



hCG

URINE WITH OBC

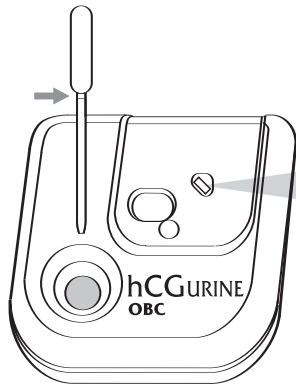
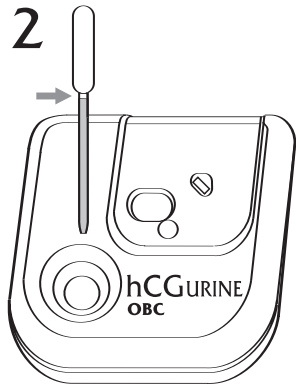
Inverness Medical

TEST PACK *+Plus*

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INTENDED USE

INVERNESS MEDICAL TESTPACK PLUS hCG URINE with On Board Controls (OBC) (TESTPACK hCG URINE) is a rapid immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine for early detection of pregnancy. For professional in vitro diagnostic use only.

SUMMARY AND EXPLANATION OF THE TEST

Human chorionic gonadotropin (hCG) is a glycoprotein hormone that is produced by the blastocyst.¹

The background concentration of hCG in urine increases with age, but is normally <5mIU/ml in women of childbearing age². This rapidly increases after conception, reaching 50-250mIU/ml by the day of the expected period and peaks at approximately 100,000 to 200,000mIU/ml during the first trimester^{3,4}. The sudden rapid rise in concentration of hCG in urine following conception makes it an excellent marker for pregnancy.

The test utilises monoclonal antibodies to detect elevated levels of hCG in urine specimens.

The immunological specificity of the test kit virtually eliminates cross-reactivity interference from the other glyco-protein hormones, present in urine at physiological levels.

PRINCIPLE OF TEST PROCEDURE

In the test procedure, urine is added to the Sample Well of the reaction disc with the aid of a transfer pipette, and allowed to migrate through the membrane until it reaches the End of Assay Window. As the urine proceeds through the membrane, it mobilises the anti hCG monoclonal antibody-colloid. If hCG is present in the specimen, it will form a complex with the antibody-colloid. The antibody-colloid complex migrates through the membrane and is captured by the immobilised anti hCG monoclonal antibody in the result window, providing a visual indication of the presence of hCG.

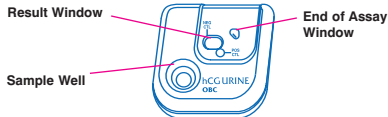
The test can be read when the End of Assay Window has turned pink/red. If hCG is present in the urine at levels of 25mIU/ml or greater, a Plus sign (+) appears in the result window. A Minus sign (-) indicates no hCG was detected.

TESTPACK hCG URINE also provides the following integral control features:

- The plus/minus format provides an easy to interpret result for positive and negative patient specimens.
- The appearance of a pink/red colour in the End of Assay Window indicates that the test is complete.
- The appearance of the Positive On Board Control (POS CTL ✓) and the Minus Sign (-) gives an extra measure of quality control by demonstrating the functionality of the antibody-colloid complex and capture antibody systems, since they will only appear if the reagents are chemically active. The POS CTL (✓) and the Minus Sign (-) should always appear for the test to be valid.
- An additional Negative On Board Control (NEG CTL X) indicates non-specific binding and invalidates the test.

KIT CONTENTS

- 20 reaction discs containing: Anti hCG Antibody [Mouse], hCG Antigen, Bovine IgG and Goat Antibody
- Pack of 20 transfer pipettes
- One package insert

**KIT STORAGE**

Store TESTPACK hCG URINE at 2-30°C for the duration of the shelf life.

Kit components are stable until expiration date when handled and stored as directed.

PRECAUTIONS

Standard guidelines for handling infectious agents should be observed throughout all procedures.

1. Do not open the foil pouch until ready to test.
2. Do not use reaction discs that have become wet or if the foil pouch has been opened or damaged.
3. Properly dispose of all contaminated waste such as reaction discs and transfer pipettes.
4. Do not use kit beyond expiration date printed on the outside of the kit carton.

SPECIMEN COLLECTION & STORAGE

A urine specimen collected at any time of the day is suitable, but a first morning specimen is recommended for early detection of pregnancy, as it should contain the highest concentration of hCG⁵.

