

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

The CLINITEK hCG pregnancy test and CLINITEK Status family of analyzers help you to report results with confidence.

The CLINITEK® hCG pregnancy test from Siemens Healthineers is ideal for busy point-of-care testing sites and emergency rooms, helping clinicians quickly clear women for further procedures. Paired with a CLINITEK Status® Connect System and POC Informatics Solutions, the CLINITEK hCG test provides one of the only instrument-read and truly connected solutions.

Test results take just 2–5 minutes and can be transferred to electronic health records, enabling hospitals to quickly move ahead with imaging diagnostics or other routine procedures.

Optimize workflow so you have more time for patient care

- Provides results for very-early-stage pregnancies to avoid potentially harmful imaging or pharmaceutical interventions.
- Quick, reliable, instrument-read results eliminate the subjectivity associated with visual interpretation.
- The CLINITEK Status family of analyzers precisely times the reading of results, reducing the hands-on waiting time.
- Results can be printed or transmitted to the LIS or data manager.

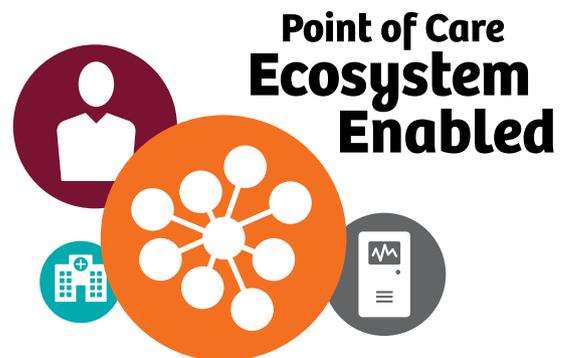
Improve risk management

- Reduces audit exposure with accurate and consistent analyzer-read and -reported results.
- Reduces transcription errors and EMR connectivity.
- Reduces the chance of error and helps to mitigate risk, as no manual documentation or visual interpretation is required.
- Provides automated QC scheduling options to ensure optimum performance and compliance.

Your POC Ecosystem™ Solution

By connecting your CLINITEK Status Connect System to POC Informatics Solutions, you can manage the complete POCT process across the healthcare continuum. We provide integrated, open-access solutions that:

- Reduce costs by consolidating POC data-management systems and IT infrastructure.
- Simplify operations by centralizing management of data, devices, and operators.
- Enable staff competency and compliance by supporting efficient certification and training.



CLINITEK hCG Pregnancy Test Specifications

Quality Control

Two procedural controls

Storage

Room temperature

Sample Size

200 µL of urine for a single test

Time to Result

5 minutes or less to confirm result

Method

Lateral flow, chromatographic result

Clinical Accuracy

>99%

Sensitivity

≥25 mIU/mL

CLINITEK Status+ Urine Chemistry Analyzer Specifications

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| Intended Use The CLINITEK Status®+ analyzer is a point-of-care urinalysis analyzer designed to read only Siemens Healthineers urine test strips and CLINITEST hCG cassettes. | Power Requirements Electrical Rating 100V–240V AC, 50–60 Hz (with in-line lead) Battery Operation 6 AA batteries, nonrechargeable | Compliance CLIA-waived, CE-marked, UL, EMC |
| Semiquantitative Tests Measured Routine urine tests: albumin, bilirubin, creatinine, glucose, ketone, leukocytes, nitrite, pH, protein, specific gravity, and urobilinogen Kidney disease test: albumin-to-creatinine ratio Pregnancy test: human chorionic gonadotropin (hCG) | Dimensions/Weight Depth 10.70 in. (27.2 cm) Width 6.70 in. (17.1 cm) Height 6.20 in. (15.8 cm) Weight 3.65 lb (1.66 kg) | Memory Patient Test Results 700 Operator IDs 700 |
| Computer Interface Unidirectional via serial port (RS232) | Operation Temperature Range 18–30°C (64–86°F) Humidity Range 18–80% relative humidity, noncondensing | Auto-Checks™ technology* Identification of strip type Humidity exposure tested on every strip with leukocyte pad Common sample-interference check available depending upon strip type (not available in the U.S.) |
| Data Entry Onboard touchscreen | Calibration Automatic, self-calibrating | |

CLINITEK Status Connect System Specifications

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| New Features Communication Capabilities Communication protocols: HL7, POCT1-A2 Data transmission options: wireless, Ethernet, or serial connection Interfaces with leading point-of-care data-management solutions:† Siemens Healthineers POC Informatics Solutions, MAS RALS Plus, Telcor QUICK-LINC | Bar-code Symbology Supported Code 93, Code 39 (with and without check digit), Code 128, Coda Bar, Interleaved 2 of 5 (with and without check digit) |
| Quality Control Management Features QC testing and reporting QC reminders or mandatory prompt QC lockout | Memory QC Test Results 200 |
| Bar-code Data Entry Patient ID, operator ID and name, QC control type, and lot number | Operator Security Features Define up to 700 operators Operator lockout to prevent unauthorized use Customize access level for each operator for the following functions: <ul style="list-style-type: none"> • Performing patient tests • Performing QC tests • Recalling results • Modifying system settings |

*Available only when using Siemens Healthineers test strips with IR or color bands.

†Interfaces in development.

Note: Current CLINITEK Status+ analyzers can be upgraded for connectivity and other new features. Ask your sales representative for information on upgrade kits.

At Siemens Healthineers, our purpose is to enable healthcare providers to increase value by empowering them on their journey towards expanding precision medicine, transforming care delivery, and improving patient experience, all enabled by digitalizing healthcare.

An estimated 5 million patients globally everyday benefit from our innovative technologies and services in the areas of diagnostic and therapeutic imaging, laboratory diagnostics and molecular medicine, as well as digital health and enterprise services.

We are a leading medical technology company with over 170 years of experience and 18,000 patents globally. With more than 48,000 dedicated colleagues in 75 countries, we will continue to innovate and shape the future of healthcare.

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Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

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