



DIAGNOSTIC ACCREDITATION PROGRAM

Laboratory Medicine Proficiency Testing Manual

Laboratory Medicine Proficiency Testing Manual

Table of Contents

| | |
|--|-----------|
| Introduction to the Proficiency Testing Process..... | 3 |
| Background | 3 |
| What is Proficiency Testing? | 3 |
| Standards | 3 |
| DAP Committee..... | 3 |
| DAP Advisory Committees | 4 |
| Overview of the Proficiency Testing Process | 5 |
| Mandated Measurands..... | 5 |
| Non-mandated Measurands | 6 |
| PT Frequency..... | 6 |
| DAP Provisionally Accredited Facility..... | 6 |
| DAP Accredited Facility..... | 6 |
| Selecting a PT Provider..... | 6 |
| Providing PT Reports to DAP..... | 6 |
| Monitoring Multiple Analyzers | 7 |
| PT Enrolment and Attestation Process..... | 8 |
| PT Enrolment and Attestation Forms | 8 |
| Submission to DAP | 8 |
| Completing the PT Enrolment and Attestation Forms..... | 8 |
| Laboratory Service | 8 |
| Laboratory Information | 9 |
| Measurand Information..... | 9 |
| Examination Performed By | 9 |
| PT Provider Information | 10 |
| PT Survey Information | 10 |
| PT Monitoring Process | 12 |
| DAP – Monitoring Activities | 12 |
| Laboratory Medicine Facilities – Monitoring Activities | 12 |
| PT Reportable Exceptions Criteria | 13 |
| Ungraded or Educational Samples..... | 13 |
| Completing the PT Investigation Response Form | 14 |
| Laboratory and PT Information..... | 14 |
| PT Exception Investigation..... | 14 |
| Sign-off..... | 15 |
| PT Exception Escalation Process | 16 |
| PT Exception Escalation Criteria..... | 16 |
| PT Reporting for Facility Assessment Process..... | 17 |
| Reporting Significant Changes | 18 |

Laboratory Medicine Proficiency Testing Manual

- Concerns and Complaints Process.....18**
- Release of Information.....18**
 - Client Information Protection 18
- How to Contact the DAP.....19**
 - Diagnostic Accreditation Program Contact Information..... 19
 - Proficiency Testing and Quality Control Specialist Contact Information..... 19
- References.....20**
- Glossary.....21**

Laboratory Medicine Proficiency Testing Manual

Introduction to the Proficiency Testing Process

The Diagnostic Accreditation Program (DAP) Proficiency Testing Manual is designed to help you understand the processes, forms, and requirements of Proficiency Testing in accredited laboratory medicine facilities.

Background

As a program of the College of Physicians and Surgeons of British Columbia, the mandate and authority of the DAP is derived from part 5, section B of the College Bylaws under the *Health Professions Act*, RSBC 1996, c.183. The DAP has a mandate to assess the quality of diagnostic services in the province of British Columbia through accreditation activities.

What is Proficiency Testing?

Proficiency testing (PT) is an evaluation of participant performance against pre-established criteria by means of interlaboratory comparison.¹ A PT program is a quality assessment tool that provides a retrospective measure of technical quality. To be most effective, PT must be used in conjunction with the laboratory's internal quality control program and be a part of the quality management system. The objectives of the PT program for the DAP are to:

- provide objective evidence of laboratory competence through continual monitoring
- identify trends in acceptable PT results and flag unacceptable PT results requiring investigation
- monitor the outcomes of investigations and subsequent corrective actions
- provide laboratories the opportunity to identify issues related to systemic error, imprecision, or human error; potentially unrecognized issues if PT is not fully incorporated into the quality management system
- consider laboratory PT performance during the assessment and accreditation process using a combination of data collected through the PT monitoring process and evidence provided during onsite assessment

Standards

The 2015 DAP Laboratory Medicine Accreditation Standards are comprehensive, best practice standards that have been referenced to recognized international and national standards for laboratory medicine. The DAP standards also include the ISO 15189 standard *Medical laboratories—Requirements for quality and competence* reflecting our commitment to ISO 15189 compliance for laboratory medicine facilities.

The DAP's accreditation standards were developed through a collaborative, consultative and consensus process that involved members of the DAP advisory committees, members of the laboratory community and other laboratory stakeholders. The 2015 Laboratory Medicine Accreditation Standards are available on the College [website](#). Standards QUA2.1.1 through QUA2.3.8 are specific to proficiency testing.

DAP Committee

The 2015 Laboratory Medicine Accreditation Standards were approved by the DAP Committee in their capacity to establish performance standards to ensure the delivery of high quality and safe diagnostic services in British Columbia. The DAP Committee also reviews all changes proposed to the DAP PT processes including the list of mandated measurands and the PT exception escalation criteria.

