



Memorandum Core #181

To: UNCMC, Hillsborough Hospital, and Eastowne Medical Office Physicians, Housestaff, Nursing Coordinators, Department Heads, and Supervisors

From: *MSU* Herbert C Whinna, MD, PhD; Medical Director
UNCMC McLendon Clinical Laboratories, UNC Hillsborough Hospital Laboratory, and Eastowne MOB Laboratory

SWC Steven W. Cotten, PhD; Director of Automated Chemistry
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Date: March 31, 2022

SUBJECT: False elevations of Estradiol results with plasma specimen types

On March 3rd, 2022, the laboratory received an urgent medical device correction confirming false elevations in estradiol measurements for specimens collected in plasma tubes. The manufacturer's investigation is still ongoing regarding the origin and appearance of these elevations.

On March 4th 2022, plasma was removed as an acceptable specimen type for estradiol measurement in EPIC and all orders for estradiol now default to serum which is unaffected.

The manufacturer recommends retesting using a serum sample in cases where plasma samples were used to assess the menopausal status of a female for the purpose of determining therapy for hormone receptor positive advanced or metastatic breast cancer and is currently undergoing a therapeutic treatment based on a plasma estradiol result above the post-menopausal reference limit (32.2 pg/mL). Based on the maximum bias observed due to this issue, only patients with plasma estradiol values between 32.2 pg/mL and 100.0 pg/mL are recommended for reassessment. When serial monitoring has occurred in this clinical context, only the most recent plasma estradiol result needs to be considered.

Out of an abundance of caution, the laboratory will invalidate all estradiol results (all ages, all populations) measured on plasma specimens since July 13th 2021. Chart review was performed on all impacted results (plasma specimens) and providers will be notified of recommendations for retesting via EPIC.

Providers are encouraged to re-measure estradiol if unexpected elevations were seen previously.

For questions please contact Dr. Cotten (Steven.Cotten@unchealth.unc.edu) or Dr. Herbert Whinna (Herbert.Whinna@unchealth.unc.edu).