



THE UNIVERSITY OF  
CHICAGO MEDICINE &  
BIOLOGICAL SCIENCES

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**To:** UCM Medical Staff, Housestaff, Nursing Staff, Patient Care Centers, and  
Outpatient Clinics

**From:** KT Jerry Yeo, PhD, DABCC, FAACC  
Professor of Pathology  
Medical Director, Clinical Chemistry Laboratories

Xander van Wijk, PhD, DABCC, FAACC  
Assistant Professor of Pathology,  
Assistant Medical Director, Clinical Chemistry Laboratories

**RE: New Qualitative Urine hCG Rapid Test (Cardinal Health)**

The Clinical Chemistry Labs were recently informed that our regular supply of qualitative urine hCG test by QuickVue is on backorder with no further information on availability in the near future. Given this, we have sourced another urine hCG replacement assay sold by Cardinal Health.

The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of hCG in urine. At the level of claimed sensitivity, the hCG Cassette Rapid Test shows no cross-reactivity interference from the structurally related glycoprotein hormone hFSH, hLH and hTSH at high physiological levels. The hCG Cassette Rapid Test has a sensitivity level of **25 mIU/mL**, and is capable of detecting pregnancy as early as 1 day after a first missed menses.

Please be aware of the following **limitations** in the use of any Qualitative test for urine hCG:

- This test provides a presumptive diagnosis for pregnancy. A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms including testicular tumors, prostate cancer, breast cancer and lung cancer can cause elevated levels of hCG. Thus a confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
- False negative results may occur when levels of hCG are below the sensitivity level of the test. When pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.
- This test reliably detects intact hCG up to 500,000 mIU/mL. It does not reliably detect hCG degradation products, including beta-free hCG and beta core fragments. Quantitative serum assays used to detect hCG may detect hCG degradation products and therefore may show discordance with the results of this rapid test.

If you have any question regarding this test, please email one of us at [jyeo@bsd.uchicago.edu](mailto:jyeo@bsd.uchicago.edu) or [xvanwijk@bsd.uchicago.edu](mailto:xvanwijk@bsd.uchicago.edu)