Memorandum – Molecular Genetics #44

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

From: Karen E. Weck, MD, Medical Director, Molecular Genetics Laboratory

Shannon Gray, PhD, Technical Director, Molecular Genetics Laboratory

Herbert C. Whinna, MD, PhD, Medical Director, McLendon Clinical

Date: January 23, 2026

Subject: **Changes to Cystic Fibrosis (CF) Carrier Screening and Diagnostic Testing**

Effective 01/26/2026, the UNC Molecular Genetics Laboratory will introduce a new methodology for CF carrier screening and diagnostic testing. The Devyser *CFTR* next-generation sequencing (NGS) assay uses massively parallel sequencing of genomic DNA to detect the ACMG-recommended 100 variant set (Deignan et al., 2023) and 8 additional copy number variants (a full variant list is available on the McLendon Clinical Laboratories website, https://www.uncmedicalcenter.org/mclendon-clinical-laboratories/directory/molecular-pathology-and-genetics/. The new methodology replaces the previous assay, which targeted 60 *CFTR* variants, and increases the detection rate to at least 95% across the following ancestral populations: African/African American, Ashkenazi Jewish, East Asian, Latino/Admixed American, Non-Finnish European, South Asian. There are no changes to ordering, specimen requirements, or turnaround time.

Questions can be directed to the UNC Molecular Genetics Laboratory at **(984) 974-1825** or Shannon Gray at Shannon.Gray@unchealth.unc.edu.

Additional information is available on the UNC Molecular Genetics Laboratory website: https://www.uncmedicalcenter.org/mclendon-clinical-laboratories/directory/molecular-pathology-and-genetics/