

[Put It on the Board](#)

written by CAP TODAY
September 17, 2020

Roche launches Preanalytical System, announces FDA OK for HER2 Dual ISH test as CDx
September 2020—Roche launched its Cobas Prime Preanalytical System to improve efficiency in molecular diagnostics laboratories. It is now commercially available in the United States and markets accepting the CE mark. The system is designed to automate all preanalytic steps and features cross-contamination control of samples. It has track-connectable modular configurations with one workflow for multiple sample types, end-to-end automation with predictable lab turnaround time, and IT integration with sample and test tracking.



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[ARUP offers COVID-19 saliva testing](#)

written by CAP TODAY
September 17, 2020

Sept. 16, 2020—ARUP Laboratories announced it now offers COVID-19 testing using saliva specimens.



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Magnolia Medical launches Mission to Zero

written by CAP TODAY
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Sept. 14, 2020—Magnolia Medical Technologies launched Mission to Zero, to bring greater awareness to the patient safety and antibiotic-associated risks caused by false-positive diagnostic test results for sepsis.



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Roche BKV test FDA cleared on Cobas 6800/8800 systems

written by CAP TODAY
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Sept. 9, 2020—Roche received FDA 510(k) clearance for the Cobas BKV test on the Cobas 6800 and 8800 systems.



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FDA clears Simplexa Flu A/B & RSV Direct Gen

[II assay](#)

written by CAP TODAY
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Sept. 8, 2020—DiaSorin Molecular received FDA clearance for its Simplexa Flu A/B & RSV Direct Gen II kit.



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[Roche receives EUA for Cobas SARS-CoV-2 & Influenza A/B test](#)

written by CAP TODAY
September 17, 2020

Sept. 4, 2020—Roche announced that the Cobas SARS-CoV-2 & Influenza A/B Test for use on the Cobas 6800/8800 systems has received emergency use authorization from the FDA.



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[Roche HIV 1/2 qualitative test approved on](#)

Cobas 6800/8800

written by CAP TODAY
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Sept. 1, 2020—Roche announced FDA approval for the Cobas HIV-1/HIV-2 Qualitative test for use on the fully automated Cobas 6800/8800 systems in the United States.



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Abbott's BinaxNow 15-minute COVID-19 antigen test gets EUA

written by CAP TODAY
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Aug. 27, 2020—The FDA has issued emergency use authorization for Abbott's BinaxNOW COVID-19 Ag Card rapid test for the detection of COVID-19 infection.



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Beckman Coulter launches SARS-CoV-2 IgM

[antibody test](#)

written by CAP TODAY
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Aug. 26, 2020—Beckman Coulter launched its Access SARS-CoV-2 Immunoglobulin M assay.



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[Qiagen expands coronavirus NGS, software solutions](#)

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Aug. 25, 2020—Qiagen has launched the QIAseq SARS-CoV-2 Primer Panel for next-generation sequencing of the novel coronavirus genome and integrated analysis and interpretation workflows for insights into the evolution and spread of the virus.



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