

PT Scheme

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Version 1.0

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1.0 Introduction

Proficiency Testing Canada Inc. (PTC) is a not-for-profit organization and operates the Proficiency Testing (PT) Program on a cost-recovery basis. The PTC PT Program is accredited by A2LA for most of its PT samples and conforms to ISO/IEC 17043:2010 Conformity Assessment-General requirements for proficiency testing. The scope of accreditation can be found at <https://portal.a2la.org/scopepdf/2298-01.pdf>

This document provides a general overview of the PTC PT scheme. Detailed procedures for the undertaking of a PT round are found in PROC09 – PT Procedures.

Other PTC documents related to the PTC PT Program include:

- PROC09 – *PT Procedures**;
- PAR05 – *Subcontractors*;
- PROC11 – *PT Regression Equations**;
- PAR02 – *Catalogue**;
- PROC07 – *PTC Subcontractors.**

*These documents can all be found in the PTC on-line library.

2.0 PT Scheme

2.1 OBJECTIVES OF THE PT SCHEME

The objective of the PTC PT program is to provide cost-effective, internationally recognized, proficiency testing services to interested parties. The purpose of the scheme is to provide laboratories with an educational tool that allows them to assess their performance relative to that of their peers, using industry standard and regulatory data quality objectives as acceptance criteria.

2.2 PT PLAN

The following table provides the general scheme information that is followed for all PTC PT offerings:

<i>Requirement from clause 4.4.1.3 of ISO/IEC 17043</i>	<i>PTC's Fulfilment of requirement</i>
<i>a) Provider</i>	Proficiency Testing Canada Inc. Suite 102, 2934 Baseline Road, Ottawa , ON K2H 1B2 (613)233-5464.
<i>b) Coordinator</i>	The PTC Executive Director is responsible for all aspects of the Proficiency Testing Schemes.
<i>c) Subcontracted Activities</i>	PTC uses Subcontractors for the production, characterization and shipping of PT samples. PTC only contracts with organizations competent for the production, characterizing and shipping of PT samples. Competence is determined as either accreditation to ISO/IEC 17043 or through periodic audits. The current list of Subcontractors is found in PAR05 – <i>PT Subcontractors</i> .

<i>Requirement from clause 4.4.1.3 of ISO/IEC 17043</i>	<i>PTC's Fulfilment of requirement</i>
<i>d) Participation</i>	Participation in the PTC PT Program is open to all testing laboratories, regardless of location. Where limitations are placed on methodology, these limitations are indicated in PAR02 - <i>Catalogue</i> .
<i>e) Participation Level</i>	The typical participation levels range between 20 and 250 participants per analyte. Participation levels lower than this will be accepted if there is an acceptable history. Participation levels lower than 11 will only be evaluated if there are no concerns identified during examination of the data.
<i>f) Selection of analyte</i>	Only analytes that are commonly performed by environmental testing laboratories are included in the PT Program. They must be sufficiently homogeneous and stable, and un-correctable matrix interference should not contribute significantly to overall uncertainty of the round.
<i>g) Concentration ranges</i>	Concentration ranges are based on typical analytical capabilities, concentrations typically found in customer samples, and specific regulatory limits. In this way, the PT samples are fit-for-purpose. Refer to PAR02 - <i>Catalogue</i> .
<i>h) Potential major sources of errors</i>	The potential major sources of error in the PTC PT Program include: sample homogeneity; sample stability; sample packaging; sample handling and shipping; differences between methods used by participants; and inter-participant variation.
<i>i) Sample production, characterization and distribution.</i>	All PT samples are produced, characterized and distributed under contract to PTC. Details on these requirements are detailed individual contracts (revised as necessary). Subcontractors are required to document their PTC specific sample production, characterization, storage and shipping procedures, and to conform to all relevant requirements in ISO/IEC 17043 and ISO/IEC 17025.
<i>j) Procedures for preventing collusion and falsification</i>	All participants must agree to PAR01 - <i>Terms and Conditions of Proficiency Testing</i> (also included in the application) before they can receive samples. In addition to PTC specific requirements, the Terms and Conditions require participants to comply with POL07 - <i>Publicity Policy</i> . As well, participants are not permitted to report PT results on the PTC Web-Data-Entry system without indicating that they have read and accept the PTC Terms and Conditions.
<i>k) Information provided to participants</i>	Details of the information provided to participants are summarized in section 2.7 Below and in PROC09 - <i>PT Procedures</i> . This is in addition to the specific PT instructions that are posted on-line for every PT Test Group.
<i>l) Dates for shipments and reporting deadlines</i>	Deadlines for changes to PT registration, dates for sample shipment and deadlines for result reporting are posted on the PTC web-site. As well, the deadline for reporting is included with each sample shipment. If there are any changes to the published schedule, all affected participants are notified by email.
<i>m) Instructions to participants on methods to use</i>	Each PT Test Group has a specific instruction sheet associated with it. Each instruction sheet provides instructions on special handling requirements and, where necessary, limitations on methods that can be used. Analytical limitations are also provided in PAR02 - <i>Catalogue</i> . The instruction sheets also contain information on how to report problems with shipping.
<i>n) PT sample homogeneity and stability</i>	The uncertainty associated with PT sample homogeneity and stability shall not contribute significantly to the overall uncertainty of the PT round. This is assessed through an examination of participant reported data. Refer to PROC09 - <i>PT Procedures</i> .

