March 2020

Important notice: IQMH response to COVID-19

IQMH Response to COVID-19
Updates regarding IQMH’s response to COVID-19 will be communicated online at www.iqmh.org. IQMH is currently in the process of moving to a completely virtual office.

Email Contact Information
Accreditation: accreditation@iqmh.org
Proficiency Testing: info@iqmh.org
Education: info@iqmh.org

IQMH has been closely monitoring developments in relation to the COVID-19 (Coronavirus) outbreak since it first emerged. We have a dedicated team assessing the situation, as it evolves, and leading our preparation and response.

Events and Meetings
All in-person events and meetings, including Scientific Committee and Advisory Panel meetings, whether inside or outside the IQMH offices will be conducted remotely using phone or video conferencing and/or online communications until further notice.

Accreditation Visits
All on-site accreditation visits scheduled between now and the end of May 2020 are cancelled and will be rescheduled for later in the year, circumstances permitting. Further cancellations beyond May may be necessary and will be communicated as decisions are made in light of the prevailing circumstances.

Contents
Important notice: IQMH response to COVID-19 ...1
IQMH moves to a virtual office in response to COVID-19.................................................................2
Centre for Accreditation........................................3
   ILAC Brochure on the Benefits of Accreditation Revised.........................................................3
Centre for Proficiency Testing.................................4
   Pathology Proficiency Testing survey PATH-2003: Slide assessment postponed.......................4
   PT Take-Away: Important notice: Proficiency Testing survey shipments ....................................4
   Antimicrobial resistance in common hospital pathogens in Ontario: Annual Survey Report 2018.........................................................5
   Hemoglobin Measurement – Pre-analytical Factors and Comparison Between Analytical Methods...............................................................7
Other Industry Events...............................................12

Continued on page 2
Continued from page 1

Education Courses
All education courses, whether on site or off site, are cancelled until further notice.

Proficiency Testing Surveys
All proficiency testing surveys will continue, as scheduled, at this time. IQMH is working closely with Public Health to develop and implement a proficiency testing program for laboratories licensed to perform testing for SARS-CoV-2, the virus that causes COVID-19. The first survey is expected to be shipped on or around April 13, 2020. Further details will be provided to those laboratories performing this testing as soon as more information becomes available.

IQMH Employees
IQMH has implemented a work-from-home policy for all employees who can perform their functions remotely, and all business travel is suspended until further notice.

With these precautionary measures and business contingency plans in place, please be assured that IQMH is doing all that we can to continue delivering services in a safe manner consistent with latest advice and guidance.

We appreciate your patience and understanding as we work through this rapidly evolving, unprecedented event.

Sincerely,
Jeff Sumner
IQMH President

IQMH moves to a virtual office in response to COVID-19

IQMH is in the process of moving to a completely virtual office. Since March 16, 2020, the majority of staff have been working from home connected to our server and applications through a secure VPN. In addition, we have replaced in-person meetings with online General Staff meetings using Microsoft Teams. Corporate Services, Accreditation and PT teams are using the software on a regular basis in both large and small groups.

If you need any assistance, Accreditation inquiries should be directed to accreditation@iqmh.org, and all other inquiries (Proficiency Testing, Education) to info@iqmh.org.
ILAC Brochure on the Benefits of Accreditation Revised

The following brochure outlining the role and benefit of accreditation in health and social care has been revised and is available for your use from the ILAC website.

- Accreditation: Supporting the Delivery of Health and Social Care

Benefits of ISO 15189 – Medical Laboratory Accreditation:

"Supplying diagnostic results for care providers, medical laboratory services play a pivotal role in; ensuring that patients receive the most pertinent treatment and care. It is imperative that medical laboratories can effectively meet the needs of all patients and clinical personnel. Medical Laboratories are accredited against the requirements of ISO 15189, which details the requirements for quality and competence within medical laboratories. Accreditation against the global standard ISO 15189, allows medical laboratories to demonstrate, through a rigorous process, the technical competence of that laboratory to all stakeholders including health care providers. ISO 15189 is also used to assess mortuaries and post-mortem facilities."

More brochures are available from the ILAC website.
Centre for Proficiency Testing

Pathology Proficiency Testing survey PATH-2003: Slide assessment postponed

The following Pathology surveys, with a submission due date of March 20, 2020 will continue, as scheduled; however, the slide assessment has been postponed to a later date, as we continue to monitor the current situation with COVID-19.

- PATH-2003-ER
- PATH-2003-HER2
- PATH-2003-IHC
- PATH-2003-ISH
- PATH-2003-PR
- PATH-2003-Gata 3

Read the IQMH response to COVID-19.

