Memorandum Molecular #42

To: UNC Health Attending Physicians, Housestaff, Nursing Coordinators, Department Heads, Supervisors and Affiliates

From: Karen Weck MD, Medical Director, Molecular Genetics Laboratory
Randa Dafalla, MD, Clinical Assistant Professor, Pathology & Lab Medicine
Herbert Whinna MD, PhD Medical Director, McLendon Clinical Laboratories

Date: November 5, 2025

Subject: **New Test: *KIT* p.D816V Mutation Analysis**

Effective November 17, 2025, the *Molecular Genetics Laboratory* at UNC Medical Center will start offering *KIT* p.D816V Mutation Analysis. This will replace the send-out test *KIT* p.Asp816Val Variant Analysis, Quantitative, Varies (Epic ID: LAB11429) to Mayo Laboratory.

KIT p.D816V is the most common mutation observed in mastocytosis and is present in >90% of systemic mastocytosis(SM). Detection of the *KIT* p.D816V is useful to assist clinical diagnosis, prognosis and therapeutic monitoring

Specimen Requirements
The preferred specimen is whole blood (EDTA or ACD), and bone marrow aspirate (BMA) anticoagulated with EDTA. Bone marrow clot sections (FFPE) or bone marrow core biopsies (FFPE) are also acceptable as ten unstained paraffin sections (5-10µM thick, plain glass), plus an H&E-stained slide with >10% malignant cells with a total area >2mm^2. Unacceptable specimen types are plasma and frozen or decalcified tissue.

Epic Test Name
KIT p.Asp816Val (D816V) Quantitative Analysis

Epic Test ID
LAB6795

Turn-around time
Within 10 days

Reporting Results
Results are interpreted by a molecular pathologist and are reported quantitatively from 0.1% VAF (Variant Allele fraction) to 50% VAF.

For additional information or questions contact the UNCMC Molecular Genetics Lab at (984) 974-1825.

Website https://www.uncmedicalcenter.org/mclendon-clinical-laboratories/directory/molecular-pathology-and-genetics/

.