QMP-LS
ONTARIO MEDICAL ASSOCIATION

Quality Management Program—Laboratory Services
2010 Annual Review

PRODUCTS AND SERVICES YOU CAN COUNT ON

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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

AN ESSENTIAL PART OF THE HEALTHCARE SYSTEM

QMP–LS uses the principles of quality management to ensure that the lab results used to make diagnosis and prognosis are reliable. QMP–LS is dedicated to enhancing the quality of laboratories and other healthcare organizations through ISO 15189-based accreditation services, external quality assessment 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 department 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).

QMP–LS also works with the Institute for Quality Management in Healthcare (IQMH) to provide medical labs with education and resource material, and labs outside of Ontario with accreditation and external assessment.

Message from the Managing Director

DR. GREGORY FLYNN

The Quality Management Program—Laboratory Services has maintained its extensive lab accreditation and external quality assessment programs in Ontario in keeping with our strategic plan. The program continues to operate under an agreement between the OMA and the Ministry of Health and Long-Term Care (MOHLTC). The agreement was renegotiated in 2010–11 and provides the over arching objectives of the Ministry and the requirements for delivering, monitoring and funding. The government funds the core program for services to Ontario licensed labs, as well as the costs of our commercial real estate, salaries and operating expenses based on an annual operating plan approved by the Programs Branch of the MOHLTC. The new agreement allows QMP–LS to distribute its services to other government regulators and individual labs.

This year we emphasize our commitment to quality and excellence in healthcare by continuing to apply the concepts of quality management to all the products and services offered through our program.

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In 2010–11 QMP–LS walked the talk by putting itself through the test and allowing its External Quality Assessment (EQA) division to be assessed against ISO/IEC 17043. We were successful in this challenge and QMP–LS is now an accredited proficiency testing provider by the American Association for Laboratory Accreditation (A2LA). Our Ontario Laboratory Accreditation (OLA) division also

underwent its third evaluation against ISO/IEC 17011 and was successful in achieving its peer evaluation by Standards Council of Canada (SCC).

Our initiatives to uphold high-quality products and services does not end there; the process involved in maintaining quality is an infinite cycle, so we continue to conduct regular internal audits to keep ourselves in check in preparation for future external audits.

As we expand our services outside of Ontario, we are faced with the challenge of ensuring we address our changing needs with respect to resources.

The lease at our current office at 250 Bloor Street East is not available for renewal in 2012, so a team of QMP–LS staff scouted the city for the best location within our budget that will accommodate our changing needs, and be accessible by both our staff and valuable committee members that travel regularly to our offices.

We were able to secure a similar space at 393 University Avenue, and the move is scheduled for late October 2011.

Sharing our knowledge. It has been QMP–LS' long standing belief that education is a critical component in its program. This belief was solidified by working with its distributor, the Institute for Quality Management in Healthcare (IQMH). The launch of the IQMH website facilitated delivery of products and services, and attracted new business relationships in other jurisdictions. QMP–LS has reached a point where there is a demand for our knowledge outside of Ontario as evidenced in the newly developed business relationships, and by the interest shown in the educational products distributed by IQMH.

The OLA program is currently providing ISO 15189Plus™ beyond Ontario. In some cases this is delivered in both French and English—a program first in QMP–LS' history. Continuing our commitment to provide added value to our customers, the Decoding ISO 15189 interactive online education series for labs preparing for accreditation is also being translated and reproduced in French. The histology and cytology EQA programs developed for Ontario labs were purchased through IQMH by a client outside of Ontario. Details about other QMP–LS knowledge sharing products and services can be found in the EQA and OLA reports.

It should be said that there would be no knowledge to transfer without the medical

lab professionals that are at the heart of QMP–LS' program. Our consultant and staff technologists, and the expert volunteers on our scientific committees hold quality and continual improvement as a critical goal in all their efforts.

Commitment to quality and excellence in healthcare. Today our program is a model of how you can make quality and continual improvement a critical goal within your organization, while efficiently making use of your resources. Ontario can be proud of this accomplishment — it is through the funding of Ontario's MOHLTC and its commitment to achieving excellence in healthcare, the efforts of the doctors of Ontario (Ontario Medical Association) and the many medical lab professionals that develop new knowledge in their fields of lab medicine and in the work of our scientific committees that QMP–LS has reached a point where there is a demand for our knowledge and access to our expertise within and outside of Ontario.

In the year ahead, we will look for further opportunities to improve our customer service with our participants in Ontario and our new clients in other jurisdictions. QMP–LS commits to delivering products and services you can count on.

In a time when providers are increasingly accountable for demonstrating proficiency and quality improvement, QMP–LS and IQMH continue to be leaders in the field of quality management, and we continue to look for opportunities to share knowledge in innovative ways.

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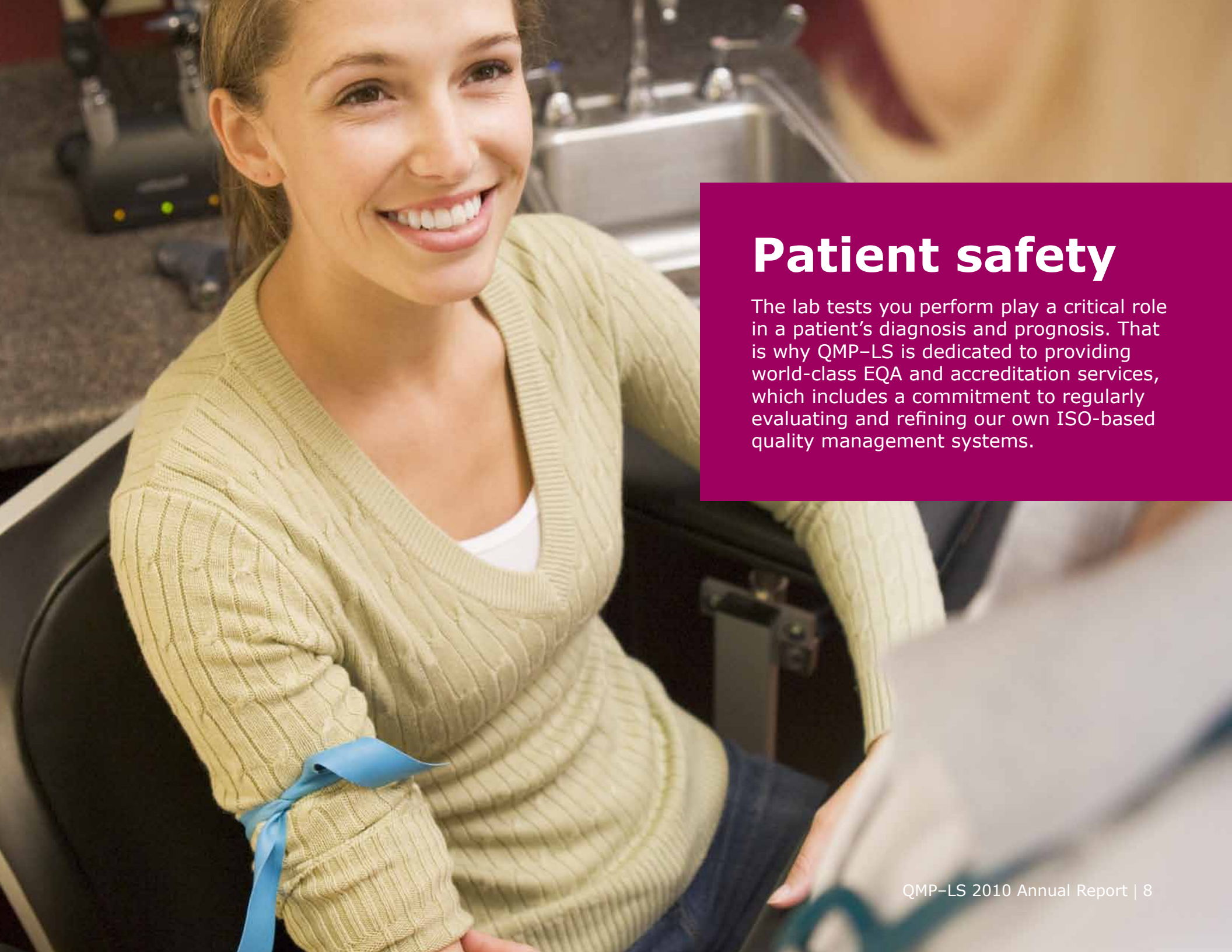
Accountability

QMP–LS strives to achieve international standards in order to offer the best programs possible. This year, our External Quality Assessment division achieved ISO/IEC 17043 accreditation and our Ontario Laboratory Accreditation division went through its third ISO/IEC 17011 assessment.

Continual improvement

QMP–LS undergoes regular internal audits, external assessments and management reviews in order to identify areas for improvement.



Patient safety

The lab tests you perform play a critical role in a patient's diagnosis and prognosis. That is why QMP–LS is dedicated to providing world-class EQA and accreditation services, which includes a commitment to regularly evaluating and refining our own ISO-based quality management systems.

17043

Accredited

QMP–LS received a certificate of accreditation in October 2010 to ISO/IEC 17043:2010 *Conformity assessment — General requirements for proficiency testing.*

PLAYING A CRITICAL ROLE IN PATIENT SAFETY

QMP–LS believes quality management systems can make a difference. In the healthcare field, they can mean hospital-acquired infections are reduced, wrong site operations are avoided and the lab test results physicians use to make their diagnosis and prognosis can be counted on.

In Ontario, licensed labs that conduct medical tests undergo rigorous scrutiny thanks to the quality management programs offered by QMP–LS and to the hard work and commitment of the province's lab professionals.

Labs must undergo proficiency testing for the entire scope of tests they offer. In many cases, this is done through the surveys offered by QMP–LS' EQA division. EQA produces comprehensive survey reports that offer cumulative results over time, allowing a lab to better understand and track its performance against its peers. EQA also produces educational committee comments which examine common errors and provide tips on how to avoid them.

QMP–LS also accredits laboratories to its OLA 15189Plus™ standard, which is based on ISO 15189 and a number of other rigorous industry standards. In order to achieve accreditation, labs set up quality management systems that allow them to standardize their processes and procedures and ensure lab technologists understand and follow procedures.

OUR OWN QUALITY MANAGEMENT SYSTEM

In order to provide our participants with the best services possible, QMP–LS also has its own quality management system in place. We meet international standards for proficiency testing bodies (ISO/IEC 17043) and accreditation bodies (ISO/IEC 17011). We undergo periodic evaluations to both standards.

In addition, QMP–LS also conducts regular internal audits to maintain compliance and gain continual improvement in between assessment visits.

Finally, we review our quality management system each year through our annual management review.

Management Review

Management reviews are a key component of a quality management system and also a requirement for ISO 9001:2008. They perform two functions — they allow organizations to check that their quality management system is functioning properly

17011

Assessed

Our OLA program, OLA 15189Plus™, is aligned with ISO/IEC 17011:2004 *Conformity Assessment — General requirements for accreditation bodies accrediting conformity assessment bodies.*

as well as to plan future goals and make necessary changes.

The management review is a formal meeting led by the quality manager in which we review the status and effectiveness of our quality management system. It is a process involving management to evaluate and analyze practices for the purpose of improving them. Organizational policies and records are reviewed during this process.

