states that if appropriate sampling procedures are not followed or if required information is not completed on the form, the sample will not be tested.

The Ministry has reviewed its policy on acceptance of private well-water samples, including the acceptance of forms with missing or incomplete postal codes and/or telephone numbers, and concluded that the current policy of not accepting these samples supports public health. However, in an effort to raise awareness of samples that will be rejected, the Ministry will produce an information sheet to be included in the Private Citizen Drinking Water kit outlining the Ministry's acceptance criteria with the goal of reducing rejection rates.