APTILAB SERVICES

PROFICIENCY TESTING SCHEMES CURRENT PROTOCOL

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Record of issue status and modifications

Version	Date Issued	DETAILS	Authorised by
1	2023-01-01	Creation of a General protocol document that provides an overview of Aptilab's proficiency testing policies and guidelines consistent with the ISO/IEC 17043 requirements.	E. Tan
2	2023-01-15	Modification in the organization team. Change in the participation frequency. Update of the number of permitted results and update of the assigned values methods list.	E. Tan
3	2023-03-08	2.2: Information adjustment for the number of participants 2.5: Note on authorities' request 4.1: Update on the timeline of reporting. 4.5: Update on assigned values evaluation 4.5: Update on ProLAB Plus software and QA	E.Tan
4	2023-11-20	3.5 : Added a list of potential sources of error. 4.3 : Added information relative to antibiotics residues. 5.2 : Added information regarding interpretation of data when the minimum number of participants is not reached. 5.5 : Removed QMQ-023 and QMQ-024. Updated reference methods information. 5.8 : Added information regarding the interpretation of results without a Z score.	PL. Filiatrault

Notes:

Where this document has been translated, the English version shall remain the definitive version.

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1 INTRODUCTION

1.1 Organizers

This Proficiency Test (PT) is organized by the Lactanet- Valacta reference laboratory team led by:

- Josée Bordeleau : National Laboratory Director
- Jean-Philippe Angers: Reference Laboratory Manager in charge of the Aptilab program and Aptilab Hub website.
- Christa Deacon: Team leader in charge of client orders, kit production, shipping, and billing

In collaboration with the quality assurance team:

- Elyna Tan: Quality Assurance and Continuous Improvement Director
- Pierre-Luc Filiatrault: Quality Leader in charge of the Prolab Software, data entry, results analysis and release of reports and certificate of analysis.

1.2 Proficiency Testing: Scope and Purpose

Proficiency Testing (PT) is defined as the evaluation of participant's performance against pre-established criteria by means of interlaboratory comparisons. The aim of proficiency testing is to provide the participating laboratories with information about their performance (e.g., the accuracy, repeatability or detection limits of a given analysis) as described in ISO/IEC 17025 (2017) "*General requirements for the competence of testing and calibration laboratories*"[1]. Moreover, proficiency tests are essential for demonstrating a laboratory's performance to third parties (e.g., to customers, to accreditation bodies or to other supervisory bodies).

Aptilab proficiency testing schemes are comprised of various sets of test samples, designed to promote the improvement of measurement quality in the chemical and microbiological analyses of milk and dairy products. Participation offers laboratories the means to assess the accuracy of their results, evaluate comparability to peer laboratories over time and provides information on technical issues and methodologies.

1.3 Quality Standards

The International standards that are relevant to proficiency testing include ISO/IEC 17025 (2017) "*General requirements for the competence of testing and calibration laboratories*"[1], ISO/IEC 17043 (2010) "*Conformity assessment – General requirements for proficiency testing*"[2] and ISO 13528 (2015) "*Statistical methods for use in proficiency testing for interlaboratory comparisons*"[3].

Aptilab proficiency testing management system policies as related to quality are defined in a quality manual. Lactanet is committed to the continuous improvement of quality. Further information regarding our certification and accreditation for international quality standards is available on the Aptilab website www.aptilab.ca and the Standards Council of Canada (SCC) website www.scc.ca.

2 SCHEME ORGANIZATION

2.1 Scheme Coordination and Responsibilities

The general operation of each scheme is managed by the Aptilab team and is Lactanet's responsibility. This team is responsible for customer service as well as technical and reporting

functions. External advisors are consulted for some schemes to provide the full range of relevant knowledge and expertise needed to operate effectively.