QMP–LS has identified the following priorities as a result of annual management reviews:

- Increasing awareness of annual objectives and progress
- Continual improvement of the overall organizational structure
- Renewing focus on long-term strategy
- Evaluating the relationship between QMP–LS and IQMH
- Identification of top categories of non-conformances and further corrective actions
- Implementation of a uniform approach across all EQA disciplines to engage committee members in improved turn-around times
- Annual overall quality system pulse check
- Identifying a venue to discuss partnerships
- Review of top pressure points from the previous year and brainstorming of solutions

MEETING INTERNATIONAL STANDARDS

ISO/IEC 17043

QMP–LS is accredited as a proficiency testing provider by the American Association for Laboratory Accreditation (A2LA). QMP–LS is accredited in accordance with the recognized International Standard ISO/IEC 17043: 2010 Conformity assessment — *General requirements for proficiency testing* and meets the management system requirements of ISO/IEC 17043:2010, which includes the principles of ISO 9000:2005. The accreditation covers the specific proficiency testing samples listed on the agreed scope of accreditation.

ISO/IEC 17011

QMP–LS' OLA 15189Plus™ accreditation process is aligned with ISO/IEC 17011:2004 Conformity Assessment — *General requirements for accreditation bodies accrediting conformity assessment bodies*. This is not an accreditation standard but a peer evaluation standard, and we undergo regular evaluation by Standards Council of Canada (SCC) to this standard.

2

Internal Audits

Internal audits are part of the checks QMP–LS has put into place to ensure our quality management system is effective.

2

External Assessments

QMP–LS is assessed periodically by A2LA to ensure it meets ISO/IEC 17043 and by SCC to ensure it complies with ISO/IEC 17011.

ILAC Guidelines

Our OLA 15189Plus™ standard is also aligned with International Laboratory Accreditation Cooperation (ILAC) policies and guidelines for assessor qualifications, training and competence.

HELPING SET THE 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 212 Working Group on ISO 15189
- Standards Council of Canada — Medical Laboratory Working Group, Partner Advisory Group and Task Group on Laboratories
- Canadian Association for Laboratory Accreditation — Accreditation Council
- International Laboratory Accreditation Cooperation — Executive, Accreditation Issues Committee, Proficiency Testing Consultative Group
- Clinical Laboratory Standards Institute — Working Group on Quality Management System: Leadership and Management Roles and Responsibilities
- Clinical Laboratory Standards Institute — Subcommittee on Development and Use of Quality Indicators

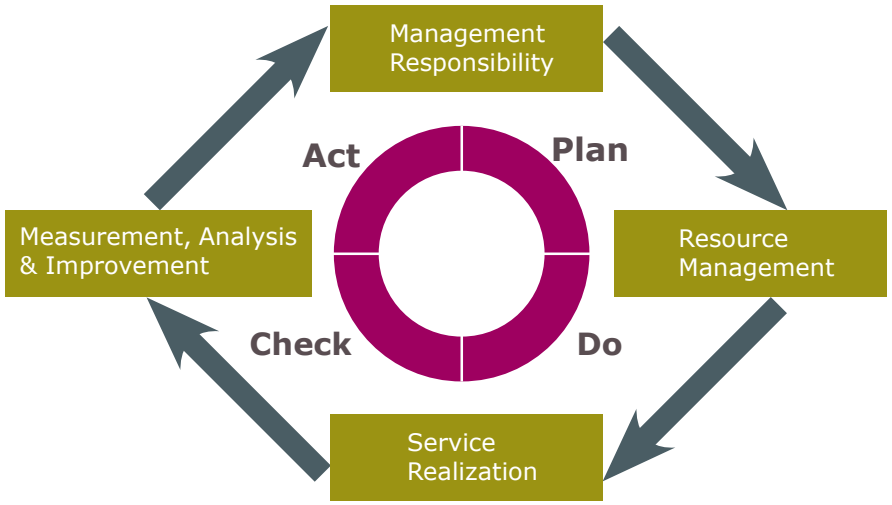
QMP–LS' Quality Management System

Management Responsibility. QMP–LS conducts an annual management review led by the Quality Manager.

Resource Management. Each year senior management sets goals for the year. These are used to determine how resources will be allocated in the coming year and which projects will take priority.

Service Realization. QMP–LS' staff work with our committees, which are made up of experts in their fields, to provide services that meet our customers' needs. QMP–LS produced 82 committee comments, conducted 46 assessment visits and produced 18 webinars and webcasts this year.

Measurement, Analysis & Improvement. QMP–LS conducts regular internal audits and undergoes assessment both to the ISO/IEC 17043 and ISO/IEC 17011 standards. This year QMP–LS achieved accreditation to the ISO/IEC 17043 standard and was assessed to the ISO/IEC 17011 standard. ISO/IEC 17011 is a peer evaluation standard rather than an accreditation standard.



External Quality Assessment

The External Quality Assessment (EQA) 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.

The EQA program plays a critical role in a lab's quality system. It complements the lab's quality control and quality assurance programs that ensure the test results physicians use to make a diagnosis and prognosis are accurate and reliable. EQA also compares different methods and instruments for the same test. This 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.

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 nine volunteer scientific committees covering all of the major disciplines of laboratory medicine.

Transparent

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

Essential

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

EQA Disciplines

- Anatomic pathology
- Chemistry
- Cytology
- Endocrinology
- Cytogenetics
- Hematology
- Immunology
- Bacteriology
- Parasitology
- Mycology
- Transfusion medicine
- Virology
- Point-of-care testing

Ontario Laboratory Accreditation

The Ontario Laboratory Accreditation (OLA) program provides medical laboratories with formal recognition of their competence to perform examinations within their scope of testing. By achieving accreditation, laboratories commit to continually: standardizing their processes, addressing diminishing resources with improved efficiency, ensuring safety for patients as well as employees, and improving quality with internal audits and quality indicators. 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.

OLA accredited laboratories may also receive an internationally-recognized ISO 15189 certificate (OLA 15189Plus™) through OLA's partnership with the Standards Council of Canada. OLA's peer-based, in-depth accreditation process helps laboratories understand ISO 15189 requirements, engage staff, implement best practices and promote patient safety. To be considered for accreditation, a laboratory must undergo an assessment visit conducted by a team of peers accompanied by an OLA staff technologist. The assessment team is comprised of both quality system and technical experts carefully tailored to the laboratory's scope of testing. If areas of non-conformance are cited, the laboratory is expected to take corrective action within 90 days of the visit. A panel then determines if the laboratory

Ontario Laboratory Accreditation

meets the criteria for an accreditation certificate. Ongoing surveillance includes mid-cycle assessment and monitoring of proficiency testing/external quality assessment and changes within the laboratory (ownership/management, space, scope of testing). These activities ensure continued competency. Requirements for OLA 15189Plus™ accreditation are based on these rigorous standards:

- ISO 15189:2007(E) Medical laboratories—particular requirements for quality and competence
- ISO 15190:2003(E) Medical laboratories—requirements for safety
- ISO 22870:2006(E) Point-of-Care Testing (POCT)—requirements for quality and competence
- CSA Z902-10 Blood and Blood Components February 2010

Accountability

Many medical laboratories are accountable to the government to ensure public protection. Mandatory OLA accreditation in Ontario and Atlantic Canada guarantees that every medical laboratory in the province has a world-class quality management system. Each accredited laboratory 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 laboratory is competent and gives staff and the public confidence that its system will identify

OLA 15189Plus™ Standards

- ISO 15189:2007(E) Medical laboratories — particular requirements for quality and competence
- ISO 15190:2003(E) Medical laboratories — requirements for safety
- ISO 22870:2006(E) Point-of-Care Testing (POCT) —requirements for quality and competence
- CSA Z902-10 Blood and Blood Components February 2010

Ontario Laboratory Accreditation

and correct 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 laboratory professionals.

Accreditation you can count on

Accreditation assessments are conducted in accordance with the ISO/IEC 17011 standard. Assessment teams consist of medical laboratory professionals who are pre-trained and pre-certified by QMP–LS using International Laboratory Accreditation Cooperation guidelines. Assessors understand and share the challenges that laboratories face on a daily basis. They are accompanied by a QMP–LS OLA staff technologist.

OLA is committed to upholding the following values in the delivery of its accreditation program:

- *Responsible*
- *Objective*
- *Consistent*
- *Transparent*
- *Open-minded*
- *Respectful*

External Quality Assessment Report

What does accountability mean to the EQA division? It means that we assume responsibility for and are transparent to our stakeholders regarding our policies, actions, products and performance. It also assures we interact and respond to stakeholder concerns through various reporting mechanisms such as interaction with peer advisory committees, distribution of participant satisfaction surveys, announcements in the *QMP–LS News* and this annual *Review*.

Who are the major stakeholders of the EQA division? The Ontario Ministry of Health and Long-Term Care (MOHLTC) as the funder of and regulator for Ontario medical laboratories and the laboratories themselves as participants are primary stakeholders; as well the Quebec Ministry of Health and their lab participants, lab participants who independently select QMP–LS for provision of EQA surveys and, last but not least, in vitro diagnostic device manufacturers.

Figure 1 demonstrates an accountability framework between QMP–LS and its primary stakeholders for the assurance of reliable quality management of medical laboratory tests in Ontario. As funder of the program, the Ontario MOHLTC is accountable to the Provincial Auditor to assure the provision of reliable laboratory tests. QMP–LS is accountable to the MOHLTC for this purpose and for assuring appropriate corrective action when problems occur. Ontario laboratories are accountable to QMP–LS to participate in its mandatory EQA programs and, when necessary provide evidence of satisfactory corrective action. The MOHLTC subsidizes the laboratory costs associated with participation in the QMP–LS programs. Ultimately we are all accountable to Ontario patients and their families for the quality of service provided.

Figure 1. Accountability framework

How does the EQA division assure accountability?

In order to assure the quality of the EQA programs provided for and to its stakeholders, QMP–LS chose to seek external accreditation to an international standard, ISO 17043:2010. *Conformity Assessment – General requirements for proficiency testing*. Although seeking accreditation to an

External Quality Assessment Report

international standard is not mandatory for QMP–LS as an organization, we elected to make ourselves accountable to an external accrediting body to assure our stakeholders that we provide world-class EQA programs.

While the EQA program framework is developed according to international standards, QMP–LS also works with its various stakeholders to ensure the provision of appropriate expertise, confirm ongoing satisfaction with the program and to identify improvement opportunities. QMP–LS communicates annually with the MOHLTC when renewing its operating plan and with other program funders at the time of contract renewal to ensure that the EQA programs meet the desired needs. The MOHLTC also convenes quarterly meetings to receive progress reports on Ontario laboratory performance issues identified through EQA surveys or Ontario Laboratory Accreditation (OLA) site visits.

The QMP–LS scientific committees are working committees comprised of peer experts that meet regularly to review and advise on development of EQA survey models and performance assessment activities. These committees (Appendix A), as well as other stakeholder advisory committees provide QMP–LS with advice regarding the future needs for quality management of current and evolving tests and technologies. Individual laboratory feedback is encouraged through use of satisfaction surveys, complaints and appeals processes or by response to *QMP–LS News* articles.

