



Laboratory Medicine Bulletin

NEW HUMAN CHORIONIC GONADOTROPIN (hCG) TEST

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As of January 26, 2016, the Providence Health Care laboratories will be utilizing a new hCG method which will decrease the turnaround time for the reporting of hCG test results. The new test is called the *hCG Stat test* (Roche) which will be run on the new Roche analyzers at MSJ (e411) and SPH (e601), respectively. The analytical time for this test is 10 minutes for hCG results <10,000 IU/L, and 20 minutes for hCG results >10,000 IU/L, as compared to 30+ minutes for most samples with the previous platform (Siemens Centaur). A major change for the emergency department is that the Roche hCG Stat test will be ordered as a single test code, due to decreased time for test analysis, as opposed to two separate test codes (one for pregnancy screen, one for pregnancy monitoring).

The performance characteristics of the Roche assay match that of the Centaur method with respect to sensitivity and specificity for the differentiation of pregnant individuals from non-pregnant individuals. However, the Roche hCG Stat test has suboptimal performance as a marker of malignancy, and therefore, all hCG tumor marker requests should be specifically directed to the BC Cancer agency.

One other difference between the two platforms is that the Roche hCG method reports values significantly lower (20 to 30%) than the Centaur method. The Roche hCG Stat test is calibrated to the 4th International Standard for Chorionic Gonadotropin (NIBSC 75/589), as opposed to the World Health Organization 3rd International Standard (75/537). Despite this difference in the absolute result, the two methods are highly correlated, with inter-method comparison regression statistics showing R² values of >0.99. The normal reference interval for non-pregnant, pre-menopausal women is ≤1 IU/L. Expected values for pregnancy are given in the following table (values provided by the manufacturer):

Gestational Age	hCG (IU/L)	Gestational Age	hCG (IU/L)
Non-pregnant (pre-menopausal)	≤1	8 weeks	31,366 to 149,094
Non-pregnant (post-menopausal)	≤7	9 weeks	59,109 to 135,901
3 weeks	5 to 72	10 weeks	44,186 to 170,409
4 weeks	10 to 708	12 weeks	27,107 to 201,615
5 weeks	217 to 8,245	14 weeks	24,302 to 93,646
6 weeks	152 to 32,177	15 weeks	12,540 to 69,747
7 weeks	4,059 to 153,767	18 weeks	9,649 to 55,271

Please do not hesitate to contact me at 604 806 8190 if you have any questions.



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