

TEST UPDATE

SMARTGENOMICS NGS SOLID TUMOR + HEME

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PathGroup has made changes to both the solid tumor and hematolymphoma panels performed via Next-Generation Sequencing (NGS) as a part of SmartGenomics™ orders. Upon review of evolving literature, incidence rates and client feedback the following changes have been made:

SOLID TUMOR: Removed 3 genes (ABL1, MPL, NPM1) and added 6 new genes (CDKN2A, FBXW7, JAK2, PTEN, TP53, VHL) for a total of 38.

HEMATOLYMPHOMA: Added 7 new genes (BTK, CALR, CD79a, PIM1, PIM2, SETBP1, SYK) for a total of 85. **In addition to these changes, the assay has also been validated to accept archive tissue from formalin fixed paraffin embedded (FFPE) tumors.** The specimen requirements for FFPE tissue on this assay remain consistent with previously defined values for archival tissue.

Specific information about genes, medical inference and inclusion/exclusion rationale is available upon request.

SENSITIVITY AND SPECIFICITY: This assay continues to offer >99% sensitivity and specificity at 5% allele burden via 1000x bi-directional mean coverage.

ORDERING INFORMATION: Specimens sent after August 25, 2014 will be tested on the new assay.

SPECIMEN COLLECTION AND STORAGE: Specimen requirements **HAVE NOT CHANGED**. FFPE tissue submitted for the hematolymphoma panel mirrors previous outlined specimen requirements for archived materials.

RESULTING: The result reporting process **HAS NOT CHANGED**. Results will encompass the genes listed above.