The Integrated Consortium of Laboratory Networks Newsletter

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The Integrated Consortium of Laboratory Networks (ICLN) is a system of interconnected federal laboratory networks that can quickly respond to high-consequence incidents and provide decision makers timely, credible, and interpretable data.

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NETWORK SPOTLIGHT:

Boosting Public Health: Why Proficiency Tests Matter for Laboratory Networks

Did you ever wonder how we ensure that our public health laboratories are at the top of their game? Public health laboratories across the nation participate in Proficiency Tests (PT) as one way to ensure that their results are reliable and accurate. PTs ensure the safety of the US food supply and are essential for quality data. PTs offer confidence in laboratory testing of human and animal foods regulated by the FDA.

Simply put, during a PT, a participant must "solve a mystery" by determining the presence or how much of a substance in a sample. PTs offer unbiased/blinded sample sets for participants to conduct these analyses. After testing, laboratories are informed if their "answer" is correct or not; ultimately, was their performance statistically satisfactory or unsatisfactory. At the FDA we rely on the Moffett Center to provide PTs to many laboratories that support public health. The Moffett Center is an ISO/IEC

The Moffett Center offers PTs that are not commercially available and are tailored to meet the unique needs of the FDA. Some examples of these unique PTs include:

- FERN laboratories testing for cyclospora in produce
- FERN laboratories testing for select agents related to bioterrorism
- Vet-LIRN laboratories testing for SARS-COV-2 in canine nasal fluid
- Vet-LIRN laboratories testing for Salmonella in dog or bovine feces
- Laboratories nationwide testing shellfish and growing area waters for coliforms and Vibrio
- Laboratories nationwide testing quality of milk for drug residues, coliforms, and vitamins
- Laboratories nationwide testing powdered infant formula for various foodborne pathogens and bacteriological quality indicators
- Laboratories and field-testing facilities monitoring health fraud such as extra-label use of drugs in dietary supplements.

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17043 PT provider that supports the quality system needs of the Grade A Milk and Shellfish programs, the Food Emergency Response Network (FERN), the Veterinary Laboratory Investigation and Response Network (Vet-LIRN), and other FDA labs.

Commercial laboratories do not routinely prepare samples in these unique sample types potentially because of high preparation cost or challenging matrix. The Moffett Center is highly experienced in working with matrices that other PT providers may traditionally shy away from. But FDA needs laboratories to test in these sometimes "yucky" matrices to ensure that participants' methods are performing successfully.

Why are PTs important? By participating in a PT each participant is evaluating their quality systems as a whole and ensuring that they can provide accurate and reliable data when called upon. Laboratories are operating under a continuous improvement environment and can identify and correct systematic errors that may be identified by a PT, boosting confidence in public health data. Data received by the FDA from public health laboratories are used by us to make consequential decisions and PTs allow FDA to trust the data and be confident in those decisions.

PTs offer advantages to the participants as well. PT results can support accreditation requirements. Technicians can develop skills by testing new methods or unique sample types. In some cases, a network may be adopting a new method and thus the PT can foster collaboration and knowledge sharing between the FDA and its laboratories. PTs provide preparedness beyond table-top exercises by offering real-life unbiased samples so that participants can demonstrate rapid response capabilities. Another significant benefit to public health laboratories is that PTs from the Moffett Center are offered free of charge and in most cases, laboratories receive money to participate. This is not something that commercial PTs providers can or will do.

Without a robust PT program available to the FDA, we would lack confidence in our ability to detect and identify potential public health threats. Confidence in public health laboratories would erode and we may begin to second guess results that we rely on for decision-making purposes. A routine mechanism for laboratories to assess their testing capabilities is a must to ensure that results are accurate and reliable. Without PTs, the laboratory may have difficulty maintaining accreditation. The loss of accreditation can have dire consequences for a laboratory. Time and money would be wasted with testing and retesting to verify the results are correct. A false positive could trigger unnecessary panic.

