Q² Solutions®

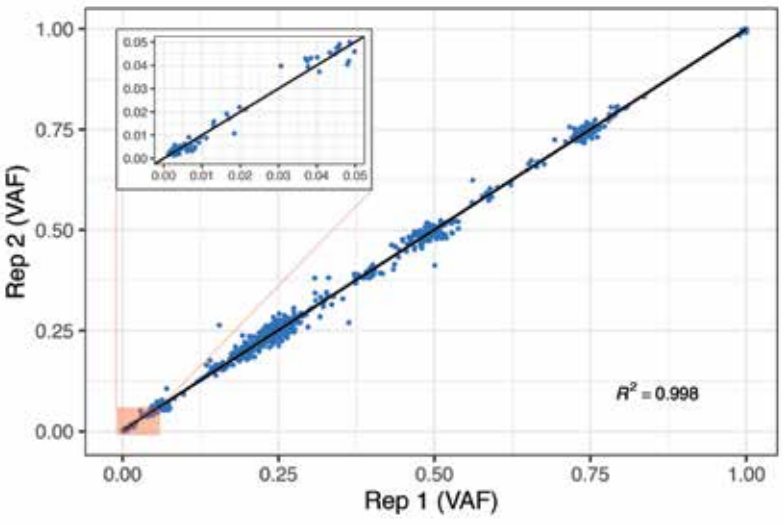
TruSight Oncology 500 (TSO500) ctDNA Assay

The TruSight Oncology 500 (TSO500) ctDNA assay employs a hybrid-capture approach for target enchrichment of 523 clinically relevant genes and leverages unique molecular indices to enable ultra-low frequency detection of SNVs, Indels, and CNVs. This comprehensive cancer panel interrogates relevant cancer biomarkers with as little as 20-30 ng of cfDNA and demonstrates robust analytical performance. In addition to variant calls, the assay reports a tumor mutational burden (TMB) score and microsatellite instability (MSI) scores. Available at our genomics laboratories in Durham, NC, US and Beijing, China.

Highlights

- Reportable biomarkers: SNVs, Indels, CNVs, MSI, and TMB
- Sample types: Streck whole blood, Streck & EDTA plasma, cfDNA
- Pre-analytical QC incudes Fragment Analysis Quantification
- Detection of variants down to 0.5% VAF
- Sensitivity of SNVs at 92.87% and Indels at 96.34%
- PPV of SNVs at 99.84% and Indels at 99.99%

Reproducible variant calling



TMB methodology

Enhanced algorithm to robustly call TMB from cfDNA. Reports include a synonymous and non-synonymous score using eligible variants that meet the following criteria:

- Variants in the coding region (RefSeq Cds)
- Variants not in low confidence regions (black list)
- Variant Frequency ≥ Minimum reporting TMB threshold
- Coverage ≥ 1000
- SNVs and Indels (MNVs excluded)
- Nonsynonymous and synonymous variants
- Variants with cosmic count > 50 excluded
- Exclude clonal hematopoiesis driver genes
- Exclude variants with VAF > 40%

Turning Hope Into Help™

TSO500-plasma specifications

Sample types	Plasma (EDTA, Streck or purified circulating-free nucleic acids)
Sample recommendations	> 3 mL plasma (minimum 2 mL plasma) Double-spun EDTA within 4 hr of collection OR Streck cfDNA BCT extends stability window to 6 days @ RT
Input requirements	20-30 ng cfDNA (as quantified using fragment analysis)
Sequencing platform	NovaSeq 6000
Read depth	> 800 M PE Reads; 150 bp PE
Software analysis	Dragen
Deliverables	QC Report, VCFs (SNVs and Indels), CNVs, MSI and TMB scores BAMs can be made available upon request for additional fee

Q² Solutions has a global testing footprint

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