Laboratory Medicine Proficiency Testing Manual

DAP Advisory Committees

The DAP's accreditation standards are developed through a collaborative, consultative and consensus building process that involves health professionals and organizations, academics, experts, health authorities, and colleges. The process for standards development and review allows for considerable input from the diagnostic services that will be using the standards.

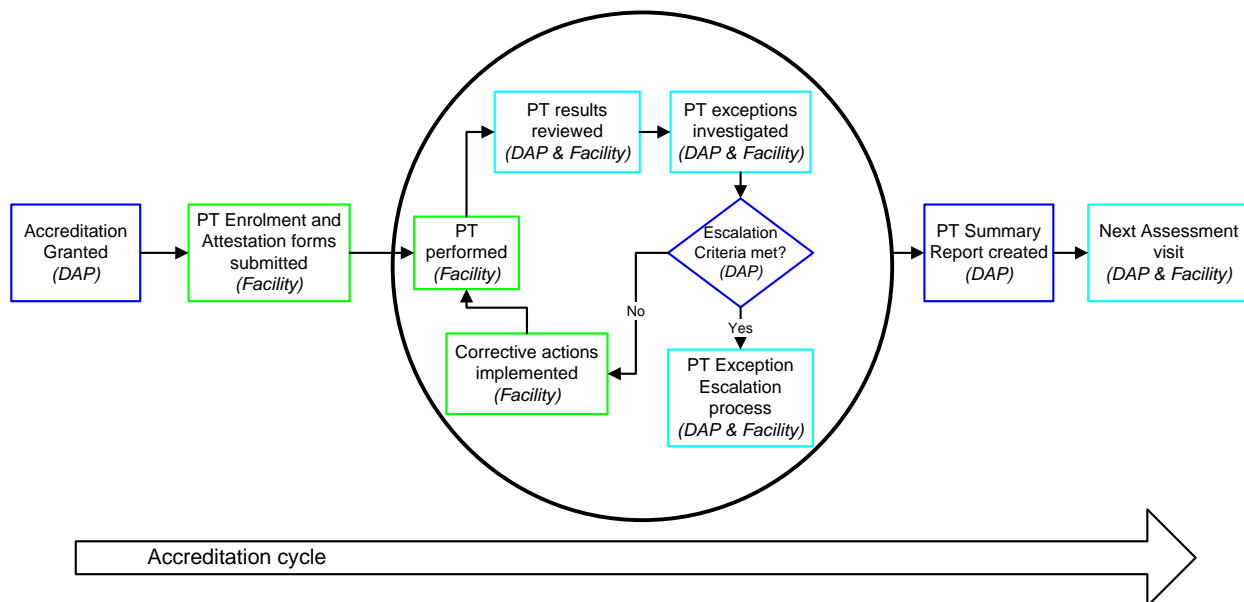
Advisory committees have been established to represent each discipline and for the general standards. Advisory committees provide advice to the DAP staff and DAP Committee on the medical, technical and management issues related to the accreditation standards. These committees, appointed by the DAP Committee and composed of medical, technical and management professionals, have significant input as it relates to the content of the accreditation standards and processes for each discipline.

Each advisory committee has specific terms of reference that outline the role, membership, term of appointment and frequency of meetings. Terms of reference guide the activities of each advisory committee.

Laboratory Medicine Proficiency Testing Manual

Overview of the Proficiency Testing Process

The DAP utilizes proficiency testing performance to monitor laboratories' technical quality throughout the accreditation cycle. The diagram below depicts how the PT processes involve both the DAP and the laboratory facility.



The DAP requires laboratories to employ proficiency testing programs to monitor all measurands within their scope of accredited services. The DAP holds the laboratory medical director responsible for defining and monitoring standards of performance and the quality of results. The laboratory medical director must be advised of all PT result exceptions.

Mandated Measurands

The DAP, in consultation with DAP advisory committees, maintains a list of mandated measurands requiring participation in a commercially available PT program. The list is published on the [Laboratory Medicine](#) page of the DAP section of the College website.

Note: Measurand includes all sample types for any specific examination/ analyte.

Laboratories must notify the PT provider to release copies of the laboratory PT reports to the DAP.

- All mandated measurands within the laboratory's scope of accredited service are to be included in the annual PT enrolment and attestation forms.
- Mandated measurands are subject to the DAP reportable exceptions criteria as outlined in the PT monitoring section of this manual.
- Proficiency testing performance for mandated measurands is monitored continually during the accreditation cycle through review of individual laboratory PT reports for all mandated measurands. A summary of this monitoring is provided to the DAP accreditation assessment officers and/or peer assessors for consideration during facility assessments.

