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Centre de toxicologie

PARTICIPANT'S GUIDE

EXTERNAL QUALITY ASSESSMENT SCHEMES (EQAS)

CENTRE DE TOXICOLOGIE DU QUÉBEC

External Quality Assessment Schemes (EQAS)

This document is available in electronic format (PDF) on the website of the Institut national de santé publique du Québec at: https://www.inspq.qc.ca/ctq/paqe

May 2024

CONTENTS

This document contains information on policies and instructions that apply to External Quality Assessment Schemes (EQAS) offered by the *Centre de toxicologie du Québec* (CTQ). The guide's content has been approved by the scheme coordinator listed in subsection 8.5 herein.

1. EXTERNAL QUALITY ASSESSMENT SCHEMES OFFERED BY THE *CENTRE DE TOXICOLOGIE DU QUÉBEC*

- AMAP: AMAP Ring Test for Persistent Organic Pollutants in Human Serum, since 2001
- Creatinine: Inter-laboratory Comparison Program for Measurement of Serum Creatinine (provided in collaboration with the SQBC), since 2013
- PCI: Inter-laboratory Comparison Program for Metals in Biological Matrices, since 1979
- QMEQAS: Quebec Multielement External Quality Assessment Scheme, since 1996
- OSEQAS: External Quality Assessment Scheme for Organic Substances in Urine, since 2015

The list of analytes available for each of the schemes is provided on the CTQ's EQAS Web site (refer to the link in paragraph 8.6.2).

2. ACCREDITATION

The CTQ's laboratory applies a quality management system accredited under the ISO/IEC 17043 standard applicable to EQASs (AMAP, PCI and QMEQAS).

3. INFORMATION REGARDING PARTICIPATION

3.1. CALENDAR OF ROUNDS

The annual schedule of EQASs is e-mailed at the beginning of the year and may be consulted at any time on the CTQ Web site under "Schedule", on each scheme page. **It contains the various shipment dates and reporting deadlines for every round of a given year.** If you do not receive your proficiency testing materials (PTM) within one week of the shipment date specified in the schedule, please notify us as soon as possible (see contact information provided in subsection 8.5).

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3.2. SUBSCRIPTION

Laboratories interested in participating in the EQASs offered by the CTQ may do so by completing the form entitled "Registration form" which is available on our website (see link at sub-section 8.6.2). Once the request has been received and approved, the person in charge of the participant account will receive a username and a temporary password to be used to log in to the system. The password will need to be changed after the first login.

3.3. PARTICIPANT ACCOUNT AUTHORITY AND SUBSCRIPTION AUTHORITY

Participant account authorities have access to all active subscriptions to the CTQ's EQAS for their laboratory. They may either designate one or more authorities for each EQAS subscription or manage them themselves. **This request must be sent to us by e-mail.** Each subscription authority has his/her own username and password.

To retrieve a lost or forgotten password, or to request a new one, please contact us (see contact information provided in subsection 8.5).

3.4. MANAGING THE PARTICIPANT ACCOUNT

Participants may access and manage their participant account at any time through the EQAS management system, whether for changing their mailing or e-mail address; viewing invoices; indicating the preferred units for reporting results; and printing comprehensive reports and certificates.

A number is attributed to each participant account created. Every scheme subscription for this participant account is assigned a random unique subscription number. This number is used to identify participants in reports.

We strongly encourage our participants to never share their subscription number to respect confidentiality in reporting

3.5. CONFIDENTIALITY

Every scheme subscription is identified by a unique subscription number. The CTQ safeguards the confidentiality of participants' identities.

All results obtained from participants remain confidential and are associated solely with the unique subscription number. However, results stripped of all identifying information may be used in reports and publications, as agreed by participants when they subscribe.

3.6. COLLUSION, FORGERY AND SUBCONTRACTING

Participants bear full responsibility for preventing collusion, as well as the forgery and subcontracting of analyses.

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3.7. PARTICIPATION CERTIFICATES

A participation certificate is issued at the end of the year to all participants who have submitted at least half the results for at least one analyte. The calculation is done yearly. Non-numerical results are excluded from the calculation. Results not submitted do not affect the calculation of the annual score.

