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PT PROTOCOL- General Information

This PT protocol is a part of Information brochure on PT Scheme(s) including the following and is in public domain

- Frequently asked questions
- Registration form
- PT calendar(s)
- Terms & Conditions for participation
- NABL Scope

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Symbols

$	Participant performance for this analyte has been assessed using a **z'-score (z-prime),** rather than a z-score, in order to account for the measurement uncertainty of the assigned value μ(x_{pt}) which is not negligible when compared to the standard deviation for proficiency assessment (σ_{pt})
#	In order to ensure that the σpt used for performance evaluations is fit for purpose in line with ISO 13528 clause 8.6.2 PT provider has used initial σpt from literature review, expert advice and or from experience for evaluating the said parameter
$$	Where number of participants for one or more measurands in a PT scheme due to 'Results Not submitted' or 'Results Not Considered' or due to removal of blunders are reduced to less than 8, in such a case the uncertainty can be high. Hence, performance evaluation given in terms of **z'-score** is only **indicative** and not confirmatory.
B	Blunder - Obvious odd values by subjecting the data to any one of the following methods (i) Grubbs test or (ii) Results that deviate from the X by more than ±5σ_{pt} or (iii) Results that deviate from the X by more than 2 times MPE (maximum Permissible Error fixed by PT Coordinator for the concerned test
RNS	Results not submitted (Results not reported by laboratory) – No score given '--'
RNC	Results not considered (Where participants in spite of instructions given- Report results as zero or non-numerical results e.g. <0.1 or >1, Nil, BDL etc. or even where some results are qualified by any symbol or given with any remarks etc.; these results are not considered for performance evaluation) – No score given '--'

d	Difference between a measurement value for a proficiency test item and an assigned value of a CRM
g	Number of proficiency test items tested in homogeneity checks
m	Number of repeat measurements made per proficiency test items
p	Number of participants taking part in round of proficiency test schemes
s_r	Estimate of repeatability standard deviation
s_R	Estimate of reproducibility standard deviation
s_s	Estimate of between sample standard deviation
s^*	Robust estimate of the participants standard deviation
s_w	Within-sample or within-laboratory standard deviation
σ_{pt}	Standard deviation for proficiency assessment (SDPA)
σ_r	Repeatability standard deviation
σ_R	Reproducibility standard deviation
u_{hom}	Standard Uncertainty due to difference between proficiency test items
u_{stab}	Standard Uncertainty due to instability during the period of proficiency testing
u_{trans}	Standard Uncertainty due to instability during transport conditions
$u(x_i)$	Standard Uncertainty of a result from participant *i*
$u(x_{pt})$	Standard Uncertainty of the assigned value
$u(x_{ref})$	Standard Uncertainty of a reference value
x	Measurement Result (generic)
x_{char}	property value obtained from characterization (determination of assigned value)
x_i	Measurement result from participant *i*
x_{pt}	Assigned value
x_{ref}	Reference value for a stated purpose
x^*	Robust estimate of the participant mean
$\bar{x}$	Arithmetic average of a set of results
w_t	Between test portion range
z	Score used for proficiency assessment (absolute value ±)
z'	Modified z-score that includes the uncertainty of the assigned value, commonly pronounced as z-prime
δ_E	Maximum permissible error criterion for differences
δ_{hom}	Errors due to difference between proficiency test items
δ_{stab}	Errors due to instability during the period of proficiency test items
δ_{trans}	Errors due to instability during under transport conditions

Abbreviations

ACV	Absolute compliant value
Amd.	Amendment
APAC	Asia Pacific Accreditation Cooperation
CRM	Certified Reference Material
DP	Decimal Point. This indicates the number of decimal places to which participants should report their measurement results.
e.g.	Stands for exempli gratia and means “for example”
etc.	Is a Latin expression that is used in English to mean "and other similar things"
E	Expert
Ex	One that formerly held a specified position or place
GUM	Guide to the Expression of Uncertainty in Measurement
HDPE	High-density polyethylene
IEC	International Electro technical Committee
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemists
Lab	Laboratory
MRA	Mutual Recognition Arrangement
MU	Measurement uncertainty
NABL	National Accreditation Board for Testing and Calibration Laboratories
NIST	National Institute of Standards and Technology
NPL	National Physical Laboratory
NMI	National Meteorological Institute
OPI	Overall performance index
PS	Performance score
PT	Proficiency Testing
PT item	Proficiency Testing Item or Sample for analysis of determination of measurands oranalytes
PT provider	Proficiency Testing Provider
PT coordinator	Proficiency Testing Coordinator
PT scheme	Proficiency Testing Scheme (Proficiency Testing Program)
SI	International System of Units
w.r.t.	acronym for with respect to
Units	This indicates the units used for the assessment of data. These are the units in which participants should report their results. For some analytes in some schemes participants may have a choice of which units to report their results, however, the units stipulated in this scheme description are the default units to which any results reported using allowable alternative results will be converted to.