QMP–LS identifies improvement projects and annual objectives for its EQA program, primarily recognized/discovered and developed from feedback provided through clients, the scientific and advisory committees, participants, staff, subcontractors and internal and external audits.

Highlights of achieved objectives for 2010–11 are summarized below.

Performance Highlights

In 2010–11, the EQA division of QMP–LS completed several objectives aimed at improving the quality of services provided to QMP–LS stakeholders:

- Successful achievement of accreditation to ISO 17043:2010. *Conformity Assessment: General requirements for proficiency testing* for all EQA surveys provided.
- Development of an EQA performance summary report for use by laboratory management.
- Centralization of preparation and distribution of EQA testing material.
- Distribution of participant satisfaction survey.
- Development of performance scores for interpretive surveys.
- Development of expertise in digital morphology.

Achieve Accreditation to ISO 17043:2010

In 2010, we successfully achieved accreditation for 46 EQA surveys offered to participants. In doing so, QMP–LS was one of the first organizations worldwide to achieve accreditation to this new standard. In addition to meeting ISO 17043:2010 requirements, QMP–LS also meets the

External Quality Assessment Report

principles of ISO 9000:2005. These standards assure that QMP–LS maintains a functional quality management system based on the ISO principles of management responsibility, resource management, product and service realization, customer service and continual improvement. The technical standards of ISO 17043:2010 specify the requirements for product and service realization. During 2011, QMP–LS will undergo a second site visit to confirm that these standards continue to be met, and then again every four years. Throughout this accreditation cycle, indication of an annual internal audit and management review activities among other evidence is required. The annual internal audit and management review activities commit QMP–LS to a cycle of continual improvement for all requirements.

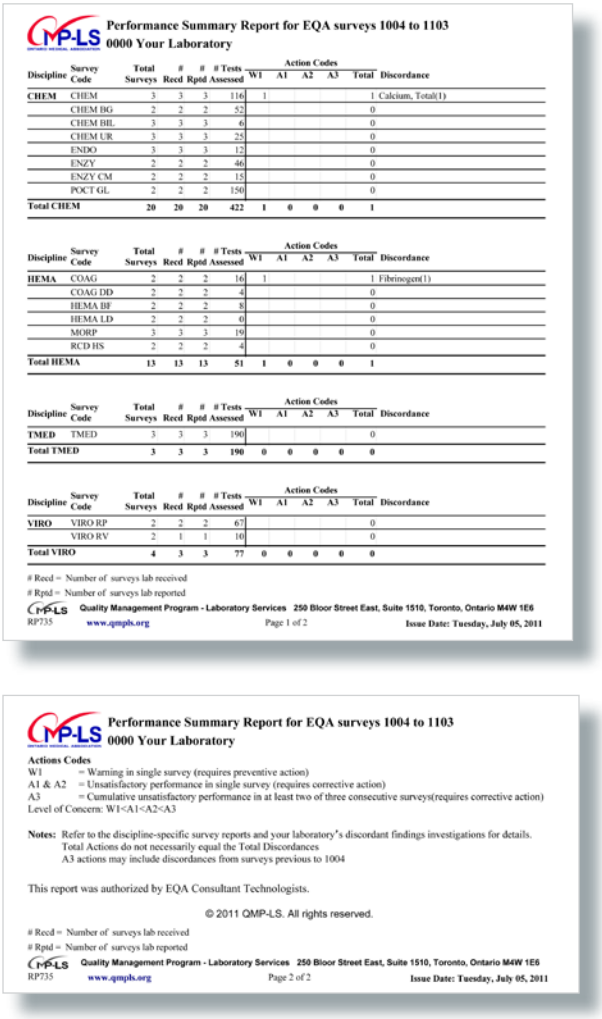
Develop EQA Performance Summary Report

The introduction of performance scores and action codes has facilitated provision of information to participants regarding survey performance and need for investigation and/or implementation of corrective action. This information was made available to participants for individual surveys during 2009–10. However, management staff, as part of their accountability to their organization, still needed to collate this survey information to understand how their laboratory was functioning in EQA surveys, either within a discipline or within the entire laboratory. During 2010–11, QMP–LS developed performance summary reports (Figure 2) to address this need. These multidisciplinary reports are based on the action codes received by laboratories for each survey performed during the last fiscal year and identify those areas where improvement was necessary.

Explore Centralization of EQA Testing Material

During 2010 QMP–LS issued a request for proposal (RFP) for preparation and distribution of EQA testing material. After careful review and consideration, it was decided that none of the applicants could successfully fulfil all of the RFP requirements. However, subsequently we negotiated with several different subcontractors for the preparation of EQA material and we were

Figure 2. Sample EQA performance summary report



Performance Summary Report for EQA surveys 1004 to 1103
0000 Your Laboratory

Discipline	Survey Code	Total Surveys	# Recd	# Rptd	# Tests Assessed	Action Codes W1	A1	A2	A3	Total	Discordance
CHEM	CHEM	3	3	3	116	1					1 Calcium, Total(1)
	CHEM BG	2	2	2	52						0
	CHEM BIL	3	3	3	6						0
	CHEM UR	3	3	3	25						0
	ENDO	3	3	3	12						0
	ENZY	2	2	2	46						0
	ENZY CM	2	2	2	15						0
	POCT GL	2	2	2	150						0
Total CHEM		20	20	20	422	1	0	0	0	1	

Discipline	Survey Code	Total Surveys	# Recd	# Rptd	# Tests Assessed	Action Codes W1	A1	A2	A3	Total	Discordance
HEMA	COAG	2	2	2	16	1					1 Fibrinogen(1)
	COAG DD	2	2	2	4						0
	HEMA BF	2	2	2	8						0
	HEMA LD	2	2	2	0						0
	MORP	3	3	3	19						0
	RCD HS	2	2	2	4						0
Total HEMA		13	13	13	51	1	0	0	0	1	

Discipline	Survey Code	Total Surveys	# Recd	# Rptd	# Tests Assessed	Action Codes W1	A1	A2	A3	Total	Discordance
TMED	TMED	3	3	3	190					0	
Total TMED		3	3	3	190	0	0	0	0	0	

Discipline	Survey Code	Total Surveys	# Recd	# Rptd	# Tests Assessed	Action Codes W1	A1	A2	A3	Total	Discordance
VIRO	VIRO IP	2	2	2	67					0	
	VIRO RV	2	1	1	10					0	
Total VIRO		4	3	3	77	0	0	0	0	0	

Recd = Number of surveys lab received
Rptd = Number of surveys lab reported

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Performance Summary Report for EQA surveys 1004 to 1103
0000 Your Laboratory

Actions Codes
W1 = Warning in single survey (requires preventive action)
A1 & A2 = Unsatisfactory performance in single survey (requires corrective action)
A3 = Cumulative unsatisfactory performance in at least two of three consecutive surveys(requires corrective action)
Level of Concern: W1<A1<A2<A3

Notes: Refer to the discipline-specific survey reports and your laboratory's discordant findings investigations for details.
Total Actions do not necessarily equal the Total Discordances
A3 actions may include discordances from surveys previous to 1004

This report was authorized by EQA Consultant Technologists.

Recd = Number of surveys lab received
Rptd = Number of surveys lab reported

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External Quality Assessment Report

able to identify a primary subcontractor for the preparation of chemistry material and the distribution of all EQA testing material. This subcontractor is Gamma Dynacare Medical Laboratories (GDML), located in Brampton, Ontario. GDML is currently preparing the majority of EQA material for chemistry and will assume the distribution function in October 2011, at the time when QMP–LS is preparing for office relocation.

Distribute Participant Satisfaction Survey

A participant satisfaction survey was issued to all participants in November 2010 to gain an understanding of participant acceptance of the significant changes made to the EQA program over the past five years. Changes included the use of web-based worksheets, reports and discordant findings investigations and the introduction of performance scores for evaluation of performance.

While the overall response to the survey was extremely positive there were several opportunities for improvement that were identified:

- Improve QView™ search function and file tree structure for easy retrieval of documents.
- Improve e-notice function (frequency, link to reports and discordant findings forms).
- Discipline-specific improvements for EQA survey instructions requested.
- Discipline-specific improvements for web-based analysis worksheets requested.
- Perform a review of the number and type of EQA survey reports issued.
- Improve turnaround time and distil content of committee comments.
- Provide more direction and time for completion of discordant findings investigation and provide feedback after submission.

These issues are currently under investigation for implementation during 2011–12 where feasible.

Develop Performance Scores for Interpretative Surveys

While performance scores were developed and implemented for the majority of EQA surveys during 2008–10, this had not been accomplished for the following interpretive surveys:

- Cytology (CYTO)
- Cytogenetics (GENE)
- Hematology Bone Marrow Aspirate (HEMA-BM)

Since it is an OLA criterion that acceptable EQA schemes grade participant performance, it was important to assure that these surveys meet the same eligibility standards as other QMP–LS EQA surveys. Scoring schemes for these EQA surveys were developed during 2010–11 and will be ready for implementation during 2011–12.

Develop Expertise in Digital Morphology

During 2010–11, a series of successful digital morphology pilot surveys were conducted for the cytology and hematology (bone marrow and morphology) interpretive slide surveys. These pilots were intended to provide insight into the value of adding whole slide imaging to the QMP–LS EQA program by hosting images on the web.

External Quality Assessment Report

Over 80% of the participants for all three surveys responded that digital morphology would be an educational benefit to themselves or their laboratories. While these surveys were considered to be successful, it was recognized that enhanced website services are necessary to further improve efficient retrieval of images, enable full slide scanning and focusing capabilities, and providing the capability for annotation of images for future review. It is proposed to continue inclusion of pilot digital morphology surveys during 2011–12 using enhanced web hosting services to explore and improve the digital morphology experience for participants.

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 2010–11, QMP–LS provided 102 challenge surveys, 5 web-based educational surveys, 3 patterns-of-practice surveys and 2 questionnaires. The scope of EQA surveys provided is shown in Table 1. The parameters monitored by the surveys are listed by discipline in Appendix C. The number and type of laboratory participants are shown in Table 2.

EQA Survey Highlights

There was very little change to the testing menu for 2010–11. See Appendix C for parameters monitored in this year's surveys. Information regarding 2010–11 EQA survey activity is well described in the survey reports and committee comments, available through QMP–LS' password-protected document server, QView™.

Patterns-of-Practice Surveys. The following patterns-of-practice surveys were conducted and reported as committee comments:

Cytology — The purpose of this survey was to gather information about cytopathology practice in 2009 and to assess general trends in distribution of cases, screening, reporting, quality assurance, methods of reporting and access to the Internet.

Bacteriology — The objectives of this survey

Table 1. 2010–11 EQA Surveys for Ontario

Survey	Challenge	Dry	Patterns of Practice	Questionnaire	Digital Morphology
Bacteriology	3		1	1	
Acid Fast Stain	1				
C. difficile Assay	2				
Routine Chemistry	11				
Drugs	4				
Enzymes	4				
Lipids	3				
Blood Gases	2				
Cytogenetics	2				
Cytology	2	1	1		1
Routine Hematology	6			1	
Coagulation	10				
Red Cell Disorders	4	1			
Morphology	3	1			1
Bone Marrow	2	1			1
Flow Cytometry	6				
Endocrinology	3				
Immunology	3				
Transfusion Medicine	5	1			
Virology	10				
Mycology	2				
Intestinal Parasites	2				
Blood Parasites			1		
Histotechnology	8				
POCT HIV	2				
POCT Glucometers	2				
Total	**102**	**5**	**3**	**2**	**3**

External Quality Assessment Report

were to evaluate practice with superficial wound swabs and to provide guidance on the interpretation of the clinical significance of culture results from superficial wound swabs.

