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Des Moines Laboratory

TECHNICAL ALERT – Estradiol Level (ESTDIOL)

Date: March 11, 2022

MercyOne Des Moines Laboratory has been notified of an issue with our Estradiol test. Siemens, the manufacturer of both the reagent and instrument we use for Estradiol testing, issued a product notification dated March 3, 2022 stating that all lots of Estradiol reagent may show falsely elevated results when using plasma specimens. The affected lots were in use at MercyOne Des Moines Laboratory since its implementation on August 23, 2019.

Siemens is requiring customers to discontinue use of plasma tubes for specimen collection of Estradiol levels and MercyOne Des Moines has implemented this change to our specimen requirements. We are aware that due to recent supply chain issues, some samples for Estradiol testing *may* have been collected in a serum tube as an alternate specimen type. However, as the primary sample requirement was plasma, we must assume samples previously sent were plasma.

Siemens is not recommending a review of previously generated results, *except* in the 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. Based on the maximum bias observed due to this issue, only patients with plasma estradiol values between 32.2 pg/mL (118.2 pmol/L) and 100.0 pg/mL (367.0 pmol/L) are recommended for reassessment with a serum sample.

If you have a patient previously tested for Estradiol level in the affected timeframe and who meets the retesting criteria, please contact Casey Henry, Manager – Outreach Operations at 515-643-4517 to order complimentary serum Estradiol testing within the next 30 days.

We apologize for any inconvenience this has caused.

Thank you for choosing MercyOne Des Moines Laboratory.