Any other symbol or abbreviation used is described at the first instance. For more details refer to ISO 13528: 2015 or ISO/IEC 17043: 2010

In this document use of ‘shall’ indicates a requirement, ‘should’ indicates a recommendation, ‘may’ indicates a permission and ‘can’ indicates a possibility. In all documents use of “masculine” gender shall include the “feminine” gender and “singular” shall include “plural” wherever relevant to the context, and vice versa.

1.0	**Introduction:**

	Envirocare Labs Pvt. Ltd. PT Cell herein thereafter referred as ENVIROCARE LABS PT CELL facilitates knowledge sharing and skill development by providing innovative capacity building programs to testing laboratories. One of the key activity in this regard includes providing PT schemes for ensuring validity of results and monitoring competence of personnel in accordance with clause 7.7 & 6.2 of ISO/IEC 17025:2017 respectively with the objective of promoting confidence in the operation of laboratories and generate valid results.
2.0	**Purpose and scope of proficiency testing:**
	PT is defined as the evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons. ENVIROCARE LABS PT CELL organizes various types of schemes as defined in ISO/IEC 17043:2010, both quantitative and qualitative to provide insight into competence of laboratories performing the testing or sampling by way of comparing it with that of their peer group. A typical feature of schemes is to help labs in improving their performance. For more details refer to PT calendars. The schemes are conducted in line with ISO/IEC 17043:2010, ISO 13528:2015, NABL-181 and customer requirements.
3.0	**Scheme organisation:**
	PT schemes are organized by ENVIROCARE LABS PT CELL and PT coordinator is Dr. Nilesh Amritkar The address of PT provider is as below: Envirocare Labs Private Limited PT Cell **A-7, A-8, Enviro House, MIDC Main Road, Wagle Industrial Estate, Thane (West), 400604 |+91-9167702413| pt@envirocare.co.in**
4.0	**Name/code for PT schemes:** Please refer to PT calendars
5.0	**Subcontracted activities:**
	ENVIROCARE PT CELL uses a competent subcontractor ISO/IEC 17025 accredited laboratory whose scope is relevant to the scope of PTP for the purpose of preparation, homogeneity and stability testing and or temporary storage of PT items.
6.0	**Participation in a PT scheme:**
	Participation is given to organizations only. Both accredited and non-accredited laboratories are eligible for participation. Labs shall use calibrated equipment's/reference material in line with NABL 142 for testing the parameters for which participation is done irrespective of status of accreditation. In order to participate in a PT scheme, participants shall fill the registration form and submit to PT provider by email. Submission of registration form may be exempted by PT provider on its sole discretion under any special circumstances as deemed fit by PT provider and registration may be accepted via other means. The decision of PT provider is final in this regard. Registration is on first cum first basis. Participants who register late may be shifted to next PT scheme. PT provider may suggest/ request for participation in a specific scheme for meeting the minimum participants requirement or otherwise. PT provider may also restrict participation depending upon the nature of the scheme and issues related to availability of infrastructure support or any other issues specific to the scheme. Registration for a scheme normally closes on the date of registration mentioned in PT Calendars unless the scheme is extended. However, PT provider can admit participants who fail to register by the given deadline and may allow registration as long as sample preparation has not started or extra samples can be provided from the lot. The decision of PT provider is final in this regard.

