



FACULTY OF MEDICINE

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

Michael Betzner MD, Adrianna Rowe

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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



+

Age 12-50

+

Urine SG \leq 1.010

Exclusion 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

Modified testing performed by Dr. Betzner or Rowe



3 drops



10 drops



20 drops

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

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

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

- 20 drop method
 - Sensitivity = 25%
 - Specificity = 100%

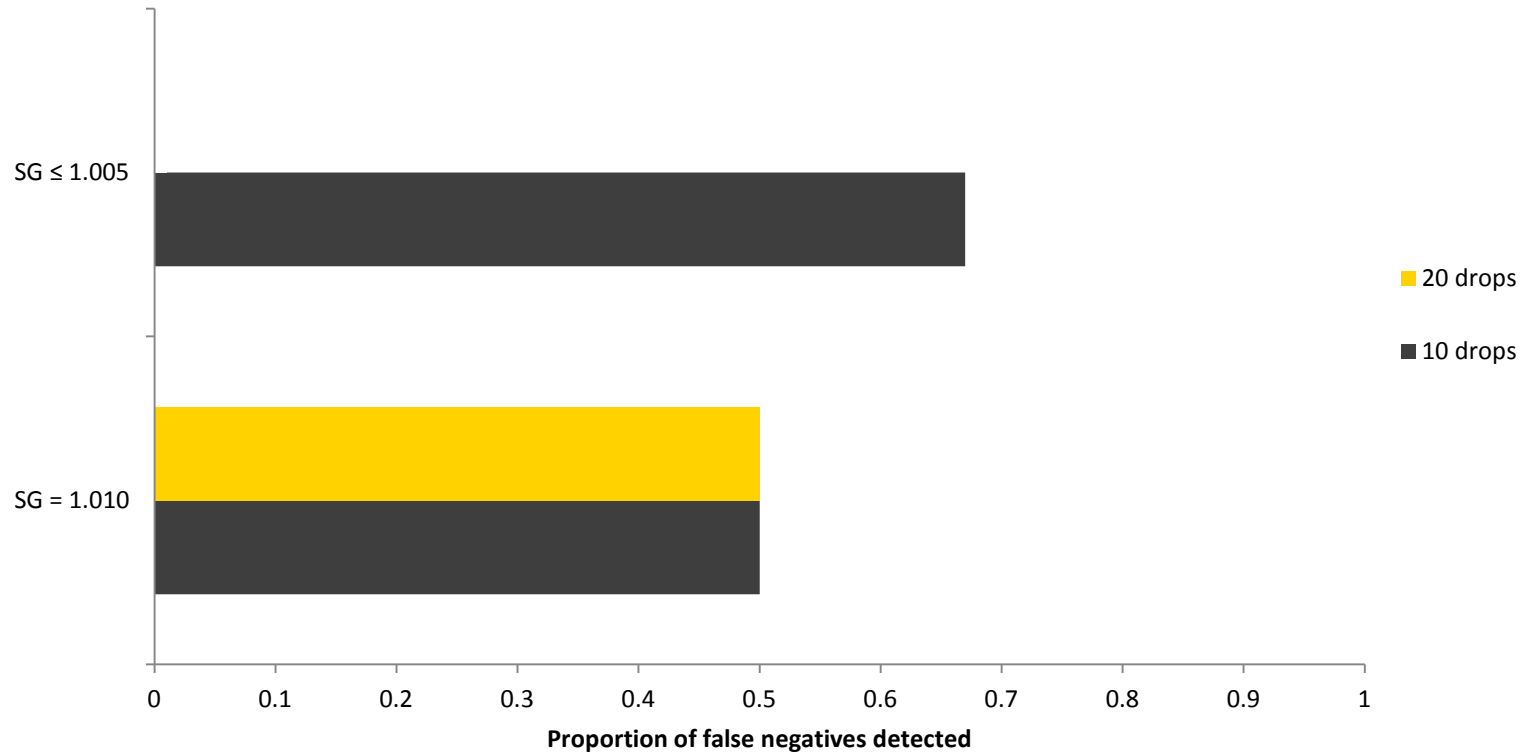


Figure 1. Proportion of false negative test results detected by extended soaking in dilute urine samples

- 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 β -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 β -HCG was 158.
- Regional cut-off should be moved to 1.015 for a sample to be considered to have passed accurate urine β -HCG rule out

When a patient requires pregnancy testing and provides a dilute urine sample, increasing the amount of 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.

- Calgary Emergency Department nursing staff
- Eddy Lang & the Calgary Department of Emergency Medicine

Questions?