CleanPlex® Ready-to-Use NGS Panels | Product Sheet

CleanPlex® TMB 500 Panel

Fast and reliable assay for measuring tumor mutational burden

Highlights

- **Comprehensive Content**
  Interrogate 516 genes associated with the major solid tumor types to assess tumor mutational burden and characterize mutation profile
- **Fast, Streamlined Workflow**
  Generate sequencing-ready libraries in just 6 hours using a rapid, three-step protocol
- **Excellent Correlation with Whole Exome Sequencing**
  Prepare high-quality targeted NGS libraries using CleanPlex® Technology to replace the costly and time-consuming workflow of hybridization-based target enrichment

The CleanPlex® TMB 500 Panel is a targeted resequencing assay designed to enable rapid and accurate assessment of tumor mutational burden and mutation profile. The panel is expertly curated using the latest research findings to target 516 genes associated with major solid tumor types and maintains >96% correlation with whole exome datasets. The panel covers 1.64 Mb of genomic content (1.19 Mb exonic) and targets both single nucleotide variants (SNVs) and insertion-deletion mutations (indels). Two pools of multiplex PCR primers are utilized to construct target-enriched libraries from either formalin-fixed paraffin-embedded (FFPE) DNA from tumor samples or high-quality gDNA from blood samples. Starting with just 20 ng of DNA (10 ng per primer pool), sequencing-ready libraries can be prepared using a streamlined workflow in just 6 hours, allowing samples to be sequenced on the same day.

CleanPlex® TMB 500 Panel Specifications

Parameter	Specification
Enrichment Method	Multiplex PCR
Sequencing Platforms	Illumina®
Number of Genes	516
Targets	Genes associated with major solid tumor types
Cumulative Target Size	1.64 Mb (1.19 Mb exonic content)
Variant Types	SNVs, indels [A]
Number of Amplicons	27,296
Amplicon Size	105 – 120 bp (113 bp on average)
Number of Primer Pools	2
Input DNA Requirement	10 – 40 ng per pool (10 ng per pool recommended for high quality gDNA; 20 ng per pool for FFPE DNA)
Sample Types	Genomic DNA from blood or FFPE DNA
Total Assay Time	6 hours
Hands-On Time	75 minutes
Design Coverage	100%
Coverage Uniformity (targets with >0.2X mean coverage)	≥ 93%
On-Target Aligned Reads	≥ 95%

A. SNVs: single nucleotide variations; indels: insertions-deletions

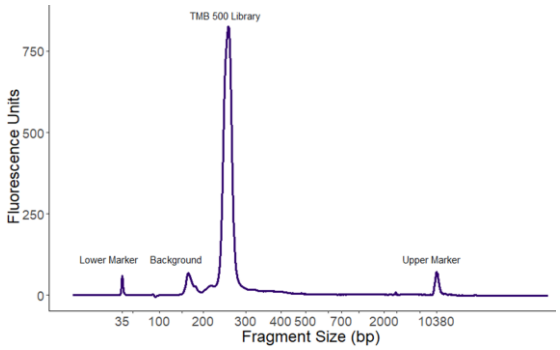
CleanPlex Streamlined Workflow

The CleanPlex TMB 500 Panel offers a simple and streamlined workflow. Starting from purified and quantitated DNA, the multiplex PCR-based protocol can be completed in just 6 hours, with 75 minutes of hands-on time, using a three-step workflow with minimal tube-to-tube transfers. Each step consists of a thermal cycling or incubation condition, followed by "with bead" purification using magnetic beads.

