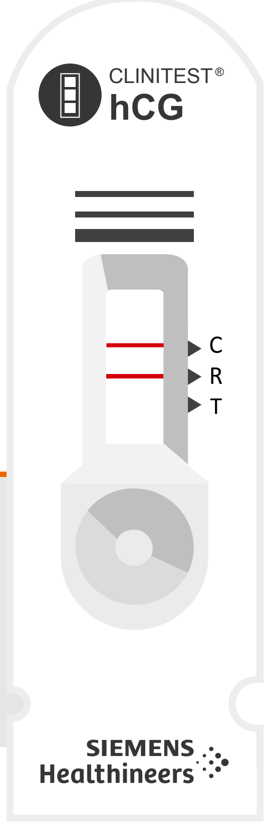
hCG Screening and Pregnancy Testing

CLINITEST® hCG Pregnancy Test: clinical evidence

siemens-healthineers.com/poc-specialty-urine-testing

Assessment of clinical performance and sensitivity



The acceptable clinical performance and sensitivity of the CLINITEST hCG test reaffirm its utility as a ***rapid and reliable method for detection of pregnancy at an early stage.***[1]

- **100%** of tests on all positive-spiked samples reported positive.
- **100%** of tests on all negative samples reported negative.

Concordance with all sensitivity acceptance criteria

The incidence of false-positive results was **3 in 13,500** negative urine samples tested (≤0.04%).

An **acceptably low incidence of false positives** with urine samples negative for hCG

Results from 4725 individual tests showed a rate of agreement for positive results **well above the acceptable criteria of ≥99.1%.**

Excellent rate of agreement of positive results with hCG-positive samples

Potential causes of false-positive results:[1]

- Undetected early spontaneous abortion
- The presence of interfering substances such as endogenous proteins, drugs, microorganisms, and erythrocytes/leukocytes
- The detection of low concentrations of hyperglycosylated hCG and beta core fragments

Greater efficiency. Less error. Improved documentation.

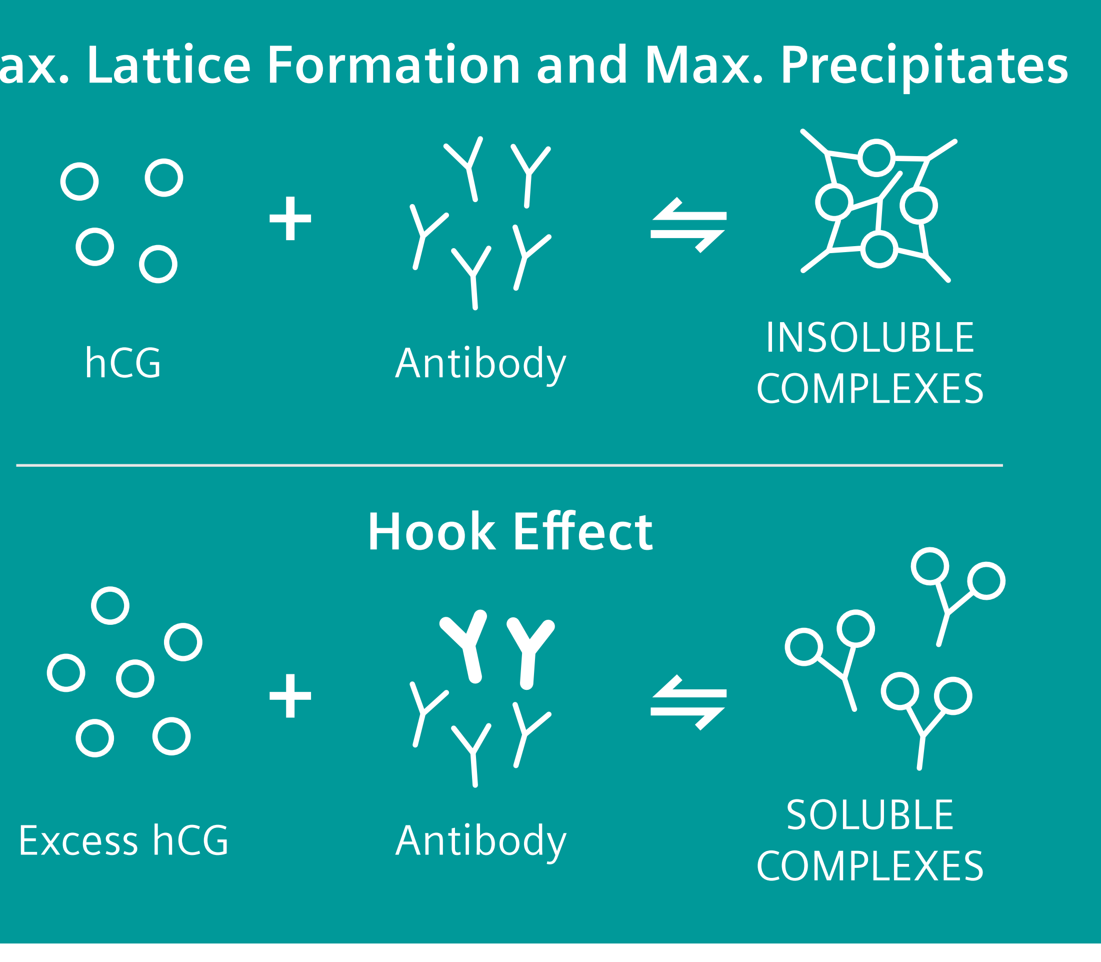
When interfaced with the EMR, the CLINITEK Status® Connect System would eliminate most pre- and post-analytical errors, ***especially transcription errors and delayed/improper/lack of documentation of some test results.***[2]

