

Memorandum - Core #208

To: UNC Medical Center, UNC Children's Raleigh, and Faculty based Clinic

Physicians

From: Nichole Korpi-Steiner, PhD; Director, UNCMC Point of Care Testing

Steven W. Cotten, PhD; Director, UNC Children's Raleigh Laboratory

Medical Director, UNCMC McLendon Clinical Laboratories

Date: March 22, 2024

Subject: Resuming Point-of-Care HbA1c testing for Hospital-based Clinics

Effective March 22nd, 2024, point-of-care HbA1c testing using the Siemens DCA Vantage Reagent lot # 0695024 may resume for hospital-based clinics.

Evaluation of DCA reagent lot # 0695024 demonstrated acceptable quality performance compared to lab testing. No intercept offset is needed for this lot. This lot sequester will be available through Cardinal Health distributor for approximately 6 months based on estimated POC testing volumes. Additional lot sequestering will be performed prior to depletion of this lot sequester.

Recommendations for CLIA Medical Directors at UNC Health Hospital-based Clinics:

- Purchase DCA Vantage reagent lot # 0695024 using item number B53761UNCH through Cardinal Health distributor.
- Report any patient safety incident(s) via online SAFE reporting system.

If indicated, submit official complaint regarding DCA Vantage performance to Siemens Healthineers by calling Technical Support line at 1-877-229-3711, prompt 14, then prompt 1.

Further updates will be provided, as available.

If you have any questions related to these changes, please contact Dr. Korpi-Steiner at 984-974-1498 or Nichole.korpi-steiner@unchealth.unc.edu .