Put It on the Board

Missteps, strains, shortages: pandemic insights now recommendations

December 2021—In the COVID-19 pandemic and future pandemics, the existing expertise of clinical laboratories should be taken advantage of and labs should be enabled to validate and offer robust clinical assays, say the authors of "The Role of Clinical Laboratories in Emerging Pathogens—Insights from the COVID-19 Pandemic," published Oct. 29 in *JAMA Health Forum* (2021;2[10]:e213154).

Eric Konnick, MD, of the University of Washington, Jordan Laser, MD, of Northwell Health, and Karen Weck, MD, of the University of North Carolina at Chapel Hill, note in their viewpoint the extensive network of clinical labs that routinely develop and implement laboratory-developed testing procedures, regulated under CLIA and administered by the CMS.

"We recommend updating existing CLIA regulations to account for the technological and medical advances that have occurred in the decades since the law was written, rather than imposing duplicative regulatory schemes," they write. "For *example,* laboratory classification could be better aligned to reflect the expertise of specific laboratories to guide the types of tests offered, especially in the midst of a pandemic or public health emergency."

Early engagement of local clinical labs via state health labs and the CDC could enable the expertise and capacity that is available in the U.S. to deploy and scale testing, they say, and they suggest the CDC include additional qualified clinical laboratories in the Laboratory Response Network. They encourage the CDC to "work with professional organizations to develop tools such as assay protocols, testing criteria, control materials, and practice guidelines to enable laboratories to stay at the vanguard of the response."

Drs. Konnick, Laser, and Weck, who are members of the AMP COVID Response Steering Committee, say that early and better use of the Defense Production Act or similar support from the federal government is needed to ensure the supply chain is not disrupted during a pandemic.

"Making the recommended key alterations to the collaborative, regulatory, and supply-chain aspects of clinical laboratory testing," they write, "will enable our critical diagnostic capacity to better respond to future pandemics as well as to the expanded testing needs of an aging population."

Hologic's COVID-19/flu test now available

Hologic's Aptima SARS-CoV-2/Flu assay for SARS-CoV-2 and influenza A and B became available in late October.

The new multiplex test is CE marked for diagnostic use in Europe, was authorized under interim order by Health Canada, and received emergency use authorization from the FDA. The assay runs on Hologic's Panther system.

It can be used with anterior nasal swab and nasopharyngeal sample types. Multiple collection devices can be used, including Hologic's direct load collection kits, recently launched in the U.S. and designed to reduce risk of viral transmission and improve laboratory efficiency. A buffer within the collection tube inactivates SARS-CoV-2 and other common respiratory viruses. Then the tubes are loaded directly onto the Panther without manual steps.