# Molecular Diagnostics Laboratory Testing

Date: April 29, 2019

Effective Date: May 1, 2019

As UR Medicine Laboratory begins the transition to 211 Bailey Rd, the Molecular Diagnostics laboratory will be immediately impacted. Due to the nature of the testing and the desire to maintain appropriate turn-around times, we will be sending select testing out to appropriate Reference Laboratories as of May 1, 2019. This change is temporary and we expect to be fully operational and bring testing back in-house July 22, 2019.

For eRecord users: results obtained during the send-out period will be reported in eRecord under "Molecular Oncology Reference Labs" tab within the "Results Review" screen. New eRecord test order codes are listed in the chart below.

This temporary measure will otherwise NOT affect the process by which these tests are ordered, and there is no change to sample requirements.

Tests impacted include: TP53, NOTCH1, SF3B1, MYD88 (Reflex CXCR4), IGHVM, EGFR, KRAS, BRAF, NRAS, CEBPA, and NPM1.

Tests that are NOT impacted: Transplant Chimerism, IDH1, FLT3, TERT promoter, JAK2, Calreticulin, lymphocyte clonality assays (IGH, IGK, TCR gamma), Factor V Leiden, Prothrombin, and HFE (hemochromatosis).

For questions or concerns please contact: Paul Rothberg (Director) 585-615-0832 or Paige Elliott (Interim Supervisor) 585-275-2709.

From: Paul G. Rothberg, Ph.D
Director, Molecular Diagnostics, UR Medicine Labs
University of Rochester Medical Center
Phone: (585) 615-0832
Email: Paul_Rothberg@urmc.rochester.edu

UR MEDICINE | Labs

| Diagnosis: | Current Tests: | Reference Lab: | New Test Name: | Description: | Includes: | Specimen Requirements |
|---|---|---|---|---|---|---|
| CLL | NGS panel (previously: TP53, NOTCH1, SF3B1) | Cancer Genetics Incorporated (CGI) | FCLL | NGS panel to evaluate Chronic Lymphocytic Leukemia / Small Lymphocytic Lymphoma biomarkers for impact on prognosis | TP53, NOTCH1, SF3B1, BIRC3, ATM, MYD88, Card11 genes | 1 lav EDTA blood or bone marrow<br>also acceptable FFPE block or 5-10 FFPE section curls |
| CLL | IGHVM | Cancer Genetics Incorporated (CGI) | IGHVG | Detection of hyper-mutation in the IGHV gene to serve as a prognostic indicator | IGHV Mutation Analysis | 1 lav EDTA blood or bone marrow |
| Lung Tumor | EGFR, KRAS, BRAF, Reflex NRAS | Mayo Clinic Laboratories | LUNGP | NGS panel to evalute samples for somatic mutations that may respond to targeted therapies | EGFR, BRAF, KRAS, HRAS, NRAS, ALK, ERBB2, and MET | Tissue block(preferred) or cytology slide |
| Myeloid Malignancies | NGS Myeloid panel, CEBPA, FLT3, IDH1, IDH2, NPM1 | Mayo Clinic Laboratories | NGSHM | NGS panel to evaluate hematologic neoplasms, specifically of myeloid origin (eg, acute myeloid leukemia, myelodysplastic syndrome, myeloproliferative neoplasm, myelodysplastic/myeloproliferative neoplasm) | ANKRD26, ASXL1, BCOR, CALR, CBL, CEBPA, CSF3R, DDX41, DNMT3A,ELANE, ETNK1, ETV6, EZH2, FLT3, GATA1, GATA2, IDH1, IDH2, JAK2, KDM6A, KIT, KRAS, MPL, NPM1, NRAS, PHF6, PTPN11, RAD21, RUNX1, SETBP1, SH2B3, SF3B1, SRP72, SMC3, SRSF2, STAG2,TERT, TET2, TP53, U2AF1, WT1, and ZRSR2. | 1 lav EDTA blood or bone marrow |
| Low-grade B-cell lymphoma | MYD88 | Mayo Clinic Laboratories | LPLFX | Establishing the diagnosis of lymphoplasmacytic lymphoma/Waldenstrom macroglobulinemia (LPL/WM) | MYD88 there is a Reflex test offered CXCR4 (CXCFX) | 1 lav EDTA blood or bone marrow or paraffin-embedded tissue/bone marrow |
| Colorectal Cancer | KRAS, BRAF | Mayo Clinic Laboratories | RASFP | Evaluation of mutations that may respond to gene targeted therapy | BRAF (exons 11 and 15), HRAS (exons 2 and 3), NRAS (exons 2, 3, 4), and KRAS (exons 2, 3, 4) genes. This includes, but is not limited to, the testing of somatic mutations in KRAS codons 12, 13, 59, 61, 117, 146; NRAS codons 12, 13, 59, 61,146; HRAS codons 12, 13, 61; and BRAF codons 594, 596, 600. | Tissue block(preferred) or cytology slide |
| Melanoma | BRAF | Mayo Clinic Laboratories | BRAFC | Identification of melanoma tumors that may respond to BRAF-targeted therapies (V600 mutations) | BRAF | Tissue block or tissue slides |