

[Roche launches comprehensive genomic profiling kit](#)

written by CAP TODAY
December 16, 2021

December 2021—Roche has launched the Avenio Tumor Tissue Comprehensive Genomic Profiling Kit, complementing the current CGP portfolio offered by Roche and Foundation Medicine.



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[FDA grants EUA for Lighthouse COVID-19 assay](#)

written by CAP TODAY
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December 2021—Lighthouse Lab Services announced that the FDA has granted emergency use authorization for its CovidNow SARS-CoV-2 assay kit. The EUA covers use for symptomatic and asymptomatic patients with a provider's order.



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[Olympus announces first results of AI-based Dx tool for gastric cancer](#)

written by CAP TODAY
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December 2021—The results of Olympus' ongoing joint research program to create an AI-based pathology diagnostic tool were announced at the Japan Society of Digital Pathology Study annual meeting. The AI tool was able to achieve 100 percent sensitivity and 50 percent or higher specificity for all gastric biopsy pathology specimens analyzed from the six facilities participating in the study.



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[Microbix expands pandemic test controls portfolio](#)

written by CAP TODAY
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December 2021—Microbix Biosystems has expanded its portfolio of quality assessment products to include controls that support PCR tests for four major variants of concern of SARS-CoV-2.



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LumiraDx COVID-19 antigen test gets expanded EUA

written by CAP TODAY
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December 2021—LumiraDx announced that the FDA’s emergency use authorization for its SARS-CoV-2 antigen test has been expanded to include screening of asymptomatic individuals. This claim builds on its existing claim that covers use of the test in individuals suspected of having COVID-19 by their health care provider within 12 days of symptom onset. The test received EUA in August 2020.



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Bio-Rad RP positive run control for SARS-CoV-2

written by CAP TODAY
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December 2021—Bio-Rad announced its Exact Diagnostics RP Positive Run Control for syndromic respiratory panels is now available with inactivated whole virus for SARS-CoV-2. The unassayed external quality control contains 23 respiratory analytes in one vial and is intended to monitor the performance of clinical respiratory assays. The control is a combination of whole, intact virus and bacteria that have been heated or chemically inactivated and synthetic RNA transcripts.



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[eGFR equation no longer Black and white](#)

written by CAP TODAY
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December 2021—There are success stories. There are overnight success stories. And then there are things that just seem to happen overnight—minus the success. In the midst of chronic discontent over the use of a race coefficient in equations for estimating glomerular filtration rate, one San Francisco hospital sought to make a change. The hope was to help end disparities in health care, such as lower kidney transplantation rates in Black people with chronic kidney disease. The change at Zuckerberg San Francisco General Hospital was pushed by what Neil Powe, MD, MPH, MBA, calls “a very small group of faculty and trainees lobbying the lab, unbeknownst to others.” The lab reported two values, using the eGFR equation with and without the race coefficient, but assigned “high muscle mass” and “low muscle mass” to the two values as a way to step around the troubling race component. Dr. Powe, the hospital’s chief of medicine, doesn’t mince words when he considers how the change was made. “And it stereotyped ethnic groups even more,” he says.



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[MMR, MSI testing guideline nears finish line](#)

written by CAP TODAY
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December 2021—No single assay can capture all cancer patients with DNA mismatch repair deficiency, and in determining a patient’s eligibility for immune checkpoint inhibitor therapy, assays for MMR deficiency, microsatellite instability, and tumor mutation burden should not be considered interchangeable.



Siemens SARS-CoV-2 testing portfolio detects omicron variant

written by CAP TODAY
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Dec. 15, 2021—Siemens Healthineers has announced that the company's SARS-CoV-2 tests are designed to detect the SARS-CoV-2 omicron variant.



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Tight and terrible: Lab leaders on budgets and staffing

written by CAP TODAY
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December 2021—The staffing crisis lives on, despite labs having plans of all kinds in place to alleviate the shortage. "It's the only thing we're talking about," Ochsner Health's Greg Sossaman, MD, said on Nov. 2 when members of the Compass Group met by Zoom. SARS-CoV-2 testing and test supplies and vaccination are "taking a back seat" to staffing, he said.



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