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Performance Testing Programs

Additional Operational Guidance

Purpose: This document serves as a companion to the ICLN policy guidance document Recommendations for Conducting Proficiency/Performance Testing Programs.[i] Its intention is to provide helpful information on operational details of managing a performance testing (PT) program that are not outlined in the above base policy document.

ICLN currently comprises seven laboratory networks, most but not all of whom utilize formal PT programs to ensure reliable analytical results from their member laboratories. A comparison of the PT programs sponsored by ICLN member networks reflects similarities in matters such as how to address a PT not passed by a member laboratory within the network, but differences in how PT services (provision of samples and reporting) are accessed.

This document draws upon the experience of those networks with structured PT programs to assist current and future member laboratories and networks in the establishment and refinement of their own PT programs.

Additional guidance for the establishment of proficiency testing/quality assessment programs may be found in the end notes.[ii]

Performance Testing (PT) Sample Providers

1. **Does ICLN offer performance testing services?**

   ICLN does not offer PT services. It does periodically offer a Confidence-Building Competency Test (CBCT) which has some elements in common with a PT but serves a different purpose. The CBCT was conceived as a way for networks to demonstrate that they can perform analyses of which they are capable but which they do not routinely execute. Replicate samples of known concentration, matrix, etc., are sent, along with method-specific instructions, to member labs of multiple networks capable of performing analyses of them. Aggregate results, not associated with specific participant labs, indicate the extent to which a network's members are competent to run the requisite analyses and can therefore provide analytical support to a lead network in a large response scenario. Such a test would not serve as a PT since it does not rigorously enable assessment of performance on methods or analyses for which labs may routinely train and be expected to be proficient. Rigorous performance assessments are considered to be the domain of the networks themselves for the analyses they require.

2. **Where can I find a list of accredited performance testing providers for methods within the scope of ICLN analytical interests?**

   For non-clinical samples, the following institutions and websites provide listings of accredited PT service providers:

   The NELAC Institute: https://nelac-institute.org/content/NEPTP/ptproviders.php

ANSI National Accreditation Board (ANAB): https://search.anab.org/

American Association for Laboratory Accreditation (A2LA): https://customer.a2la.org/index.cfm?event=directory.index

For clinical samples, which fall under HHS (Health and Human Services) CMS (Centers for Medicare and Medicaid Services) CLIA (Clinical Laboratory Improvement Amendments) oversight, a list of approved proficiency testing providers can be found at https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Proficiency_Testing_Providers.

A sampling of providers of PT services that have been used by ICLN networks include:

The Moffett Campus Proficiency Testing Laboratory (Moffett PT) located at the Center for Food Safety and Nutrition (CFSAN) Division of Food Processing Science and Technology (Moffett Center) and the Institute for Food Safety and Health Illinois Institute of Technology (IFSH-IIT): https://www.ifsh.iit.edu/facilities/proficiency-testing-laboratories

The National Veterinary Services Lab: https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/sa_reagents/ct_reagents

The College of American Pathologists: https://www.cap.org/laboratory-improvement/proficiency-testing

Signature Science, LLC: https://sigscipt.com/

(NOTE: The identification of potential sources and providers of PT services in this document is not intended to, and does not, constitute a recommendation or endorsement of these entities. Additionally, the list of providers identified here is not intended to be, and is not, a comprehensive list of all possible providers.)

3. **What options exist for preparation of PT samples if an accredited PT provider does not exist for a given analyte/matrix/method combination?**

If operating in the ICLN environment, inquire with an ICLN member network coordinator. Contact the ICLN coordinator who maintains a performance testing regime that addresses analytes and matrices related to those in your field of concern. They may be aware of a high-performance laboratory that can prepare appropriate samples and may be able to suggest creative ways to resource services.

