# Recommendations for Conducting Proficiency/Performance Testing Programs of the Integrated Consortium of Laboratory Networks

# November 14, 2021

**BACKGROUND**

Proficiency/Performance Testing (PT) is one of the key mechanisms for assuring the measurement capability and competency of individual network member laboratories and of the network as a whole to conduct analytical methods in a satisfactory manner. A proficiency or performance test (PT) is one of many quality assurance measures where samples are submitted to a group of laboratories for analysis, with results being compared to expected/standard/consensus values to assess the quality of the work relative to the particular challenge sample analyte/matrix combinations. It is recognized that there are other valuable interlaboratory comparison tools that may be utilized to assess other laboratory capabilities that are a part of an overall quality assessment program.

**PURPOSE/SCOPE**

The Integrated Consortium of Laboratory Network’s (ICLN) primary or lead response network is typically managed by or overseen by the responsible Federal Department/Agency for a given phase of response. The lead response network has the statutory obligation to respond to the incident due to its capabilities for analyzing samples of a specific matrix or agent of concern.

The purpose of this document is to recommend and promote the understanding and use across ICLN member networks of common elements of effective PT programs. Neither the ICLN nor any agency other than a network’s proponent Federal agency, operating through a Network Program Office (NPO), can impose requirements on that network’s member laboratories in service to the NPO.

The Federal agency/NPO administering PTs is responsible for establishing the PT requirements incumbent on its network laboratory members. Minimum requirements for PT programs are subject to existing authorities, policies, and protocols within a department/agency or relevant external accrediting organizations. To reflect these considerations, all recommendations in this document are directed at the Network Program Office (NPO) and use the non-directive term ‘should.’

Each individual NPO ensures compliance of its member laboratories with PT requirements through membership policies. Resources permitting, the information provided in this document outlines recommended best practices among member networks of the ICLN. The objective of this document is to promote consistent laboratory PT practices across the ICLN. If available and consistent within the constraints of the Federal agency/NPO PT program, the NPO should use a PT provider accredited to ISO 17043 or Center for Medicaid and Medicare Services (CMS) [Clinical Laboratory Improvement Amendments (CLIA)] as applicable. Per CMS, “The Clinical Laboratory Improvement Amendments (CLIA) program regulates laboratories that test human specimens and ensures they give accurate, reliable, and timely patient test results regardless of where the test is performed.” All NPOs will need to use CLIA certified (or similarly certified, such as DoD’s Clinical Laboratory Improvement Program [CLIP], which is DoD’s CLIA-equivalent regulatory framework) procedures if analyzing human clinical samples. A more complete set of links to relevant proficiency testing guidance documents are available in Section 6 of this document.

1. **Policies Regarding Participation in PTs**
   1. As part of its agreement with laboratories regarding membership in the laboratory network, the NPO should define requirements for participation in PTs to include, for example, the anticipated number of PTs annually, qualifications of staff providing services to the NPO, and minimum number of PTs per staff member. Requirements should be reviewed annually to ensure NPO quality assurance objectives are met.
   2. The NPO policy should incorporate for all parties an understanding of the implication of failure to meet the assessment criteria for a given PT. The policy also should express the process for remediation of failed assessments.
2. **NPO Administration of PTs**

In its role as administrator of PTs, the NPO should:

* 1. Establish and document policies, systems, programs, procedures, and instructions to the extent necessary to assure the quality of the PT program services provided to its network.
  2. Ensure that PT program information is communicated to and understood by all member laboratories.
  3. At the start of a new calendar/fiscal year, determine the PT schedule for the following year and share with participants and the ICLN, as appropriate.
  4. Identify and establish an agreement with an appropriately accredited or qualified provider(s) of samples for PTs.
  5. Document procedures utilized for production of samples and retain for future PTs as well as for process improvement, whether PT samples are prepared internally within a network or supplied by an outside commercial sample provider.
  6. For each PT event, determine PT assessment objectives, create a project plan, and develop or revise evaluative criteria along with other instructions for participants in preparation for the PT test. Document pass/fail or other evaluative criteria in a project plan. Communicate evaluative criteria to PT participants along with other instructions for participants in preparation for a PT test. Some or all of these elements may be covered by one or more policy, Standard Operating Procedures, and/or other agreed upon standard guidance documents.
  7. Ensure the participating laboratory has access to the current PT process procedure and/or testing method.
  8. Develop a final report for each PT event and circulate it in accordance with its policy.
  9. Establish and utilize a mechanism to report results and evaluation of performance back to the laboratories.
  10. Establish and utilize procedures to maintain the confidentiality of individual results while sharing overall results within and outside the network

1. **Quality Control Measures for Sample Production**

In preparation for a PT, the NPO should:

* 1. Determine specific types of analytes to be tested, the matrix in which samples should be provided, and the methods to be employed.
  2. Develop a contract/other understanding with sample provider(s) specifying a sufficient number of samples for the labs being assessed, the sample composition, concentration range (or another measure) desired, and timeframe required for the provision of the samples.
  3. Ensure that samples are prepared, packaged, and shipped in such a manner that prevents degradation or alteration of the sample prior to analysis.
  4. Ensure materials used for PT samples are well-characterized or have traceability to a national standard or to the SI (International System of Units), as appropriate.
  5. Identify reference/referee laboratories (i.e., qualified laboratories not being assessed in the PT), where possible, to confirm PT samples are prepared as ordered and incorporate this QA step into the PT schedule.
  6. Ensure control test samples (e.g., blanks, spikes, duplicates and others) are included with the set of samples supplied to each participant, where applicable.

1. **Coordination of Samples and Results**

The NPO should:

* 1. Have procedures in place for notifying participating laboratories when samples will arrive at the laboratory and advising them on special handling/storage requirements.
  2. Establish timelines for submitting PT results after receipt of samples.
  3. Instruct participating laboratories on reporting values (including uncertainty, as appropriate) for each sample.
  4. Provide a mechanism to report results from labs to the NPO.

1. **Safety Considerations**

The NPO should ensure:

* 1. Samples, especially chemical, biological, and radiological samples, are packaged and shipped in accordance with appropriate regulations and permits, such as International Air Transport Association (IATA) and Department of Transportation (DOT).
  2. Where possible, the least hazardous testing material is used (e.g., inactivated or attenuated strains, surrogate materials).
  3. Hazardous aspects and special safety concerns for handling and testing of samples are clearly communicated to the participants.
  4. Sample storage and disposal requirements are clearly communicated (including archival storage, depending on the policy of the lab).

**6)** **Relevant Guidance Documents**

* 1. ISO 17043:2010: Conformity assessment — General requirements for proficiency testing
  2. ISO Guide 35:2017(E): Reference materials — Guidance for characterization and assessment of homogeneity and stability
  3. ISO 13528:2015(E): Statistical methods for use in proficiency testing by interlaboratory comparison
  4. ISO/FDIS 22117:2018(E): Microbiology of the food chain — Specific requirements and guidance for proficiency testing by interlaboratory comparison
  5. ISO 16140-2:2016(E): Microbiology of the food chain — Method validation

Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method

* 1. ANSI National Standards Institute, ANSI N42.22-1995, “Traceability of Radioactive Sources to the National Institute of Standards and Technology (NIST) and Associated Instrument Quality Control.”
  2. ANSI National Standards Institute, ANSI N13.30-2011, “Performance Criteria for Radiobioassay.”
  3. ISO 17034:2016. General requirements for the competence of reference material producers
  4. ISO/IEC 17025:2017. General requirements for the competence of testing and calibration laboratories
  5. ANSI N42-23-1996 - Measurement and Associated Instrument Quality Assurance for Radioassay Laboratories