CleanPlex Target Enrichment and Library Preparation
6 hours of total assay time, 75 minutes of hands-on time

PARAGON GENOMICS

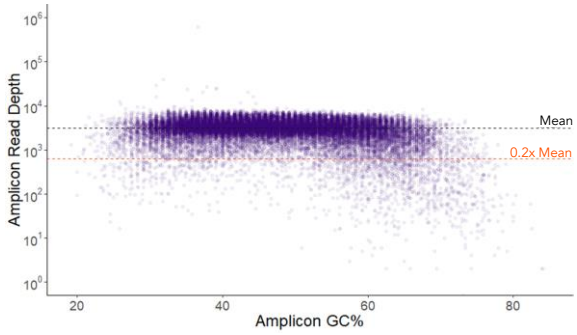
CleanPlex Background Cleaning Chemistry



The CleanPlex TMB 500 Panel is powered by Paragon Genomics' CleanPlex Technology, which uses a proprietary multiplex PCR background cleaning chemistry to effectively remove non-specific PCR products, resulting in best-in-class target enrichment performance and efficient use of sequencing reads.

Sequencing Performance and High Coverage Uniformity Reduces Drop-outs and Saves Costs

Sequencing of libraries generated using the CleanPlex TMB 500 Panel shows consistently high mapping rates, on-target rates, and uniformity. These high sequencing metrics demonstrate superb performance and eliminates the need to repeat tests, saving time and costs.



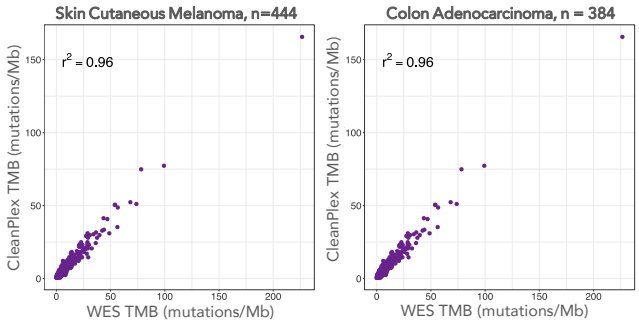
Performance Statistics		
	Reference gDNA (n=3)	*Tumor Cell Line gDNA (n=42)*
Uniformity (0.2X mean)	94% ± 1%	93% ± 2%
Mapped Reads	94% ± 4%	91% ± 2%
On-Target	96% ± 1%	96% ± 1%

Learn More

To learn more about CleanPlex Ready-to-Use NGS Panels, visit www.paragongenomics.com/cleanplex_panels/

To learn more about CleanPlex Technology, visit www.paragongenomics.com/cleanplex_technology/

Excellent Correlation with Whole Exome Sequencing



In silico analysis shows that the CleanPlex TMB 500 Panel provides >96% correlation with whole exome sequencing. Genomic data from The Cancer Genome Atlas (TCGA) program was used to calculate the somatic mutation counts detected by the CleanPlex TMB 500 Panel versus whole exome sequencing.

Recommended Sample Multiplexing for CleanPlex TMB 500 Panel

Instrument	Samples per Run [A]
NextSeq 550 System (mid-output)	4
NextSeq 550 System (high-output)	14
NovaSeq 6000 System (SP)	29
NovaSeq 6000 System (S1)	58
NovaSeq 6000 System (S2)	150

A. Samples per run at an intended average 2000 PE reads per amplicon

Ordering Information

The CleanPlex TMB 500 Panel contains CleanPlex Multiplex PCR Primers and CleanPlex Targeted Library Kit. CleanPlex Indexed PCR Primers and CleanMag® Magnetic Beads are ordered separately to complete the workflow from input DNA to sequencing-ready NGS libraries. For more indexing options and additional product configurations visit www.paragongenomics.com/store/

Product	SKU
CleanPlex TMB 500 Panel (6 reactions)	916073
CleanPlex TMB 500 Panel (96 reactions)	916074
CleanPlex Dual-Indexed PCR Primers for Illumina® Set A (96 indexes, 96 reactions)	716006
CleanPlex Dual-Indexed PCR Primers for Illumina® Set B (96 indexes, 96 reactions)	716018
CleanMag Magnetic Beads (5 mL)	718002
CleanMag Magnetic Beads (60 mL)	718003

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