Precise™ Tumor

Molecular Profile Test

A pan-cancer solid tumor comprehensive genomic profiling test

Precise™ Tumor simplifies patient care for oncologists by providing straightforward interpretations, prioritization of therapies, and the next steps specific to each patient's genomic results.

Precise Tumor is a comprehensive laboratory test offered by Myriad Genetics that uses state-of-the-art next-generation targeted exome sequencing to discover and target important variants within tumors. This hybrid capture DNA- and RNA-based test detects Single Nucleotide Variants (SNVs), Insertions/deletions (INDELs), Copy Number Variants (CNVs), splice variants and fusions in solid tumors. Sequencing of over 500 genes, identified as relevant to cancer treatment, as well as testing of important immunotherapy (IO) biomarkers provides a comprehensive picture for the oncologist to formulate a treatment plan with their patients.

Product Features:

- **Actionable:** 500+ solid tumor-related genes with broad coverage of key guidelines and clinical trials for multiple solid tumor types.
- **Key selected biomarkers:**
  - Microsatellite Instability (MSI)
  - Tumor Mutational Burden (TMB)
  - Programmed Death-Ligand 1 (*PD-L1*), if requested
  - Hormone Receptor Status: HER2 (*ERBB2*), ER (*ESR1*) and PR (*PGR*)
- **Clinically Validated and Comprehensive** genomic coverage necessary for accurate selection of FDA-approved targeted and IO therapies, while also evaluating many genes relevant to early phase drug development efforts that may have future clinical applications in all solid tumors[1].
- **Accurate:** Sensitivity: 98.91% Specificity >99.99% using orthogonal methods, including DNA- and RNA-based next generation targeted exome sequencing with full coverage of all exons. Accurately measures TMB, microsatellite instability, SNVs, indels, copy-number/structural variation and gene fusions when compared to WGS and orthogonal technologies[2].
- **Cutting edge technologies:** Fusions and splice variants assessed via RNA analysis, which may detect more actionable fusions and splice variants, as compared to DNA tests only[3-6].

Precise Tumor detects clinically relevant DNA & RNA variants for multiple solid-tumor cancer types.

Content for Precise Tumor includes key guideline biomarkers for multiple cancer types, plus current and emerging pan-cancer biomarkers. **Some key cancer-specific biomarkers include:**

Breast	Ovarian	Endometrial	Colon	Pancreatic	Prostate	Lung	Pan-Cancer
AR	*BRAF*	*ERBB2*	*BRAF*	*ALK*	*ATM*	*AKT1*	*NTRK1*
BRCA1	*BRCA1*	*ESR1*	*ERBB2*	*BRAF*	*AR*	*ALK*	*NTRK2*
BRCA2	*BRCA2*	*MLH1*	*KRAS*	*BRCA1*	*BRCA1*	*BRAF*	*NTRK3*
ERBB2	*MLH1*	*MSH2*	*NRAS*	*BRCA2*	*BRCA2*	*DDR2*	*TMB*
ESR1	*MSH2*	*MSH6*	*MLH1*	*ERBB2*	*CDK12*	*EGFR*	
PD-L1	*MSH6*	*PMS2*	*MSH2*	*FGFR2*	*CHEK2*	*ERBB2*	
PGR	*PMS2*	*POLE*	*MSH6*	*KRAS*	*FANCA*	*FGFR1*	
PIK3CA		*TP53*	*PMS2*	*NRG1*	*MLH1*	*FGFR2*	
PTEN				*PALB2*	*MSH2*	*FGFR3*	
				RET	*MSH6*	*KRAS*	
				ROS1	*PALB2*	*MAP2K1*	
					PMS2	*MET*	
					RAD51D	*NRAS*	
						PIK3CA	
						PTEN	
						RET	
						TP53	
						PD-L1	

Myriad genetics

Health. Illuminated.