The typical scheme framework is as follows:

1. Participants contact Aptilab's team to place an order.
2. Procurement, preparation, dispensing and quality control testing of test materials.
3. Dispatch of test materials to participants.
4. Participants analyse the test materials and report their results via the Aptilab Hub website, as instructed within the specified deadline.
5. Closing the data entry.
6. Reference values are determined using various reference methods specific to the selected analytes.
7. A statistical analysis of the results is carried out using validated software and the laboratory performance is assessed.
8. Reports are compiled and distributed to participants via the Aptilab Hub website.
9. Rounds are reviewed, and requirements for subsequent rounds are identified.
10. Planning for the next round is initiated.

Reports are issued as soon as possible following the closure of the round. The timeline between the closing date and the issuing of the final report will vary from scheme to scheme. A flowchart showing the typical course of a PT round is provided in Annex I.

2.2 Subscribing to a PT Scheme

A registration form is available for all schemes, with information on the terms and conditions, distribution dates, format, and availability of test materials.

To subscribe to a scheme, participants must complete the registration form, indicating which test materials they would like to receive. We aim to have a minimum of 6 participants. If the minimum of 6 participant could not achieve, the assigned values will be used for comparison based on the fact than the statistic methodology of *z score* is not applicable. Subscribers can participate in more than one proficiency test. Each sample set will be treated as a separate participation. Participants will be informed in the event that the availability of test materials changes during the scheme year.

2.3 Participation Frequency

Third parties, such as regulatory bodies and accreditation bodies, may recommend minimum levels of participation. To be conform to the ISO 17025 accreditation, participation in all rounds is mandatory and non-modifiable.

2.4 Participation Costs

Participation costs are reviewed annually by Aptilab. The current prices for each scheme are provided on the registration form or corresponding pricelist. Payment terms are detailed on the registration form. Non-payment or late payment may result in test materials and/or reports being withheld.

2.5 Confidentiality

To ensure confidentiality, participants in all schemes are assigned a unique laboratory reference number. This number facilitates the reporting of results without divulging the identities of participating laboratories. In a case where anonymity is suspected to have been breached, the participating laboratory can request that the laboratory reference number be

modified. The treatment of this request is subject to the discretion of Aptilab. For some tests, participants may agree to have their identity made known to others, but this will only be carried out with the full knowledge and permission of the participant.
In exceptional circumstances, when a regulatory authority requires proficiency testing results to be directly provided to the authority by the proficiency testing provider, the affected participants shall be notified of this action in writing. Otherwise, the proficiency testing results can be provided to the relevant party or authority by the participants themselves.

2.6 Testing Trials and New Products

Aptilab strives to continually improve their current schemes and to introduce new schemes/test materials/test parameters where appropriate. Before formally being offered in a scheme, new products may initially be introduced on a trial basis. If this is the case, it will be indicated to the trial participants.

3 TEST MATERIALS

3.1 Preparation of Testing Materials

Testing materials are prepared within the Lactanet laboratory and have been carefully designed and tested to meet the ISO 17043 (2010) standard. Test materials will be as similar as possible to the samples routinely tested by participating laboratories, however, in some cases, in order to achieve the required degree of homogeneity and stability, test materials may be in the form of simulated samples or concentrated spiking solutions. The range of test materials will usually vary from round to round in efforts to provide more realistic and challenging testing.

3.2 Quality Control

The factors used to determine the quality control testing required for each type of test material include the degree of natural homogeneity, the stability of the test material, and the use of process control during production. Homogeneity assessment is carried out based on a procedure described in ISO 13528 (2015) "*Statistical methods for use in proficiency testing for interlaboratory comparison*" [3] when appropriate. Further details regarding homogeneity testing are included in the scheme descriptions and/or reports.

Homogeneity testing may not be carried out where the process has been proven to provide homogeneous samples. In these instances, the participants' results are used to assess sample homogeneity and any issues will be treated as described below for non-conforming products.

