Pro ADVANTAGE by NDC

Package Insert

English

Urine Pregnancy Test Strip

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

CLIA Category

Urine — Waived

INTENDED USE

The Urine Pregnancy Test Strip is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine 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 Pregnancy Test Strip is a rapid test that qualitatively detects the presence of hCG in urine 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. At the level of claimed sensitivity, the Urine Pregnancy Test Strip shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at high physiological levels.

PRINCIPLE

The Urine Pregnancy Test Strip is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. The test utilizes a combination of antibodies including a monoclonal hCG antibody to selectively detect elevated levels of hCG. The assay is conducted by immersing the test strip in a urine specimen 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 antibody-hCG-colored conjugate to 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 strip contains anti-hCG particles and anti-hCG coated on the membrane.

PRECAUTIONS

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

STORAGE AND STABILITY

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

SPECIMEN COLLECTION & PREPARATION

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.

Specimen Storage

Urine specimens 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 strips
- Package insert

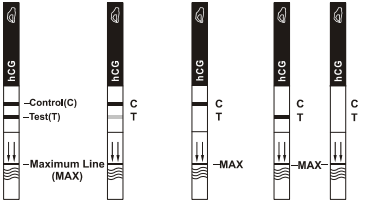
Materials Required But Not Provided

- Specimen collection container
- Timer

DIRECTIONS FOR USE

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

1. Remove the test strip from the sealed pouch or closed canister and use it as soon as possible. Note: for canister packaging, immediately close the canister tightly after removing the required number of test strips. Record the initial opening date on the canister. Once opened, the remaining test strips are stable for 12 months.
2. With arrows pointing toward the urine specimen, immerse the test strip vertically in the urine specimen for at least 5 seconds. Do not pass the maximum line (MAX) on the test strip when immersing the strip. See the illustration below.
3. Place the test strip on a non-absorbent flat surface, start the timer and wait for the red line(s) to appear. The result should be read at 3 minutes. It is important that the background is clear before the result is read.



Note: A low hCG concentration might result in a weak line appearing in the test region (T) after an extended period of time; therefore, do not interpret the result after 10 minutes.

INTERPRETATION OF RESULTS

(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 strip. 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) 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 internal quality system procedures.

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 specimen should be collected 48 hours later and tested.
3. Very low levels of hCG (less than 50 mIU/mL) are present in urine 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 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 should not be used to diagnose pregnancy unless these conditions have been ruled out.
5. 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 Pregnancy Test Strip 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 Pregnancy Test Strip to another commercially available urine membrane hCG test. The study included 150 urine specimens: both assays identified 72 negative and 78 positive results. The results demonstrated 100% overall agreement (for an accuracy of >99%) of the Urine Pregnancy Test Strip when compared to the other urine membrane hCG test.

		Reference hCG Method	
		Positive	Negative
Urine Pregnancy Test Strip	Positive	78	0
	Negative	0	72

Sensitivity and Specificity

The Urine Pregnancy Test Strip 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 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
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.

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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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Prospecto del envase

Español

Tiras de prueba de embarazo en orina

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

Categoría de CLIA
Orina — Exenta

USO PREVISTO

La tiras de prueba de embarazo en orina es un inmunoanálisis cromatográfico rápido para la detección cualitativa de gonadotropina coriónica humana (hCG) en la orina 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 tiras de prueba de embarazo en orina es una prueba rápida que detecta cualitativamente la presencia de hCG en muestras de orina con una sensibilidad de 25 mUI/mL. En la prueba se utiliza una combinación de anticuerpos monoclonales y policlonales para detectar selectivamente las concentraciones elevadas de hCG en la orina. Al grado de sensibilidad declarado, la tiras de prueba de embarazo en orina no muestra interferencia por reactividad cruzada de las hormonas glucoproteicas relacionadas estructuralmente hFSH, hLH y hTSH a concentraciones fisiológicas elevadas.