Questions?
Contact Wayne Ozanne
Pathology Consultant Technologist at wozanne@iqmh.org or info@iqmh.org

PT Take-Away: Important notice: Proficiency Testing survey shipments

PLEASE NOTIFY IQMH OF ANY CHANGES IN RECEIVING PROTOCOLS

With the uncertainty surrounding COVID-19, your facility may be revising its shipping/receiving protocols. To ensure proficiency testing surveys are delivered to your site without interruption, we ask that you provide any changes in receiving dock protocol to info@iqmh.org. We will work with you on a survey-by-survey basis to ensure your survey materials are received.

Read the IQMH response to COVID-19.
Antimicrobial resistance in common hospital pathogens in Ontario: Annual Survey Report 2018

Public Health Ontario (PHO), in partnership with the Institute for Quality Management in Healthcare (IQMH), has published its annual laboratory and hospital survey report on antimicrobial resistance in common hospital pathogens in Ontario.

Background

Antimicrobial resistance poses a serious threat to patient safety and global public health, as current antimicrobials become less effective at treating resistant organisms. Health care-associated infections contribute to increased length of hospitalization, mortality and use of health care resources. In Canada, it is estimated that antimicrobial resistance causes 5,400 deaths and costs the health care system $1.4 billion per year.1 Patients colonized with antimicrobial resistant organisms (AROs) are a major reservoir for health care-associated pathogens; screening and surveillance programs further our understanding of the burden of AROs and the impact of infection control programs in health care settings.

For nearly 20 years, the Institute for Quality Management in Healthcare (IQMH), formerly Quality Management Program—Laboratory Services (QMP–LS), administered an annual survey on antimicrobial resistance in common hospital pathogens to all licensed Ontario bacteriology laboratories and summarized the data in an annual report. In 2016, Public Health Ontario (PHO) and IQMH established a partnership to conduct an annual survey of AROs across all laboratories and hospitals for surveillance. As part of this collaboration, IQMH resumed laboratory survey administration, while PHO administered the hospital survey on infection control programs. Questions have evolved each year to capture the changing trends in AROs in Ontario.

The 2018 survey was distributed to all licensed microbiology laboratories and all public hospitals in Ontario. Participants were surveyed on screening and infection control programs, as well as the prevalence of AROs: methicillin-resistant Staphylococcus aureus (MRSA), vancomycin-resistant enterococci (VRE), extended spectrum beta-lactamases (ESBLs), carbapenemase-producing organisms (CPO) and Clostridioides difficile infections (CDI).

The objective of this report is to summarize the findings of the annual survey on antimicrobial resistance of common hospital pathogens from 2018.
Download the report.


PHO and IQMH would like to thank those who participated in this 2018 survey and in the current 2019 survey which is due March 31, 2020.

Reference

Hemoglobin Measurement – Pre-analytical Factors and Comparison Between Analytical Methods

Manisha Shah, IQMH Chemistry Scientific Committee; Danijela Konforte, IQMH Chemistry Scientific Committee; Miranda Wozniak, IQMH Hematology Scientific Committee

Hemoglobin (Hb) is a blood protein that carries oxygen to the body’s organs and tissues. Its measurement is part of a complete blood count – a commonly ordered blood test that aids in the screening and diagnosis of many diseases.

A person’s hemoglobin level or concentration (measured in g/L) is the most commonly used indicator of anemia. Anemia is defined by a Hb concentration below an age, sex and life stage-specific reference interval, keeping in mind that reference intervals may vary based on methods and guidelines. Given its utility in screening and evaluating the impact of clinical intervention, accurate Hb measurement is essential for optimal patient care.

This article provides an overview of the pre-analytical factors that affect Hb measurement, common analytical methods used in measurement of Hb, as well as the interchangeability of results between methods.

Pre-analytical factors

There are a number of physiological and sample collection factors that can affect Hb measurement.

**Biologic variation:** Hb measurement can vary over time, even in stable patients. Systematic review and meta-analysis of within-subject (CVi) and between-subject (CVg) biological variation estimated CVi of 2.85% and CVg of 6.8% for Hb. The CVi and CVg estimates are based on 21 different publications where sampling intervals vary from hourly to monthly.

**Exercise:** Sustained exercise (i.e. endurance exercise or training) produces an increase in plasma volume which may lead to a decrease in Hb.

**Hydration status:** Hb concentration is higher in dehydrated versus normovolemic patients.

**Positioning during phlebotomy:** Hb results can be as much as 10 g/L lower if a sample is obtained from a patient in upright versus supine position due to changes in plasma volume.

**Blood source:** Arterial Hb measurements can be on average 7–10 g/L lower than venous measurements mostly due to decreased plasma volumes in arterial blood. Capillary blood samples also show broad variation in hemoglobin values. For example, capillary blood Hb results obtained from different fingers on the same patient can have a deviation of ±7 g/L. This could be due to the fact that capillary sample collection sometimes involves squeezing (“milking”) of a finger or heel; this dilutes the sample with interstitial fluid leading to a falsely low Hb result.