Parasitology — The objective of this survey was to determine the current practices in Ontario labs for blood parasites including rapid diagnostic tests (RDTs) for malaria.

Questionnaires. The Hematology HEMA-1005-Q questionnaire was conducted and reported as committee comments. It was designed to determine current practice of participants performing automated body fluid cell counts, focusing on validation of the hematology analyzer to perform these counts. The results highlighting practice were presented at the McMaster/QMP–LS Hematology Education Day and at the 2011 International Council for Standardization in Hematology (ICSH) general meeting. Subsequently, a collaboration with CAP and UK NEQAS to distribute the same questionnaire and co-publish the findings of the three programs has been scheduled to take place in 2011–12.

The Bacteriology BACT-1101-Q questionnaire is conducted annually to gather data and report on antimicrobial resistance in common hospital pathogens in Ontario. The summary of the 15th annual survey was published as a report: *Antimicrobial Resistance in Common Hospital Pathogens in Ontario* and is available on the QMP–LS website.

Reports to Participants. Reports provided to participants at the end of each survey include preliminary reports of the assigned values (consensus or reference values), summary information of all participant responses as well as reports of individual laboratory performance. Committee comments provide a narrative report of the survey which includes educational comments provided by the scientific committees. The following reports were provided:

- 100 provisional reports
- 121 comprehensive reports
- 44 concise reports
- 97 cumulative reports
- 82 committee comments

Table 2. Comparison of Types of Ontario Labs Participating in QMP–LS EQA Surveys

Type	EQA and OLA	OLA Only
Hospital labs	170	3
Community labs	26	1
Public health labs	12	0
Other labs	5	0
Total	**213**	**4**

Laboratory Performance

Investigation of Discordant Findings. Labs reporting discordant results in EQA surveys are requested to investigate and, if appropriate, report a summary of the investigation and corrective actions to QMP–LS. The overall discordance rate for the 12-month period between April 2010 and March 2011 for the major disciplines was 0.70% compared to 0.67% in 2009–10.

Summary information for causes of discordances of the major disciplines is included in Figure 3.

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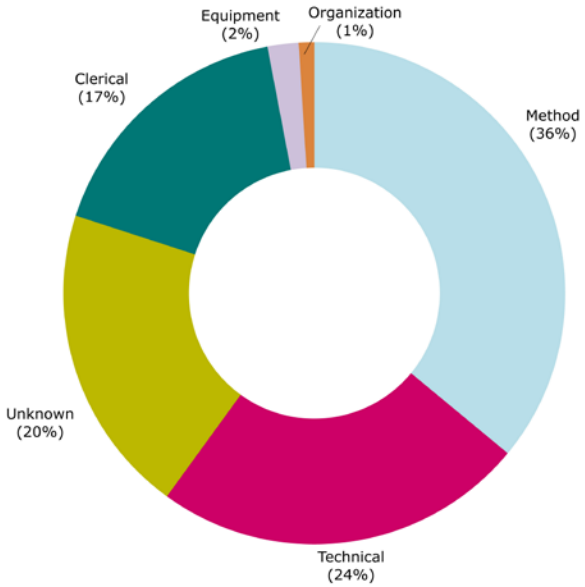
The most common categories of discordance are similar to those reported in 2009–10 and were associated with method (36%) and technical (24%) (Figure 3). The majority of method-related contributing causes were associated with manufacturer issues, followed by accuracy and/or sensitivity/specificity of automated systems and kit methods. Key technological contributing causes included failure to follow written procedures or survey instructions, sample handling issues and failure to correctly interpret results or perform additional testing. The third most common category was unknown causes (20%). This has increased from 14% in 2009–10. The increasing number of unknown causes (largely attributed to random error or unexplained causes) is of concern since the laboratories reporting these have no basis for understanding how to prevent similar errors from recurring.

This information is shared with scientific committees to identify opportunities for improvement when planning future surveys and educational activities.

Figure 3. EQA discordant findings



QMP–LS Scientific Committees and Volunteers

Eleven scientific committees provide advice and support to the EQA program. In 2010–11, QMP–LS hosted a total of 50 scientific committee meetings involving 59 laboratory physicians, scientists and medical laboratory technologists. The names of these volunteers are listed in Appendix A. 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 staff members are extremely grateful for the commitment and support of Ontario laboratory professionals and thanks all of those individuals that donate so much of their valuable time and expertise to the program.

Showcasing Scientific Committee Activity

Hematology Committee. For a second year, in October 2010, the Hematology Committee members planned and participated in an education day, held at McMaster University, Hamilton, Ontario. The objective of this symposium was to provide an overview of various hematology topics presented by members of the QMP–LS Hematology Scientific Committee. The target audience for the two day event was physicians and laboratory professionals. The following presentations from this symposium are available for

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purchase as webcasts through the IQMH website www.IQMH.org.

- Case Studies in Leukocyte Disorders
- Bone Marrow Examination: A Basic Approach
- A Multicenter Pilot Study of 10 Colour Immunophenotyping in the Diagnosis of Leukemia and Lymphoma
- Out of Africa: Clues from Hemoglobin Investigations
- Malaria Diagnosis from the Peripheral Blood Film
- Novel Anticoagulants: A New World Awaits
- Factor Assays and Inhibitors: What Clinical Laboratories Should Consider
- Establishing Guidelines for a Quality Assurance Program for INR Testing with POC Devices
- Body Fluids: The Implementation of Automated Analyzers

Subsequent to the presentation, "Malaria Diagnosis from the Peripheral Blood Film" the Hematology Committee published the broadsheet, Red Cell Morphology Terminology and Grading and prepared a red cell morphology wall chart for use by medical laboratory technologists and laboratory physicians. It is available for purchase through the IQMH website www.IQMH.org.

In addition to the advice and educational input provided as part of the routine EQA committee comments, all scientific committees provide educational feedback in the form of broadsheets and practice guidelines. During 2010–11, the following were provided to participants:

- Broadsheet – Analytical Method Validation: What does the laboratory need to do and when?
- Guideline – Routine Processing and Reporting of Superficial Wound Swabs

Looking Ahead, Continual Improvement

During 2011–12, the EQA division will receive its second accreditation visit to confirm compliance with ISO 17043:2010. Significant changes will occur with the use of EQA testing material subcontractors and in the transition of distribution of EQA samples to a subcontractor. Further use of digital morphology for slide-based surveys will be explored and the opportunities for improvement identified through the participant satisfaction survey will be further investigated for implementation.

Ontario Laboratory Accreditation Report

Ontario Laboratory Accreditation (OLA) was conceived in 2000 to provide the Government of Ontario a formal process to ensure that its licensed medical laboratories are competent. Assessments in Ontario began in 2003. OLA's success in Ontario attracted widespread attention and its accreditation is now mandatory for all medical laboratories in the provinces of Ontario, Newfoundland & Labrador, and New Brunswick. In addition, other laboratories voluntarily participate. OLA has a total of 217 accredited laboratories and at the end of fiscal 2010/2011. OLA's requirements for accreditation are comprehensive and its assessment process rigorous. This report highlights OLA's activities during the fiscal year 2010/2011, and focuses on its commitment to supporting regulators in the pursuit of public protection. This is accomplished by accreditation contracts with three provincial governments, for accreditation services that meet rigorous ISO standards and adhere to comprehensive principles set by the International Laboratory Accreditation Cooperation (ILAC). These pursuits result in accreditation you can count on.

Fiscal 2010/2011 was an expansion year in which OLA's accreditation services grew outside of Ontario's licensed medical laboratory network. OLA client laboratories now number 286. This includes laboratories subject to accreditation under additional provincial government contracts provide mandatory accreditation of medical laboratories in Newfoundland & Labrador (40) and New Brunswick (23). One additional laboratory voluntarily applied for accreditation bringing the total number of voluntary participants to six.

Significant Achievements

- The number of laboratories participating in the OLA accreditation program is 286.
- Moving toward our goal of international recognition, QMP–LS became an Associate (voting) member of the International Laboratory Accreditation Cooperation (ILAC) and a full member of the Asia Pacific Regional Laboratory Cooperation (APLAC). Our application for signatory status to the Mutual Recognition Arrangement was accepted, and our formal evaluation to ISO/IEC 17011:2004 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies is pending.
- Our partnership with Standards Council of Canada (SCC) was renewed and we are a partner in its national medical laboratory ISO 15189 accreditation program.
- In 2010, New Brunswick invited OLA and three other accreditation bodies to present proposals for accreditation of its 23 medical laboratories. OLA was the unanimous choice of the selection panel, which utilized 16 selection criteria. Early in 2011, a contract was signed. New Brunswick laboratories will be assessed every two years and OLA will offer its services in both English and French. This exciting initiative will benefit any laboratory whose primary

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language is French. Translation of accreditation requirements, many other documents and the information contained within the accreditation database has commenced.

- A bilingual Staff Technologist (English/French) was hired.
- Laboratory professionals in Newfoundland and Labrador were educated about OLA accreditation in an introductory symposium, four focus sessions, and four assessor-training sessions. Accreditation began with self-assessments conducted by all 40 medical laboratories and assessment visits conducted in nine laboratories. Assessment visits started in November 2010 and nine laboratories in Newfoundland have received assessment visits (the remaining laboratories are scheduled for visits later in 2011 and early in 2012).
- OLA requirements, guidance information and reference sources were reviewed and Version 5 was published in December 2010.
- The Ontario assessor pool was replenished with 20 applicants trained and certified. The number of assessors is now 292. Four face-to-face refresher seminars were offered as an option to the online refresher exercise.
- The QView™ web portal was expanded to allow laboratories to download and submit their self-assessment checklists, print their own conformance reports, and submit visit evaluations directly. Special QView™ accounts also now allow OLA to share confidential data with assessors and advisers in order to save paper.
- QTrak™ was introduced to monitor participation and performance in proficiency testing/external quality assessment.

Program Model

OLA accreditation is granted for four years. Assessment visits determine if applicant laboratories conform to rigorous accreditation requirements based on the following standards along with government laws and regulations and consensus guidelines that represent the generally accepted principles of good practice:

- 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
- CSA Z902-10 Blood and Blood Components February 2010

Assessment visits are conducted by a team of peers accompanied by an OLA Staff Technologist. The assessment team is comprised of both quality system and technical experts carefully tailored to the laboratory's scope of testing. The objective of each team is to determine if a laboratory conforms to requirements and if not, to identify non-conformances. If areas of non-conformance are cited, the laboratory is expected to take corrective action within 90 days of the visit. A panel then determines if the laboratory meets the criteria for an accreditation certificate. Accreditation

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certificates are issued once all major non-conformances are resolved, and minor non-conformances are either resolved or satisfactorily addressed with ongoing action plans to correct them before the next assessment visit. 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-assessment (half-way between assessment visits)
- Monitoring of participation and satisfactory performance in EQA/PT
- Monitoring changes in laboratory management, location and the scope of testing

Accreditation is renewed only after a return assessment visit and receipt of satisfactory corrective action.

