

[Put It on the Board](#)

written by CAP TODAY
June 15, 2021

June 2021—The Food and Drug Administration on March 30 allowed the use of the Binx Health IO CT/NG assay in physician offices, community-based clinics, urgent care settings, outpatient health care facilities, and other patient care settings operating under a CLIA certificate of waiver, certificate of compliance, or certificate of accreditation.



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[Grail introduces Galleri multicancer early detection blood test](#)

written by CAP TODAY
June 15, 2021

June 14, 2021—Grail introduced its Galleri multicancer early detection blood test, intended for use in people with an elevated risk of cancer, such as adults aged 50 or older, and as a complement to single-cancer screening tests.



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[Labcorp, OmniSeq launch Insight NGS genomic profiling test](#)

written by CAP TODAY
June 15, 2021

June 10, 2021—Labcorp and OmniSeq announced the launch of OmniSeq Insight, a next-generation-sequencing, pan-cancer, solid tumor test that combines genomic and immune profiling, including tumor mutational burden, microsatellite instability, and immune gene expression.



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[Sysmex America adds XN-10 blood bank mode to its portfolio](#)

written by CAP TODAY
June 15, 2021

June 9, 2021—Sysmex America has added the FDA-cleared XN-10 Automated Hematology Analyzer with Blood Bank mode to its portfolio of hematology solutions.



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[Diazyme launches beta-hydroxybutyrate assay](#)

written by CAP TODAY

June 15, 2021

June 8, 2021—Diazyme launched its FDA 510(k)-exempt Beta-Hydroxybutyrate Assay for the quantitative determination of beta-hydroxybutyrate.



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[Lumakras OK'd for patients with KRAS G12C-mutated NSCLC](#)

written by CAP TODAY

June 15, 2021

June 7, 2021—Amgen announced that the FDA approved Lumakras (sotorasib) for the treatment of adult patients with *KRAS* G12C-mutated locally advanced or metastatic non-small cell lung cancer, as determined by an FDA-approved test, who have received at least one prior systemic therapy.



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[FDA approves targeted therapy for subset of](#)

[NSCLC](#)

written by CAP TODAY
June 15, 2021

May 28, 2021—The U.S. Food and Drug Administration approved Janssen Pharmaceutical's Rybrevant (amivantamab-vmjw) as the first treatment for adult patients with non-small cell lung cancer whose tumors have epidermal growth factor receptor exon 20 insertion mutations.



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[DiaSorin releases Simplexa SARS-CoV-2 Variants Direct assay](#)

written by CAP TODAY
June 15, 2021

May 25, 2021—DiaSorin Molecular has released the Simplexa SARS-CoV-2 Variants Direct assay, for research use only, to enable the detection and discrimination of four SARS-CoV-2 mutations associated with circulating virus variants without requiring upfront RNA extraction.



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Hologic receives approval for ThinPrep Genesis

written by CAP TODAY
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May 24, 2021—Hologic announced the FDA has granted premarket approval of the company's ThinPrep Genesis processor for cytology processing and specimen transfer for downstream applications.



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Bio-Rad launches InteliQ Diabetes Control

written by CAP TODAY
June 15, 2021

May 21, 2021—Bio-Rad Laboratories launched its InteliQ Diabetes Control, the 10th product offered in the InteliQ format.



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