DiaSorin COVID-19 assay gets CE mark for saliva specimens

written by CAP TODAY
January 19, 2021

January 2021—DiaSorin Molecular has attained CE marking for the addition of saliva specimens for use with the Simplexa COVID-19 Direct assay.

Roche CE-marked Cobas PIK3CA Mutation Test

written by CAP TODAY
January 19, 2021

January 2021—Roche launched the Cobas PIK3CA Mutation Test CE-IVD for patients with advanced or metastatic breast cancer in countries accepting the CE mark. The test was previously available for research use only.

FDA authorizes POC antibody test for COVID-19

written by CAP TODAY
January 19, 2021

January 2021—The FDA issued an emergency use authorization for the first serology antibody point-of-care test for COVID-19. The Assure COVID-19 IgG/IgM Rapid Test Device (Azure Biotech) was first authorized in July for emergency use by certain labs to help identify individuals with antibodies to SARS-CoV-2. The EUA has been reissued to authorize the test for POC use using fingerstick blood samples. The lateral flow assay is authorized for use with venous whole blood, serum, plasma, and fingerstick whole blood.

Saliva-based COVID-19 assay gets EUA

written by CAP TODAY
January 19, 2021

January 2021—Fluidigm received emergency use authorization from the FDA for the Advanta Dx SARS-CoV-2 RT-PCR assay, an extraction-free, saliva-based test to detect nucleic acid from the SARS-CoV-2 virus. The test runs on the Fluidigm Biomark HD microfluidics platform, which can generate as many as 6,000 test results in one day.

FDA authorizes direct-to-consumer COVID-19 test kit

written by CAP TODAY
January 19, 2021

January 2021—The FDA authorized the first COVID-19 direct-to-consumer test system—LabCorp's Pixel COVID-19 Test Home Collection Kit, for use by any person 18 years and older without a prescription.

510(k)-cleared, CLIA-waived Accula Strep A test

written by CAP TODAY
January 19, 2021

January 2021—Mesa Biotech received 510(k) clearance and CLIA waiver from the FDA for its Accula Strep A test. The strep A cassette, for the molecular detection of group A *Streptococcus* bacterial nucleic acid, is cleared for diagnosing children and adults and provides results in 30 minutes at the point of care.

Putting labs front, center in pandemic plans

written by CAP TODAY
January 19, 2021

January 2021—Susan Butler-Wu, PhD, D(ABMM), is clear about who she is and what she does. “I’m just a microbiologist,” she says. But in a viral pandemic, a microbiologist—and everyone else associated with clinical laboratory testing—becomes so much more than the job title. (For the record, Dr. Butler-Wu is director of the clinical microbiology laboratory, LAC+USC Medical Center, Los Angeles, and associate professor of clinical pathology, Keck School of Medicine of USC.) Likewise, a test becomes more than a lab value. The very fact that testing has become the focus of national discourse is a testament to the upending nature of the pandemic, she says. “The public are having conversations about Ct values. It’s mind-blowing.”

Primary HPV screen only? Experts warn of risks

written by CAP TODAY
January 19, 2021

January 2021—It’s a watershed moment when an influential standard-setting organization, the American Cancer Society, announces that a test widely used for decades should be supplanted—especially when the test is the linchpin of the most successful cancer screening program in U.S. history.

For POC molecular, pauses, plans, and testing precautions

written by CAP TODAY
January 19, 2021

January 2021—The use of molecular assays at the point of care is exciting but a bit scary. That's how Raquel Martinez, PhD, D(ABMM), described the state of the science for molecular infectious disease POC testing when she spoke in a virtual AMP session in November with Omai Garner, PhD, D(ABMM), of UCLA Health.

No letup in pandemic struggle for supplies, staff

written by CAP TODAY
January 19, 2021

January 2021—Wrestling with rapid test shortfalls and with open laboratory positions. Expecting the post-holiday surge, frustrated by federal level disconnect. That is what Compass Group members were doing and feeling on Dec. 1 last year, when they gathered on Zoom for another conversation about COVID-19.