3.3 Non-conforming Products

If the homogeneity and/or the stability of test materials are deemed not acceptable, the test materials will be withdrawn prior to their distribution to participants. Occasionally, issues with test materials may not be identified until after their distribution. Under these circumstances, this will be taken into consideration when assessing the participant's results and may result in reporting of performance scores for information only, or the provision of replacement test materials. In these instances, full details will be provided to participants.

3.4 Packaging and Transportation

Test materials are shipped in appropriate packaging, under set conditions, intended to maintain the integrity of the test materials during transit. Once delivered, Aptilab cannot be held responsible if they subsequently fail to reach the correct personnel or are not stored under

the recommended conditions.

Participants are asked to verify the package contents immediately upon receipt, and to contact Aptilab without delay at contact@aptilab.ca if there are any issues with the accompanying documentation, or the condition of the test materials (damage to vials, spoiled milk and/or cheese, etc). When possible, Aptilab will replace any faulty test materials. In the event that a package was improperly handled, or negligence was involved, shipping costs for the replacement kit will be charged to the participant.
If packages are received damaged, photographic evidence should be provided to assist in the investigation process. A refund or credit may be issued to the participant if the investigation shows that Aptilab was at fault. The investigation report issued by Aptilab may be shared with the applicant upon request. Further information will be specified on the instruction form that is provided with the shipment.

3.5 Potential major sources of errors

Aptilab has identified multiple potential risks and developed the associated contingency plan for its activities to alleviate short- or long-term issues for its participants.

Here is a non-exhaustive list of them:

- The proficiency testing provider does not ensure impartiality.
    - Lactanet-Valacta is not directly involved with the promotion or sale of raw milk nor are any of the laboratory employees. Impartiality agreements are required from all employees working in or around the Aptilab service. Specific situations may be investigated by an unbiased 3rd party (QA, HR).
- The proficiency testing provider does not ensure confidentiality.
    - Information regarding participants, samples preparation, shipping and inscriptions is limited to specific personnel. Physical and electronic access are limited to authorized personnel only.
- The proficiency testing provider does not take reasonable precautions to prevent collusion or falsification of results.
    - Aptilab Services are separated between two distinct departments. Organisation, logistics and reference analyses are handled by the reference laboratory team. Data entry verification, statistical analysis, release of reports and Certificates of Participations are handled by the quality assurance team. Both teams are under different administrations.
- The Aptilab operations cannot be performed at the current site.
    - A contingency plan is developed to have the samples prepared in a distinct location. Assigned values may be obtained through an accredited subcontractor laboratory.
- Failure of instruments and/or equipment.
    - Use of generator, power surge protection and UPS batteries are available throughout the laboratory for optimal performance even under minor disaster events. Multiple redundancies are available for most of the instruments used.
- Failure of courier to deliver the PT kits and/or inadequate kits condition upon reception by the participants.
    - Extra kits are prepared to replace inadequate or missing kits. Alternate couriers may used in specific cases.

4 REPORTING OF RESULTS

4.1 Timelines

It is important, that deadlines for submitting results are strictly adhered to. For certain test parameters, there may be one or more date(s) specified, by which the analysis of the test

material is recommended to have been begun and/or completed. Results received after the deadline will not be included in the report. Unless specified otherwise, reports can be expected within 3 to 4 weeks following the data entry deadline. The report will still be available to all participants regardless of whether their results were submitted or not.

4.2 Choice of Methodology

Participants are expected to use a technically appropriate test or measurement procedure, of their choice, which best describes the method that they are using. Participants are asked to treat the test materials as routine samples as much as possible. Information on the test method used will be requested with the results.

4.3 Reporting Your Results

Results are made available through the Aptilab Hub (full instructions are provided). For some schemes (or parts of a scheme), alternative reporting mechanisms may be provided, the details of which will be emailed to participants prior to their receipt of the samples.

It is recommended that all results and calculations be thoroughly verified before reporting. It is the participant's responsibility to ensure the adequacy of the results submitted. Results should be reported clearly, in the requested format and unit. Once results have been submitted and received, they cannot be amended, and no changes can be made after the report has been issued. Results may be rounded up or down for the purposes of reporting and may therefore differ from to the participant's original reported result (percentage totals may not add up to exactly 100%).