	ENVIROCARE PT CELL ensures that a minimum of 8 laboratories participate in any PT Scheme where either assigned value, x_{pt} or evaluation criteria (such as σ_{pt}) or both are determined on the basis of consensus value of participants. However, when these two parameters are not determined on the basis of consensus value approach, there is no restriction on the number of laboratories in the PT Scheme. Minimum number of participants are 3 for running a PT scheme where qualitative parameters are there and results are reported as present/absent etc. or schemes as on sampling. Parameters in a PT scheme are decided based on customer requirements and aligned as per regulatory standards or product protocols. The technical feasibility as interferences and related issues including costs and PT item handling issues also play a role in deciding parameters covered in a scheme. Participants do not necessarily have to analyse/sample all the measurands (analytes/parameters) in a PT scheme. ENVIROCARE PT CELL team can advise on which PT schemes are most suitable for participants and help draw a 4-year PT plan. ENVIROCARE PT CELL, however, tries it best to provide PT schemes and incorporate parameters to deliver optimum solutions to laboratories in terms of cost without compromising quality. Participation in PT scheme is given in good faith. ENVIROCARE PT CELL may refuse participation to testing lab of a competitor PT provider or any other organizations due to issues of conflict of interest, involvement in collusion, engagement in activities deterrent to the interests of PT provider, bringing disrepute to PT provider or any other reason as deemed fit. The decision of PT provider is final in this regard. Further, if it is found that any participant is misusing registration or making any other false claims to meet the requirements of accreditation or regulatory bodies and subsequently drop their registration or do not respond or does not make payments, the PTP has a right to bring the same to the notice of the concerned accreditation or regulatory body and disclose the identity of such participant including taking any other appropriate action as deemed fit.
7.0	**Fees:**
	The fee for taking participation in a PT scheme are provided in PT calendar. Programs may have to be re-run due to problems in homogeneity and stability or any other technical or unavoidable circumstances, including requisite numbers of participants are not available for a particular scheme by the registration closure date. Fee is refunded except for tax part only when scheme cannot be run for more than 18 months from date of closure of registration. Refund of fee else otherwise is subject to sole discretion of PT provider on such grounds as found to be satisfactory.
8.0	**Use of advisors and advisory group:**
	ENVIROCARE PT CELL uses an advisory committee titled 'Steering Committee' that have on board a range of stakeholders in line with clause 4.4.1.4 / 4.4.1.5 of ISO/IEC 17043:2010 as per the requirements of the relevant PT schemes such as (I) Personnel from regulatory authorities (II) Personnel from institutions of repute (III) Personnel from laboratories (IV) Personnel from subcontractor (V) Independent experts well versed in subject matter and or ISO/IEC 17025 and or ISO/IEC 17043 and or ISO 17034 etc. Where relevant to a PT scheme persons association is declared to registered participants.
9.0	**Proficiency test items:**
	PT scheme design discusses selection of the measurand(s) or characteristic(s) of interest, including information on what the participants are to identify, measure, or test or sample in the specific PT scheme

	as well as description of the range of values or characteristics, or both, to be expected for the PT items. Relevant information is available to participants initially in PT calendars. Registered participants are provided all relevant information subsequently in detail during the operation of the PT scheme. The determinants in PT items may either be at natural levels, incurred or spiked at a particular formulation level and or manipulated. The range of PT items can usually be varied from round to round in order to be realistic and challenging. A parameter can be removed/added in a scheme or range of testing may be varied at the time of running; This may be due to operational reasons; new developments; due to nature of product or matrix; homogeneity or stability issues and or reasons beyond control. PT provider may also add additional not-accredited parameters in a scheme in line with NABL-181 / NABL-163. These are clearly identified. Report is issued for such parameters in line with NABL-133. The non-accredited parameters are brought under accreditation in next cycle of reassessment by PT provider or otherwise as deemed fit. Decision of PT provider in this regard is final. Registered participants are informed as applicable.
10.0	**Homogeneity and Stability:**
	For homogeneity ten replicates (g ≥10) at random are used for initial PT scheme or during trials. It is done prior to distribution of the PT items to the participants and after the PT items are packed and unique ID numbers are given. For subsequent schemes, the number of proficiency test items included in homogeneity check is reduced to six or four replicates over a period based on experience under repeatable conditions. All measurands in a program are analysed irrespective of replicates used. The PT items are ensured to be sufficiently stable for the duration of the program. Stability checks involve establishing suitable transport and storage conditions initially that may involve combination of simulated conditions, expert advice and assessment of historic data as applicable and documented in PT design. Stability check may include comparing PT items retained at the PT provider's premises with PT items subjected to shipping and return. Studies based on exposure to reasonably foreseeable conditions of transport may also be used. Stability is ensured by checking for stability every time over the duration of PT scheme by selecting a minimum of six replicates and testing two replicates at the conclusion of the PT testing scheme and compare these with one replicate tested prior to run. The homogeneity and stability are established initially using expected σ_{pt} chosen from literature or expert experience, by experience from previous PT schemes or predicted from model by Thompson based on Horwitz equation and establishing $s_s \leq 0.3\ \sigma_{pt}$ for homogeneity and Homogeneity Average (X)- Stability Average (Y) ≤ $0.3\ \sigma_{pt}$ for stability. This is subsequently revalidated using σ_{pt} derived from participants algorithm. The PTP also uses Cochran's C Test Cmax< C critical (implying no evidence of analytical outliers); Test for Sufficient Analytical Precision $s_{w\leq}\ \sigma_{pt}$ and Test for Acceptable Between Sample Variance s_s< SQRT C for ensuring homogeneity. In case of non-compliance, heterogeneity and or instability of the PT items is considered for evaluating the performance of participants as per procedures. In these circumstances further explanation shall be given in the report. The sampling schemes may not require proficiency test items as usual. These are conducted by way of case studies. Participants are asked to perform sampling on the given case study and correct application of a sampling method to obtain a representative sample is evaluated. Such schemes do not involve homogeneity and stability testing.

