ProADVANTAGE by NDC

Package Insert

English

Urine/Serum Pregnancy Cassette Device

A rapid, one step test for the qualitative detection of human chorionic gonadotropin (hCG) in urine or serum.
For professional in vitro diagnostic use only.

CLIA Category

Serum	Moderately Complex
Urine	Waived

INTENDED USE

The Urine/Serum Pregnancy Cassette Device is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine or serum to aid in the early detection of pregnancy.

SUMMARY

Human chorionic gonadotropin (hCG) is a glycoprotein hormone produced by the developing placenta shortly after fertilization. In normal pregnancy, hCG can be detected in both urine and serum as early as 7 to 10 days after conception.[1-4] hCG levels continue to rise very rapidly, frequently exceeding 100 mIU/mL by the first missed menstrual period,[2-4] and peaking in the 100,000-200,000 mIU/mL range about 10-12 weeks into pregnancy. The appearance of hCG in both urine and serum soon after conception, and its subsequent rapid rise in concentration during early gestational growth, make it an excellent marker for the early detection of pregnancy.

The Urine/Serum Pregnancy Cassette Device is a rapid test that qualitatively detects the presence of hCG in urine or serum specimen at the sensitivity of 25 mIU/mL. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of hCG in urine or serum. At the level of claimed sensitivity, the Urine/Serum Pregnancy Cassette Device shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at high physiological levels.

PRINCIPLE

The Urine/Serum Pregnancy Cassette Device is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine or serum to aid in the early detection of pregnancy. The test utilizes a combination of antibodies including mouse monoclonal anti-hCG antibodies and goat polyclonal anti-hCG antibodies to selectively detect elevated levels of hCG. The assay is conducted by adding urine or serum specimen to the specimen well of the test device and observing the formation of colored lines. The specimen migrates via capillary action along the membrane to react with the colored conjugate.

Positive specimens react with the specific colored antibody conjugates and form a colored line at the test line region of the membrane. Absence of this colored line suggests a negative result. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

REAGENTS

The test device/cassette contains mouse anti-beta hCG antibody conjugated to colloidal gold and goat anti-alpha hCG antibody coated on the membrane.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test device should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test device should be discarded in a proper biohazard container after testing.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C. The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

A urine specimen must be collected in a clean and dry container. A first morning urine specimen is preferred since it generally contains the highest concentration of hCG; however, urine specimens collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

Serum Assay

Blood should be collected aseptically into a clean tube without anticoagulants. Separate the serum from blood as soon as possible to avoid hemolysis. Use clear non-hemolyzed specimens when possible.

Specimen Storage

Urine or serum specimen may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

MATERIALS

Materials Provided

- Test devices
- Disposable specimen droppers
- Package insert

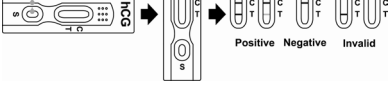
Materials Required But Not Provided

- Specimen collection container
- Timer

DIRECTIONS FOR USE

Allow the test device, urine or serum specimen and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine or serum (approx. 100 µL) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
3. Wait for the red line(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 results after the appropriate read time.** It is important that the background is clear before the result is read.



INTERPRETATION OF RESULT

(Please refer to the illustration.)

POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).

NEGATIVE: One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

NOTE: The intensity of the red color in the test line region (T) will vary depending on the concentration of hCG present in the specimen. However, neither the quantitative value nor the rate of increase in hCG can be determined by this qualitative test.

QUALITY CONTROL

Internal procedural controls are included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.

It is recommended that a positive hCG control (containing ≥ 25 mIU/mL hCG in urine or ≥ 25 mIU/mL hCG in serum) and a negative hCG control (containing "0" mIU/mL hCG) be evaluated to verify proper test performance. For urine testing, controls should be tested with each new lot or shipment of product, with each new operator, monthly as a check on continued storage conditions, or as otherwise required by your laboratory's internal quality system procedures. For serum testing, federal, state, and local guidelines should be followed.