In general, zero results should not be reported; results should be reported depending on the detection limit of the method used, for example, <10. Zero results and truncated results, such as < or > cannot be included in the data analysis and therefore cannot be allocated a numerical performance score. There are a small number of parameters, where it may, exceptionally, be appropriate to report a result of zero, depending on the measurement scale being used.
When the result of an analysis is not a direct concentration, associated values are used instead. For example, for the analysis of antibiotic residues, a value of "1" would correspond to a negative result (not detected), and a value of "100" would correspond to a positive result (detected).

4.4 Number of Permitted Results

Aptilab limits the number of results each participant can report to 2 (duplicates) per sample, per instrument to avoid potential bias to the dataset.

4.5 Collusion and Falsification of Results

Certain measures have been built into the scheme to prevent collusion between Aptilab and its participants. For example, assigned values will be determined once all the participants have submitted their results. Furthermore, the assigned values are not made public to anyone before the report is issued and no results are accepted after the publication of the report. The software, ProLAB Plus will be used to perform the statistical analyses and the generation of reports. The Quality Assurance department will ensure the accuracy of the results and warrants that it will not participate in any collusion. It is the responsibility of each participant to behave in a professional manner by keeping their results confidential. Offenders will be warned, and such warning will be on record.

5 DATA ANALYSIS AND PERFORMANCE ASSESSMENT

5.1 Approaches to Data Analysis

Aptilab organizes schemes which may include qualitative, quantitative, and semi-quantitative tests. Further information on the statistical approaches for specific schemes is also provided in the scheme descriptions (Annex II).

The advantages of using a performance score are that results can be expressed in a form that is relatively easy to interpret and understand and are summarised in graphical or tabular form to depict overall performance allowing participants to directly compare their own result with others. If consistent statistical values are applied, a performance score enables participants to monitor trends in their own performance, over time.

When reviewing results, participants should consider the methods used to analyse the data and to assess performance, and should review their performance in context, taking into account the performance of the whole dataset.

5.2 Qualitative Schemes

For qualitative tests, participant results will be compared with the intended result, also called the assigned value, based on expert assessment. A result which is the same as the assigned value is considered satisfactory. This approach is also used for quantitative tests when the target analyte is absent and for semi-quantitative tests where the assigned value may be a range of results. This option can also be used when the minimum number of participants is not reached for an adequate Z score calculation.

5.3 Quantitative schemes

For quantitative data, participants are assessed on the difference between their result and the assigned value (see 5.4); with this difference being represented by a performance score called *z* or *z'* (*z* prime) score (see also Annex II).

5.4 Setting Assigned Values

An assigned value is the value selected as being the best estimate of the 'true value' for the parameter being tested. The method used to determine the assigned value may vary according to the scheme and test parameter, and is detailed in the relevant scheme description, along with the traceability details in each case.

For quantitative tests, all assigned values are derived in accordance with ISO 13528 (2015). Where appropriate, practicable and technically feasible, the assigned value will be derived through formulation (or occasionally using a certified reference material) to provide metrological traceability; the associated uncertainty of the value can therefore be estimated. All assigned values are derived in accordance with ISO 17025 (2017). The uncertainty of the assigned value is specified by the corresponding analytical method.

5.5 Reference Values methods

Reference values, where applicable, are determined based on the following methods:

- QMR-001 Determination of Fat - Rose Gottlieb Method (modified ISO 1211 and modified ISO 23318)
- QMR-002 Determination of Nitrogen Content by Kjeldahl Method and Calculation of Protein Equivalent (modified ISO 8968-1/IDF 20-1, ISO 8968-4/FIL 20-4, ISO 17997-2/IDF 29-2)