Test time + total time	Transcription errors	Lack of documentation
Semiautomated testing <manual	0.3–1.7% manual vs. 0% semiautomated	20.5% lower than manual entry

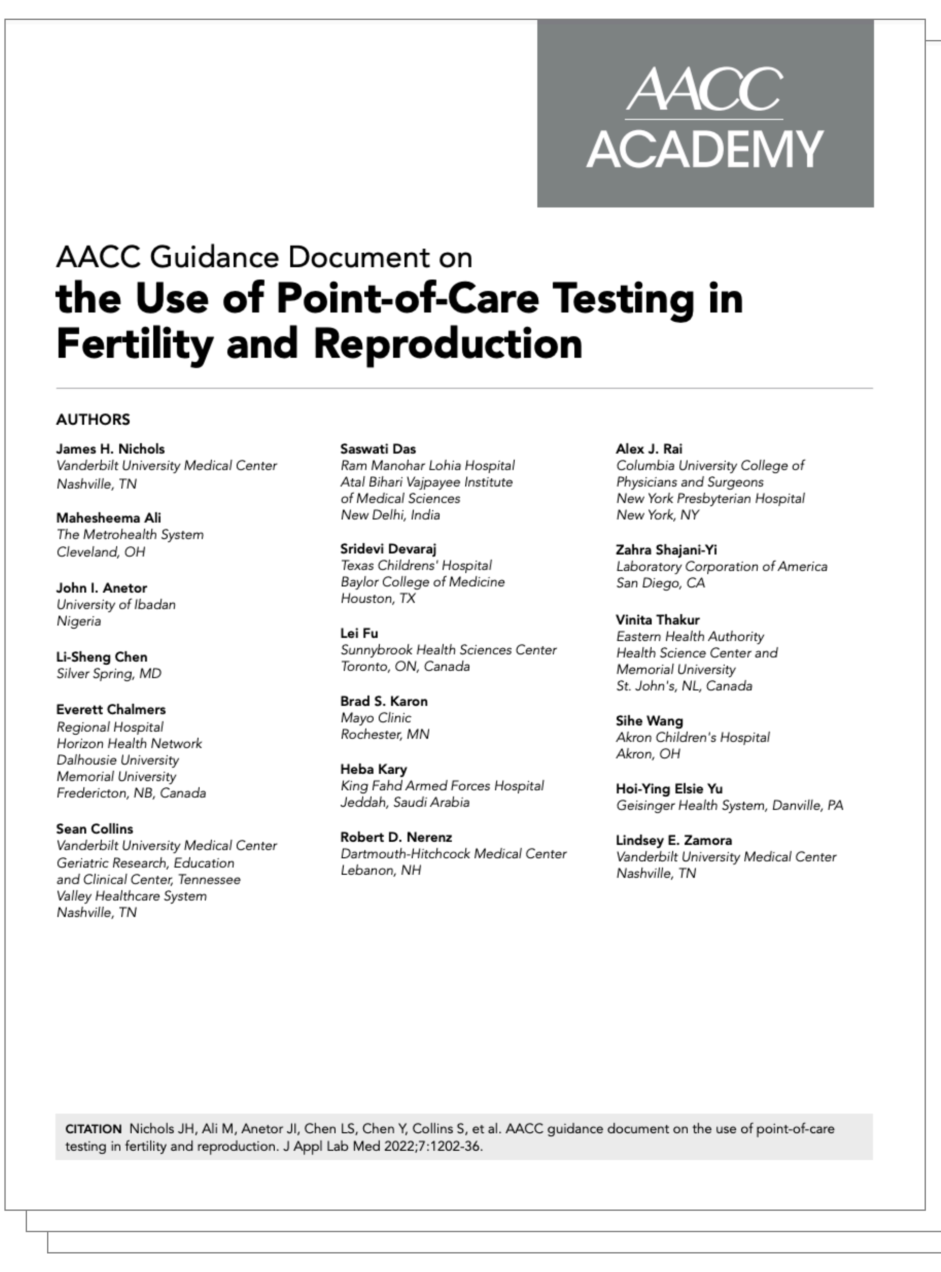
Assessment of false-negative risk due to high-dose hook interference sensitivity