Assay Specifications:

Sample Requirements*	**Cancer Type:** Solid Tumor **Specimen Types:** Cytology Cell Block
FFPE block requirement*	Cross-sectional tumor area of 25mm^2 containing at least 40 µm of tumor
Tumor Purity Minimum	20%
DNA input required	40 ng
RNA input required	40 ng
Limit of detection	5% VAF for SNV and INDELs 10 copies/ng for fusions 2.5-fold change for CNV
Panel size	523 genes assessed by DNA analysis 56 genes assessed by RNA analysis
Average total coverage/Depth of coverage	Average 825x (Validated average of >500x) Since launch, average DNA reads (80M, or 825x) has remained above the stated validated average. Similarly, the average RNA reads (25M, or 1818x) is also high.
Analytical Sensitivity	99.25%
Analytical Specificity	>99.9%

*See Precise Tumor Pathology Guide for additional details

Overview of Performance Characteristics (at ≥20% Tumor Nuclei)**:

Variant Type	Sensitivity (Positive Percent Agreement- PPA) (95% CI)	Specificity (Negative Percent Agreement-NPA) (95% CI)
All Variants	98.91% (98.31-99.34%)	>99.99% (>99.99%)
SNV	99.42% (98.81-99.76%)	>99.99% (>99.99%)
INDEL (≤ 40bp)	97.22% (94.36-98.83%)	>99.99% (>99.99%)
CNV	97.98% (95.27-99.31%)	100% (99.52-100%)
Fusions	99.12% (95.94-99.90%)	100% (99.45-100%)
MET exon 14 skipping	100% (46.44-99.98%)	100% (73.78-99.99%)

Variant Type	Positive Predictive Value (PPV) (95% CI)	Negative Predictive Value (NPV) (95% CI)
All Variants	100% (99.95-100%)	>99.9% (>99.99%)
Single Nucleotide Variants (SNV)	100% (99.95%-100%)	>99.99% (>99.99%)
Insertions/Deletions (INDEL)	100% (97.69-100%)	>99.99% (>99.99%)
Copy Number Variants (CNV)	100% (66.96-99.99%)	100% (99.52-100%)
Fusions	100% (91.49-100%)	99.78% (99.45-100%)
MET exon 14 skipping	100% (46.44-99.98%)	100% (73.78-99.99%)

**PPV, PPA, NPA, NPV were determined to be acceptable for all variant types (≥90% for SNVs, CNVs, fusions, and MET exon 14 skipping; ≥85% for INDELs.

Positive Percent Agreement (PPA): The conditional probability that a variant will be correctly identified by a clinical test, i.e. the number of true positive results divided by the total number of variants identified by the test (which is the sum of the numbers of true positive plus false negative results).

Negative Percent Agreement (NPA): The conditional probability that a negative/wildtype variant will be correctly identified by a clinical test, i.e. the number of true negative results divided by the total number of those without the disease (which is the sum of the numbers of true negative plus false positive results).

Positive Predictive Value (PPV): The conditional probability that positive/mutant variants will be correctly identified by a clinical test, i.e. the number of true positive results divided by the total number detected or classified as mutant (which is the sum of the numbers of true positive plus false positive results).

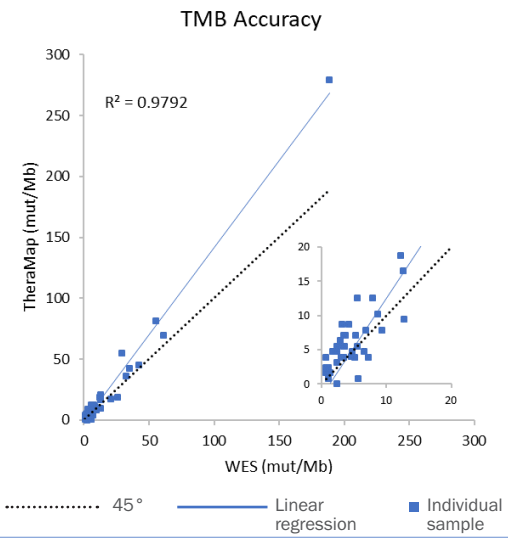
Negative Predictive Value (NPV): The conditional probability that the absence of a variant will be correctly identified by a clinical test, i.e. the number of true negative results divided by the total number without the disease (which is the sum of the numbers of true negatives plus false positives results).