Laboratory Medicine Proficiency Testing Manual

Non-mandated Measurands

Measurands not included in the list of mandated measurands are considered non-mandated. Non-mandated measurands must participate in proficiency testing activities as deemed appropriate by the laboratory medical director. This could involve participation in commercially available PT programs or the development of alternate assessment procedures.

Alternate assessment procedures should be developed in accordance with good scientific and clinical laboratory practice, utilize external comparisons wherever possible, and include the evaluation criteria to be used in assessing performance of the measurand. A useful resource is provided by the Clinical and Laboratory Standards Institute (CLSI) – QMS24 “Using Proficiency Testing and Alternate Assessment to Improve Medical Laboratory Quality; Approved guideline – Third Edition” September 2016.

- All non-mandated measurands within the laboratories scope of accredited service are to be included in the annual PT enrolment and attestation forms.
- Non-mandated measurands are not subject to the DAP reportable exceptions criteria.
- Proficiency testing performance for non-mandated measurands is assessed during the facility assessment by DAP accreditation assessment officers and/or peer assessors.

Note: Point-of-care testing (POCT) is considered analysis outside the confines of the laboratory, and for the purposes of proficiency testing is considered non-mandated measurands.

PT Frequency

DAP Provisionally Accredited Facility

| | | |
|-------------------------|--------------|---|
| Mandated measurands | All services | Minimum two samples and one test event prior to full DAP assessment |
| Non-mandated measurands | | |

DAP Accredited Facility

| | | |
|-------------------------|--------------|-------------------------------------|
| Mandated measurands | All services | Minimum four samples per year |
| Non-mandated measurands | | Minimum two testing events per year |

Selecting a PT Provider

The DAP maintains a list of available PT providers that offer programs covering the range of mandated measurands. The list is published on the [Laboratory Medicine](#) page of the DAP section of the College website.

Providing PT Reports to DAP

In most instances these PT providers also offer the DAP direct access to copies of individual laboratory PT reports once the laboratory grants consent for copies to be released. The list of available PT providers indicates when the provider does not provide copies to the DAP. If the laboratory chooses to monitor mandated measurands by utilizing PT providers that do not provide copies to the DAP, the laboratory is required to submit copies of PT reports directly to the DAP via email at ptqc@cpsbc.ca.

Laboratory Medicine Proficiency Testing Manual

If the laboratory chooses to source PT programs from providers not on the list, they must submit details of the PT program, including a schedule of shipments, directly to the DAP along with the annual PT enrolment and attestation forms. Additionally, laboratories utilizing these providers to monitor mandated measurands are required to submit copies of PT reports directly to the DAP via email at ptqc@cpsbc.ca.

Monitoring Multiple Analyzers

The DAP does not have a standard which requires PT be performed on multiple analyzers within a facility. Rather the DAP has developed standards specific to verification of comparability QUA3.1.1 to QUA 3.1.6.

The DAP [guidance document](#) regarding DAP comparability standards indicates that PT material can be used as a comparability sample; however, “vendors’ summary reports of proficiency testing (PT) cannot be used for comparability testing, PT data can be used if the laboratory develops a mechanism to demonstrate comparability.”

When laboratories choose to enroll in PT programs that offer multiple analyzer reporting (i.e. subscriptions) PT reports are provided to DAP for all analyzers, which in turn means all [reportable exceptions](#) from all analyzers are subject to submitting the PT Investigation Response form.

If laboratories choose to use PT material to assess comparability between instruments they need to consider the pros and cons of formally subscribing to multiple analyzer reports when designing their comparability procedures.

Laboratory Medicine Proficiency Testing Manual

PT Enrolment and Attestation Process

This section provides information related to the PT enrolment and attestation process. Through annual enrolment accredited laboratories provide DAP the information necessary to effectively monitor ongoing participation and performance in proficiency testing activities relative to the laboratories' scope of accredited service.

The enrolment includes an attestation statement which indicates all measurands participate in proficiency testing programs that meet the mandates of the DAP. This attestation must be signed by the laboratory medical director, as the DAP holds the laboratory medical director responsible for defining and monitoring standards of performance and the quality of results.

PT Enrolment and Attestation Forms

Submission to DAP

PT enrolment and attestation forms are submitted by the laboratory:

- within three weeks of receiving a provisional accreditation award
- by the annual due date thereafter

The DAP notifies medical directors and facility leaders, by email, annually when the PT enrolment and attestation forms are due for the coming year. Completed PT enrolment and attestation are to be returned to DAP by email to ptqc@cpsbc.ca.

