

[Verichem Labs offers data reduction services](#)

written by CAP TODAY
January 19, 2021

January 2021—Verichem Laboratories is offering its customers free access to the company's online, web-based data reduction services. Designed for use with Verichem's products, the service supports the necessary statistics required within the clinical laboratory to satisfy current CLIA and CAP requirements for the calibration verification of clinical assays.



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[Streck launches rapid, modular qPCR instrument](#)

written by CAP TODAY
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January 2021—Streck has launched its Zulu RT, a rapid, modular qPCR instrument. The instrument consists of four independent thermal modules. A user can operate any combination of modules—one module for a small sample set, leaving other modules for other users, or up to four modules simultaneously for a large sample set. It can perform a 40-cycle, six-channel real-time PCR in less than 20 minutes.



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BD FacsLyric 510(k) cleared with FacsDuet sample prep system

written by CAP TODAY
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January 2021—BD received FDA 510(k) clearance for the BD FacsLyric flow cytometer integrated with the BD FacsDuet sample preparation system. Physical integration between the two instruments allows technicians to load samples and reagents onto the BD FacsDuet and obtain results once the samples are acquired and analyzed on the BD FacsLyric. Data integration using the BD FacsLink middleware solution offers bidirectional communication between the instruments and connectivity with laboratory information systems.



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COVID-19, flu combo test for home-collected samples

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January 2021—The FDA authorized the first diagnostic test for at-home collection of patient samples to detect COVID-19 and influenza A and B. Quest Diagnostics' RC COVID-19 +Flu RT-PCR Test for prescription use was authorized with Quest's Self-Collection Kit for COVID-19 +Flu for individuals who are suspected of respiratory viral infection consistent with COVID-19 when home collection is determined to be appropriate by an individual's health care provider.



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Siemens test measures neutralizing antibodies

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January 2020—Siemens Healthineers' SARS-CoV-2 IgG Antibody Test has proven to measure neutralizing antibodies, the company announced. The test reports quantitative results measuring the amount of neutralizing antibodies present in a patient's blood sample.



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GenMark ePlex RP2 panel receives EUA

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January 2021—GenMark Diagnostics received FDA emergency use authorization for its ePlex Respiratory Pathogen Panel 2. The test provides results in less than two hours for more than 20 viruses and bacteria that cause respiratory infections, including COVID-19, flu, bronchitis, and the common cold.



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Radox multiplex controls for respiratory disease

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January 2021—Radox Laboratories has unveiled its Qnostics Multiplex Respiratory Pathogen Controls for respiratory diseases, including for SARS-CoV-2, influenza A and B, and respiratory syncytial virus. The RTX controls are used to monitor the full testing process, from extraction to amplification and detection, and are compatible with a majority of commercial and in-house assays.



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TechLab to supply ASRs for SARS-CoV-2

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January 2021—TechLab has partnered with New River Valley COVID-19 Task Force to expand future COVID-19 testing capacity. Under the agreement, the New River Health District, headquartered in Christianburg, Va., secures access to TechLab's analyte-specific reagents for SARS-CoV-2 for \$7 to \$9 per use.



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Saliva-based COVID-19 assay gets EUA

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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.



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

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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.



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