Additional information about immuno-oncology biomarkers:

Tumor mutation burden (TMB):

Results are reported as low or high. A high TMB score has been shown to correlate with response to checkpoint inhibitor therapy and in some clinical contexts may indicate the use of Pembrolizumab or other immunotherapies. Following the FDA's labeling for Pembrolizumab in solid tumors, a TMB value of 10 or greater is considered "High", while values below 10 mut/Mb are considered "Low". The cutoffs were determined across several tumor types in an internal validation study in comparison to whole exome sequencing. TMB Accuracy was measured by comparing the TMB values generated by Precise Tumor against reference TMB generated from paired tumor normal Whole Exome Sequencing (WES). For the sample set evaluated and presented in Fig. 1. TMB accuracy exceeded the acceptability criteria with an R2 = 0.9792 (acceptability criteria $R^2 \geq 0.85$ between WES and Precise Tumor TMB values). This cutoff is supported by Wei et al. and the Friends of Cancer TMB Harmonization Project, which establishes 10 mut/Mb as a TMB-high cutoff in pembrolizumab monotherapy study-enrolled patients[7,8,9]

Fig. 1: WES TMB and Precise Tumor TMB Correlation-



Microsatellite instability (MSI):

The Precise Tumor assay evaluates 130 loci. Samples with >10% unstable sites are considered "MSI-High". The assay does not distinguish between "MSI-Stable" and "MSI-Low" due to the limitations of tumor only MSI testing. MSI status may be reported as "Indeterminate" if the total number of usable sites is less than 55. The percentage of unstable microsatellites in 26 orthogonally confirmed microsatellite stable (MSS) samples were used to establish MSS cutoff of 10% unstable sites based on 3 standard deviations from the mean. A second cohort of orthogonally confirmed clinical specimens with MSS and MSI High and 1 MSI positive cell-line were tested utilizing a 10% cutoff. PPA, PPV, and NPA were above the acceptability criteria of 90%. Based on limited availability and lack of clinical actionability, there is insufficient evidence to establish a low/intermediate range and MSI low samples were excluded from the analysis. MSI classification is reported as either high or stable for MSI.

Variant Type	Sensitivity (PPA) (95% CI)	Positive Predictive Value (PPV) (95% CI)	Negative Percent Agreement (NPA) (95% CI)
MSI	100% (72.25-100%)	100% (78.28-100%)	100% (94.6-100%)

PD-L1:

Precise Tumor uses an immunohistochemical assay (SP263 clone) for the assessment of PD-L1 protein in solid tumor formalin-fixed paraffin-embedded (FFPE) tissue stained with OptiView DAB IHC Detection Kit. Results may be reported as either Tumor Proportion Score (TPS) or Combined Positive Score (CPS) depending on the cancer type. A TPS score of ≥1% PD-L1 is reported as positive. A CPS score ≥1 or ≥10 expression is reported as positive.

Tumor Proportion Score (TPS)	Combined Positive Score (CPS)
All primary lung cancers (≥1%)	Gastric and Gastroesophageal Adenocarcinomas (≥1)
Melanoma (≥1%)	Head and Neck Squamous Cell Carcinomas (≥1)
All remaining solid tumors (≥1%)	Cervical Carcinoma (≥1) Urothelial Carcinoma (≥10) Esophageal Squamous Cell Carcinoma (≥10) Triple negative breast cancer (≥10)

Table 1: PD-L1 positive expression ranges by cancer type.

Solid tumor panel

523 genes by DNA sequencing: • SNVs • Indels • CNVs

(Content shaded in grey is analyzed for CNV detection.)