**IV line contamination:** Contamination with infusion fluids when a specimen is collected close to an infusion site can cause spuriously low Hb due to dilution.

Continued on page 8
Continued from page 7

Prolonged tourniquet use: Venous stasis of more than one minute during venipuncture can increase Hb by as much as 4 g/L due to hemo-concentration.  

Inadequate sample mixing: Variability of sample manual mixing techniques can lead to falsely increased Hb results in cases where samples are not homogenously mixed before analysis.

Analytical methods used in Hb testing
Most hemoglobin values used for clinical purposes are obtained from invasive methods. However, Hb can be measured by invasive and noninvasive analytical methods.

Noninvasive methods: these methods include pulse oximetry and occlusion spectroscopy which have the ability to estimate Hb concentration through the skin of a finger using a spectrophotometric sensor or by assessing the colour of the conjunctiva of the eye (Photo biosensor). These methods are used predominantly for Hb screening in blood donors or monitoring hemoglobin concentration during surgery in hospitalized patients.

Invasive methods: these methods involve obtaining a blood sample. Examples include automated hematology analyzers, CO-oximeters, or point-of-care (POC) devices.

Invasive analytical methods for obtaining a hemoglobin value can be divided into two general categories — measured and calculated.

Measured Hb methods:

Hematology analyzers:
The hemoglobincyanide method (HiCN) has traditionally been the standard quantitative measurement of Hb. Potassium ferricyanide oxidizes Hb in the whole blood to form methemoglobin (metHb). Potassium cyanide then combines with metHb to form hemoglobincyanide (HiCN) which is a stable pigment read photometrically at a wavelength of 540 nm.

Due to concerns about the disposal of potassium cyanide, most automated hematology analyzers use a photometric method based on sodium lauryl sulfate (SLS) which is similar to the HiCN method. SLS is a surfactant which lyses erythrocytes and forms a complex with the released Hb called SLS-MetHb. This complex is stable for a few hours and has characteristic spectrum with maximum absorbance at 539 nm.

CO-oximeters are specialized spectrophotometers
A CO-oximeter measures concentrations of different hemoglobin derivatives — oxygenated hemoglobin, deoxygenated hemoglobin, carboxyhemoglobin and methemoglobin. Blood gas analyzers can have an incorporated CO-oximeter. Each hemoglobin derivative absorbs light at a specific wavelength and has characteristic absorbance spectra. Absorbance measurements of a lysed blood sample at multiple wavelengths (520–620 nm) are used by the CO-oximeter software to calculate the concentration of each hemoglobin derivative, the sum of which is equal to total Hb concentration.

Sample turbidity caused by lipemia, high plasma protein, and cellular matter (e.g. high white blood cell counts) can sometimes interfere with photometric Hb methods.

Point of Care Devices:
Hemoglobinometers
These portable devices (e.g. HemoCue) also use photometry similar to automated analyzers but use different reagents and measure Hb at a wavelength of 506 nm. These devices are factory calibrated against the HiCN method.

Continued on page 9
Calculated Hb Methods

Conductivity methods commonly used by certain POC devices measure electrical conductance of the blood sample, which then is converted to hematocrit (Hct). Hb concentration is then calculated based on the assumption that Hb is approximately one-third of the hematocrit (hematocrit × 0.34 = Hb). However, conductivity methods tend to underestimate the hematocrit and therefore the calculated Hb level. For example, Hct derived by conductivity has been shown to be inaccurate at a hematocrit below 0.30, or Hb levels of 100 g/L or less, making this methodology less accurate in detecting anemia.

Furthermore, the accuracy of hematocrit/Hb measurement by conductivity-based methods is affected by several factors such as sodium levels, protein concentrations in the blood, the use of plasma volume expanders, lipemia, and the presence of elevated white cell counts.

Standardization of Hb Measurement

A reference Hb cyanide (HiCN) solution is used for standardization and calibration of whole blood Hb measurement on automated analyzers and hemoglobinometers. Its hemoglobin concentration is determined based on criteria assigned and reviewed periodically by the International Council for Standardization in Hematology (ICSH). Despite availability of reference HiCN solution there are still gaps in standardization between different Hb methods as described in the studies below.

Comparison Between Hb Methods

Automated hematology instruments are considered the standard laboratory method for hemoglobin measurement and all common platforms compare well to each other with regard to hemoglobin. In a 2015 publication, inter-instrument comparison of five automated hematology analyzers, Abbott CELL-DYN Sapphire, Beckman Coulter DxH 800, Siemens Advia 2120i, Sysmex XE-5000 and XN-2000 show good agreement for Hb using patient samples. However, studies comparing hemoglobin results from CO-oximetry and hemoglobinometers to automated methods have not shown such good agreement.

