

Most hospital pregnancy tests found to be unreliable after first few weeks of pregnancy

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(Medical Xpress)—Though the 11 most popular hospital urine pregnancy tests perform well in the first month after conception, a new study published in *Clinical Chemistry*, the journal of AACC, reveals the alarming statistic that nine of these tests become significantly more likely to produce false-negative results after the 5th to 7th week of pregnancy.

When a human egg is fertilized, it begins producing the hormone [human chorionic gonadotropin](#) (hCG), which can be detected in either urine or blood. This is what healthcare providers test for to determine if a woman is pregnant. Around the 5th to 7th week of gestation, however, urine concentrations of an hCG variant known as the hCG beta core fragment rise dramatically, interfering with hCG detection and causing false-negative test results. In a hospital setting, this failure to detect pregnancy can lead to major consequences such as administration of medications that cause birth defects, fetal radiation exposure, or failure to diagnose [ectopic pregnancy](#), which is the leading cause of first-trimester pregnancy-related maternal death.

Earlier studies have shown that hCG beta core fragment can interfere with pregnancy test accuracy, but a team of researchers led by Ann M. Gronowski, PhD, of the Washington University School of Medicine, St. Louis, is the first to discover that this problem affects the majority of common hospital urine pregnancy tests. The team determined this after developing a screening method that allowed them to evaluate the ability of these tests to detect hCG when high concentrations of hCG beta core

fragment are also present.

Of the 11 tests the researchers screened, only two—the BC Icon 20 and the Alere—were not significantly affected by hCG beta core fragment. Two other tests, the OSOM and the Cen-Med Elite, were so inhibited by hCG beta core fragment that Gronowski's team concluded that these two tests present an unacceptable risk of false-negative results to patients after 5–7 weeks of pregnancy. The accuracy of the remaining seven tests was moderately affected by hCG beta core fragment.

"There are three important take home messages here," said Gronowski. "One, physicians, nurses, and other healthcare professionals need to be educated that this is a problem. Two, manufacturers need to make the possibility of false negatives clearly visible in their package inserts and work to develop better tests. And three, in centers where quantitative blood hCG testing is available, this should be the preferred [pregnancy test](#). Blood testing is not subject to this effect because hCG beta core fragment is not present in serum."

The screening method Gronowski's team devised is easy and cost-effective, and she believes it will help manufacturers to develop urine pregnancy tests that are not susceptible to interference from hCG beta core fragment. Until the quality of all urine pregnancy tests improves, however, she advises healthcare providers to choose pregnancy tests that perform well during all stages of pregnancy, instead of just in the first few weeks.

More information: Robert D. Nerenz, Haowei Song, and Ann M. Gronowski. "Screening Method to Evaluate Point-of-Care Human Chorionic Gonadotropin (hCG) Devices for Susceptibility to the Hook Effect by hCG β Core Fragment: Evaluation of 11 Devices." *Clinical Chemistry* 2014; v. 60, p.667-674. Published January 24, 2014. [DOI: 10.1373/clinchem.2013.217661](https://doi.org/10.1373/clinchem.2013.217661)

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