The CLINITEST hCG Test-CLINITEK Status hCG device is ***unlikely to exhibit false-negative urinary hCG results due to high-dose hook interference*** *for women in early healthy pregnancy.*[3]

The **hook effect** occurs when the hCG concentration is so high that it saturates both antibodies and there are so many molecules that the antibodies do not actually form a sandwich, producing a false-negative result



AACC recommendations to reduce the hCG hook effect


AACC ACADEMY

AACC Guidance Document on
the Use of Point-of-Care Testing in Fertility and Reproduction

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CITATION Nichols JH, Ali M, Anetor JI, Chen LS, Chen Y, Collins S, et al. AACC guidance document on the use of point-of-care testing in fertility and reproduction. J Appl Lab Med 2022;7:1202-36.

- When clinically appropriate, **quantitative hCG measurement should be performed** in serum or plasma specimens to avoid hCGβcf interference.
- **If urine testing is required,** a device with minimal susceptibility to hCGβcf variant effect should be used.

If a false-negative result due to the hook effect is suspected:

- **The urine specimen should be diluted** using an hCG-free material and retested.
- **A positive result** upon dilution confirms the hook effect.
- Alternatively, a serum hCG test can be conducted.[4]

References:
1. CLINITEST hCG testing on the CLINITEK Status analyzer achieves clinical performance and sensitivity criteria: an internal validation study. Siemens Healthcare Diagnostics Inc. 2014. Order No. A91DX-POC-131828-GC1-4A00.
2. Young PE, Diaz GJ, Kalariya RN, Mann PA, Benbrook MN, Avandsalehi KR, Petersen JR. Comparison of the time required for manual (visually read) and semiautomated POCT urinalysis and pregnancy testing with associated electronic medical record (EMR) transcription errors. Clin Chim Acta.2020;504:60-3.
3. Milhorn D, Korpi-Steiner N. Using a simulation model to assess risk of false negative point-of-care urinary human chorionic gonadotropin device results due to high-dose hook interference. Clin Biochem. 2015 Feb;48(3):99-104.
4. Nichols JH, Ali M, Anetor JI, Chen LS, Chen Y, Collins S, et al. AACC guidance document on the use of point-of-care testing in fertility and reproduction. J Appl Lab Med. 2022;7:1202-36.

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