



# Playing a critical role in patient safety

The Quality Management Program—Laboratory Services performs proficiency testing on all licensed medical laboratories in Ontario, as well as accredits them using the ISO 15189 standard. The program uses the principles of quality management to ensure that the laboratory results used to make diagnosis and prognosis are reliable. These services are also available throughout Canada and internationally.

## Table of Contents

|    |                                                |    |                                                  |
|----|------------------------------------------------|----|--------------------------------------------------|
| 4  | Vision, Mission, Value                         | 22 | Ontario Laboratory Accreditation Report          |
| 5  | QMP–LS Overview                                | 31 | Knowledge Transfer & Business Development Report |
| 6  | Message from the Managing Director             | 33 | Corporate Services Report                        |
| 8  | Error-Proof Systems                            | 35 | Quality Management System Report                 |
| 9  | Helping Set Standards                          | 37 | Appendix A: Committee Membership                 |
| 10 | External Quality Assessment                    | 40 | Appendix B: QMP–LS Volunteers                    |
| 12 | Ontario Laboratory Accreditation               | 42 | Appendix C: QMP–LS Staff                         |
| 14 | Institute for Quality Management in Healthcare | 43 | Appendix D: Parameters Monitored                 |
| 16 | External Quality Assessment Report             | 46 | Appendix E: Publications and Education           |



Building quality management into Ontario's healthcare system for over 30 years.



## Vision

To be a world-class provider of accreditation, quality assessment and supports to laboratories and related services for diagnosis and treatment of disease, and the promotion of health.

## Mission

To promote quality improvement of laboratories and other related services for the public good and the benefit of health professionals.

## Values

Quality  
Collaboration  
Integrity



**Q**MP-LS is dedicated to enhancing the quality of laboratories and other healthcare organizations through ISO 15189-based accreditation services, proficiency testing programs, guideline development, education and innovation. With over 30 years of experience in designing quality assurance programs for healthcare, QMP-LS has a long-standing tradition of excellence in quality management. QMP-LS is a division of the Ontario Medical Association (OMA) and is a mandatory program for licensed laboratories in Ontario that is funded by the Ministry of Health and Long-Term Care (MOHLTC).



**Dr. Gregory Flynn**

## Message from Managing Director

**Q**MP-LS has been guided over the past two years by a strategic plan that was approved in the fall of 2007. The plan rested on two strategic objectives. First, we were committed then and still committed now to improving our core services to Ontario laboratories in our role as the Ontario Medical Association's department providing a quality management program to Ontario's licensed laboratories. The second strategic objective has been to extend the expertise we have in quality management beyond Ontario's licensed labs in order to promote the use of a quality systems approach in other areas of healthcare.

In this annual review, the directors of the four operating divisions detail the activities QMP-LS has undertaken and highlight the improvements we have made in the last year. Both the Ontario Laboratory Accreditation (OLA) and External Quality Assessment (EQA) divisions continue to undergo internal audits against the relevant international standards for proficiency testing organizations and conformity assessment.

The Knowledge Transfer and Business Development division is working hard to develop programs and products that help laboratories, physicians and patients get the very best information about laboratory testing. The Corporate Services division works effectively with all the operating divisions

QMP-LS has achieved its vision of becoming a world-class provider of quality management services, thanks to the hard work, integrity and support of many members of the laboratory profession in Ontario.

to deliver functional assistance to our clients and stakeholders, making the use of our programs easier and more valuable.

To the second objective, as much by necessity as by design, we have laid the foundation for the expansion of the OMA's involvement in quality management.



This year, the OMA Board approved the incorporation of the Institute for Quality Management in Healthcare (IQMH). This not-for-profit corporation will provide the corporate structure that will allow the organization to spread its wings beyond the licensed laboratories in Ontario, while protecting the investments the Ministry of Health and Long-Term Care has made in developing our approach to the quality management of Ontario's licensed laboratories. The EQA division has offered selected programs outside of Ontario for many years, and currently we are promoting a number of programs for national participation. OLA also accredits other labs and has made proposals to assist other jurisdictions implement laboratory accreditation to the ISO 15189 standard and together both divisions are providing input into enhancements to the overall approach to pathology, molecular diagnostics and proficiency testing beyond Ontario's licensed laboratories.

Finally after languishing without sufficient resources for some years, the educational and knowledge transfer efforts of the organization are being reinvigorated. Using the power of the Internet and advanced, interactive online educational tools, QMP-LS is taking its current knowledge and

packaging it in ways that are convenient for users worldwide in order to share the expertise that our laboratory professionals in Ontario have helped to build. The same community of experts that has helped set our organization apart is also bringing its expertise to the table in order to help

The same community of experts that has helped set our organization apart is also bringing its expertise to the table in order to help us develop new, pragmatic testing guidelines that are evidence-based and endorsed by experts in the field.

us develop new, pragmatic testing guidelines that are evidence-based and endorsed by experts in the field.

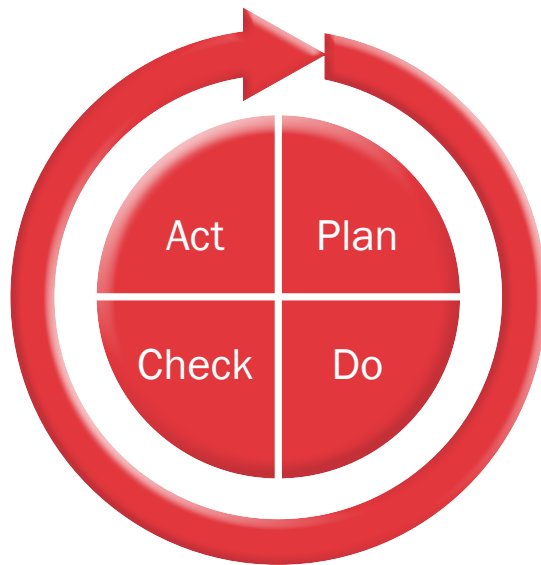
QMP-LS has achieved its vision of becoming a world-class provider of quality management services, thanks to the hard work, integrity and support of many members of the laboratory profession in Ontario. And now that the program is available through IQMH, we can share our success with other organizations seeking that same knowledge.

# Providing tool kits to make error-proof healthcare systems

QMP-LS helps medical labs implement quality management systems and improve the quality of test results that patients and physicians count on.

QMP-LS helps:

- ✓ Identify best practice standards for laboratory processes
- ✓ Educate laboratories on new standards
- ✓ Regularly reassess laboratory practices
- ✓ Conduct comprehensive proficiency testing to assess reliability
- ✓ Build a community through collaboration with laboratory professionals and management
- ✓ Assist labs in performing root cause analysis and corrective action guidance for discordant findings
- ✓ Perform risk assessments of results that may negatively impact patient care



## Quality Management Systems

Management commitment  
Resource allocation  
Document control  
Inventory control  
Quality control and quality assurance  
Training and assessment  
Internal audits  
Management reviews  
Occurrence management



## Helping Set Standards

QMP-LS contributes to the development of international standards and guidelines and sits on a number of standards and industry organizations dedicated to improving the standards of quality in medical laboratories.



### International Organization for Standardization Technical Committee and Working Group on ISO 15189

The technical committee and working group helped write the ISO 15189 standard which provides medical laboratories with a framework for quality management systems.



### SCC Medical Laboratory Working Group, Partner Advisory Group and Technical Group on Laboratories

The Standards Council of Canada facilitates the development and use of national and international standards to enhance Canada's competitiveness and social well-being.



### Clinical and Laboratory Standards Institute Subcommittee on Development and Use of Quality Indicators

The subcommittee is developing guidelines for the development of quality indicators and their use in medical laboratories.



### Canadian Coalition for Quality in Laboratory Medicine

CCQLM's mission is to provide a national structure to support provincial activities in medical laboratory quality management and to promote collaboration.



### Canadian Association for Laboratory Accreditation

CALA is a non-profit accreditation body and provider of proficiency testing and training services dedicated to raising the level of competency, consistency, capability and communication in environmental testing laboratories in Canada.



### International Laboratory Accreditation Cooperation

ILAC's goal is to promote the use and acceptance of results from accredited laboratories and inspection bodies, including results from laboratories in other countries, as well as to laboratory and inspection accreditation practices.



### ISO CASC Working Group 28 on ISO 17043

This working group is developing the new ISO 17043 standard which provides quality management system and technical requirements for proficiency testing providers.



## Improving the reliability of your test results

### External Quality Assessment

The External Quality Assessment division improves the quality of laboratory services through the assessment of laboratory test performance and education. EQA evaluates analytical processes using challenge surveys with fresh and simulated patient samples, while patterns-of-practice surveys and questionnaires address pre- and post-analytical issues. Laboratory results are peer reviewed and examined for reliability.

EQA ensures that the test results physicians use to make diagnosis and prognosis are accurate and reliable. Inter-laboratory test comparison is not the sole function or outcome of EQA. It also demonstrates comparison of different methods and instruments for the same test, reveals state-of-the-art practice, facilitates the recommendation of selected methods and assesses standards of participant performance. Unsatisfactory performance in EQA by a single lab may indicate the need for assistance and retraining. Unsatisfactory performance by several labs using the same method may indicate problems with the method or kit. EQA helps manufacturers as well as labs.

Education is also an important component of the EQA program. Along with detailed survey reports, QMP-LS produces educational committee comments, broadsheets (review articles) and best practice guidelines, all crafted to facilitate performance improvement.

- |                      |                            |                |                         |
|----------------------|----------------------------|----------------|-------------------------|
| ✓ Anatomic Pathology | ✓ Cytogenetics             | ✓ Bacteriology | ✓ Transfusion medicine  |
| ✓ Chemistry          | ✓ Hematology               | ✓ Parasitology | ✓ Virology              |
| ✓ Cytology           | ✓ Immunology               | ✓ Mycology     | ✓ Point-of-care testing |
| ✓ Endocrinology      | ✓ Maternal serum screening |                |                         |



## External Quality Assessment

### Practical

Assessments use real patient material where possible to assess routine practice. EQA provides undisclosed actual or simulated patient material along with patient history.

### Peer-based

Assessments are performed by peer-based committees consisting of laboratory physicians, scientists and technologists who are experts in their field. EQA has 12 volunteer scientific committees covering all of the major disciplines of laboratory medicine.

### Transparent

Challenge surveys test the proficiency of a laboratory's analytical processes. Assessments are transparent, objective and capable of distinguishing good and poor performance.

### Essential

EQA ensures that lab tests are accurate and works with labs that receive discordant findings to perform root cause analysis. Labs that cannot improve their performance receive further assistance through on-site reviews in which experts assess all facets of testing and provide recommendations for implementation. Those unable to implement corrective action may be considered non-proficient and referred to the MOHLTC for further remedial action that may ultimately include suspension of testing.

