



LABORATORY UPDATE

August 31st, 2015

Effective Monday, August 31st 2015, Enzo Clinical Labs, Inc. will be converting from the discontinued Roche[®] Estradiol II reagent to the new and improved Roche[®] Estradiol III immunoassay test.

The newly formulated Roche[®] Estradiol III reagent consists of a mixture of high and moderate affinity monoclonal mouse antibodies, allowing more sensitive and specific analysis than the previous method with an enhanced analytic range. The use of two capture antibodies in the formulation of the assay results in a reduction in cross-reactivity of typical cross-reactants and helps ensure a long term supply of the product. ***The reduction in non-specific cross-reactivity of the Roche[®] Estradiol III reagent results in 10-15% lower measurements.***

The new Roche[®] Estradiol III reagent offers improved traceability to the reference method, ID-GC/MS, and an updated reference ranges (see below):

	NEW pg/mL	OLD pg/mL
Healthy Men:	23.8 – 60.7	7.63-42.6
Healthy Women:		
Follicular Phase	16.2 - 313	12.5 - 166
Ovulation Phase	41.0 - 323	85.8 - 498
Luteal Phase	10.9 - 346	43.8 - 211
Postmenopausal	< 5.0 - 145	< 5.0 - 54.7
Healthy Pregnant Women:		
1 st Trimester	127 - 4,133	215 - > 4,300
2 nd Trimester	1,498 - 22,030	N/A
3 rd Trimester	8,525 - 30,000	N/A
Children:		
Boys	N/A*	< 5.0 - 20.0
Girls	N/A*	6.0 - 27.0

*Reference range currently not available due to limited sample size of study. Update to follow.

Roche[®] Estradiol III Test	
Enzo Test Code:	6833 (remains the same)
Specimen Collection:	SST; red
Turn-Around-Time:	24 hours (routine) 4 hours (STAT)**

**Available during certain times only

Enzo Clinical Labs is committed to the highest level of quality in lab services to you and your patients. Please do not hesitate to contact us with any questions or concerns that you may have. We appreciate the continued opportunity to serve you and your patients.

Sincerely,

Dieter Schapfel, MD
Medical Director
Chief Scientific Officer