- QMR-003 Determination of Lactose by HPLC (ISO 22662/IDF 198)
- QMR-004 Determination of the solids content or moisture content in milk and dairy products (modified AOAC 990.20 and ISO 6731/IDF 21)
- QMR-045 Determination of b-hydroxybutyric acid in milk by Continuous Flow Analyzer (Skalar 388-301)
- QMR-059 Determination of Urea Content in Milk by Continuous Flow Analyzer (Skalar 612-322)
- ISO 16958 / IDF 231 Milk, milk products, infant formula and adult nutritionals – Determination of fatty acids composition - Capillary gas chromatographic method

5.6 Calculating *z scores*

$$z\ score = \frac{(x_i - x_{pt})}{\sigma_{pt}}$$

where; x_i = the result reported by the participant
x_{pt} = the assigned value
σ_{pt} = standard deviation for proficiency assessment

The *z score* expresses performance in relation to an acceptable variation between the participant results and the assigned value. A *z score* of 2 represents a result that is 2 x σ_{pt} from the assigned value.

The returned results are rounded to the required number of decimal places specified in the scheme descriptions. The statistical calculations are performed on unrounded data and displayed as rounded to the required number of decimal places in the report.

5.7 Standard Deviation for Proficiency Assessment (SDPA)

The method used to determine the SDPA may vary depending on the scheme and test parameter and is derived in accordance with ISO 13528 (2015). When the SDPA is determined from the dispersion of participant results, robust statistical methods are used for the standard deviation as calculated by our software. Where applicable, the SDPA value is reported in the scheme description and/or report.

5.8 Interpreting Results

For qualitative and semi-quantitative results, laboratories reporting the assigned result or range of results will be considered correct, and therefore have satisfactory performance.

For quantitative examinations, the following interpretation is applied to *z score* results.

$\|z\| \leq 2.000$	Satisfactory result
$2.000 < \|z\| < 3.000$	Questionable result
$\|z\| \geq 3.000$	Unsatisfactory result

For the analytes that use a formulation or reference value as the assigned value, and a fixed fit for the purpose of the SDPA (see 5.6) *z scores* will be provided. For data sets with very limited results or with a large result spread, *z scores* may not be provided.

Interpretation of results without Z score can be done by comparing the assigned value to the participant's value. In this case, the accepted variability between the two values would be given by the analytical method used. This thus becomes the interpretation of a satisfactory or unsatisfactory result.

5.9 Trend Analysis

A single test result simply reflects the laboratory's performance on the day that the test was carried out, and therefore only provides limited information. Frequent participation in PT schemes over time can provide better insight into long-term performance and can help identify incidence of internal bias. Participants are therefore advised to monitor their PT results over time. For further information, consult the IUPAC "*International Harmonised Protocol for the Proficiency Testing of Analytical Chemistry Laboratories*"[4] and ISO 13528 (2015).

6 INFORMATION DISTRIBUTED TO PARTICIPANTS

6.1 Reports

Reports are made available electronically. The report contents will vary from scheme to scheme but include details about the composition of test materials, assigned values, and tabular and/or graphical representations of the participants' results and performance. Aptilab has copyrights to all reports, but participants are granted permission to make copies for their own internal use (for quality control and regulatory purposes). No other copies may be made without Aptilab's prior written permission.

Aptilab cannot, under any circumstances, be held responsible for any problem related to the proficiency testing results of any participant laboratory, considering that such testing results are entered in Aptilab Hub by the participant laboratory.

6.2 Renewal Information

Renewal information is sent to participants a few months before the start of the new scheme year. This information will provide details on how to renew, including sample availability, and changes from the previous scheme year. Participants should review the new scheme year information and return their order to Aptilab, via the Aptilab website or using the registration form.

6.3 Advice and Feedback

Communication with participants will be carried out using scheme-related documentation sent via e-mails.

Part of the challenge of participating in a proficiency testing scheme is carrying out appropriate investigations and actions in response to unsatisfactory or questionable results.