Note: If forms are altered they will be returned to laboratories for re-entry into an unaltered form.

Completing the PT Enrolment and Attestation Forms

The DAP PT Enrolment form is an Excel workbook, with a worksheet for each laboratory service. The DAP PT Attestation form is a fillable PDF form, with facility contact information and the attestation statement which indicates all measurands participate in proficiency testing programs that meet the mandates of the DAP. Both of these forms are published on the [Laboratory Medicine](#) page of the DAP section of the College website.

Note: The DAP Enrolment form is an Excel workbook compatible with Excel 2010 and newer. Older versions do not support the functionality in this workbook. If a facility does not have access to Excel 2010 please contact the DAP to consider an alternate format for submission.

Laboratory Service

The DAP PT Enrolment form is divided into a separate worksheet for each laboratory service. Laboratories are required to complete each worksheet that is relevant to the laboratories' scope of accredited services, including mandated and non-mandated measurands.

- coagulation is considered part of hematology
- urinalysis is considered part of chemistry
- virology is considered part of microbiology
- molecular diagnostics and point-of-care testing should be included in the specific laboratory service for the measurand

| | | | | | | | |
|-------------|--------------|-----------------------|-----------------|-----------|------------|-----------------------|----------------------|
| AP_Cytology | Cytogenetics | Molecular Diagnostics | Chem_Urinalysis | Hema_Coag | Immunology | Micro_Para_Myco_Viral | Transfusion Medicine |
|-------------|--------------|-----------------------|-----------------|-----------|------------|-----------------------|----------------------|

Laboratory Medicine Proficiency Testing Manual

Laboratory Information

Each worksheet contains a section to provide laboratory specific information. This includes:

| | |
|----------------------------|--|
| Facility name | Provide the facility name on file with the DAP. |
| Email for facility contact | Provide the email for the individual capable of answering questions about the information provided in the form. |
| Enrolment year | This is the year in which PT will be performed. |
| PT provider client numbers | <p>Indicate the PT provider and each client number for your laboratory. If multiple analyzers are monitored, include the subscription number to each analyzer.</p> <p>Example:</p> <div style="border: 1px solid black; padding: 2px;"> PT Provider Client number(s) EQAS – 111 & 12345 / CAP – 1009999-07 / OWA – BC9999 subscriptions 123789 & 908765 </div> |

Measurand Information

Selecting the measurand involves indicating the examination, methodology, and sample type. These columns are formatted to select from a drop-down list. The **Examination** drop-down list includes all mandated measurands.

Typically the **Sample Type** column should be selected to reflect that of patient samples routinely processed, and thus monitored by proficiency testing. When PT surveys offer various sample types throughout the year (e.g. cytogenetics), select **Other** from the drop-down and complete the **Sample Type – Other** column with “As per PT provider.”

For consistency the last choice on each drop-down list is the option “other.” When “other” is selected the laboratory must complete the corresponding field, which allows free text.

| Examination (Analyte) | Examination (Analyte) – Other (Specify) | Methodology | Methodology – Other (Specify) | Sample Type | Sample Type – Other (Specify) |
|-----------------------|---|----------------|-------------------------------|--|-------------------------------|
| Other, specify | XYZ Test | Other, specify | Magic wand | <div style="border: 1px solid black; padding: 2px;"> Semen Serum Stool Swab Tissue Urine Whole Blood Other </div> | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

Examination Performed By

This section is specific to examination of patient samples, and is used to assess whether the examination is considered solely point-of-care testing. From the drop-down list select the appropriate response.

Laboratory Medicine Proficiency Testing Manual

| Examination of patient samples performed by | PT Provider Code |
|---|------------------|
| non-lab personnel | |
| lab personnel | |
| non-lab personnel | |
| both lab/ non-lab | |

Note: Examination Performed By is only included on worksheets for lab services with measurands that are considered point-of-care testing.

PT Provider Information

Selecting the PT provider information involves selecting the PT provider code from a drop-down list. Once selected the spreadsheet will auto-populate the **PT Provider Name** field.

For consistency the last choice on each drop-down list is the option “other.” When “other” is selected the laboratory must complete the corresponding field, which allows free text.

| PT Provider Code | PT Provider Name | PT Provider Name – Other (Specify, and submit details to DAP) | Survey Code (from provider) | Survey Name | Survey Name – Other (Specify) | PT provider sends copies to DAP |
|------------------|--|---|-----------------------------|-------------|-------------------------------|---------------------------------|
| CAP | College of American Pathologists (CAP) | | | #N/A | | Yes |
| Alternate | Alternate Assessment | | | #N/A | | No |
| OWA | Oneworld Accuracy (OWA) | | | #N/A | | Yes |
| Other | Other Commercial Provider | | | #N/A | | No |
| | #N/A | | | #N/A | | #N/A |
| | #N/A | | | #N/A | | #N/A |
| | #N/A | | | #N/A | | #N/A |
| | #N/A | | | #N/A | | #N/A |
| | #N/A | | | #N/A | | #N/A |
| | #N/A | | | #N/A | | #N/A |
| | #N/A | | | #N/A | | #N/A |
| | #N/A | | | #N/A | | #N/A |

Note: See [Selecting a PT Provider](#) for additional information regarding laboratory accountabilities when utilizing a PT provider that does not provide copies to the DAP.

