ICLN
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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 give decision makers timely, credible, and interpretable data.

ICLN's First Internetwork Laboratory Coordination Exercise is Complete

After several months of planning, under the auspices of the ICLN Interlaboratory Comparability/Quality Assurance (IC/QA) Subgroup, ICLN's first Internetwork Laboratory Coordination Exercise (ILCE) has reached completion.

THE FIRST ILCE ADDRESSED THE FOLLOWING KEY OBJECTIVES:

- Assess the ability of network laboratories to perform a method of which they are capable, but which they seldom or never perform; and,
- Assess the ability of participating networks to consolidate their member laboratory results and to integrate the results with all networks' data by uploading data to the ICLN Data Exchange Utility (DEU).

This first ILCE exercise *simulated* the environmental assessment phase of a laboratory response to the release of fentanyl into drinking water utilities and a sports arena, with drinking water and surface wipes being the predominant sample matrices. For this notional incident, EPA was the lead federal agency and the Environmental Response Lab Network (ERLN) served as the lead network. Four networks identified themselves as supporting networks: DoD Laboratory Network; Food Emergency Response Network (FDA and USDA); Laboratory Response Network-Chemical (CDC); and Veterinary Laboratory Investigation and Response Network (FDA).

ERLN specified the required data elements for reports on sample analyses and communicated these to supporting networks via a mock ICLN Incident-specific Data Sharing Agreement. EPA also offered two SOPs for analysis of samples by participating laboratories, but required only that the participating laboratories demonstrate that the methods they use are equivalent in performance to the EPA methods.

EPA's process for the incorporation of new laboratories to provide a service is simulated in the ILCE by conducting a two-phase event. The first phase, an Initial Demonstration of Capability (DOC), used a limited set of samples to permit the labs to demonstrate their detection capabilities for the target analyte in relevant matrices. A total of 28 labs participated in Phase I. Key elements of the first phase included determining method limit of detection and demonstrating analytical precision in correctly detecting (and quantifying, where possible) the analyte in a small set of replicate samples. In Phase I of the ILCE, sample sets containing three replicates each of water and wipe samples (with concentrations unknown to labs), along with standards and positive and negative controls, were shipped

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CDC photo: Laboratory Leadership Service (LLS) fellow, Anna Llewellyn, as she was in the process of vacuum filtering a sample through a membrane, for contamination analysis.

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to labs on January 8, 2024, with two weeks allocated for analysis and reporting of data. Some labs chose to not move forward to Phase II based on equipment and methodology issues.

Phase II, the Challenge sample phase, began with the shipment on February 5, 2024, of two sets of water and wipe samples, comprising a range of unknown concentrations, along with standards and positive and negative control samples.

The exercise demonstrated that labs can successfully analyze sample/matrix combinations for which they have appropriate equipment but do not normally perform such analyses. Most importantly, the ICLN DEU was demonstrated to be capable of merging data submitted from multiple networks in their native data formats.

RESULTS WERE AS FOLLOWS:

- **PHASE I:** Twenty-five of 27 labs receiving samples reported results before the submission deadline. Of those providing results, eight labs submitted qualitative results and 17 submitted quantitative results. The assigned values (determined by consensus mean of participants' results) for quantitatively assessed samples were 2.96 ng/mL and 122.38 ng/wipe for water samples spiked with 3.5 ng/mL fentanyl and wipe samples spiked with 125 ng/wipe fentanyl, respectively. The goal of Phase I was to (1) help participants establish a method or evaluate their current capabilities in analyzing fentanyl in water and wipe samples and (2) to provide information to allow participants to assess the likelihood of success in Phase II.
- **PHASE II:** Twenty-two laboratories provided results for water samples: four laboratories reported qualitative results and 18 reported quantitative results. The assigned (consensus mean) values were 2.05 and 4.34 ng/wipe for water samples spiked with 2.5 ng/mL fentanyl (W-01) and 4.5 ng/mL fentanyl (W-03), respectively. Twenty-two laboratories provided results for wipe samples, with five laboratories reporting qualitative results, and 17 reporting quantitative results. The assigned values were 50.2 and 193.6 ng/wipe for the wipe samples spiked with 50 ng/wipe (S-02) and 200 ng/wipe (S-01), respectively.
- **Phase II quantitative results:** A Z-score analysis of permitted an assessment of result correctness. Taking a Z-score of two or less as satisfactory (meaning a lab's average result was within two standard deviations of the mean), satisfactory results for Phase II for quantitative water analysis were 92%, 88%, and 92% for the unspiked samples and the spiked samples were 2.5 and 4.5 ng/ml, respectively. Satisfactory results for quantitative wipe analysis were 100%, 80%, and 88% for the unspiked samples and the spiked samples were 50 and 200 ng/wipe, respectively.