Comments on any aspect of the scheme are welcome either by e-mail or phone. Any complaints will be fully investigated according to Lactanet's quality system, to determine the underlying cause and to decide upon a course of action. The results of any such investigation will be communicated to the participants concerned.

For questions regarding proficiency testing programs, such as sample status, shipping, data entry, reporting, etc., please contact:

Jean-Philippe Angers:
Reference Laboratory Manager in charge of the Aptilab program and Aptilab Hub website.

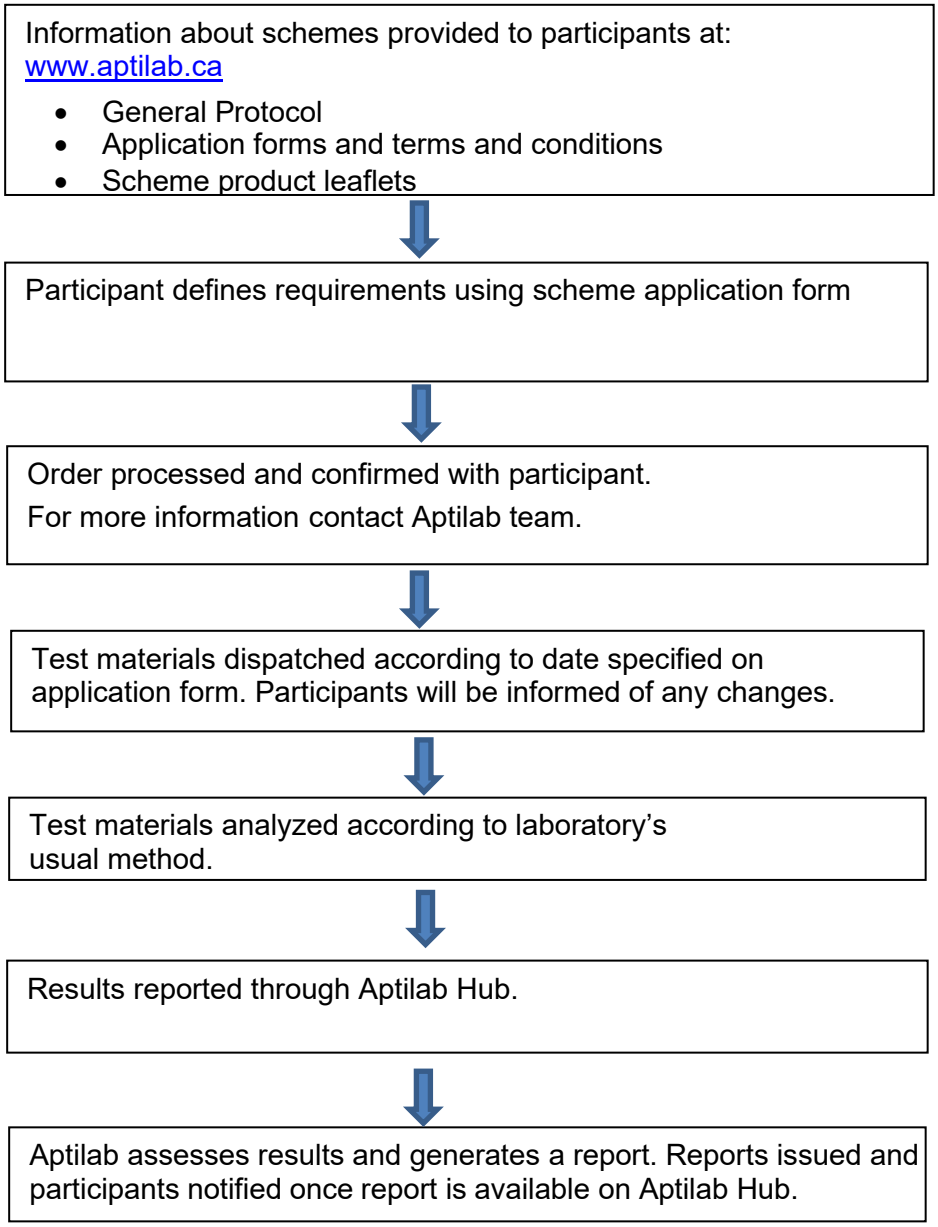
Christa Deacon:
Team Leader in charge of client orders, kit production, shipping, and billing.