LIMITATIONS

1. Very dilute urine specimens, as indicated by a low specific gravity, may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.
2. False negative results may occur when the levels of hCG are below the sensitivity level of the test. When pregnancy is still suspected, a first morning urine or serum specimen should be collected 48 hours later and tested.
3. Very low levels of hCG (less than 50 mIU/mL) are present in urine and serum specimen shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons,[5] a test result that is weakly positive should be confirmed by retesting with a first morning urine or serum specimen collected 48 hours later.
4. This test reliably detects intact hCG up to 500,000 mIU/mL. It does not reliably detect hCG degradation products, including free-beta hCG and beta core fragments. Quantitative assays used to detect hCG may detect hCG degradation products and therefore may disagree with the results of this rapid test.
5. A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms including testicular tumors, prostate cancer, breast cancer, and lung cancer, cause elevated levels of hCG.[6-7] Therefore, the presence of hCG in urine or serum specimen should not be used to diagnose pregnancy unless these conditions have been ruled out.
6. 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.
7. This test provides a presumptive diagnosis for pregnancy. A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

EXPECTED VALUES

Negative results are expected in healthy non-pregnant women and healthy men. Healthy pregnant women have hCG present in their urine and serum specimens. The amount of hCG will vary greatly with gestational age and between individuals.

The Urine/Serum Pregnancy Cassette Device has a sensitivity of 25 mIU/mL, and is capable of detecting pregnancy as early as 1 day after the first missed menses.

PERFORMANCE CHARACTERISTICS

Accuracy

A multi-center clinical evaluation was conducted comparing the results obtained using the Urine/Serum Pregnancy Cassette Device and another commercially available serum/urine

membrane hCG test. The urine study included 159 specimens and both assays identified 88 negative and 71 positive results. The serum study included 73 specimens and both assays identified 51 negative and 21 positive and 1 inconclusive results. The results demonstrated a 100% overall agreement (for an accuracy of >99%) of the Urine/Serum Pregnancy Cassette Device when compared to the other urine/serum membrane hCG test.

Sensitivity and Specificity

The Urine/Serum Pregnancy Cassette Device detects hCG at concentrations of 25 mIU/mL or greater. The test has been standardized to the W.H.O. Third International Standard. The addition of LH (300 mIU/mL), FSH (1,000 mIU/mL), and TSH (1,000 µIU/mL) to negative (0 mIU/mL hCG) and positive (25 mIU/mL hCG) specimens showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to hCG negative and positive specimens.

All substances listed in mg/dL unless otherwise noted.

Acetaminophen	20	Ethanol	1%
Acetone	1,000	Estriol	2
Acetylsalicylic Acid	20	Estrone 3-Sulfate	10
Acetoacetic Acid	2,000	Gentisic Acid	20
Ampicillin	20	Glucose	2,000
Ascorbic Acid	20	Hemoglobin	1,000
Atropine	20	Heroin	1
Albumin	2,000	Ibuprofen	20
β-Hydroxybutyrate salt	2,000	Methadone	10
Benzoylecgonine	10	Methamphetamine	10
Bilirubin	20	Methanol	10%
Brompheniramine	20	Morphine	0.6
Caffeine	20	Oxalic Acid	40
Cannabinol	10	Phenothiazine	20
Clomiphene	100	Phenylpropanolamine	20
Cocaine	10	Pregnanediol	2
Codeine	10	Salicylic Acid	20
Cholesterol	500	Tetracycline	20
Creatine	20	Triglycerides	1,200
Dextromethorphan	20	Theophylline	20
DMSO	5%	Urea	2,000
EDTA	80	Uric Acid	20
Ephedrine	20		

None of the substances at the concentration tested interfered in the assay.

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Pro Advantage by NDC,
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DN: 1155962904

Printed in China

Revise Date: 2009-12-11

ProADVANTAGE® by NDC

Prospecto del envase

Español

Tarjeta de prueba de embarazo en suero u orina

Una prueba rápida en un solo paso para la detección cualitativa de gonadotropina coriónica humana (hCG) en orina o suero.
Para uso profesional exclusivo para diagnóstico in vitro.

Categoría de CLIA

Suero	Moderadamente complejo
Orina	Exenta

USO PREVISTO

La tarjeta de prueba de embarazo en suero u orina es un inmunoanálisis cromatográfico rápido para la detección cualitativa de gonadotropina coriónica humana (hCG) en la orina o el suero para contribuir a la detección precoz del embarazo.

