MEMORANDUM # 129

TO: UNCHCS Attending Physicians, Housestaff, Nursing Coordinators, Department Heads and Supervisors

FROM: Nichole Korpi-Steiner, Ph.D.
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DATE: June 14, 2016

SUBJECT: Pre-analytical Limitations in Point of Care Glucose Meter Testing

Effective June 15th, 2016, an updated point of care (POC) glucose meter testing procedure and a new Learning Management System (LMS) training module will be implemented for all personnel performing POC glucose meter testing within UNC Healthcare System (excluding affiliate hospitals) in order to enhance education regarding pre-analytical limitations in POC glucose meter testing.

To do:

- Please review the POC glucose meter testing procedure which can be found on the intranet: (http://intranet.unchealthcare.org/intranet/policies/mclendon_policies_general/)
  - Scroll down to glucose testing
  - Select Nova StatStrip or Nova StatStrip Xpress procedure depending on which glucose meter is used in practice (most sites use the Nova StatStrip).
- An LMS module will be assigned to POC glucose meter testing personnel, please complete by September 30, 2016.

Background: Nationwide, numerous medical device incidents related to glucose meter testing have been reported to the Food and Drug Administration (FDA) prompting considerable attention to be focused on how glucose meter testing is being used in clinical practice. All glucose meters have test limitations and the FDA requires that these limitations be indicated in the manufacturer's instructions. For example, the manufacturer of the Nova StatStrip glucose meter used here in the UNC Healthcare System has highlighted pre-analytical patient conditions and specimen type limitations as potential sources of erroneous results: **Capillary whole blood specimens should not be used if the patient has decreased peripheral blood flow or is receiving invasive medical intervention/therapy. Examples include, but are not limited to, severe hypotension, shock, hyper-osmolar-hyperglycemia (with or without ketosis), or severe dehydration.** In these situations, an alternative specimen type (e.g. arterial, venous whole blood) should be used for glucose meter testing or a specimen may be sent to the Core Lab for testing.

Manufacturer's instructions and test limitations are incorporated into UNC Point of Care Testing procedures. POC testing in clinical practice must comply with UNC procedures as well as the FDA-approved manufacturer's instructions per federal law (CLIA) and accrediting organization standards (TJC, CAP).

If you have any questions related to POC glucose meter testing, please contact the POCT office at 984-974-1416 or Dr. Korpi-Steiner at 984-974-1498.