

Comprehensive Solid Tumor Panel

TEST NAME: COMPREHENSIVE SOLID TUMOR PANEL

TEST CODE: STP198

CPT CODE: 81455

CLINICAL USE:

Alterations in oncogenes and tumor suppressor genes can cause dysregulation of signaling pathways and cellular processes controlling proliferation, migration, metabolism, and apoptosis. Identification of these genetic alterations in the tumors is essential in the diagnosis, prognosis, and treatment of cancers.

The genes and regions covered in our panel are listed below.

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|--------|--------|--------|--------|--------|--------|---------|-------|
| ABL1 | CBLB | CLSTN1 | FUBP1 | MAP2K2 | PIK3CA | SHH | ZRSR2 |
| ABL2 | CCND1 | CREBBP | GATA1 | MCL1 | PIK3CB | SMAD4 | |
| AKT1 | CCND2 | CRLF2 | GATA2 | MEF2B | PIK3CG | SMARCB1 | |
| AKT2 | CCND3 | CSF1R | GATA3 | MET | PIK3R1 | SMC1A | |
| AKT3 | CCNE1 | CSF3R | GNA11 | MPL | PIK3R2 | SMC3 | |
| ALK | CD79B | CTNNB1 | GNA13 | MTOR | PIK3R5 | SMO | |
| APC | CDH1 | CUX1 | GNAQ | MYBL2 | PLCG2 | SOCS1 | |
| AR | CDK12 | DDR2 | GNAS | MYD88 | PRDM1 | SOD2 | |
| ARAF | CDK4 | DNAJB1 | HNF1A | NF1 | PRKACA | SRC | |
| ARID1A | CDK6 | DNMT3A | HNRNPK | NF2 | PRMT5 | SRSF2 | |
| ARNTL | CDKN1A | EGFR | HRAS | NFE2L2 | PTCH1 | STAG2 | |
| ASXL1 | CDKN1B | EP300 | ID3 | NOTCH1 | PTEN | STAT3 | |
| ATM | CDKN2A | EPHA2 | IDH1 | NOTCH2 | PTPN11 | STK11 | |
| ATR | CDKN2B | ERBB2 | IDH2 | NOTCH3 | PTPRD | SUFU | |
| ATRX | CDKN2C | ERBB4 | IKZF1 | NPM1 | PTPRT | SUZ12 | |
| AURKA | CEBPA | ESR1 | IL7R | NRAS | RAC1 | TCF3 | |

Comprehensive Solid Tumor Panel

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|--------|--------------------------|-------|--------|---------|---------|----------|--|
| BAP1 | chr10:43606914-43607546 | ETV1 | JAK1 | NSD1 | RAD21 | TERT | |
| BARD1 | chr10:43607673-43608300 | ETV6 | JAK2 | NT5C2 | RAF1 | TET1 | |
| BCL2 | chr10:43608412-43609003 | EWSR1 | JAK3 | NTRK1 | RB1 | TET2 | |
| BCL6 | chr10:43609124-43609927 | EZH2 | KDM6A | NTRK2 | RELB | TMC6 | |
| BCOR | chr10:43610185-43612031 | FAM5C | KDR | NTRK3 | RET | TNFAIP3 | |
| BCORL1 | chr2:29446395-29448326 | FBXW7 | KEAP1 | PAWR | RHEB | TNFRSF14 | |
| BIRC3 | chr4:55140793-55141007 | FGFR1 | KIF17 | PAX5 | RHOA | TP53 | |
| BRAF | chr6:117641194-117642421 | FGFR2 | KIT | PBRM1 | RIT1 | TSC1 | |
| BRCA1 | chr6:117642558-117645494 | FGFR3 | KLHL6 | PDGFRA | ROS1 | TSC2 | |
| BRCA2 | chr6:117645579-117647386 | FLT3 | KMT2A | PDGFRB | RPS6KB1 | U2AF1 | |
| BTK | chr6:117647578-117650491 | FLT4 | KMT2C | PHF6 | RUNX1 | VHL | |
| CALR | chr6:117650610-117658334 | FOXL2 | KMT2D | PIAS2 | SETBP1 | WHSC1 | |
| CARD11 | chr8:38275892-38277050 | FOXO1 | KRAS | PIK3C2A | SF3B1 | WNT1 | |
| CBL | CIC | FOXP1 | MAP2K1 | PIK3C2B | SH2B3 | WT1 | |

METHODOLOGY: DNA is extracted and hybridized with custom-designed probes to enrich the targeted regions of 198 genes and 13 regions associated with cancer. Samples are then sequenced on the Illumina HiSeq 2500 (Illumina, Inc, CA). A custom bioinformatics pipeline aligns the data to human reference genome GRCh37 to call variants. The limit of detection (related in part to depth of coverage, neoplastic cell percentage, and allelic frequency for the mutation) was determined to be 5% allele frequency, at which our assay has sensitivity of 98% and 94%, respectively, to detect single nucleotide variants (SNVs) and insertions/deletions (indels). Mutant allele

Comprehensive Solid Tumor Panel

populations below this detection limit will not be reliably detected by this method. Pseudogenes, highly homologous regions, and repeat regions may interfere with the detection of variants in this assay. This assay targets genes involved in cancer. Some of the genes targeted may also cause inherited genetic disorders; variants in these genes will not be reported unless they are determined to contribute to the diagnosis, prognosis, or treatment of cancer in the specimen analyzed.

COMPONENTS:

REFERENCE RANGE: NA

SPECIMEN REQUIREMENTS:

- Tissue sections and cell block preparations of FNAs and fluids
- 10-15 unstained FFPE slides, at 5-10 micron thickness (with 1 H&E slide indicating the location of the tumor).

SPECIAL HANDLING: NA

TEST PERFORMANCE SCHEDULE: Weekly

TURN AROUND TIME: 2-3 Weeks

STAT AVAILABILITY: NA