

Protocol for Proficiency Testing

Issue No. 2, September 2016

1. Introduction

Target Laboratory Systems was established in 2004 as a training and consultancy provider for all types of laboratories. In 2009, Target Laboratory Systems provided its first proficiency testing scheme in water analysis.

1.1. Proficiency Testing

Proficiency Testing is the evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons as defined in ISO/IEC 17043:2010. The primary aim of proficiency testing is to provide a quality assurance tool for individual laboratories to enable them to compare their performance with similar laboratories, to take any necessary remedial action and facilitate improvement.

1.2. Importance of Proficiency Testing

Proficiency testing is one of the powerful tools to assess laboratory competence. Acceptable performance must be demonstrated prior to accreditation being granted and for ongoing maintenance of accreditation as requested by ISO/IEC 17011. Proficiency testing enables laboratories to monitor their performance over time. Longer-term trends can therefore be identified, and any necessary corrective action considered.

2. Organization of Schemes

2.1. Organization

All the PT schemes organized by Target Laboratory Systems are organized in agreement with international principles and in compliance with ISO/IEC 17043:2010.

A team of experts is designated as necessary for each PT scheme that are responsible for the overall technical aspects and professional delivery of our PT services.

2.2. Confidentiality

Target Laboratory Systems treats all information provided from the laboratories as well as their scores as confidential data. The laboratories entities are not revealed in the PT reports and results are not disclosed to anyone unless explicitly requested by the participant laboratory. In exceptional circumstances, if a regulatory authority requires proficiency testing results to be directly provided to the authority by the proficiency testing provider, Target Laboratory Systems notifies the affected participants in writing

2.3. Typical Timetable

Target Laboratory Systems organizes its PT schemes in accordance with its predetermined schedule that is announced annually on its website and announced to potential participants by email.

2.4. Management System

Target Laboratory Systems maintains and implements a management system that complies with the requirements of ISO/IEC 17043.

2.5. Subcontractors

Target Laboratory Systems does not currently have laboratories of its own. Test materials are obtained from the market or prepared and tested for homogeneity and stability by subcontractors.

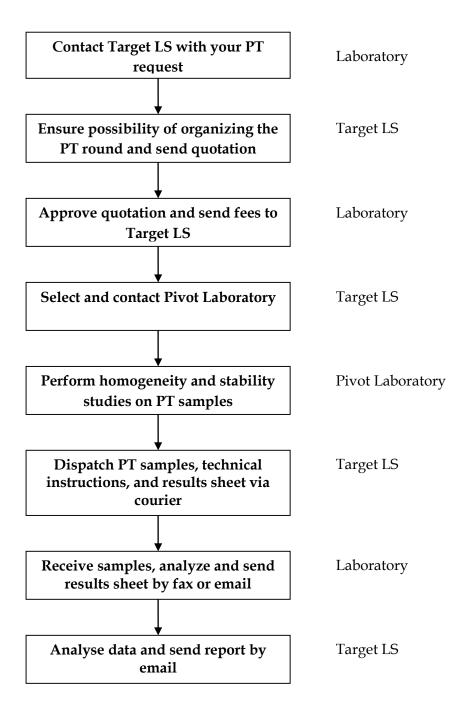
3. Participation in Schemes

3.1. Enrolment and Fees

Target Laboratory Systems PT schemes are announced on the company's website and are communicated to potential participants through email. Participants contact Target Laboratory Systems by phone, fax or email to apply for the required scheme. A confirmation email is sent to the participant by the company staff.

Details on fees are communicated to participants through the announcement emails and are available to participants upon request.

3.2. The Process



4. Proficiency Testing in Testing Laboratories

4.1. Introduction

Target Laboratory Systems uses subcontractors for most of its PT schemes to prepare and/or ensure the homogeneity and stability of the testing samples. All other activities are undertaken by Target Laboratory Systems staff in collaboration with Technical Freelancers as required.

In the majority of PT schemes conducted by Target Laboratory Systems, subdivided samples (taken from a bulk sample) are distributed to participating laboratories which test these concurrently. They then return results to Target Laboratory Systems for analysis.

4.2. Program Design

Once a program has been selected, a small Advisory Committee is formed. This group usually comprises one or more Technical Advisors (Freelancers) and Target Laboratory Systems staff including the Technical Manager.

The Advisory Committee takes charge of the following:

- Planning of the PT Scheme including identification of tests to be conducted, range of values to be included, test methods to be used and number/design of samples required;
- Preparation of paperwork (instructions and results sheet) particularly with reference to reporting formats, number of significant figures/decimal places to which results should be reported and correct units for reporting;
- Identification and resolution of any difficulties expected in the preparation and maintenance of homogeneous PT samples, or in the provision of a stable assigned value for a proficiency test item;
- Technical interpretation in the final report and in some cases answer questions from participants.

4.3. Sample preparation

One of the Advisory Committee, usually the Technical Manager, will be nominated as the Program Coordinator. The Program Coordinator is responsible for organising the supply and preparation of the samples and communicates with subcontractors as necessary. Subcontractors are not used unless evaluated as competent by Target Laboratory Systems. The Program Coordinator (if different) liaises with the Technical Manager for all the details of the PT scheme.