PT Survey Information

Selecting the survey information involves selecting the survey code from a drop-down list. Once selected the spreadsheet will auto-populate both the **Survey Name** field and the **PT provider sends copies to DAP** field.

For consistency the last choice on each drop-down list is the option “other.” When “other” is selected the laboratory must complete the corresponding field, which allows free text.

If using an alternate assessment procedure, the survey code “N/A” should be used.

| Survey Code (from provider) | Survey Name | Survey Name – Other (Specify) | PT provider sends copies to DAP |
|-----------------------------|---|-------------------------------|---------------------------------|
| FH13P | Automated Diff Series, FH13 with images | | Yes |
| N/A | Not Applicable, Alternate Assessment | | No |
| ERSR432 | Erythrocyte Sedimentation Rate | | Yes |
| Other | Other, Specify | POCT INR | No |

Laboratory Medicine Proficiency Testing Manual

Note: The **Survey Code** drop-down lists are generated from historical enrolment data provided to DAP by laboratory facilities in British Columbia. These lists are not intended as endorsements for any single PT provider or survey.

Laboratory Medicine Proficiency Testing Manual

PT Monitoring Process

DAP – Monitoring Activities

DAP maintains a PT tracking database by receiving, reviewing and collating the following:

- PT enrolment and attestation forms submitted by laboratory medicine facilities
- PT program reports from commercial PT provider
- PT Investigation Response forms submitted by laboratory medicine facilities

The DAP will contact facility medical directors and technical leaders when PT Investigation Response forms have not been received proactively within the eight-week time frame. Additionally, when monitoring activities identify instances of repeated and/or unresolved PT exceptions, the DAP will escalate these cases as described in the PT exception escalation process.

Laboratory Medicine Facilities – Monitoring Activities

Laboratories are required to monitor and document all PT results in accordance with the 2015 DAP Laboratory Medicine Accreditation Standards. When PT results exceed acceptable performance limits or demonstrate trends, laboratories are required to investigate, determine root cause, consider impact on patient results and when necessary take corrective action to prevent recurrence.

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

- has confirmed a clinically significant impact to patient results
- cannot verify the accuracy and reliability of test results
- cannot determine the cause of significant or ongoing PT exceptions

The laboratory medical director, or designated senior medical leader, must review the PT program summaries and corrective actions on a regular basis. This will be evaluated as part of the facility assessment.

Laboratory Medicine Proficiency Testing Manual

PT Reportable Exceptions Criteria

The table below describes the instances where laboratories are required to complete and submit PT Investigation Response forms to ptqc@cpsbc.ca. These criteria are applicable only to mandated measurands. When required, forms must be submitted proactively within **eight weeks** of receiving the PT report from the PT provider.

| PT Provider | Reportable Exceptions Criteria |
|--|---|
| General criteria applicable to all PT programs | <ul style="list-style-type: none"> Failure to perform PT survey* Failure to submit PT results on time, including discontinuation of the PT survey |
| AAB API CAP One World Accuracy WSLH | <ul style="list-style-type: none"> For programs with three to five samples per testing event: <ul style="list-style-type: none"> Any single measurand with two or more unacceptable results, in a single event Any single measurand with one or more unacceptable results on two consecutive events For programs with two or less samples per testing event: <ul style="list-style-type: none"> Any single measurand with an unacceptable result in a single event Transfusion medicine and microbiology: Any unacceptable result |
| Bio-Rad EQAS | <ul style="list-style-type: none"> Any result greater than ± 3.0 Z-score Any measurand with results greater than ± 2.0 Z-score on three consecutive events Three or more measurands with results greater than ± 2.0 Z-score on a single sample Any result exceeding the “truncation” limits by which Bio-Rad filters data |
| ciQc, CMPT Other | <ul style="list-style-type: none"> Any unacceptable result |
| IQMH | <ul style="list-style-type: none"> Any unacceptable result scored as A1, A2, A3 |
| Randox | <ul style="list-style-type: none"> Any result greater than ± 3.0 SDI RMSDI of greater than ± 1.5 Any measurand with results greater than ± 2.0 SDI on three consecutive events Three or more measurands with results greater than ± 2.0 SDI on a single sample Any gross outlier referred to by Randox as a “Deactivated” result |

* In the case of a missed survey, the laboratory must provide evidence that an alternate assessment was conducted to ensure accuracy during that time frame.