112

Surveys performed annually by EQA for a variety of disciplines

210

Approximate number of tests assessed annually by EQA

12

Scientific committees consisting of physicians, PhDs and technologists who are leaders in their chosen fields



Reaching new heights of excellence

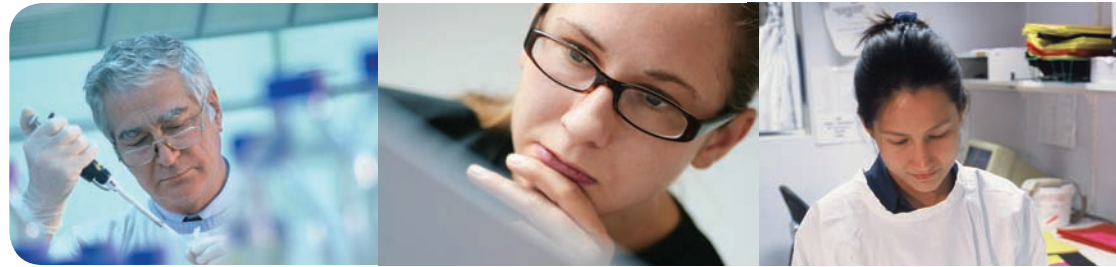
## Ontario Laboratory Accreditation

The Ontario Laboratory Accreditation (OLA) program provides formal recognition of the competence of a laboratory to perform its scope of testing. It also provides medical laboratories with the tools they need to standardize their processes, address diminishing resources and set a quality benchmark. OLA 15189Plus™ accreditation requirements are based on ISO 15189 and are augmented with international standards for safety and point-of-care testing, national standards for blood safety, government regulation and generally accepted principles of good practice.

As a partner of Standards Council of Canada, OLA can help laboratories receive an internationally recognized ISO 15189 certificate. OLA's peer-based, in-depth accreditation process helps laboratories understand ISO 15189 requirements, engage staff, implement best practices and promote patient safety. To achieve this, a laboratory undergoes an accreditation assessment visit conducted by a team of peers comprised of both quality system and technical experts carefully tailored to the scope of testing of the laboratory. If areas of non-conformance are cited, the laboratory is expected to take corrective action within 90 days of the visit. A panel determines if the laboratory meets the criteria for an accreditation certificate of either two or four years. Ongoing surveillance that includes a self-assessment mid-cycle, monitoring of proficiency testing/external quality assessment and changes within the laboratory ensures continued competency between assessment visits.

These rigorous standards provide the basis for our OLA 15189 Plus™ accreditation:

- ✓ ISO 15189:2007(E) *Medical laboratories—particular requirements for quality and competence*
- ✓ ISO 22870:2006(E) *Point-of-Care Testing (POCT)—requirements for quality and competence*
- ✓ ISO 15190:2003(E) *Medical laboratories—requirements for safety*
- ✓ CSA Z902-04 *Blood and Blood Components March 2004*



## Ontario Laboratory Accreditation

### Pursuing excellence

Mandatory accreditation in Ontario has guaranteed that every medical lab in the province has a world-class quality management system. Each accredited lab has a solid quality base on which to implement further improvements to eliminate waste, address diminishing resources and improve patient safety. A laboratory's accreditation certificate provides recognition that the lab's work is important and gives staff and the public confidence that the system will catch mistakes before they affect patient care. Along the way, the process has provided new venues for career advancement in laboratory medicine and pride in the profession by empowering and involving all lab professionals.

### Upholding values

Assessments are carried out by medical laboratory professionals trained and certified by QMP-LS using ILAC guidelines. Assessors understand and share the challenges that labs face on a day-to-day basis. OLA is committed to upholding the following values in the delivery of the accreditation program:

- ✓ Responsible
- ✓ Objective
- ✓ Consistent
- ✓ Transparent
- ✓ Open-Minded
- ✓ Respectful

229

Labs accredited by OLA

513

Number of OLA  
accreditation requirements

93%

Percent of labs describing  
the OLA accreditation  
process as beneficial



**T**he Institute for Quality Management in Healthcare (IQMH) helps healthcare organizations improve the healthcare services they deliver. Whether they require proficiency testing, accreditation services, need to develop new best practice guidelines or want to broaden their knowledge, IQMH can help organizations reach new heights of excellence. As a partner of QMP-LS, IQMH has 30 years of experience in quality management behind it.



# Tap into the power of quality management

## Medical Laboratory Proficiency Testing

IQMH provides organizations with access to QMP-LS' comprehensive quality assessment programs which are designed to promote optimal patient care and test reliability and performance improvement through the use of authentic clinical material, comprehensive reports and interactive educational feedback.

## Laboratory 15189 Accreditation

OLA 15189Plus™ provides medical laboratories with the tools to standardize their processes, address diminishing resources and set a quality benchmark. As a partner with the Standards Council of Canada, QMP-LS can help organizations receive an internationally-recognized ISO 15189 certificate.

## Guideline Development

IQMH helps healthcare organizations develop guidelines for best practices in order to ensure they are adhering to the principles of quality management. Through a survey of current practices around the world, focus groups with stakeholders and consultation with a panel of experts, IQMH helps organizations set a new standard for excellence.

## Decoding ISO 15189™

Becoming a world-class lab doesn't have to be complicated. IQMH's online interactive educational series helps medical laboratories implement the internationally-recognized ISO 15189 standard. Fifteen interactive modules help labs decipher ISO 15189 requirements, understand quality management systems, and measure, analyze and improve performance.



Play demo

# External Quality Assessment

## Introduction

There was a significant amount of activity associated with the External Quality Assessment division of QMP-LS during 2008–9, as we implemented the work developed in previous years. The three major projects outlined in 2007–8 were implemented for the majority of disciplines:

- ✓ Alignment of QMP-LS EQA surveys with international standards
- ✓ Use of information systems applications to create lean EQA operations
- ✓ Development of improved EQA information for participants

## Performance Highlights

### Aligning EQA Surveys with International Standards

There are two current international guidelines that address activities associated with EQA:

- ✓ ISO/IEC 43-1 (1997). *Proficiency testing by inter-laboratory comparisons—Part 1: Development and operation of proficiency testing schemes*
- ✓ ILAC G13:2007. *ILAC Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes*

An ISO standard is under development and is based on the above standards:

- ✓ ISO/IEC 17043 2008. *Conformity Assessment—General requirements for proficiency testing*

This document is now in final draft format (FDIS). Once it is an approved standard, it will replace the former two documents. During the past few years, QMP-LS has been striving to align all of its processes with these three documents. During 2008–9, the following were accomplished in achieving alignment with these standards:

- ✓ Implementation of performance scores for quantitative and qualitative EQA surveys
- ✓ Standardization and revision of processes and procedures for all discipline surveys
- ✓ Second internal audit of the program against ILAC G13:2007

### Use of Information Systems Applications to Create Lean EQA Operations

During 2008–9, QMP-LS implemented the new information processes developed in 2007–8 to address inefficiencies. These included the use of:

- ✓ A web-based data entry system for EQA survey responses
- ✓ Computer-assisted performance scores
- ✓ A web-based data entry system for discordant finding investigations

These new processes were implemented for all but a handful of surveys by the end of 2008–9.

### Development of Improved EQA Information for Participants

The introduction of performance scores facilitates provision of prompt information to participants regarding survey-related need for investigation and/or implementation of corrective action. This is included in the following reports:

- ✓ Individual survey reports that include scores and notification of need for investigation
- ✓ Cumulative survey reports that track performance over time and provide a one-page summary of performance for management and supervisory personnel

### Introduction of Changes to EQA Programs

QMP-LS now has the ability to provide webinars and webcasts to its participants in order to facilitate education and information exchange. Webinars and webcasts were used in 2008–9 to introduce changes in the EQA programs to participants. The following webinars were presented:

- ✓ Performance Scores (Q Scores) for Bacteriology Surveys
- ✓ Performance Scores (Q Scores) for Morphology and Red Cell Disorders Surveys

In addition, the following supporting articles were published in the QMP-LS newsletter:

- ✓ Performance Scores for Quantitative Chemistry and Hematology EQA Surveys (April 2008)
- ✓ Performance Scores for Qualitative Chemistry and Hematology EQA Surveys (August 2008)

### EQA Core Activities

#### Provision of EQA Services to Ontario Medical Laboratories

Provision of EQA services to Ontario medical laboratories is the primary objective of the EQA division. In 2008–9, QMP-LS provided 104 challenge surveys, four web-based educational surveys, one patterns-of-practice survey and three questionnaires. The scope of EQA surveys provided is shown in Table 1.

The parameters monitored by the surveys are listed by discipline in Appendix D. The number and type of laboratory participants are shown in Table 2.

#### QMP-LS Scientific Committees and Volunteers

Twelve scientific committees provide advice and support to the EQA program. In 2008–9, QMP-LS hosted a total of 43 scientific committee meetings involving 60 laboratory physicians, scientists and medical laboratory technologists. The names of committee members are listed in Appendix A and other volunteers are listed in Appendix B. As representatives of the Ontario laboratory community, scientific committee members provide advice to QMP-LS regarding the fundamental design of EQA surveys and ensure clinically relevant selection of challenges and appropriate performance evaluation. As always, QMP-LS is extremely grateful for the commitment and support of Ontario laboratory professionals and wishes to thank all of those individuals who donate so much of their valuable time and expertise to the program.

### EQA Survey Highlights

Information regarding 2008–9 EQA survey activity is well described in the survey reports and Committee Comments, available through QMP-LS' password-protected document server, QView™.

Table 1: EQA Surveys of Ontario

| EQA Surveys of Ontario—Fiscal 2008–9 |            |          |                      |               |
|--------------------------------------|------------|----------|----------------------|---------------|
| Survey                               | Challenge  | Dry      | Patterns of Practice | Questionnaire |
| Bacteriology                         | 4          |          |                      | 1             |
| Acid Fast Stain                      | 2          |          |                      |               |
| <i>C. difficile</i> Assay            | 2          |          |                      |               |
| Routine Chemistry                    | 11         |          |                      |               |
| Drugs                                | 6          |          |                      |               |
| Enzymes                              | 4          |          |                      |               |
| Lipids                               | 3          |          |                      |               |
| Blood Gases                          | 2          |          |                      |               |
| Cytogenetics                         | 2          |          |                      |               |
| Cytology                             | 2          |          | 1                    |               |
| Routine Hematology                   | 7          | 1        |                      |               |
| Coagulation                          | 10         |          |                      | 1             |
| Red Cell Disorders                   | 4          | 1        |                      |               |
| Morphology                           | 3          | 1        |                      |               |
| Bone Marrow                          | 2          | 1        |                      |               |
| Flow Cytometry                       | 6          |          |                      |               |
| Endocrinology                        | 3          |          |                      |               |
| Immunology                           | 3          |          |                      |               |
| Transfusion Medicine                 | 6          |          |                      |               |
| Virology                             | 10         |          |                      |               |
| Mycology                             | 2          |          |                      | 1             |
| Intestinal Parasites                 | 2          |          |                      |               |
| Histotechnology                      | 6          |          |                      |               |
| Glucometers                          | 2          |          |                      |               |
| <b>Total</b>                         | <b>104</b> | <b>4</b> | <b>1</b>             | <b>3</b>      |

Table 2: Comparison of Types of Ontario

## Laboratories Participating in QMP–LS EQA Surveys

| Comparison of Types of Ontario Laboratories Participating in QMP–LS EQA Surveys |            |            |            |            |            |            |            |
|---------------------------------------------------------------------------------|------------|------------|------------|------------|------------|------------|------------|
| Type                                                                            | 2002       | 2003       | 2004       | 2005       | 2006       | 2007       | 2008       |
| Community Laboratories                                                          | 54         | 47         | 44         | 40         | 34         | 34         | 32         |
| Hospital laboratories                                                           | 182        | 180        | 182        | 182        | 179        | 178        | 175        |
| Public health laboratories                                                      | 12         | 12         | 12         | 12         | 12         | 12         | 12         |
| Psychiatric                                                                     | 0          | 0          | 1          | 1          | 1          | 1          | 0          |
| Canadian Blood Services                                                         | 6          | 6          | 6          | 5          | 2          | 2          | 0          |
| Federal Government                                                              | 1          | 1          | 1          | 1          | 1          | 1          | 0          |
| Other                                                                           | 2          | 2          | 1          | 1          | 2          | 1          | 5          |
| <b>Total</b>                                                                    | <b>257</b> | <b>248</b> | <b>247</b> | <b>242</b> | <b>231</b> | <b>228</b> | <b>224</b> |

### Introduction of Immunohistochemistry Surveys for Predictive Breast Tumour Markers

Various national guidelines for the screening of tumour markers in breast cancer, including Canada, unanimously recommend the participation of labs in an external quality assessment program to confirm acceptability of laboratory performance. Until this year, QMP–LS had previously offered surveys for estrogen receptor (ER), but there was no program available to assess progesterone receptor (PR) or Her2/*neu*. To fill this gap, QMP–LS introduced surveys to assess all three markers simultaneously. These surveys utilized macro-arrays of tissue with different levels of expression for ER and PR and cell blocks with different levels of expression for Her2/*neu*. Unstained material was provided to Ontario labs for staining. The stained slides were scored against predetermined criteria by trained assessors. One pilot survey and three challenge surveys were conducted during 2008–9. Overall, Ontario laboratories performed very well in these surveys.

