PT Scheme

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Version 1.9

PTC | Proficiency Testing Canada

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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 17043:2023 Conformity assessment- General requirements for the competence of proficiency testing providers. 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 Evaluation Procedures.

Other PTC documents related to the PTC PT Program include:

- PROC09 – *PT Evaluation Procedures**
- PAR05 – List of PT *Subcontractors**
- PROC11 – *PT Regression Equations**
- PAR02 – *Catalogue**
- PROC07 – *PTC Subcontrators*.

*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:

Requirement from clause 7.2.1.3 of ISO/IEC 17043	*PTC's Fulfilment of requirement*
a) Personnel involved in design and operation	Proficiency Testing Canada Inc. Suite 102, 2934 Baseline Road, Ottawa , ON K2H 1B2 (613)233-5464. The Executive Director and Program Officer, in consultation with external experts, are responsible for the design and operation of the PT schemes
b) Subcontracted Activities	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 through accreditation to ISO/IEC 17043 and/or through periodic audits. The current list of Subcontractors is found in PAR05 – List of PT Subcontractors.

Requirement from clause 7.2.1.3 of ISO/IEC 17043	*PTC's Fulfilment of requirement*
c) Participation	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 - Catalogue.
d) Participation Level	The typical participation levels range between 20 and 250 participants. 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.
e) Description of activities performed and results to be reported by participants	Only analytes that are commonly performed by 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. Participants must report a single result per analyte, in the units specified.
f) Concentration ranges	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 - Catalogue.
g) Potential major sources of errors	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.
h) Sample production, characterization and distribution.	All PT samples are produced, characterized and distributed under contract to PTC. Details on these requirements are detailed in 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) Procedures for preventing collusion and falsification	All participants must agree to PAR01 - *Terms and Conditions of PT Participation* before they can register for PT and again before they can report results and receive samples. In addition to PTC specific requirements, the Terms and Conditions require participants to comply with POL07 – Publicity Policy.
j) Information provided to participants	Details of the information provided to participants are summarized in section 2.7 below and in PROC09 - PT Evaluation Procedures. This is in addition to the specific PT instructions that are posted on-line for every PT Test Group.
k) Dates for shipments and reporting deadlines	Deadlines for changes to PT registration, dates for sample shipment and deadlines for result reporting are posted on the PTC website. As well, the deadline for reporting is included with each sample shipment and displayed in the customer Portal. If there are any changes to the published schedule, all affected participants are notified by email.
l) Instructions to participants on methods to use	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 – *Catalogue*. The instruction sheets also contain information on how to report problems with shipping.
m) PT sample homogeneity and stability	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 – *PT Evaluation Procedures* .

Requirement from clause 7.2.1.3 of ISO/IEC 17043	*PTC's Fulfilment of requirement*
n) Participant reporting	Participants report their PT results to PTC using the PTC portal. Access to this system is restricted through the use of user names and passwords.
o) Statistical analysis	The PTC PT Schemes are consensus-based. The assigned value is the Robust Mean of participant results after obvious outliers have been removed. The standard deviation for proficiency testing assessment 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 – *PT Evaluation Procedures* (Appendix I) for details.
p) Metrological traceability and uncertainty of the assigned value	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.
q) Treatment of results from different test methods	Unless otherwise specified, participants may report results from whatever test method they use. Assigned values are based on consensus, regardless of method used. However, the Test Group Summary reports provide a visualization of performance by method.
r) Evaluation of participant performance	Laboratory performance is determined by use of a *z*-score. Refer to section 2.6 below and PROC09 - *PT Evaluation Procedures* for details.
s) Preliminary reports, confidential reports and generic reports	Reports provided to participants are detailed in section 2.7 below.
t) Confidentiality	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.
u) Lost or damaged samples	When notified by participants of lost or damaged samples, replacement samples will be provided as per PAR01 – *Terms and Conditions of PT Participation*. Further instructions are provided with each instruction sheet.

2.3 ADDITION OF NEW ANALYTES AND TEST GROUPS

Recommendations for new PT can come from any party, 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 Subcontractor organization 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*.

Prior to initiation of a new PT Scheme, the plan and design of the scheme is documented.

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

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 website.

Most Test Groups consist of four separate samples, of different analyte concentration. Approximate analyte concentration ranges are detailed in PAR02 –*Catalogue*. 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 Evaluation 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 evaluate 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 scheme use 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 on 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 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 future participation;

Although performance evaluations are not made on a method specific basis, a Summary Report is produced for each Test Group in each round that provides *z*-score plots that are colour-coded by method. PROC09 – *PT Evaluation 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 analytes is as follows:

I. qualified values are temporarily removed from the set of reported data. This is done because it has been observed that including the qualified values in the determination of the assigned value would result in a positive or negative bias;
II. obvious reporting errors (e.g., wrong units) are removed temporarily;
III. Robust consensus mean, $\overline{X}$, 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,

$$z\ score = \frac{(x_i - \overline{X})}{stdev}$$

or (if RDL is reported)

$$z\ score = \frac{(x_i - \overline{X})}{\sqrt{stdev^2 + (RDL/3)^2}}$$

if stdev < s! then,

$$z\ score = \frac{(x_i - \overline{X})}{s!}$$

or (if RDL is reported)

$$z\ score = \frac{(x_i - \overline{X})}{\sqrt{s!^2 + (RDL/3)^2}}$$

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

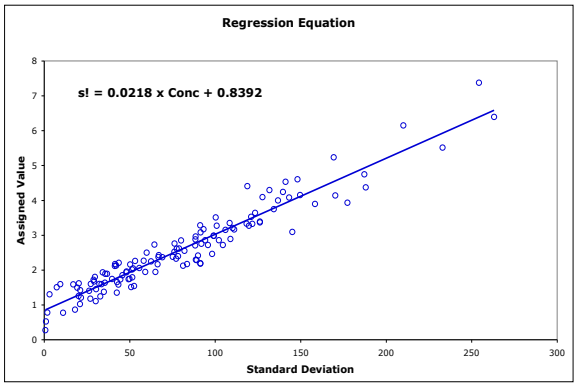
I. the average absolute *z*-score is calculated from the four samples for each analyte,
II. an average absolute *z*-score of 2.0 or lower is considered an acceptable score.

The regression equations are in the following format,

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

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. These reports are not an official evaluation and final evaluations may change throughout the course of data examination by PTC.

2.7.2 Final Proficiency Testing Report

Within two weeks after the Preliminary reports are issued, 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 Reports described below. Within 30 days after the Final report is issued, the lab may reach out to PTC if there are any issues or omissions and PTC will review the request and a Revised Report could be issued.

The final report is composed of:

- **Cover Page**: consisting of information about the participant, the PT rounds and any deviations from the published PT scheme.
- **Proficiency Testing Evaluation Overview**: A tables countaining the evaluation summary for each reported Test Groups. This includes the PT code, Analyte, Method, Laboratory Information, Bias, PT Score and Evaluation Summary. These tables consist of one row for each Test Group/Analyte/Method that the participant was registered for in that round.
- **Detailed PT Summary**: These tables contain detailed information including the PT Code, Analyte, Method, Units, Sample Number, Number of Participants, Assigned Value, Standard Deviation for Proficiency Testing Assemsnt, Reported Value and z-Score.

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;
- Summary statistics;
- Sorted scatter plots;
- *z*-score plots;
- Kernel density plots;
- Homogeneity and stability regression plots;
- Box-and-whisker plots; and,
- A plot of robust mean against robust standard deviation for the samples over the last ten PT rounds, with the data from the current round highlighted.

3.0 Participant Notifications

Whenever there is a change to a PT Scheme, with the exception of PT fees, affected registered PT participants will be notified by email idealy three months before implementation of the change. Significant negative feedback to the change may result in a decision to delay or modify the extent of the change.

Changes that could result in a notification could include, but is not limited to:

- Changes to the evaluation criteria;
- Changes in formulation of the PT samples;
- Changes to the published PT schedule*;
- Changes to the organization that prepares and ships PT samples - if samples are changing or if new subcontractor to PTC;
- Changes to the Terms and Conditions of participation;

* This change does not require a three month notification.

4.0 Definitions

The following provides definitions for the column headers displayed in the final PT report:

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

Assigned Value: 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 assigned value.

Evaluation: The overall evaluation, displayed as *Acceptable* of *Unacceptable*.

Laboratory Information: Option participant defined information that the participant would like to see on the report. This is often information such as SOP number or preparation procedure.

Method: The analytical method (instrument) used for analysis.

N: The number of results reported by all participants. For quantitative tests, this value is the number of results used for the summary statistics.

PT Code: A unique code assigned to each unique Test Group/Analyte/Method registration.This code remains unchanged until the participant changes the method used.

PT Score: A composite score for a test group/analyte method. This score is from zero to one hundred, seventy being the pass mark.

Reported Value: The value reported by the participant.

Sample: The identification of the PT item that the participant analyses (e.g., C01A-1, C01A-2, etc.).

SDPTA: An acronym for *Standard Deviation for Proficiency Assessment Testing Assessment*. The measure of dispersion used to determine the allowable deviation for reported results. This value is determined according to the PT scheme.

Units: The units that participants must use to report results (e.g., mg/L).

z-Score: The number of standard deviations the reported result is away from the assigned value. These values are used to determine the PT score.

5.0 References

- ISO/IEC 17043: 2023 – Conformity assessment- General requirements for the competence of proficiency testing providers;
- ISO/IEC 17025: 2017 – *General requirements for the competence of testing and calibration laboratories*;
- IUPAC/ISO/AOAC - *The international harmonized protocol for the proficiency testing of analytical Chemistry laboratories;* and,
- ISO 13528: 2022 – *Statistical methods for use in proficiency testing by interlaboratory comparisons*.

6.0 History of Changes

Date	Rev. No.	Sections	Changes
05/23/2023	1.4		Updated 17043 title throughout document to match the new 17043 Standard released May 2023.
06/05/2024	1.5		Replaced Web-data entry with PTC portal.
06/18/2024	1.6	General 2.2 2.7.2	Updated references to the new version of 17043. Updated table with reference to new 17043 revision. Added details on the new report format.
06/24/2024	1.7	3.0	Added section 3.0 on notification to participants
12/09/2024	1.8	2.72	Added information on timing for Final Reports review and request for revised reports.
11/10/2025	1.9	3.0	Updated section 3.0 on notification to participants