The annual score (%) is calculated based on the total points accumulated, with a maximum total of three (3) points per result. The score is calculated using the absolute value of the z'-score:

- 3 points if $0.0 <$ $|z\text{'-score}| \leq 1.0$
- 2 points if $1.0 <$ $|z\text{'-score}| \leq 2.0$
- 1 point   if $2.0 <$ $|z\text{'-score}| < 3.0$
- 0 point if $|z\text{'-score}| \geq 3.0$

Scores falling under the pass threshold appear under the pass threshold line and indicate unsatisfactory performance.

The pass threshold has been set at 65%.

4. COSTS, INVOICING AND PAYMENT

Scheme subscriptions are renewed in October. However, a participant may subscribe to a scheme at any time during the year, in which case the subscription fees are prorated for the remaining rounds.

Participation in the CTQ's EQASs is a prepaid service. Annual subscription fees, including fees for selected PTM, are payable within 30 days after the reception of the invoice for the following year.

For each scheme, you will find the number of rounds and annual PTM, the subscription fees, the cost of each PTM grouping and the cost of additional PTM on the CTQ's EQAS Web site (see link at sub-section 8.6.2).

You may view your invoices online on the "Billing" tab of your participant account. Please note that we do not send any invoices by post, and that all amounts are in Canadian dollars.

You may pay your invoice in three ways:

- by cheque (payable to: Centre de toxicologie du Québec);
- via bank transfer (refer to Appendix 1 for information);
- via the online credit card payment system (Visa or MasterCard) on the Web site (refer to paragraph 8.6.2 for details).

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5. INFORMATION REGARDING PROFICIENCY TESTING MATERIALS (PTM)

5.1. CODING SYSTEM

Standard PTM numbering is used for all EQASs. The identification code consists of the following characters:

- The first two letters of the scheme;
- One letter identifying the matrix (B=blood, S=serum, U=urine, H=hair);
- One letter representing the analytes;
- The last two digits of the year;
- A PTM sequence number.

For example, the first serum aluminum PTM for the PCI in 2020 will have the following code: PC-S-A2001.

5.2. PREPARATION AND VERIFICATION

The PTM are prepared in our laboratory using biological matrices obtained from non-exposed donors. When needed, analytes are added to each matrix. Homogeneity and stability are verified in conformance with the ISO 13528:2022[1] standard. The PTM are stored frozen at -20 °C until shipped to participants.

5.3. RECEIPT

Please notify us of any discrepancies between the shipping list and the PTM received, including any damaged items. Missing or damaged PTM will be replaced as soon as possible. Follow the storage instructions printed on the shipping list.

5.4. REPLACEMENT PTM

In case of mishaps, lab accidents or analytical problems, additional PTM for the current round are available. To order replacements, please contact us. Additional fees will apply to cover the cost of the PTM, as well as shipping and handling. Depending on availability, PTM for previous rounds may be purchased through the Web site's virtual store (refer to the details in paragraph 8.6.3).

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5.5. HANDLING AND ANALYSIS

Biological matrices consisting of blood and serum are tested for hepatitis B and C, HIV and syphilis. However, no known test is able to guarantee that human blood products are completely free of infectious agents.

PTM must be considered as routine samples and therefore submitted to the same analytical procedures as any routine sample.

> PTM must be handled as potentially infectious. PTM must be disposed of in accordance with the same methods used for other human biological matrices. Prior to analysis, bring the PTM to room temperature and stir thoroughly.

6. INFORMATION REGARDING ANALYTICAL RESULTS

6.1. REPORTING RESULTS

All results must be reported through the participant account in the EQAS management system. For the AMAP and OSEQAS, results must be reported in conventional units. For the PCI and QMEQAS schemes, the preferred units (conventional or SI) must be specified at the beginning of the year. All PCI and QMEQAS results will be converted into conventional units before being published in the reports. For the Creatinine scheme, the results must be transmitted in SI units.

The deadline for the transmission of results is 6 weeks after the shipment of PTM, except for the PCI programme, where the deadline is 5 weeks after shipment of PTM.