**Patterns-of-Practice Surveys**

Results of the following patterns-of-practice survey were reported as Committee Comments:

- ✓ Status of Practice in Cytology

**Questionnaires**

The following three questionnaires were conducted:

- ✓ Antimicrobial Resistance in Common Hospital Pathogens in Ontario
- ✓ Clinical Relevance of Mycology Nomenclature Reported by Laboratories
- ✓ Platelet Function

**Reports to Participants**

Reports provided to participants include provisional reports of the assigned values (consensus or reference values), summary information of all participant responses as well as reports of individual laboratory performance. In addition, the scientific committees provide educational feedback in the form of Committee Comments, BROADSHEETS and Practice Guidelines. During 2008–9, the following were provided to participants:

- ✓ 103 provisional reports
- ✓ 115 general survey reports
- ✓ 116 Committee Comments
- ✓ 2 supplementary Committee Comments
- ✓ 4 broadsheets were introduced or updated this year

- The new broadsheets published are:

- Laboratory Water
- Body Fluid Cell Counts and Differential Analysis

- The broadsheets that were updated during 2008–9 are:

- Quality Control Target Levels in Chemistry
- Precision Goals in Endocrinology and Immunology

- ✓ 5 guidelines were updated during 2008–9. They include:

- Reporting Antimicrobial Susceptibility Results on Bacteriology Specimens
- Routine Processing and Reporting of Cerebrospinal Fluid Specimens
- Routine Processing and Reporting of Female Genital Specimens
- Standards of Practice Guidelines for Gynecologic and Non-Gynecologic Cytology
- Reporting Enteric Parasitology Specimens

**Laboratory Performance**

During 2008–9, performance scores were introduced and so performance evaluation of participant performance was evaluated through a combination of error assignment and performance scores. In addition, since the use of web-based discordant findings forms was introduced following the introduction of performance scores, notification to laboratories of the

need for investigation was a combination of committee correspondence (for errors) and survey reports (for performance scores). In either case, laboratories were required to complete the discordant findings form and provide feedback on the cause and corrective action. Unacceptable or incomplete participant responses prompt further communication, continued monitoring of performance and/or an offer of an on-site review.

Four on-site reviews were conducted during 2008. No laboratory was declared non-proficient.

### **Investigation of Discordant Findings**

Participants that report discordant results in EQA surveys are requested to investigate and report a summary of the investigation and corrective actions to QMP-LS. The overall discordance rate for the 12-month period between April 2008 and March 2009 for the Chemistry, Hematology and Microbiology disciplines was 1.2%. Summary information for causes of discordances is included in Figure 1.

The most common categories of discordance were associated with method-related issues (36%) and technological causes (29%). Key method-related contributing causes were associated with accuracy and precision of automated systems and kit methods, and use of inadequate or out-dated procedures or reporting protocols. Key technological contributing causes included failure to follow written procedures or survey instructions, incorrect instrument calibration, sample handling issues and failure to correctly interpret results. For more detailed discussions regarding causes of discordant findings, see the discipline-specific supplementary Committee Comments on QView™.

### **Services to Other Jurisdictions**

In addition to the services QMP-LS provides to Ontario laboratories, we offer EQA services to other jurisdictions on a cost-recovery basis. The surveys

most commonly provided are listed in Table 3. In 2008, QMP-LS developed and introduced an EQA Program for Point-Of-Care Testing for HIV for 45 clinics associated with the Provincial AIDS Bureau. In addition, we provided separate microbiology surveys to 22 member countries of CARICOM and separate cytology surveys to six Alberta laboratories.

**Figure 1: Causes of discordant findings in chemistry, hematology and microbiology surveys, 2008–9.**

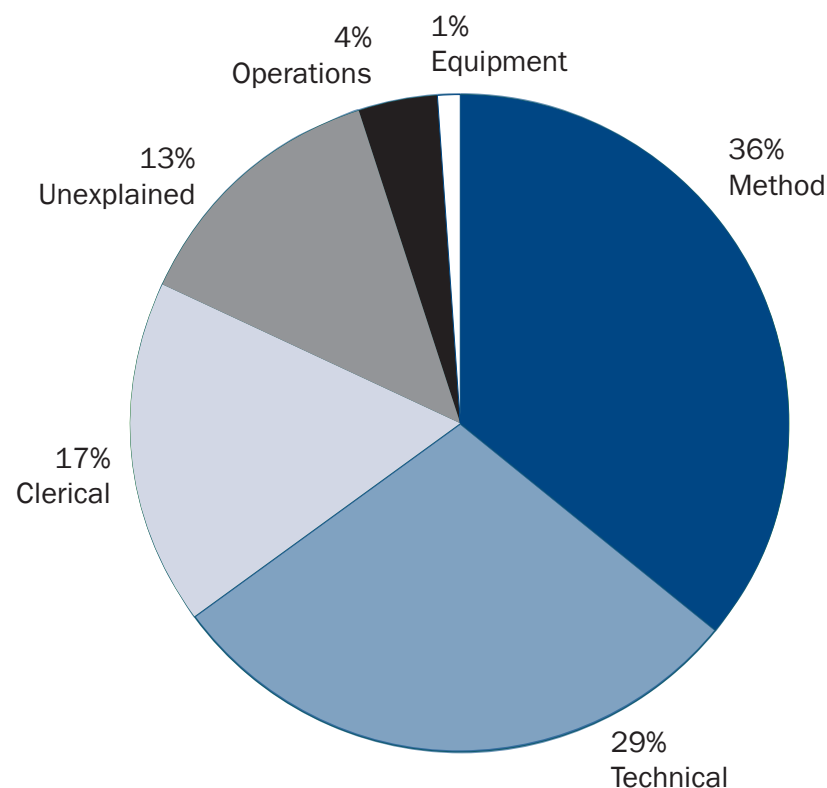


**Table 3: Number of Licensed Ontario Labs and Voluntary Participants**

| Number of Participating Licensed Ontario and Voluntary Labs |                       |                        |
|-------------------------------------------------------------|-----------------------|------------------------|
| Discipline                                                  | Licensed Ontario Labs | Voluntary Participants |
| Anatomic Pathology                                          | 74                    | 1                      |
| Chemistry                                                   | 193                   | 2                      |
| Drug Monitoring                                             | 163                   | 2                      |
| Endocrinology                                               | 127                   | 1                      |
| Enzymes                                                     | 189                   | 2                      |
| Immunology                                                  | 60                    | 1                      |
| Lipids                                                      | 131                   | 1                      |
| Cytology                                                    | 74                    | 1                      |
| Genetics                                                    | 10                    | 9                      |
| Coagulation                                                 | 186                   | 4                      |
| Flow Cytometry                                              | 190                   | 2                      |
| Hematology                                                  | 199                   | 6                      |
| Morphology                                                  | 192                   | 0                      |
| Red Cell Disorders                                          | 69                    | 1                      |
| Bacteriology                                                | 101                   | 0                      |
| Mycology                                                    | 20                    | 3                      |
| Parasitology                                                | 18                    | 0                      |
| Virology                                                    | 77                    | 4                      |
| Point-of-Care Testing                                       | 176                   | 60                     |
| Transfusion Medicine                                        | 164                   | 0                      |

## Looking Ahead

During 2009–10, the changes to EQA survey models should be completed. Participants will be able to access all current EQA survey-related instructions, worksheets, reports and educational information through QView™ at any time. Once the changes are in place, QMP–LS will seek external assessment of the EQA Program. In addition, it is hoped that method manufacturers will be able to access general survey information to enable them to track performance of their kits, instruments and reagents and enable them to implement prompt corrective actions for their products as required.

# Ontario Laboratory Accreditation

## Introduction

The pursuit of quality requires considerable effort by laboratory personnel, management and regulators. Ontario Laboratory Accreditation was conceived in 2000 to set a recognizable standard for laboratory quality and competence. It was implemented in 2003 as a condition of licensure for Ontario's medical laboratories. Other laboratories may voluntarily participate. The requirements for accreditation are comprehensive and the assessment process rigorous. Achieving accreditation is a significant accomplishment.

## Performance Highlights

During 2008–9 OLA achieved a remarkable milestone in the pursuit of accreditation for Ontario's licensed medical laboratories. Accreditation assessments on all labs were complete by August 31, 2008 and every licensed medical laboratory in Ontario held an accreditation certificate by March 15, 2009. To celebrate this accomplishment, wall flags were offered to laboratories, which were encouraged to display them in public areas during Med Lab Week April 19–25, 2009 (see Figure 2).

OLA's accreditation services are available to other medical laboratories who voluntarily apply. This year, two laboratories (one located within the Public Health Agency of Canada and the other in the Republic of Trinidad and Tobago) achieved accreditation.

During the year, some enhancements to the program were accomplished:

- ✓ Version 4.1 of the requirements for accreditation was released
- ✓ Guidance on requirements for traceability and uncertainty of measurement were developed and distributed
- ✓ Electronic reporting through QView™ was achieved on two fronts (see below)

The assessor pool was replenished with 18 new applicants trained and certified. Four face-to-face refresher seminars were offered as an option to the online refresher exercise.

Quality improvement opportunities were pursued internally through assessment feedback, internal and external audits, and a customer satisfaction survey. That survey was conducted in October 2008 to allow participants to comment on their experience with the OLA accreditation process. According to that survey, although “stressful” was the top choice of a word describing the accreditation experience, 94.3% agreed that meeting accreditation requirements enhanced their laboratory service.

## Ontario Laboratory Accreditation Assessments

OLA conducts periodic assessment visits to determine if laboratories conform to their accreditation requirements. Accreditation certificates are issued once all major non-conformances are resolved, and minor non-conformances are either resolved or satisfactorily addressed with ongoing action plans. Ongoing surveillance is carried out and laboratories must comply in order to maintain accreditation. Surveillance includes the following activities that may result in a surveillance on-site visit:

- ✓ Reviewing conformance in regular self-assessments (half-way between peer assessments)
- ✓ Monitoring of participation and satisfactory performance in EQA/PT

- ✓ Monitoring changes in laboratory management, location and the scope of testing

Assessment visits are conducted by pre-trained and certified volunteers who are accompanied on-site by an OLA staff coordinator. The competence of assessors is evaluated at every assessment, and assessors must do any one of the following annually in order to maintain active certified status: participate in a minimum of one assessment; complete an online refresher exercise; or participate in a face-to-face refresher exercise. Every assessor is expected to participate in a face-to-face refresher exercise every three to five years. There are 258 active assessors. During 2008–9, 91 assessors were contracted for 430 assessment days. Four face-to-face refresher exercises were hosted, and the remaining assessors recertified using the online refresher exercise. Eighteen new assessors were trained and certified. Training replenishes the assessor pool. It replaces inactive or retired assessors and increases the number of certified assessors with flexible skills in the core disciplines.