RESUMEN

La gonadotropina coriónica humana (hCG) es una hormona glucoproteica producida por la placenta en desarrollo al poco tiempo de la fecundación. En el embarazo normal, la hCG puede detectarse tanto en la orina como en el suero ya a los 7 a 10 días de la concepción.[1-4] La concentración de hCG continúa aumentando muy rápidamente y con frecuencia excede los 100 mUI/mL a la fecha de la primera menstruación faltante,[2-4] y alcanza su valor máximo de 100,000 a 200,000 mUI/mL aproximadamente entre las semanas 10 y 12 de embarazo. La aparición de hCG tanto en la orina como en el suero al poco tiempo de la concepción, y su posterior aumento rápido durante las primeras etapas del crecimiento gestacional, hacen que sea un excelente marcador para la detección precoz del embarazo. La tarjeta de prueba de embarazo en suero u orina es una prueba rápida que detecta cualitativamente la presencia de hCG en la muestra de orina o suero con un sensibilidad de 25 mUI/mL. En la prueba se utiliza una combinación de anticuerpos monoclonales y policlonales para detectar selectivamente concentraciones elevadas de hCG en orina o suero. Al grado de sensibilidad declarado, la tarjeta de prueba de embarazo en suero u orina no muestra interferencia por reactividad cruzada de las hormonas glucoproteicas relacionadas estructuralmente hFSH, hLH y hTSH a concentraciones fisiológicas elevadas.

PRINCIPIO

La tarjeta de prueba de embarazo en suero u orina es un inmunoanálisis cromatográfico rápido para la detección cualitativa de gonadotropina coriónica humana (hCG) en la orina o el suero para contribuir a la detección precoz del embarazo. En esta prueba se utiliza una combinación de anticuerpos que incluyen anticuerpos monoclonales anti-hCG murinos y anticuerpos policlonales anti-hCG caprinos para detectar selectivamente concentraciones elevadas de hCG. El análisis se realiza agregando una muestra de orina o suero en el pocillo para la muestra de la tarjeta de prueba y observando la formación de líneas de color. La muestra migra por capilaridad por la membrana para reaccionar con el conjugado coloreado.
Las muestras positivas reaccionan con los conjugados de anticuerpos coloreados específicos y forman una línea de color en la región de la línea de prueba de la membrana. La ausencia de esta línea de color sugiere un resultado negativo. Como control del procedimiento, siempre aparecerá una línea de color en la región de la línea de control si la prueba se ha realizado correctamente.

REACTIVOS

El dispositivo para la prueba cuenta con una membrana recubierta con anticuerpos de cabra contra la subunidad alfa de la hCG y anticuerpos de ratón contra la subunidad beta de la hCG conjugados con oro coloidal.

PRECAUCIONES

- Para uso profesional exclusivo para diagnóstico *in vitro*. No use el producto pasada la fecha de vencimiento.
- La tarjeta de prueba debe permanecer en la bolsa sellada hasta que se use.
- Todas las muestras deben considerarse potencialmente peligrosas y manipularse de la misma manera que un microorganismo infeccioso.
- La tarjeta de prueba debe desecharse en un recipiente apropiado para peligros biológicos una vez realizada la prueba.

CONSERVACIÓN Y ESTABILIDAD

Conserve tal como viene envasado en la bolsa sellada a una temperatura de 2 a 30 °C. La tarjeta de prueba es estable hasta la fecha de vencimiento impresa en la bolsa sellada. La tarjeta de prueba debe permanecer en la bolsa sellada hasta su uso. **NO CONGELE EL PRODUCTO.** No use el producto pasada la fecha de vencimiento.

OBTENCIÓN Y PREPARACIÓN DE LA MUESTRA

Análisis de orina

Debe obtenerse una muestra de orina en un recipiente limpio y seco. Es preferible utilizar la primera orina de la mañana ya que generalmente contiene la mayor concentración de hCG; no obstante, se pueden usar muestras de orina obtenidas a cualquier hora del día. Las muestras de orina en que se observen precipitados visibles deben centrifugarse y filtrarse, o bien dejar que estos se decanten para obtener una muestra transparente para la prueba.

Análisis sérico

La sangre debe extraerse mediante técnica aséptica en un tubo limpio sin anticoagulantes. Separe el suero de la sangre lo antes posible para evitar la hemólisis. Utilice muestras no hemolizadas transparentes siempre que sea posible.

