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# In Brief This Week: Natera, Bruker, Bayer, and More

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NEW YORK – Natera said this week that the Centers for Medicare & Medicaid Services, or CMS, has granted Advanced Diagnostic Laboratory Test, or ADLT, status to the company's Signatera molecular residual disease test. The initial ADLT rate established by CMS is $3,500 for each Signatera assay used in the recurrence monitoring setting, the company said. Signatera received Medicare coverage for use in stage II-III colorectal cancer in late 2020, while finalization of a draft local coverage determination for use in immunotherapy response monitoring is anticipated for release in late 2021.

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Bruker said this week that it expects year-over-year revenue growth of 16 percent to 18 percent for fiscal year 2021, including a positive foreign currency effect of 3 percent. Non-GAAP earnings per share are expected to be $1.84 to $1.89, representing a year-over-year increase of 36 percent to 40 percent. In fiscal year 2024, the firm projects revenues between $2.7 billion and $3.0 billion, excluding acquisitions and currency effects, and non-GAAP EPS between $2.60 and $3.00.

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Bayer this week announced it is accepting applications for two grants, one for $50,000 and another for $25,000, through which it hopes to encourage innovation and collaboration around improving patient access to precision oncology treatments globally. With these awards, the drugmaker is aiming to ease access to genomic testing for cancer patients who may harbor rare, targetable biomarkers. Nonprofit institutions, such as patient advocacy organizations and educational groups, may apply for the grants to support new initiatives or expand existing programs for adult and pediatric cancer patients. An independent panel of experts, including representatives from the clinical and patient advocacy communities, will review the applications.

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Hologic said this week that it has completed its previously announced acquisition of Mobidiag for an enterprise value of approximately $808 million. Mobidiag provides near-patient, molecular diagnostic instruments, and tests for acute care conditions including gastrointestinal and respiratory infections, antimicrobial resistance management, and healthcare associated infections. Its Amplidiag and Novodiag testing platforms deliver results in 50 minutes to two hours, Hologic said.

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NeoGenomics said this week that it has completed its previously announced acquisition of Inivata as part of its plans to enter the minimal residual disease testing market. The firm will become a liquid biopsy-focused division alongside NeoGenomics' clinical, pharma, and informatics divisions. Inivata CEO Clive Morris will become president of Inivata and will report to NeoGenomics CEO Mark Mallon.

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Rover Labs, a New York-area COVID-19 testing service, said this week that it is providing saliva-based testing to approximately 50 New York City public schools during a two-month pilot period that began on June 1. Rover Labs uses Fluidigm PCR assays and technology to provide its testing services. Test recipients in the pilot program will provide their saliva samples through a self-collection process overseen by school nurses. Samples from students, teachers and staff are picked up by Rover Labs and delivered to their partner lab in Eatontown, New Jersey, for processing. Rover Labs' first round of testing began on June 1 and will continue through the end of the school year and into summer programming, the company said.

Inteliquet said this week that St. Petersburg, Florida-based Comprehensive Hematology and Oncology will join Inteliquet's Cancer Center Research Consortium. The consortium currently includes 12 academic centers, community oncology practices, and integrated delivery networks that Inteliquet has selected based on the centers' personalized approaches to cancer treatment. As a member of the consortium, Comprehensive Hematology and Oncology will have access to Inteliquet's patient-clinical trial matching technology, dubbed OncWeb, which uses artificial intelligence and anonymized patient data to identify eligible patients for clinical trials.

Holista Colltech announced this week that it has been granted special access under the Medical Device Exemption Order 2016 from the Medical Devices Authority of Malaysia's Ministry of Health to import and distribute up to 45,000 units of a rapid SARS-CoV-2 antigen test in the next three months. The test was developed by Chinese company Guangdong Hecin Scientific and can detect the presence of SARS-CoV-2 from nasal swabs in less than 15 minutes. Holista Colltech secured an initial order of 15,000 tests worth about $73,000 after receiving access, and the tests will be shipped by the end of June.

Holista has the rights to distribute the test kits in Brunei, Thailand, Indonesia, the Philippines, Taiwan, Vietnam, Cambodia, Laos, Myanmar, Singapore, and the UK.

Holista also received import and distribution approval for the Hecin Antibody Test, which detects levels of SARS-CoV-2 antibodies to determine immunity after vaccination.

HTG Molecular Diagnostics said this week that it has completed product design lock for its HTG Transcriptome Panel. The firm has also announced three undisclosed early adopter program collaborators.

Saga Diagnostics said this week that is has received ISO 17025 accreditation for its mutation detection laboratory services from the Swedish Board for Accreditation and Conformity Assessment. Based in Lund, Sweden, Saga commercializes technologies to quantify cancer-associated genetic aberrations in tissue and liquid biopsy samples. Its platform technologies are based on digital PCR and next-generation sequencing.

*In Brief This Week is a selection of news items that may be of interest to our readers but had not previously appeared on GenomeWeb.*