> The results submitted by participants must be precise to a minimum of three significant digits or to a different precision level dictated by their method.
>
> No extension is granted for the reporting of results, as the EQAS system will automatically block results reporting as of midnight (Eastern Standard Time) on the specified reporting deadline date.

6.2. PROCEDURE FOR ENTERING RESULTS IN THE EQAS MANAGEMENT SYSTEM

6.2.1 DATA REPORTING

1. Log in to the participant account;
2. Click on "Results" tab;
3. Select the appropriate year and scheme;

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4. Then click the PTM grouping and the PTM for which you wish to report results;

5. Type the result corresponding to the analyte in the "Result" box according to the specified unit, **indicating a minimum of three significant digits, or according to the precision level of the method**;

6. In the pull-down menus, select the instrumentation methods and other factors related to this result. Use the horizontal scroll bar to view all method categories. **Important:** The selected methods are automatically reproduced for the following rounds, in order to avoid having to enter them every time. The reliability of statistics by type of method is proportional to the number of participants who report the instrumentation methods related to their results;

7. Click **Save** at the bottom of the page before leaving the page;

8. Repeat this procedure for each PTM.

6.2.2 PRINTING RESULTS

The **Print** icon at the bottom of the page is used to print all results for the round as a single document. We strongly recommend that you keep a paper or electronic copy as proof that you have submitted your results.

6.2.3 QUESTIONS AND COMMENTS

You can send us your questions and comments in any of two ways:

1. Include a comment on the results page. Information in the "Comment" box applies to all PTMs in the current round. Specify the PTM or analyte to which the comment applies.

2. Send an e-mail message; remember to specify your unique subscription number or your participant number (see contact information provided in subsection 8.5).

6.3. UNREPORTED RESULTS

Only numerical results reported are taken into account in the statistical treatment of the data. The only allowable non-numerical results are: <LD, <LQ or >LL. An unreported result will not lead to a penalty regarding the issuance of participation certificates (refer to subsection 3.7).

6.4. ANALYTICAL METHODS

For all schemes and for each PTM grouping, participants must specify which preparation, instrumentation and benchmarking methods were used in the analyses. This information will be used for the statistical analysis of the results by method group and to provide detailed statistics by analysis method in the

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reports. To participate in a scheme and to be assessed using two different analysis methods for the same analyte, please contact us.

7. INFORMATION REGARDING REPORTS

7.1. PROCESSING RESULTS

Results are processed for report production purposes after the reporting deadline. Reports are available on your participant account's "Reports" tab four weeks after the reporting deadline. Participants will be notified of the posting by e-mail. Please verify your results and promptly notify the program coordinator of any errors or discrepancies on the data contained in the report. **We will correct only those errors for which we are responsible.**

7.2. REPORT

Reports contain the following information:

- Results submitted by participants for each analyte/matrix in the scheme. Unless specified otherwise, aberrant results are not excluded unless the aberration can be explained by something like a unit or conversion error.
- Robust statistics calculated for all results combined and for subgroups of results (when there are at least three results) per type of analytical method.
- The assigned value (AV) derived from the consensus value calculated using the robust average of Algorithm A[1].
- The robust standard deviation based on Algorithm A[1].
- The AV's standard uncertainty.
- The arithmetic mean and standard deviation.
- The median and median absolute deviation (MAD).
- The coefficient of variation (CV) or variability.
- The proficiency standard deviation (σ_{pt}) modelled for each analyte/matrix using CTQ's EQAS data from recent years.
- The acceptable range based on the concentration of the analyte/matrix.
- The performance calculation: z'-score (including the AV's standard uncertainty).
- The graph of results in increasing order. For QMEQAS, the graphics are included in a separate report

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7.3. CRITERIA FOR INTERPRETING PERFORMANCE BASED ON THE OBTAINED z'-SCORE

$\lvert\text{z'-score}\rvert \leq 2.0$	Satisfactory
$2.0 < \lvert\text{z'-score}\rvert < 3.0$	**Questionable**
$\lvert\text{z'-score}\rvert \geq 3.0$	**Unsatisfactory**

The blue and red colors are used in round report to identify questionable and unsatisfactory results.

