



Technical Memorandum

TO: Physicians, Staff
From: Wesley Kim, MD, Medical Director
Date: July 20, 2015
Subject: Estradiol III

Effective Aug 3, 2015, Estradiol testing on our Roche test platform will change from Estradiol II to Estradiol III. Reagent vendor has replaced Estradiol testing with new formulated Estradiol III reagent which consists of a mixture of high and moderate affinity monoclonal mouse antibodies directed against 17 β -estradiol, allowing for high specificity and high sensitivity. The use of two capture antibodies in the formulation of the assay results in a reduction in cross-reactivity of typical cross reactants. The new generation III reagent offers improved traceability to the reference method, ID-GC/MS. The old reagent will no longer be available.

Below is our current reference range and the new reference range. Based on the validation study, clinicians may see a slight variation in the numerical values when comparing results between the previous and new reagent. As such, there will be some variation in the reference ranges.

Test Information:

TEST	ORDER CODE		OLD REFERENCE RANGE	NEW REFERENCE RANGE	UNITS
Estradiol	7711	Male	< 43	< 61	pg/mL
		Female: Follicular	13 - 166	12 - 233	pg/mL
		Ovulation	86 - 498	41 - 398	
		Luteal	44 - 211	22 - 341	
		Postmenopause	< 55	< 138	

DLS will monitor the new reagent very closely and make adjustments as needed to ensure optimal performance. Because of this, it is important that any feedback, questions, or concerns that you may have in regards to laboratory performance, be immediately communicated to our client services, your marketing representative, or a DLS Laboratory Director, so that they may be addressed to ensure the quality and safety of laboratory results.

You may contact DLS Client Services at 589-5101, or Dr. Wesley J. Kim at 589-5131.