

PRC-PALM-5.18 polpro 1-frm1: New Test Announcement Form

Test Name: Pan Solid Tumor Gene Fusion Panel

Test Change Effective Date: 04-02-2025

Memo Release Date: 04-17-2025

Test Background:

Gene fusions play a key role in carcinogenesis. Many of the driver mutations are in genes that express kinases. Fusions in these genes often unlink the kinase domains of the proteins from regulatory subunits, resulting in constitutive activation of the kinase function.

Pan-Solid Tumor Fusion Panel is a targeted sequencing assay that utilizes Next Generation Sequencing (NGS) technology for targeted sequence analysis of RNA extracted from formalin fixed paraffin-embedded (FFPE) tissue blocks to identify known and novel gene fusions, oncogenic transcripts and other alterations in 129 genes commonly altered in solid tumor cancer types including carcinomas, sarcomas, and some hematological malignancies. The genes and type of variant analysis for each gene were carefully selected to include content cited by professional organizations such as the National Comprehensive Cancer Network (NCCN) and the European Society for Medical Oncology (ESMO). Comprehensive fusion identification is enabled by open-ended targeted amplification using one gene-specific primer and one universal primer site, delivering detection of gene fusions with both known and novel fusion partners.

Genes Tested:

ACVR2A, AKT1, AKT2, AKT3, ALK, AR, ARHGAP26, ARHGAP6, AXL, BCOR, BRAF, BRD3, BRD4, CAMTA1, CCNB3, CCND1, CIC, CRTC1, CSF1, CSF1R, DNAJB1, EGF, EGFR, EPC1, ERBB2, ERBB4, ERG, ESR1, ESRRA, ETV1, ETV4, ETV5, ETV6, EWSR1, FGF1, FGFR1, FGFR2, FGFR3, FGR, FOS, FOSB, FOXO1, FOXO4, FOXR2, FUS, GLI1, GRB7, HMGA2, IGF1R, INSR, JAK2, JAK3, JAZF1, KIT, MAML2, MAP2K1, MAST1, MAST2, MBTD1, MDM2, MEAF6, MET, MGEA5, MKL2, MN1, MSMB, MUSK, MYB, MYBL1, MYC, NCOA1, NCOA2, NCOA3, NFATC2, NFE2L2, NFIB, NOTCH1, NOTCH2, NR4A3, NRG1, NTRK1, NTRK2, NTRK3, NUMBL, NUTM1, PAX3, PAX8, PDGFB, PDGFD, PDGFRA, PDGFRB, PHF1, PHKB, PIK3CA, PKN1, PLAG1, PPARG, PRDM10, PRKACA, PRKACB, PRKCA, PRKCB, PRKCD, PRKD1, PRKD2, PRKD3, RAD51B, RAF1, RELA, RET, ROS1, RSPO2, RSPO3, SS18, SS18L1, STAT6, TAF15, TCF12, TERT, TFE3, TFEB, TFG, THADA, TMPRSS2, USP6, VGLL2, WWTR1, YAP1, YWHAE

<u>This Test Replaces</u>: Sarcoma Gene Fusion Panel (MOL8008, HFHMO8) and Solid Tumor Gene Fusion Panel (MOL8006, HFHMO6)

Link(s) To Medical Literature:

- Global survey of phosphotyrosine signaling identifies oncogenic kinases in lung cancer PubMed
- Comprehensive molecular characterization of gastric adenocarcinoma | Nature
- Mechanistic insight into ALK receptor tyrosine kinase in human cancer biology PubMed
- <u>The integrated landscape of driver genomic alterations in glioblastoma PubMed</u>
- <u>Molecular detection and targeting of EWSR1 fusion transcripts in soft tissue tumors PMC</u>
- <u>Rearrangements of the RAF Kinase Pathway in Prostate Cancer, Gastric Cancer and Melanoma PMC</u>
- <u>Survey of 548 oncogenic fusion transcripts in thyroid tumors supports the importance of the already established thyroid fusions genes PubMed</u>
- Breakpoint Analysis of Transcriptional and Genomic Profiles Uncovers Novel Gene Fusions Spanning Multiple Human
 <u>Cancer Types | PLOS Genetics</u>

Report Content:

Includes tumor gene fusions detected as well as a molecular pathologist interpretation of results. **Location of Testing Results In Epic:**

Located in Chart Review: Path tab and Results Review: PAN-Solid Tumor Gene Fusion Panel



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For Non-Epic Users, You May Access Your Report: will be sent to the provider's office

Result Interpretation:

Information is specific and based on each patient's molecular findings. Results interpretation combines computational predictions of variant pathogenicity, crowdsourcing of population genomic data and cancer variant databases, internally managed variant databases and other medical and clinical databases, followed by expert review of relevant medical literature and clinical management guidelines by board-certified Molecular Pathologists and PhD scientific staff specializing in molecular genetics and genomics. Results are available in 5-10 business days.

Epic/Atlas Order code:

Epic: Pan Solid Tumor Gene Fusion Panel **Test Code** = coming soon **Atlas Test Code** = coming soon **CPT Code**:

81456, G0452

Insurance Prior-Authorization:

Required by most insurance companies. Patient insurance benefit packages vary.

Acceptable Specimen Source(S):

Formalin Fixed Paraffin Embedded (FFPE) blocks, 5-10 Unstained Slides, or RNA Extracted from a CLIA Certified Laboratory

Causes For Rejection:

Insufficient tumor cell content or quantity, and decalcified specimens

For More Information:

For Questions About This Specific New Test Contact:

http://pathology.hfhs.org/lug Search our Electronic Lab Users Guide Test Catalog

313.916. LABS (5527) for Lab Customer Service or to speak with a Pathologist

313.916.4DNA (4362) Molecular Genomic Subject Matter Expert