8. GENERAL AND ADMINISTRATIVE INFORMATION

8.1. COMMUNICATION

The success of any quality assessment scheme is highly dependent on the effectiveness of communication between participants and the scheme provider. To this end, we strongly encourage you to send your comments and suggestions to the scheme coordinator. Please note that we strongly encourage the use of email to communicate with us.

8.2. CHANGES TO SCHEMES DURING THE YEAR

You will promptly receive written notification of any major changes to the way schemes operate - addition of analytes, additional rounds, etc.

8.3. COMPLAINTS

Contact the scheme coordinator or the EQAS administrator regarding any complaints or comments about the scheme.

8.4. BUSINESS HOURS

Customer Service regarding the CTQ's EQAS is available weekdays from 8:30 a.m. to 4:30 p.m. Eastern Time, except on statutory holidays. Outside of these hours, you are welcome to contact us by email.

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8.5. CONTACTS

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Schemes Coordinator: David Bisson
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Technical Coordinator: William Molon Noblot
Telephone: 418-650-5115, extension 4035
E-mail: william.molon-noblot@inspq.qc.ca

EQAS Secretary: Annabelle Dubreuil
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8.6. COMMUNICATION TOOLS

8.6.1. TO ACCESS PARTICIPANT ACCOUNTS VIA THE EQAS MANAGEMENT SYSTEM

paqe.inspq.qc.ca

8.6.2. WEB SITE

www.inspq.qc.ca/en/ctq/eqas

8.6.3. TO PURCHASE REFERENCE MATERIALS

The virtual store at http://ctqvente.inspq.qc.ca offers a range of reference materials that can be ordered online at very competitive prices.

9. REFERENCES

(1)   ISO 13528, Statistical methods for use in proficiency testing by inter-laboratory comparisons, ISO, third edition, 2022-08

(2)   ISO/IEC 17043, Conformity assessment – General requirements for proficiency testing, first edition, 2010-02-01

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APPENDIX 1

BANKING IDENTIFICATION

Name of beneficiary:	Institut national de santé publique du Québec
Name of financial institution:	BANQUE NATIONALE DU CANADA 1385, chemin Sainte-Foy Québec, Qc G1S 2N2 Tel.: 418-684-0328 Fax: 418-684-0329
Financial institution number:	006
Branch number:	10641
Our account number:	01-898-20
Swift address:	BNDCCAMMINT
Routing number:	000610641
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APPENDIX 2

Statistical Approach Used in Reports

1 Statistical Treatment

Statistical parameters are calculated for each set of data in the section « All methods ». Such parameters are also determined in different sections for a subset of data corresponding to a grouping of analytical methods, for schemes allowing the use of various analytical methods. A table describing the groupings of analytical methods included in each of them is presented in this report.

1.1 Outliers

For each PTM and for each analyte, the statistics are calculated after having removed, if required, outlying results. No outlier exclusion test is used since the assigned values are determined from robust statistics as recommended in the document ISO 13528:2022.

Results can be considered outliers and removed from the statistical treatment for several reasons such as:

- Wrong units reported;
- Wrong conversion factor used;
- Results entered for the wrong PTM (inversion with another PTM);
- All other reasons believed appropriate by the scheme coordinator.

Results having been identified and removed as outliers are indicated in **_bold italics_** in the report. For the statistical treatment per method type, the calculations are made from subsets of data corresponding to a grouping of analytical methods. Results considered outliers in the all methods category are the same as those for each grouping of analytical methods.

1.2 Assigned Value (AV)

The AV is determined by consensus of participants by calculating the robust average of Algorithm A, from the results reported by all the participants in the round, as described in ISO 13528:2022.

There may not always be consensus from the participants for the AV for the following reasons:

- Too few results (N too small);
- Abnormal distribution of results;
- Use of biased methods by some participants;
- Difficulty for some participants to measure specific chemical forms of the analyte;

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- Difficulty for some participants to measure low level concentrations with acceptable reliability;

The AV may be determined using other methods, such as:

- Median;

- Arithmetic mean;

- Assigned value obtained by inclusion of the same PTM within another EQA scheme operated by the CTQ (Inter-program correspondence);

- AV obtained from participants that have demonstrated a good past performance;

- The theoretical concentration of the analyte in the PTM;

- Reference value obtained using a reference analytical method (ex.: ID-ICP-MS);

The selection of an AV other than the robust average of the Algorithm A is documented in the report, if necessary.