ABL1	*CALR*	*DNAJB1*	*FGF14*	*HIST1H3A*	*KEAP1*	*MYCL1*	*PIK3CD*	*RHOA*	*SUFU*
ABL2	*CARD11*	*DNMT1*	*FGF19*	*HIST1H3B*	*KEL*	*MYCN*	*PIK3CG*	*RICTOR*	*SUZ12*
ACVR1	*CASP8*	*DNMT3A*	*FGF2*	*HIST1H3C*	*KIF5B*	*MYD88*	*PIK3R1*	*RIT1*	*SYK*
ACVR1B	*CBFB*	*DNMT3B*	*FGF23*	*HIST1H3D*	*KIT*	*MYOD1*	*PIK3R2*	*RNF43*	*TAF1*
AKT1	*CBL*	*DOT1L*	*FGF3*	*HIST1H3E*	*KLF4*	*NAB2*	*PIK3R3*	*ROS1*	*TBX3*
AKT2	*CCND1*	*E2F3*	*FGF4*	*HIST1H3F*	*KLHL6*	*NBN*	*PIM1*	*RPS6KA4*	*TCEB1*
AKT3	*CCND2*	*EED*	*FGF5*	*HIST1H3G*	*KMT2B*	*NCOA3*	*PLCG2*	*RPS6KB1*	*TCF3*
ALK	*CCND3*	*EGFL7*	*FGF6*	*HIST1H3H*	*KMT2C*	*NCOR1*	*PLK2*	*RPS6KB2*	*TCF7L2*
ALOX12B	*CCNE1*	*EGFR*	*FGF7*	*HIST1H3I*	*KMT2D*	*NEGR1*	*PMAIP1*	*RPTOR*	*TERC*
ANKRD11	*CD274*	*EIF1AX*	*FGF8*	*HIST1H3J*	*KRAS*	*NF1*	*PMS1*	*RUNX1*	*TERT*
ANKRD26	*CD276*	*EIF4A2*	*FGF9*	*HIST2H3A*	*LAMP1*	*NF2*	*PMS2*	*RUNX1T1*	*TET1*
APC	*CD74*	*EIF4E*	*FGFR1*	*HIST2H3C*	*LATS1*	*NFE2L2*	*PNRC1*	*RYBP*	*TET2*
AR	*CD79A*	*EML4*	*FGFR2*	*HIST2H3D*	*LATS2*	*NFKBIA*	*POLD1*	*SDHA*	*TFE3*
ARAF	*CD79B*	*EP300*	*FGFR3*	*HIST3H3*	*LMO1*	*NKX2-1*	*POLE*	*SDHAF2*	*TFRC*
ARFRP1	*CDC73*	*EPCAM*	*FGFR4*	*HLA-A*	*LRP1B*	*NKX3-1*	*PPARG*	*SDHB*	*TGFBR1*
ARID1A	*CDH1*	*EPHA3*	*FH*	*HLA-B*	*LYN*	*NOTCH1*	*PPM1D*	*SDHC*	*TGFBR2*
ARID1B	*CDK12*	*EPHA5*	*FLCN*	*HLA-C*	*LZTR1*	*NOTCH2*	*PPP2R1A*	*SDHD*	*TMEM127*
ARID2	*CDK4*	*EPHA7*	*FLI1*	*HNF1A*	*MAGI2*	*NOTCH3*	*PPP2R2A*	*SETBP1*	*TMPRSS2*
ARID5B	*CDK6*	*EPHB1*	*FLT1*	*HNRNPK*	*MALT1*	*NOTCH4*	*PPP6C*	*SETD2*	*TNFAIP3*
ASXL1	*CDK8*	*ERBB2*	*FLT3*	*HOXB13*	*MAP2K1*	*NPM1*	*PRDM1*	*SF3B1*	*TNFRSF14*
ASXL2	*CDKN1A*	*ERBB3*	*FLT4*	*HRAS*	*MAP2K2*	*NRAS*	*PREX2*	*SH2B3*	*TOP1*
ATM	*CDKN1B*	*ERBB4*	*FOXA1*	*HSD3B1*	*MAP2K4*	*NRG1*	*PRKAR1A*	*SH2D1A*	*TOP2A*
ATR	*CDKN2A*	*ERCC1*	*FOXL2*	*HSP90AA1*	*MAP3K1*	*NSD1*	*PRKCI*	*SHQ1*	*TP53*
ATRX	*CDKN2B*	*ERCC2*	*FOXO1*	*ICOSLG*	*MAP3K13*	*NTRK1*	*PRKDC*	*SLIT2*	*TP63*
AURKA	*CDKN2C*	*ERCC3*	*FOXP1*	*ID3*	*MAP3K14*	*NTRK2*	*PRSS8*	*SLX4*	*TRAF2*
AURKB	*CEBPA*	*ERCC4*	*FRS2*	*IDH1*	*MAP3K4*	*NTRK3*	*PTCH1*	*SMAD2*	*TRAF7*
