Quality Assurance Study Examining the Utility of Extended Soaking of the β-HCG Cartridge in the Setting of Dilute Urine Samples

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No conflicts of interest to disclose
26 year old female presenting with vaginal bleeding and pelvic pain

- Blood and urine samples obtained at triage
- Problem: urine specific gravity < 1.005
Point of care urine hCG immunoassays have a decreased sensitivity in dilute urine samples

— Greene et al. (2013) found sensitivity to be as low as 53-78% when hCG levels were between 20-300IU/L
Modified testing method by Cartwright et al. (1986)

- They had 5/884 patients with false negative results and urine SG ≤ 1.010
- They said using 20 drops instead of 5 drops in these dilute urine cases improved the performance of the assay
Could this technique work in our ED’s to improve the sensitivity of urine immunoassays?

- Avoid having to send a serum hCG
- Cheap and quick alternative to serum testing
- Improve patient safety
60 ED patients at FMC and PLC entered into the study
November 2013-December 2014

Inclusion criteria

- Positive urine hCG test with 3 drops
- PMHx preventing them from being pregnant (ie. hysterectomy, bilateral oophorectomy)
- < 30 days post delivery
- Known current pregnancy

Exclusion criteria

- Age 12-50
- Urine SG ≤ 1.010
Modified testing performed by Dr. Betzner or Rowe

Serum hCG level measured in each patient after modified urine testing was performed.
Results

- Modified soaking method in urine samples with SG ≤ 1.010
  - Sensitivity = 60%
  - Specificity = 98%

- 10 drop method
  - Sensitivity = 60%
  - Specificity = 98%

- 20 drop method
  - Sensitivity = 25%
  - Specificity = 100%
Figure 1. Proportion of false negative test results detected by extended soaking in dilute urine samples
This method was found to occasionally catch a false negative result with a sensitivity of 60%, but certainly can’t rule out pregnancy as definitively as measuring serum $\beta$-HCG levels.

Better sensitivity of 10 drop method likely because developer windows were more prone to flooding with more urine.
- Inter-interpreter variability was not quantified nor analyzed, and may have influenced the results

- Low sample size
We found one case with a negative urine β-HCG and a SG <1.005 which had a positive serum β-HCG of 14327 mIU/mL, demonstrating the extreme of how important not ruling out pregnancy on the basis of a dilute urine sample can be.

Check urine SG before interpreting the validity of a pregnancy test result.
- We also found one case with a SG of 1.010, our standard regional cut-off for accuracy, wherein the serum \( \beta \)-HCG was 158.

- Regional cut-off should be moved to 1.015 for a sample to be considered to have passed accurate urine \( \beta \)-HCG rule out.
When a patient requires pregnancy testing and provides a dilute urine sample, increasing the amount urine used in point of care HCG tests is a quick and inexpensive way of increasing the sensitivity of this test.

In cases where the point of care HCG test is negative and urine specific gravity <1.015, a serum β-HCG should still be drawn to rule out pregnancy.
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Questions?