Assessors

OLA relies heavily on professionals within the medical laboratory community. Assessment visits are conducted by pre-trained and certified volunteers who are accompanied on-site by an OLA staff technologist. Assessor applicants are screened to ensure they have sufficient technical knowledge and experience. Acceptable candidates undergo initial training that consists of 18 hours of on-line study, 2½ days of classroom training and a final examination. 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 292 active assessors. During 2010/2011, 99 assessors were contracted for 355 assessment days. Forty-seven assessors attended face-to-face refresher seminars (4), and the remaining assessors re-certified using the online refresher exercise. Twenty new assessors were trained and certified. Training replenishes the assessor pool and enhances our technical expertise.

Assessments

OLA began assessing Ontario's licensed medical laboratories in 2003, and under the terms of an agreement with the Ontario Ministry of Health and Long-Term Care (MOHLTC), five-year certificates were initially issued. To meet international standards, assessments are now conducted at minimum once every four years and renewed certificates lasting four years are issued. If an Ontario laboratory has outstanding major non-conformances with a satisfactory action plan, a two-year certificate may be issued, which could be upgraded to a four-year certificate once all major non-conformances have been addressed. Additional surveillance activities occur, including a comprehensive self-assessment mid-cycle with the possibility of an on-site visit. The current agreement with Standards Council of Canada (SCC) allows laboratories assessed by OLA to receive an ISO 15189 certificate issued by SCC but international conditions apply, including a surveillance visit one year after

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the initial certificate is issued, visits at two-year intervals, and annual maintenance fees. Ontario laboratories may choose to also receive an ISO 15189 certificate. All other OLA applicant laboratories are accredited according to these international rules. Assessment activity is shown in Tables 3 and 4. Average laboratory conformance in 2010/2011 was an impressive 96.77%, based on an average of 434 requirements per assessment. At the end of the fiscal year, 222 laboratories were accredited by OLA.

Surveillance

Accreditation bodies routinely utilize proficiency testing/external quality assessment data as a measure of ongoing competence in accredited laboratories, and OLA is no exception. Accredited laboratories must employ formal (such as proficiency testing or external quality assessment) or informal inter-laboratory comparisons (such as split sampling) for all tests included on their scopes of accreditation. A large undertaking in 2010/2011 was to improve the mechanism used by OLA to monitor participation and performance in proficiency

Table 3. OLA Assessment Activity

Activities	No. 2009-10	No. 2010-11
Labs Notified of Assessment	Ontario: 49 Voluntary: 4	Ontario: 57 Newfoundland & Labrador: 24 Voluntary: 4
Peer Assessments Conducted	Ontario: 53 full Voluntary: 3 full, 2 focused	Ontario: 38 full, 7 focused Newfoundland & Labrador: 9 full Voluntary: 1 full
4-year Certificates Issued	Ontario: 48	Ontario: 47 Voluntary (by SCC): 4
2-year Certificate Issued	Ontario: 1	Ontario: 0

Table 4. OLA Self-assessment Activity

Activities	No. 2009-10	No. 2010-11
Labs Notified	Ontario: 41 Voluntary: 1	Ontario: 66 Newfoundland & Labrador: 40 Voluntary: 3
Labs Submitting Self-assessment Data	Ontario: 41 Voluntary: 3	Ontario: 48 Newfoundland & Labrador: 40 Voluntary: 3
Summary Reports Issued by OLA	Ontario: 38 Voluntary: 3	Ontario: 59 Newfoundland & Labrador: 40 Voluntary: 3

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testing/external quality assessment that was implemented in 2009. The result is a simplified QTrak™ form available through the QMP–LS QView™ Web portal. Using this form, laboratories not only submit their data on participation and performance to OLA, but can track their own compliance with OLA's requirements for inter-laboratory comparison.

On May 1, 2010 OLA introduced a new and improved process for self-assessments. It uses a QView™ form that is similar in appearance to the assessment visit checklist. The form is designed to enhance laboratories' abilities to electronically submit conformance data and planned corrective action directly into OLA's accreditation database. Improved aspects of this process make it more efficient for use: colour-coded discipline-specific guidance information, copy-and-paste capability and fewer steps in submitting the final report to OLA. On a separate form, laboratories continue to provide ongoing corrective action to address non-conformances cited at previous assessment visits.

Accreditation Requirements

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 Z902-10 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. 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.

The reference sources supporting all requirements and guidance information are reviewed every year and changes (such as new or updated sources) are shared with participants. There are currently 255 individual reference sources. In addition, the impact changes may have on the wording of requirements and guidance information is assessed by the OLA Advisory Panel to determine if a complete review of requirements and guidance information is warranted. A new version of the requirements will be released at minimum once every three years. A large undertaking in 2010 was a complete review of the requirements and guidance information, which commenced in April 2010 and culminated in December 2010 with the release of Version 5.

Three-step approach to assessment

1. Observe laboratory practice and engage laboratory staff in conversation about the process.
2. Look at records and other evidence that demonstrate the laboratory follows the described practice.
3. Review procedures and written instructions to determine if they are in sync with current practices.

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Version 5 contains 505 requirements and four good practice recommendations, slightly fewer than the number in the previous version. There are 17 new requirements but 23 previous requirements were deleted because they were redundant. One hundred eighty-three requirements were revised. Key changes are:

- Requirements for different jurisdictional areas were separated. This allows OLA to produce a customized checklist that displays all universal requirements and any requirements specific to Canada, Ontario, Newfoundland, etc. With this enhancement, laboratories will receive checklists that are specific to their regional area.
- Requirements were re-worded to promote a three-step approach to assessment.
  1. Observe laboratory practice and engage laboratory staff in conversation about the process.
  2. Look at records and other evidence that demonstrate the laboratory follows the described practice.
  3. Review procedures and written instructions to determine if they are in sync with current practices.

- Requirements and discipline-specific guidance information were added because of changes in legislation, regulation, and/or updated reference sources.
- Valuable feedback was received that facilitated changes to existing requirements and discipline-specific guidance information—generally to clarify their intent.
- The OLA checklist continues to contain much discipline-specific application guidance in the major practice disciplines of laboratory medicine, as well as a cross-reference to clauses within the international and national standards upon which requirements are based.

Advisers

The OLA Advisory Panel is the management board for OLA. There are nine voting members and four ex-officio members without voting rights representing Standards Council of Canada and the governments of Ontario, Newfoundland & Labrador and New Brunswick. Its meetings occur periodically with additional conference calls scheduled as required for decision-making, appeals, certificate issue and recommendations for withdrawing or reducing accreditation. four full meetings occurred this year. one additional conference call was convened, for reviewing laboratory corrective actions and recommending certificate issue or referral to government regulators. OLA staff members meet monthly and the Director discusses operational enhancements with the QMP–LS Senior Management Group. Accreditations are recommended by the Director and certificates signed by the Managing Director, QMP–LS or (for ISO 15189 certificates) by SCC. Reporting to the appropriate regulator (e.g. Ontario MOHLTC) or SCC when a laboratory fails to meet the conditions for accreditation (or when surveillance monitoring culminates in the suspension or withdrawal of accreditation) is the responsibility of the Director.

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Assuring OLA is an Accreditation Program You Can Count On

OLA's program information guide, guidelines for Traceability and Uncertainty of Measurement as well as its position statement on Inter-laboratory Comparison Surveillance are available on QView™ and the public QMP–LS website. Work continued to improve these documents. Additional guidance on internal auditing and management review was posted on QView™. Twelve "Eye on OLA" columns appeared in *QMP–LS News*.

Between September 1, 2008 and March 31, 2011 OLA conducted reassessment visits in 117 laboratories. To assess the effectiveness of accreditation in improving laboratory practice, the number of laboratories with repeat non-conformances was monitored. During this period, the number of laboratories with repeat non-conformances was 30 (17.6%) and there were 68 total repeat non-conformances (Table 5). OLA staff continue to work with the QMP–LS EQA divisional staff and the Ontario government through the Conjoint Committee on collaborative surveillance to improve ongoing competence in accredited laboratories.

Table 5. Incidence of Repeat Non-conformances between September 1, 2008 and March 31, 2011

No. of Repeat Non-conformances at Reassessment	No. of Labs
1	13
2	8
3	4
4	0
5	3
6	2

QMP–LS and Accreditation Canada continue to discuss means to avoid duplication of oversight in medical laboratories participating in OLA accreditation under government contracts. Accreditation Canada is a voluntary accreditation program for healthcare facilities, including hospitals with medical laboratories. In 2006, Accreditation Canada released its own laboratory and blood bank standards with the intent of integrating laboratory accreditation within the facility-wide accreditation process. However, with the pre-existence of mandatory laboratory accreditation programs such as OLA, in 2007, Accreditation Canada agreed to explore mutual reciprocity and recognition with mandated provincial laboratory accreditation bodies. Accreditation Canada has agreed that the comprehensive standards and rigorous assessment process employed by OLA are comparable to its own standards based on ISO 15189 and Z902-10. Starting in 2011, Accreditation Canada does not duplicate the assessment of conformance to these standards in the laboratory. During its survey process, Accreditation Canada limits its assessment to the integration of the laboratory and blood bank services in the continuum of care within the health system. OLA-accredited laboratories may be asked by Accreditation Canada to share a copy of their OLA certificate of accreditation, their most recent assessment visit summary

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report and possibly the corrective actions submitted to QMP–LS after the previous OLA assessment visit. Laboratories may share these documents with Accreditation Canada in order to avoid a duplicate assessment within the laboratory.

A partnership with SCC has been in place since 2005, in which any laboratory assessed by OLA may apply for recommendation of an ISO 15189 certificate issued by SCC. This partnership was renewed in 2010 and QMP–LS continues to be a partner in SCC's national medical laboratory accreditation program. SCC is an ILAC signatory and in January SCC evaluated OLA operations against ISO/IEC 17011:2004 *Conformity assessment—General requirements for accreditation bodies accrediting conformity assessment bodies*. Satisfied with our responses to its 11 non-conformances, SCC continues to issue ISO 15189 certificates to 10 Ontario licensed laboratories and six laboratories that OLA assessed following voluntary application for accreditation.

Strengthening and Building Program Confidence through Collaboration

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 OLA Director is chair of the SCC's Medical Laboratory Working Group and a member of its Partner Advisory Group and TG Laboratories committee. The Managing Director, QMP–LS, is a member of the CSA Z252 Medical Laboratory Quality Systems committee. The International Organization for Standardization (ISO) develops standards for the operation of accreditation bodies (ISO/IEC 17011:2004) and requirements for quality and competence of medical laboratories (ISO 15189:2007). 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 a member of the ILAC Executive Committee, chairs its Proficiency Testing Consultative Group and is the secretary of its Accreditation Issues Committee.

