



Clinitest hCG

In-Service Training

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hCG Testing

What is hCG?

- Human Chorionic Gonadotropin (hCG) is a hormone released early in pregnancy
- hCG is detected in the urine as early as 14 days after conception
- Rapid and reliable marker for early detection of pregnancy



hCG Levels and Pregnancy

- hCG helps track the early stages of pregnancy
- Initially, the level of hCG rises very rapidly, approximately doubling in quantity every 2 days until a peak is reached between the sixth and eighth week
- Over the next ten or more weeks, the level of hCG decreases
- Detectable levels of hCG may be present a month or two after delivery
- The first catch of urine in the morning will contain the highest level of hCG



hCG Presence Differences – Serum vs. Urine

In normal pregnancy, hCG can be detected in serum as early as seven days following conception

Detected as early as
7 Days
(in serum)

Urine hCG concentrations are approximately one half (or less than one half) of serum concentrations

Urine hCG concentrations
< 1/2
of that in serum

hCG in urine can be detected as early as 14 days from the date of conception

Detected as early as
14 Days
(in urine)

Clinitest hCG Overview



Clinitest® hCG Test Overview

- Qualitative test for early detection of pregnancy
- For use on CLINITEK Status® family of analyzers
- Instrument-read test only, not approved for visual testing
- Uses urine sample only
- Results reported as early as 2 minutes if positive and up to 5 minutes to confirm a negative result
- CLIA-waived when tested on the CLINITEK Status® family of analyzers



Why Clinitest hCG Pregnancy Test?

Eliminates error sources

- Accurately times the test
- Automatically interprets and transmits test results

Improves workflow efficiency

- True walkaway convenience—add sample and the analyzer does the rest
- Results in as little as 2 to 5 minutes
- Bar-code scanning options —saves time, simplifies data entry, and eliminates transcription errors



Provides fail-safe measures

- Unique borderline result—eliminates forced interpretation
- Operator lock out—prevents use by unauthorized users

Improves data capture and traceability

- Connectivity—automatically records and transmits results to EMR or LIS
 - ✓ 100% data capture for billing purposes
- Audit-ready—results linked to patient, operator ID, material lot number and expiration date

Clinitest® hCG Kit Content

- 25 individually, foil-wrapped hCG cassettes
Each foil pack contains:
 - ✓ 1 hCG test cassette
 - ✓ 1 single-use pipette
 - ✓ desiccant to prevent moisture
- Instructions for Use



Test Kit Storage and Stability

- Store test kit at either refrigerated or at room temperature, 2° to 30°C (36° to 86°F) for the duration of the shelf-life
- If refrigerated, bring the wrapped cassettes to room temperature before opening the protective pouch to avoid moisture condensation
- Do not use the test cassettes beyond the expiration date





Getting Ready for Testing

Supplies Needed to Conduct Testing

Analyzer and Tests

(supplied by Siemens or authorized distributor):
CLINITEK Status Family of Analyzers
Clinitest hCG test kit



Recommended Supplies:

(non-Siemens Healthineers items):
Urine specimen collection containers
Quality control materials





Performing Quality Control Testing

Quality Control Testing Modes

CLINITEK Status+ Analyzer (stand-alone):

No QC mode.

Control samples are treated and stored as patient samples. User must enter control name or ID to distinguish results

Control results must be manually compared to the values assigned by the control manufacturer

If the control results are not favorable, do not test patient samples until quality control is passed



CLINITEK Status Connect System (with connector base):

Has a separate QC mode and database for QC results

CLINITEK Status® Connect Systems can be set-up by user to automatically check QC results and initiate a QC lock out when results fail

If the control results are not favorable, do not test patient samples until quality control is passed

Quality Control Testing

Analyzer Checks:

- Analyzer automatically performs the following quality checks with each test for:
 - ✓ sufficient sample
 - ✓ proper sample flow
 - ✓ proper technique
- Analyzer will generate errors when these conditions are detected

QC Testing Tips:

- Use recommended quality control solutions
- Use only the pipette provided with the hCG cassette to ensure only 200 μL of QC material is dispensed
- If using dropper bottles for QC materials, ensure only 200 μL of QC material is added for testing
- Counting the number of drops of QC material may lead to incorrect sample volume and erroneous QC test results
- Using more or less than the required 200 μL may cause an error