Conservación de la muestra

Las muestras de orina o suero se pueden conservar a una temperatura de 2 a 8 °C durante un máximo de 48 horas antes de realizar la prueba. Para conservarlas por períodos prolongados, las muestras pueden congelarse y guardarse a menos de -20 °C. Las muestras congeladas deben descongelarse y mezclarse antes de realizar la prueba.

MATERIALES

Materiales provistos

- Tarjetas de prueba
- Goteros desechables para obtener la muestra
- Prospecto del envase

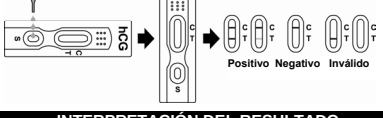
Materiales necesarios pero no provistos

- Recipiente para obtener la muestra
- Cronómetro

INSTRUCCIONES DE USO

Permita que la tarjeta de prueba, la muestra de orina o suero y los controles alcancen la temperatura ambiente (entre 15 y 30 °C) antes de realizar la prueba.

1. Retire la tarjeta de prueba de la bolsa sellada y úsela lo antes posible.
2. Coloque la tarjeta de prueba sobre una superficie limpia y nivelada. Sostenga el gotero en posición vertical y transfiera 3 gotas completas de orina o suero (aproximadamente 100 µL) al pocillo para la muestra (S) de la tarjeta de prueba, y luego ponga en marcha el cronómetro. Evite que queden burbujas atrapadas en el pocillo para la muestra (S). Consulte la ilustración de abajo.
3. Espere a que aparezca(n) la(s) línea(s) roja(s). **Lea el resultado al cabo de 3 minutos en el caso de una muestra de orina, y de 5 minutos en el caso de una muestra de suero. Los resultados deben interpretarse en el momento adecuado.** Es importante que el fondo esté limpio antes de leer el resultado.



INTERPRETACIÓN DEL RESULTADO

(Consulte la ilustración.)

POSITIVO: Se observan dos líneas rojas definidas. Una línea debe estar en la zona de control (C) y la otra, en la zona de prueba (T).

NEGATIVO: Se observa una línea roja en la zona de control (C). No se advierte ninguna línea roja o rosa en la zona de prueba (T).

INVÁLIDO: No aparece la línea de control. Las razonas más probables de que no aparezca la línea de control son un volumen insuficiente de muestra o el empleo de técnicas incorrectas en el procedimiento. Repase el procedimiento y repita la prueba con una nueva tarjeta. Si el problema persiste, deje de usar el kit de prueba de inmediato y comuníquese con el distribuidor local.

NOTA: La intensidad del color rojo en la región de la línea de prueba (T) variará según la concentración de hCG presente en la muestra. Sin embargo, esta prueba cualitativa no puede determinar ni el valor cuantitativo ni la velocidad del aumento de hCG.

CONTROL DE CALIDAD

La prueba incluye controles internos del procedimiento. La línea roja que aparece en la región de control (C) es el control interno del procedimiento. Confirma que el volumen de muestra es suficiente y que se ha empleado la técnica correcta para el procedimiento. El fondo transparente es un control interno negativo. Si la prueba está funcionando correctamente, el fondo de la zona de resultado debe ser de un color entre blanquecino y rosa pálido y no debe impedir leer el resultado de la prueba.

Se recomienda evaluar un control hCG positivo (con ≥ 25 mUI/ml de hCG en orina o ≥ 25 mUI/ml de hCG en suero) y un control de hCG negativo (con "0" mUI/ml de hCG) a fin de comprobar que la prueba funcione correctamente. Para las pruebas con orina, los controles se deben evaluar cada vez que se utiliza un nuevo lote o remesa de productos; cada vez que cambia el operador; cada mes, para controlar que las condiciones de almacenamiento sean constantes; y toda vez que sea necesario conforme a los procedimientos del sistema de calidad interno de su laboratorio. En el caso de las pruebas con suero, se deben seguir las pautas federales, estatales y locales.