11.0	**Potential major sources of errors involved in PT schemes offered:**
	Potential major sources of errors are discussed in PT design for each PT scheme. PT design is improved from time to time on the basis of experience gained in running the PT schemes. The errors may be related to issues with selection of PT items, PT item preparation, homogeneity, stability, packing, environmental factors etc. and vary scheme wise. Where, prior to dispatch, the homogeneity and or the stability is not acceptable, the PT items are not distributed to participants. If this may cause a delay in the distribution of PT items, participants will be informed. There are chances, that issues with PT items may not be identified until after distribution. If this happens this is considered when assessing participants performance. The outcome will vary depending upon the situation but may involve reporting of evaluation scores for information only, or the provision of replacement PT items. Under such circumstances, relevant details are provided to participants and scheme may be rerun or action taken as per ISO 13528:2015.
12.0	**Packaging and transportation:**
	PT items are sent in appropriate packaging and under conditions intended to maintain the integrity of the PT item during transit. The packaging guidelines as given in standard methods or on the basis of experience and trials are followed in choosing a suitable packaging. The PT item supplied is sufficient for the analysis required, including any reanalysis where permitted by the PT scheme design. On receipt of PT item, participants are asked to fill the PT item receipt acknowledgment form and email scanned copy (pdf format) to PT provider within two days from the receipt of the sample. This is to bring to notice of PT provider that it has received the PT item intact. If PT item is received damaged than PT provider may issue another item subject to its satisfaction of genuineness of the issue after due diligence as per its procedures. Decision of PT provider in this regard is final. Once PT item have been delivered, ENVIROCARE PT CELL cannot be held responsible if it subsequently fails to reach the correct personnel or are not stored under the recommended conditions. Delays in the dispatch of PT item may occasionally arise. Dispatch of a PT item may be delayed sometime due to unforeseen circumstances, participants are informed and updated regularly. PT provider cannot be held responsible for the delay in delivery of PT items due to un-foreseen circumstances or to causes beyond their reasonable control, including but not limited to acts of God, war, riot, embargos, and acts of civil or military authorities, fire, floods, energy, labour or material. Appropriate decision is taken after discussion with the participants. For PT schemes as on sampling packaging and transportation of samples is not applicable.
13.0	**Reporting of results:**
	Results should be reported clearly, in the format titled 'Result submission sheet' and provided to registered participants. The handling and analysis instructions as given along shall be followed by participants.

Once submitted and received by PT provider, results cannot be amended unless allowed by PT provider for the reasons to be documented prior to due date of submission. This is, however, strongly discouraged. PT provider can consider an appeal from participant in this regard if there are valid reasons. Decision of PT provider in this regard is final.

Results cannot be altogether amended after the due date of submission for any reason. PT provider although can seek resubmission of result sheet without any change in result values prior to circulation of draft result sheet to avoid any misinterpretations at its own end e.g. from mentioning of wrong lab code allotted, changes done in reporting format etc.

After the completion of analysis or sampling, the results sheet or records desired as per instructions given only is to be sent back by participants on email provided as a scanned attachment in 'PDF' format within stipulated timeline, unless extended due to fall of holidays or any other circumstances beyond control as documented. The participants are advised to keep record of all calculations, graphs and other raw data to demonstrate that testing is done by them in their lab. The PTP is not seeking this information along with test reports but may ask for the same if required. The said information may also be verified by regulatory authorities or accreditation bodies during their audits. The said information is also useful in doing root cause analysis. The failure of laboratory to provide above information any time as asked by PTP may lead to 'Results Not Considered' / Cancellation of participation and decision of PTP in this regard shall be final.

Results reported in a semi-quantitative manner as "less than" or "more than" a value, or results reported as zero except where it may be appropriate to report a result of zero together with qualitative results, will be collated and listed in the PT round report as Results not Considered' but shall not be included in the statistical analysis including any results that are tagged i.e. any comments are given.

Results may be rounded up or down for the purposes of reporting and may not be identical to your original reported result. The effects of rounding may also mean that occasionally percentage totals do not add up exactly to 100%.

It should be noted that ENVIROCARE PT CELL cannot be held responsible for the misinterpretation of results submitted for a PT scheme, e.g. the use of a comma can be ambiguous and could be interpreted as either a decimal point or a thousand separators. The participants are advised to type the results rather writing by hand.