OLA began assessing Ontario's licensed medical laboratories in 2003, and assessed all of them once by the end of August 2008. Following initial assessment visits, five-year certificates were issued, but on reassessments, certificates lasting four years will be issued. If a laboratory has outstanding major non-conformances with a satisfactory action plan, a two-year upgradable certificate may be issued. The OMA's current agreement with the Standards Council of Canada (SCC) allows laboratories to receive an ISO 15189 certificate issued by the SCC, but additional conditions apply, including a surveillance visit one year after the initial certificate is issued, and annual maintenance fees.

By March 2009, all Ontario licensed laboratories held accreditation certificates. See Tables 4 and 5. Average laboratory conformance in 2008–9 was an impressive 94.15%, based on an average of 427 requirements per

assessment. Visits conducted as of September 2008 are reassessments to Version 4.1 of the OLA Requirements. Therefore, it is worth noting 2008–9 conformance both before and after that date (see Table 6).

**Table 4: OLA Peer Assessment Activity**

| OLA Peer Assessment Activity<br>Fiscal 2008–9 |                    |
|-----------------------------------------------|--------------------|
| Activity                                      | Number             |
| Labs Notified of Assessment                   | 54 full, 1 focused |
| Peer Assessments Conducted                    | 48 full, 3 focused |
| 5-year Certificates Issued                    | 38                 |
| 4-year Certificates Issued                    | 7                  |
| 2-year Certificates Issued                    | 1                  |

**Table 5: Self-Assessment Activity**

| OLA Self-Assessment Activity<br>Fiscal 2008–9 |        |
|-----------------------------------------------|--------|
| Activity                                      | Number |
| Laboratories Notified                         | 50     |
| Laboratories Submitting Self-Assessment Data  | 49     |
| Summary Reports Issued by OLA                 | 51     |

**Table 6: Assessment Visit Conformance**

| Assessment Visit Conformance<br>Fiscal 2008–9 |             |
|-----------------------------------------------|-------------|
| Time Frame                                    | Conformance |
| Initial Assessment Visits April–August 2008   | 94.98%      |
| Reassessment Visits September 2008–April 2009 | 93.25%      |

The largest number of non-conformances observed in reassessment visits conducted after September 2008 were:

1. Various deficiencies to technical procedures
2. Equipment maintenance issues
3. Inconsistent labelling of reagents and solutions with dates of expiration, receipt or reconstitution
4. Uncertainty of measurement for quantitative results not determined
5. Inadequate monitoring of environmental conditions

## In Pursuit of Quality

OLA Advisory Panel meetings occur periodically with additional conference calls scheduled as required for decision-making, appeals, certificate issue, recommendations for withdrawing or reducing accreditation. Three full teleconference meetings occurred this year. Six additional conference calls were convened, for reviewing laboratory corrective actions and recommending certificate issue or referral to the MOHLTC.

Significant improvements were initiated over the past year.

1. Requirements for accreditation are based on ISO 15189:2007 *Medical laboratories—Particular requirements for quality and competence*, ISO 15190:2003 *Medical Laboratories—Requirements for safety*, ISO 22870:2006 *Point-of-care testing (POCT)—Requirements for quality and competence*, and CAN/CSA Z902-04 *Blood and Blood Components*. Additional sources are federal and provincial law, Health Canada and other guidelines from consensus bodies that represent principles of good practice within Ontario. OLA is committed to

ensuring its requirements for accreditation reflect current international and national standards and law, plus additional consensus guidelines representing generally accepted principles of good practice. In July 2008, Version 4.1 of the requirements for accreditation was released due to changes in regulation and QMP-LS seized the opportunity to make additional changes as well as to update references. Changes of note are shown in Table 7. There are currently 513 requirements and three good practice recommendations. These set a rigorous standard for laboratory management, reagent and equipment maintenance, pre-analytical, analytical and post-analytical operations, quality assurance, laboratory information systems, point-of-care testing, and personnel safety, as well as safety considerations for physical facilities and the environment. Guidance is provided for their application in every discipline. Some Molecular Diagnostics guidance specifically relating to inherited disorders was moved to Cytogenetics guidance, now labelled “Genetics.” Reference sources were also updated.

2. QMP-LS posted the listing of voluntary accredited laboratories on its website. Ontario laboratories were added to the list in August 2009.
3. To assist laboratory personnel in applying the concepts of traceability and uncertainty of measurement, Advisory Panel member Dr. Godfrey Moses and Director Linda Crawford wrote a guidance document titled *Traceability and Uncertainty of Measurement for Medical Laboratories*, which was released in April 2009.
4. Electronic reporting through QView™ was achieved on two fronts. (1) Surveillance of interlaboratory comparison was introduced so that laboratories can now report their participation and performance in external proficiency testing/external quality assessment schemes, allowing OLA to monitor this as part of routine surveillance in accredited laboratories. (2) Electronic assessment visit evaluation

forms were introduced to allow laboratories to submit their assessment visit evaluation forms electronically. In addition, development occurred on a program that will allow laboratories to enter their self-assessment findings directly into the database, which will save transcription time and reduce the potential for transcription errors.

5. Replenishment of the assessor pool—18 new applicants were trained and certified, and four face-to-face refresher seminars were offered as an alternative to the online refresher exercise.
6. In 2008–9, four articles appeared in *QMP–LS News* along with 12 “Eye on OLA” columns. The articles covered management review, the release of the OLA Requirements Version 4.1, a report on assessments conducted in the implementation phase plus key changes for reassessments, and PT/EQA surveillance. “Eye on OLA” columns highlighted the application of specific requirements, addressed new requirements and developments, and provided updates on accreditation processes (see Table 8).

## Measuring the Quality of Service Provision

OLA has, from its inception, based its requirements for accreditation on the ISO 15189 standard for quality and competence of medical laboratories and designed its operations to comply with ISO 17011:2004(E) *Conformity assessment—General requirements for accreditation bodies accrediting conformity assessment bodies* and the International Laboratory Accreditation Cooperation (ILAC) guidelines for accreditation bodies. QMP–LS’ OLA division conducted its third internal audit in November 2008, to ensure its ongoing compliance with the ISO 17011 standard for accreditation bodies. Six non-conformances and five suggestions were received. The previous two internal audits identified 21 and 16 opportunities for improvement. Through a partnership with the SCC, OLA is recognized both nationally and internationally as a program of the highest standards.

**Table 7: Changes of note to OLA Requirements**

| Changes of note in OLA Requirements Version 4.1                      |                                                                                                                                           |                                                                                                                                                               |
|----------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Requirement/<br>What to Look For<br>(WTLF)                           | Summary of Change                                                                                                                         | Rationale                                                                                                                                                     |
| VIII.2.10                                                            | WTLF has been revised to include the release of patient reports to the Chief Medical Officer of Health                                    | Revised Act – Health Protection and Promotion Act, R.S.O. 1990, Part VI.1, Section 77.8                                                                       |
| V.A.10                                                               | Requirement reworded to allow for the use of safety engineered needles.                                                                   |                                                                                                                                                               |
| WTLF revised to include varied effective dates for medical services. | New regulation — Ontario Regulation, Needle Safety, O. Reg. 474/07                                                                        |                                                                                                                                                               |
| VII.9.1                                                              | Requirement reworded to require the participation in external quality assessment for all tests included within accreditation.             | OLA has an obligation to ensure laboratories are competent to perform specific tests (according to ISO 43-2, ISO 15189:2007, ISO 17011:2004 and ILAC P9:2005) |
| VIII.12.1                                                            | Requirement and WTLF revised to streamline reporting of reportable diseases to the Chief Medical Officer of Health where patients reside. | Revised regulation — Ontario Regulation, Laboratories, O.Reg. 682                                                                                             |

Ongoing evaluation by the SCC and the Asia Pacific Laboratory Accreditation Cooperation (APLAC) maintains this recognition. The SCC conducts

periodic audits with assessment observation to ensure that QMP-LS is in compliance. The second SCC audit occurred in February 2009 and eight non-conformances were cited and one further suggestion made.

The following strengths were noted:

- ✓ Commitment of staff
- ✓ Assessor training program
- ✓ Planning process for conducting assessment visits
- ✓ Well-developed information and document control systems

Collaboration at the international, national and provincial level ensures that QMP-LS stays abreast of new developments and remains a leader in the accreditation of medical laboratories. The SCC, through an agreement with the OMA, endorses QMP-LS as its English-language partner accreditation assessment body for medical laboratories. The OLA Director is chair of the SCC's medical laboratory working group and a member of its Partner Advisory Group and TG Laboratories. The Canadian Standards Association hosts the Canadian advisory committee that has input into revisions of ISO 15189. The Managing Director, QMP-LS, is a member. The Canadian Coalition for Quality in Laboratory Medicine provides a network for provincial accreditation bodies. The OLA Director is its president. The International Organization for Standardization develops standards for the operation of accreditation bodies (17011:2004(E)) and requirements for quality and competence of medical laboratories (15189:2007(E)). The QMP-LS Managing Director is a member of the Canadian delegation to ISO TC/212. The International Laboratory Accreditation Cooperation's committees develop guidance documents to utilize and apply the ISO standards that QMP-LS' operations are based on. The OLA Director is the secretary of its

**Table 8: "Eye on OLA" topics**

| "Eye on OLA" articles |                                                                                                                                                                                                        |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Month                 | OLA Article for QMP-LS News                                                                                                                                                                            |
| 2008-04               | Management Reviews                                                                                                                                                                                     |
| 2008-05               | Contract Review                                                                                                                                                                                        |
| 2008-06               | Accreditation: Delivering Trust in Competence of Laboratories                                                                                                                                          |
| 2008-07               | The Accreditation Cycle Repeats Itself                                                                                                                                                                 |
| 2008-08               | OLA Requirements for Referral Laboratory Management, Section II.G                                                                                                                                      |
| 2008-09               | Proposed Federal Human Pathogens and Toxins Act                                                                                                                                                        |
| 2008-10               | OLA launches its first participant satisfaction survey                                                                                                                                                 |
| 2008-11               | Ontario laboratorians urged to participate in November webinars to explain surveillance of participation and performance in external proficiency testing/external quality assessment (PT/EQA) programs |
| 2008-12               | OLA Assessment History QView™ Reports – An Explanation                                                                                                                                                 |
| 2009-01               | OLA Division Completes Third Internal Audit                                                                                                                                                            |
| 2009-02               | Accreditation Requirements for Physical Facilities – Floors, Ergonomics and Frost-free Refrigerators                                                                                                   |
| 2009-03               | QMP-LS commences biennial review of OLA Requirements and Guidance Information                                                                                                                          |

Accreditation Issues Committee and a member of its Proficiency Testing Consultative Group.

The QMP-LS quality system ensures that all processes and procedures are subject to annual review. Feedback is solicited from laboratories and assessors on the assessment process and reviewed on a quarterly basis by staff and the OLA Advisory Panel. In September 2008, OLA conducted a participant survey to determine if it delivers on its values. Although respondents said that the accreditation process was stressful, 94.3%

acknowledged that meeting the accreditation requirements enhanced their laboratory service. Several improvements were initiated based on feedback.

