DIAGNOSTIC ACCREDITATION PROGRAM
College of Physicians and Surgeons of British Columbia
300–669 Howe Street
Vancouver BC V6C 0B4
www.cpsbc.ca
Telephone: 604-733-7758
Toll Free: 1-800-461-3008 (in BC)
Fax: 604-733-3503

MEMORANDUM

To: Laboratory Medical Leader/Director, Administrative Leader/Director, Laboratory Managers/ Chief Technologists/ Regional/Section Supervisors, Professional Practice Leaders

From: Karin Kijek, Proficiency Testing/QC Specialist

Date: September 3, 2015

Re: DAP Processes for Proficiency Testing 2016

Please ensure distribution to all relevant departments and individuals.

Mandated Analytes/Procedures

Laboratories are required to ensure the accuracy of all analytes within their test menu. The DAP has identified the list of mandated analytes and procedures that require a formal PT program as provided by a commercial vendor.

Selection of proficiency testing providers

Laboratories may select the proficiency testing provider that best meets their needs from the *DAP-approved Proficiency Testing Providers 2016* list.

Handling exceptions for mandated analytes

Laboratories are required to fill out a DAP *Investigation and Exception Response Form* for exceptions that occur with mandated PT, including if surveys were missed. The laboratory must have a quality system in place to monitor all mandated analytes, record corrective actions for unacceptable results and monitor the effectiveness of these actions.

In the case of a missed survey, the laboratory should indicate that an alternative assessment procedure was conducted to ensure accuracy during that time frame. The senior medical leader should review the PT program summaries and corrective actions on a regular basis.

The laboratory should discontinue testing of any analyte when the laboratory:

- cannot verify the accuracy and reliability of its test results
- cannot guarantee that patient results are not affected
- cannot determine the cause of the PT discrepancies

Note: The *Investigation and Exception Response* forms may be updated periodically. Consult the DAP website for the current version of this form.

Ungraded results

The laboratory is required to self-assess ungraded results from mandatory (as well as voluntary) PT programs. Ungraded PT challenges should be compared to the most common responses given. Again, any remedial or corrective actions are to be monitored for effectiveness.

Supplemental/remedial PT

In the case of repeated and unresolved exceptions, the DAP may ask the laboratory to perform additional PT. Laboratories may choose to run remedial samples on a proactive basis as well. The remedial sample is considered part of the laboratory's corrective action and a test of the effectiveness of that action.

PT vendors can provide a remedial service allowing the laboratory to test PT materials and receive performance markings, outside of the normal testing timetable. These materials may be referred to by the vendor as "off-cycle samples." Laboratories may choose their current vendor to provide this service or may contact another vendor from the DAP-approved PT provider list.

Reporting to the DAP

Laboratories registering with approved proficiency testing vendors for 2016 are reminded to notify the vendor that the DAP must receive copies of laboratory results. The vendor must release to the DAP either electronic and/or paper data of the laboratory's results, at the time results are sent to the facility. Optionally, the laboratory may send copies of their PT reports to the DAP indicating their participation and performance.

These PT reports will be monitored for ongoing laboratory performance and are used to produce a summary for the on-site accreditation survey.

Non-Mandated Programs/Analytes

Non-mandated analytes are all analytes not listed in the document *Mandated Proficiency Testing by Specialty 2016*. The DAP does not require enrolment in a commercial PT program for non-mandated analytes but does require that laboratories verify the accuracy of these test results at least twice a year using alternative assessment procedures. Alternative assessment procedures should include external comparisons wherever possible. The senior medical leader should define such procedures, including evaluation criteria, in accordance with good scientific and clinical laboratory practice.

Point-of-care testing

Point-of-care (POC) testing is considered analysis outside the confines of the laboratory. As POC tests are non-mandated procedures, the laboratory has the option of enrolling in formal PT programs **or** performing alternative assessment procedures to ensure the accuracy of POC results.