Summary of test results of participants as used by the PT provider are made available in draft result sheet, except for sampling schemes, prior to release of final report. Draft result sheet is submitted only to verify that data read and entered by PT provider is correct and there are no readings or typing errors on PT provider's part. The data values are, however, rounded to the decimal points as per standard practice laid down by IS e.g. if reporting decimal point (DP) asked is 2 and lab report results as 23.445, then it is recorded 23.45 and if lab reports as 23.444 then it is recorded as 23.44. No requests for any change in results are accepted except if there are typing and reading errors at PT providers end. Participants are asked to crosscheck and confirm in two days from the date of sending email and no claims are entertained later.

	PT provider does not provide draft result sheet or final report to participants who have not cleared the payment. In such a case, PT provider is not responsible if subsequently it is found that any results provided by participants are entered wrong due to lack of cross checking or otherwise. The ENVIROCARE PT CELL also cannot be held responsible for **'Results Not Considered'** due to above or any other reasons as not following instructions; following methods not allowed in the PT scheme or choosing sampling scenarios that are different to case studies given or submitting information by manipulating formats or submitting partial information in case of schemes as sampling. The data values are however rounded to the decimal points as per standard practice laid down by IS e.g. if reporting decimal point (DP) asked is 2 and lab report results as 23.445, then it is recorded 23.45 and if lab reports as 23.444 then it is recorded as 23.44 For PT schemes as on sampling instead of 'Result submission sheet' information may be asked in other formats as relevant to the PT scheme. In addition, participants are also asked to submit certain information in formats used in their laboratory.
14.0	**Test or sampling methods:**
	Participant shall use a specified method in accordance with the design of the PT scheme as given in handling and analysis instructions. The participants should use a different test method only with prior permission in writing e.g. if they want to validate a method; The risk of results not being considered or failure in PT scheme in such a scenario lies totally with participant Methods based on same principle and methodology in any other standard method, however, can be used. Participants to use latest methods with amendments if any. For some parameters in an area there may be large variation in test methods followed by labs due to non-availability of standard methods or otherwise; in such scenario's PT provider may provide specific instructions for the purpose of uniformity. The above is also applicable in case of PT schemes on sampling.
15.0	**Timeline:**
	Timeline is given in PT Calendars. ENVIROCARE PT CELL endeavours to follow timeline and complete schemes in time. PT scheme can be run earlier/postponed or two schemes may be merged; This may be due to operational reasons; new developments; due to nature of product or matrix; homogeneity or stability issues and or reasons beyond control. There may be changes in timeline of PT schemes due to holiday(s). Registered participants are informed.
16.0	**Prevention of collusion and falsification:**
	Collusion is strongly discouraged.

PT providers can take number of steps to minimize the chances of collusion among participants as well as to ensure confidentiality. The participating laboratories are given code numbers; The assigned values are not made known to anyone before the report is issued. PT scheme design may be varied. However, PT provider is not responsible for preventing collusion.

Collusion is sole responsibility and risk of participating lab.

17.0 Analysis of data and performance assessment:

ENVIROCARE PT CELL uses consensus value of laboratories in order to ensure the reliability in the values of x_{pt} or σ_{pt} or other evaluation criteria determined. While evaluating the performance of participants for each test parameter — the distribution of the results used for determination of both x_{pt} and σ_{pt} are examined to verify the presence of any odd values (obvious blunder due to decimal point errors, use of wrong PT items by participants and reporting of results in a different unit erroneously). ENVIROCARE PT CELL identifies such odd values by subjecting the data to any one of the following methods (i) Grubbs test or (ii) Results that deviate from the x by more than $\pm 5\sigma_{pt}$ or (iii) Results that deviate from the x by more than 2 times δ_E (Maximum Permissible Error) fixed by PT provider for the concerned test. In such cases the odd value identified are not included for determination of both x_{pt} and σ_{pt} by consensus value approach, but performance of all participants is evaluated using the same criteria.

However, when participants report results as zero or non-numerical results e.g. <0.1 or >1, nil, BDL etc. or even where some results are qualified by any symbol or given with any remarks etc.; then such results are not considered for determination of x_{pt} and $\sigma_{pt.}$ Evaluation of such participants is also not done.

PT provider calculates reports following summary and performance statistics using robust analysis: Algorithm A as given in ISO 13528:2015:

Summary statistics	**Performance statistics**
Number of evaluated results	Participants assigned value
Number of excluded results- Blunder	Uncertainty of assigned value
Average	SDPA (σpt)
Robust average	Total number of Scores
Standard deviation	Number of scores z ≤ 2
Robust standard deviation	% Satisfactory performance
Range- Result lowest	Number of scores 2 < z < 3
Range- Result highest	% Questionable performance
	Number of scores z ≥ 3
	% Unsatisfactory performance

Where performance is based on the participants reporting the same result as the assigned result e.g. absent or present, the scoring is done as colour coding of green (satisfactory) if it exactly matches the assigned value or red (unsatisfactory) otherwise (11.4.3 ISO 13528:2015)

For sampling schemes, participants are assessed as per section-11 ISO 13528:2015.