LIMITACIONES

1. Una muestra de orina muy diluida, es decir, de muy baja densidad específica, puede no contener concentraciones de hCG representativas. Si igualmente se sospecha de embarazo, se debe obtener una muestra de la primera orina de la mañana 48 horas después y repetirse la prueba.
2. Pueden producirse resultados negativos falsos cuando las concentraciones de hCG se encuentran por debajo del grado de sensibilidad de la prueba. Cuando igualmente se sospeche de embarazo, se debe obtener una muestra de la primera orina de la mañana o de suero 48 horas después y repetirse la prueba.
3. Al poco tiempo de la implantación, las concentraciones de hCG en las muestras de orina y suero son muy bajas (menos de 50 mUI/mL). Sin embargo, debido a que una cantidad significativa de embarazos termina en abortos espontáneos durante el primer trimestre,[5] toda prueba que sea débilmente positiva debe confirmarse con una segunda prueba de una muestra de la primera orina de la mañana obtenida 48 horas después.
4. Esta prueba detecta en forma precisa concentraciones de hasta 500,000 mUI/ml de hCG intacta. Sin embargo, no detecta en forma precisa productos de la degradación de la hCG, entre los que se incluyen la subunidad beta libre de la hCG y los fragmentos núcleo beta. Los análisis cuantitativos utilizados para señalar la presencia de hCG pueden llegar a detectar productos de la degradación de la hCG, por lo que es posible que sus resultados difieran de los de esta prueba rápida.
5. Además del embarazo hay varias afecciones, entre ellas las enfermedades trofoblásticas y ciertos neoplasmas no trofoblásticos, como tumores testiculares, cáncer de próstata, cáncer de mama y cáncer de pulmón, que causan concentraciones elevadas de hCG.[6-7] Por lo tanto, la presencia de hCG en una muestra de orina o de suero no debe usarse para diagnosticar un embarazo a menos que se hayan descartado estas afecciones.
6. Como en cualquier análisis en el que se empleen anticuerpos murinos, existe la posibilidad de interferencia de los anticuerpos antimurinos humanos (HAMA) en la muestra. Las muestras de pacientes que han recibido preparados con anticuerpos monoclonales con fines diagnósticos o terapéuticos pueden contener HAMA. Dichas muestras pueden causar resultados positivos falsos o negativos falsos.
7. Esta prueba proporciona un diagnóstico provisional de embarazo. Sólo un médico puede confirmar un diagnóstico de embarazo después de haber evaluado todos los hallazgos clínicos y de laboratorio.

VALORES ESPERADOS

Es de esperarse un resultado negativo en mujeres sanas que no están embarazadas y en hombres sanos. La hCG debe estar presente en las muestras de orina y suero de todas las mujeres embarazadas sanas. La cantidad de hCG varía ampliamente con la edad gestacional y entre una mujer y otra.

La tarjeta de prueba de embarazo en suero u orina posee una sensibilidad de 25 mUI/mL y es capaz de detectar el embarazo tan solo 1 día después de la primera falta de menstruación.

CARACTERÍSTICAS DE RENDIMIENTO

Exactitud

Se llevó a cabo una evaluación clínica multicéntrica para comparar los resultados obtenidos con la tarjeta de prueba de embarazo en suero u orina con otra prueba con membrana de detección de la hCG en orina/suero disponible en el mercado. El estudio con orina incluyó 159 muestras y ambos análisis identificaron 88 resultados negativos y 71 resultados positivos. El estudio con suero incluyó 73 muestras y ambos análisis identificaron 51 resultados negativos, 21 resultados positivos y un resultado inconcluso. Los resultados demostraron una coincidencia global de un 100% (exactitud >99%) de la tarjeta de prueba de embarazo en suero u orina cuando se la comparó con la otra prueba con membrana de detección de la hCG en orina/suero.

Sensibilidad y especificidad

La tarjeta de prueba de embarazo en suero u orina detecta la hCG a concentraciones de 25 mUI/mL o más. La prueba ha sido estandarizada en conformidad con el Tercer Estándar Internacional de la W.H.O. El agregado de LH (300 mUI/mL), FSH (1,000 mUI/mL) y TSH (1,000 µUI/mL) a muestras negativas (0 mUI/mL hCG) y positivas (25 mUI/mL hCG) no demostró reactividad cruzada alguna.

Sustancias que interfieren en la prueba

Se agregaron las siguientes sustancias que pueden interferir en la prueba a las muestras hCG negativas y positivas.

Todas las sustancias se indican en mg/dL a menos que se señale lo contrario.