In two separate studies it was shown that CO-oximeters and POC devices generally overestimate hemoglobin concentration compared to standard laboratory methods. IL-GEM, Abbott i-STAT and Siemens RapidPoint all showed systematic overestimation of Hb values when compared to the automated hematology analyzers. GEM 4000 consistently overestimated across the analytical range and i-STAT showed a negative bias at lower Hb values.

Additionally, in a study performed by UK NEQAS a significant variation was noted in the results from blood gas analyzers compared to standard laboratory methods. Using partially fixed whole blood samples with a mean Hb value of 93.8 g/L, the blood gas analyzers produced a hemoglobin result in the range of 83–111 g/L compared to hemoglobinometer (HemoCue) in the range of 93–103 g/L, and automated hematology analyzers in the range of 92–100 g/L. With regard to hemoglobinometers, the HemoCue has shown greater bias and higher variability in Hb measurement compared with automated hematology instruments. This discrepancy may be a result of different blood sampling procedures, biological differences in capillary versus venous blood, hydration status, or other factors.

The IQMH proficiency testing (PT) performance expectations for both automated hematology analyzers in addition to CO-oximeters are also worth noting in the section.

The IQMH Hematology PT survey assesses Hb performance of automated lab analyzers based on the instrument mean using the following Allowable Performance Limits (APLs): <100 g/L ±4 g/L; ≥100 g/L ±5%. The IQMH survey material is instrument specific and therefore does not allow for comparison between different instrument groups.
The IQMH CHEM-OX survey assesses performance of CO-oximeters that includes total Hb. The survey is assessed based on all-methods’ mean (AMM) with the following APLs: <100 g/L ±15 g/L; if ≥100 g/L ±15%.
Desirable performance specifications based on biological variation are: Imprecision: 1.43%, Bias: 1.84%, Total Error: 4.19%.¹⁷

Conclusion
These studies collectively show it is important to consider the possible pitfalls associated with each analytical method when making a clinical decision regarding treatment or transfusion. Additionally, reference intervals should be adjusted to account for analytical biases to avoid misinterpretation of results.

The laboratory hematology analyzer is usually considered the reference platform within an organization. Regular sample comparisons and establishment of acceptable performance criteria are necessary in any quality assurance program. Observed differences when comparing Hb values from hematology instruments and POC devices that impact patient care must be shared with stakeholders to ensure quality clinical decision making.

References
Continued from page 10


Other Industry Events

MLPAO Conference
Explore 2020
Ottawa: June 19-20, 2020
Sheraton Hotel
150 Albert St, Ottawa, ON K1P 5G2
More Information, CLICK HERE

MLPAO Connect Day – North York
Saturday, October 17, 2020
North York General Hospital
4001 Leslie St, North York ON M2K 1E1
Visit the MLPAO website for details - CLICK HERE

2019-2020 CSCC Education Roundtables
Canadian Society of Clinical Chemists
All CSCC Education Roundtables will be held on Thursday and will be one (1) hour in length.
Visit the CSCC website for more information.

Subscribe
https://iqmh.org/ess
Sign up for our newsletter and join our offers subscription list for the latest updates.

IQMH Newsletter
Elevate features articles on accreditation, proficiency testing, quality management and other issues related to medical diagnostic services, treatment of disease, and the promotion of health.

IQMH Offers
Offers provide email announcements for IQMH educational and quality management offerings (symposia, forums, workshops, webinars, posters, guidelines, white papers, case studies) and other related products and services.
Confidence. Elevated.

About Us

The Institute for Quality Management in Healthcare’s mission is to elevate the integrity of the medical diagnostic testing system by providing rigorous, objective, third-party evaluation according to international standards.

Our services have achieved world-wide recognition: The Centre for Proficiency Testing is accredited by the American Association for Laboratory Accreditation (A2LA); and the Centre for Accreditation is a signatory of the Mutual Recognition Arrangement with the International Laboratory Accreditation Cooperation (ILAC). These achievements set IQMH apart through proven demonstration that it meets rigorous international standards for quality and competence.

IQMH is a not-for-profit corporation without share capital, incorporated under the Ontario Corporations Act.

Our vision is to be the Standard for Confidence, within the international medical diagnostic testing community, through our three independent Centres of Excellence: Accreditation, Proficiency Testing, and Education.

Contact
1500–393 University Ave.
Toronto, ON M5G 1E6
Canada

T 416-323-9540
F 416-323-9324
E info@iqmh.org
www.IQMH.org

Stay connected

Important notice:
IQMH response to COVID-19

The IQMH physical office is closed.
Please contact info@iqmh.org for Corporate Services related inquiries.

Read the IQMH response to COVID-19.