Samples are obtained/prepared and tested to ensure their homogeneity and stability as well as being similar to samples routinely tested by laboratories. Randomly selected samples are tested to ensure that they are sufficiently homogeneous for use in the PT scheme. Whenever possible, this is done prior to samples being distributed to participants. The results of this homogeneity testing are analysed statistically and may be included in the final report.

4.4.Documentation

Communication with the customers regarding participation in PT schemes is done through the following:

Announcement Email

Announcement email is sent to potential participants according to the annual PT Plan to advise that the program will be conducted and provides information on the type of samples and tests which will be included, the schedule and participation fees.

• Instructions to Participants

Instructions sheet to participants accompany samples upon dispatch and are carefully designed for each individual program. Participants are always asked to adhere closely to them.

• Results Sheet

Results sheet also accompany samples upon dispatch. Participants are advised to report their results in these sheets to enable consistency in the statistical treatment of results.

4.5. Packaging and Dispatch of Samples

Samples are packed carefully to ensure the sample integrity and protection against any damage. Samples are transported using courier companies to ensure their delivery as early and safe as possible. In rare cases, if it is not feasible to use courier for the transportation of the samples due to their type or status, samples are dispatched by Target Laboratory Systems representative.

4.6. Receipt of Results

Participants are advised to submit their results by fax or email. A deadline for each round is identified in the dispatch letter usually allowing two to four weeks to test the samples. Delayed results can only be accepted if the data analysis process had not started.

4.7. Analysis of Data and Reporting of Results

Results received from participating laboratories are entered and analysed as soon as practicable so that the final report can be issued to participants within six weeks of the deadline of submitting the results.

Participants' results are compared to some estimate of the 'true value' to evaluate their performance by calculating z-scores. It is important to emphasize that participating in PT provides a snapshot of the whole laboratory performance at the time of the PT only.

A final report is produced at the completion of a program and includes data on the distribution of results from all laboratories, together with an indication of each participant's performance.

4.8.Scoring

Participants' results are expressed as standardized score to provide a simple and transparent methodology of interpreting laboratory performance. Scores are readily understood and can be easily compared over time.

Different approaches are used to provide the laboratories scores. The z-score approach is one of the most popular and classical approaches and is based on the mean (\overline{X}) and standard deviation (s) of the set of results.

However, these "classical" statistics can be significantly influenced by the presence of extreme results (i.e. inordinately high or low values) in the data set. Therefore robust statistics can be used and in some cases preferred. A robust alternative to the mean and standard deviation is the median and normalised inter-quartile range (IQR) respectively which are used as robust methods that ignores results labelled as outliers.

Target Laboratory Systems examines the results of the participants for outliers to decide on the need for using robust statistics. In all cases, a z-score is developed to evaluate each participant's result.

4.9.Interpreting Scores

The results of a typical chemical assessment will be normally distributed. That is to say, the majority of results will be centred on a mean value but, inevitably, some results will lie at the extremes of the distribution. The statistics of a normal distribution mean that about 95% of the data points will lie between a z-score of -2 and +2. It follows that if the participant's z-score lies outside |z| > 2 there is about a 1 in 20 chance that their result is in fact an acceptable result from the extreme of the distribution. If a participant's z-score lies outside |z| > 3 the chance that their result is actually acceptable is only about 1 in 300.

However, it is important to understand the statistical limitations of proficiency testing as an external means of quality assessment when gauging the competence of the laboratory. Successful performance in a specific proficiency testing scheme may represent evidence of competence for that exercise, but may not reflect ongoing competence. Similarly, unsuccessful performance in a specific proficiency testing scheme may reflect a random departure from a participant's normal state of competence. It is for these reasons that proficiency testing should not be the only tool used to assess the competence of laboratories.

5. References

- 1. BS ISO 13528:2015, Statistical methods for use in proficiency testing by inter-laboratory comparisons.
- 2. Thompson, M., Ellison, S.L.R., and Wood, R., 2006, The International Harmonised Protocol for the Proficiency Testing of Analytical Chemistry Laboratories, Pure Applied Chemistry, 78(1), 145-196.
- 3. ISO/IEC 17043:2010, Conformity assessment General requirements for proficiency testing.

DOCUMENT HISTORY				
#	Section	Nature of Amendment	Date	Authorization
		Elimination / Correction / Addition		
01	All	Restarting the issue number as a result of changing	16 May 16	Technical
		the issue numbering system to omit the letters		Manager
02	2.2	Include the special case of regulatory authority	30 Sep 16	Technical
		requesting results of a participant		Manager

Target Laboratory Systems

Your Laboratory Excellence.. Our Duty



154 Sector Ein, Gate Four, Hadayek Al Ahram, Giza, Egypt Telfax: (+202) 33806124 Tel: +2 (011)41521526 pts@targetls.net info@targetls.net www.targetls.net