18.0 Assigned values (x_{pt}):

The assigned value x_{pt} is the value selected as being the best estimate of the 'true value' for the parameter under test. A consensus value of participants is taken by PTP as assigned value. When the assigned value is determined from the consensus value of participant results robust statistical methods are used for

	calculation of the consensus value. The standard uncertainty of assigned value $u(x_{pt})$ is calculated using the following formula: $u(x_{pt}) = 1.25 \times \frac{s^*}{\sqrt{p}}$ The $u(x_{pt})$ is compared with the following criteria to ensure compliance: $u(x_{pt}) \leq 0.3\ \sigma_{pt.}$ In case of non-compliance with the above criteria, performance evaluation is not done using z-score but using z'-score (z-prime) by taking into consideration the standard uncertainty of the assigned value also in the denominator. The validity of the assigned value for measurands or characteristics on interest determined in PT items is done as. Determine the estimate of the reference value of the PT items determined independent of the participants results, x_{ref} (for example homogeneity average of the concerned measurand determined by an accredited laboratory which is not a participant i.e. laboratory that has done homogeneity or stability testing). Calculate the difference between homogeneity average and consensus average of participants and ensure that this is less than 2 times u_{diff} where $u_{diff} = \sqrt{[\ u(x_{pt})^2 + u(x_{ref})^2]}$ The assigned value is traceable to SI units in line with requirements of ISO/IEC 17025: 2017 read along NABL-142 and the availability of traceable calibrations and reference materials. For qualitative schemes, assigned value is given as per section-11 ISO 13528:2015. When the test results reported on categorical (nominal) scale such as identity of adulterants present in milk, **mode** (most common observation) reported by participants is used as the **assigned value.** Each participant laboratory which has reported the result should be marked as acceptable **(or scored as a success)** if it exactly matches the assigned value. Otherwise, the participant laboratory should be marked as unacceptable, or given an **adverse performance score.** Where a reliable independent estimate (denoted x_{ref}) is available, for example from knowledge of preparation or from a reference value, the consensus value x_{pt} should be compared with x_{ref} For sampling PT schemes assigned values are based on expert opinion and consensus.
19.0	**Standard deviation for proficiency assessment (σ_{pt}):**
	Initially expected or target σ_{pt} can be chosen from literature or expert experience, by experience from previous PT schemes or predicted from model by Thompson based on Horwitz equation. In the PT scheme, the general model is used as per the formula stipulated below: $\sigma_{pt} = 0.22 \times c$ when c is less than 1.2×10^{-7} $\sigma_{pt} = 0.02 \times c^{0.8495}$ when $1.2 \times 10^{-7} < c < 0.138$ $\sigma_{pt} = 0.01 \times c^{0.5}$ when c is more than 0.138 where c is the concentration of the analyte Subsequently, the robust standard deviation of the participants results - s* is treated as σ_{pt} and the same is determined by using Algorithm A as given in ISO 13528:2015. σ_{pt} is not applicable for qualitative schemes.

20.0 Performance evaluation:

Performance evaluation is conducted in terms of z-score which is calculated using the following formula:

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

It is possible for the z-scores published in this report to differ slightly from the z-score that can be calculated using the formula given above. These differences arise from the necessary rounding of the data prior to its publication in report.

When $u(x_{pt})$ is not meeting the criteria: $u(x_{pt}) \leq 0.3\ \sigma_{pt.}$ performance evaluation is done using z'-score (z-prime) by taking into consideration the standard uncertainty of the assigned value also in the denominator:

$$\text{z-score} = \frac{(x_i - x_{pt})}{\sqrt{[(\sigma_{pt})^2 + u(x_{pt})^2]}}$$

Interpretation of z-score / z'-score

For quantitative examinations, the following interpretation is given to results

|z-score|	**Interpretation**	**Coding**
|z-score| ≤ 2.0	Satisfactory result	z-score Normal Black **z'-score (z-prime) Dark Blue** **z'-score** is only indicative p<8 **Dark Magenta**
2.0 < |z-score| <3.0	Questionable result (straggler)	**Bold Black**
|z-score| ≥ 3.0	Unsatisfactory result	**Bold Red**
No score	See below	--

Where |z| denotes the absolute value of the z-score. When an outlier is identified the sign of the z-score indicates whether the result is too high (positive z-score) or too low (negative z-score).

