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Action OncoKitDx

Analysis of solid tumors

For diagnostic use.
Format: 24 rx / Technology: NGS / Reference: IMG-365

> Characteristics

- Panel for the study of regions of interest involved in the treatment, diagnosis, and prognosis of solid tumors (lung, colorectal, breast, melanoma, gastric, ovarian, endometrial, brain, thyroid, urinary tract, etc.)
- It allows detecting SNVs, indels, genetic fusions, CNVs, pharmacogenetic variants, and microsatellite instability analysis (MSI) from a single DNA sample.
- Bioinformatics analysis using the software Datagenomics.
- Automated generation of a report, including functional and clinical classification of the variants.
- STIDs can be included: Integrated system for the identification of samples for their traceability.
- Based on high sensitivity RNA-probe technology with UMI barcoding (unique molecular identifiers).
- Mean coverage: 2500X.
- Mean coverage after UMI analysis: 1600X.
- Coverage: 99.3% of bases covered at 100X depth.
- Uniformity: 98.9% of bases covered at >20% mean coverage.
- Specificity: >99%
- Sensitivity: >99%
- Repeatability: >99.9% Reproducibility: >99.9%

> Added value

- Technical support from first protocol implementation, both online and on-site. All protocols will be fine-tuned in collaboration with laboratory personnel.
- Clinical support or genetic counseling, with clinical geneticists available to answer any clinical questions.
- Possibility of externalizing 10% of the samples to our laboratory at the same price during periods of excess laboratory workload or urgent deadlines.
- Possibility to request this service to the Health in Code laboratories (TAT: 10 working days).

Contact our oncology team for clinical counseling on this product:
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> Specifications

- **Compatible sequencers**: Illumina NextSeq
- **Number of reactions**: 24
- **Number of samples per run**: 8 to 12 samples in a cartridge MID 150 cycles on NextSeq.
- **Sequencing**: Paired-end (2 x 75 cycles)
- **Type of sample**: DNA from peripheral blood and fresh, frozen, and paraffin-embedded tissue.
- **Amount of input DNA**: 50-200 ng
- **Limit of detection**: SNVs, indels, and structural variants: 5%; CNVs: 3 copies for duplications and 1 copy for deletions in samples with non-tumoral cell infiltration over 30%.
- Fully automated panel for Magnis NGS Prep System Dx equipment.
- CE-IVD and analysis software labeling.

> Panel composition

- Sequecing of full exonic region for **55 genes**:

ALK	*CHEK2*	*H3F3A*	*MLH1*	*PBRM1*	*SDHB*
ARID1A	*EGFR*	*HIST1H3B*	*MSH2*	*PDGFRA*	*SDHD*
ATM	*ERBB2/HER2*	*HIST1H3H*	*MSH6*	*PIK3CA*	*TERT+5'UTR*
ATRX	*ESR1*	*HRAS*	*MTOR*	*PMS2+5'UTR*	*TP53*
BAP1	*FGFR1*	*IDH1*	*MYC*	*PTEN*	*VHL*
BRAF	*FGFR2*	*IDH2*	*NRAS*	*POLD1*	
BRCA1	*FGFR3*	*KIT*	*NTRK1*	*POLE*	
BRCA2	*FGFR4*	*KRAS*	*NTRK2*	*RET*	
CDH1	*GNA11*	*MAP2K1*	*NTRK3*	*ROS1*	
CTNNB1	*GNAQ*	*MET*	*PALB2*	*SDHA*	

- Sequencing of hotspot regions in genes *TSC1* and *TSC2*, 36 regions in total, and variant E17K in *AKT1*
- Capture of **11 fusion genes** in any of their potential rearrangements (inclusion of intronic regions described as breakage points in the literature)::

LK	*BRAF*	*ETV6*	*FGFR3*	*NTRK2*	*ROS1*
ATP1B1	*EGFR*	*FGFR2*	*NTRK1*	*RET*	

- **Microsatellite instability analysis (MSI)**
- Detection of **CNVs** throughout the whole genome (detection of hypo- and hyperploidias) or in a whole gene included in the panel. Validation of results and detection of copy-neutral LOH through a low-density SNP array throughout the genome
- Detection of pharmacogenetics-related variants:

DPYD	*XRCC1*	*UGT1A1*	*CYP2D6*	*MTHFR*	*TPMT*	*CYP2C9*