Using the following contact information:

- email: contact@aptilab.ca or
- Telephone #: 514-459-3030 Ext. 7717

Coordinate comments, complaints and results calls with your supervisors/staff and submit them to contact@aptilab.ca.

ANNEX I - Scheme Operation Flowchart



ANNEX II - Procedure for Calculating Robust Statistics

Robust Mean (median)

The consensus value can be calculated using the robust mean of all participant results.
For PT schemes the robust mean used is the median. Where there are an odd number of results if the data are arranged in order of magnitude (x1, x2,……, xn) the median is the central member in the series, i.e. there are equal numbers of observations smaller and greater than the median. Where there is an even number of results, the median is the average of the middle pair of numbers within the series. With normal distribution, the mean and median have the same value. The median is more robust, in that it is virtually unaffected by extreme values.

Robust Standard Deviation

PT schemes where the normalised median of absolute deviations (MAD_E) from the sample median is used as a robust standard deviation.

MAD = median $\{ |x_i - X|_{i = 1,2,.....n}\}$ where n = number of results

For example:

Data (g)	5·6	5·4	5·5	5·4	5·6	5·3	5·2
Ordered Data	5·2	5·3	5·4	**5·4**	5·5	5·6	5·6

Sample median = 5.4

$\|x_i - X\|$	0·2	0·1	0·0	0·0	0·1	0·2	0·2
Ordered Difference	0·0	0·0	0·1	**0·1**	0·2	0·2	0·2

Therefore MAD = 0.1

MAD is then scaled by a factor of 1.483 to make it equivalent to a normal deviation (MAD_E).

Hence MAD_E = 1.483 x MAD = 0.1483

If MAD_E is equal to zero SMAD should be calculated:

SMAD = mean $\{ |x_i - X|_{i = 1,2,.....n}\}$ x 1.2531

The robust standard deviation may be used as the standard deviation for proficiency assessment (SDPA) for the calculation of *z scores*. Other statistical methods for the calculation of robust estimators are available.

Removal of Errors and Blunders

Although robust estimators are used to minimize the influence of outlying results, extreme results or results that are identifiably invalid should not be included in the statistical analysis of the data. For example, these may be results caused by calculation errors or the use of incorrect units. However, such results can be difficult to identify by the PT organizer. For this reason, the robust mean and standard deviation will be calculated as above, but those results that are out ofthe range of the assigned value ± 5 x SDPA will be excluded, and the robust mean and standarddeviation will then be recalculated. These recalculated values will be used for the statistical analysis. All results, including excluded results, will be given performance scores.

ANNEX III - General Procedure and Assessment Criteria for a Homogeneity Check

Test materials are assessed for homogeneity using the procedures described in Annex B of ISO 13528 (2015) [3]. A brief description of the procedure is provided below:

a) Choose a property (or properties) to be assessed for homogeneity.
b) Choose a laboratory to carry out the homogeneity check and the measurement method to use. The method should have a sufficiently small repeatability standard deviation (s_r) so that any significant inhomogeneity can be detected. If possible, s_r should be less than 0.5 x σ_{pt} (the standard deviation for proficiency assessment).
c) Prepare and package the proficiency test items for a round of the scheme ensuring there are sufficient items for the participants and the homogeneity check.
d) Select a number *g* of the proficiency test items in their final packaged form, using a suitable random selection process, where g $\geq$ 10. This number may be reduced if suitable data are available from previous homogeneity checks on similar proficiency test items prepared by thesame procedures.
e) Prepare *m* $\geq$2 test portions from each proficiency test item using techniques appropriate to theproficiency test item to minimize between-test-portion differences.
f) Taking the *g* x *m* test portions in a random order, obtain a measurement result on each,completing the whole series of measurements under repeatability conditions.
g) Calculate the general average *x,* within-sample standard deviation s_w, and between-samplestandard deviation s_s.