Acetona	1,000	Dimetil sulfóxido (DMSO)	5%
Ácido acetilsalicílico	20	Efedrina	20
Ácido acetoacético	2,000	Estriol	2
Ácido ascórbico	20	Estrona 3-sulfato	10
Ácido edético (EDTA)	80	Etanol	1%
Ácido gentísico	20	Fenilpropanolamina	20
Ácido oxálico	40	Fenotiacina	20
Ácido salicílico	20	Glucosa	2,000
Ácido úrico	20	Hemoglobina	1,000
Albúmina	2,000	Heroína	1
Ampicilina	20	Ibuprofeno	20
Atropina	20	Metadona	10
Benzoilecgonina	10	Metanfetamina	10
Bilirrubina	20	Metanol	10%
Bromfeniramina	20	Morfina	0.6
Cafeína	20	Paracetamol(acetaminofeno)	20
Canabinol	10	Pregnanediol	2
Clomifeno	100	Sal de β-hidroxibutirato	2,000
Cocaína	10	Teofilina	20
Codeína	10	Tetraciclina	20
Colesterol	500	Triglicéridos	1,200
Creatina	20	Urea	2,000
Dextrometorfano	20		

Ninguna de las sustancias interfirió en el análisis a la concentración probaba.

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2. Catt KJ, ML Dufau, JL Vaitukaitis "Appearance of hCG in pregnancy plasma following the initiation of implantation of the blastocyte", *J. Clin. Endocrinol. Metab.* 1975; 40(3): 537-540
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5. Steier JA, P Bergsjo, OL Myking "Human chorionic gonadotropin in maternal plasma after induced abortion, spontaneous abortion and removed ectopic pregnancy", *Obstet. Gynecol.* 1984; 64(3): 391-394
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Pro Advantage by NDC,
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Impreso en China

Fecha de vigencia: 2009-xx-xx

Laboratory: _____ Date Implemented_____

Address: _____

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ProAdvantage® by NDC Urine/Serum Pregnancy Cassette Device

I. Test Principle

The Urine/Serum Pregnancy Cassette Device is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine or serum to aid in the early detection of pregnancy. The test utilizes a combination of antibodies including mouse monoclonal anti-hCG antibodies and goat polyclonal anti-hCG antibodies to selectively detect elevated levels of hCG. The assay is conducted by adding urine or serum specimen to the specimen well of the test device and observing the formation of colored lines. The specimen migrates via capillary action along the membrane to react with the colored conjugate.

Positive specimens react with the specific colored antibody conjugates and form a colored line at the test line region of the membrane. Absence of this colored line suggests a negative result. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

II. Specimen Collection/Treatment

A. Specimen:	Acceptable: Urine and serum specimens Unacceptable: Specimens from other sources
B. Specimen Collection:	**Urine:** Clean, dry collection container. A first morning specimen is preferred; however urines collected any time of day may be used. **Serum:** Collect aseptically into a clean tube without anticoagulants.
C. Specimen Storage:	Urine and serum samples may be stored 2-8°C up to 48 hours. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing. **Urine:** Specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing. **Serum:** Separate the serum from blood as soon as possible to avoid hemolysis. Use clear non-hemolyzed specimens when possible.
D. Handling Precautions:	All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent. The test cassette should be discarded in a proper biohazard container after testing. If samples are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

III. Reagents and Equipment

A. Reagents and Materials Provided

Component	Content	Quantity
Test Devices	The test device contains anti-hCG particles and anti-hCG coated on the membrane	40
Disposable specimen dropper		40
Package insert		1

B. Materials not Provided

- Specimen collection container
- Timer

C. Storage and Stability

Store as packaged at 2-30°C. The test device is stable through the expiration date printed on the sealed pouch or canister label. The test device must remain in the sealed pouch or closed canister until use. **DO NOT FREEZE.** Do not use beyond the expiration date. Note: Once canister has been opened, the remaining test devices are stable for 12 months.

D. Quality Control

Internal procedural controls are included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test.

It is recommended that a positive hCG control (containing ≥25 mIU/mL hCG) and a negative hCG control (containing "0" mIU/mL hCG) be evaluated to verify proper test performance with each new lot, each new shipment, monthly as a check on storage, each new untrained operator and as otherwise required by your lab's internal quality system procedures.

E. Precautions

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test device should remain in the sealed pouch or closed canister after use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test device should be discarded in a proper biohazard container after testing.

