





Memorandum – Core #205

To: UNCMC, UNC Children’s Raleigh, UNC Hospitals and Faculty-based clinics

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

 Steven W. Cotten, PhD; Medical Director
UNC Children’s Raleigh

 Herbert C Whinna, MD, PhD; Medical Director
UNCMC McLendon Clinical Laboratories; UNC Hillsborough Hospital
Laboratory; UNC Eastowne MOB Laboratory, UNC Chatham Hospital
Laboratory

Date: January 26, 2024

Subject: **Temporary cessation of Point-of-Care HbA1c testing**

Effective January 29th, 2024, point-of-care HbA1c testing using the Siemens DCA Vantage will be discontinued at the UNC Medical Center and UNC Children’s Raleigh due to quality concerns regarding test performance. Evaluation of select reagent cartridge lots (Lot 0655103, Lot 0672123, Lot 0658113) showed a positive bias in measured HbA1c values using point-of-care DCA Vantage compared to lab testing that may potentially impact patient care management decisions. It is unclear at this time if all, or some, reagent cartridge lots at UNC Health are affected. We understand that temporary cessation of point-of-care HbA1c testing has a negative impact on patient satisfaction and clinical operations; however, patient safety is our top priority.

We are exploring a potential reagent lot sequester of HbA1c reagent cartridges for additional quality assurance and potential solution. We appreciate your patience as we work with Siemens partners regarding this investigation.

Important notes:

- Discontinue use, remove and sequester Siemens HbA1c reagents for potential credit
- Send patient EDTA whole blood for lab HbA1c testing

- Report any patient safety incident(s) via online SAFE reporting system

Recommendation for CLIA Medical Directors at other UNC Health clinic locations:

- Consider temporary cessation of point-of-care HbA1c testing using the Siemens DCA Vantage at your clinic sites until the reagent performance issue is resolved

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

You may type your memo here.