Put It on the Board

Siemens Healthineers to collaborate with CDC to define threshold for NAb sufficient to confer immunity

October 2020—Siemens Healthineers will collaborate with the Centers for Disease Control and Prevention and the Joint Research Centre of the European Commission on a research project to develop a novel process for standardizing SARS-CoV-2 assays.

Comparing test results across manufacturers has not been possible, and thus establishing immunity associated with SARS-CoV-2 assays has been challenging.

The collaboration will produce a novel process for standardizing SARS-CoV-2 assays by anchoring each protein to a neutralizing antibody titer. The thresholds displayed in the standardized unit of measure for IgG—arising from natural infection or vaccination—may likely contribute to a standardized interpretation of immunity through test results.

“One barrier to antibody test adoption is we don’t currently have an established process to determine immunity,” Deepak Nath, PhD, president of laboratory diagnostics, Siemens Healthineers, said in a Sept. 15 statement. “Different SARS-CoV-2 antibody targets produce different levels of neutralization. Our R&D team recognized that if you could define a level at which neutralization is conferred for different targets, you could create a common ground to standardize assays—not just on antibody production, but their ability to provide immunity.”

Siemens Healthineers will collaborate with the CDC and JRC to “develop the framework,” he said, “that all antibody test manufacturers would be expected to adopt moving forward for greater benefit to patient care as the pandemic evolves.”

Developing a standardized process will define which concentration confers neutralization for different manufacturers’ antigen targets. Each manufacturer now standardizes its assays independently with internal standards not linked to a common reference. The results of the collaborative research project will support the JRC’s production of a reference material, which, with assigned concentrations of antibody specific to each viral protein, will allow manufacturers to refer to standardized values.

FDA approves HIV-1/HIV-2 Qualitative, expanded use of CINtec Plus Cytology

The Food and Drug Administration approved Roche’s Cobas HIV-1/HIV-2 Qualitative test for use on the Cobas 6800/8800 systems in the United States. The test provides a single result to confirm HIV diagnosis and differentiate HIV-1 and HIV-2.

The FDA also approved the expanded use of CINtec Plus Cytology and cleared the Cobas BKV test.

The Cobas HIV-1/HIV-2 Qualitative test is an in vitro nucleic acid amplification test for the qualitative detection and differentiation of HIV-1 and HIV-2 RNA in human serum and plasma.

The CINtec Plus Cytology test detects the simultaneous presence within a single cell of p16 and Ki-67. This abnormality is associated with HPV infections that are transforming and can, if left untreated, progress to pre-cancer or cancer. A positive result of these two biomarkers in a single cell signals that a woman is more significantly at risk for disease.

This latest expanded use approval gives laboratories access to the Roche cervical cancer portfolio offering in the U.S., which includes the Cobas HPV test, CINtec Plus Cytology, and CINtec Histology.

For U.S. approval of CINtec Plus Cytology, the FDA considered data from the Roche-sponsored registrational

IMPACT trial.

The now cleared Cobas BKV test was previously granted breakthrough device designation by the FDA, together with the Cobas EBV test.

The BKV test is a PCR test with dual-target technology that provides quantitative accuracy and guards against the risk of sequence variations that may be present in the BK virus. The test has a limit of detection of 21.5 IU/mL and an expanded linear range from 21.5 IU/mL to 1E+08 IU/mL in EDTA plasma.

The fully automated Cobas BKV test and the Cobas CMV and Cobas EBV tests can run on the 6800/8800 systems simultaneously.

HHS changes its COVID-19 lab reporting rules

The Department of Health and Human Services responded to the CAP's advocacy by giving laboratories additional relief and more flexibility to meet new COVID-19 data reporting requirements.

Top agency officials said on Sept. 9 that the government would penalize laboratories only for failing to report positive or negative test results.

The CAP had called the original reporting rules unworkable and strongly opposed penalties the HHS sought to impose on those that did not meet the COVID-19 data reporting requirements.

The HHS responded to the CAP's requests for clarification and said its policy "provides extensive guidance regarding other information, such as data transmission and reporting language via Logical Observation Identifiers Names and Codes and Systematized Nomenclature of Medicine that, at this time, is not regulatory." Laboratories are encouraged to implement those elements, but the HHS will only enforce whether laboratories are reporting COVID-19 positive or negative results to their respective public health departments.

Latest on COVID-19

Editor's note: See captodayonline.com for news on SARS-CoV-2 tests (Top News), plus COVID-19 coverage that becomes available between print issues. A list of FDA EUAs for COVID-19 can be found at https://j.mp/covid-19-EUA.