RESEARCH HIGHLIGHTS AT THE

2024 AMP Annual Meeting

Enabling access to genomic profiling through decentralized liquid biopsy solution, PGDx elio™ plasma focus Dx. Valkenburg CK, et al. AMP 2024—**Poster Board #ST093**

The PGDx elio™ plasma focus Dx is a next-generation sequencing assay that aids in treatment selection for patients with advanced stage cancers. Analytical validation demonstrated high specificity (≥99.99%), sensitivity (detecting variant allele frequencies as low as 0.31%) and reproducibility across multiple independent labs. These findings support an FDA-authorized, decentralized liquid biopsy assay to provide comprehensive genomic profiling for use by qualified healthcare professionals in accordance with professional guidelines.

Validation of automated nucleic acid extraction using Covaris® Gen3 extraction. Collins M, et al. AMP 2024—**Poster Board #TT075**

Using archival tumor biopsy specimens, this study demonstrated the truXTRAC® FFPE tNA Auto 96 assay-ready workstation (ARW) nucleic acid extraction system achieved significantly higher DNA and RNA yields from archival formalin-fixed paraffin embedded tumor samples compared to a previously validated method. The ARW method showed improved sample quality and yield with less sample requirement, thereby improving comprehensive genomic profiling to inform patient treatment decisions.

Comprehensive genomic and immune profiling for the detection of clinically significant tumor biomarkers. Green MF, et al. AMP 2024—**Poster Board #ST079**

This study evaluated biomarker detection rates from a multimodal comprehensive genomic and immune profiling (CGIP) assay combining DNA and RNA sequencing, immunohistochemistry (IHC) and gene expression profiling (GEP) performed on 20,645 solid tumor specimens across 48 tumor types. CGIP testing demonstrated high success rates, ranging from 90.2%-99.8% across test components. Biomarker detection rates varied across tumor types and increased with the addition of testing modalities, including the detection of clinically significant biomarkers in 61.0% (9,650/15,815) of cases. Overall, utilization of a multimodal CGIP testing strategy resulted in a high rate of test success and detection of clinically relevant biomarkers while optimizing tissue usage.

Analytical validation of OmniSeq® INSIGHT whole exome sequencing assay to facilitate precision oncology through tumor-only testing in solid tumors. An J, et al. AMP 2024—**Poster Board #ST021**

Using DNA from formalin-fixed paraffin embedded samples, this study rigorously tests the performance of the OmniSeq® INSIGHT WES Solid Tumors assay (OI-WES) that supports its application to detect genomic alterations in solid tumors. The results demonstrate high accuracy with positive percent agreement (PPA) of 98.4% and negative percent agreement (NPA) of 99.9%, along with high sensitivity, specificity and reproducibility across different DNA inputs, flow cells and conditions, establishing OI-WES as a reliable tool to support precision oncology drug development.

Analytical validation of OmniSeq® INSIGHT whole transcriptome sequencing assay to facilitate precision oncology through tumor-only testing in solid tumors. An J, et al. AMP 2024—**Poster Board #ST023**

The study evaluates the OmniSeq® INSIGHT WTS Solid Tumors (OI-WTS) assay for its ability to detect and quantify gene expression in solid tumors using RNA from formalin-fixed paraffin embedded samples. The assay was tested for sensitivity, specificity, precision and reproducibility in genomic profiling showing strong accuracy and correlation when compared to two orthogonal next-generation sequencing (NGS) assays (KAPA and AmpliSeq). The OI-WTS assay demonstrated 100% sensitivity (PPA) and specificity (NPA) for antifolate and FGFR predictive response signatures with high reproducibility across RNA inputs and test conditions, thus validating OI-WTS for transcriptomic profiling in precision oncology drug development.

Visit the poster session on **Nov. 23, 9:15-10:15 a.m.** or scan the QR code to view our full posters.

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