Sharing Our Expertise

OLA staff are internationally recognized for their expertise in medical laboratory accreditation and quality systems. Staff were invited to speak at the following:

- CLMA Trillium Chapter Education Sessions, October and November 2010, Burlington, Ontario
- CSMLS Annual Congress, May 2010, Edmonton, Alberta
- Lab Quality Confab/Process Improvement Institute, November 2010, San Antonio, Texas

Continuing to Improve our Operations

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

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Advisory Panel. All opportunities for improvement are captured using the QMP–LS HelpDesk. In 2010/2011, there were 33 cases related to OLA.

OLA's fifth internal audit was conducted in March, and yielded eight opportunities for improvement.

OLA utilizes ongoing performance measures to assess the efficiency of its assessment service. Turnaround times associated with the delivery of assessments are 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 Director, OLA, OLA staff and the Quality Manager (Table 6).

Looking Ahead

OLA is now a mature, internationally respected medical laboratory accreditation program. Our planned future activities will build on our success and improve our accreditation model.

Plans for fiscal 2011/2012 include:

- Achieve signatory status in the Asia Pacific Laboratory Accreditation Cooperation Mutual Recognition Arrangement and full membership in the International Laboratory Accreditation Cooperation.
- Improve customer service by providing services in English and French, providing a combined assessment visit

Table 6. OLA Quality Indicators and Performance Monitoring, 2009–10 and 2010–11

Quality Indicator	Performance 2009–10	Performance 2010–11
Assessment Visit: Time from Visit to Issue of Summary Report	Target: 14 days Mean: 8 days Range: 0–15 days	Target: 14 days Mean: 9 Range: 3–20
Assessment Visit: Time from Receipt of Corrective Action to Issue of Certificate	Target: 60 days Mean: 43 days Range: 0–79 days	Target: 60 days Mean: 79 Range: 0–102
Assessment Visit: Total Time from Visit to Issue of Certificate	Target: 150 days Mean: 123 days Range: 0–169 days	Target: 150 days Mean: 123 Range: 0–282
Self-assessment: Time from Receipt of Laboratory Data to Issue of Summary Report	Target: 45 days Mean: 25 days Range: 0–73	Target: 30 Mean: 19 Range: 4–48
Errors of Fact: Number of Submissions Received	4	3
Errors of Fact: Number of Reports Revised	4	2

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report for multi-site laboratories and enhancing the QView™ web portal to allow participants to download QForms and upload corrective action data directly into the OLA database.

- Design a customer satisfaction survey.
- Promote the ISO 15189 certificate program for Ontario's licensed medical laboratories.
- Collaborate with Corporate Services to connect with laboratory personnel regarding the value of accreditation.
- Conduct an internal audit to monitor compliance with ISO/IEC 17011 and identify opportunities for operational improvement.
- Collaborate in national and international initiatives in accreditation with other bodies.
- Publicize program achievements and maintain regular communication in *QMP–LS News*.
- Improve on our articulation of the accreditation standard with a review of all reference sources and the release of a sub-version 5.1 OLA requirements and guidance information.
- Strengthen the assessor pool.
- Implement a formal competency program for OLA staff and advisers.

Special Acknowledgements

OLA would like to acknowledge the assistance of Jim Moran in leading OLA assessor training.

Education Report

QMP–LS' philosophy is to deliver education within areas identified through our External Quality Assessment (EQA) or Ontario Laboratory Accreditation (OLA) activities. Collaboration 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 2010, QMP–LS published 3 articles on significant developments in the medical and scientific literature, 12 invited presentations were made at provincial, national and international meetings. Eighteen webinars and webcasts were conducted (see Appendix D).

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, although its target audience is Ontario laboratories. 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 through our secure password-protected access QView™ document server. New tools have been developed to enable web-based communications, including enhancements to QView™, such as electronic submissions and worksheets.

Performance Highlights

Key Objectives

QMP–LS collaborated with other organizations in the development, promulgation and sharing of knowledge:

- QMP–LS Hematology Education Day
- Red Blood Cell Morphology kit (poster, webcast, reference guide) was produced by the EQA Hematology Committee

Looking Ahead

In 2011–12, education services, guideline development and special projects for QMP–LS will continue to be delivered through the Knowledge Development division. The provision of EQA and OLA products and services to other jurisdictions and healthcare organizations will continue to be managed through IQMH.

Corporate Services Report

In 2010–11 Corporate Services collaborated with our EQA division to begin the reengineering of our survey administration software. The first phase of this initiative was completed with the implementation of the survey distribution modules of our internal QView Office software and its newly integrated survey notification functionality.

In collaboration with our OLA division, our web-based external PT/EQA data collection application was replaced with QTrak™ forms.

Our Communications team redesigned and replaced both the QMP–LS website and intranet.

We also worked with our Quality Manager to enhance our HelpDesk application to classify occurrences and with our parent organization, the Ontario Medical Association, to implement a new financial information system.

Goal: To Maintain and Improve Our Core Services

Key objectives

- Complete the reengineering of the LEQA application including the integration of the survey notice functionality and replacement of the Laboratory Performance History.
- Reengineer the web-data entry system through which laboratories may directly enter participation and performance data in external PT/EQA.

Actions

We completed the implementation of phase one of QView Office (Figure 4), the reengineering of our Survey Administration software. We also implemented QTrak™ (Figure 5), a forms-based replacement for the existing web-based External PT/EQA data entry application.

Key objectives

- Redesign the QMP–LS website and the QMP–LS intranet.
- Enhance the quality system HelpDesk application to be able to classify occurrences.

Actions

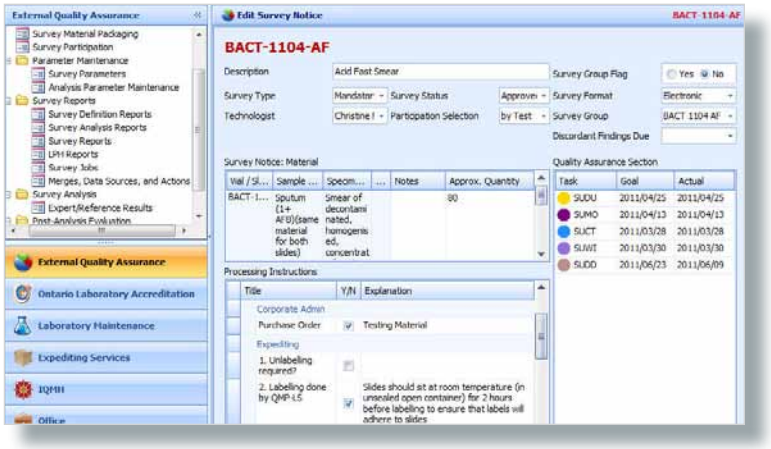
The QMP–LS website (Figure 6) and internal intranet (Figure 7) were both redesigned and replaced with software supporting current Web 2.0 technology. HelpDesk was enhanced to enable the classification of occurrences (Figure 8).

Goal: Support Volunteers and Staff

Key objectives

- Implement the new OMA Financial Information System for QMP–LS.

Figure 4. QView™ Office survey notice



Corporate Services Report

Actions

A new financial information system (Figure 9) was implemented by the Ontario Medical Association.

QMP–LS collaborated with the OMA Financial Services team to implement a portal to access the system via a secure virtual private network (VPN) connection.

Key objectives

- Replace obsolete desktop computers
- Acquire a digital camera for digital morphology
- Acquire better lighting system for webcast video recording

Actions

In 2010–11 Corporate Services replaced two obsolete notebook computers and three desktop workstations. A digital camera was acquired for our virtual microscopy pilot projects. And a new lighting system and video camera were acquired to improve our video recording capability.

Looking Ahead

In 2011–12 we will complete the implementation of the Laboratory Performance History component of our revised EQA survey administration software application. QView will be enhanced to support multiple languages and our quality system software will be upgraded. Corporate Services will manage the relocation of the QMP–LS offices to 393 University Avenue in Toronto.