<i>Requirement from clause 4.4.1.3 of ISO/IEC 17043</i>	<i>PTC's Fulfilment of requirement</i>
<i>o) Participant reporting</i>	<p>Participants report their PT results to PTC using the PTC Web-Data-Entry System. Instructions for use of the Web-Data-Entry System are available on the PTC website. Access to this system is restricted to participants through the use of user names and confidential passwords.</p> <p>The Web-Data-Entry System is available to all participants from the date of sample shipping to midnight of the reporting deadline. Participants may verify entered results and make corrections until the reporting deadline. No changes can be made after the reporting deadline.</p> <p>With every web-entry page, there is the opportunity for participants to enter comments. These comments are reviewed and, where necessary, acted on before final PT reports are issued. As well, participants may add analytes for reporting for any test group that they receive.</p> <p>PTC controls the number of significant figures that can be reported by participants. Generally, the number of significant figures allowed is 3.</p>
<i>p) Statistical analysis</i>	<p>The PTC PT Program is essentially a consensus-based program. The assigned value is the Robust Mean of participant results after obvious errors have been removed. The standard deviation of proficiency is established from either historic studies (regression equations), fixed limits based on common data quality objectives, or specific to the Robust Standard Deviation of the actual round. Laboratory performance is determined by use of a z-score. Refer to section 2.6 below and PROC09 – <i>PT Procedures</i> (Appendix I) for details.</p>
<i>q) Metrological traceability and uncertainty of the assigned value</i>	<p>The PTC PT scheme is an evaluation of participant performance as it compares to other participants. As such, metrological traceability, other than through metrological traceability of participant laboratories, is not applicable.</p> <p>Standard uncertainty of the assigned value is detailed in PROC09 – <i>PT Procedures</i>.</p>
<i>r) Evaluation of participant performance</i>	<p>Laboratory performance is determined by use of a z-score. Refer to section 2.6 below and PROC09 – <i>PT Procedures</i> for details.</p>
<i>s) Preliminary reports, confidential reports and generic reports</i>	<p>Reports provided to participants are detailed in section 2.7 below.</p>
<i>t) Confidentiality</i>	<p>Unless otherwise agreed or requested by the participant, all communication between PTC and the participant, and all participant specific PT reports, are maintained in confidence. An exception to this are any data required by regulation.</p>
<i>u) Lost or damaged samples</i>	<p>When notified by participants of lost or damaged samples, replacement samples will be provided as per PAR01 – <i>Terms and Conditions of PT Participation</i>. Further instructions are provided with each instruction sheet.</p>

Stakeholder Committee

The PTC Stakeholder Committee is an ad-hoc panel of experts and stakeholders that provide technical advice to PTC. This committee is comprised of representatives from participant laboratories, technical experts and regulators. Input to this committee is also obtained through surveys, workshops, feedback from presentations, outcome of complaint and non-conformance investigations, etc. The committee meets as needed and is used to provide recommendations to PTC. These recommendations are reviewed and approved by the Executive Director.

