COLLEGE OF PHYSICIANS AND SURGEONS OF BRITISH COLUMBIA

Diagnostic Accreditation Program

MANUAL

Laboratory Medicine Proficiency Testing

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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

DAP Committee

The DAP 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 DAP reportable measurands, the PT reportable exception criteria and the PT exception escalation criteria.

DAP advisory committees

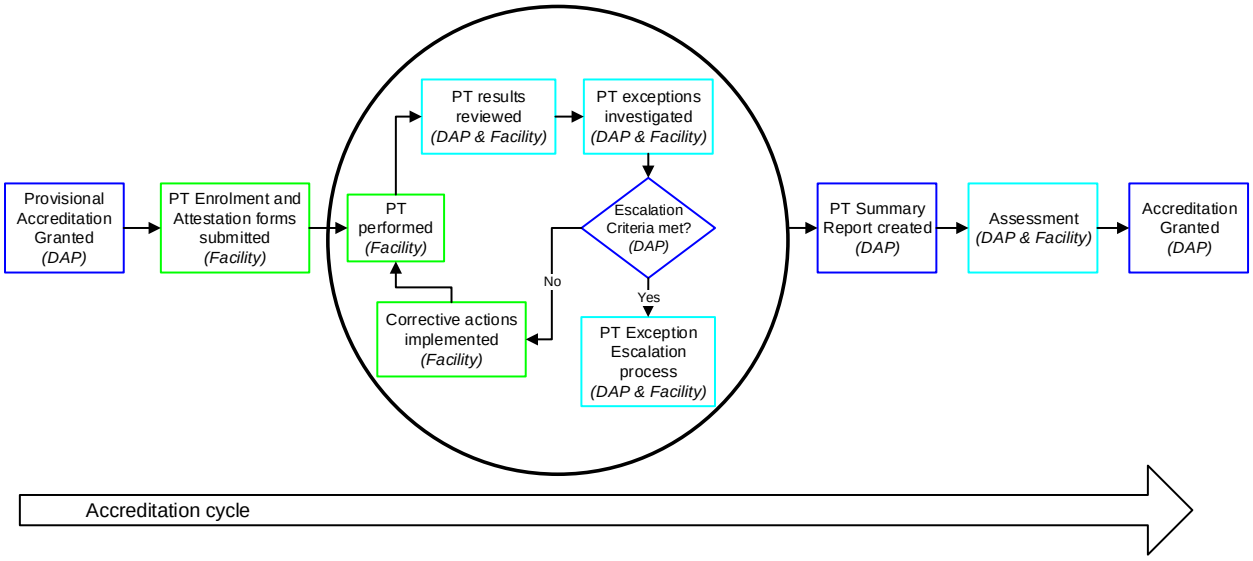
The DAP's accreditation standards are developed through a collaborative, consultative and consensus building process that involves health professionals and organizations, academics, experts, health authorities, and colleges. The process for standards development and review allows for considerable input 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 PT processes for each laboratory discipline.

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.

DAP reportable measurands

The DAP, in consultation with DAP advisory committees, maintains a list of DAP reportable 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 DAP reportable measurands within the laboratory's scope of accredited service are to be included in the annual PT enrolment and attestation forms.
- DAP reportable measurands are subject to the DAP reportable exceptions criteria as outlined in the PT monitoring section of this manual.
- Proficiency testing performance for DAP reportable measurands is monitored continually during the accreditation cycle through review of individual laboratory PT reports for all DAP reportable measurands. A summary of this monitoring is provided

to the DAP accreditation assessment officers and/or peer assessors for consideration during facility assessments.

Non-reportable measurands

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

PT frequency

DAP provisionally accredited facility

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

DAP accredited facility

DAP reportable measurands	All services	Minimum four samples per year Minimum two testing events per year
Non-reportable measurands		

Selecting a PT provider

The DAP maintains a list of available PT providers that offer programs covering the range of DAP reportable measurands. The list is published on the Laboratory Medicine page of the DAP section of the College website. Whenever possible, DAP-accredited medical laboratories should use PT providers accredited to ISO/IEC 17043 or approved by CLIA to meet the DAP requirements for participation in proficiency testing for the DAP reportable measurands.

