Proficiency Testing Guidance
For
Integrated Consortium of Laboratory Network Programs

Proficiency testing is one of the key processes for assuring the capability of individual network member laboratories and of the network as a whole to conduct analytical methods in a satisfactory manner. A proficiency test (PT) is defined as the process of submitting samples to a group of laboratories for analysis with results being compared to expected/standard/consensus values. The responsible Federal agency will determine minimum PT requirements for its network members. Establishing minimum requirements is subject to existing authorities, policies and protocols within a department/agency or external accrediting organizations. To reflect these considerations, all recommendations in this document are directed at the Network Program Office (NPO) and qualified as 'should.' Each individual NPO ensures compliance through membership policies regarding proficiency testing. Resources permitting, the information below provides goals that can be achieved by sharing best practices among member networks of the Integrated Consortium of Laboratory Networks (ICLN), with the objective of developing consistency in laboratory proficiency testing across the ICLN.

1. Participation
    a. Define participation policies/requirements and have individual agreements with each participating laboratory.

2. Management System
    a. Establish and document policies, systems, programs, procedures and instructions to the extent necessary to assure the quality of the PT program services provided to members.
    b. Ensure that the above information is communicated to, understood by and available to all member laboratories as appropriate.
    c. At the start of a new calendar/fiscal year determine the PT schedule for the following year and share with participants, and as appropriate other networks of ICLN.

3. Quality Control Measures for Sample Production
    a. Whether PT samples are prepared internally within a network or supplied by an outside commercial PT provider, procedures utilized during the production should be documented and retained for future PTs as well as process improvement.
    b. Materials used for PT samples should be well characterized, or have traceability to a national standard, as appropriate.
    c. The samples should be tested and documented to perform on all assays as expected.
    d. Provide parameter ranges for control samples as appropriate.
    e. Reference/Referee laboratories (i.e., a group of select laboratories within the network) should be utilized, if appropriate, to confirm suitability of PT samples.

4. Coordination of Samples and Results
    a. Have procedures in place for notifying participating laboratories that samples will be arriving in the laboratory.
    b. Establish and communicate to participants timelines for submitting results.
    c. Provide participating laboratories with a mechanism to report results.
    d. Ensure the participating laboratory has, or has access to, the most up-to-date process procedure for the testing method to be used in the proficiency testing

5. Safety Considerations
    a. Ship samples according to appropriate regulations and permits that follow relevant shipping guidelines.
    b. Where possible, least hazardous testing material should be used (e.g. inactivated or attenuated strains).
    c. Special safety concerns for handling and testing of samples must be clearly communicated.

6. Results Evaluation and Exercise Report

    a. Establish criteria for evaluation of performance (pass/fail) and communicate policies to participating member laboratories.
    b. Have a mechanism to report individual results and evaluation of performance back to the laboratories.
    c. Establish policies and procedures to maintain the confidentiality of individual results while sharing overall results within and outside of the network
    d. Network laboratories that fail a single PT event should not be "disqualified" from performing the test method. Rather, Network Program Offices should assist with the development of corrective action procedures for laboratories that do not pass a PT event.
    e. Laboratories that do not pass a PT event should be given a subsequent opportunity to demonstrate competency. Failure of multiple PT events could result in disqualification for that method/analyte.