The method of calculation of the selected AV is indicated by a gray shaded background in the statistics page of each PTM.

1.3 Calculated Statistical Parameters

The following statistical parameters are provided for all results (for all methods) and for subsets of results per grouping of analytical methods (per method type).

Number of Results (N)

Non numerical results and results identified as outliers are listed in the table of results but excluded from the statistical treatment.

We calculate the statistical parameters for an analyte when we have a dataset of at least 3 results.

For each analyte, a minimum dataset of 20 results is necessary in order to obtain meaningful statistics. However, if fewer than 20 results are available, the statistics are still provided. When fewer than 20 results were considered for statistical treatment of all or a subset of results, the accuracy of statistical data may be questionable.

Robust Average (x*) and Robust Standard Deviation (s*) per the Algorithm A

This method of calculation is the default method used to generate the AV by consensus of all participants.

The robust analysis of the Algorithm A is performed by iterations based on estimations of the robust average (x*) and the robust standard deviation (s*) refreshed many times using the modified data up until the process converges. This process is assured when the third significant figure of the robust standard deviation no longer changes from one iteration to the

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other. To better understand the details of this method, please consult the ISO 13528:2022 documentation.

Median

The median is the value, in a series of incremented results, located where the number of results preceding it is equal to the number of results following it.

- For a number of **odd results**, the median is the result of the rank (n+1)/2

- For a number of **even results**, the median is equal to 0.5 x [result of rank n/2 + result of rank (n+1)/2]

The median is considered robust, meaning that it is little affected by an outlier result.

Standard Deviation from MAD

The standard deviation associated with the median can be calculated from the median absolute deviation (MAD).

The MAD is obtained by considering the median of the absolute values of the deviations between the median and each result. The median of those deviations equals the MAD.

The standard deviation from MAD is estimated by 1.483 x MAD.

Arithmetic Mean

The arithmetic mean is the value corresponding to the sum of the N results divided by N.

For a perfectly normal distribution, the arithmetic mean, the median or the robust average of the Algorithm A coincide. Since outliers influence considerably the arithmetic mean, they must be removed prior to calculations.

Standard Deviation

The standard deviation is equal to the square root of the sum of the deviations between each result and the arithmetic mean squared and divided by N-1.

$$s = \sqrt{\frac{\sum_{i=1}^{n}(x_i - \bar{x})^2}{n-1}}$$

Coefficient of Variation (CV) or Variability (%)

The % CV is equal to the standard deviation divided by the arithmetic mean multiplied by 100.

If the method of calculation for the AV is the robust average of the Algorithm A, the CV indicated is called Variability. The variability (%) indicated in the report is then calculated by replacing the standard deviation and the arithmetic mean with the robust standard deviation and the robust average of the Algorithm A.

Similarly, if the method of calculation of the AV is in fact the median, the standard deviation and the arithmetic mean are replaced by the standard deviation from MAD and the median to obtain the calculation of the variability (%).

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Standard Uncertainty of the AV (μ_x)

The standard uncertainty of the AV can be calculated in several ways. However, it is always calculated according to the method used to calculate the AV. Since the default method used to calculate the AV is the robust mean according to the Algorithm A (1.3.2), the standard uncertainty of the AV will be default calculated according to the formula described in Section 1.3.8.1. If the AV has been determined using the median (1.3.3) or the arithmetic mean (1.3.5), the standard uncertainty of the AV will be calculated using the formulas in Sections 1.3.8.2 or 1.3.8.3. If another method is used for the determination of the AV, the determination of the uncertainty shall be in accordance with the method. So, for example, if a reference material is used the uncertainty of the AV will be the uncertainty of the reference material. If an analytical reference method is used then the uncertainty of the AV will be the uncertainty of that method.

AV Obtained Using the Algorithm A

If the selected AV is calculated using the Algorithm A, the standard uncertainty is calculated as:

$$\mu_x = \frac{1.25 \times s^*}{\sqrt{N}}$$

where s* is the robust standard deviation calculated using Algorithm A (1.3.2) and N the number of numerical results reported.

