

Performing a Urinalysis Strip Test and a hCG Cassette Test on the Clinitek Status® Connect System/Clinitek Status®+ Analyzer

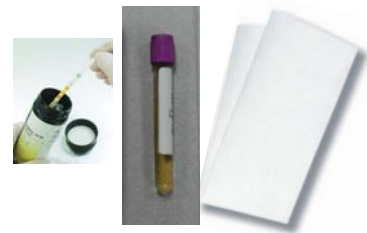
READ THIS GUIDE BEFORE PERFORMING A TEST. FOR DETAILED INFORMATION, REFER TO THE OPERATOR'S GUIDE. Test for Quality Control as directed on page 6. See information about CLIA waiver on page 6.

Urinalysis Strip Testing: Performing a Full Test

Test fresh urine samples within 2 hours of collection. Refrigerated urine samples must be brought to room temperature (20° to 30°C) before testing. Do not test urine that looks bloody or is not a normal color.

Before beginning the strip test, make sure you have the following items:

- Siemens Healthcare Diagnostics reagent test strip
- Urine specimen
- Paper towel to blot strip



STEP 1

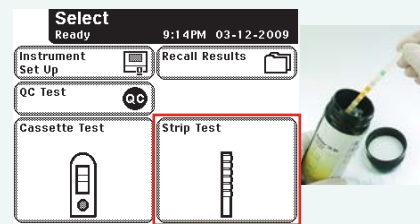
Getting Started

- Turn ON the Clinitek Status®+ analyzer.
- Turn the table insert so reagent strip holder is facing up.
- Be sure the test table, the table insert, and the calibration bar are clean.



STEP 2

- Select Strip Test from Select Ready screen.
- Remove a reagent strip from the bottle and quickly replace the cap.



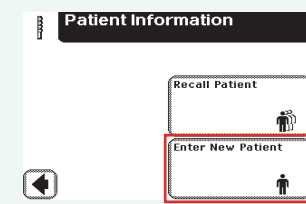
BIOHAZARD
Wear personal protective equipment. Use universal precautions. Refer to your Clinitek Status+ Operator's Manual for recommended precautions when working with biohazardous materials.

Abnormal results marked by “*”. Refer to package insert for product limitations, storage, and expiration date. Do not use reagent strip past the expiration date. If error occurs, follow screen prompts or consult the Clinitek Status+ Operator's Manual. For assistance, or if the system does not work as expected, call 877-229-3711.

Urinalysis Strip Testing: Performing a Full Test

STEP 3

- Select Enter New Patient from Patient Information screen.
- Read Steps 5 and 6 and then proceed with Step 4.



STEP 4

Bar code entry (with Clinitek Status Connect System only)

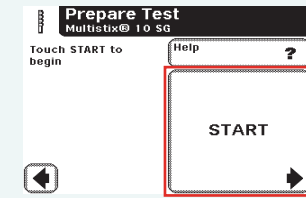
- 1 Enter patient information with bar code scanner. 2 The name automatically appears. 3 Select Enter.



NOTE: You can also enter patient information using the keyboard screen.

STEP 5

- Select Start from Prepare Test screen.
- Complete Step 6 in 8 seconds.



STEP 6

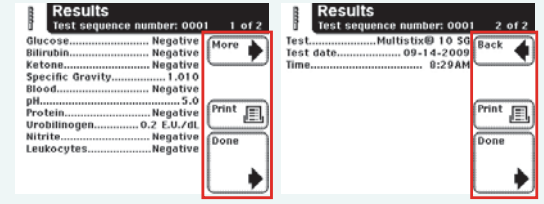
- Dip 1 strip in urine sample. Wet all pads.
- Quickly remove strip from urine.
- Drag 2 the edge of the strip against the side of the sample container as you remove it.
- Blot 3 by touching the edge of the strip to a paper towel to remove excess urine.
- Place 4 strip in channel of table with pads facing up.
- Slide or push strip to end of the channel. Do not touch the pads on the test strip.



Urinalysis Strip Testing: Performing a Full Test

STEP 7

- After 8 seconds, the instrument pulls in the test table.
- When test completes, the Results screen displays.
- Select More to view the second screen of Results.
- Select Print to print the Results.
- Select Done to return to the Select Ready screen.



STEP 8

When Test Is Finished

- Discard the reagent strip.
- Wipe the table insert with damp tissue between tests to remove any urine residue, if needed.
- Record or print result, and report with patient information, as per laboratory practice.

hCG Cassette Testing: Performing a Full Test

Test fresh urine samples within 2 hours of collection. Refrigerated urine samples must be brought to room temperature (20° to 30°C) before testing. Do not test urine that looks bloody or if it is not a normal color.