2.3 ADDITION OF NEW ANALYTES AND TEST GROUPS

Recommendations for new PT can come from any party, including the Stakeholder Committee, as the result of a survey of PTC participants, or recommendations from other stakeholders.

Approval of new PT is the responsibility of the Executive Director. The Executive Director ensures that the selected Collaborator laboratory is advised of the requirements and that a discussion on capability, resources and the decisions made takes place. Information generally required before PTC authorizes delivery of new PT samples or existing PT samples from a new Subcontractor is included in PROC07 - *PTC Subcontractors*.

Unless otherwise specified, new PT follows the same general scheme as used for existing PT.

At least the first two studies for newly added PT are designated as Pilot studies. The participant receives a copy of their own data from PTC at the conclusion of the round along with the normal summary data, including z-scores. However, final PT scores and composite evaluations are not assigned.

2.4 ROUND FREQUENCY AND COMPOSITION

In general, each Test Group is shipped twice per year. They are split into two groups, one group that is shipped in January and June, and a second group that is shipped in March and October. The water microbiology samples are shipped in March and October to avoid the hottest and coldest times of the year.

Important dates for each round (i.e., shipping date, reporting deadline and deadline for changes to PT registration) are posted on the PTC web site.

Most Test Groups consist of four separate samples, of different analyte concentration. Approximate analyte concentration ranges are detailed in PAR02 - *Catalogue* and are referenced in the PT Instruction Sheets. These are approximate concentrations intended to provide guidance to laboratories about the appropriateness of the PTC PT samples; actual sample concentrations may be marginally outside these ranges.

Each test group contains one or more analyte.

2.5 SAMPLE CHARACTERISTICS

PT samples used in the PTC program are generally whole samples, not ampoules, concentrates or extracts. Whenever possible, the samples are designed to mimic typical matrices experienced by participant laboratories. The concentration range for each analyte is established based on typical analytical capabilities, typical sample concentrations, regulatory limits (where available) and the ability to produce homogeneous and stable samples.

When a new formulation of an existing PT is considered (e.g., different preservative, simulated wastewater, etc.), the new formulation may be tested on one of the four samples during a normally scheduled round. When this occurs, participants are notified in advance and the final performance evaluation is limited to the three samples using the existing formulation.

The quantity of sample provided is sufficient for analysis and generally consistent with typical sample volumes collected by laboratories.

Each individual PT sample in a production lot is individually numbered in the order it is packaged, and tracked to a participating laboratory to facilitate assessment of homogeneity.

Each production lot of samples is assessed for homogeneity and stability using participant data as per procedures detailed in PROC09 – *PT Procedures*.

2.5.1 Challenge Samples

On occasion, PTC may introduce a Challenge sample into the scheme. A Challenge sample is presented as one of the samples in a test group. However, it may be presented in a matrix that is known to be more challenging or contain a known interference. When a Challenge sample is used, the participants are not made aware of it until after the round is closed. The Challenge sample is not used to determine the performance of the participant but a separate summary report, or a summary on the cover page of the confidential report, is produced and provided to all participants for educational purposes.

2.6 SCORING SYSTEM

Participant performance is evaluated for each analyte in the PT round by a quantitative method that is conformant with ISO/IEC 17043, ISO 13528 and the International Harmonized Protocol for Proficiency Testing of (Chemical) Analytical Laboratories.

