Put It on the Board

AMP reports findings of SARS-CoV-2 molecular testing survey

November 2020—In an Association for Molecular Pathology survey, 62 percent of U.S. labs reported using only commercial testing kits with FDA EUA for SARS-CoV-2 molecular testing. Five percent reported using laboratory-developed tests only, 26 percent said they were using a combination of LDTs and EUA commercial kits, and six percent reported using LDTs, IRB-approved/non-EUA assays, and commercial kits. Less than one percent reported using a combination of LDTs and IRB-approved/non-EUA assays or a combination of IRB-approved/non-EUA assays and commercial kits.

The survey took place from Aug. 13 to Sept. 11 and was open to AMP members and nonmembers. More than 100 responses came from U.S. labs.

Ninety-eight percent of U.S. respondents reported running SARS-CoV-2 diagnostic testing, 72 percent screening testing, and 29 percent surveillance testing. Labs had the option to choose all that apply.

The majority of respondents did not report experiencing significant numbers of false-negatives (87 percent) or false-positives (89 percent), but they indicated that the absence of a clinical gold standard and variability of testing platforms with regard to limits of detection presented analytical challenges.

To increase lab or hospital system capacity, 63 percent said (in selecting all that apply) that they plan to add more platforms or tests, 59 percent said they would add tests or test kits, and 62 percent said they would increase the lab workforce.

Sixty percent are running seven days per week at full staffing/test capacity to perform SARS-CoV-2 testing, but about 85 percent have experienced staff shortages. And supply chain problems continue, though the percentage of labs reporting shortages of swabs and viral transport media in an AMP survey conducted in April (67 percent for swabs and 62 percent for viral transport media) declined to 21 percent and 29 percent, respectively, in the August-September survey.

About 42 percent of the U.S. labs categorized their lab as an academic medical center lab, 26 percent as a commercial reference lab, 24 percent as a community hospital or health system lab, three percent as a public or state lab, and six percent selected other settings. The AMP says the survey had broad participation from across the U.S.

Magnolia launches Steripath Micro

Magnolia Medical Technologies launched its Steripath Micro Initial Specimen Diversion Device.

The Steripath Micro architecture uses syringe-driven negative pressure to divert and sequester the initial 0.6 to 0.9 mL of blood. Once diversion is complete, the user presses a button to isolate the diverted blood and automatically a second independent blood flow pathway opens to collect the blood specimen for culture into the syringe.

In other news from Magnolia, Lucy Tompkins, MD, PhD, a Stanford Health Care physician and professor, presented in October at IDWeek 2020 an oral abstract of a study of the Steripath Gen2 Initial Specimen Diversion Device. She reported zero blood culture contamination events and zero false-positive central-line-associated bloodstream infections out of 4,462 blood cultures drawn with the Gen2 ISDD during a four-month study, versus 29 contaminated sets in 922 blood cultures using traditional methods (3.15 percent contamination rate).

“Our results confirm those of Dr. Mark Rupp whose seminal Steripath ISDD study clearly demonstrated that the ISDD is the most effective way to reduce, and even eliminate, blood culture contamination,” Dr. Tompkins said in an Oct. 27 Magnolia release.

EGFR test v2 approved as CDx for expanded therapies

The Food and Drug Administration approved expanded claims for the Cobas EGFR Mutation Test v2 as a companion diagnostic for a broad group of therapies in the treatment of non-small cell lung cancer.

This claim expansion allows the test to be used as a companion diagnostic for all five currently FDA-approved EGFR tyrosine kinase inhibitor therapies targeting *EGFR* mutations L858R and exon 19 deletions in accordance with the approved therapeutic product labelling.

The group claim will also enable the test to be used as a CDx for any future approved EGFR TKI therapies targeting the same mutations, without the need to conduct individual clinical studies with the test for each new therapy.

EUA awarded to IL-6 test

Beckman Coulter received from the FDA emergency use authorization for its Access Interleukin-6 assay. It is a fully automated immunoassay designed to detect IL-6 levels in serum and plasma, which can be used to aid in identifying a severe inflammatory response and determining the risk of intubation with mechanical ventilation in COVID-19 patients.

“Our goal is to keep patients off the ventilator as that’s the best way to help COVID-19 patients. IL-6 can help us treat the patient before they need a ventilator,” Joshua Hayden, PhD, D(ABCC), chief of chemistry at Norton Healthcare, said in an Oct. 1 release from Beckman Coulter. He added, “Any time you can have more objective measures, such as testing with IL-6 to predict which patients are going to get worse, it is helpful.”

Latest on COVID-19

Editor’s note: See captodayonline.com for news on SARS-CoV-2 tests (Top News). A list of FDA EUAs for COVID-19 can be found at https://j.mp/covid-19-EUA.