PT15-04 - CALA PT Program - Collaborator Laboratories
Revision 1.5 – June 17 2013

CALA
Proficiency Testing

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CALA PT PROGRAM - COLLABORATOR LABORATORIES

1.0 INTRODUCTION

CALA, as a Proficiency Testing Provider, is responsible for the design, planning, coordination, evaluation and reporting of PT. However, CALA does not physically produce, characterize or ship the samples. For this task, CALA contracts to Collaborators. The list of current Collaborators is found in PT33-*List of PT Collaborators*.

2.0 SELECTION OF COLLABORATORS

Collaborators are selected through a request-for-proposal process that is open to all interested parties. The document PT12A-*Request for Proposal for the Provision of Proficiency Testing Samples* is used as the template for any request and as the basis for any subsequent contract between CALA and the Collaborator. This documents are reviewed and modified as needed before each request for proposal or contract is issued.

Selection of a Collaborator is the responsibility of the CALA PTM. The choice of Collaborator is based on the following:

- experience and past performance in the production, validation and shipping of PT samples for the CALA program;
- experience in the production of PT samples outside of the CALA program;
- provision of technical data on the specific PT samples to be provided;
- resumes and experience of key personnel;
- accreditation to ISO/IEC 17043:2010 or equivalent or successful assessment against the appropriate parts of ISO/IEC 17043:2010; and,
- Proposed costs.

Before a decision is made to change from one Collaborator to another, the benefits of the change must outweigh the risk associated with the change.

3.0 MONITORING OF COLLABORATORS

If the Collaborator is accredited to ISO/IEC 17043:2010, formal evaluations of their competence as a PT provider is not required, although the PTM may audit any or all of their operation should any issue arise that calls into question their ability to perform as specified.

The PTM monitors the Collaborators on a continuing basis. At a minimum, this includes annual:

- Discussions with management on their knowledge of the specific PT samples they provide;
- Maintenance of resumes of management and staff who provide PT samples;
- Monitoring of non-conformances and corrective actions; and,
- Monitoring of the Inter-laboratory standard deviation of each round of PT samples to ensure comparability with past performance.

In the event the Collaborator is not accredited under ISO/IEC 17043:2010 the PTM will, where feasible, conduct a biennial assessment of the Collaborator facility that will include the preceding items and a review of conformance to relevant clauses of Sections 2 and 3 of ISO/IEC 17043:2010. PT30-*Collaborator Laboratory Checklist and Interpretation* will be used for these evaluations.

Records of assessments are kept in the Collaborator files. The PTM and the President & CEO (hereinafter referred to in this document as the CEO) will consider the cost and time involved in performing the assessment activities described above when choosing Collaborators for work with CALA.

3.1 Information Kept On Each Collaborator

- Accreditation/qualification status of Collaborator (ISO/IEC 17043:2010 and ISO/IEC 17025);
- Accreditation status of Reference laboratories (ISO/IEC 17025) used by the Collaborator are filed with each PT study;
- Rationale behind selection of the Collaborator;
- Current resumes of management and key staff;
- List of PT samples provided;
- Contract documents (Request for Proposal, Proposal, and Acceptance Letter);
- Statement that the Collaborator and Reference laboratory communicates verification analysis only with CALA;
- Signed Conflict of Interest and Confidentiality Codes;
- Records of biennial visit to the Collaborator;
- Records of any other assessments carried out; and,
- Records of non-conformances and corrective actions (filed with each study).

4.0 REFERENCE LABORATORIES

Reference laboratories provide testing for the characterization of the PT samples under the authority of the Collaborator. Because CALA is an accreditation body, and because accreditation is the primary means of assessing competence, CALA does not select the

reference laboratories that are used by the Collaborator, this is the responsibility of the Collaborator. However, CALA reserves the right to veto the use of any Reference laboratory.

All Reference laboratories must be competent for the analysis being performed in support of the CALA PT program. Accreditation to ISO/IEC 17025:2005 for the analyte in question is generally considered acceptable demonstration of competence. If the Reference laboratory is not accredited to ISO/IEC 17025, the Collaborator (or CALA) will ensure compliance with the standard through biennial assessments using A02-*Rating Guide*, A03-*Rating Guide Appendix*, and/or any other appropriate test-specific checklist. These assessments must be conducted by a person who:

- Is trained as an ISO/IEC 17025 assessor;
- Is not an employee of the Reference laboratory;
- Is an active CALA assessor; and,
- Has signed the CALA conflict of interest policy.

The assessment findings and Reference laboratory responses will be forwarded to CALA for review and final approval. The Collaborator may not use the Reference laboratory until the Reference laboratory has, in CALA's judgment, provided adequate responses to all assessment non-conformances. This approval is not to be considered the equivalent of CALA accreditation.

Reference laboratories providing data used in PT sample production must be identified.

5.0 COLLABORATOR REQUIREMENTS

General requirements for Collaborator and Reference Laboratories are found in sections 2 and 4 above. Other, more specific, requirements are found in this section.

5.1 Sample Production And Labeling

Collaborators use materials and bottles that meet analytical requirements for volume, storage, cleanliness, compatibility and sterility. Each bottle is clearly labeled with:

- Test Group;
- Sample ID (e.g., C02A-1);
- Serial number (i.e., order of production);
- Name of Collaborator; and,
- Shipping date.

Collaborators shall have documented procedures for the production, storage and shipping of PT samples. These shall detail any technical requirements for handling, materials used and storage that may affect the PT samples.

Labels for the PT samples are legible, clearly identify the PT sample and are capable of remaining on the bottles under the packaging and shipping conditions experienced by the PT samples. The packaging used is designed to prevent mechanical damage to the samples or inappropriate warming or freezing, particularly as may occur during international shipments. Shipping is done by overnight courier, wherever possible, in a safe manner compliant with the Transport of Dangerous Goods Act.

5.2 Characterization Of Samples

During each study, PT samples are characterized to ensure that samples are prepared as designed.

For a new PT sample formulation being proposed, the first two studies are "Pilot studies" and are used to confirm that the samples are suitably homogeneous and stable. During these studies, final PT scores are not assigned.

5.3 Selection Of Samples For Characterization Testing

Samples for Microbiology PT must be selected from the production run in a systematic, statistically random fashion. This is accomplished by:

- Sort all samples for a unique Sample ID by order of production (i.e., by serial number);
- N = total number of samples produced;
- g = Number of samples required for characterization testing;
- G = N/g (the selection interval);
- T = a random number between 1 and G, selected using random number tables or a random number generator; and,
- Samples are removed for testing from the production run in the order T, T+G, T+2G, T+3G, etc.