HHS Administration for Strategic Preparedness and Response

The COVID-19 pandemic made it abundantly clear how important a robust and resilient public health industrial base is to ensure the health and security of the country. At the U.S. Department of Health and Human Services Administration for Strategic Preparedness and Response (ASPR), we gained a heightened understanding of U.S. vulnerabilities, and we considered how best to work with industry to strengthen the private sector's medical supply chain. We have gone to great lengths to focus on this problem and on long-term solutions, including standing up the Office of Industrial Base Management and Supply Chain (IBMSC), which is designed to specifically focus on the need for domestic industrial base expansion.

IBMSC focuses on expanding, securing, and building resiliency across the entire public health and medical industrial base.

The office addresses shortages of life-saving medical countermeasures and works to coordinate strategic industrial base expansion and innovation efforts across ASPR as well as with federal partners, academia, and the private sector. Our focus lies in key areas, including:

- **Defense Production Act & Emergency Response Authorization**
- **Advanced Manufacturing Technologies**
- **Supply Chain Optimization**
- **Personal Protective Equipment and Durable Medical Equipment**
- **Testing and Diagnostics**

Testing and diagnostics are vital to helping ensure the security of the Nation's medical supply chain. The IBMSC Testing and Diagnostics Domain (TDx), with the support of federal policymakers and industry leaders, has a range of options to prepare the Nation's diagnostics apparatus for future threats. These options range from basic, "no regrets" actions, to long-term, strategic investments in national infrastructure and transformational changes in planning and coordination. We must engage, build, and maintain a reliable testing ecosystem by engaging our public and private sector partners to exchange information on threats, system vulnerabilities, and potential resources. We must maintain distribution channels to ensure tests and diagnostics can be distributed when and where they are needed within a sufficient timeframe to be effective. To accomplish this quickly, we need to utilize what we have built already—the TDx stockpile, relations and communications with industry, and our distribution partnerships with organizations supporting our most vulnerable populations.

In establishing our goals, we drew upon the lessons we learned during the COVID-19 pandemic response, finding ways to accelerate the pace at which the testing industrial base can ramp up production. We have seen how quickly demand can spike, and we need to be able to maximize the Nation's response capacity so we can meet peak demand. Hopefully we can capitalize on a greater public acceptance of testing to increase the steady state demand for tests, thereby reducing the supply gaps caused by demand peaking and waning repeatedly over time. The COVID response also necessitated that we create new communication channels with industry, and these improved communications have provided us with significantly better insight into the needs and challenges industry faces in providing reliable and affordable tests at high volumes. We will need to draw upon a wide range of strategic actions to sustain and increase testing capacity, including but not limited to procurements, stockpiling, distribution, industrial mobilization/capacity building, and other flexible contracting and policy actions.

As we look to the future, we must work together to prepare for future health security threats by ensuring the resiliency of our supply chain for essential products, to revitalize and rebuild domestic manufacturing capacity, maintain America's competitive edge in research and development, and create well-paying jobs. **But we cannot do this alone. We must work alongside partners, like you, to get a full scope of the challenges we face and to develop novel ideas for how to solve them.**