De novo AML panel

Indication: Targeted next generation sequencing assay for detection of hot spot mutations in cancer-related genes. The de novo acute myeloid leukemia (AML) panel is to be used once the diagnosis of AML has been established by morphology or for follow-up as class-defining or risk modifier according to WHO 2016 guidelines. Additional genes will be evaluated when requested.

Gene	Target Region (exon):
NPM1	Exon 12
CEBPA	Full
RUNX1	Full
FLT3	Exons 14 + 15 + 20
KIT	Exons 2 + 8-11 + 12 +17
TP53	Exons 2-11
IDH1	Exon 4
IDH2	Exon 4
TET2	Exons 3-11
DNMT3A	Full
WT1	Exons 7+9

Testing Method: Amplicon based targeted next generation sequencing.

Fluorescently-labeled primers are used to detect the *FLT3* ITD mutations. Capillary electrophoresis and gene scan analysis are performed to distinguish the wild type.

Test Parameters:

Diagnostic sensitivity: This assay is designed to detect known single nucleotide variants only within defined regions. Nucleotide insertions and deletions more than 25bp or outside of the defined regions may not be detected. Gene rearrangements are not detected.

Technical sensitivity: This assay may not detect certain mutations if the proportion of tumor cells in the sample studied is less than 5%.

Turnaround Time: 5-7 business days

Sample Requirements:

Blood - Specimen stability: Ambient - 72 hours; Refrigerated - 1 week

- 3 ml peripheral blood in lavender top tube (EDTA)

Bone marrow aspirates (anticoagulated with either heparin or EDTA and, if possible, placed into tissue culture medium) **- Specimen stability: Refrigerated - 1 week** (ship cold)

Billing codes: 81450, G0452