Urine specimens must be collected in clean, dry, plastic or glass containers. Specimens may be stored in the refrigerator (2-8°C) for up to 48 hours, or frozen once (-20°C) for up to 3 months.

TESTPACK hCG URINE has not been validated for use with specimens containing preservatives other than sodium azide (0.1%).

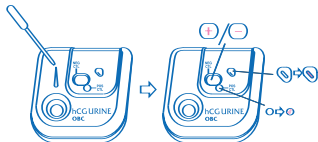
No centrifugation or filtration of specimens is required prior to testing. However, particulate matter in specimens should be allowed to settle before removing a sediment-free aliquot for testing.

TEST PROCEDURE

Reaction discs must be brought to 18-30°C for a minimum of 30 minutes, if stored refrigerated at 2-8°C, before beginning the assay. Specimens should be 18-30°C prior to use. Do not open foil pouches until ready to perform the assay.

1. Remove the reaction disc from its foil pouch. Label with patient or control identifications. Place on a clean, flat, dry surface.
2. Draw specimen to the line marked on the transfer pipette. Dispense the entire contents drop wise into the sample well on the reaction disc.

For each specimen, use a separate transfer pipette and reaction disc.



3. Wait for a pink/red colour in the End of Assay Window to appear (approximately 5 minutes). Read results. Ignore any results after this time.

Refer to the Interpretation of Results and Performance Characteristics sections.

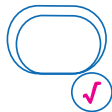
QUALITY CONTROL

Quality control procedures monitor the quality of the assay testing process. The On Board Controls will monitor substantial reagent failure or procedural error, but will not monitor optimal performance of reagents.

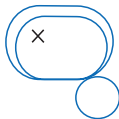
The following process is recommended for quality control for TESTPACK hCG URINE. In addition, refer to your laboratory standard operating procedures and/or quality assurance plan for additional quality control requirements/documentation.

Internal Quality Control

TESTPACK hCG URINE utilises an internal On Board Control system consisting of four control features in the performance of each assay to ensure the assay is functioning properly. The following procedural control features are performed with each patient specimen.



- Positive On Board Control (POS CTL ✓): When the patient specimen is added, the anti hCG monoclonal antibody-colloid complex migrates along the test strip. It binds to the deposited hCG which is then captured by the anti hCG monoclonal antibody to form the POS CTL (✓). The presence of the POS CTL (✓) indicates that both the antibody-colloid complex and the capture antibody systems are functional. The POS CTL (✓) will appear whether there is hCG present in the test specimen or not. The POS CTL (✓) must appear for a valid test.



- Negative On Board Control (NEG CTL X): The NEG CTL (X) is composed of non-specific mouse antibody. Formation of the NEG CTL (X) in the Result Window indicates that the test specimen may contain a non-specific entity that could cause a false positive result. If the NEG CTL (X) appears in the result window, the test is invalid.
- Minus sign (-): As the specimen migrates along the test strip, bovine IgG colloid complex binds to the immobilised Goat anti-

bovine IgG antibody on the Minus Sign to form a (-). The appearance of the Minus sign (-) indicates that migration of the specimen has occurred across the reaction disc. The absence of the Minus sign (-) may indicate improper addition of specimen or deterioration of the reaction discs. Any colour on the Minus sign (-) should be interpreted as a valid Quality Control result. The Minus sign (-) must appear for the assay to be valid.

- End of Assay Window: The pink or red colour in the End of Assay Window after specimen addition indicates specimen migration has completed across the reaction disc, the test is complete and the result can be read. The pink/red colour must appear in the End of Assay Window for the assay to be valid.

Repeat any invalid test with a new reaction disc and read for presence of the above controls. If problem persists, please contact your local distributor.

External Quality Controls

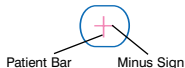
The use of external controls will also monitor the entire assay process. Good laboratory practice recommends the use of control materials to ensure proper kit performance.


External controls should result in a positive or negative result, similar in colour to those of patient specimens. However, colour intensity of the Plus sign (+) in the Result Window on the reaction disc for positive results from actual patient specimens may be fainter than that achieved with the positive external control. See Interpretation of Results section below. If the external controls do not produce the expected result, the test is invalid and the patient test result should not be reported. Repeat testing of Positive/Negative Controls and patient specimens with new reaction discs. If the problem persists, contact your local distributor.


Due to variation in analyte composition and/or matrices, external quality control materials and proficiency survey samples may not elicit identical results across all hCG assays. Each laboratory needs to determine the suitability of each control material for specific immunoassays and validate the material prior to use.