Note: “Unacceptable results” fall outside the evaluation criteria, as defined by the PT provider.

Ungraded or Educational Samples

Laboratories are expected to perform a self-evaluation on all PT programs with results that are not graded/ not evaluated or deemed educational by the PT provider. Results achieved by the laboratory are to be compared with the intended response given in the PT Provider’s summary. An internal investigation and corrective action should be undertaken for each exception. Submission of a PT Investigation Response form is not required.

Laboratory Medicine Proficiency Testing Manual

Completing the PT Investigation Response Form

The PT Investigation Response (PTIR) form is periodically updated. Check the most current version on the [Laboratory Medicine](#) page of the DAP section of the College website.

Laboratory and PT Information

This is the demographics section of the form, which includes submitting laboratory contact information, details of the PT program and the measurand(s) being investigated. When a single root cause is identified and pertains to multiple measurands, only one PTIR form is required. Otherwise, a form is required for each measurand being investigated.

A check box is included in this section as a reminder to include a copy of the PT providers final evaluation report including the reported results, peer groups, SDIs and evaluation criteria.

PT Exception Investigation

This section provides space for details regarding steps taken during the investigation of PT exceptions. Forms should be submitted with adequate information to recall the investigation at some future date. If the form does not provide adequate space for explanations, additional documents can be submitted along with the form. A useful resource is provided by the Clinical and Laboratory Standards Institute (CLSI) – *QMS24 Using Proficiency Testing and Alternate Assessment to Improve Medical Laboratory Quality; Approved guideline – Third Edition, September 2016.*

Notes:

- QC results at the time of challenge refers to daily internal quality control samples.
- Previous PT/QC trends or unacceptable results for this measurand refers to historical performance of both proficiency testing and internal quality control.
- PT samples should be properly stored to facilitate repeat analysis if required. Repeat results should be assessed against PT evaluation criteria and the SDI calculated. If repeat testing is not performed an explanation is required.
- Investigations should always include a review of the impact to patient results. The laboratory medical director is responsible for defining this review process. A brief description of the review along with the conclusion should be included in the investigation response.
- The DAP expects laboratories to investigate all exceptions to the fullest extent possible. Classification of the problem should align with the PT Investigation Sources of Error document located on the [Laboratory Medicine](#) page of the DAP section of the College website.
- Identification of root cause/contributing factors refers to the known root cause. Laboratories are expected to look beyond the surface in problem solving; however, refrain from speculation if the root cause is undetermined.
- Corrective action/system change(s) to prevent recurrence should reflect the specific actions taken or planned to address both the immediate corrective actions and the actions taken to prevent recurrence. Investigation should include a review of current procedures to determine whether they are adequate to prevent recurrence of the problem. Undocumented reminders to staff are not acceptable corrective and preventative actions.

