

Biodesix launches GeneStrat NGS, IQLung testing strategy

written by CAP TODAY
February 21, 2022

February 2022—Biodesix announced the launch of its GeneStrat NGS genomic test, a blood-based tumor profiling test. The 52-gene panel includes guideline-recommended mutations to help physicians treating advanced-stage lung cancer patients identify targeted therapy mutations, such as EGFR, ALK, KRAS, MET, NTRK, ERBB2, and others.



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Qiagen, Denovo to develop CDx for treatment of DLBCL

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February 2022—Qiagen and Denovo Biopharma will collaborate to develop a blood-based companion diagnostic test to identify patients expressing Denovo Genomic Marker 1 (DGM1) who are likely to respond to Denovo's investigational cancer drug DB102 for treatment of diffuse large B-cell lymphoma. DB102 (enzastaurin) is an investigational small molecule inhibitor of PKC-beta, which, if present, has been linked to DLBCL cases.



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EliTechGroup PCR kit differentiates SARS-CoV-2 omicron variant

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February 2022—EliTechGroup MDx announced its research use only SARS-CoV-2 Extended test kit reliably differentiates the SARS-CoV-2 omicron (B.1.1.529) variant from other variants of concern. The in silico analysis was confirmed by testing patient samples positive for different SARS-CoV-2 variants including omicron. The SARS-CoV-2 Extended RUO reagents differentiate the alpha, beta, gamma, delta, and omicron variants in a single multiplex PCR and test for the presence of specific mutations in the regions of the S gene corresponding to positions 452, 484, and 501 of the spike protein. The combination of the melting curve analysis and the optical channel information allows for unambiguous differentiation of the five SARS-CoV-2 variants. The results can be interpreted and released when the reagents are used on the sample-to-result Elite InGenius system.



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Roche COVID-19 at-home test granted EUA

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February 2022—Roche announced that the FDA has granted emergency use authorization for its COVID-19 At-Home Test. The test uses an anterior nasal swab sample that can be self-collected and self-tested by people ages 14 years and older and by an adult for children ages two to 13 years old. Results are available in as few as 20 minutes for SARS-CoV-2 and all known variants of concern, including omicron.



[After the switch: high-sensitivity troponin](#)

written by CAP TODAY

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February 2022—Like growing old gracefully, moving to high-sensitivity cardiac troponin is both easier and more complex than it often appears. Stacy Beal, MD, thought clinical colleagues might be intimidated by switching assays. Dr. Beal was fully prepared to field worries about increased admissions, more consults, and other disaster scenarios. Instead, what surprised Dr. Beal, a member of the CAP Quality Practices Committee, was the ease with which some thought change could occur. “We heard people saying, ‘Just move the decimal point over two spots,’” she recalls. “I think we started hearing that from the day we started talking about it.” Could simply moving the decimal work? As Dr. Beal notes, “It’s hard to argue with that method, but we truly tried to tell them not to—that they needed to interpret this in a totally different way, and to view the different units as a new assay that’s very different from our previous assay.” “Maybe it’s our own fault,” Dr. Beal concedes. When the lab presented its correlation data, the new units were presented on one axis, while the old ones appeared on another.



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[Steps to preventing coag test processing error](#)

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February 2022—It was Isaac Asimov who surmised: “The most exciting phrase to hear in science is not ‘Eureka!’ but ‘That’s funny . . .’” And it was coagulation processing in the clinical laboratory that, in a small way, illustrated Asimov’s axiom for Dorothy Adcock, MD, former chief medical officer, Labcorp Diagnostics.

[A look ahead at AI-based assistance in anatomic pathology](#)

written by CAP TODAY
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February 2022—In a survey of the international pathology community on the integration of artificial intelligence into diagnostic pathology practice, 80 percent of the 487 respondents predicted integration within the next five or 10 years.

[Gastric intestinal metaplasia—the need to classify and how](#)

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February 2022—How to classify gastric intestinal metaplasia, when to classify it, and the implications of a GIM diagnosis were the focus of a CAP21 presentation in a session on advances in gastric neoplasms. The big question, said presenter Namrata Setia, MD, is, “Why are we suddenly talking about classifying intestinal metaplasia in the stomach?”

[Staff out, instruments down—coping as the year begins](#)

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February 2022—New year, new variant. For Compass Group lab leaders on a call with CAP TODAY publisher Bob McGonnagle on Jan. 4, omicron was new but the struggles were similar. They spoke of staffing and supplies but also of the CDC's day-five guidance, crisis planning, instrument downtimes and hard-to-get parts, and doing such things as limiting routine phlebotomy draw times for COVID-positive inpatients.

[Molecular oncology tumor board: Pathologist, oncologist dip into head and neck case](#)

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February 2022—Up first in a CAP21 molecular oncology tumor board session was an unusual case of head and neck cancer, one that raises questions about what salivary duct carcinoma is and the role of next-generation sequencing. Justin Bishop, MD, the Jane B. and Edwin P. Jenevein, MD, distinguished chair in pathology and professor and chief of anatomic pathology, UT Southwestern, along with Saad Khan, MD, assistant professor of medicine (oncology) at Stanford, teamed up to present the case, along

with a second case that will be reported in the March issue. (Dr. Khan practiced at one time at UT Southwestern, so this wasn't their first tumor board together.)



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