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TEST UPDATE- SmartGenomics™ Complete & New SmartGenomics™ Cancer Specific Profiles

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PathGroup is pleased to announce the release of SmartGenomics™ Complete, a pan cancer assay encompassing 160 cancer related genes, 126 gene fusions and whole genome copy number changes via cytogenomic array.

Also included in this major release are five new solid tumor disease specific profiles for use at diagnosis of various malignancies especially for metastatic, aggressive and/or high grade tumors in the following cancer types: Bladder, Breast, Gynecological (including ovarian carcinoma), Prostate and Sarcoma. Additionally, two new hematologic malignancy profiles have been introduced for myeloid neoplasms and lymphoid neoplasms respectively.

Existing SmartGenomics Profiles have also been improved to include the latest relevant assays such as PDL-1 for NSCLC, Her2 for colorectal cancer, gene fusions for thyroid carcinoma and neurological malignancies, copy number support for melanoma, plus other clinically supported additions. Additional information including the genes of interest, fusion partners and profile breakdowns are available by contacting Oncology Customer Support at OncologySupport@pathgroup.com.

Multiple benefits of high-throughput sequencing (commonly referred to as Next-Generation Sequencing or NGS) include: smaller input DNA requirements, greater sensitivity/specificity, advanced bioinformatics processing and rapid turn-around time.

Sensitivity and Specificity:

This assay is validated to offer >99% sensitivity and specificity at 5% allele burden via 1000x bi-directional mean coverage.

Ordering Information:

For clients utilizing SSR, test code changes have already been made to your system. No further action is required on your part.

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For reference and manual ordering purposes the following test codes are now live:

Test Code	Test Name	CPT Code
SMGPROBRST	SmartGenomics: Breast	81445 +
SMGPROPRST	SmartGenomics: Prostate	81445 +
SMGPROBLAD	SmartGenomics: Bladder	81445 +
SMGPROBRST	SmartGenomics: Gyn	81445 +
SMGPROMEL	SmartGenomics: Sarcoma	81445 +
SMGPROMYE	SmartGenomics: Myeloid	81445 +
SMGPROLYMP	SmartGenomics: Lymphoid	81445 +
SMGPROEST	SmartGenomics: Complete (Solid Tumor)	81455 +
SMGPROEHM	SmartGenomics: Complete (Heme Malignancy)	81455 +

Specimen Collection and Storage:

For solid tumor malignancies and hematologic malignancies for which FFPE tissue is available:

EITHER: One formalin fixed paraffin embedded (FFPE) block from a biopsy or surgical resection.
*Tissue must have a minimum area of 25^{mm}, 20% tumor AND 25ng of DNA. Smaller areas from multiple sections of the block can be combined to reach 25^{mm}.

OR: Minimum of five (5) unstained, uncharged slides, cut at 7-10 um, for a single gene OR ten (10) unstained, uncharged slides, cut at 7-10 um, for up to five genes

For hematologic malignancies:

EITHER: Peripheral Blood 0.5-1ml in purple top (EDTA) tube with a minimum 20% nucleated cells

OR: Bone Marrow Aspirate 0.5-1ml in purple top (EDTA) tube

Resulting:

The result reporting process **HAS NOT CHANGED**. Results will encompass the genes ordered.

For further questions, please contact
Oncology Customer Support at 1-855-854-6473