Laboratory Medicine Proficiency Testing Manual

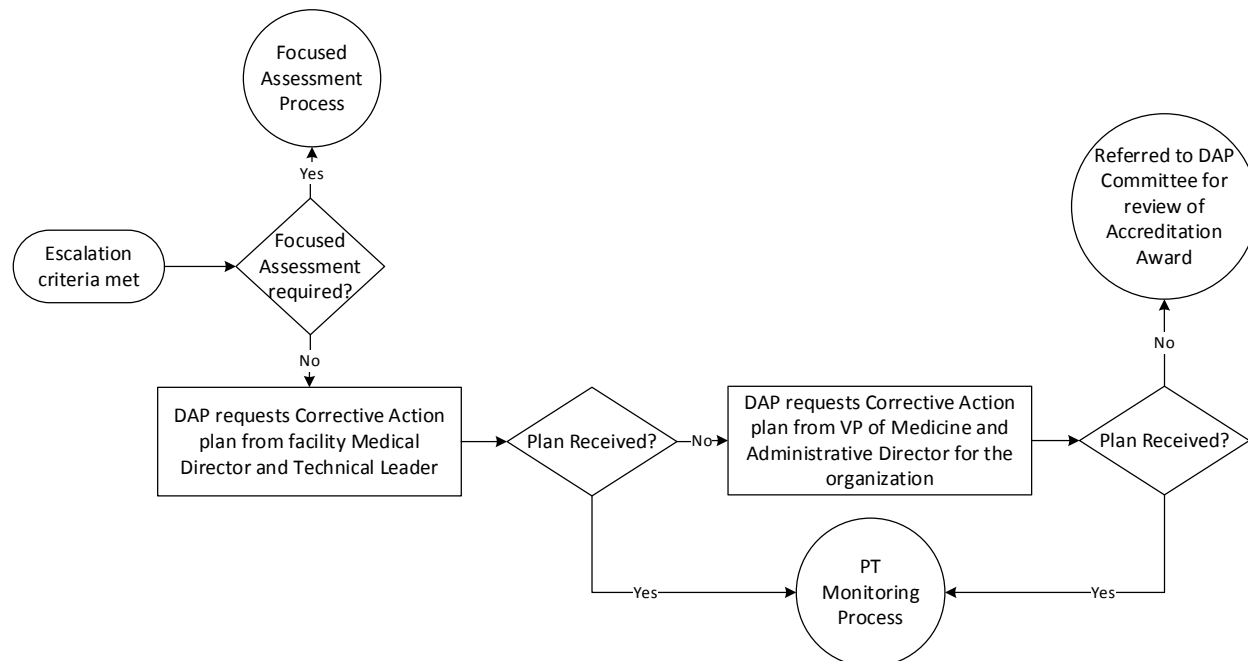
Sign-off

This section provides evidence that laboratory leadership is aware of the PT result exception and subsequent investigation being reported to the DAP. While the DAP holds the laboratory medical director responsible for defining and monitoring standards of performance and the quality of results, and expects the laboratory medical director is advised of all PT result exceptions, the DAP recognizes the investigation and subsequent reporting is often delegated. As such, the DAP does not require a signature from the laboratory medical director when the laboratory is proactively submitting PTIR forms. However, when the DAP monitoring process notifies laboratories that PTIR forms in response to PT reportable exceptions are overdue, it suggests the laboratory quality management system is not functioning effectively. In this case, the laboratory medical director must sign the PTIR form prior to submission to the DAP to provide evidence the medical leadership is providing guidance to the quality management system and subsequently the quality of laboratory results.

Laboratory Medicine Proficiency Testing Manual

PT Exception Escalation Process

This section provides information related to the DAP process for escalation of ongoing performance issues with proficiency testing.



PT Exception Escalation Criteria

The table below describes the criteria that will trigger the DAP process for escalation of ongoing performance issues with proficiency testing, including instances that will trigger the DAP focused assessment process. These criteria are applicable only to mandated measurands.

| Escalation Criteria | Focused Assessment Required? |
|---|------------------------------|
| Failure to submit PT Investigation Response form | No |
| A single measurand meeting DAP reportable criteria on two consecutive test events | No |
| A single measurand meeting DAP reportable criteria on three consecutive test events | Yes |

Laboratory Medicine Proficiency Testing Manual

PT Reporting for Facility Assessment Process

The PT Reportable Exceptions Summary Report is generated by the DAP in preparation for facility assessment by the DAP. These reports provide the DAP assessors objective evidence of the facility's PT performance, specific to the mandated measurands. Data summarized in these reports is derived from the PT tracking database used in monitoring PT performance throughout the accreditation cycle.

The DAP assessors will consider PT programs for non-mandated measurands during the facility assessment, as outlined in the 2015 DAP Laboratory Medicine Accreditation Standards.

Laboratory Medicine Proficiency Testing Manual

Reporting Significant Changes

An organization must report any significant changes, such as changes to governance structure, medical leadership, facility location, scope of service and technical staffing model. Reporting occurs by completing and submitting the Notification of Significant Change in Service form that is located on the College [website](#).

Upon receipt, the form will be reviewed by the DAP to determine if the change affects the accreditation award and warrants reassessment. The facility or region will be contacted with the outcome of the review.

Concerns and Complaints Process

All concerns or complaints regarding DAP staff, assessors, processes or services should be directed to the director. Concerns and complaints are encouraged to be made in writing and the letter should provide a clear outline of the concern or complaint. The DAP will provide an acknowledgement of the written concern or complaint within five working days of receipt and if necessary, the complainant will be contacted to clarify facts.

Release of Information

Client Information Protection

The names of facilities that have current accreditation status are disclosed by the DAP on the College [website](#).

The DAP and its assessors will treat with confidence any information acquired during the course of conducting an accreditation assessment or during the ongoing monitoring process. Please be aware that some records obtained during the accreditation process may be disclosed in response to freedom of information requests. For further details, please request a copy of the DAP Client Information Protection Policy.