4. **What steps should be taken to qualify a potential PT sample provider not accredited to an established standard?**

Seeking a provider recommended by others and established in their field is a good initial step. Additionally, when starting a new service relationship with a sample provider, critically evaluate services and support by the following process:

1. Negotiate for a small lot of samples to be submitted to a portion of the laboratories you need to assess.
2. Assign a laboratory experienced with performance testing the role of *reference lab* to check that sample results are within a nominal range of the expected target values (of concentration, cfu/vol, etc.).
3. If the reference lab finds agreement between expected and observed values, expand the test to a larger set of labs.

Three successful trial rounds should confirm the sample provider's reliability.

Reporting PT Outcomes

5. **What steps should a network take when a member laboratory does not pass the performance test?**

   The overall goal of the network is to assist the lab in improving performance. ICLN networks running PT programs for their member labs may use some or all of the following sequence of steps to address an instance of a PT not passed:

   - A lab that does not pass a PT may be requested by the network to submit a corrective action plan (CAP) to the network program office (NPO). The network may also request the lab suspend testing using methods related to the failed challenge samples until the issue is resolved.
   - The NPO typically provides comments and/or advice on the CAP.
   - The NPO might offer the lab that does not pass a PT an opportunity to participate in a remedial test of the same type. The lab CAP should be addressed before the retest.
   - If the lab does not pass a retest, the NPO may provide additional focused guidance for improvement and another remedial test opportunity.
   - Continued poor performance may disqualify the lab from analyzing samples (specifically, for the non-passed method) for the NPO and may result in reduced NPO-supported funding to the lab.
   - A disqualified lab can demonstrate that it has identified the reasons for unsuccessful performance and has corrected them before reinstatement by NPO. The NPO will establish guidelines for reinstatement, such as successful performance in two consecutive PT events.

6. **What approaches are recommended for communicating aggregate network results for a PT back to laboratories while maintaining confidentiality?**

   Member labs benefit by seeing comparisons between all PT results. An approach to developing an aggregate report on labs' PT performance is to assign participating labs a non-identifying designation (such as a number or letter or combination thereof). The NPO can maintain a table correlating with anonymous lab designations. The NPO should periodically change the anonymous designations among participant labs. A generalized report may be sent to all labs, and/or each participating lab may be provided a specific report describing its own PT results.

PT Sample Characterization

7. **Provide a definition of "well-characterized material" as an alternate for "materials traceable to a national standard" used in PT samples.**

   Not all PT materials are traceable to a national standard. A well-characterized material consists of an analyte, or multiple analytes, of known composition or *character.* The analyte is part of a matrix, a background or mixture of known composition or character, that is determined to not interfere with the test.

   Well-characterized materials have defined critical quality attributes (CQAs), described by the International Conference on Harmonisation (ICH) as physical, chemical, biological, or microbiological properties or characteristics that should be within an appropriate limit, range, or distribution to ensure the desired product quality.[iii] While the ICH scope focuses on the pharmaceutical industry, numerous concepts carry over to similar chemical and biological disciplines. In this case, to paraphrase ICH Q8, CQAs of a well-characterized material are identified through assessments to the extent their variation might impact the material's quality; thus, it is a *well-characterized material*.

   In some cases, the matrix may contain materials of known composition or character that intentionally confound an analysis and presents a challenge to identify the best analysis approach. Introduced interfering materials provide valuable information for test developers and emergency programs. Results from these materials can support quality management systems and might not be graded equally to the more standard case of non-interfering materials in a PT.

Point of Contact

Questions related to this document may be directed to ICLN@hq.dhs.gov.

[i] The link for the document Recommendations for Conducting Proficiency/Performance Testing Programs is https://www.icln.org/documents/ICLNRecommendationsforUniformityAcrossPTPrograms_PTGuidanceNovember142021_final_version2.docx

[ii] See, for example, the Clinical and Laboratory Standards Institute guideline, "Design of Molecular Proficiency Testing/ External Quality Assessment," published 2013 (Second Edition), which is available for purchase or through your Agency library or professional organization in which you are a member. It can be identified through several sources by searching on the document title.

[iii] ICH Q8: see FDA Guidance for Industry, Q8(R2) Pharmaceutical Development, located at https://www.fda.gov/media/71535/download, p 10-15.