With the milestone met in September 2008 when QMP-LS' Ontario Laboratory Accreditation (OLA) program completed the assessment of all 229 licensed medical laboratories in Ontario. This accomplishment presented an opportunity to canvas our participants on the perceived success of the program. An electronic survey was conducted in October 2008 to allow participants to comment on their experience with the OLA accreditation process. An online survey tool offered by SurveyMonkey was chosen as the survey vehicle because of its ease of use and anonymity. The survey remained open for one month. Knowing that the survey could explore an infinite number of issues, the questions were limited to those issues that have the largest impact on our participants as identified by OLA and the OLA Advisory Panel:

- ✓ Objectivity
- ✓ Transparency
- ✓ Open-mindedness
- ✓ Consistency

Four survey statements were created to match these themes. A fifth statement was included in this section to gauge if participants feel that the program enhanced their laboratory service. Recognizing that the five statements may not be inclusive of all participant issues, space was added for open-ended comments and a separate open-ended question was included to allow participants to express their overall impression of the program. A final question determined the job title of the respondent and whether or not the respondent is an OLA assessor.

There was considerable agreement that the assessment teams based their decisions on factual evidence. The word "fair" was used 12 times in the open-ended comments and ranked among one of the most frequently used words. This suggests that objectivity and fairness is a matter of importance to participants, and that assessors were successful in achieving this with most assessments. There were several negative comments expressing frustration when assessors articulated differing perspectives. Several respondents complained about assessor bias. Of the four values explored in this survey, we achieved the most success with transparency. Of the respondents, 91.1% agreed the assessment team kept them informed throughout the visit process. However, a filter of responses of bench technologists alone reveals that this group was the least satisfied with the transparency of the team. In that group, 16.3% did not agree that the team kept them informed throughout the assessment visit. Of the respondents, 89% agreed that the team understood the laboratory's unique needs and considered those in its decisions. However, this issue did come up repeatedly in negative comments, with phrases such as:

- ✓ Some members of the team came in with set ideas
- ✓ Brought in their own biases
- ✓ Very rigid in their thinking
- ✓ Personal perspectives are present

Of the respondents, 23.8% did not agree that the Requirements and Guidance Information are clear enough to facilitate consistent application; i.e. the respondent's expectations were not consistent with that of the OLA team. A filter of responses to view how assessors perceived this issue reveals that those who are trained as OLA assessors have greater confidence in the OLA Requirements and Guidance Information as a tool to

ensure consistent application. Only 10.5% of assessors did not agree with the statement.

Analysis of the open-ended responses shows that some respondents feel that assessors may apply personal interpretations to the requirements, that some requirements are vague, others complain that one laboratory may receive a non-conformance on an issue, but another laboratory does not. Despite some disagreement on our success at meeting the program values, a staggering 94.3% of survey respondents agreed that meeting the accreditation requirements enhanced their laboratory service. Prior to launching this survey, the OLA Advisory Panel hoped this statement would have the highest level of agreement.

There were a few comments that spoke negatively about the value of the program, specifically that the requirements address bureaucracy and not customer services, that perhaps there needs to be a better assessment of the scope of practice being delivered and to assess compliance in relation to the delivery. One participant commented that there was minimal client interview and interaction with providers. Stress was revealed to be the number one issue among our respondents (see Table 9). This was conveyed in a negative sense, in neutral comments and in a positive light. Respondents used synonyms such as “nerve wracking.” Stress factors appear to be focused on the interpretation of the requirements, perceived biased or opinionated assessors and the limited human resources available to laboratories to prepare for the assessment, and to dedicate to the assessment visit days. Many of the respondents who used the word “stressful” were referring to the stress level prior to the assessment, but clarified that the assessment visit days were satisfying and the team worked to put them at ease during the assessment. However, there were a number of comments about the stress level during the assessment visit. A filter of responses of assessors alone revealed that the word “stress” was used only twice by those who are trained OLA assessors. This suggests that the level of individual stress is reduced

with empowerment, involvement and education about the OLA process.

The action plan focuses primarily on the education of assessors and participating laboratories to address objectivity, assessor bias, transparency and stress. As part of their annual recertification exercise, assessors will be required to review the results of the participant satisfaction survey and to reflect on those results. Modifications will be implemented for our assessor training and classroom refresher to help address objectivity and assessor bias. Assessment team members will be reminded with every assessment that personal bias should not enter into the assessment and that each requirement must be assessed based on the objective evidence presented.

Participating labs require education to understand that to maintain objectivity assessors are never provided with information regarding the conformance of other laboratories to a particular requirement. The goal is to assess each situation objectively and fairly. As such, assessors are never provided with information on what non-conformances were assessed in other laboratories. The OLA coordinator has knowledge that can guide team decisions, but we refrain from overly influencing the outcome of an assessment by prompting assessment teams to look for specific issues. Modifications will be made to the assessment process in an effort to reduce stress, and to improve interaction and transparency with bench technologists.

All opportunities for improvement are captured using the QMP-LS HelpDesk. In 2008–9, there were 12 cases related to OLA.

OLA utilizes ongoing performance measures to assess the efficiency of its assessment service. Turnaround times associated with the delivery of assessments is monitored on a quarterly basis, along with the incidence of error-of-fact submissions following assessment visits. These measures determine if OLA staff are meeting targets, if targets are realistic and appropriate, and are used to identify opportunities for improvement. Data

for this monitoring is captured and extracted from the OLA database, summarized and reviewed by the OLA director, OLA staff, and the quality manager, before being incorporated into the annual QMP–LS Management Review.

**Table 9: Most Frequently Used Words to Describe the Accreditation Experience**

| Most Frequently Used Words to Describe the Accreditation Experience |                                |
|---------------------------------------------------------------------|--------------------------------|
| Word                                                                | Number of Times Word was Cited |
| Stressful                                                           | 42                             |
| Educational                                                         | 18                             |
| Positive                                                            | 15                             |
| Fair                                                                | 12                             |
| Learning                                                            | 10                             |
| Rewarding                                                           | 9                              |
| Nerve-racking                                                       | 8                              |
| Worthwhile                                                          | 8                              |
| Helpful                                                             | 7                              |
| Professional                                                        | 7                              |
| Satisfying                                                          | 7                              |
| Good                                                                | 6                              |
| Intense                                                             | 6                              |
| Necessary                                                           | 6                              |
| Thorough                                                            | 6                              |

1. Assessment visit turnaround time (monitoring started in January 2005): The time elapsed over four events during peer assessment visit follow-up is evaluated:

✓ Visit end date to report issued

- ✓ Visit end date to corrective action received
- ✓ Corrective action received to certificate issued
- ✓ Visit end date to certificate issued

The percentages of certificates issued that exceeded the target of 150 days in 2008–9 (starting with the most recent quarter) are 62%, 9%, 22% and 15%. In all cases where the certificates were late there was a reason beyond our control (see Table 10). The percentages of corrective action reviews at OLA that exceeded the target of 60 days in 2008–9 (starting with the most recent quarter) are 15%, 33%, 9% and 23%. There were extenuating circumstances when targets were not met and therefore no corrective or preventive action was required. In April 2008, the target for issue of summary reports after visits was shortened to 14 days from the previous 30 days because past performance was consistently better than 30 days. In the four quarters of 2008–9, assessment visit summary reports were issued in 13, 8, 16 and 13 days.

2. Self-assessment turnaround time (begun in Q4 of calendar 2006): The time elapsed from receipt of the laboratory exception report to issue of the self-assessment summary report is evaluated. The target for completion of the review of laboratories' submitted reports is 45 days (from receipt to issue of the formal summary report). See Table 11 for composite data on self-assessment turnaround times.
3. Errors of fact submissions received: The number of laboratories that were assessed during a given period—and that submitted an error of fact is monitored. There was only one error of fact submitted in 2008–9, and it turned out to be a post-visit correction rather than an error of fact.

## Looking Ahead

Though every licensed laboratory in Ontario now holds an accreditation certificate, OLA's work is far from complete. ISO 15189 emphasizes continued improvement and monitoring as well as recertification. To that end, OLA has scheduled 55 laboratory assessment visits for 2009–10 and is also coordinating 42 laboratory self-assessments. OLA will also update its list of accredited laboratories to the QMP–LS website and strengthen its assessor pool through face-to-face assessor retraining and adding 15–30 new assessors. A review of requirements reference sources will be conducted to determine any impact of changes on existing requirements. Program achievements will be submitted to a peer-reviewed journal. OLA also has plans to expand its web data entry system using QView™, enhancing features to directly enter external EQA/PT data, feedback from assessment visits and self-assessment conformance data. OLA will also promote the ISO 15189 certificate program for Ontario laboratories and explore expanding to other provinces.

**Table 10: OLA Peer Assessment Turnaround Times**

| OLA Peer Assessment Turnaround Times — Fiscal 2008–9 |                                                             |                                                              |                                                                           |                                                        |
|------------------------------------------------------|-------------------------------------------------------------|--------------------------------------------------------------|---------------------------------------------------------------------------|--------------------------------------------------------|
|                                                      | Time from<br>Assessment<br>Visit to<br>Certificate<br>Issue | Time from<br>Corrective<br>Action<br>to Certificate<br>Issue | Time from<br>Assessment<br>Visit to<br>Receipt of<br>Corrective<br>Action | Time from<br>Visit<br>to Issue of<br>Summary<br>Report |
| Target                                               | 150 days                                                    | 60 days                                                      | 90 days                                                                   | 14 days                                                |
| Actual mean                                          | 129 days                                                    | 58 days                                                      | 69 days                                                                   | 13 days                                                |
| Range                                                | 0–299 days                                                  | 0–30 days                                                    | 0–91 days                                                                 | 0–29 days                                              |
| <b>N</b>                                             | <b>44</b>                                                   | <b>44</b>                                                    | <b>44</b>                                                                 | <b>44</b>                                              |

**Table 11: OLA Self-Assessment Turnaround Times**

| OLA Self-Assessment Turnaround Times<br>Fiscal 2008–9           |           |
|-----------------------------------------------------------------|-----------|
| Time from Receipt from Laboratory to<br>Issue of Summary Report |           |
| Target                                                          | 45 days   |
| Actual Mean                                                     | 34 days   |
| Actual Median                                                   | 41 days   |
| Actual Mode                                                     | 42 days   |
| Range                                                           | 2–66 days |
| <b>N</b>                                                        | <b>51</b> |

**Figure 2: OLA Wall Flag**



# Education

**Q**MP-LS' philosophy is to deliver education within areas identified through our External Quality Assessment (EQA) or Ontario Laboratory Accreditation (OLA) activities. Collaborations and shared experiences continue with partners in healthcare nationally and internationally. In addition, specific educational activities are detailed in the EQA and OLA reports.

In 2008, QMP-LS published three articles on significant developments in the medical and scientific literature, four invited presentations were made at provincial or national meetings and two at international meetings. Two posters were presented at international, national or provincial meetings and three webinars were conducted (Appendix E).

*QMP-LS News* is our principal communications vehicle and is posted once a month on our website. Additional information on products and services is available through the newsletter, which has a large, international audience. It highlights developments in laboratory medicine, details of QMP-LS operational changes and provides information on upcoming activities and events. Information is also shared with participants through the website via secure password-protected access to QMP-LS QView™. New tools have been developed to enable web-based communications.

