Analytical Validation of the Labcorp® Plasma Complete™ Test, a Cell-Free DNA Comprehensive Genomic Profiling Tool for Precision Oncology

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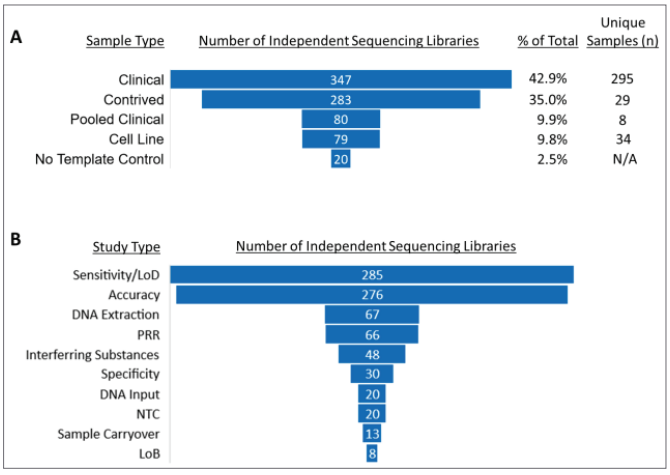
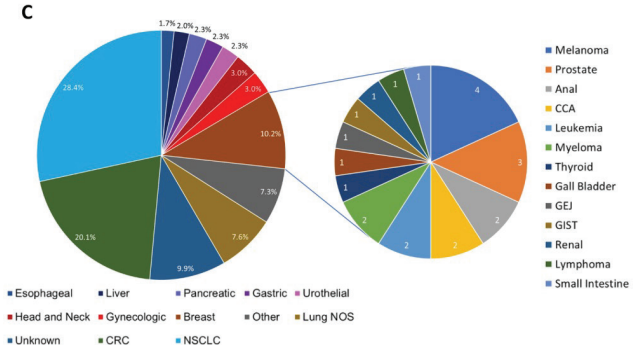
Background and Objective

- Liquid biopsy is a complementary approach to tissue testing for tumor molecular profiling.
- Labcorp Plasma Complete, a next-generation sequencing test, identifies somatic variants in 521 genes for advanced solid tumors.
- To analytically validate the Labcorp Plasma Complete test for launch as a laboratory developed test (LDT) at a Labcorp CAP/CLIA Laboratory.



Methods

Analytical validation of the Labcorp Plasma Complete test was performed across 809 independent sequencing libraries derived from 366 unique samples, including 295 unique clinical specimens from patients with cancer, 34 unique cell lines, 29 unique contrived samples and eight unique pooled clinical samples. Funnel charts depict the number of independent sequencing libraries per (A) sample type and (B) analytical validation study type, (C) Sample cohort was enriched for solid tumor types representing over 20 indications.



LoD, limit of detection; PRR, precision, reproducibility and repeatability; NTC, no template control; LoB, limit of blank; NSCLC, non-small cell lung cancer; CRC, colorectal cancer; NOS, not otherwise specified; HNSCC, head and neck squamous cell carcinoma; CCA, cholangiocarcinoma; GEJ, gastroesophageal junction; GIST, gastrointestinal stromal tumor.

Results

Study	Results			
	Sequence Variants	CNAs	Translocations	MSI
Accuracy	**SNVs** PPA: 97.8% NPA:>99.9% **Indels:** PPA: 91.6% NPA:>99.9%	PPA: 100.0% NPA: 99.9%	PPA: 86.4% NPA: 100.0%	PPA: 100.0% NPA: 100.0%
Sensitivity (LoD)	**SNVs** Observed MedianLoD: 1.2% VAF **Indels** Observed Median LoD: 1.3% VAF	ObservedMedian LoD: 1.7-fold	Observed Median LoD: 0.5% FRF	Observed Median LoD (using driver gene alterations): 0.5% VAF Sensitivity: 100%
Specificity	**SNVs** 99.9% **Indels** 100.0%	100.0%	100.0%	100.0%
Precision, reproducibility, repeatability	**SNVs and Indels** APA: 94.9% ANA: 99.9%	APA: 100.0% ANA: 100.0%	APA: 100.0% ANA: 100.0%	APA: 100.0% ANA: 100.0%

Key Takeaway

- The Labcorp Plasma Complete test demonstrates high sensitivity, specificity, accuracy and robustness.
- This liquid biopsy test enables tumor molecular profiling to inform treatment decisions.

Reference:
Verner EL, Jackson JB, Maddox C, et al. Analytical Validation of the Labcorp Plasma Complete Test, a Cell-Free DNA Comprehensive Genomic Profiling Tool for Precision Oncology. *J Mol Diagn*. 2025.

View the full manuscript on oncology.labcorp.com or scan the QR code

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