Alternative assessment procedures for non-mandated analytes

For non-mandated analytes laboratories must use **one or more** of the following procedures to verify the accuracy of their test results at a minimum of twice a year. During on-site surveys, the accreditation assessment officer may request documentation of the methods used for each analyte:

- participation in formal, vendor-operated PT programs (as required with mandated analytes)
- participation in ungraded PT programs
- split sample analysis with reference or regional laboratory
- split sample with an established in-house method
- use of assayed material, standard reference material, or regional pools
- other suitable and documented means as defined by your senior medical leader

A useful resource for additional information is the CLSI document GP29-A *Assessment of Laboratory Tests When Proficiency Testing is Not Available; Approved Guideline*, Volume 22, Number 26.

Handling exceptions for non-mandated analytes

Laboratories are **not** required to fill out an *Investigation and Exception Response Form* for exceptions that occur with alternative assessment procedures. However, the laboratory is required to take action for any results that are graded as unacceptable. The laboratory must have a quality system in place to monitor all non-mandated analytes, record corrective actions for unacceptable results and monitor the effectiveness of these actions. The senior medical leader should review the alternative assessment procedure summaries and corrective actions on a regular basis.

The laboratory should discontinue testing of any analyte when the laboratory:

- cannot verify the accuracy and reliability of its test results
- cannot guarantee that patient results are not affected
- cannot determine the cause of the PT discrepancies

Regional approaches

Regional coordinators responsible for monitoring the PT and alternative assessment procedures performed at their sites, are encouraged to provide samples for their own regional alternative assessment procedures, as well as educational programs to participants.

Results summaries for the DAP

Individual laboratories or regional coordinators may be asked periodically to submit to the DAP a summary of results and corrective actions for any alternative assessment procedures. During on-site surveys, the accreditation assessment officer may ask to see the records of these procedures as well.

Changes and Additions to the DAP Mandated Proficiency Testing by Specialty List for PT2016

Chemistry/Immunology

Analytes that have been added to the mandated list:

- 1,25-diOH Vitamin D
- ACTH
- Arsenic
- Ceruloplasmin
- Cyclic citrullinated peptide (CCP)
- IgD
- Kappa/lambda light chains
- Mercury
- Progesterone

Hematology/Coagulation

Analytes that have been added to the mandated list:

- Heparin
- Heparin-induced thrombocytopenia

Microbiology

Laboratories performing microbiology procedures should see below for clarification of PT testing in this specialty.

Mandatory proficiency testing is required for:

- Microscopic:
    - Gram stains
    - Acid fast stains
    - Parasites
    - Detection/identification of other bacteria, and fungi (e.g. direct KOH preparations)
- Isolation, identification and susceptibility testing of organisms
- Serological, antigen and/or molecular detection of commonly encountered:
    - Bacteria (e.g. MRSA, VRE, C. difficile toxin, Chlamydia, N. gonorrhoeae)
    - Viruses (e.g. Hepatitis B, HIV)
    - Parasites (e.g. Trichomonas vaginalis)
    - Fungi (e.g. Cryptococcus)

All other microbiology testing is subject to alternative assessment procedures.

Anatomic Pathology and Cytology

Laboratories performing anatomic pathology or cytology are encouraged to utilize PT and/or educational programs for their disciplines.

Laboratories performing class II immunohistochemistry (IHC) testing are required to take part in a formal PT program. The approved PT providers are as follows:

- Canadian Immunohistochemistry Quality Control (cIQc)
- College of American Pathologists (CAP)
- Nordic Immunohistochemistry Quality Control (NordiQC)
- United Kingdom National External Quality Assessment Service (UK NEQAS)

For a definition of a class II test, please reference the following journal article:

Canadian Association of Pathologists-Association canadienne des pathologistes National Standards Committee. Canadian Association of Pathologists-Association canadienne des pathologistes National Standards Committee/Immunohistochemistry: best practice recommendations for standardization of immunohistochemistry tests. Am J Clin Pathol. 2010 Mar;133(3):354-65. Available from: http://ajcp.ascpjournals.org/content/133/3/354.long

2016 Proficiency Testing Enrolment and Attestation Forms

The proficiency testing enrolment and attestation forms will be sent out to laboratories in late 2015, and are to be completed and returned to the DAP by January 31, 2016.

For further information:

Please visit our website at www.dap.org under the heading Proficiency > Laboratory Medicine > PT 2016 or contact Karin Kijek at kkijek@cpsbc.ca.