

[Agena granted EUA for SARS-CoV-2 panel](#)

written by CAP TODAY
December 17, 2020

December 2020—Agena Bioscience's MassArray SARS-CoV-2 Panel for qualitative detection of the SARS-CoV-2 coronavirus has been granted emergency use authorization from the FDA.



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[FDA approves liquid biopsy NGS CDx](#)

written by CAP TODAY
December 17, 2020

December 2020—The FDA approved the Guardant360 CDx assay (Guardant Health), a liquid biopsy companion diagnostic that also uses next-generation sequencing technology to identify patients with specific types of mutations of the epidermal growth factor receptor gene in a deadly form of metastatic non-small cell lung cancer. This is the first approval to combine NGS and liquid biopsy in one diagnostic test in order to guide treatment decisions.



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[Eppendorf adjustable spacing pipettes](#)

written by CAP TODAY
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December 2020—Eppendorf released its Move It Adjustable Spacing Pipettes. Move It was designed for the synchronous pipetting of a series of samples between different vessel formats, such as between tubes and plates, without tubing connections between cone and piston-cylinder system. The format of microplates can be adjusted directly with the format limiters. For other sample tubes or tubes in holders, the cone spacing is selected by using the rotary knob.



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FDA authorizes first OTC at-home test for COVID-19

written by CAP TODAY
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Dec. 16, 2020—The FDA issued an emergency use authorization for the first over-the-counter, at-home diagnostic test for COVID-19.



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Roche launches CE-marked Cobas PIK3CA Mutation Test

written by CAP TODAY
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Dec. 15, 2020—Roche launched the Cobas PIK3CA Mutation Test CE-IVD for patients with advanced or

metastatic breast cancer in countries accepting the CE mark.



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[In SARS-CoV-2, small steps but big wins](#)

written by CAP TODAY
December 17, 2020

December 2020—By its very nature, the global pandemic has forced laboratories to look far and wide, to bring binoculars, in essence, to their views of supply chains, testing platforms, personnel, and the like. As COVID-19 churns on, some labs are looking through a tinier lens as well. These labs aren't trading their binoculars for a jeweler's loupe, exactly, but they have found small and significant success stories closer to home. Like so many others, Erin Graf, PhD, D(ABMM), has confronted a spinning roulette wheel since the pandemic's start. In a talk she gave in an AMP webinar in October, Dr. Graf posted a vibrantly colored wheel titled, "Which supply chain issue will impact us this week?" Each segment contained a phrase familiar to everyone in 2020, ranging from "swabs" and "sheep blood agar" to "pipette tips" and "chlamydia and gonorrhea tests." As she surveys these continuous claims on her attention, Dr. Graf says, "I think none of us could have ever thought that COVID would have an impact on all these arms of the testing that we do."



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[Digging into drug's effect on aPTT-based](#)

assays

written by CAP TODAY
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December 2020—As ongoing studies reveal the merits of emicizumab for hemophilia A patients—fewer bleeding episodes, longer duration between treatments—laboratories need to be alert to the drug’s effect on coagulation testing.



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How to right the wrongs of clinical decision support alerts

written by CAP TODAY
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December 2020—Always think about timing, maintain a log of malfunctions, and make the right decision the easy decision. These are a few of the clinical decision support tips that Ronald Jackups Jr., MD, PhD, and Amanda Blouin, MD, PhD, presented last month in a CAP20 session.



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Journeys to alternative SARS-CoV-2 strategies

written by CAP TODAY
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December 2020—In Colorado, Joan Coleman, MBA, MT(ASCP), and her UCHHealth colleagues launched an expansive pooled testing program this summer that, after much work, worked well—until it didn't, thanks to rising positivity rates in October.



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Identifying respiratory pathogens: Pneumonia panel studied against standard of care

written by CAP TODAY
December 17, 2020

December 2020—In an evaluation performed at Washington University in St. Louis and published recently, BioFire's FilmArray pneumonia panel was found to have strong agreement with standard-of-care methods in identifying viral and bacterial targets in 200 lower respiratory tract specimens (Webber DM, et al. *J Clin Microbiol.* 2020;58[7]:e00343-20). It was also found to have strong agreement with the BioFire upper respiratory panel for common targets, making it unnecessary to perform both. In comparison to standard-of-care methods, it has the potential to detect more *Staphylococcus aureus* and *Haemophilus influenzae* and to detect more antimicrobial resistance, particularly at low organism concentrations or in mixed cultures.



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