QMP-LS collaborated with other organizations in the development and promulgation of knowledge:

- ✓ Cancer Care Ontario Molecular Oncology Task Force
- ✓ Canadian Network for Public Health Intelligence, Breast Cancer Project

- ✓ Health Canada, Public Health Agency of Canada, and the Canadian Institutes of Health Research—Institute of Genetics “Genetic Testing: Quality Assurance and Beyond,” February 2–3, 2009 Symposium, Toronto

## Performance Highlights

### Key Objectives

- ✓ Provide education for areas identified through EQA or OLA activities.
  - Developing virtual microscopy capabilities for EQA surveys has been incorporated within the Professional Interpretation and Its Quality Management (PIQM) Task Force.
  - Developing the Ontario breast cancer molecular genetics database.
  - Developing a series—Decoding ISO 15189™—a comprehensive and interactive web-based program to assist laboratories in any jurisdiction to prepare for ISO 15189 accreditation.
- ✓ Develop web-based training, education and interaction capabilities with participants.
- ✓ Provide education to physicians and healthcare providers as direct consumers of laboratory services regarding guidelines for laboratory services in the prevention and management of chronic diseases.

- In accordance with the Ministry of Health and Long-Term Care (MOHLTC) agreements, develop and publish the following guidelines for the use of laboratory services in the management of chronic disease and prevention of complications:

**Diabetes:** Primary glycemic control monitoring for hyperlipidemia and chronic renal disease secondary complications.

**Cardiac:** Cardiac markers in acute coronary syndrome.

**Monitoring of Oral Anticoagulant Therapy (OAT):** Provide guidance on the existing access to care, clinical guidelines and quality assurance issues pertaining to monitoring OAT in Ontario including point-of-care INR testing devices.

- ✓ Professional Interpretation and Its Quality Management (PIQM) Task Force

In 2008, QMP–LS created the PIQM Task Force at the request of the Ontario Medical Association, Section on Laboratory Medicine which was funded by a one-time grant from the Ministry of Health and Long-Term Care (MOHLTC).

The role of the PIQM Task Force is to provide research and advice to QMP–LS in the assessment of, and accountability for, professional interpretation as it relates to pathology. The Task Force created a consultation draft based on a review of the current status of assessment and accountability in Ontario and other jurisdictions. PIQM also held focus groups with stakeholders in order to take their recommendations and concerns into account.

- ✓ Relationship management with other organizations and support for the development of non-core business.
- ✓ Corporate oversight of educational resources, staff training, enrichment and travel are coordinated through this department.

## Looking Ahead

In 2009–10, education services, guideline development and special projects for QMP–LS will continue to be delivered through the Knowledge Transfer & Business Development division. The provision of EQA and OLA products and services to other jurisdictions and healthcare organizations will be managed through the new Institute for Quality Management in Healthcare (IQMH).

# Corporate Services

## Performance highlights

In 2008–2009 Corporate Services collaborated with our EQA division to implement improved data collection facilities, objective scoring algorithms and enhanced client reports.

We worked with our OLA division to implement the web-based data entry system for participant reporting of responses to external EQA/PT schemes and other alternative assessment programs.

We enhanced our knowledge transfer capabilities by developing the processes and procedures for providing webinar and webcast services at QMP–LS.

## Goal

Implement improved methods of providing EQA and OLA services.

Figure 3: EQA Survey Response Form

**Key objective:** Develop comprehensive online capabilities for QMP–LS services.

- ✓ We implemented web-based data entry for EQA survey responses and EQA discordant finding forms utilizing QView™, our document and data collection server. We also implemented the web-based data entry system for participant reporting of responses to external EQA/PT schemes and other alternative assessment programs along with OLA participant self-assessment conformance data.

**Key objective:** Implement criteria-based scoring schemes and cumulative performance tracking for objective performance evaluation.

- ✓ Scoring algorithms and cumulative performance reports for quantitative EQA surveys were implemented effective with the April 2008 surveys. Development and implementation of cumulative performance reports for qualitative surveys continued through 2008 and will be completed in 2009–2010.

Figure 4: EQA Discordant Findings Form

## Goal

Transform the business model to integrate support and ensure human resources for QMP-LS programs

**Key objective:** Reorganize Corporate Services.

- ✓ We integrated Information Services, Communications, Financial Services, Expediting and Administrative Services into one Corporate Services division to improve work flow and ensure appropriate resource capacity for QMP-LS initiatives

## Goal

Provide planned services to the Ontario medical laboratory community.

**Figure 5: OLA Participation Self-Assessment Conformance Form**

| LB.13.1 | Personnel records shall include professional and educational qualifications - In Canada, this includes certification or license granted by a Canadian body authorized by articles of incorporation to grant such qualifications (24) | Major Non-Conformance | Description of the Conformance | Correction Action & Response Date |
|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------------------------|-----------------------------------|
|         |                                                                                                                                                                                                                                      | 2009/10               | 1B13.1                         | 1B13.1                            |
| LB.13.2 | Records of staff training shall be maintained. These shall be signed by the employee and the issuer (25)                                                                                                                             | Major Non-Conformance | Description of the Conformance | Correction Action & Response Date |
|         |                                                                                                                                                                                                                                      | 2009/10               | 1B13.2                         | 1B13.2                            |

**Figure 6: External PT/EQA Data Entry**

| Site | Provider | Program | Challenge    | #Tests | Results | Save |
|------|----------|---------|--------------|--------|---------|------|
| 0908 | CAP      | CBC     | Jan 29, 2009 | 2      |         |      |

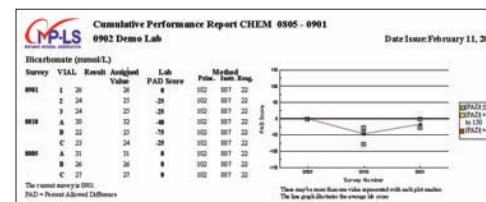
**Key objectives:** Conduct peer assessment visits to approximately 44 laboratories.

- ✓ We provided OLA application support for 49 laboratory peer assessment visits and 51 laboratory self-assessments.
- ✓ Provide EQA surveys in accordance with survey plans.
- ✓ In 2008–2009 Corporate Services performed data entry and analysis, and generated participant survey reports for 108 challenge EQA surveys, three pattern-of-practice surveys and two questionnaires.

## Looking Ahead

In 2009–2010 we will complete the implementation of web-based data collection for EQA and OLA programs along with the implementation of cumulative EQA performance reports for all disciplines. Our webinar and webcast production capabilities will be expanded. This year we will also begin developing and implementing improved registration and receivables processes to ensure timely and convenient client access to QMP-LS products and services.

**Figure 7: Cumulative Performance Report**



## Quality Manager's Report

Underpinning our delivery of world-class external quality assessment and accreditation is our own comprehensive quality management system. Our quality system—like that of all laboratories in Ontario—is aligned to ISO 9001:2008 and a number of very specific ISO standards that address our programs. We continually strive to “do what’s right” and work diligently to maintain the same level of excellence we demand of the laboratory community.

2008–9 was a year best characterized with the words “independent momentum.” Our quality system is now in a mature state where all processes

and procedures have been fully defined, document control is second nature, internal audits are no longer feared and occurrence reporting is viewed as the right thing to do to prevent recurrence. The Quality Manager has two key responsibilities:

- ✓ To ensure staff compliance with the quality management system
- ✓ To ensure the voice of the customer is heard

To meet these two outcomes, the following specific activities occurred in 2008–9 (see Table 12), led by the Quality Manager:

**Table 12: Quality management activities**

| Quality Management Activities 2008–9                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|--------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Input                                                                                      | Output                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Second annual internal audit of the EQA division to measure alignment to ILAC G13:2007.    | Identification of 14 non-conformities and six suggestions to meet the international standard and prepare the EQA division for external assessment.                                                                                                                                                                                                                                                                                            |
| Third annual internal audit of the OLA division to measure alignment to ISO 17011:2004(E). | Identification of six non-conformities and five suggestions to meet the international standard.                                                                                                                                                                                                                                                                                                                                               |
| Second external audit of the OLA division by the Standards Council of Canada               | <p>Submission and acceptance of corrective actions to the eight non-conformities cited by the audit.</p> <p>The OLA division was found to have the following strengths:</p> <ul style="list-style-type: none"> <li>✓ Commitment of staff</li> <li>✓ Excellence of assessor training program</li> <li>✓ Strong planning process for conducting assessments</li> <li>✓ Well-developed information system and document control system</li> </ul> |

Continued on page 36

Continued from page 35

| Quality Management Activities 2008–9                                                               |                                                                                                                                                                                                                                                                                                                 |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Input                                                                                              | Output                                                                                                                                                                                                                                                                                                          |
| Management Review of the previous fiscal year that encompassed all operations                      | Defined action plans addressing shortfalls in meeting objectives, resource management, further opportunities arising from the analysis of occurrences, performance monitoring. Thirty-four action items were defined and fed into our strategic plans.                                                          |
| Participant satisfaction survey of the OLA program                                                 | Invaluable feedback was received to help us understand customer needs and measure if we delivered on our values. Ten action items for improvement were defined and implemented. Most focused on efforts to reduce stress felt by participants through improved education of assessors.                          |
| All processes and procedures subjected to annual review                                            | Written evidence that processes meet international standards, standardization of processes, clear understanding of what we do. A solid base was created on which to layer new streamlining initiatives such as Lean.                                                                                            |
| Ongoing performance measures of efficiency and timeliness of both EQA and accreditation activities | <p>Shorten target turnaround time for OLA summary reports to 14 days post-assessment visit.</p> <p>Implement uniform approach across disciplines to engage committee members in prompt production of committee comments.</p> <p>Plan to reduce iterative review process between EQA and corporate services.</p> |

## QMP–LS Committee Membership 2008–9

### Conjoint Committee

#### Ministry of Health and Long-Term Care Representatives:

Ms. Marnie Cooper, Co-chair

Mrs. Patricia Anderson

#### Ontario Medical Association/Quality Management Program—Laboratory Services Representatives:

Dr. Gregory J. Flynn, Co-chair

Dr. Michael Thoburn

Dr. Virginia Walley

### Advisory Council

#### Ontario Medical Association

Dr. Michael Thoburn, Chair

#### Ontario Hospital Association

Ms. Sudha Kutty/Dr. Robert Lester

#### Ontario Laboratory Accreditation Advisory Panel, Chair

Ms. Janice Nolan

#### Ontario Society of Medical Technologists

Ms. Blanca McArthur

#### College of Medical Laboratory Technologists

Mrs. Kathy Wilkie

#### Ontario Association of Medical Laboratories

Mr. Jeffrey Sumner

#### College of Physicians & Surgeons of Ontario

Mr. Dan Faulkner

#### Ontario Medical Association

Dr. Virginia Walley

#### Professional Advisory Committee, Chair

Dr. Sheila Boss

#### Ontario Society of Clinical Chemists

Dr. Lynn Allen

#### Ontario Medical Association Section on Laboratory Medicine

Dr. John Doucet

#### Ontario Association of Pathologists

Dr. Frank E. Thompson

#### Association of Medical Microbiologists of Ontario

Dr. Deborah Yamamura

#### Ministry of Health and Long-Term Care

Ms. Marnie Cooper/Mr. Tim Burns

Mrs. Patricia Anderson (observer)

#### Quality Management Program—Laboratory Services

Dr. Gregory J. Flynn (ex-officio)

Ms. Linda Crawford (observer)

Ms. Jane Gun-Munro (observer)

