

Reliable Results That Take the Guesswork out of Pregnancy Testing

Eliminate subjectivity and improve accuracy with the CLINITEK hCG pregnancy test and CLINITEK Status family of analyzers

siemens-healthineers.com/urinalysis-products



Early professional screening helps avoid pregnancy misdiagnosis



Worldwide (2020 estimated)



Birth rate:
18.1 births per 1000 population¹



U.S. (2021 estimated)



3,664,292 births²

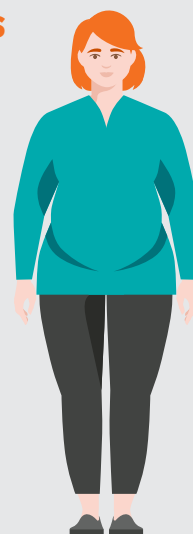


Fertility rate: **56.3 births per 1000 women aged 15–44 years**

6–16% of pregnant women who go to ED for bleeding, pain, or both have ectopic pregnancy.³

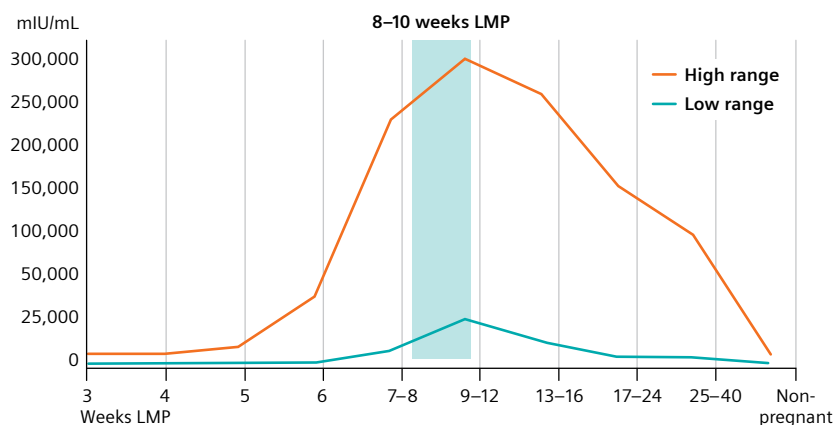
1 in 475 pregnancies is cryptic pregnancy.⁴

Later-state pregnancy occurs **>8–14 weeks** of pregnancy, also as early as **6 weeks** of pregnancy.⁵



Human chorionic gonadotropin (hCG) is a hormone released by the developing placenta during pregnancy⁶

After conception, the placenta begins producing and releasing hCG into blood and urine. The hormone reaches a detectable level in the urine of pregnant women as early as 14 days after conception. This rapid rise in concentration makes hCG a reliable marker for the early diagnosis of pregnancy.



hCG Levels during Pregnancy
(in weeks since last menstrual period)

3 weeks LMP	5–50 mIU/mL
4 weeks LMP	5–426 mIU/mL
5 weeks LMP	18–7340 mIU/mL
6 weeks LMP	1080–56,500 mIU/mL
7–8 weeks LMP	7650–229,000 mIU/mL
9–12 weeks LMP	25,700–288,000 mIU/mL
13–16 weeks LMP	13,300–254,000 mIU/mL
17–24 weeks LMP	4060–165,400 mIU/mL
25–40 weeks LMP	3640–117,000 mIU/mL
Non-pregnant	55–200 ng/mL

Early symptoms⁷



Fatigue



Tender, swollen breasts



Nausea with or without vomiting



Increased urination



Missed period



CLINITEK Status+ Analyzer and Connect System paired with **CLINITEK hCG Pregnancy Test**

Reliable, instrument-read results are available in 2–5 minutes and eliminate the subjectivity associated with visual interpretation. Test results can be printed or transferred to electronic health records, reducing transcription errors and audit exposure.

Paired with a CLINITEK Status® Connect System and POC Informatics Solutions, the CLINITEK® hCG Test provides a widely trusted instrument-read connected solution.



