FDA clears Cobas BKV test for urine samples

written by CAP TODAY
February 12, 2021

Feb. 12, 2021–Roche announced FDA 510(k) clearance of stabilized urine samples to be used with the Cobas BKV test on the Cobas 6800/8800 systems.

BioDiscovery releases upgrade to NxClinical software system

written by CAP TODAY
February 12, 2021

Feb. 11, 2021–BioDiscovery has released N_xClinical 6.0, the company's fifth major upgrade to its software for integrated analysis of copy number, sequence variants, and allelic changes obtained from multiple technologies.

Seegene rolls out COVID-19 mutant

identification test

written by CAP TODAY
February 12, 2021

Feb. 9, 2021–Seegene announced it has developed the first COVID-19 diagnostic variant test capable of screening COVID-19 and identifying multiple mutant variations in a single reaction.

LGC acquires Technopath Clinical Diagnostics

written by CAP TODAY
February 12, 2021

Feb. 5, 2021–LGC announced its acquisition of Technopath Clinical Diagnostics, expanding LGC's position in the clinical diagnostics QC market.

Sarstedt Microvette automated processing tubes

written by CAP TODAY
February 12, 2021

Feb. 3, 2021–Sarstedt introduced the Microvette APT for capillary blood collection.

Beckman launches tabletop DxH 560 AL hematology analyzer

written by CAP TODAY
February 12, 2021

Jan. 29, 2021—Beckman Coulter launched the DxH 560 AL, a tabletop analyzer geared to reduce the time and resource constraints faced by small to mid-sized laboratories.

Tecan launches automated whole blood processing system

written by CAP TODAY
February 12, 2021

Jan. 22, 2021—Tecan has launched the Fluent Mix and Pierce Workstation to provide end-to-end automation for whole blood pipetting in clinical environments.

FDA authorizes OTC at-home test for COVID-19

written by CAP TODAY
February 12, 2021

January 2021—The FDA issued an emergency use authorization for the first over-the-counter, at-home diagnostic test for COVID-19. The Ellume COVID-19 Home Test is a rapid, lateral flow antigen test that detects fragments of proteins of the SARS-CoV-2 virus using a mid-turbinate nasal swab sample from any person two years of age or older. The Ellume home test correctly identified 96 percent of positive samples and 100 percent of negative samples in people who had symptoms. In people without symptoms, the test correctly identified 91 percent of positive samples and 96 percent of negative samples. The home test uses an analyzer that connects with a software application on a smartphone to help users perform the test and interpret results. Results are delivered in as little as 20 minutes via a person's smartphone. "By authorizing a test for over-the-counter use, the FDA allows it to be sold in places like drug stores, where a patient can buy it, swab their nose, run the test, and find out their results in as little as 20 minutes," FDA commissioner Stephen M. Hahn, MD, said in a statement released by the agency. "As we continue to authorize additional tests for home use, we are helping expand Americans' access to testing, reducing the burden on laboratories and test supplies, and giving Americans more testing options from the comfort and safety of their own homes."

©2026 CAP TODAY, all rights reserved.

Siemens test measures neutralizing antibodies

written by CAP TODAY
February 12, 2021

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.

GenMark ePlex RP2 panel receives EUA

written by CAP TODAY
February 12, 2021

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.