Factors to consider when selecting a PT program

The selection of an appropriate proficiency testing program has significant impact on the effectiveness of monitoring performance and results quality. As such, there are many factors to consider when selecting a provider and PT program:

1. The measurand in the PT program is comparable to the measurand being monitored.
   Considerations: relevant peer group is available rather than an all method comparison; BNP is not the same as NTpro-BNP; plasma potassium is not the same as serum potassium.
2. The characteristics employed by the PT provider to determine suitability of the PT materials
   Considerations: homogeneity; stability; and where appropriate, metrological traceability
3. The frequency at which the PT program is operated
   Considerations: at minimum frequency should meet the DAP requirements
4. The suitability of the PT provider evaluation criteria (i.e. for judging acceptable performance)
   Considerations: criteria are sufficient to identify clinically relevant performance issues
5. The suitability of the organizational logistics for the PT program
   Considerations: transportation of samples (duration, storage, custom brokers, import permits); time from sample receipt to submission deadline; timeline for analyzing results and providing reports.
6. The availability of details about the program
   Considerations: procedures for establishment of assigned values, procedures for statistical treatment of data, criteria for defining peer groups
7. The PT providers policy on maintaining participant confidentiality
   Considerations: relevant processes in place for participants to waive confidentiality and grant permission for PT provider to grant the DAP access to laboratory PT reports
8. The costs
   Considerations: currency exchange rates; brokerage fees; labour and reagent costs

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 DAP reportable 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.

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 DAP reportable 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.

Scope of accreditation and PT enrolment and attestation process

This section provides information related to the scope of accreditation and PT enrolment and attestation process. As part of initial assessment, new facilities provide DAP the information specific to their scope of service and the related proficiency testing activities necessary to effectively monitor ongoing performance.

Annually thereafter, the DAP will request accredited facilities review the scope of service and PT information on record with the DAP. Acknowledgement of this review is recorded through completion of an attestation form.

Completing the enrolment and attestation forms

The DAP Scope of Accreditation and PT Enrolment form is an Excel workbook, which contains instructions for how to complete the form.

The DAP Scope of Accreditation and PT Attestation form is a fillable PDF form, with facility contact information and the attestation statement which indicates the information on record with the DAP is accurate and meets the mandates of the DAP for proficiency testing. 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.

Both of these forms are published on the Laboratory Medicine page of the DAP section of the College website.

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 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.

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 DAP reportable 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	• Failure to perform PT survey[1] • Failure to submit PT results on time, including discontinuation of the PT survey

[1]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.

API
CAP
WSLH
	• For programs with three to five samples per testing event:
	  ○ 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:
	  ○ Any single measurand with an unacceptable result in a single event
	• Transfusion medicine and microbiology: Any unacceptable result

Bio-Rad EQAS	• Any result greater than ± 3.0 z-score and exceeds the QSR BC DAP limits • 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 • Transfusion medicine: Any unacceptable result
cIQc, CMPT, CEQAL, Other	• Any unacceptable result
IQMH	• Any unacceptable result scored as A1, A2, A3

One World Accuracy	• For monthly programs
	  ○ 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
	• For programs with three to five samples per testing event:
	  ○ 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:
	  ○ Any single measurand with an unacceptable result in a single event
	• Transfusion medicine and microbiology: Any unacceptable result

Randox	• 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

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.

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.

