SAMPLE PROCEDURE

This “Sample Procedure” is not intended as a substitute for your facility’s Procedure Manual or reagent labeling, but rather as a model for your use in customizing for your laboratory’s needs.

Space has been provided within the document to allow you to update this template with information specific to your facility. It is suggested that a current version of the manufacturer’s directional insert be maintained as a supplement.

PROCEDURE

Title: EKLA CORPORATION NOVAPLUS® hCG Pregnancy Serum/Urine Combo Test

Procedure #:

Institution: _____

Prepared by: _____ Date: _____

Title: _____

Accepted by: _____ Date adopted: _____

Title: _____

Reviewed by: _____ Date: _____

_____ _____

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_____ _____

Discontinued by: _____ Date: _____

I. TEST NAME

NOVAPLUS ® hCG Pregnancy Serum/Urine Combo Test
CLIA Complexity: Waived for urine, Non-waived for serum

II. INTENDED USE

The NOVAPLUS® hCG Combo Test is a rapid visual immunoassay for the qualitative, presumptive detection of human chorionic gonadotropin in human urine or serum specimens. This kit is intended for use as an aid in early detection of pregnancy.
This product is intended for prescription use in clinical laboratories and point-of-care use settings.

III. SUMMARY AND EXPLANATION OF TEST

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.

IV. PRINCIPLE OF THE TEST

The NOVAPLUS® hCG Pregnancy Combo Test 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.

V. KIT CONTENTS AND STORAGE

40 Test Devices individually pouched, each containing a disposable pipette
1 Package insert

STORAGE CONDITIONS
Store NOVAPLUS hCG Combo Tests at room temperature, 4° to 30° C (39° to 86° F), out of direct sunlight. Test Devices are stable until the expiration date printed on the kit or foil pouch. **DO NOT FREEZE**.
If the control band does not appear when running the test, the Test Cassette or kit may have been stored or handled improperly or the foil pouch may not have been intact.
At this facility, kits are stored:_____

VI. MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection container
- Timer
- Centrifuge
- External control materials

VII. PRECAUTIONS

· Do not use 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.

· Read the entire procedure carefully prior to testing.

· Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.

· Humidity and temperature can adversely affect results.

· Used testing materials should be discarded according to local regulations.

VIII. SPECIMEN COLLECTION & STORAGE

· The NOVAPLUS hCG Pregnancy Combo Test 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° to 8° C (36-46°F) for up to 48 hours. For long term storage, specimens should be kept below -20° C (-4°F).

· 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.

· If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

· Icteric, lipemic, hemolysed, heat treated and contaminated sera may cause erroneous results.Specimen Collection and Handling

This facility's procedure for patient preparation is:_____

_____

This facility's procedure for sample labeling is:_____

_____

This facility's procedure for transporting specimens is:_____

_____

This facility's procedure for rejected specimens is:_____

_____

IX. QUALITY CONTROL

· Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.

· External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

QC Testing Frequency and Documentation

For this facility, External QC is run:_____

Results of External QC and action(s) taken when control results are unacceptable are documented:

_____

X. TEST PROCEDURE

Bring tests, specimens, and/or controls to room temperature 15 to 30°C (59-86°F) before use.

For Cassette Format --

• 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.

• 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.

For Strip Format –

• Hold the strip by the end, where the product name is printed. To avoid contamination, do not touch the strip membrane. Vertically dip the test strip in the sample for at least 10 seconds. Do not immerse past the maximum line (MAX) on the test strip.
• Remove the strip from the sample and place it on a non-absorbent flat surface.

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.

XI. 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:
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.
Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.
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.

In the event this test becomes inoperable, this facility's course of action for patient samples is: ____
_____
_____

XII. RESULT REPORTING

This facility's procedure for patient result reporting is: _____
_____
_____

XIII. LIMITATIONS

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. 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.
5. A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

XIV. EXPECTED VALUE

hCG concentration in pregnant women rises very rapidly after implantation, reaching a peak concentration in excess of 200IU/mL about 2-3 months after the last menstrual period. The hCG Rapid Test Device (Urine/Serum) has a sensitivity of 10mIU/ml in serum and 20mIU/ml in urine.
Reportedly, a level of 10-25 mIU/mL or more, is present 7-10 days after conception. Patients suspected to be pregnant but showing negative test results should be re-tested with first morning specimens obtained 48-72 hours later.

XV. CROSS REACTIVITY

The addition of luteinizing hormone (300 mIU/mL of LH), follicle stimulating hormone (1000 mIU/mL of FSH), or thyroid stimulating hormone (1000 IU/mL of TSH) to negative urine and serum specimens gives negative results in the NOVAPLUS hCG Combo Test.

XVI. INTERFERING SUBSTANCES

Tests were performed for samples with 0 and 20 mIU/mL hCG in urine, and 0 and 10 mIU/mL hCG in serum. No interference was found for the following substances at the giving concentrations.

Acetaminophen (20mg/dL)	Codeine (6ug/dL)
Acetoacetic Acid (2000mg/dL)	Ethanol (1.0%)
Asorbic Acid (20mg/dL)	Methanol (10%)
B-hydroxybutyrate (2000mg/dL)	Albumin (2000mg/dL)
Caffeine (20mg/dL)	Glucose (2000mg/dL)
Ephedrine (20mg/dL)	Bilirubin (2mg/dL)

Gentisic Acid (20mg/dL)	Atropine (20mg/dL)
Phenylpropanolamine(20mg/dL)	Estriol-17-beta (1400ug/dL)
Salicylic Acid (20mg/dL)	Hemoglobin (500mg/dL)
Phenothiazine (20mg/dL)	Pregnanediol (1500ug/dL)
EDTA (80mg/dL)	Thiophene (20mg/dl)
Acetylsalicylic Acid (20mg/dL)	Ampicillin (20mg/dl)
Benzoylecgonine (10mg/dL)	Tetracycline(20mg/dl)
Cannabinol (10mg/dL)	Ketone(20mg/dl)

XVII. PERFORMANCE CHARACTERSITICS

Refer to Package insert – NOVAPLUS® hCG Pregnancy Serum/Urine Combo Test

XVIII. REFERENCES

Refer to Package insert – NOVAPLUS® hCG Pregnancy Serum/Urine Combo Test

XIX. ASSISTANCE

For technical assistance contact EKLA CORPORATION Technical Service at (800) 328-4215.