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SeraCare develops first multiplexed cardiomyopathy reference material

SeraCare Life Sciences has launched a multiplexed reference material for inherited disease testing by next-generation sequencing. The Seraseq Inherited Cardiomyopathy Reference Material was developed in collaboration with Birgit Funke, PhD, director of clinical research and development at the Partners HealthCare Laboratory for Molecular Medicine. This work was published in the November 2016 issue of the Journal of Molecular Diagnostics (Kudalkar EM, et al. 18[6]:882–889).

The reference material combines 10 common pathogenic and/or technically challenging variants in a single reference sample. The variants were chosen based on a careful review of clinical sequencing data obtained over 10 years at the Laboratory for Molecular Medicine. The final product configuration was determined based on proof-of-concept evaluation of two different design concepts and performance that was comparable to patient-derived data. This product combines hypertrophic cardiomyopathy variants in a well-characterized genomic background at a 50 percent target allele frequency that can be used for assay development, analytical validation, or routine quality control.

“Because of the high prevalence of HCM in the general population (1:500 individuals),” the authors write, “NGS gene panels for this disorder are among the most widely offered NGS tests; however, public reference sample repositories have not yet incorporated sufficient and relevant variants, likely because genetic testing for this disorder is merely a decade old. We show that multiplexed gDNA-based reference samples harboring a collection of spiked-in, synthetic DNA fragments with common, clinically significant HCM variants yield consistent results among both SNVs and indels and are essentially indistinguishable from patient-derived DNA.”
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Thermo Fisher submits PMA application for multigene CDx

Thermo Fisher Scientific has filed the final module of a premarket approval application with the Food and Drug Administration for its Oncomine Universal Dx test, a multigene, next-generation sequencing-based assay for non-small cell lung cancer.

If approved, the universal gene panel would serve as a companion diagnostic to select patients for specific NSCLC therapies. The companion diagnostic is designed to simultaneously screen patient tumor samples for multiple gene variants with a single test. It can return genetic data in fewer than five days using 10 ng of DNA, according to the

company.

Thermo Fisher's PMA submission includes clinical and analytical claims associated with NSCLC biomarkers and comes after the successful completion of clinical trials using patient samples that Novartis and Pfizer provided.

The end-to-end, highly sensitive solution has been developed using Thermo Fisher's Oncomine and AmpliSeq technologies and validated on the Ion PGM Dx system, the company said in a statement. The genes and biomarkers included in the test were selected from the Oncomine Knowledgebase and confirmed with pharmaceutical partners.
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Ventana ALK CDx approved for use on BenchMark Ultra

The Food and Drug Administration has approved the Roche Ventana ALK (D5F3) CDx Assay for use on the Ventana BenchMark Ultra automated slide stainer. The assay is a companion diagnostic to aid in identifying ALK-positive lung cancer patients who are eligible for treatment with Pfizer's FDA-approved therapy Xalkori (crizotinib).
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Siemens Healthineers acquires Conworx

Siemens Healthineers has acquired Conworx Technology GmbH, the Berlin-based developer of point-of-care device interfaces and data-management solutions. The addition of the Conworx suite—including UniPOC and POCcelerator—complements the Siemens Healthineers RapidComm Data Management System and will deliver open connectivity for more than 100 different POC instruments from all major manufacturers, the company said in a statement.

The Siemens and Conworx open connectivity offerings will enable seamless data integration from any manufacturer's point-of-care analyzer—managed by a single informatics solution to streamline operations and access to data and to improve risk management, according to Siemens Healthineers.

Conworx's team of 75 employees will merge with the Siemens Healthineers team to become Siemens Healthineers Point of Care Informatics.
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Qiagen GeneReader NGS system to be relaunched in U.S.

Qiagen N.V. announced the validation of new sequencing chemistry for its GeneReader NGS system, which it is relaunching for U.S. customers.

Qiagen published new performance data of the GeneReader NGS system using the new sequencing chemistry and its GeneRead QIAact Actionable Insights Tumor Panel. Data generated from the GeneReader NGS system with the new chemistry showed 100 percent concordance with results of Qiagen's FDA-approved Therascreen KRAS RGQ PCR assay, the company's CE-labeled Therascreen RAS Extension Pyro Assay, as well as with an alternative next-generation sequencer from another vendor, the company said in a statement. In this study, 42 metastatic colorectal cancer FFPE samples were tested with previously confirmed RAS mutational status.

Qiagen is resuming commercialization of the GeneReader NGS system in the U.S. early next year. The new GeneReader chemistry was made available to select customers in the U.S. as part of an early access phase starting Dec. 1, and it will be followed by broad commercial launches in the U.S. in the first quarter of 2017 and in other regions of the world during the second quarter of 2017.
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Illumina launches TruSight Tumor 170 NGS assay

Illumina has launched TruSight Tumor 170, a 170-gene next-generation sequencing solution to support the transformation of tumor profiling from a series of single-gene tests to a multianalyte approach.

TruSight Tumor 170 offers an integrated DNA and RNA enrichment-based workflow, targeting cancer-related genetic aberrations, including small variants, gene amplifications, gene fusions, and splice variants. With bioinformatics tools and automation options, laboratories can implement the assay on an in-house, research-use-only NextSeq instrument. It will begin shipping in the first quarter of 2017.
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FDA clears Ortho Vision Max analyzer

The Ortho Vision Max, a fully automated blood analyzer for high-volume transfusion medicine laboratories, has received 510(k) clearance and is now commercially available in the United States.

The Vision Max launch follows the 2015 release of the Ortho Vision analyzer, an instrument designed for small to midsize transfusion labs.

The Vision Max was developed for labs conducting more than 50 types and screens per day, and it supports more complex immunohematology testing such as serial dilutions for titration studies, reflex tests, and selected cell antibody identification.
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