AXIN1	*CENPA*	*ERCC5*	*FUBP1*	*IDH2*	*MAPK1*	*NUP93*	*PTEN*	*SMAD3*	*TSC1*
AXIN2	*CHD2*	*ERG*	*FYN*	*IFNGR1*	*MAPK3*	*NUTM1*	*PTPN11*	*SMAD4*	*TSC2*
AXL	*CHD4*	*ERRFI1*	*GABRA6*	*IGF1*	*MAX*	*PAK1*	*PTPRD*	*SMARCA4*	*TSHR*
B2M	*CHEK1*	*ESR1*	*GATA1*	*IGF1R*	*MCL1*	*PAK3*	*PTPRS*	*SMARCB1*	*U2AF1*
BAP1	*CHEK2*	*ETS1*	*GATA2*	*IGF2*	*MDC1*	*PAK7*	*PTPRT*	*SMARCD1*	*VEGFA*
BARD1	*CIC*	*ETV1*	*GATA3*	*IKBKE*	*MDM2*	*PALB2*	*QKI*	*SMC1A*	*VHL*
BBC3	*CREBBP*	*ETV4*	*GATA4*	*IKZF1*	*MDM4*	*PARK2*	*RAB35*	*SMC3*	*VTCN1*
BCL10	*CRKL*	*ETV5*	*GATA6*	*IL10*	*MED12*	*PARP1*	*RAC1*	*SMO*	*WISP3*
BCL2	*CRLF2*	*ETV6*	*GEN1*	*IL7R*	*MEF2B*	*PAX3*	*RAD21*	*SNCAIP*	*WT1*
BCL2L1	*CSF1R*	*EWSR1*	*GID4*	*INHA*	*MEN1*	*PAX5*	*RAD50*	*SOCS1*	*XIAP*
BCL2L11	*CSF3R*	*EZH2*	*GLI1*	*INHBA*	*MET*	*PAX7*	*RAD51*	*SOX10*	*XPO1*
BCL2L2	*CSNK1A1*	*FAM123B*	*GNA11*	*INPP4A*	*MGA*	*PAX8*	*RAD51B*	*SOX17*	*XRCC2*
BCL6	*CTCF*	*FAM175A*	*GNA13*	*INPP4B*	*MITF*	*PBRM1*	*RAD51C*	*SOX2*	*YAP1*
BCOR	*CTLA4*	*FAM46C*	*GNAQ*	*INSR*	*MLH1*	*PDCD1*	*RAD51D*	*SOX9*	*YES1*
BCORL1	*CTNNA1*	*FANCA*	*GNAS*	*IRF2*	*MLL*	*PDCD1LG2*	*RAD52*	*SPEN*	*ZBTB2*
BCR	*CTNNB1*	*FANCC*	*GPR124*	*IRF4*	*MLLT3*	*PDGFRA*	*RAD54L*	*SPOP*	*ZBTB7A*
BIRC3	*CUL3*	*FANCD2*	*GPS2*	*IRS1*	*MPL*	*PDGFRB*	*RAF1*	*SPTA1*	*ZFHX3*
BLM	*CUX1*	*FANCE*	*GREM1*	*IRS2*	*MRE11A*	*PDK1*	*RANBP2*	*SRC*	*ZNF217*
BMPR1A	*CXCR4*	*FANCF*	*GRIN2A*	*JAK1*	*MSH2*	*PDPK1*	*RARA*	*SRSF2*	*ZNF703*
BRAF	*CYLD*	*FANCG*	*GRM3*	*JAK2*	*MSH3*	*PGR*	*RASA1*	*STAG1*	*ZRSR2*
BRCA1	*DAXX*	*FANCI*	*GSK3B*	*JAK3*	*MSH6*	*PHF6*	*RB1*	*STAG2*	
BRCA2	*DCUN1D1*	*FANCL*	*H3F3A*	*JUN*	*MST1*	*PHOX2B*	*RBM10*	*STAT3*	
BRD4	*DDR2*	*FAS*	*H3F3B*	*KAT6A*	*MST1R*	*PIK3C2B*	*RECQL4*	*STAT4*	
BRIP1	*DDX41*	*FAT1*	*H3F3C*	*KDM5A*	*MTOR*	*PIK3C2G*	*REL*	*STAT5A*	
BTG1	*DHX15*	*FBXW7*	*HGF*	*KDM5C*	*MUTYH*	*PIK3C3*	*RET*	*STAT5B*	
BTK	*DICER1*	*FGF1*	*HIST1H1C*	*KDM6A*	*MYB*	*PIK3CA*	*RFWD2*	*STK11*	
C11orf30	*DIS3*	*FGF10*	*HIST1H2BD*	*KDR*	*MYC*	*PIK3CB*	*RHEB*	*STK40*	