IV. Test Procedure

Allow the test device, urine or serum specimen and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine or serum (approx. 100 µL) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
3. Wait for the red line(s) to appear**. Read the result at 3 minutes when testing a urine specimen**, **or at 5 minutes when testing a serum specimen**. It is important that the background is clear before the result is read.

V. Interpretation of Test Results

POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).

NEGATIVE: One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

NOTE: The intensity of the red color in the test line region (T) will vary depending on the concentration of hCG present in the specimen. However, neither the quantitative value nor the rate of increase in hCG can be determined by this qualitative test.

VI. Limitations

1. Very dilute urine specimens, as indicated by a low specific gravity, may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.
2. False negative results may occur when the levels of hCG are below the sensitivity level of the test. When pregnancy is still suspected, a first morning urine or serum specimen should be collected 48 hours later and tested.
3. Very low levels of hCG (less than 50 mIU/mL) are present in urine and serum specimen shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons,[5] a test result that is weakly positive should be confirmed by retesting with a first morning urine or serum specimen collected 48 hours later.
4. A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms including testicular tumors, prostate cancer, breast cancer, and lung cancer, cause elevated levels of hCG.[6-7] Therefore, the presence of hCG in urine or serum specimen should not be used to diagnose pregnancy unless these conditions have been ruled out.
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. This test provides a presumptive diagnosis for pregnancy. A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

VII. Expected Values

Negative results are expected in healthy non-pregnant women and healthy men. Healthy pregnant women have hCG present in their urine and serum specimens. The amount of hCG will vary greatly with gestational age and between individuals.

The Urine/Serum Pregnancy Cassette Device has a sensitivity of 25 mIU/mL, and is capable of detecting pregnancy as early as 1 day after the first missed menses.

VIII. Performance Characteristics

A. Accuracy

A multi-center clinical evaluation was conducted comparing the results obtained using the Urine/ Serum Pregnancy Cassette Device and another commercially available serum/urine membrane hCG test. The urine study included 159 specimens and both assays identified 88 negative and 71 positive results. The serum study included 73 specimens and both assays identified 51 negative and 21 positive and 1 inconclusive results. The results demonstrated a 100% overall agreement (for an accuracy of >99%) of the Urine/ Serum Pregnancy Cassette Device when compared to the other urine/ serum membrane hCG test.

B. Sensitivity and Specificity

The Urine/Serum Pregnancy Cassette Device detects hCG at a concentration of 25 mIU/mL or greater. The test has been standardized to the W.H.O. Third International Standard. The addition of LH (300 mIU/mL), FSH (1,000 mIU/mL), and TSH (1,000 mIU/mL) and positive (25 mIU/mL hCG) specimens showed no cross-reactivity.

C. Interfering Substances

The following potentially interfering substances were added to the hCG negative and positive specimens. All substances listed in mg/dL unless otherwise noted.

Acetaminophen	20	Ethanol	1%
Acetone	1,000	Estriol	2
Acetylsalicylic Acid	20	Estrone 3-Sulfate	10
Acetoacetic Acid	2,000	Gentisic Acid	20
Ampicillin	20	Glucose	2,000
Ascorbic Acid	20	Hemoglobin	1,000
Atropine	20	Heroin	1
Albumin	2,000	Ibuprofen	20
β-Hydroxybutyrate salt	2,000	Methadone	10
Benzoylecgonine	10	Methamphetamine	10
Bilirubin	20	Methanol	10%
Brompheniramine	20	Morphine	0.6
Caffeine	20	Oxalic Acid	40
Cannabinol	10	Phenothiazine	20
Chlomiphene	100	Phenylpropanolamine	20
Cocaine	10	Pregnanediol	2
Codeine	10	Salicylic Acid	20
Cholesterol	500	Tetracycline	20
Creatine	20	Triglycerides	1,200
Dextromethorphan	20	Theophylline	20
DMSO	5%	Urea	2,000
EDTA	80	Uric Acid	20
Ephedrine	20		

None of the substances at the concentration tested interfered in the assay.

IX. References

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8. ProAdvantage® by NDC Urine/Serum Pregnancy Cassette Device Package Insert

Test Procedure Review

Supervisor	Date Reviewed	Supervisor	Date Reviewed