Regional Medical Center®

Standard Operating Procedure

SUBJECT: Novaplus hCG Rapid Pregnancy Combo Test Device (Urine/Serum)		
ORIGINATION DATE: November 2024	**PREPARED BY:** LAB	**APPROVED BY (If Applicable):**
LAST REVIEWED: NA		

PRINCIPLE:

Human chorionic gonadotropin (hCG), a glycoprotein hormone secreted by viable placental tissue during pregnancy, is excreted. hCG levels rise rapidly, reaching peak levels after 60-80 days. The appearance of hCG in urine after implantation and its rapid rise in concentration makes it an ideal marker for the early detection of pregnancy.
The hCG Pregnancy Combo Test Cassette detects human chorionic gonadotropin through visual interpretation of color development in the internal strip. Anti-hCG antibodies (goat anti HCG polyclonal antibody)are immobilized on the test region of the membrane, and goat anti-mouse IgG antibodies immobilized on the control region. During testing, the specimen reacts with anti-hCG antibodies (mouse anti-hCG monoclonal antibodies) conjugated to colored particles and precoated onto the sample pad of the strip. The mixture then migrates through the membrane by capillary action and interacts with reagents on the membrane. If there is sufficient hCG in the specimen, a colored band will form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS PROVIDED

- Individually packed test devices
- Disposable pipettes
- Package insert
- Located in lower shelf of island

MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection container
- Centrifuge
- Timer
- Quality control materials:BIO-Rad qUAntify Plus Bilevel UA control and Quidel Serum hCG control Set both located in Hematology refrigerator on top right or serum in white freezer after reconstitution.

External control material - Quidel Serum hCG Control Set REF 00281

REAGENT STORAGE

• The kit should be stored at 39-86°F until the expiry date printed on the sealed pouch.
• The test must remain in the sealed pouch until use.
• Do not freeze.
• Care should be taken to protect the components of the kit from contamination. Do not use it if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

PRECAUTIONS:

• For in vitro diagnostic use only.
• Do not use it after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
• This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions.
• Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.

SPECIMEN:

• The hCG Pregnancy Combo Test Cassette is intended for use with human urine or serum specimens only.
. • Although urine specimens from any time of day can be used, first morning urine specimens are preferable as they contain the highest concentration of hCG.
• Only clear specimens are recommended for use with this test. Serum should be separated as soon as possible to avoid hemolysis.
• Turbid specimens should be centrifuged, filtered or allowed to settle and only the clear supernatant should be used for testing.
• Collected urine/serum specimens must be put in clean, dry containers.
• Perform testing after specimen collection. Do not leave specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 48 hours. For long term storage, specimens should be kept below-20°C.
• Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
. • Icteric, lipemic, hemolyzed, heat treated and contaminated sera may cause erroneous results.If hemolysis or lipemia interfere with the viewing of the control line on the test cartridge a new specimen must be obtained.

QUALITY CONTROL:

Quality control testing should be performed with each new lot and/or each new shipment upon the arrival of the kits. Both urine and serum QC materials are used
BIO-Rad qUAntify Plus Bilevel UA control
Quidel Serum hCG Control Set REF 00281.

- Dilute with 5 mL dih20. Let sit for 30 minutes at room temperature.
- Aliquot into 200 uL, label and store frozen.
- Good until expiration date on bottle or 60 days frozen.

Record the QC results in Green QC log by the Bactec.
The internal procedural control line must also be in the test device of the control region to be valid.
Please contact our Technical Support at 1-800-328-4215 (9-5 CST M-F) if controls are not acceptable.

PROCEDURE:

Bring tests, specimens, and/or controls to room temperature before use.
1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. For best results the assay should be performed within one hour.
2. Add 3 drops of specimen (approximately 120 µL) directly into the specimen well (S) and start the timer. Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result area. As the test begins to work, color will migrate across the result area in the center of the device.
3. Wait for the colored band(s) to appear. Read the result at 3 minutes when testing a urine specimen, or at 5 minutes when testing a serum specimen. Do not interpret the result after 10 minutes. NOTE: Low hCG concentrations may produce very weak T lines after a prolonged period of time. Therefore, do not interpret the result after 10 minutes.

INTERPRETATION OF RESULTS

POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).
NEGATIVE: Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T).
INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded.
Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

3. Negative results are expected in healthy non-pregnant women. The amount of hCG in a sample can vary greatly with gestational age and between individuals.

LIMITATIONS OF THE TEST;

1. Very dilute urine specimens, exhibiting low specific gravity, may not contain representative levels of hCG. If pregnancy is suspected after a negative result, a first morning urine sample should be obtained 48-72 hours later and tested.
2. Very low levels of hCG are present in urine or serum shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons, a test result that is weakly positive should be interpreted in conjunction with other clinical and laboratory data.
3. When hCG levels are below the minimum detection level of the test, a false negative result may be obtained. If pregnancy is suspected after a negative result, a first morning urine specimen should be collected 48-72 hours later and tested.
4. A positive result may be obtained with β-core fragment hCG at concentrations over 200 pmol/L. A negative result may be obtained with β-core fragment hCG at concentrations below 200 pmol/L. A false negative result may be obtained with β-core fragment hCG at concentrations above 2 x 10^6 pmol/L.
5. As with any assay employing mouse antibodies, the possibility exists for interference by human anti-mouse antibodies (HAMA) in the specimen. Specimens from patients who have received preparations of monoclonal antibodies for diagnosis or therapy may contain HAMA. Such specimens may cause false positive or false negative results.
6. A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
7. Refer to the Instructions for Use included in the box for a list of interfering substances.

REFERENCES:

NOVAPLUS® hCG Pregnancy Serum/Urine Combo Test Cassette CLIA Waived - Urine CLIA Moderate - Serum. Revision: hCG S10 09031 REV1.1/Package Insert.
ELKA hCG Serum Quality Control Test Package Insert.