PRINCIPIO

La tiras de prueba de embarazo en orina es un inmunoanálisis cromatográfico rápido para la detección cualitativa de gonadotropina coriónica humana (hCG) en la orina para contribuir a la detección precoz del embarazo. En la prueba se utiliza una combinación de anticuerpos que incluye un anticuerpo monoclonal anti-hCG para detectar selectivamente concentraciones elevadas de hCG. Este análisis se realiza sumergiendo la tira reactiva en una muestra de orina 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 el conjugado del anticuerpo específico para hCG coloreado y se forma 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

La tira reactiva contiene partículas anti-hCG y la membrana está recubierta con anti-hCG.

PRECAUCIONES

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

CONSERVACIÓN Y ESTABILIDAD

Conservar tal como viene envasada en la bolsa sellada a una temperatura de 2 a 30 °C. La tira reactiva es estable hasta la fecha de vencimiento impresa en la bolsa sellada o la etiqueta del envase. La tira reactiva debe conservarse en la bolsa sellada o en el envase cerrado hasta que se use. **NO CONGELE EL PRODUCTO.** No use el producto pasada la fecha de vencimiento. Nota: una vez abierto el envase, las tiras restantes permanecen estables durante 12 meses.

OBTENCIÓN Y PREPARACIÓN DE LA MUESTRA

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.

Conservación de la muestra

Las muestras de orina pueden conservarse 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

- Tiras reactivas
- Prospecto del envase

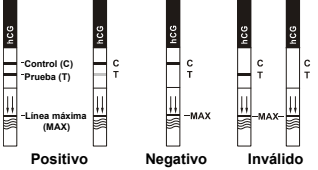
Materiales necesarios pero no provistos

- Recipiente para obtener la muestra
- Cronómetro

INSTRUCCIONES DE USO

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

1. Retire la tira reactiva de la bolsa sellada o del recipiente cerrado y úsela lo antes posible. Nota: en el caso del envase del recipiente, ciérrelo herméticamente de inmediato después de haber extraído la cantidad de tiras necesaria. Anote la fecha en que se abrió el envase por primera vez. Una vez abierto el envase, las tiras restantes permanecen estables durante 12 meses.
2. Con las flechas apuntando hacia la muestra de orina, sumerja la tira reactiva en sentido vertical en la muestra de orina durante un mínimo de 5 segundos. No sobrepase la línea de máximo (MAX) en la tira al sumergirla. Consulte la ilustración de abajo.
3. Coloque la tira reactiva sobre una superficie plana absorbente, ponga en marcha el cronómetro y espere a que aparezca(n) la(s) línea(s) roja(s). El resultado debe leerse al cabo de 3 minutos. Es importante que el fondo esté limpio antes de leer el resultado.



Nota: Una concentración baja de hCG puede hacer que aparezca una línea débil en la región de prueba (T) después de un período prolongado, por lo tanto no interprete el resultado después de 10 minutos.

INTERPRETACIÓN DE LOS RESULTADOS

(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 tira reactiva. 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.

A fin de comprobar que la prueba funcione correctamente, se recomienda evaluar un control hCG positivo (con ≥ 25 mUI/ml de hCG) y un control de hCG negativo (con “0” mUI/ml de hCG) cada vez que se utiliza un nuevo lote o una nueva remesa; cada mes, para controlar las condiciones de almacenamiento; con cada operador nuevo sin capacitación; y toda vez que sea necesario conforme a los procedimientos del sistema de calidad interno de su laboratorio.

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 48 horas después y repetirse la prueba.
3. Al poco tiempo de la implantación, las concentraciones de hCG en las muestras de orina 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. 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 no debe usarse para diagnosticar un embarazo a menos que se hayan descartado estas afecciones.
5. 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 tiras de prueba de embarazo en 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 tiras de prueba de embarazo en orina con otra prueba con membrana de detección de la hCG en orina disponible en el mercado. El estudio incluyó 150 muestras de orina: ambos análisis identificaron 72 resultados negativos y 78 resultados positivos. Los resultados demostraron una

coincidencia global de un 100% (exactitud >99%) para la tiras de prueba de embarazo en orina cuando se la comparó con la otra prueba con membrana de detección de la hCG en la orina.

