

[FDA clears Simplexa Congenital CMV Direct assay](#)

written by CAP TODAY
November 11, 2022

Nov. 11, 2022—DiaSorin announced it has received FDA 510(k) clearance for its Simplexa Congenital CMV Direct kit.



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[ZeptoMetrix launches NATtrol MS2 bacteriophage stock](#)

written by CAP TODAY
November 11, 2022

Nov. 10, 2022—ZeptoMetrix launched its NATtrol MS2 Bacteriophage quantitative stock, intended for use as an internal process control for rt-PCR assays.



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[Roche introduces Cobas 5800 system](#)

written by CAP TODAY
November 11, 2022

Nov. 9, 2022—Roche announced plans for the U.S. launch of the Cobas 5800 system, a compact, fully-automated molecular instrument that aims to offer a flexible, PCR testing solution to help clinicians diagnose infectious diseases.



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[Werfen to acquire Immucor](#)

written by CAP TODAY
November 11, 2022

Nov. 4, 2022—Werfen announced it has agreed to acquire Immucor from asset management firm TPG.



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[Thermo Fisher Scientific buys Binding Site](#)

written by CAP TODAY
November 11, 2022

Oct. 31, 2022—Thermo Fisher Scientific announced today that it has entered into a definitive agreement to acquire the Binding Site Group from a shareholder group led by European private equity firm Nordic Capital.



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[Bio-Rad launches Exact Diagnostics CT/NG, STI run controls](#)

written by CAP TODAY
November 11, 2022

Oct. 28, 2022—Bio-Rad Laboratories has launched two Exact Diagnostics products, CT/NG Positive Run Control, intended to be used with *Chlamydia trachomatis* and *Neisseria gonorrhoeae* molecular assays, and STI Negative Run Control, which monitors the absence of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in various molecular assays, the company says, and can be used to detect errors in laboratory testing procedures, including potential contamination events, while controlling for sample adequacy assessment.

FDA clears COVID-19 PCR test on Cobas 6800/8800 systems

written by CAP TODAY
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Oct. 25, 2022—Roche announced that the FDA has granted 510(k) clearance for the Cobas SARS-CoV-2 Qualitative PCR test for use on the automated Cobas 6800 and Cobas 8800 systems.

Cofactor Genomics reports OncoPrism data

written by CAP TODAY
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October 2022—Cofactor Genomics presented initial results from the PREDAPT (Predicting Immunotherapy Efficacy from Analysis of Pre-treatment Tumor Biopsies) multicenter clinical trial at the Advances in Genome Biology and Technology Precision Health Meeting in September. The company says its data show that Cofactor's OncoPrism test using predictive immune modeling was nearly twice as accurate as PD-L1 assays in determining who will benefit from immunotherapies such as Keytruda (pembrolizumab).

Roche launches digital PCR system

written by CAP TODAY
November 11, 2022

October 2022—Roche launched its Digital LightCycler system, the company's first digital polymerase chain reaction system, for precise DNA and RNA analysis in areas such as oncology and infectious diseases. The instrument features three unique reaction plates, six channel multiplexing capabilities, and a 5× concentrated master mix reagent. Run time is two to four hours with up to 96 samples per run.