Laboratory Medicine Proficiency Testing Manual

How to Contact the DAP

Diagnostic Accreditation Program Contact Information

Diagnostic Accreditation Program
College of Physicians and Surgeons of British Columbia
300–669 Howe Street
Vancouver BC V6C 0B4

Telephone: 604-733-7758
Toll Free: 1-800-461-3008

Office Hours: 8 a.m. to 4:30 p.m. Monday to Friday

Proficiency Testing and Quality Control Specialist Contact Information

Terri McCaskill
Proficiency Testing and Quality Control Specialist, Laboratory Medicine
ptqc@cpsbc.ca

Laboratory Medicine Proficiency Testing Manual

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2. Clinical and Laboratory Standards Institute (CLSI). *Using Proficiency Testing and Alternative Assessment to Improve Medical Laboratory Quality; Approved Guideline-Third Edition*. Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2013, September 2016.
3. International Organization for Standardization. *Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies*. Reference Number ISO/IEC 17011:2004(E). Published in Switzerland, 2004.
4. International Laboratory Accreditation Cooperation (ILAC). *Policy for Participation in Proficiency Testing Activities*. Reference Number ILAC-P9:11/2010.
5. Bureau International des Poids et Mesures (BIPM). *International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM, 3rd edition, JCGM 200:2012)*

Laboratory Medicine Proficiency Testing Manual

Glossary

| | |
|---------------------------------------|--|
| accuracy (of measurement) | Closeness of agreement between a measured quantity value and a true quantity value of a measurand. ² |
| alternate assessment procedure | <p>Procedure for determining the reliability of tests for which proficiency testing is either not available or is not mandated.²</p> <p>Examples include:</p> <ul style="list-style-type: none">• split sample analysis with reference or other laboratories• split sample analysis with established in-house method• use of assayed materials, standard reference material or regional pools• other suitable and documented means as defined by laboratory medical director |
| analyte | Component represented in the name of a measuring quantity. Also see measurand. ² |
| bias (of measurement) | Estimate of a systematic measurement error. ² |
| challenge | <p>For quantitative tests – an assessment of the amount of substances or analyte present or measured in a sample.²</p> <p>For qualitative tests – the determination of the presence of the absence of a measurand, organism, or substance in a sample.²</p> |
| corrective action | Action to eliminate the cause of a nonconformity and to prevent recurrence. ¹ |
| coefficient of variation (CV) | <p>Standard deviation divided by the mean.²</p> <p>Note: CV is often multiplied by 100 and expressed as a percentage.</p> |
| error | <p>A deviation from truth, accuracy or correctness. Error in the PT process leads to an unacceptable result. Error in PT has many classifications, including:²</p> <ul style="list-style-type: none">• clerical• method• equipment• technical |
| event (proficiency testing) | A single round of proficiency testing which may include more than one challenge (specimen or sample). ² |
| interlaboratory comparisons | The organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions. ¹ |

Laboratory Medicine Proficiency Testing Manual

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| measurand | <p>A quantity intended to be measured.⁵</p> <p>Note: The specification of a measurand requires knowledge of the kind of quantity, description of the substance carrying the quantity, including any relevant component, and the chemical entities involved.</p> <p>Example: Enzymatic activity of alkaline phosphatase in human serum at 37°C.</p> |
| nonconformity | <p>Nonfulfillment of a stated requirement, need of expectation.²</p> |
| precision (measurement) | <p>Closeness of agreement between indications or measured quantity values obtained by replicate measurements on the same or similar objects under specific conditions.²</p> <p>Note: Precision is typically expressed quantitatively in terms of imprecision—the standard deviation or the coefficient of variation of the results in a set of replicate measurements.</p> |
| proficiency sample | <p>A sample containing measurands of undisclosed concentration or composition that is sent to laboratories participating in interlaboratory comparison programs in order to independently verify the laboratories technical competence.²</p> |
| proficiency testing (PT) | <p>Evaluation of participant performance against pre-established criteria by means of interlaboratory comparison.¹</p> |
| proficiency testing provider | <p>Organization which takes responsibility for all tasks in the development and operation of a proficiency testing scheme.¹</p> |
| proficiency testing scheme | <p>Proficiency testing designed and operated in one or more rounds for a specified area of testing, measurement, calibration or inspection.¹</p> |
| random error (of measurement) | <p>Component of measurement error that in replicate measurements varies in an unpredictable manner.⁵</p> |
| root cause | <p>The most basic reason for a problem, which, if corrected, will reduce or eliminate recurrence of that problem.²</p> |
| standard deviation (SD) for proficiency assessment | <p>Measure of dispersion used in the evaluation of results of proficiency testing, based on the available information.¹</p> |
| systematic error (of measurement) | <p>Component of measurement error that in replicate measurements remains constant or varies in a predictable manner.²</p> |
| target value | <p>The assigned measurand content for a material to which a laboratory should compare its own measurement results.²</p> |