To: Medical Staff, House Staff, Patient Care Centers, and Outpatient Clinics

From: Jeremy Segal, MD, PhD, Vice Chair, Genomic Pathology
Medical Director, Molecular Diagnostics Laboratory

Peng Wang, MD, PhD, Associate Medical Director, Molecular Diagnostics Laboratory

Melissa Tjota, MD, PhD, Assistant Medical Director, Molecular Diagnostics Laboratory

Kelly Arndt, Manager, Clinical Genomic Laboratories

Date: 11/18/2024

Subject: Measurable Residual Disease (MRD) Assay by NGS, HemeMRD-UChicago

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Effective Date: 11/5/2024

Laboratory Section: Molecular Diagnostics

Effective November 5, 2024 the UCM Clinical Molecular Diagnostic Laboratory implemented a new next-generation sequencing (NGS)-based measurable residual disease (MRD) test. The ultrasensitive test allows us to detect mutations commonly seen in hematologic malignancies at low allele frequencies.

In acute leukemia, MRD has been defined as the presence of residual leukemic cells in bone marrow (BM) or peripheral blood (PB) in patients who have achieved morphologic complete remission (mCR). Molecular MRD detection and monitoring is an important biomarker for prognostic, predictive and treatment-response assessments, mainly for acute myeloid leukemia, but it can be applied for other hematologic malignancies.

The test is a hybrid-capture NGS panel that utilizes dual unique molecular identifiers (UMIs) to detect variants at 0.1% variant allele frequency (VAF) across 29 genes associated with both MRD as well as clonal hematopoiesis of indeterminate significance (CHIP). For previously identified mutations by other NGS panels in our lab, such as *FLT3*-ITD and *NPM1* frameshift mutations, the limit of detection is 0.05%. The intended use of this panel is for MRD testing of any applicable hematological malignancy as well as potential early detection and monitoring of CHIP.

Please note the following regarding the new test:

- Epic test order: *HemeMRD-UChicago [LABMDHEMEMRD]*
- Specimen: Bone marrow (BM) or Peripheral blood (PB)
- Collection: Lavender Top
- Optimal Volume: 3 ml
- Transportation: Room Temperature
- Turnaround time: 18 days from receipt in the Molecular Diagnostics Laboratory

Questions: If there are any questions regarding the change, test requirements or ordering, please contact:

Kelly Arndt Kelly.Arndt@uchicagomedicine.org

Bekim Ameti Bekim.Ameti@uchicagomedicine.org