Figure 5. OLA QTrak™ external PT/EQA data collection form

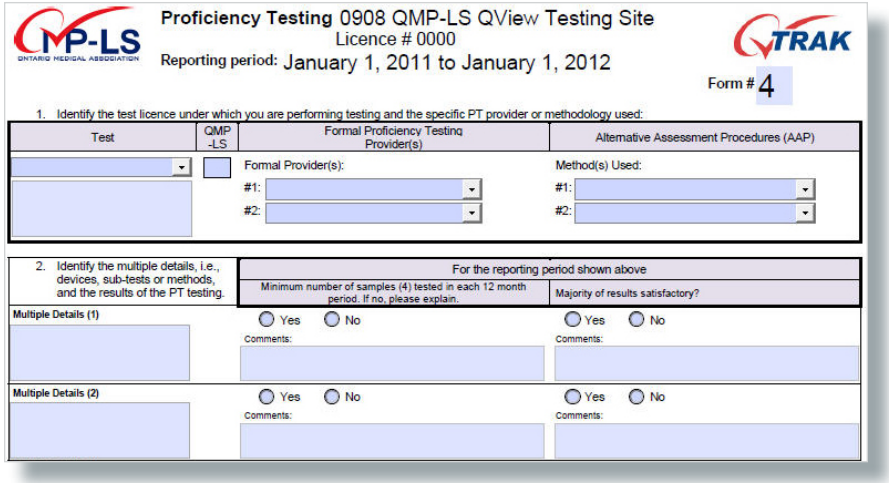


Figure 6. QMP–LS website

Corporate Services Report

Figure 7. QMP–LS intranet

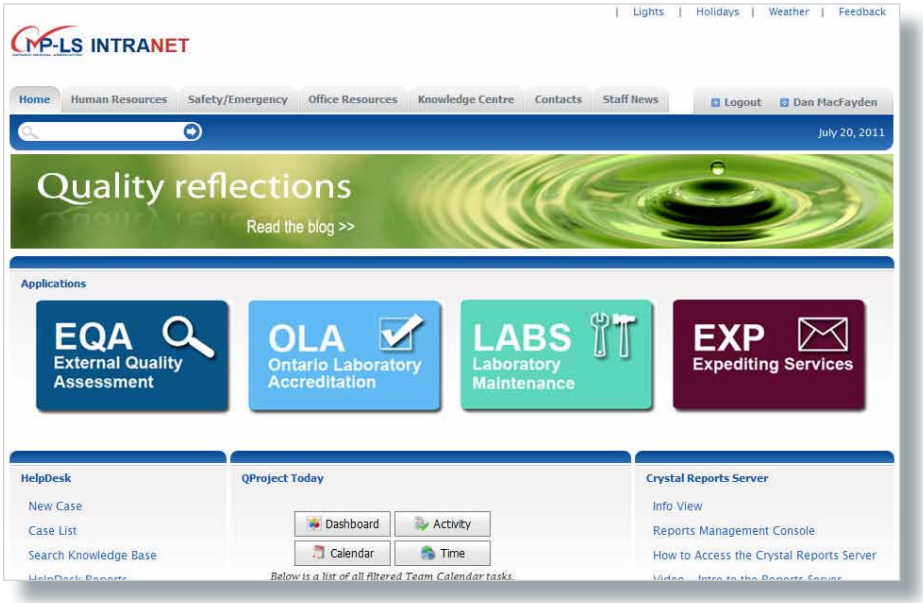


Figure 8. HelpDesk classification of occurrences

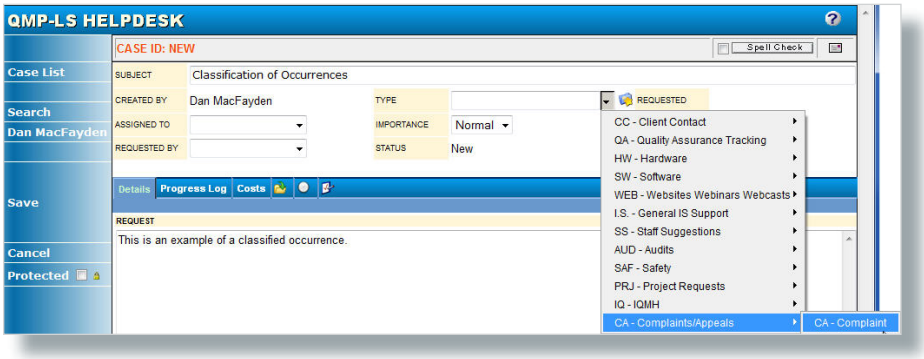


Figure 9. Financial information system portal

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Dr. Deborah Yamamura
College of Medical Laboratory Technologists of Ontario (CMLTO)
Mrs. Kathy Wilkie
College of Physicians & Surgeons of Ontario (CPSO)
Mr. Dan Faulkner
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Ms. Janice Nolan
Professional Advisory Committee (QMP–LS), Chair
Mr. Michael Keeney
Ministry of Health & Long-Term Care
Mr. Tim Burns
Ontario Association of Medical Laboratories (OAML)
Mr. Jeffrey Sumner
Ontario Association of Pathologists (OAP)
Dr. Suhas Joshi
Ontario Hospital Association (OHA),
Dr. Robert Lester (until October 2010)
Ontario Medical Association Section on Laboratory Medicine
Dr. John Doucet
Ontario Society of Medical Technologists (OSMT)
Mrs. Blanca McArthur
Ontario Society of Clinical Chemists (OSCC)
Dr. Lei Fu

Ex-Officio, Non-voting Members

Ministry of Health & Long-Term Care
Mr. Leo Tse
Quality Management Program—Laboratory Services
Dr. Gregory J. Flynn

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Ministry of Health & Long-Term Care
Mr. George Clarke
Quality Management Program—Laboratory Services, Ontario Laboratory Accreditation Division
Mrs. Linda Crawford
Quality Management Program—Laboratory Services, External Quality Assessment Division
Ms. Jane Gun-Munro

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Mr. Leo Tse
Mr. George Clarke

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Mr. Stephen Cross (ex-officio)
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Director, External Quality Assessment, QMP–LS

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Ms. Ping Chao
Mrs. Patti Cheatley
Ms. Pam Chedore
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Ms. Jacky Fok
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Dr. Michael J. Raymond
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
Ms. Lynn Towns
Ms. Liese Bolte
Ms. LaiLing Wat
Ms. Patricia Wegrynowski
Dr. Bret Wehrli
Ms. Lori White
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Mr. Bill Parks
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Dr. Barry Hoffman
Dr. Wendy Meschino
Dr. Alan Dennis
Dr. Sandra Farrell
Mr. Keyur Dixit
Ms. Cathy Gale
Ms. Karen Boucher
Ms. Sandra Lazzaro
Ms. Laura Harrison
Mr. Sam Pizzolato
Ms. Suzie Ho
Mr. Herman Ng
Mr. Cedric Reid

Ontario Laboratory Accreditation

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Dr. Vina Alexopoulou
Ms. Myonne Allan
Dr. Lynn Allen
Ms. Marjorie Allen
Dr. Diane Allingham-Hawkins
Ms. Beate (BJ) Anding
Ms. Janice Archer
Ms. Judy Ash
Ms. Berna Aslan
Mr. Gamal Badawoy
Ms. Jeanine Baker
Ms. Alison Bear
Ms. Sherri Beckner
Mr. Conrad Jr. Begin
Ms. Deborah Benson
Ms. Nancy Beresford
Mr. Karim Bhaloo
Ms. Johanne Bietola
Ms. Joanne Bishop

Ms. Heather Black
Mr. Chris Blagg
Dr. Michel Bonin
Ms. Diana Booth
Ms. Rhonda Borchardt
Ms. Karen Bortolon
Ms. Linda Borycheski
Dr. Sheila Boss
Ms. Gini Bourner
Ms. Patti Boyd
Ms. Nellie Bradbury
Mr. Shawn Brennan
Ms. Nathalie Breton
Ms. Marjorie Brooks
Ms. Gail Brown
Ms. Marie Burelle
Mr. Len Burger
Ms. Patricia Burton
Ms. Pamela Calverley
Ms. Margaret Cameron
Ms. Christine Campbell
Ms. Johanna Campbell
Dr. Nancy Carson
Ms. Vassilici (Bessie) Carydis
Dr. Peter Catomeris
Dr. Pak Cheung Chan
Mr. Nikolaos Chantziantoniou
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Mr. Robert Cheslo-Trengrove
Ms. Suk Ching Crystal Chow
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Mr. Daryl Corriveau
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Ms. Mary Costantino
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Ms. Helen (Susie) Davies
Mr. Frank Demizio
Ms. Linda Diebold
Mr. Glen Dietz
Mr. Keyur Dixit
Ms. Annamarie Donati
Ms. Karen Downard
Ms. Louise Dwyre
Ms. Anne Ecobichon-Morris
Mr. Doug Ems
Mrs. Kemi Erhiaganoma
Mr. Awny Estafanous
Ms. Denise Evanovitch
Ms. Susan Evans
Mr. Mark Evert
Ms. Mary Falls
Ms. Louise Farrar
Ms. Helen Felstein
Ms. Marikay Files
Mr. Robert C. Fitz-James
Ms. Christine Fleming
Ms. Juelle Foucault
Ms. Rosanne Frassetto
Ms. Viola Freeman
Ms. Suzanne Froment
Ms. Christine Fry
Dr. Lei Fu
Ms. Theresa Funk-Goudreau
Mr. Mukesh Gandhi
Ms. Cheryl A. Gervais
Ms. Diana Gillie
Mr. Manuel Giraldo
Ms. Syddnay Glinz
Dr. Douglas Gornall
Mr. Maurice Goulet
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Ms. Joanne Guzda
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Ms. Laura Harrison
Ms. Lorraine Hart
Mr. Mario Hemens
Ms. Susan Hemmerling
Ms. Valerie Hencze
Ms. Tina Louise Henderson
Ms. Gina Hendrick
Ms. Darlene Henrickson
Ms. Rosemary Henry
Ms. Cathy Hinschberger
Mr. Daniel Ho
Ms. Karen Hodgins
Mr. Gary Holly
Mr. Allan Howe
Mr. Verner Hurst
Ms. Kathleen Irving
Ms. Aisha (Rishmah) Ismail

Ms. Tammy Ison
Ms. Sarah James
Ms. Rosanne Janicki
Mr. Chetankumar Jariwala
Ms. Violet Jewitt
Ms. Gayle Johnson
Ms. Tanya Jorden
Ms. Jennine E. Kafka
Mr. Edward Kasprzak
Dr. Kevin Katz
Mr. Robert Kendrick
Ms. Eartha Kent
Mr. Robert Kerekes
Ms. Peggy Kerk
Dr. Stephen Keys
Ms. Pam Kirwan
Ms. Tanya Knopf
Ms. Joan Koury
Ms. Suba Krishnan
Ms. Sumedha Kulkarni
Dr. Lianna Kyriakopoulou
Mr. Luc Lafrance
Mr. Ivan Lam
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Mr. Keith Lau
Ms. Debbie Lauzon
Mr. Ambrose Law
Ms. Lilian Law
Ms. Norma Layno
Ms. Jennifer Leach
Ms. Susan Leask
Mr. Albert Lee
Ms. Barbara Lemay
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Mr. Victor Leung
Ms. Jean Lew
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Ms. Patricia Ludlow
Mr. Allan Lupish
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Ms. Christine Mackay
Ms. Joanie Mackay
Ms. Lorraine MacLean
Ms. Marg Maddock
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Ms. Ellen Mak-Tam
Mr. Rick Mancini
Ms. Lisa Martin
Ms. Tracy Martin
Ms. Cornelia Mascherin
Ms. Viki Massey
Ms. Tina Mattice
Ms. Judy Maxwell
Dr. Tony Mazzulli
Ms. Marion McChesney
Mr. Michael McConnell
Ms. Patricia McGillis
Ms. Laurie McIntosh
Ms. Sharon McMillan
Ms. Chee-Yuen (Helen) Meaney
Mr. Adly Messiha
Ms. Lisa Milligan
Mrs. Shawne Milne
Mr. Dennis Miskie
Mr. Mark Mitchell
Mr. Gaman Modi
Mr. David More
Mr. Les Morgan
Ms. Sarah Morrison
Ms. Donna Murphy
Ms. Jean Neville
Mr. John Nishikawa
Mr. Sean Normore
Ms. Bevoline Nwachukwu
Ms. Joann O'Brien
Ms. Cindy O'Neill
Dr. Kenneth Onuska
Ms. Marion O'Sullivan
Ms. Wendy Owens
Mr. Wayne Ozanne
Ms. Terry (Theresa) Paradis
Mr. Patrick Paulusse
Ms. Rachel Peters
Dr. Astrid K. Petrich
Ms. Anne Marie Phillips
Ms. Tatjana Poje
Mr. Robert Poulin
Ms. Bernice Power
Mr. Raija Principe
Ms. Melanie Proulx
Ms. Susan Pugh
Ms. Georgina Ralevski
Ms. Corinne Ramey
Dr. Karam Ramotar
Ms. Susan Randell

Ms. Shamim Rashid
Ms. Louise Regnier
Ms. Rena Retallick
Ms. Anna Robinson
Ms. Darlene Rosbottom
Ms. Stephanie Rossanese
Ms. Leslie Rowbotham
Ms. Mary Rozmanc
Ms. Micheline Sabourin
Ms. Katia Saliba
Mr. Brad Sauve
Ms. Marion Savory
Ms. Susan Schaub
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Dr. Rita Selby
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Ms. Carolin Smart
Ms. Sandra Smith
Ms. Deirdre Soares
Ms. Susan Souckey
Ms. Marilyn Spagnoli
Ms. Karen Stewart
Ms. Luba Stoakes
Dr. Tracy Stockley
Ms. Michelle Strul
Ms. Laurie Sweeting
Ms. Colette Swift
Ms. Joanna Tam
Mr. Alain Thibault
Ms. Joanne Thususka
Ms. Linda Turner-Smith
Ms. Sylvia Uicich
Dr. Hilde Vandenberghe
Mrs. Pamela VanSteelandt
Ms. Angella Vanwyck
Mr. Samuel Varghese
Ms. Loreen Veno
Dr. Christie L. Vermeiren
Ms. Priti Vyas
Ms. Marsha Ward
Ms. Cheryl Watt
Ms. Heather Watts
Mr. Kevin Webb
Ms. Lori-Ann Webster
Ms. Laura White
Mr. Tony Wong
Ms. Michelle Wood
Dr. Jie Xu
Ms. Maimin Xu
Dr. Deborah Yamamura
Mr. Greg Young