The future of PTs looks strong. The FDA understands the importance of a robust PT program to support networks and public health laboratories nationwide. PTs will continue to offer routine mechanisms for laboratories to assess their quality systems. We can also look forward to emerging technologies. This year, the Moffett Center offered a PT for laboratories to assess their whole genome sequencing capabilities. We also offered a unique interlaboratory comparison exercise to laboratories to ensure they can detect Avian Influenza in milk samples. The ability to provide an exercise for laboratories to assess method performance in a safe environment is critical to ensure large participation and evaluation of emerging testing needs. By re-establishing the Moffett Center as a premier PT provider, we can remain confident in the work conducted by our networks.

Celebrating 20 years of the Integrated Consortium of Laboratory Networks

This year marks 20 years since the inception of the Integrated Consortium of Laboratory Networks (ICLN). Over the past two decades, the ICLN has made significant progress in strengthening laboratory capabilities in support of national security. The integration of federally-sponsored laboratory networks began quickly. In late 2004, founding agencies agreed to participate; by March 2005, the Network Coordinating Group held its first meeting. Later that year, the agencies signed a Memorandum of Agreement and conducted the first workshop to establish technical subgroups.

Since then, the ICLN has continued to advance its mission. In 2007, the first strategic planning meeting brought together members of the Network Coordinating Group, technical subgroup leaders, and experts to develop a coordinated federal laboratory system capable of delivering rapid, reliable results for detecting and mitigating the impacts of terrorism and other emergencies. These efforts led to the creation of essential tools that support the ICLN's response today, including a Standard Operating Procedure for Laboratory Response managed through a web portal, which enables data from all member networks to be combined in a standard format. The ICLN also developed a Combined Registry tool to keep members informed about available methods for detecting chemical, biological, and radiological agents, as well as proficiency testing activities across the networks.

ICLN's Exercises

The ICLN's response tools are leveraged through two types of exercises:

1. Tabletop exercises across a range of scenarios.
2. Live sample exercises that demonstrate a member lab's ability to analyze using methods they may not routinely perform.

Since 2005, the ICLN has coordinated more than 20 tabletop and live sample exercises, addressing a wide variety of biological, chemical, and radiological threats. These exercises help ensure that the ICLN and its member networks are well prepared to coordinate responses to complex incidents that could threaten national security.

The Role of the ICLN

The consortium also plays a key role in improving information sharing among member agencies. By establishing secure communication channels and data-sharing platforms, the ICLN enables real-time collaboration during incidents. This capability is critical for responding to events such as disease outbreaks, chemical spills, and radiological emergencies. The importance of the ICLN's role was codified in law in 2011, through the Food Safety Modernization Act.

Looking to the Future

The nation faces complex and ever evolving challenges, and the ICLN must continue to adapt to meet new demands. The DHS Office of Health Security, which oversees the ICLN program, is committed to providing the consortium with the resources and support needed to address emerging threats. The ICLN's achievements over the past 20 years reflect the dedication and expertise of its member networks and their personnel. Moving forward, the ICLN and its member networks will continue to advance laboratory methods, uphold quality assurance, and use consistent data standards (see the call out box) to fulfill their mandate: delivering timely, high-quality, and interpretable results for early detection and effective mitigation of the impacts of terrorism, and other incidents that require a coordinated laboratory response.

The ICLN uses specialized subgroups to address gaps and challenges in laboratory response:

- **Data Standardization Subgroup:** Works to reduce barriers to data transfer between member networks and partners during large-scale incidents. This subgroup also leads efforts to standardize analytical data elements to improve data sharing during events.
- **Laboratory Logistics Subgroup:** Develops resource lists for essential items needed by biological, chemical, and radiological/nuclear laboratories, and identifies best practices to address logistical challenges for laboratory consumables.
- **Methods and Technology Subgroup, Interlaboratory Comparability/Quality Assurance Subgroup, and Radiological Lab Subgroup:** Ensures validated methods are available for a wide range of chemical, biological, and radiological threats; reviews standards for laboratory testing; and supports enhanced radiological laboratory response activities.