



Technical Memorandum

TO: Physicians, Staff

From: Wesley Kim, MD, Medical Director
Ana Ortega-Lopez, Medical Director

Date: July 8, 2010

Subject: HCG-Beta Quantitative and Qualitative

Effective July 19, 2010, human chorionic gonadotropin β -subunit (hCG-Beta), qualitative and quantitative tests will be moved to our new Roche modular test platform at Central Core Lab and Queen's Medical Center Laboratory.

Below is a list of Beta-hCG tests, including the current reference ranges and the new reference ranges. Based on the validation study, clinicians may see slight variations in the numerical values when comparing results between the previous and new system. As such, there will be some variation in the respective reference ranges. It is important to remember that results for any given test do not always correlate between two different manufacturers. For tumor marker being used to routinely monitor patients over time, it is recommended that, where clinically indicated, patients should be re-baselined with the new assay before making clinical decisions.

Test Information:

TEST	ORDER CODE	OLD REFERENCE RANGE	NEW REFERENCE RANGE	UNITS
HCG, Quant, Pregnancy	468P	Non-pregnant <5 Borderline Positive 5-25 0-1 Week 0-50 1-2 Weeks 40-300 2-3 Weeks 200-1000 3-4 Weeks 500-6000 1-2 Months 5000-200000 2-3 Months 10000-100000 2 nd Trimester 3000-50000 3 rd Trimester 1000-50000	Non-Pregnant <5 Gestation: 3 rd Week 6-71 4 th Week 9-750 5 th Week 217-7138 6 th Week 158-31795 7 th Week 3697-163563 8 th Week 32065-149571 9 th Week 63803-151410 10 th Week 46509-186977 12 th Week 27832-210612 14 th Week 13950-62530 15 th Week 12039-70971 16 th Week 9040-56451 17 th Week 8175-55868 18 th week 8099-58176	mIU/mL
HCG, Quant, Tumor	468T	<5	<3	mIU/mL
HCG Qualitative	450	Negative <5 Weak Positive 5-25 Positive >25	Negative < 5 Positive \geq 5	mIU/mL

DLS will monitor the new test platform very closely and make adjustments 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, Dr. Ana Ortega-Lopez at 547-4470 or Dr. Wesley J. Kim at 589-5131.