DIAGNOSTIC LABORATORY SERVICES, INC.

Technical Memorandum

TO: Physicians, Staff

From: Wesley Kim, MD, Medical Director

Date: December 13, 2016

Subject: New Progesterone III assay

Effective December 14, 2016, Progesterone testing on our Roche test platform will change from Progesterone II to Progesterone III. Per manufacturer, the change results in improved standardization and accuracy, and reduced interference secondary to the effect of cross reactants. The new generation III reagent offers improved traceability to the reference method, ID-GC/MS.

Below is a comparison of the current reference range and the new reference range. Based on our internal validation study, clinicians may see a slight decrease in the numerical values when comparing results between the previous and new reagent.

Test Information:

TEST	ORDER CODE		OLD REFERENCE RANGE	NEW REFERENCE RANGE	UNITS
Progesterone	3130	Male:	0.2 – 1.4	<0.2	ng/mL
		Female: Follicular	0.2 – 1.5	<1.0	ng/mL
		Ovulation	0.8 – 3.0	<12.1	ng/mL
		Luteal	1.7 – 27.0	1.8 – 23.9	ng/mL
		Postmenopause	<0.8	<0.2	ng/mL

DLS will monitor the new reagent very closely and make adjustments as needed to ensure optimal performance.

Depending on the clinical presentation, you may need to re-baseline your patient(s) if you are following Progesterone value trends over time.

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 DLS Laboratory Director, so that they may be addressed to ensure the quality and safety of laboratory results.

DLS Client Services can be reached at 589-5101. Dr. Wesley J. Kim can be reached at 589-5131.