Before beginning the strip test, make sure you have the following items:

- Clinitest® hCG cassette
- Urine specimen



STEP 1

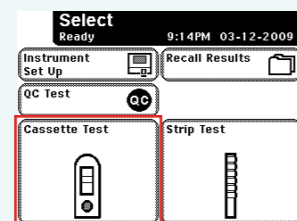
Getting Started

- Turn ON the Clinitek Status®+ analyzer.
- Turn the table insert so the cassette holder is facing up.
- Be sure the test table, the table insert, and the calibration bar are clean.



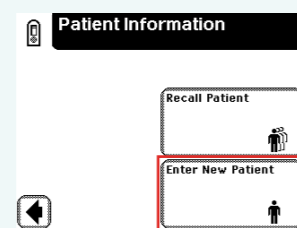
STEP 2

- Select Cassette Test from Select Ready screen.
- Remove a cassette from its package.



STEP 3

- Select Enter New Patient from Patient Information screen.



hCG Cassette Testing: Performing a Full Test

Bar code entry (with Clinitek Status Connect System only)

- 1 Enter patient information with bar code scanner. 2 The name automatically appears. 3 Select Enter.

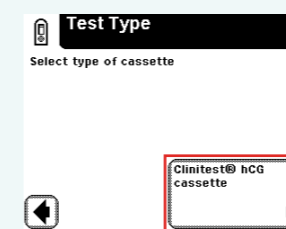


NOTE: You can also enter patient information using the keyboard screen.

STEP 4

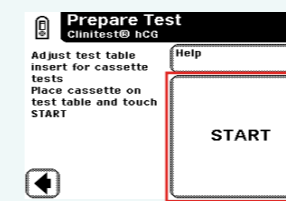
STEP 5

- Select Clinitest hCG cassette.



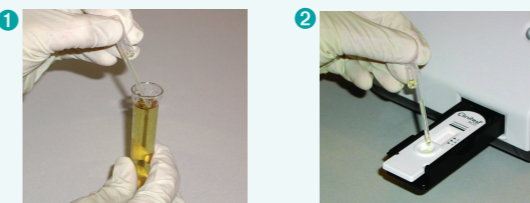
STEP 6

- Select Start. You now have 8 seconds to perform Step 7.



STEP 7

- Draw 1 the urine sample into the pipette to fill the stem completely. Excess urine will go into the lower bulb (reservoir).
- Add 2 entire contents of the pipette stem into the sample well of the test cassette. Excess fluid will remain in the reservoir. Do not push or pull the test table.

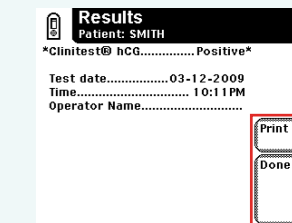


BIOHAZARD
Wear personal protective equipment. Use universal precautions. Refer to your Clinitek Status+ Operator's Manual for recommended precautions when working with biohazardous materials.

hCG Cassette Testing: Performing a Full Test

STEP 8

- After 8 seconds, the instrument pulls in the test table.
- When test completes, the Results screen displays.
- Select Print to print the Results.
- Select Done to return to the Select Ready screen.



STEP 9

When Test Is Finished

- Discard the cassette.
- Record or print result, and report with patient information, as per laboratory practice.

Cleaning: Clean the table weekly or more often if you see dirt buildup.

Refer to the Clinitek Status+ Operator's Manual for complete testing and maintenance information.

Quality Control

Test quality control specimens with each new lot and new shipment of reagents. Test reagents monthly that are stored for more than 30 days.

Run QC tests to ensure reagent storage integrity; train new users; confirm test performance; and when patients' clinical conditions or symptoms do not match. Also, run QC tests per your laboratory procedures. Liquid ready-to-use controls are available. For recommendations, call Technical Support at 877-229-3711.

Compare QC results to the QC manufacturer's acceptable results list. If the QC results are not acceptable, do not test the patient samples until you solve the problem. Repeat QC tests until you have acceptable results.

For Technical Support, call 877-229-3711.

CLIA Waiver Information

The Clinitek Status+ system is CLIA-waived only when used with Siemens brand urinalysis reagent strips and hCG cassette tests.

To run the test in a waived setting, you need a CLIA Certificate of Waiver. Contact your state department of health or visit the CMS Web site for an application, Form CMS-116.

Failure to adhere to intended use instructions and limitations, or perform QC testing, is considered off-label use. Off-label test results are categorized as high complexity and subject to all CLIA regulations.

Origin: UK

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Tarrytown, NY 10591-5097 USA
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Sir William Siemens Sq.
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