### Professional Advisory Committee

#### Dr. Sheila Boss, Chair

#### Mr. Michael Keeney, Vice-chair

#### Dr. Margaret Fearon

#### Dr. Karen Harrison

#### Mrs. Laura J. Harrison

#### Dr. Nathalie Lepage

#### Ms. Laurie Mason

#### Dr. Golnar Rasty

#### Dr. Baldwin W. Toye

#### Dr. Pui-Yuen Wong

#### Mrs. Patricia Anderson (ex-officio)

#### Dr. Gregory J. Flynn (ex-officio)

**Ontario Laboratory Accreditation Advisory Panel**

Ms. Janice Nolan, Chair  
 Dr. James Kerry MacDonald, Vice-chair  
 Dr. William Brien  
 Ms. Ruth C. Jaeger  
 Ms. Cathie McCallum  
 Dr. Anna G. Morris  
 Dr. Godfrey Moses  
 Mrs. Kathryn Snell  
 Mr. Barry Vermeersch  
 Ms. Marnie Cooper (ex-officio)  
 Mrs. Patricia Anderson (ex-officio)  
 Dr. Gregory J. Flynn (ex-officio)  
 Ms. Linda Crawford (ex-officio)

**Test Review Committee**

Dr. Robert Moore, Chair  
 Dr. Kenneth Arnold  
 Dr. Frank E. Thompson  
 Mr. Sam Thomson  
 Ms. Marnie Cooper (ex-officio)  
 Ms. Patricia Anderson (observer)  
 Dr. Gregory J. Flynn (ex-officio)

**Anatomic Pathology**

Ms. Laurie Mason, Chair  
 Dr. Kathy Chorneyko  
 Ms. Cathie Crukley  
 Dr. Kelly Laurence  
 Mr. William R. Parks  
 Dr. Susan Robertson  
 Ms. Sue Seguin  
 Dr. Sharyn Smith

**Chemistry-General and Enzymes**

Dr. Sheila Boss, Chair  
 Dr. Stephen A. Hill, Vice-chair  
 Dr. Lynn Allen  
 Ms. Jackie Barten  
 Dr. Douglas Gornall  
 Mr. Robert Kerekes  
 Dr. Alex Romaschin  
 Dr. Edward Dunn, Advisor, Drug Monitoring

**Cytology**

Dr. Golnar Rasty, Chair  
 Dr. Caroline Rowlands, Vice-Chair  
 Ms. Sharon Crafter  
 Mr. David Kuni  
 Dr. Michelle Sapp

**Endocrinology and Immunology**

Dr. Pui-Yuen Wong, Chair  
 Dr. David E. C. Cole  
 Mr. Mark Donahoe  
 Dr. Lois E. Shepherd  
 Dr. Sonya Tokmakejian

**Genetics**

Dr. Karen Harrison, Chair  
 Dr. Diane Allingham-Hawkins, Vice-Chair  
 Dr. Ron Carter  
 Dr. Kathy Chun  
 Dr. Jean McGowan-Jordan  
 Ms. Michelle Wood

### **Hematology**

Mr. Michael Keeney, Chair  
 Mr. Len Burger  
 Dr. Ian H. Chin-Yee  
 Dr. Mark Crowther  
 Ms. Karen Moffat  
 Dr. Adam Ninos  
 Dr. Ruth Padmore  
 Mr. John Lafferty, Advisor, Red Cell Disorders

### **Maternal Serum Screening**

Dr. Nathalie Lepage, Chair  
 Dr. Alan Dennis  
 Dr. Barry Hoffman  
 Ms. Shamim Rashid  
 Dr. Tianhua Huang, Consultant, OMSSD

### **Microbiology**

Dr. Baldwin W. Toye, Chair  
 Dr. Alicia Sarabia, Vice-Chair  
 Ms. Chee-Yuen Meaney  
 Dr. Susan Poutanen  
 Ms. Candy Rutherford  
 Dr. Frances B. Jamieson, Advisor  
 Mr. David Raymondo, Advisor, Parasitology

### **Mycology Advisory Committee**

Dr. Baldwin W. Toye, Chair  
 Ms. Ursula Bunn  
 Mr. Jorge Musa  
 Dr. Richard Summerbell  
 Dr. Debbie Yamamura

### **Transfusion Medicine**

Mrs. Laura J. Harrison, Chair  
 Mrs. Debbie Lauzon, Vice-Chair  
 Mr. Jeff Kinney  
 Dr. Alan Tinmouth  
 Dr. Kathryn Webert

### **Virology**

Dr. Margaret Fearon, Chair  
 Mr. John Nishikawa, Vice-Chair  
 Dr. Astrid Petrich

## QMP–LS Volunteers 2008–9

**External Quality Assessment**

Ms. Laura Baillie  
 Mrs. Linda Borycheski  
 Ms. Wendy Brown  
 Ms. Debra Browning  
 Ms. Laura Burton  
 Dr. Peter Bunting  
 Ms. Alison Carey  
 Ms. Jessica Carson  
 Ms. Hoan Canavan  
 Ms. Ping Chao  
 Mrs. Patti Cheatley  
 Ms. Pam Chedore  
 Dr. Maureen Clement  
 Dr. Christine Collier  
 Mr. Leio Coloquio  
 Ms. Karen DeRuiter  
 Dr. Sandra Farrell  
 Dr. Denice Feig  
 Ms. Jacky Fok  
 Ms. Joy Francis-Everd  
 Dr. John Freedman  
 Ms. Esther Geisbrecht  
 Mr. Ron Giesler  
 Ms. Anne Hamid-Allie  
 Mr. Michael Ho  
 Dr. Jon H. Johnsen  
 Ms. Jennine Kafka  
 Mr. Iam Kasperski  
 Dr. John Kim

Ms. Leona Kotowich  
 Ms. Tina Kozlowski  
 Mr. Ivan Lam  
 Mr. Scott MacDonald  
 Ms. Theresa Mahony  
 Ms. Laurie Malloch  
 Ms. Cathie McCallum  
 Mr. Andrew McFarlane  
 Dr. David Mendelssohn  
 Dr. David Murray  
 Mr. Sam Nagra  
 Ms. Karen Olech  
 Ms. Bonnie Page  
 Dr. Valerie Palda  
 Mrs. Connie Pletch  
 Ms. Cindy Poulos  
 Dr. Russell Price  
 Ms. Georgina Ralevski  
 Mr. Prasad Rawte  
 Dr. Michael J. Raymond  
 Ms. Rhonda Reardon  
 Ms. Gwen Rosenfield  
 Dr. Corwyn Rowsell  
 Dr. Brian Rudrick  
 Ms. Debra Saunders  
 Ms. Elisa Shore  
 Ms. Heather Siebert  
 Mr. Glen Small  
 Ms. Deirdre Soares  
 Ms. Joanne Sverha

Ms. Carol Swantee  
 Mr. Jeff Sumner  
 Ms. Lynn Towns  
 Ms. Liese Walchuk  
 Ms. Lai Ling Wat  
 Ms. Patricia Wegrynowski  
 Dr. Bret Wehrli  
 Ms. Lori White  
 Ms. Susan Wolnik  
 Mr. Alexander Yeboah  
 Mr. Billy Yu

**Ontario Laboratory Accreditation**

Ms. Mona Ackerman  
 Dr. Vina Alexopoulou  
 Ms. Myonne Allan  
 Ms. Marjorie Allen  
 Ms. Beate (BJ) Anding  
 Ms. Janice Archer  
 Ms. Jane Barry  
 Mr. Conrad Begin  
 Ms. Johanne Bietola  
 Mr. Chris Blagg  
 Ms. Linda Borycheski  
 Ms. Patti Boyd  
 Ms. Nellie Bradbury  
 Ms. Mary Breadner  
 Ms. Marjorie Brooks  
 Ms. Marie Burelle  
 Mr. Len Burger

Ms. Patricia Burton  
 Ms. Pamela Calverley  
 Ms. Johanna Campbell  
 Dr. Nancy Carson  
 Ms. Bessie Carydis  
 Dr. Peter Catomeris  
 Mr. Robert Cheslo-Trengrove  
 Dr. Pak Cheung Chan  
 Ms. Betty Anne Clark  
 Ms. Sandra Comand  
 Mr. Daryl Corriveau  
 Ms. Susie Davies  
 Ms. Louise Dwyre  
 Ms. Susan Evans  
 Ms. Mary Falls  
 Mr. William Fayle  
 Ms. Rosanne Frassetto  
 Dr. Lei Fu  
 Dr. Douglas Gornall  
 Ms. Margaret Grabowski  
 Ms. Joanne Guzda  
 Ms. Susan Hemmerling  
 Ms. Rosemary Henry  
 Ms. Karen Hodgins  
 Ms. Susan Hodgins  
 Ms. Tammy Ison  
 Ms. Tanya Jorden  
 Ms. Peggy Kerk  
 Ms. Elizabeth King  
 Mr. Ivan Lam  
 Ms. Lilian Law  
 Ms. Norma Layno

Ms. Susan Leask  
 Ms. Aline Letourneau  
 Mr. Victor Leung  
 Ms. Pauline Lo  
 Mr. Al Lupish  
 Ms. Christine Mackay  
 Ms. Lorraine MacLean  
 Ms. Marg Maddock  
 Ms. Leslie Maillouz  
 Ms. Carol Major  
 Ms. Cornelia Mascherin  
 Ms. Viki Massey  
 Ms. Tina Mattice  
 Ms. Judy Maxwell  
 Ms. Marion McChesney  
 Mr. Michael McConnell  
 Ms. Patricia McGillis  
 Ms. Laurie McIntosh  
 Ms. Shawne Milne  
 Mr. Jim Moran  
 Mr. David More  
 Ms. Donna Murphy  
 Ms. Wendy Owens  
 Mr. Patrick Paulusse  
 Ms. Anne Marie Phillips  
 Dr. Karam Ramotar  
 Ms. Susan Randell  
 Ms. Rena Retallick  
 Ms. Stephanie Rossanese  
 Ms. Susan Schaub  
 Ms. Pam Scholey  
 Ms. Dawn Scott

Dr. Rita Selby  
 Ms. Judy Sherman-Jones  
 Ms. Carolin Smart  
 Ms. Deidre Soares  
 Dr. Tracy Stockley  
 Ms. Joanna Tam  
 Ms. Cheryl Watt  
 Mr. Kevin Webb  
 Ms. Lori-Ann Webster  
 Ms. Laura White  
 Mr. Tony Wong  
 Ms. Michelle Wood

## QMP–LS Staff as at March 31, 2009

### Management

Gregory Flynn, Managing Director

Brenda Todd, Executive Assistant, Corporate

### Corporate Services

Dan MacFayden, Director

### Communications

Maritess Koerner, Supervisor (on leave)

Poonam Khanna, Coordinator

Margaret Hall, Website Officer

Nikki Rampersad, Assistant

### Information Services

Darlene Cameron, Data Officer

Jason Chard, Systems Analyst

Neela Khatri, Senior Systems Analyst

Alex Lesniara, Senior Systems Analyst

Shelly Rowe, Senior Systems Analyst

### Financial and Administrative Services

Matt O'Connor, Coordinator

Emily Lee, Receptionist

Jeff Pennington, Expeditor

### Quality Systems

Julie Coffey, Quality Manager

### External Quality Assessment (EQA)

Jane Gun-Munro, Director

Christine Fleming, Senior Consultant Technologist—Bacteriology,  
Mycobacteriology and Parasitology

Carol Julian, Consultant Technologist—Cytology, Pathology

Joanne Miyazaki, Consultant Technologist—Genetics

Andrea Park, Coordinator, EQA Services

Astrid Petersons, Consultant Technologist—Flow Cytometry, Transfusion  
Medicine, Point-of-Care Testing