Quality Control Testing Recommendations

- For CLIA-waived laboratories, both a negative and positive level should be tested when opening a new lot of reagents, new shipment of reagents, or when reagents stored for more than 30 days.
 - ✓ Note: Water should not be used as a negative control
- For all other laboratories, run QC testing as per the quality control procedure defined by your institution to ensure compliance to local and State regulatory requirements



Quality Control Materials

- Some urinalysis commercial controls tend to be very dark in color because of added analytes
- This dark color has been shown to cause background color on the Clinitest hCG test cassette, and can contribute to E67 and E68 errors
- See below the commercial controls that are compatible with Clinitest hCG tests:
 - ✓ Quantimetrix Dipper Dipstick Control
 - ✓ Quantimetrix Dipper POCT Liquid Urinalysis Control
 - ✓ Quantimetrix Dropper Plus POC Urine Dipstick Control Set
 - ✓ Bio-Rad qUAnitfy Plus Control, Bi-level
 - ✓ Bio-Rad qUAntify Control, Bi-level
 - ✓ MAS Urinlaysis Liquid Assayed Urinalysis Control
 - ✓ Kenlor Liquid Urine Dipstick Control
 - ✓ StanBio hCG Bi-Level Urine Control



Performing Patient Testing

Specimen Collection and Handling

- Collect urine into a clean, dry container
- Specimens collected at any time of day may be used
- Refrigerate specimens at 2° to 8°C (36° to 46°F) for up to 72 hours, if the testing is not performed immediately
- If samples are refrigerated, bring them to room temperature (20°C to 30°C) before testing



Performing a Test

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.



Performing a Test

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 Clinitek hCG cassette.



To Avoid Errors:

Do not add sample to the cassette until prompted by the analyzer.

STEP 6

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



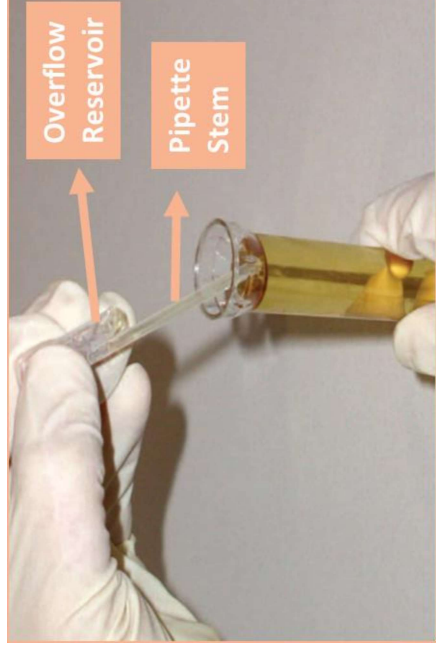
To Avoid Errors:

Do not add sample to sample well until after you press the “START” button.

Performing a Test

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.



To Avoid Errors:

- Only use the pipette provided with each cassette.
- Ensure the pipette stem is completely filled.
- Do not overfill the sample; only one pipette stem is required.
- Ensure the entire pipette stem is dispensed.
- Do not attempt to dispense any sample that is in the overflow chamber.
- If you are using dropper bottles for QC materials, ensure that only 200 μL of control material is added.

Performing a 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.

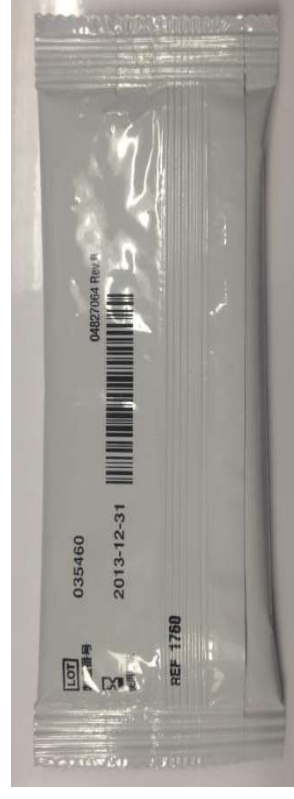


STEP 9

- When Test Is Finished**
- Discard the cassette.
 - Record or print result, and report with patient information, as per laboratory practice.

