

Test Catalog

Diagnostic. Prognostic. Predictive. Predisposition.





NeoTYPE® MDS/CMML Profile

Alternative Name

MDS/CMML Profile

Methodology

Molecular

Test Description

This test is performed by sequencing the entire coding regions of the genes listed unless another method is noted. ASXL1, BCOR, BCORL1, BRAF, CALR, CBL, CEBPA, CUX1, DDX41, DNMT3A, ETNK1, ETV6, EZH2, FLT3, GATA2, GNB1, HRAS, IDH1, IDH2, JAK2, KIT, KRAS, MPL, NF1, NPM1, NRAS, PDGFRA, PHF6, PIGA, PPM1D, PTEN, PTPN11, RUNX1, SETBP1, SF3B1, SRSF2, STAG2, STAT3, STAT5B, TET2, TP53, U2AF1, WT1, and ZRSR2.

Note: FLT3 by PCR (via <u>FLT3 Mutation Analysis</u>) is available to be ordered, as Client-Bill only, in conjunction with the NeoTYPE MDS/CMML Profile. It is reported separately from the NeoTYPE Profile for the purpose of prompt therapy selection in patients with a *new* diagnosis of AML.

Clinical Significance

This molecular profile analyzes genes frequently mutated in myelodysplastic syndrome (MDS) and the related MDS/MPN overlap disease chronic myelomonocytic leukemia (CMML). Testing is useful to establish diagnosis and develop strategies for treatment and management, as mutations can signify poor or favorable prognosis and they inform of the underlying disease biology. Molecular profiling in MDS and CMML complements and should be interpreted with cytogenetic/FISH test findings. This Profile may also be used in AML cases that evolved from MDS, therapy-related AML, and AML with myelodysplasia.

Specimen Requirements

- Bone marrow (Preferred): 2 mL in EDTA tube.
- Peripheral blood: 5 mL in EDTA tube.
- FFPE tissue: Paraffin block. Alternatively, send 1 H&E slide plus 10-14 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative is the recommended fixative. Do not use zinc or mercury fixatives (B5). Highly acidic or prolonged decalcification processes will not yield sufficient nucleic acid to accurately perform molecular studies.

Storage & Transportation

Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens <7 days old preferred.

CPT Code(s)*

81450x1

Medicare MoIDX CPT Code(s)*

81450

New York Approved

Yes

Level of Service

Global

Turnaround Time

14 days

Medical Necessity Resource

Medical Necessity for NeoTYPE Myeloid Profiles

Please direct any questions regarding coding to the payor being billed.

^{*}The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party.

NeoGenomics Laboratories is a specialized oncology reference laboratory providing the latest technologies, testing partnership opportunities, and interactive education to the oncology and pathology communities. We offer the complete spectrum of diagnostic services in molecular testing, FISH, cytogenetics, flow cytometry, and immunohistochemistry through our nation-wide network of CAP-accredited, CLIA-certified laboratories.

Committed to research as the means to improve patient care, we provide Pharma Services for pharmaceutical companies, in vitro diagnostic manufacturers, and academic scientist-clinicians. We promote joint publications with our client physicians. NeoGenomics welcomes your inquiries for collaborations. Please contact us for more information.

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