AV from the Median

If the selected AV is calculated from the median, the standard uncertainty is calculated as:

$$\mu_x = \frac{1.25 \times standard\ deviation\ from\ MAD}{\sqrt{N}}$$

where the standard deviation from MAD is calculated according to the equation in Section 1.3.4.

AV from the Arithmetic Mean

If the selected AV is calculated from the arithmetic mean, the standard uncertainty is calculated as:

$$\mu_x = \frac{standard\ deviation}{\sqrt{N}}$$

where the standard deviation is calculated according to the equation in Section 1.3.6.

Kolmogorov-Smirnov (Lilliefors) Test

The Kolmogorov-Smirnov (Lilliefors) statistical test is a tool used to evaluate the normality of a distribution of results. The test can be performed with N ≥ 4.

The power of the test increases rapidly with the number of observations. For a high N (> 30), the test will be sensitive to account for small deviations from normality even with the

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presence of only one outlier.

For a small sample size (N ≤ 10), the hypothesis that the observations follow a normal distribution will generally be accepted. However, if normality is rejected for N ≤ 10, this indicates that the observations are far from following a normal distribution and that one or more observations are most likely outliers.

When the normality hypothesis is rejected, the use of robust methods for the determination of the AV by consensus such as the Algorithm A allows to obtain a better estimation of the AV. Outliers are retained except if their deviation from the other observations can be clearly explained as indicated in section 1.1.

The normality hypothesis is rejected when the statistical value is too weak according to the Kolmogorov-Smirnov (Lilliefors) critical value table. The result of the normality of the distribution of each set of observations is provided in the report whether the test is "Accepted" or "Rejected" under the column labeled "KS (Lilliefors)"

Proficiency Standard Deviation (σ_{pt})

The standard deviation for proficiency testing is a measure of dispersion used in the evaluation of proficiency. It is established for any given concentration and based with regards to past participants' performance.

For each EQAS operated by the CTQ and for each analyte-matrix combination, the Proficiency Standard Deviation **(σ_{pt})** has been modelled using standard deviations of several PT rounds and according to corresponding AV.

For each analyte-matrix combination of each program, one or two equations representing a straight line describe the relationship between the proficiency standard deviation (σ_{pt}) and the concentration (or AV) according to the following parameters:

$\boldsymbol{\sigma_{pt}}$ = m x + OAO

where m is the slope of the straight line and OAO is the intercept point of the straight line.

2 Acceptable Range

The acceptable range is calculated by defining the outer limits from the AV using the following equation:

$$AV \pm 2 \times \sqrt{\left(\sigma_{pt}\right)^2 + (\mu_x)^2}$$

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3   Calculation of z'- score and Performance Criteria

The z'-score considers the standard uncertainty of the AV (μ_x) and the standard deviation for proficiency testing (σ_{pt}) at a given level of concentration.

For each result submitted by a participant, a z'-score is calculated from unrounded results.

The z'-score is defined as:

$$z' = \frac{(x - AV)}{\sqrt{(\sigma_{pt})^2 + (\mu_x)^2}}$$

The z'-scores should be interpreted using the same criteria as the z-scores and the same critical values, 2.0 and 3.0.

$\lvert$**z'-score**$\rvert \leq 2.0$	Satisfactory
$2.0 < \lvert$**z'-score**$\rvert < 3.0$	Questionable
$\lvert$**z'-score**$\rvert \geq 3.0$	Unsatisfactory

Performance is deemed satisfactory for results between $\pm$ 2.0. A z'-score equal to $\pm$ 2.0 corresponds to a result at the limit of the acceptable range.

When the standard uncertainty of the AV is negligible, z'-scores are almost identical to z-scores.

z'-scores comprised between 2.0 and 3.0 are colored in blue in the report. Those above or equal to 3 are indicated in red.

The blue and red colors are used in round report to identify questionable and unsatisfactory results.

4   Distribution Graph in Ascending Order

For each PTM, the distribution of results from participants is presented in ascending order. Outliers are not included in the graph.

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