Performing a Test

- Lot number and expiration dating of the test cassette foil can be entered in one single scan if:
 - ✓ Barcode is connected and enabled
 - ✓ Lot information is enabled in set-up



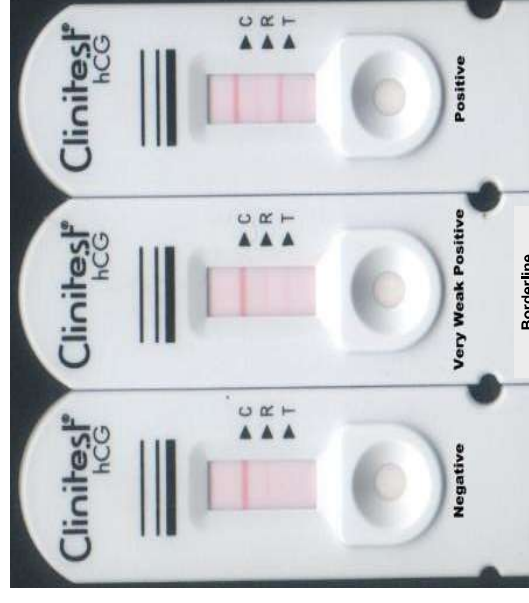


Interpreting Test Results

Result Interpretation Review – for illustration purposes only (This test is **NOT** approved for visual reading)

Each test cassette has 3 important areas that the analyzers uses to perform integrity checks and interpret test results

C	Control Line	Analyzer checks for presence of the control line to confirm cassette integrity.
R	Reference Line	Line intensity is anchored to reflect a level for positive result comparison.
T	Test Line	Development of this line represents the intensity line of a patient sample or control based upon the amount of hCG present in the urine.



Note:

- This test is for instrument interpretation only and is not approved for visual interpretation
- This test is approved for urine only, other sample types cannot be tested

Analyzer Interpretation of Results for Clinitest hCG

Positive:

- If the hCG intensity is more than 25 mIU/mL and both the control and reference regions meet the minimum intensity
- (Note: hCG levels of 100 mIU/mL can be reached on the day of the first missed menstrual period.)

Borderline:

(repeat in 48-72 hours)

- If the hCG intensity is less than 25 mIU/ml, but more than 5 mIU/ml and both the control and reference regions meet the minimum intensity

Negative:

- If the hCG intensity is less than 5 mIU/ml

Invalid:

- The instrument will automatically determine if a procedural error or a test reagent deterioration has occurred
- The user will be advised to repeat the test and contact support if the problem persists

Analyzer Result Interpretation Review

CLINITEK Status® family of analyzers are optically looking for the development of lines to interpret results:

- The analyzer compares the intensity of the Test line to the Reference line to determine if the sample is positive or negative
- If analyzer cannot determine if the intensity of the line is clearly negative or positive, it will report a borderline result





Avoiding Errors

Conditions which may produce borderline hCG result (5-25 mIU/mL)

- Women of childbearing age who have experienced a spontaneous abortion:
 - ✓ 22% of pregnancies abort spontaneously, undetected¹
 - ✓ At the beginning of normal pregnancy, hCG concentrations rise rapidly, and hCG levels slowly return to normal (< 5 mIU/mL) after spontaneous abortion¹
- hCG levels may remain detectable for several weeks following delivery, miscarriage or hCG injections (*in vitro* fertilization treatments)
 - ✓ Low levels of hCG in these urine samples may cause false-positive results for any qualitative hCG pregnancy test
- Passively acquired hCG levels from a blood transfusion
- Trophoblastic diseases, including a variety of cancers
- If a borderline result is obtained repeat test in 48–72 hours

Conditions which may produce borderline hCG result (5-25 mIU/mL)

NCCLS Guidelines for borderline results:

“For general diagnosis of pregnancy, the result can be safely regarded as negative, and the test can be repeated at a later time, if warranted...In cases where pregnancy must be ruled out - for example, before performing an elective test or treatment that is contraindicated in pregnancy - a borderline result can be taken as not ruling out pregnancy.”