		Método por hCG de referencia	
		Positivo	Negativo
Tiras de prueba de embarazo en orina	Positivo	78	0
	Negativo	0	72

Sensibilidad y especificidad

La tiras de prueba de embarazo en orina detecta la hCG a una concentración 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 las muestras negativas (0 mUI/mL hCG) y positivas (25 mUI/mL hCG) no demostraron reactividad cruzada.

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	Paracetamo (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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Laboratory: _____ Date Implemented_____

Address: _____

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ProAdvantage® by NDC Urine Pregnancy Test Strip

I. Test Principle

The Urine Pregnancy Test Strip is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. The test utilizes a combination of antibodies including a monoclonal hCG antibody to selectively detect elevated levels of hCG. The assay is conducted by immersing the test strip in a urine specimen 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 antibody-hCG-colored conjugate to 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 specimen Unacceptable: Specimens from other sources
B. Collection Container:	Clean, dry collection container. A first morning specimen is preferred since it generally contains the highest concentration of hCG; however urines collected any time of day may be used.
C. Specimen Storage:	Urine 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. Specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.
D. Handling Precautions:	All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent. The test strip should be discarded in a proper biohazard container after testing.

III. Reagents and Equipment

A. Reagents and Materials Provided

Component	Content	Quantity
Test Strip	The test strip contains anti-hCG particles and anti-hCG coated on the membrane	100

B. Materials not Provided

- Specimen collection container
- Timer

C. Storage and Stability

Store as packaged at 2-30°C. The test strip is stable through the expiration date printed on the sealed pouch or canister label. The test strip 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 strips 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 strip 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 strip should be discarded in a proper biohazard container after testing.

IV. Test Procedure

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

1. Remove the test strip from the sealed pouch or closed canister, and use it as soon as possible. Note: for canister packaging, immediately close the canister tightly after removing the required number of test strips. Record the initial opening date on the canister. Once opened, the remaining test strips are stable for 12 months.
2. With arrows pointing toward the urine specimen, immerse the test strip vertically in the urine specimen for at least 5 seconds. Do not pass the maximum line (MAX) on the test strip when immersing the strip.
3. Place the test strip on a non-absorbent flat surface, start the timer and wait for the red line(s) to appear. The result should be read at 3 minutes. It is important that the background is clear before the result is read.

   Note: A low hCG concentration might result in a weak line appearing in the test region (T) after an extended period of time; therefore, do not interpret the result after 10 minutes.

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 strip. 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 should be collected 48 hours later and tested.
3. Very low levels of hCG (less than 50 mIU/mL) are present in urine 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 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 should not be used to diagnose pregnancy unless these conditions have been ruled out.
5. 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 Pregnancy Test Strip 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 Pregnancy Test to another commercially available urine membrane hCG test. The study included 150 urine specimens: both assays identified 72 negative and 78 positive results. The results demonstrated 100% overall agreement (for an accuracy of 99%) of the Urine Pregnancy Test Strip when compared to the other urine membrane hCG test.

		Reference hCG Method	
		Positive	Negative
ProAdvantage Urine Pregnancy Test Strip	Positive	78	0
	Negative	0	72

B. Sensitivity and Specificity

The Urine Pregnancy Test Strip 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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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
3. Braunstein GD, J Rasor, H. Danzer, D Adler, ME Wade “Serum human chorionic gonadotropin levels throughout normal pregnancy”, *Am*. *J. Obstet. Gynecol.* 1976; 126(6): 678-681
4. Lenton EA, LM Neal, R Sulaiman “Plasma concentration of human chorionic gonadotropin from the time of implantation until the second week of pregnancy”, *Fertil. Steril.* 1982; 37(6): 773-778
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
6. Dawood MY, BB Saxena, R Landesman “Human chorionic gonadotropin and its subunits in hydatidiform mole and choriocarcinoma”, *Obstet. Gynecol.* 1977; 50(2): 172-181
7. Braunstein GD, JL Vaitukaitis, PP Carbone, GT Ross “Ectopic production of human chorionic gonadotropin by neoplasms”, *Ann. Intern Med.* 1973; 78(1): 39-45
8. ProAdvantage® by NDC hCG Urine Pregnancy Test Strip Package Insert

Test Procedure Review

Supervisor	Date Reviewed	Supervisor	Date Reviewed