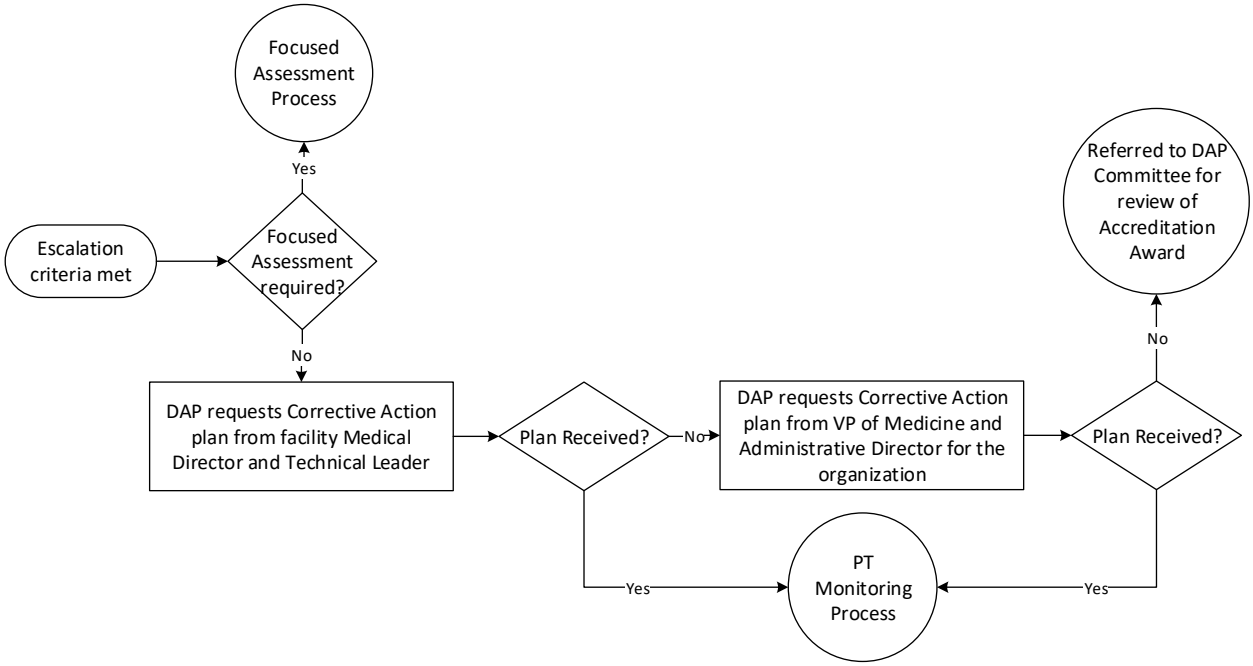
Sign-off

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.

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 DAP reportable 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

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 DAP reportable 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-reportable measurands during the facility assessment, as outlined in the DAP Laboratory Medicine Accreditation Standards.

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

Email: dap@cpsbc.ca

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

Email: ptqc@cpsbc.ca

References

1. International Organizations for Standardization. *Conformity assessment – General requirements for proficiency testing*. Reference Number ISO/IEC 17043:2010(E). Published in Switzerland, 2010.
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 17011:2017(E). Published in Switzerland, 2017.
4. International Laboratory Accreditation Cooperation (ILAC). *Policy for Participation in Proficiency Testing Activities.* Reference Number ILAC-P9:06/2014.
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)

Glossary

accuracy (of measurement)	Closeness of agreement between a measured quantity value and a true quantity value of a measurand.[2]
alternate assessment procedure	Procedure for determining the reliability of tests for which proficiency testing is not available.[2] Examples include: • 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	For quantitative tests – an assessment of the amount of substances or analyte present or measured in a sample.[2] For qualitative tests – the determination of the presence of the absence of a measurand, organism, or substance in a sample.[2]
corrective action	Action to eliminate the cause of a nonconformity and to prevent recurrence.[1]
coefficient of variation (CV)	Standard deviation divided by the mean.[2] **Note:** CV is often multiplied by 100 and expressed as a percentage.

error	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] • 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]
measurand	A quantity intended to be measured.[5] **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. **Example:** Enzymatic activity of alkaline phosphatase in human serum at 37°C.
nonconformity	Nonfulfillment of a stated requirement, need of expectation.[2]
precision (measurement)	Closeness of agreement between indications or measured quantity values obtained by replicate measurements on the same or similar objects under specific conditions.[2] **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.
proficiency sample	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]
proficiency testing (PT)	Evaluation of participant performance against pre-established criteria by means of interlaboratory comparison.[1]
proficiency testing provider	Organization which takes responsibility for all tasks in the development and operation of a proficiency testing scheme.[1]

proficiency testing scheme	Proficiency testing designed and operated in one or more rounds for a specified area of testing, measurement, calibration or inspection.[1]
random error (of measurement)	Component of measurement error that in replicate measurements varies in an unpredictable manner.[5]
root cause	The most basic reason for a problem, which, if corrected, will reduce or eliminate recurrence of that problem.[2]
standard deviation (SD) for proficiency assessment	Measure of dispersion used in the evaluation of results of proficiency testing, based on the available information.[1]
systematic error (of measurement)	Component of measurement error that in replicate measurements remains constant or varies in a predictable manner.[2]
target value	The assigned measurand content for a material to which a laboratory should compare its own measurement results.[2]