Unless otherwise specified, the PTC PT program uses three significant digits when accepting and reporting analytical data. Computer routines and other calculated values such as reference value reports and summary statistics use more than three significant digits to avoid rounding error.

Numbers ending in a five (5) are always rounded up in the PTC Database.

The PTC scoring system is a comparison against peers. The Assigned values are based the Robust Mean of participant results. The standard deviation for proficiency assessment is based on historic data (regression equations or TNI limits), or the robust standard deviation of the current round, whichever is higher. This approach is used because it has been demonstrated to work well for the standard environmental tests. It is also robust enough to accommodate for minor problems with formulation, homogeneity and stability. This

scheme was developed, and continues to be modified, through the input of participants, accreditation bodies and regulators. The scoring system is based on the following general assumptions:

- The distribution of reported data approximates a normal distribution with no significant and recurring skewing or bi-modality;
- For any analyte, average results are similar, regardless of method used. When this is observed not to be the case, biased methods are excluded from participation;

Although performance evaluations are not made on a method specific basis, a report is produced for each analyte in each round that provides a statistical summary by method. PROC09 – *PT Procedures* describes how this report is reviewed by PTC and the actions that may be taken as a result of this review.

The general procedure for evaluating participant performance for most test groups is as follows:

- I. non-detect values are temporarily removed from the set of reported data. This is done because it has been observed that including the non-detect levels in the determination of the assigned value would result in a positive bias;
- II. obvious reporting errors (e.g., wrong units) are removed temporarily;
- III. Robust consensus mean, \bar{X} , and robust standard deviation, *stdev*, are calculated from the remaining data;
- IV. regression equation standard deviation, *s!*, is estimated from the regression between consensus mean and consensus standard deviation of historic studies (PROC11 – PT Regression Equations);
- V. z-scores are calculated for each reported result as follows:

if *stdev* > *s!* then,
$$z \text{ score} = \frac{(x_i - \bar{X})}{stdev}$$

or (if RDL is reported)
$$z \text{ score} = \frac{(x_i - \bar{X})}{\sqrt{stdev^2 + (RDL/3)^2}}$$

if *stdev* < *s!* then,
$$z \text{ score} = \frac{(x_i - \bar{X})}{s!}$$

or (if RDL is reported)
$$z \text{ score} = \frac{(x_i - \bar{X})}{\sqrt{s!^2 + (RDL/3)^2}}$$

where x_i = the reported result,
 \bar{X} = consensus robust mean,
 $stdev$ = inter-laboratory robust standard deviation,
 $s!$ = regression equation standard deviation,
RDL = the participant detection level

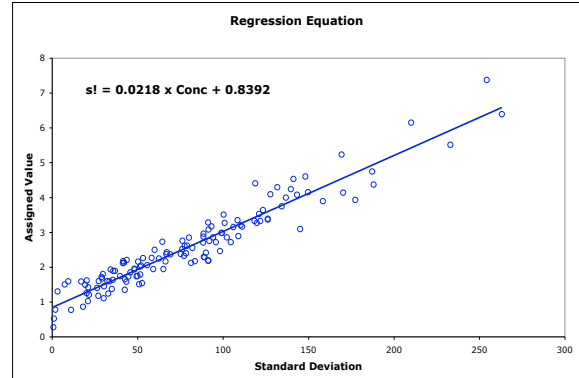
- I. the average absolute z-score is calculated from the four samples for each analyte,
- II. an average absolute z-score of 2.0 or lower is considered an acceptable score.

The regression equations are in the following format,

$$s! = m \times Conc + b$$

where m = the slope of conc vs inter-lab stdev of historic studies,
 $Conc$ = the consensus robust mean from participant results,
 b = the intercept of conc vs inter-lab stdev of historic studies. Where the limits are based on + %, $b = 0$.
 $s!$ = regression equation standard deviation.

The procedures for establishing the regression equations as well as current regression equation values are found in PROC11 - *PT Regression Equations*. The plot to the right displays a typical regression equation plot.