56 genes by RNA sequencing: • Fusions • Breakpoints • Splice variants

(All genes listed are assessed for known and novel fusions, In addition, the content shaded in grey is analyzed for splice variants.)

ABL1	*BRAF*	*EML4*	*ETV4*	*FGFR4*	*KIF5B*	*MSH2*	*NRG1*	*PX7*	*RAF1*
AKT3	*BRCA1*	*ERBB2*	*ETV5*	*FLI1*	*KIT*	*MYC*	*NTRK1*	*PDGFRA*	*RET*
ALK	*BRCA2*	*ERG*	*EWSR1*	*FLT1*	*MET*	*NOTCH1*	*NTRK2*	*PDGFRB*	*ROS1*
AR	*CDK4*	*ESR1*	*FGFR1*	*FLT3*	*ML*	*NOTCH2*	*NTRK3*	*PIK3CA*	*RPS6KB1*
AXL	*CSF1R*	*ETS1*	*FGFR2*	*JAK2*	*MLLT3*	*NOTCH3*	*PAX3*	*PPARG*	*TMPRSS2*
BCL2	*EGFR*	*ETV1*	*FGFR3*	*KDR*					

Sequencing Laboratory Methods:

DNA and RNA are isolated from formalin-fixed, paraffin-embedded (FFPE) tissues. Sequencing libraries are generated using the Illumina® TruSight™ Oncology 500 panel library preparation reagents. A panel of biotinylated single stranded probes are used to enrich the DNA derived libraries for all exons of 523 cancer related genes and 130 microsatellite instability loci. A separate panel of biotinylated single stranded probes are used to enrich the RNA derived libraries for all exons of 56 cancer-related genes. The enriched libraries are sequenced on Illumina® NextSeq™ and NovaSeq™ sequencing platforms.

Depth of coverage:

To generate the low coverage table, the laboratory calculates the percentage of the gene that is covered below 100X for the regions covered by the assay. A gene is listed as low coverage if 10% of its exon region is below 100x. The low coverage regions and a description of how they are calculated are included in the patient report.

Limitations:

Variants below the limit of detection, insertions/deletions >40 bp, and fusions that do not alter expressed messenger RNA may not be detected by this assay. A stable result does not exclude the presence of a variant beyond these detection limitations. The assay is not informative for mutations outside the 523 cancer-related genes or for those regions for which the assay achieves limited coverage. This assay is not validated for large (> 40bp) indels, complex structural variants, or gene-level deletion events. Further, the assay is not validated to detect fusions that do not alter the expressed transcript (such as those that occur in the MYC gene). Given the overlap between the RNA and DNA capture, a total of 523 genes are interrogated across the RNA and DNA components of the test. This test targets coding regions and may not detect intronic variants, including those that may affect splicing. MSI analysis can identify MSI High and MSI Stable; however, MSI-Stable may not be detected. The threshold for reporting amplifications in genes is 2.5 fold normalized increase in coverage. Lower Limit of Detection (LLOD) that meet the lab's performance criteria is 5%. The lab can report below 5%, however, there is reduced sensitivity (PPA) below 5% and may not detect low VAF variants. Treatment recommendations are based on ASCO and NCCN guidelines, and other peer reviewed literature. All recommended therapies are FDA approved, both for the indication, and outside the indication where supported by guidelines or compendia.

This is a laboratory developed test, and its performance characteristics have been determined by Intermountain Precision Genomics. It has not been cleared or approved by the U.S. Food and Drug Administration. The U.S. Food and Drug administration does not require this test to go through premarket review. This test is used for clinical purposes. It should not be regarded as investigational or for research. This laboratory is certified under the Clinical Laboratory Improvement Amendments (1988) as qualified to perform high complexity testing.

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