Instrument-read



Qualitative



Urine



Results interpretation

The CLINITEST hCG Test provides results for early stage pregnancies to avoid potentially harmful imaging or pharmaceutical interventions. 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.**⁸



Low incidence of borderlines and false positives

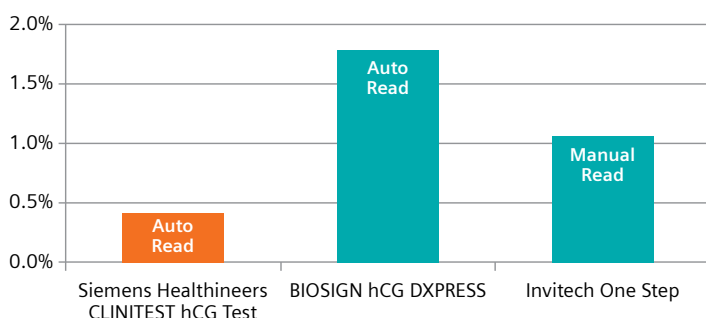


Excellent rate of agreement for positive results



Concordance with all sensitivity acceptance criteria

Error Rate



Results show the instrument-read CLINITEK Status+ urine hCG lowers litigation risk through systematic, documented testing, decreases the likelihood of missed weak-positive results due to poor precision at low concentrations, and reduces the risk of repeat testing and misdiagnosis, e.g., ectopic pregnancy.

Barking, Havering and Redbridge University Hospitals, United Kingdom.

The CLINITEST-CLINITEK Status hCG device is unlikely to exhibit false-negative urinary hCG results due to high-dose hook interference for women in early healthy pregnancy⁶

Clinical Biochemistry. 2015 Feb;48(3).

Risk exposure



Electronic recording and print function reduces transcription errors.



User lockout ensures that only trained operators can use the device, reducing risk.



Reduces reporting errors with a connected solution that documents and transfers test results to LIS/HIS/EMR systems.



Provides automated QC scheduling options to ensure optimum performance and compliance.

As a result of the implementation of the Siemens Healthineers CLINITEK Status Connect Systems and RAPIDComm® System version 5.0 data management solution, Horizon Health Network now meets all accreditation standards, can now track Quality Control (QC) and reagent lot numbers, which is a significant improvement for the point of care testing program, has implemented full traceability with operator and QC lock-out, has established a training program with certification and operator competency review, and achieved regional standardization in its Standard Operating Procedure (SOP).

Horizon Health Network, New Brunswick, Canada

Operator productivity

- Results in 2–5 minutes.
- The CLINITEK Status family of analyzers precisely times the reading of results, reducing hands-on waiting time.
- Frees up time for patient care.
- Eliminates the need for central lab testing, allowing around-the-clock testing with the CLINITEK Status Connect System at the point of care.

Central Lab Testing



Results in 60 minutes or more
+ transportation time



Testing available
8 hours/5 days

Point-of-care Testing



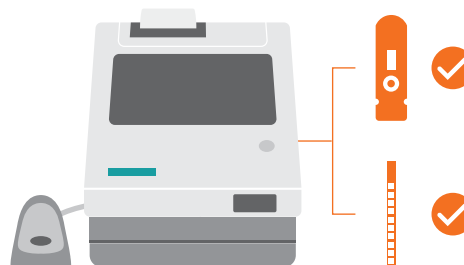
Results in 2–5 minutes



Testing available
24 hours/7 days

Compliance

- CLINITEK Status+/Connect System offers a comprehensive menu for routine urinalysis, specialty tests such as ACR, and hCG.
- Analytical sensitivity is among the top professional POC alternatives.¹⁰



System enables compliance with MHRA/CNST/ISO/CQC/Clinical Pathology Accreditation Standards.

Barking, Havering and Redbridge University Hospitals,
United Kingdom

Both OTC and POC devices are capable of detecting hCG concentrations in early pregnancy urine.

Clin Chim Acta. 2009 Aug;406(1-2):81-5.

Data storage

Results can be printed or transmitted to EMR, LIS/HIS, and data management system.



Result time
Semiautomated
testing < manual



Documentation rate
0.3–1.7% manual vs.
0% semiautomated



Transcription errors
20.5% lower
than manual entry

We conclude that 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.¹¹

Comparison of manual and semi-automated urinalysis and pregnancy testing with associated EMR manual entry errors.
Clin Chim Acta. 2020;504:60–3.

At Siemens Healthineers, we pioneer breakthroughs in healthcare. For everyone. Everywhere. By constantly bringing breakthrough innovations to market, we enable healthcare professionals to deliver high-quality care, leading to the best possible outcome for patients.

Our portfolio, spanning from in-vitro and in-vivo diagnostics to image-guided therapy and innovative cancer care, is crucial for clinical decision-making and treatment pathways. With our strengths in patient twinning, precision therapy, as well as digital, data, and artificial intelligence (AI), we are well positioned to take on the biggest challenges in healthcare. We will continue to build on these strengths to help fight the world's most threatening diseases, improving the quality of outcomes, and enabling access to care.

We are a team of 66,000 highly dedicated employees across more than 70 countries passionately pushing the boundaries of what's possible in healthcare to help improve people's lives around the world.

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