Performance scores will not be given for the following:

RNS - Results not submitted (Results not reported by laboratory) – No score given '--'
RNC - Results not considered (Where participants in spite of instructions given- Report results as zero or non-numerical results e.g. <0.1 or >1, Nil, BDL etc. or even where some results are qualified by any symbol or given with any remarks etc.; these results are not considered for performance evaluation) – No score given '--'

In some cases, performance scores may not be provided or may be provided but with coding and or colour as below:

$$ Where number of participants for one or more measurands in a PT scheme due to 'Results Not submitted' or 'Results Not Considered' or due to removal of blunders are reduced to less than 8, in such a case the uncertainty can be high. Hence, performance evaluation given in terms of **z'-score** is only **indicative** and not confirmatory (indicating that scores need to be interpreted with caution).

B -Obvious odd values by subjecting the data to any one of the following methods (i) Grubbs test or (ii) Results that deviate from the *x* by more than $\pm 5\sigma_{pt}$ or (iii) Results that deviate from the *x* by more than 2 times δ_E (Maximum Permissible Error) fixed by PT provider for the concerned test.

In some schemes there may be situations as:

- in case of non-compliance, heterogeneity and or instability of the PT items is considered for evaluating the performance of participants.
- Due to large heterogeneity in lab results initial σ_{pt} derived from Horwitz equation is used as per expert advice to calculate and report z-score

In these circumstance's specific identification of scores and further explanation shall be given in the report.

For qualitative results, where satisfactory performance is based on the participants reporting the same result as the assigned result e.g. Absent or Present, the scoring is done as colour coding of green (satisfactory) if it exactly matches the assigned value or red (unsatisfactory) otherwise (11.4.3 ISO 13528:2015)

For PT schemes on sampling, the features for performance evaluation are based on Section-11 of ISO:13528:2015

a) expert consensus, where the advisory group, or other qualified experts, directly determine whether reported results are fit for their intended purpose; agreement of experts is the typical way to assess results for qualitative tests.
b) fitness for purpose, predetermined criteria that consider, for example, method performance specifications and participants' recognized level of operation.

ENVIROCARE PT CELL does the evaluation using "Overall Performance Index (OPI) Model" which makes uses of a number of latent multiple performance indicators- termed as "Key Criteria". OPI is defined as the overall evaluation of individual key criteria indicators. The obvious strength of this approach is that it involves the study of operational performance of individual sequential steps adopted by lab according to standard procedure.

Operational performance of sequential steps is determined on the basis of assigned score by expert consensus w.r.t clause 11.4.3 of ISO 13528:2015 as:

Assigned Performance Score (PS) by Expert Consensus	Remarks
3	Acceptable (Full compliant)
2	Followed to large extent

1	Followed to some extent
0	Unacceptable (Non-compliant)

The performance scores in sampling scheme and data interpretation scheme are converted to Overall Performance Index (OPI) to reflect the overall performance of the laboratory as below:

OPI = [Total PS obtained by Lab ÷ (n x ACV)X Absolute Complaint Value for PS

Absolute Compliant Value (ACV) for PS =	3
n=	No. of Key Criteria Indicators
Total PS obtained by Lab=	Sum of Individual Performance Scores obtained (0 or 1 or 2 or 3) against each Criteria

The OPI interpretation is as:

OPI ≤ 0.75	Unsatisfactory	
0.75 < OPI ≤ 1.50	Questionable	
1.50 < OPI ≤ 2.25	Satisfactory	
2.25 < OPI ≤ 3.00	Good	

Unsatisfactory	Needs comprehensive action / training and validation of competence on test parameter
Questionable	Needs thorough action / training on key critical parameters
Satisfactory	There are areas for improvement in key critical parameters
Good	No Further action, except if any individual performance score is less than equal to1.5, the issues in key critical parameter be addressed

21.0 Confidentiality:

Identity of participants is kept confidential by unique coding. Participants may be given the same code number in different PT scheme by chance. ENVIROCARE PT CELL has a continuing obligation to identify and report any actual or potential conflicts of interest arising during the performance of this program. If an actual or potential organizational conflict of interest is identified, ENVIROCARE PT CELL will immediately make a full disclosure to the appropriate parties.

The information provided by participants to PT providers is kept confidential:

- When PT provider is required by law or authorized by contractual arrangements to release confidential information, the consent of participating laboratory is taken, unless prohibited by law.