Chemistry

Chemistry-general

Albumin
Bicarbonate
Calcium, Total
Chloride
Creatinine
Glucose
Magnesium
Phosphate
Potassium
Protein, Total
Sodium
Total Iron
TIBC
UIBC
Transferrin Saturation
Transferrin
Urate
Urea

Chemistry-urine

Albumin
Albumin:Creatinine Ratio
Amylase*
Calcium*
Chloride*
Creatinine
Glucose*
Magnesium*
Phosphate*
Potassium
Protein
Osmolality
Sodium
Uric Acid*
Urea*

Chemistry-blood gases

Glucose
Ionized Calcium
Lactate*
pCO_2
pH
pO_2
Potassium
Sodium

CHEMISTRY-BILIRUBIN
Bilirubin, Total

Chemistry-hemoglobin a1c

HbA1c

Drug monitoring

Drugs of Abuse:
- Amphetamines
- Ecstasy (MDMA/MDA)
- Barbiturates
- Benzodiazepines
- Cannabinoid Metabolites
- Cocaine Metabolites
- Methadone
- Methadone Metabolites (EDDP)
- Methamphetamine
- Opiates
- Oxycodone
- Phencyclidine
- Tricyclic Antidepressants

Therapeutic Drugs:
- Acetaminophen
- Carbamazepine
- Digoxin
- Ethanol
- Gentamicin
- Lithium
- Phenobarbital
- Phenytoin
- Salicylate
- Theophylline

Tobramycin
- Valproic Acid
- Vancomycin

Endocrinology

25 Hydroxy Vitamin D
Alpha Fetoprotein (AFP)
Cancer Antigen 125 (CA 125)*
Carcinoembryonic Antigen (CEA)*
Chorionic Gonadotropin (CG)
Cortisol
Dehydroepiandrosterone sulphate (DHEA-S)
Estradiol
Ferritin
Free Thyroxine (FT_4)
Free Triiodothyronine (FT_3)

* New parameters

Follicle Stimulating Hormone (FSH)
Growth Hormone*
Homocysteine*
IgE
Insulin*
Luteinizing Hormone (LH)
Parathyroid Hormone (PTH)
Progesterone
Prolactin
Prostate Specific Antigen, Total (PSA)
PSA, Free
Thyroid Stimulating Hormone (TSH)
Testosterone
Vitamin B_{12}

Enzymes &cardiac markers

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
Myoglobin
Troponin I
Troponin T

Lipids

Cholesterol
Triglycerides
HDL-cholesterol (HDL-C)
LDL-cholesterol (LDL-C)
Total Cholesterol:HDL-C Ratio

Immunology

Antinuclear Antibody (ANA)
Rheumatoid Factor (RF)
High Sensitivity CRP (hsCRP)
Specific Proteins:
- IgG
- IgA
- IgM
- C3
- C4

Protein Electrophoresis (Albumin, Alpha 1, Alpha 2, Beta, Gamma)

Maternal serum screening (data analysis)

Multiple of Median (MoM):
- Alpha Fetoprotein (AFP)
- Human Chorionic Gonadotropin (hCG)
- Unconjugated Estriol (μE_3)
- Dimeric Inhibin-A (DIA)
- Free beta Human Chorionic Gonadotropin (free β-hCG)
- Pregnancy-Associated Plasma Protein A (PAPP-A)

Hematology

Bone marrow

Aspirate and/or Biopsy preparation
Descriptive Morphology
Diagnosis

Coagulation

International Normalized Ratio (INR)
Activated Partial Thromboplastin Time (APTT)
Fibrinogen
Thrombin Time
Heparin Assay
Factor VII
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

* New parameters

investigation of hematological disorders (lymphoma/leukemia)
CD34+ 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

Microbiology
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

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:
- Hepatitis A, B, and C
- HIV
- Rubella IgG

Antigen Detection:
- Chlamydia trachomatis
- Respiratory Syncytial Virus (RSV)
- Influenza A virus
- Influenza B virus
- Parainfluenza virus

Genetics
Cytogenetics
- Blood
- Bone Marrow
- Fixed cell pellet
- Cell culture

Anatomic pathology
Histopathology

Histotechnology
- Routine stains
- Special stains
- Immunohistochemistry stains

* New parameters

Predictive markers

- Breast cancer markers ER/PR and HER2
- C-kit marker*

Cytopathology

Gynecological

- Direct (Conventional)
- Liquid-based

Non-Gynecological

- Respiratory
- Urinary
- Body fluids
- Fine needle aspiration of breast
- Fine needle aspiration of head and neck

Other

Point-of-care testing

Glucose Meters

HIV

* New parameters

2010–2011

Articles and Posters

Moffat KA, Raby A, Hayward C. Standardization Initiative for the Performance of Platelet Function Testing in the Province of Ontario. International Society for Laboratory Hematology: XXIII International Symposium on Technological Innovations in Laboratory Hematology. International Society for Laboratory Hematology: The Brighton Centre, Brighton, UK. May 2010.

Moffat KA, Raby A, Hayward C. Standardization Initiative for the Performance of Platelet Function Testing in the Province of Ontario. In: Abstracts of the XXIII International Symposium on Technical Innovations in Laboratory Hematology. International Society for Laboratory Hematology: XXIII International Symposium on Technological Innovations in Laboratory Hematology. Wiley-Blackwell. International Journal of Laboratory Hematology. 2010, Volume 32 (Suppl. 1), p. 168. Abstract.

Raby A, Crowther M, Flynn G, Cursio C, Keeney M, Khan T, Rozmanc M, Schaus M, Selby R. Guidelines: Quality Assurance Program for INR Testing with Point-of-Care Devices in Ontario. International Society for Laboratory Hematology: XXIII International Symposium on Technological Innovations in Laboratory Hematology. The Brighton Centre, Brighton, UK. May 10-12, 2010. International Journal of Laboratory Hematology. 2010, 32 (Suppl. 1).

Hayward CPM, Moffat KA, Raby A, Israels S, Plumhoff E, Flynn G, Zehnder JL. Development of North American consensus guidelines for medical laboratories that perform and interpret platelet function testing using light transmission aggregormetry. Am J Clin Pathol. 2010 Dec;134(6):955–63.

Cuker A, Raby A, Moffat KA, Flynn G, Crowther MA. Interlaboratory variation in heparin monitoring: lessons from the Quality Management Program of Ontario coagulation surveys. Thromb Haemost. 2010 Oct;104(4):837-44. Epub 2010 Jul 20. PMID: 20664895.

Schirripa C. Under the Microscope. OSMT journal. November 2010.

Invited Presentations and Talks

Dr. Gregory Flynn. Healthcare Leadership and Innovation Forum Raising the Bar for Excellence in Canadian Healthcare. Healthcare Forum (Insight/ALM).

Linda Crawford. Canada's new continental divide: Alberta and Ontario medical laboratory accreditation models. LABCON 2010, Canadian Society for Medical Laboratory Science. Edmonton, AB. May 2010.

Linda Crawford. Medical Laboratories — Assessment of Sampling Activities for Body Fluids. International Laboratory Accreditation Cooperation Mid-year Meeting. Accreditation Issues Committee Workshop on Accreditation of Sampling Activities. Vedbaek, Denmark. June 2010.

Christine Fleming. Quality Indicators: Measure to Manage. APHL/CLSI Teleconference series.

Jane Gun-Munro. QMP–LS Use of Performance Scores for Long Term Evaluation of EQA Performance. EQALM. Lisbon, Portugal. October 2010.

Jane Gun-Munro. Implications of ISO 17043 for Microbiology PT Providers. EQALM. Lisbon, Portugal. October 2010.

Carol Julian. Internal Auditing. CLMA Trillium Chapter Symposium. Burlington, ON. October 2010.

Jane Gun-Munro. Utilizing PT as a Tool for Laboratory Improvement. CROSQ, Bridgetown, Barbados. November 2010

Jane Gun-Munro. Use and Interpretation of PT Reports/Investigation of Laboratory Performance Issues. HRLMP. Hamilton, ON.

Carol Julian. Management Review — Planning for the Future. CLMA Trillium Chapter Symposium. Burlington, ON. November 2010.

Julie Coffey. Eight Years of ISO 15189 in Ontario Give Both Labs and Med Techs a Top Reputation and Better Access to Resources and Funding. San Antonio Texas. November 2010.

Julie Coffey. Understanding How Quality Management Systems (QMS) Represent a New Paradigm in the Management and Operation of Clinical Laboratories.

Jean McGowan-Jordan, PhD, Mary Shago, PhD. (With acknowledgements: Lynn Yawney, Jane Gun-Munro). Consistency, or lack thereof, among laboratories examining the same ALL pellet. Children's Oncology Group 2012 Cytogenetics Workshop. Children's Oncology Group Cytogenetics committee. St. Louis MO, USA . February 2011.

Symposium Presentations

QMP–LS Hematology Education Day. Hematology Education Day. October 23, 2010. Healthcare Program, St. Joseph's Healthcare, Institute for Quality Management in Healthcare. McMaster University, Hamilton, ON.

- Farah Moid. Case Studies in Leukocyte Disorders
- Charles Ye. Bone Marrow Examination: A Basic Approach.
- Michael Keeney. A Multicenter Pilot Study of 10 Colour Immunophenotyping in the Diagnosis of Leukemia and Lymphoma.
- Andrew McFarlane, Out of Africa: Clues from Hemoglobin Investigations
- Ruth Padmore. Malaria Diagnosis from the Peripheral Blood Film.
- Mark Crowther. Novel Anticoagulants: A New World Awaits.
- Karen Moffat. Factor Assays and Inhibitors: What Clinical Laboratories Should Consider.
- Anne Raby. Establishing Guidelines for a Quality Assurance Program for INR Testing with POC Devices.
- Gini Bourner. Body Fluids: The Implementation of Automated Analyzers.

Webinars/Webcasts

Christine Schirripa. The New Pathology EQA Model.

Carol Julian. Internal Audit — All in an Audit.

Carol Julian. Management review — Planning for the Future.

Terri Molloy. OLA QTrak — External PT Data Entry. (8 modules)

- Introduction to QTrak Forms
- Accessing the Forms
- Explaining the Forms
- Filing out the QTrak Forms
- POCT (Multi-device/Multi-test Reporting)
- Using Other Pages
- Saving the Form
- Generating Reports

Webcasts of QMP–LS presentations from the 5th Annual McMaster Update in Thromboembolism. October 3-5, 2009

- Ian Chin-Yee. Who is WHO in 2008 – Hematology Case-based Discussions.
- Mark Crowther. Thrombophilia Testing: More Questions Than Answers.

- Michael Keeney. Updated QMP–LS EQA Broadsheet – Best Practice Guidelines for the Investigation of Neoplastic Hematological Disorders.
- Wendy Brown. Validating a Hematology Analyser.
- Ruth Padmore. New QMP–LS EQA Broadsheet – Erythrocyte Morphology – Terminology and Grading.
- Andrew McFarlane. Updated QMP–LS EQA Guideline – Good Practice Guidelines for the Laboratory Investigation of Hemoglobinopathies.
- Karen Moffat. New QMP–LS EQA Coagulation Broadsheets – Evaluating a New Reagent Lot Number & Setting Up Factor Assays.

QMP-LS
ONTARIO MEDICAL ASSOCIATION

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