

 **TP53**  
OncoKitDx

## NGS genetic molecular analysis of the *TP53* gene.

For in vitro diagnostic use.

Format: 48 rx / Technology: NGS / Reference: IMG-317



### > Technology

Due to the high frequency at which mutations in *TP53* are found in different tumors, *TP53 OncoKitDx* is optimized to detect germline and somatic mutations in DNA from both peripheral blood and tumor tissue through multiplex PCR and subsequent sequencing using an NGS platform with high-throughput sequencing technology.

### > Characteristics

- Qualitative NGS analysis designed to identify point mutations and small insertions/deletions in coding regions, splice sites, and the promoter region [5'UTR] of the *TP53* gene, as well as in the non-coding regions located in exons 1 and 2.
- Cannot detect large deletions and/or insertions.
- Bioinformatic analysis with the Datagenomics software.
- Amplicon-based NGS protocol.
- STIDs can be included: Integrated sample identification and tracking system.
- Optimized for the detection of germline and somatic variants in DNA from both peripheral blood and tumor tissue.
- Coverage: 99.4% of bases covered at 500x, and 98.5% of bases covered at 1000x.
- Uniformity: 100% of bases covered at >20% of the mean coverage.
- Sensitivity and specificity >99%.
- Repeatability and reproducibility >99%.
- Limit of detection: 2.5%
- Compliant with the ISO 13485 and ISO 14001 standards regarding quality measures for medical device manufacturing.

## > Specifications

- **Compatible sequencing platforms:** Illumina iSeq, Illumina MiSeq, Illumina NextSeq500, Illumina NextSeq2000, Illumina HiSeq, Illumina NovaSeq.
- **Necessary amount of DNA:** 40 ng of gDNA.
- **Sample type:** DNA from peripheral blood or fresh, frozen, or formalin-fixed paraffin-embedded tissue.
- **Optimal number of reads per sample:**  $\geq 20.000$  PF clusters.
- **Number of samples per run:** Illumina Miseq Micro (300 cycles): 48  
Illumina Miseq V2 (300 ciclos): 160
- **Sequencing:** Paired-end (2 x 160 cycles).
- **Set-up and preparation:** 1 hour.

## > Related products

- IMEGEN-Sample tracking A and B (REF: IMG-234 and IMG-311).

Contact our oncology team to learn more about the clinical value of this product:  
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