DIAGNOSTIC LABORATORY SERVICES, INC.

Technical Memorandum

TO: Physicians, Staff

From: Wesley Kim, MD, Medical Director

Date: December, 6 2010

Subject: Estradiol, Progesterone, Homocysteine, AFP Non-Maternal, and Intact PTH

Effective 12/20/10, Estradiol, Progesterone, Homocysteine, AFP Non-Maternal, and Intact PTH tests will be moved to our new automated Roche modular test platform at Central Core Laboratory. This change will allow for improved standardization, quicker assay turn-around time, and better system redundancy with more consistent up-time and less result delays. This will hopefully translate into better service for our clients and improved patient care.

Below is chart showing the name of the tests being moved over as well as the current reference ranges and the planned new reference ranges. Based on the validation study, the current and new platform showed good correlation with real patient sample results. No major clinically significant bias patterns were identified between the two systems. However, as with all immunoassay tests, slight variations between two different manufacturer's platforms can always be seen. Patients who have their testing performed on the current system may not necessarily show the same numerical results on the new system. In addition, there are slight differences in the recommended manufacturer's reference range as stated in the table below. DLS has performed a limited verification of the reference range with samples from the local population. However, following the change, DLS will continue to monitor and validate these new ranges and make adjustments to them as needed to ensure they accurately reflect Hawaii's patient population. In addition, for those tests that are being used to monitor patients, it may be prudent, if clinically indicated, to re-baseline your patients with the new system before making clinical decisions that may alter therapy or prognosis.

Test Information:

TEST	ORDER CODE	OLD REFERENCE RANGE	NEW REFERENCE RANGE	UNITS
Estradiol	771	Males: <76 Females: Follicular Phase: <161 Periovulary: 34-400 Luteal: 27-246 Postmenopause: <111	Males: <42.6 Females: Follicular Phase: 12.5-166 Ovulation Phase: 85.8-498 Luteal Phase: 43.8-211 Postmenopause: <12.0-54.7	pg/mL
Progesterone	313	Males: 0.3-0.9 Females: Follicular Phase: 0.3-1.2 Luteal Phase: 0.7-17.8 Postmenopause: <1.0	Males: 0.2-1.4 Females: Follicular Phase: 0.2-1.5 Ovulation Phase: 0.8-3.0 Luteal Phase: 1.7-27 Postmenopause: 0.1-0.8	ng/mL
AFP Non-Maternal	106	0.0-9.0	$\leq$ 9.0	ng/mL
Homocysteine	4686	5.0-15.0	$\leq$15.0	umol/L
PTH, Intact	315	12.0-65	15 - 65	pg/mL

To ensure best quality of care and patient safety, 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.

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