

C. Pregnancy

Pregnancy Test

- Alfthan H, Björnses UM, Tiitinen A, Stenman UH. Specificity and detection limit of ten pregnancy tests. *Scandinavian Journal of Clinical Laboratory Investigation* 1993;53(Suppl 216):105-113
- Christensen H, Thyssen HH, Schebye O, Berget A. Three highly sensitive “bedside” serum and urine tests for pregnancy compared. *Clinical Chemistry* 1990;36(9):1686-8
- Neinstein L, Harvey F. Effect of low urine specific gravity on pregnancy testing. *Journal of American College Health* 1998;47(3):138-9
- Olshaker JS. Emergency department pregnancy testing. *Journal of Emergency Medicine* 1996;14(1):59-65

Author: Alfthan H, Björres UM, Tiitinen A, Stenman UH
Title: Specificity and detection limit of ten pregnancy tests
Source: Scandinavian Journal of Clinical Laboratory Investigation 1993;53(Suppl 216):105-113

This study evaluated the specificity and detection limits of ten pregnancy tests using diluted and native pregnancy urine and samples from non-pregnant subjects spiked with purified preparations of hCG, hCG β , and hCB β cf. Ten patients participating in *in vitro* fertilization programs gave serum samples during their first six weeks of pregnancy. 115 serum samples were obtained from patients with proven ectopic pregnancy. Twenty-one paired serum and urine samples were also analyzed. The project studied the following pregnancy tests: hCG-Nostick, Pregnospia Duocon, Neo Panotest Duocon, Pregnosticon 'All-In' 1000M, Tandem Icon II hCG, Clearview hCG, Abbott TestPack hCG-Urine, Abbott TestPack Plus hCG-Combo, Roche hCG Tubetest, and Roche hCG Rapid Test. Hybritech (Tandem Icon) had the lowest detection limit of 12-25 IU/L of hCG with no overlapping in concentration between positive and negative samples. Abbott Plus Combo, Abbott Plus Urine, hCG Nostick, and Clearview all had detection limits in the range 20-50 IU/L. Roche Rapid had a limit of 50-60 IU/L, and the other tests had limits 100-1000 IU/L. The results of this study show that the detection limits of the tests studied are close to those claimed by the manufacturers. An important advantage of tests with low detection limits is their ability to detect ectopic pregnancy, but the drawback is that early subclinical abortions are diagnosed as pregnancies. The detection limit of the methods appears to be safe, but a further reduction in detection limit would be risky.

Author: Christensen H, Thyssen HH, Schebye O, Berget A
Title: Three highly sensitive "bedside" serum and urine tests for pregnancy compared
Source: Clinical Chemistry 1990;36(9):1686-8

This project compared three serum and three urine pregnancy tests for sensitivity, specificity, false positive, false negative, and convenience of use. Using paired urine and serum samples, the examiners compared the diagnostic sensitivity and specificity of the urine tests with the serum tests. The study assessed the following pregnancy tests: Tandem Icon II hCG Urine, Tandem Icon II hCG serum, NovoClone Target hCG Test for urine and serum, and Abbott TestPacks hCG-urine and hCG serum. Twenty-seven women who had legally induced abortions during their first trimester provided 99 serum and 99 urine samples; women gave samples one to three days before the induced abortion and once a week afterwards until all kits gave negative results.

Clinical performance of hCG pregnancy test kits with 99 urine and 99 serum samples

| Test | Sensitivity | Specificity | False + | False - | True + | True - | Accuracy |
|-------------|-------------|-------------|---------|---------|--------|--------|----------|
| Urine tests | | | | | | | |
| Tandem | 90.6 | 100 | 0 | 8 | 77 | 14 | 91.9 |
| NovoClone | 70.6 | 92.9 | 1 | 25 | 60 | 13 | 73.7 |
| Abbott | 84.7 | 100 | 0 | 13 | 72 | 14 | 86.9 |
| Serum tests | | | | | | | |
| Tandem | 89.4 | 85.7 | 2 | 9 | 76 | 12 | 88.9 |
| NovoClone | 67.1 | 100 | 0 | 28 | 57 | 14 | 71.7 |
| Abbott | 94.1 | 78.6 | 3 | 5 | 80 | 11 | 91.9 |

The authors recommend the Tandem Icon II and Abbott TestPack for pregnancy tests with serum and with urine but cannot recommend NovoClone Target hCG Test because of its lower sensitivity and high number of false negative results. The sensitivity and specificity were not significantly higher with serum specimens than with urine samples even though serum tests are more expensive and more difficult to use.

Author: Neinstein L, Harvey F
Title: Effect of low urine specific gravity on pregnancy testing
Source: Journal of American College Health 1998;47(3):138-9

This study sought to determine the effect of low specific gravity on the sensitivity of a urine immunoassay for HCG. The researchers also reviewed the literature for reports documenting this presumed effect of dilute urine on the sensitivity of pregnancy tests. This study evaluated 410 urine specimens and found 106 (25.9%) to have a specific gravity of less than 1.015, considered to be dilute. If urine tested negative in this dilute urine category, the examiners performed a serum confirmatory test. Of the 106 dilute tests, 91 were negative. 80 women with negative urine specimens with a specific gravity below 1.015 agreed to have a serum test and all tested negative; this results in a 0% false negative rate. Some investigators have expressed concern about the effect of dilute urine on urine pregnancy tests, but the findings of this study demonstrate that the immunoassays currently used are sensitive enough even when using dilute urine.

Author: Olshaker JS
Title: Emergency department pregnancy testing
Source: The Journal of Emergency Medicine 1996;14(1):59-65

This article discusses the rapid and accurate diagnosis of pregnancy using inexpensive tests that give very few false positive or false negative results. Pregnancy tests detect hCG, which is produced at the time of implantation, in serum or urine. HCG is first detectable in the serum within 24 hours of fertilization and rises, rapidly doubling every 1.4-2.1 days until it reaches a peak at 50 to 80 days or 8-11 weeks gestational age. Pregnancy tests usually cost between \$15 and \$30 for the consumer, but labs can purchase a package of 30 urine kits for approximately \$85. False positive results occur less than 1% with current tests but may occur more often in post-menopausal women with low circulating levels of hCG. Home pregnancy tests used by women in their homes have a much higher rate of false negatives than when done by skilled lab technicians, but researchers attribute the high number of false negatives to patient misunderstanding of directions and results. Concerning ectopic pregnancy, qualitative hCG tests do not reliably differentiate between ectopic, viable intrauterine, and non-viable intrauterine pregnancies, but quantitative hCG tests can be helpful, because serum B-hCG levels tend to be lower in patients with ectopic pregnancies.