My Heme (Myeloid Hematologic Malignancy) Panel

TEST DETAILS

My Heme Panel is a New York State-approved next generation sequencing (NGS) test which interrogates mutation status of recurrently mutated genes that play an important role in the diagnosis, prognosis and clinical management of patients with myeloid neoplasms, including acute myeloid leukemia (AML), myelodysplastic syndrome (MDS), myeloproliferative neoplasm (MPN), and MDS/MPN. In addition, with the emergent clinical relevance of clonal cytopenia of undermined significance (CCUS), this NGS panel serves as a useful ancillary test in the initial evaluation of patients with cytopenia. This assay provides clinically relevant, myeloid-related molecular profiles from hematologic samples of patients in a timely and accurate fashion for the clinicians and pathologists. Results generated from this assay can be integrated into routine clinical practice.

Specimen Requirements:

- A minimum of 1 ml of fresh peripheral blood or bone marrow aspirates collected in EDTA (purple top) tubes.
- At least 20 million cells of mononuclear cells isolated (fresh or frozen)
- At least 1 µg of DNA
**Ordering the Test**

The test can be ordered by through EPIC and Copath.

**Test details and methodology**

Targeted enrichment of 45 genes recurrently mutated in myeloid malignancies is performed by the microdroplet-based PCR target enrichment method from purified, fragmented DNA using the Thunderstorm system (RainDance Technologies, Billerica, MA) with a custom primer panel, followed by sequencing using the Illumina MiSeq (v3 chemistry) yielding 260-bp paired end reads. After the raw data is passed through a custom bioinformatics pipeline, filtered variant cells are reviewed and interpreted by certified molecular pathologists. The results will be signed out and released to the clinical information management system (EPIC).

The detection sensitivities of the assay for single nucleotide variants (SNV) and insertions/deletions (INDEL) are ~2 to 5% and ~1%, respectively.
**Limitations of the assay**

1. The assay is not designed for formalin-fixed, paraffin-embedded (FFPE) samples.

2. The detection sensitivity of this assay is (~2%) is not adequate for minimal residual disease (MRD) detection; therefore, use of this assay for MRD evaluation is not recommended.

3. This is a target gene sequencing panel, interrogating coding exons of 45 genes recurrently mutated in myeloid malignancies. A negative result in these 45 genes does not entirely exclude the possibility of a myeloid neoplasm. The list of these genes is not exhaustive. Mutations can be present in other genes not covered by this panel. We will continue to expand the list based on published literature and limits of technical feasibility in subsequent versions of the panel.

4. There are regions consistently with low coverage depth (<100); however they represent only a very minor portion of the entire panel. Mutations cannot be detected in these regions as any variants will be filtered out because of low coverage depth.

**Disclaimer**

My Heme Panel was developed and its performance was determined by the Molecular Hematopathology Laboratory at Weill Cornell Medicine. This method has not been cleared by the Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary.

Absence of detection of a genetic alteration by this assay implies that it is not identified within the detection limit of the assay, and does not necessarily rule out its absence in the specimen. Variants of low frequency, for example, subclonal mutations, may escape detection in this assay when the coverage depth is relatively low.

High prevalence germline alterations (e.g., germline polymorphisms with population allele frequency of >1%) are not reported. Although this test may identify some low prevalence germline alterations, this is a tumor-only NGS assay which is designed to detect recurrent somatic mutations associated with myeloid disorders. If a possible pathogenic germline (inherited) mutation is suspected, then separate clinical germline testing and counseling by a board certified genetic counselor is recommended.
Contact information:

For further information on this assay or for questions on the results of this assay, please contact:

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