Anne Raby, Consultant Technologist—Hematology, Coagulation,  
Morphology, Bone Marrow and Red Cell Disorders

Maureen Singh, Senior Administrative Assistant

Julia Stemp, Consultant Technologist—Chemistry-General, Drug  
Monitoring, Endocrinology, Immunology and Enzymes,  
Cardiac Markers and Lipids, Maternal Serum Screening

Donna Thompson, Consultant Technologist—Mycology and Virology

### Knowledge Transfer and Business Development

Joanne Miyazaki, Director (A), Relationship & Business Development

Marnie Cooper, Director, Research & Program Development

### Ontario Laboratory Accreditation (OLA)

Linda Crawford, Director

Julie Coffey, Staff Technologist

Sukanya Shankar, Senior Administrative Assistant

Miralla Suares, Senior Administrative Assistant

QMP–LS would also like to thank the following staff members who retired  
or left in 2008–9 to pursue other endeavours and to wish them luck:

Joanne Bishop, Staff Technologist

Christine Fry, Staff Technologist

Bryan Hewlett, Consultant Technologist

Janine Marmulak, Senior Administrative Assistant

Carol Turner, Staff Technologist

Sharon Webb, Consultant Technologist

Manny Zamora, Assistant, Expediting

## EQA Parameters Monitored by QMP–LS by Discipline 2008–9

**CHEMISTRY****Chemistry-General**

Albumin  
 Albumin excretion rate (AER)  
 Bicarbonate  
 Bilirubin, total  
 Blood gases (pH, pCO<sub>2</sub>, pO<sub>2</sub>, Na<sup>+</sup>, K<sup>+</sup>, glucose, ionized calcium)  
 Hb A<sub>1c</sub>  
 Calcium, Total  
 Chloride  
 Creatinine  
 Glucose  
 Magnesium  
 Phosphate  
 Potassium  
 Protein, total  
 Sodium  
 Total iron, TIBC, UIBC, transferrin saturation  
 Urate  
 Urea  
 Urine chemistry (quantitative protein, sodium, potassium, creatinine, osmolality)

**Drug Monitoring**

Acetaminophen  
 Carbamazepine  
 Digoxin  
 Ethanol  
 Gentamicin

Lithium  
 Phenobarbital  
 Phenytoin  
 Salicylate  
 Theophylline  
 Tobramycin  
 Valproic Acid  
 Vancomycin

**Drugs of Abuse**

Amphetamines  
 Methamphetamine  
 Ecstasy (MDMA/MDA)  
 Barbiturates  
 Benzodiazepines  
 Cannabinoid metabolites  
 Cocaine metabolites  
 Methadone  
 Methadone metabolites (EDDP)  
 Opiates  
 Oxycodone  
 Phencyclidine  
 Tricyclic antidepressants

**Endocrinology**

Thyrotropin (TSH)  
 Free thyroxine (FT<sub>4</sub>)  
 Free triiodothyronine (FT<sub>3</sub>)  
 Vitamin B<sub>12</sub>  
 Ferritin

Cortisol  
 Total testosterone  
 Follicle stimulating hormone (FSH)  
 Luteinizing hormone (LH)  
 Parathyroid hormone  
 Progesterone  
 Prolactin  
 Chorionic gonadotropin (CG)  
 Alpha fetoprotein (AFP)  
 Estradiol  
 Prostate specific antigen (PSA)  
 Free PSA  
 Dehydroepiandrosterone sulphate (DHEA-S)  
 25 hydroxy Vitamin D

**Enzymes, Cardiac Markers & Lipids**

Alkaline phosphatase (ALP)  
 Alanine aminotransferase (ALT)  
 Amylase  
 Aspartate aminotransferase (AST)  
 Gamma glutamyl transferase (GGT)  
 Lactate dehydrogenase, total (LD)  
 Lipase  
 Total creatine kinase (Total CK)  
 CK-2  
 Serum myoglobin  
 Serum troponin I  
 Serum troponin T  
 Cholesterol  
 Triglycerides

HDL-cholesterol (HDL-C)  
 LDL-cholesterol (LDL-C)  
 Cholesterol : HDL-C ratio  
 Immunology  
 Antinuclear antibody (ANA)  
 Rheumatoid factor (RF)  
 High sensitivity CRP (hsCRP)

Specific proteins:

IgG

IgA

IgM

IgE

C3

C4

Protein electrophoresis

## HEMATOLOGY

### Bone Marrow

Aspirate and/or biopsy preparation  
 Descriptive morphology  
 Diagnosis

### Coagulation

International normalized ratio (INR)  
 Activated partial thromboplastin time (APTT)  
 Fibrinogen  
 Heparin assay  
 Factor VIII  
 Factor IX  
 D-dimer  
 Thrombophilia investigation:

Activated protein C (APC) resistance  
 Antithrombin  
 Protein C  
 Protein S  
 Anticardiolipin antibody (ACA)  
 Factor V leiden  
 Prothrombin gene mutation  
 Russell viper venom (dilute and confirm)

### Flow Cytometry

Lymphocyte CD3/CD4/CD8 quantitation by immunophenotyping  
 Leukocyte immunophenotyping in the investigation of hematological disorders (lymphoma/leukemia)  
 CD34<sup>+</sup> stem cell enumeration

### Red Cell Disorders

Hemoglobin S screen  
 Hemoglobin fraction quantitation

### Morphology

Peripheral blood film:  
 Differential leukocyte count  
 Descriptive morphology  
 Diagnosis

### Routine Hematology

Leukocyte count  
 Erythrocyte count  
 Hemoglobin  
 Hematocrit

Mean corpuscular volume  
 Thrombocyte count  
 Automated leukocyte differential  
 Reticulocyte count  
 Manual body fluid cell count

### Transfusion Medicine

ABO and Rh grouping and interpretation  
 Antibody detection  
 Antibody identification  
 Direct antiglobulin testing (DAT)  
 Crossmatching  
 Phenotyping  
 Antibody titration

### Bacteriology

Isolation and identification of aerobic/anaerobic organisms from:  
 Blood  
 Genital specimens  
 Throat swabs  
 Urine  
 Body fluids  
 Other swabs/pus  
 Sputum  
 Stool samples  
 Quantitative urine cultures  
 Interpretation and reporting of cultures  
 Antimicrobial susceptibility testing  
 Interpretation and reporting of antimicrobial susceptibility findings

Serological grouping and identification  
 Gram stain interpretation  
 Detection of *Clostridium difficile* toxin  
 Detection of acid-fast bacilli from direct smears  
 Quantification of acid-fast bacilli

### **Mycology**

Isolation and identification of:  
   Dermatophytes  
   Moulds  
   Yeasts  
 Wet preparations for fungal elements

### **Parasitology**

Wet preparation examination of stool samples  
 Preparation of faecal concentrates  
 Staining of samples for gastrointestinal parasites  
 Identification and quantification of parasites  
 Use of special stains

### **Virology**

Antibody detection:  
   Cytomegalovirus (CMV)  
   Hepatitis A, B, and C  
   HIV  
   Varicella zoster virus (VZV)  
 Antigen detection:  
   *Chlamydia trachomatis*  
   Respiratory syncytial virus (RSV)  
   Influenza A virus  
   Influenza B virus

Parainfluenza virus

### **GENETICS**

#### **Cytogenetics**

Blood  
 Bone marrow  
 Tumour  
 Tissue  
 Amnion cells  
 Fixed cell culture

### **ANATOMIC PATHOLOGY**

#### **Histopathology**

#### **Histotechnology**

Routine stains  
 Special stains  
 Immunohistochemistry stains  
 Breast cancer markers ER/PR and HER2

#### **Cytopathology**

Gynecological  
 Non-Gynecological  
 Respiratory:  
   Sputum  
   Bronchial washings  
   Bronchial brushings  
 Urinary  
 Body fluids  
 Fine needle aspiration of breast

Fine needle aspiration of head and neck:  
   Thyroid  
   Lymph node  
   Salivary glands

### **OTHER**

#### **Point-of-Care Testing**

Glucose meters  
 HIV

#### **Ontario Maternal Serum Screening (Database Review)**

Serum analytes:  
 Alpha fetoprotein (AFP)  
 Total human chorionic gonadotropin (Total hCG)  
 Unconjugated estriol ( $\mu E_3$ )  
 Dimeric Inhibin-A (DIA)  
 Free beta human chorionic gonadotropin (free  $\beta$ -hCG)  
 Pregnancy-associated plasma protein A (PAPP-A)  
 Multiple of median (MoM):  
 AFP, hCG,  $\mu E_3$ , DIA, free  $\beta$ -hCG and PAPP-A

## Publications and Education (April 1, 2008–March 31, 2009)

### April 1, 2008–March 31, 2009

#### Scientific Communications

Crawford L. Accreditation – Setting the standard for Ontario laboratory practice. *OSMT Advocate* (Volume 15 Issue 3). Fall 2008.

Crowther M, Bates S, Keeney M and Raby A. Human Derived D-dimer for External Quality Assessment: Results of Four Surveys in Ontario. *Am J Clin Pathol*. *In Press*.

Turner C. Ontario Laboratory Accreditation — An Update. The ORBCoN Report (Ontario Regional Blood Coordinating Network). February 2009.

#### Invited Presentation and Talks

Thompson D. HIV Testing as Prevention — Strategy, Program Implementation and Epidemiology. HIV Testing Conference. AIDS Bureau, Ministry of Health and Long-Term Care. Toronto, ON. May 2008.

Crawford L. Latest Initiatives in Laboratories Services. Insight. St. Andrew's Club and Conference Centre, Toronto, ON. April 2008.

Crawford L. Furthering Laboratory Accreditation. Latest Initiatives in Laboratory Services. inSight Information. Toronto, ON. April 2008.

Jaeger R. Ontario's Experience with Mandating ISO:15189 Accreditation: Valuable Lessons Learned. Lab Quality Confab on Quality Management in Diagnostic Medicine. Atlanta, GA, USA. September 2008.

Raby A. Coagulation External Quality Assessment—The Ontario Perspective. 4th Annual McMaster Update for Thromboembolism. Hamilton, ON. November 2008.

Gun-Munro J. The new ISO 17043 standard — preferred standard for EQA Providers of medical laboratories. EQALM Symposium. EQALM. Birmingham, UK. September 2008.

#### Posters

Fleming CA, Toye B, Jamieson F, Meaney H, Poutanen S, Rutherford C, Sarabia A, Gun-Munro J, Flynn G. Quality Management Program — Laboratory Services (QMP–LS). Use of quality indicators by clinical bacteriology laboratories in Ontario, Canada—External quality assessment (EQA) survey by Quality Management Program—Laboratory Services (QMP–LS). 18th European Congress of Clinical Microbiology and Infectious Diseases. Barcelona, Spain. April 2008. (QMP–LS website)

Petersons A, Gun-Munro J, Flynn G. Process Validation in Transfusion Medicine Laboratories. AABB 2008. Montreal, QC. April 2008. (QMP–LS website)

#### Webinars

Turner C. OLA External PT/EQA Data Entry. January 2009.

Fleming CA. Performance Scores (Q Scores) for Bacteriology Surveys. November 2008.

Raby A. Performance Qualitative (Q Scores) for Morphology and Red Cell Disorder Surveys. December 2008.



**[www.QMPLS.org](http://www.QMPLS.org)**

Quality Management Program—Laboratory Services  
1510–250 Bloor Street E.  
Toronto, ON M4W 1E6  
Tel.: 416.323.9540 | Toll-Free: 1.877.323.9540  
Fax: 416.323.9324