1) Chorionadotropin Testing: Nomenclature, Reference Preparations, Assay Performance, and Clinical Application; Approved Guideline /LA 10-A Vol. 16 No. 14 – December 1996

Sample Integrity Issues

Check for the following sample integrity issues prior to using the Clinitest® hCG test:

- ✓ Visibly bloody or severely turbid urine samples could indicate a compromised sample. If a qualitative interpretation is inconsistent with the clinical evidence, results should be confirmed by an alternative hCG detection method.
- ✓ Viscous (mucoïd) samples may interfere with the sample flow.
- ✓ Highly colored samples may interfere with the test.
- If these conditions exist, do not use the test and re-test with a fresh sample, if possible.
- In acute situations, you may opt to have a blood sample drawn from the patient and confirm result by a quantitative lab test

In Summary – To Avoid Common Errors

Improper technique may cause errors. To minimize errors:

- Use only pipette provided with the test kit. It is metered to delivery 200 µL sample
- Do not overfill sample well; only one pipette stem is required. Overfilling leads to erroneous results
- Only empty sample in pipette stem. Do not attempt to empty sample from overflow reservoir
- Add sample to sample well only after pressing the START button
- Use recommended quality control solutions
- Properly store test cassettes
- Use CLINITEK Status® family of analyzers to interpret results – this test is not cleared for visual use

Avoiding Common Error Codes

Common Errors	Potential Causes	Proper operator actions
E67 Errors – Insufficient Sample	Highly colored control materials	Use recommended control solutions.
	Highly colored or extremely bloody patient sample.	Do not test. Collect new sample and run new test.
	Insufficient sample or empty cassette.	Ensure that you are using the pipette provided in the kit to deliver the proper amount. If using external controls, ensure that 200 µL of control material is being added. Again, use the pipette provide in the kit to deliver the proper amount.
	Excess sample, overfilling of sample well with more than one pipette-full.	Ensure that you are using the pipette provided in the kit, which has been designed to deliver 200 µL. Only use one pipette-full.
E68 Errors- Insufficient Sample	Viscous sample.	Collect fresh sample and retest.

What substances may interfere with hCG results?

The following substances may interfere with test results:

- Preservatives
- Micro-organisms
- Erythrocytes and/or leucocytes



Should I use only urine as the sample type?

- Urine is the **ONLY** sample type that has been validated for use with Clinitest® hCG test on the CLINITEK Status family of analyzers
- Other samples (such as whole blood, plasma, water, and non-urine based controls) may give invalid results due to their ionic strength, pH, or matrix components



What are False Positives?

- A false positive is when a positive result is generated from a sample containing <25 mIU/ml hCG.
- All qualitative pregnancy tests will produce a small number of false positive results ($<1\%$).
- Always evaluate not only the diagnostic test result, but also all other clinical signs and symptoms.



What are potential causes of false positive results?

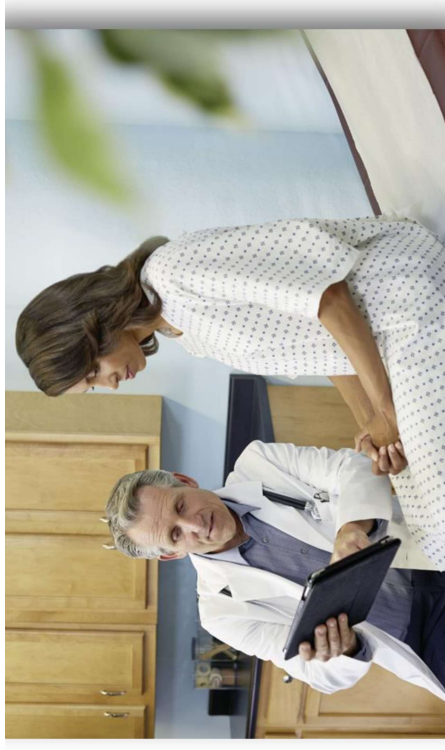
- Borderline results are “indeterminate” and should not be considered as a false positive results
 - Spontaneous abortions may cause false results; hCG may remain in the bladder for hours before being voided
 - Use of contaminated urine collection containers, if contaminated with detergent, for example
 - Improper sample addition: overfilling with more than 200 μ L or under filling with less than 200 μ L of sample
 - Use of a cassette that is too warm or running the test in a warm environment
 - A soiled instrument calibration bar
- The presence of interfering substances:
 - ✓ Endogenous proteins
 - ✓ Drugs
 - ✓ Microorganisms
 - ✓ Erythrocytes and/or Leukocytes

What are potential causes of false negative results?

