Implementation of a Qualitative Plasma B-hCG Test for Rapid Emergency Department Pregnancy Screening

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Introduction

Determination of pregnancy status is often an important checkpoint for medical decision-making in the emergency department (ED). Although urine screening is convenient, patients may not be able to produce urine on demand—requiring serum or plasma-based B-hCG testing.

Quantitative serum B-hCG tests are not ideal due to requiring time to clot and specimen dilutions to quantify high biomarker concentrations. Delays in quantitative B-hCG testing impacts ED workflow and creates a situation where the determination pregnancy status could be delayed or missed.

This project saw the development of a qualitative plasma B-hCG test for use in the ED. Plasma samples do not require clotting compared to serum and qualitative testing eliminates the need for specimen dilution—thereby accelerating test turnaround time.

Methods

The UC Davis Clinical Chemistry Laboratory adapted an existing FDA approved quantitative B-hCG assay (Beckman Coulter, Brea, CA) for qualitative use.

As required by Clinical Laboratory Improvement Amendment (CLIA) regulations, new cut offs require validation prior to implementation. A plasma B-hCG cut off of 25 mIU/mL was identified based on literature review and consensus among a multidisciplinary UCD Health team.

Chart review was performed for 510 (492 females and 18 males) patients who had undergone quantitative serum B-hCG testing from June 2018 through August 2018. Receiver operator curve (ROC) analysis was performed to verify the performance of the 25 mIU/mL cut off. Total and analytical turnaround time was compared pre- and post-implementation.

Patient Distribution

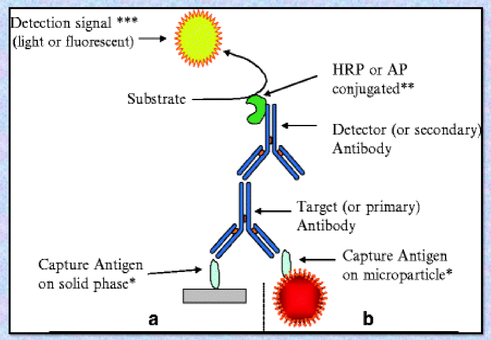
Quantitative serum B-hCG testing (6/1/2018 – 8/31/2018)

	Pregnant	Non-pregnant	Total
Female	137	355	492
Male	0	18	18

Qualitative plasma B-hCG testing (10/18/2018 – 11/17/2018)

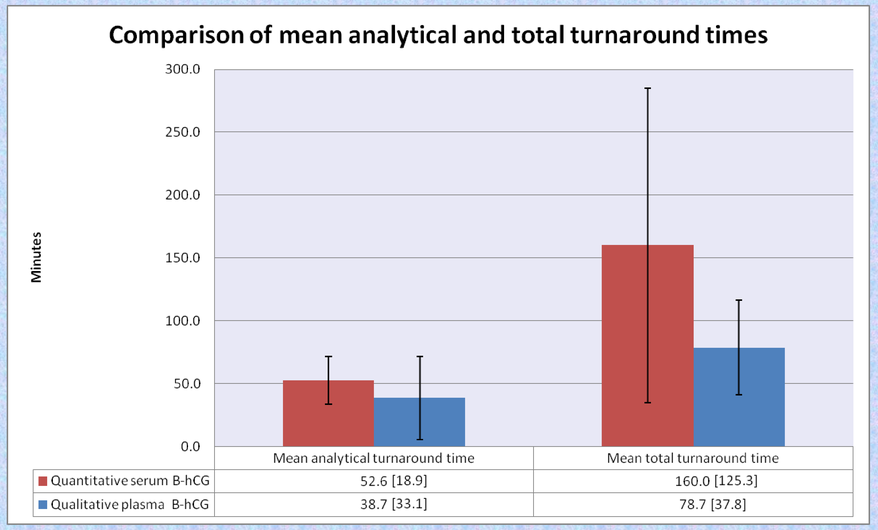
	Pregnant	Non-pregnant	Total
Female	3	112	115
Male	0	0	0

Beckman Coulter
UniCel Dxl 800 Access Immunoassay System



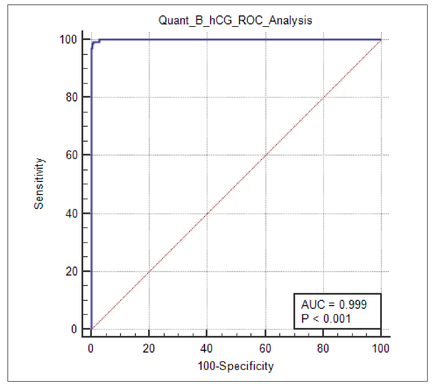
Assay Principle

- Paramagnetic particle, chemiluminescent immunoassay.
- Sample is added to a reaction vessel along with a citrate buffer. After an initial incubation, rabbit anti-βhCG alkaline phosphatase conjugate and paramagnetic particles coated with goat anti-mouse IgG: mouse monoclonal anti-βhCG complexes are added.
- hCG binds to the immobilized monoclonal anti-βhCG on the solid phase while, at the same time, the rabbit anti-βhCG alkaline phosphatase conjugate reacts with different antigenic sites on the hCG.
- After incubation in a reaction vessel, materials bound to the solid phase are held in a magnetic field while unbound materials are washed away.
- Chemiluminescent substrate is added to the vessel and light generated by the reaction is measured with a luminometer. The light production is directly proportional to the concentration of βhCG in the sample.



Results

- Using the new 25 mIU/mL cut off, clinical sensitivity was 96% and specificity was 100%, which is comparable to existing plasma- and urine-based qualitative B-hCG tests on the market.



- Mean (SD) analytical turnaround was significantly faster with the new qualitative test (38.7 [18.9] vs. 52.6 [33.1] minutes, P<0.001).
- Additionally, mean total turnaround time was also significantly reduced with the new B-hCG test (78.7 [37.8] vs. 160.0 [125.3] minutes, P<0.001).
- Post-implementation case review of 100 patients did not identify erroneous reclassification of pregnancy status. ED physician response was unanimously positive.

Conclusions

Pregnancy screening in patients that do not produce urine require serum or plasma B-hCG testing. Existing quantitative B-hCG tests may not be compatible with ED turnaround time requirements. Safe implementation of a qualitative plasma B-hCG test improved ED workflow by accelerating the total turnaround time.

References:

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