

MEMORANDUM #2

TO:

UNC Hospitals Attending Physicians, Housestaff, Department Heads, Nursing

Coordinators and Supervisors

FROM:

John F. Chapman, Dr. P.H., Director, Point of Care Testing

Connie Bishop (MT-ASCP) Associate Administrative Director, Core Laboratory

Herbert C. Whinna, M.D., Ph.D., Chair, McLendon Clinical Laboratories

SUBJECT:

Falsely Decreased Point of Care Glucose Values SureStep Pro Test Strips

DATE:

April 9, 2010

Lifescan has notified us of a potential bias with the new lot of glucose test strips to be used with our current hospital-based Point of Care Glucose instruments. These recently manufactured SureStep®Pro® test Strips may provide falsely low test results when the whole blood glucose result is greater than 400 mg/dL.

The Sure Step meter we use is designed to provide a numeric result up to 500mg/dL. With values above this the meter is designed to display "High" or "HI" instead of a numerical result. Currently any result greater than 400 mg/dL will flag as critical. However, the manufacturer has advised users that recently manufactured SureStep Pro test strips may actually cause the meter to display a falsely low numerical result instead of "High or "HI" for values above 400 mg/dL. For example, with our new lot of strips whole blood glucose of 650 mg/dL may actually be displayed incorrectly as 469 mg/dL instead of "HIGH" or "HI".

The new lot of test strips (code 10) that will be released for use next week is one of the lots affected, so please interpret your results accordingly. Until such time as the manufacturer can provide us with replacement strips, we recommend that all whole blood glucose meter results above 400 mg/dL be confirmed by venous sample in the Core Lab. Glucose values below 400 mg/dL are NOT affected by this problem.

Please direct any questions to the Point of Care Testing Coordinator at 966-2449.