	○ As per NABL-181 Issue-2 Dated 5.2.18 the records of PT program participation shall be accessible to NABL if so desired by it. ○ Participants can also be asked to waive of confidentiality within the PT scheme for the purpose of discussion and mutual assistance or as required due to very nature of PT scheme ○ PT provider shall share data with organizations providing recognition e.g. NABL as part of its audit or assessment requirements. ○ PT provider may also use data and experience from operation of PT schemes for the purpose of further developments including, but not be limited to, use for research publications or conferences, however, identity of participants shall be kept confidential ○ The identity of any subcontractor used is not disclosed in report to ensure confidentiality.
22.0	**Post programme support, comments on performance and recommendations:**
	In case of an outlier participant laboratory have to do root cause analysis, take corrective action and identify improvements or risks in line with ISO/IEC17025:2017. Outlier in proficiency testing is not a negative issue, rather the purpose of entire exercise is to help laboratory monitor and identify the problem areas and in turn help improve laboratory's performance. The root cause and corrective action is to be completed within one month as per NABL 163. A sample root cause cum risk analysis format is provided along with the report. Laboratories that want further specific assistance for improving their performance may discuss and same can be undertaken as mutually agreed upon using skype, email, and or telephone. However specific on-site inputs may involve additional cost depending upon the nature of inputs desired. Once corrective action has been taken by a laboratory, in order to establish effectiveness of corrective action taken PT provider encourages re-participation in outlier measurands for PT item by offering the PT scheme at a nominal cost. More details are provided while providing the report.
23.0	**Feedback, complaints and appeal:**
	All due diligence is exercised in conducting the PT scheme yet if a participant has any concern about any aspect of PT scheme, they should contact undersigned: **Quality Manager** Envirocare Labs Private Limited PT Cell If a complaint is received, an investigation is conducted in accordance with ENVIROCARE PT CELL management system and the participant is conveyed of the outcome. Complaint can be filed within 15 days from the date of release of final report. Appeal can be made on adverse decisions including but not limited to as (I) Denial of registration in PT scheme (II) Denial of provision of additional sample if a sample is found damaged or unfit for analysis (III) Denial of extension in time period for submission of results (IV) Decision taken by PT provider as 'Results not Considered' and (V) Denial to release the PT report (VI) Denial to refund the payment if PT scheme is not completed within 18 months from date of closure of registration.
24.0	**PT report:**

	The report is released by PT provider in soft in pdf format only (Controlled Copy). Printed copies of this report including scans of coloured prints made thereafter are uncontrolled. Disclaimer(s) ▪ The report is produced by PT provider in good faith and in accordance with best industry practice. Neither ENVIROCARE PT CELL nor any individual or any other organization involved accepts any liability whatsoever from application or use of information contained therein or from any inadvertent error in the information in report including without limitation indirect or consequential loss or damage. This statement does not affect your statutory rights. ▪ Comments or recommendations in PT report does not construe to be any legal or technical advice to anybody. PT provider is also not soliciting any action based on it. • The parties agree that any matters are governed by Indian law. All disputes are subject to original jurisdiction of Courts in district Thane, Maharashtra India ▪ Use of reports: The report is strictly for use by participant laboratory for (i) to monitor its performance and, if applicable, to improve the laboratory's activities and or (ii) to show to the laboratory's customers, regulatory authorities and organizations providing recognition as part of audit or assessment requirements.PT report in part or whole shall not be given by participant laboratory to anybody for any reason other than stated above without taking the permission of PT coordinator in writing. ▪ If recipient is not the intended individual or organization for the report, it has been sent to you by mistake. Do not circulate the report or its contents further and inform to Envirocare PT cell ▪ PT provider reserves the right to make any modifications or alterations in the report as may be required from time to time without any prior notice. All affected participants are informed when an issue is detected
25.0	**Other important information:**
	Participants are requested to go through all related documents as PT calendar, registration form, terms and conditions for participation, NABL scope and handling and analysis instructions and clarify if there are any doubts any time. All these documents are in public domain including website All clarifications must be taken in writing on email, conclusions drawn from telephonic discussions are at participants own risk. PT samples are sent on address given in registration form and all communications are done on emails given in registration form.

	ENVIROCARE PT CELL is not be responsible for any lapses due to incomplete or illegible registration forms / non-payments or delay in receipt of payments or information on account of problems with email / internet / online transactions and similar issues. We acknowledge all emails within 72 hours (3 Days). In case no acknowledgement is received and or no information is received as per timeline provided for the PT scheme please contact on telephone and or email. Communications are through email only. It is for participating laboratory to update its contacts with PT provider if there are any changes. We are not responsible for any miscommunication due to change in staff of the laboratory or otherwise. In any other scenario arising out of unexpected issues the decisions are taken in line with ISO/IEC 17043:2010 and ISO 13528:2015 and the PT design is amended for future schemes to address the issue and participants are informed.