   NOTE When it is not possible to conduct replicate measurements, for example with destructive tests, then the standard deviation of the results can be used as s_s.

h) Examine the results to look for possible trends in analysis or production order and to comparedifferences between replicates.
i) Compare the between-sample standard deviation s_s with the standard deviation for proficiency assessment σ_{pt}. The proficiency test items may be considered adequately homogenous if $s_s \leq 0.3\sigma_{pt}$.

   NOTE When the above criterion is met then the between-sample standard deviation contributesless than 10% of the variance for evaluation of performance.

j) Calculate the allowable sampling variance $\sigma^2_{allow} = (0.3 \times \sigma_{pt})2$

k) Calculate $c = F_1\sigma^2_{allow} + F_2s^2_w$, where s_w is the within-sample standard deviation and F_1 and F_2 are from standard statistical tables as shown below:

m	20	19	18	17	16	15	14	13
***F*1**	1.59	1.60	1.62	1.64	1.67	1.69	1.72	1.75
***F*2**	0.57	0.59	0.62	0.64	0.68	0.71	0.75	0.80

m	12	11	10	9	8	7	6	5
***F*1**	1.79	1.83	1.88	1.94	2.01	2.10	2.21	2.37
***F*2**	0.86	0.93	1.01	1.11	1.25	1.43	1.69	2.10

If $s_s > \sqrt{c}$, then there is evidence that the batch of proficiency test items is not sufficientlyhomogenous.

ANNEX IV - Estimated Standard Uncertainty of the Assigned Value

The assigned value (x_{pt}) has a standard uncertainty ($u(x_{pt})$) that depends on the method used to derive the assigned value. When the assigned value is determined by the consensus of participants' results, the estimated standard uncertainty of the assigned value can be calculated by:

$u(x_{pt})$ = 1.25 x robust standard deviation/$\sqrt{n}$ where n = number of results)

When the assigned value is determined by formulation, the standard uncertainty is estimated bythe combination of uncertainties of all sources of error, such as gravimetric and volumetric measurements.

If $u(x_{pt})$) is ≤ 0.3 x SDPA, then the uncertainty of the assigned value can be considered negligible and unnecessary to consider in the interpretation of results.

If $u(x_{pt})$) is > 0.3 x SDPA, then the uncertainty of the assigned value is not negligible in relation to the SDPA and so *z'* (*z* prime) scores, which include the uncertainty of the assigned value in theircalculation, will be reported in place of *z scores*.

z' scores are calculated as follows:

$$z' = \frac{(xi - xpt)}{\sqrt{\sigma pt^2 + u(xpt)^2}}$$

Where:

$\underline{x_{pt}}$ = assigned value
$\underline{x_i}$ = participant result
$\sigma_{p\,t}$ = standard deviation for proficiency assessmentu
(x_{pt}) = standard uncertainty of the assigned value $\underline{x_{pt}}$

Expanded SDPA = $\sqrt{\sigma_{pt}^2+u(x_{pt})^2}$

The magnitude of *z' scores* should be interpreted in the same way as *z scores*.

Estimated standard uncertainty was evaluated for all Lactanet concerned methods accredited under ISO/IEC 17025 (2017).

ANNEX V - References and Sources of Information

[1] ISO/IEC 17025 (2017) “General requirements for the competence of testing and calibration laboratories”.

[2] ISO/IEC 17043 (2010) “Conformity assessment – General requirements for proficiency testing”.

[3] ISO 13528 (2015) “Statistical methods for use in proficiency testing by interlaboratory comparison”.

[4] M Thompson, S L R Ellison, R Wood, ‘International Harmonised Protocol for the Proficiency Testing of Analytical Chemistry Laboratories’, Pure Appl. Chem., 2006, 78, 145-196.