

CRC panel, thyroid cancer kits, 6/17

June 2017—EntroGen announced CE-IVD marking of its Colorectal Cancer Panel (CRC), Thyroid Cancer Mutation Analysis kit (THDNA), and Thyroid Cancer Fusion Gene Detection kit (THRNA).

The CRC panel is a highly multiplexed PCR-based assay that enables simultaneous screening of 50 somatic mutations in five oncogenes associated with colorectal cancer tumors: KRAS, NRAS, BRAF, PIK3CA, and AKT. The CRC panel kit meets the guidelines from the CAP, ASCO, AMP, and ASCP and is compatible with formalin-fixed, paraffin-embedded and fresh frozen tissue. It also includes data analysis software for automated reporting and sample quality assessment reagents designed to optimize sample input and avoid common run failures when using DNA isolated from formalin-fixed tissues.

The THDNA and THRNA kits are multiplexed PCR-based assays that aim to prevent unnecessary surgeries due to indeterminate cytology specimens by detecting molecular markers associated with malignant thyroid tumors. THDNA detects point mutations in BRAF, KRAS, NRAS, and HRAS in isolated DNA; THRNA detects the chromosomal translocations RET/PTC1, RET/PTC3, and PAX8/PPAR γ in RNA. Both kits are compatible with FFPE, fine needle aspiration, and fresh frozen samples. All are validated for several leading real-time PCR instruments and produce results in less than three hours.

The company also announced the launch of its BRCA Complete, a targeted NGS panel for BRCA1 and BRCA2 exome sequencing on Illumina MiniSeq, MiSeq, and NextSeq platforms.

BRCA Complete is a full solution for BRCA1/BRCA2 sequencing that includes reagents for target enrichment, library preparation, and PCR cleanup. It comes with user-friendly data interpretation software for reporting clinically relevant somatic and germline mutations. BRCA Complete is compatible with blood, fresh frozen, and FFPE samples. EntroGen's proprietary enrichment technology enables detection of somatic mutations in BRCA1/BRCA2 genes with approximately two percent limit of detection. The uniformity and average sequencing coverage are 95 percent and 0.2 \times , respectively. The panel received CE-IVD marking in May for use in Europe.

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