- Pre-embryo implantation
- Urine samples collected in containers contaminated with, for example, detergent
- Improper sample addition: under filling of the sample well
- Concentrated (high specific gravity) urines containing low levels of hCG (near the sensitivity level)
- Urine contaminated with protease (proteolytic enzymes)
- Using a cassette that is too cold, or running the test in a cold environment
- An instrument calibration bar that is soiled

What if a positive hCG result is not in line with other clinical signs?

- As is true with any diagnostic test, clinical diagnosis should not be based solely on a single test result
- Clinical diagnosis should incorporate all clinical and laboratory data and look at “the bigger picture”
- Ensure the proper sample application steps are being followed and that the recommended controls are being used



What hCG results will we obtain on dark-colored urine (bilirubin or hemolyzed blood)?

- It is unlikely that non-hemolyzed blood cells will give invalid results. However, if these cells accumulate at the edge of the membrane, they may cause reduced flow, which could give invalid results
- It is unlikely that bilirubin will cause a problem as it has limited solubility and is photosensitive – No interference from bilirubin was noted in clinical trials
- It is likely that dark-colored urines would give an error message for high background or improper reference line formation (E67 or E68 error) instead of an incorrect result
- Visibly bloody or severely turbid urine samples could indicate a compromised sample. If a qualitative interpretation is inconsistent with the clinical evidence, results should be confirmed by an alternative hCG detection method

If in doubt...

- If a positive test result is obtained and non-pregnancy is suspected, it is standard laboratory and clinical practice to have the test repeated with another urine sample obtained 48 hours later (bear in mind that hCG levels in pregnant women approximately double every 2 days)
- In acute situations, it is recommended that the result is confirmed with a quantitative laboratory test



Performing Routine Maintenance/ Cleaning



CLINITEK Status® Family - Analyzer Maintenance

- Clean the test table at least once a week to remove any build up. The test table can be soaked in 5% hypochlorite and rinsed thoroughly – do not use solvents.



CLINITEK Status® Family - Maintenance

- Check that the calibration strip on the instrument is clean every day. If not, clean with a cotton swab or soft cloth and water only, ensuring that you do not scratch it.



Replacing the Printer Paper





Ordering Information

Ordering Information



CLINITEK Status® Analyzers and Accessories			
10379675	1780	CLINITEK Status+ Analyzer	– 1
10376323	1790	CLINITEK Status Connector	– 1
10484591	1782	CLINITEK Status Upgrade Kit (includes Status Connector, Bar-code Reader, and most recent software kit)	– 1
10282579	6502880	Bar-code Scanner (CLINITEK Status Connect and DCA Vantage Analyzers)	– 1
10470849	1797	CLINITEK Status Connect System (includes CLINITEK Status+ Analyzer, Status Connector, and Bar-code Reader)	– 1
11046800	N/A	CLINITEK Status+ V2.62/2.4.2.0 SW UPG KIT U.S. USB (for instruments with connector base)	– 1
11046802	N/A	CLINITEK Status+ V2.62/2.4.2.0 SW UPG KIT U.S. MMC (for instruments without connector base)	– 1
10376825	1795	CLINITEK Status Wireless Adapter	– 1
10328736	5773	Thermal Printer Paper (CLINITEK Advantus, CLINITEK Status, and DCA Vantage Analyzers)	– 5/pk
10324219	1759	Label Printer Paper (CLINITEK Status and DCA Vantage Analyzers)	– 5/pk
10310618	1760	CLINITEK® hCG Pregnancy Test (test for qualitative determination of human chorionic gonadotropin (hCG) in urine for use with CLINITEK Status Analyzer)	– 25s = 1 EA



Quiz

Quiz

1. Name two of the essential points to remember when collecting a specimen.
2. At what level does the Clinitest® hCG test report a positive result?
3. Name some scenarios where you may get a positive hCG in a non-pregnant woman.
4. What would you do if you get a borderline test result?
5. Name three proper techniques that minimize errors?
6. What are the recommended cleaning procedures for the CLINITEK Status® analyzer?

Thank you!

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