Alternately, the standard deviation may be based on fit-for-purpose fixed limits (+ ##%) based on input from technical experts, regulators and common data quality objectives. When these are used, the fixed limit is used unless the robust standard deviation is higher, in which case the robust standard deviation is used.

2.7 PROFICIENCY TESTING REPORTS

Several reports are provided to the participant during the course of a PT round.

2.7.1 Preliminary Report

An electronic report that contains all of the evaluation data that are found in the final report is emailed to participants within one week of the close of the round and is intended to provide participants with an

indication of their performance so that investigations may commence without unnecessary delay. These reports use the evaluation protocol detailed above but are produced before the detailed data examination is performed. These reports are not an official evaluation and final scores may change throughout the course of data examination by PTC.

2.7.2 Final Proficiency Testing Report

Within 3 weeks of the deadline for submission of results, PTC issues a Final Proficiency Testing Report that contains both the confidential results of the individual participant's performance (pdf), an excel file containing the same information, and Test Group Summary Report described below.

2.7.3 Test Group Summary Report

A Test Group Summary Report is produced for each quantitative Test Group. Each report contains:

- Summary of evaluation procedure;
- Comparison between PTC assigned value, robust mean and median;
- Kernel density plots;
- z-score plots; and,
- Statistical summary of the most commonly used methods.

2.8 NOTIFICATION OF PT RECOGNITION

PTC grants proficiency testing recognition for analytes following a successful PT round. After each PT round, participants are notified in writing of any new tests for which PTC PT recognition has been granted and for any status changes resulting from PT performance.

A password-protected directory is available on the web site that contains all PT registration and current status for each participant.

3.0 Definitions

Analyte: The component of the sample that is quantified and reported. Often referred to as a parameter (e.g., Phosphorus).

Assigned Standard Deviation s: The measure of dispersion used to determine the allowable deviation for reported results. This value is determined according to the PT scheme.

Assigned Value \bar{X} : The value attributed to a particular property of a proficiency test item. Participants will often refer to this as the target value or the expected value.

Bias: A systematic, non-random, deviation from the true value.

Subcontractor: organization or individual contracted by the proficiency testing provider to perform activities specified in ISO/IEC 17043 and that affects the quality of a proficiency testing scheme. Analogous to a subcontractor in ISO/IEC 17025.

Coordinator: one or more individuals with responsibility for organizing and managing all of the activities involved in the operation of a proficiency testing scheme.

Design Value: This is the sample concentration that the collaborator laboratory is aiming for in production of the PT sample. Due to the large volumes involved, losses during production, and the use of natural materials, these values are not used as the assigned value.

Participant: A laboratory, organization or individual, that receives proficiency test items and submits results for review by the proficiency testing provider.

PT Provider: The organization that takes responsibility for all tasks in the development and operation of a proficiency testing scheme.

PT Scheme: Proficiency testing designed and operated in one or more rounds for a specified area of testing, measurement, calibration or inspection.

PT Sample: A sample, product, artifact, reference material, piece of equipment, measurement standard, data set or other information used for proficiency testing.

PT Round: A single complete sequence of distribution of proficiency test items, and the evaluation and reporting of results to the participants.

Test Group: A specific PT offering with a unique matrix and analyte composition (e.g., C01A Major Ions).

z-score: The normalized score upon which the final PT score is determined.

4.0 References

- ISO/IEC 17043: 2010 – *Conformity assessment – General requirements for proficiency testing*;
- ISO/IEC 17025: 2017 – *General requirements for the competence of testing and calibration laboratories*;
- IUPAC/ISO/AOAC –2006. *The international harmonized protocol for the proficiency testing of analytical Chemistry laboratories*; and,
- ISO 13528: 2015 – *Statistical methods for use in proficiency testing by interlaboratory comparisons*.

5.0 History of Changes

Date	Rev. No.	Sections	Changes
12/18/2019	1.0		Initial publication