INTERPRETATION OF RESULTS

The TESTPACK hCG URINE result format consists of one vertical line and one horizontal line that form a Plus Sign. The vertical line is the Patient Bar and the horizontal line is the Minus Sign.



 A **positive** result at end of assay is indicated by a plus sign (+) in the Result Window. Pink or red colour (darker than the background) on the Patient Bar is interpreted as a positive result even if it has less colour than the Minus Sign.

 A **negative** result at end of assay is indicated by the Minus Sign (-) in the Result Window.

A negative result means that no hCG was detected, or that the levels of hCG in the specimen were below the detection limit of the assay.

A valid TESTPACK hCG URINE with on board controls (OBC) test consists of all of the following:

- Appearance of the Minus Sign (-) in the Result Window on the reaction disc.
- Absence of NEG CTL (X) within the result window on the reaction disc.
- Appearance of POS CTL (✓) within the designated POS CTL window on the reaction disc.
- Appearance of pink/red colour in the End of Assay window on the reaction disc.

An invalid result or the absence of a Plus (+) or Minus (-) sign may indicate improper addition of specimen or deterioration of the reaction disc.

If the test is invalid, retest with a new specimen and a new reaction disc, ensuring sufficient specimen addition and read for presence of the above controls. If the problem persists, contact your local distributor.

Weak positive results may occur with hCG levels below 25 mIU/mL. It is good laboratory practice to resample and retest these weak positive specimens after an additional 48-72 hours. The use of controls at hCG levels near the assay sensitivity may guide in the interpretation of weak positive results.

The reaction area may, on occasion, exhibit outlines. An outline can be described as a colourless area which surrounds all or part of the Patient Bar. If outlines are present, an impression of the Patient Bar may be seen. However, in the absence of hCG (negative specimens) this impression is comparable to the background and should be interpreted as a negative result.

Randomly occurring dots may occasionally be visible in the result window on the reaction disc, but should not be evaluated in the interpretation of results.

Specimens with high levels of hCG may yield colour on the Patient Bar as quickly as 1 minute after specimen addition. Specimens with levels of hCG at or above the level of sensitivity of the assay remain positive with time. Specimens with levels of hCG below the sensitivity of the assay may yield some colour on the Patient Bar with time however the test should be read at the end of Assay (EOA).

LIMITATIONS OF THE TEST

1. Positive results from very early pregnancy may later prove negative due to natural termination of the pregnancy. This is

estimated to occur in 31% of all conceptions⁶. It is recommended when using a sensitive pregnancy test such as TESTPACK hCG URINE that weak positive results be retested with a first morning urine specimen taken 48-72 hours later.

2. A negative result may be obtained if the urine specimen tested is too dilute.
3. If a negative result is obtained and pregnancy is still suspected, the patient should be retested 48-72 hours later using a first morning urine specimen.
4. Abnormal pregnancies (e.g. ectopic) may produce lower concentrations of hCG than expected for a given gestational age. Abnormal pregnancy cannot be distinguished from normal pregnancy by hCG levels alone^{7,8}.
5. hCG remains elevated for a time after pregnancy⁹. Pregnancy tests carried out fewer than 3 weeks after giving birth, or 9 weeks after natural loss or termination, may need further evaluation.
6. A number of conditions other than pregnancy can cause elevated levels of urinary hCG, e.g. menopause, ovarian cysts, trophoblastic disease, and certain non-trophoblastic neoplasms¹⁰.
7. Occasionally, specimens containing <25mIU/ml hCG may test positive.
8. Drugs containing hCG may interfere with TESTPACK hCG URINE and produce misleading results.
9. False positive and false negative pregnancy tests may be observed in patients with abnormal bladder or kidney function e.g. enterocystoplasties and renal failure.
10. Inconsistent results may be obtained if the urine specimen contains an excessive amount of bacteria.
11. If the test result is not consistent with clinical evidence, further evaluation may be required.

EXPECTED VALUES

Urine specimens from pre-menopausal females generally contain <5mIU/ml hCG; levels are generally <10mIU/ml in healthy males and post-menopausal females². On the first day of the first missed period, the levels of maternal hCG are normally 50-250mIU/ml³.

PERFORMANCE CHARACTERISTICS

Sensitivity

TESTPACK hCG URINE can detect hCG in urine at concentrations of 25mIU/ml or greater. This sensitivity has been determined against the 4th International hCG Standard (WHO)¹. Specimens containing less than 5mIU/ml should give negative results.

Prozone effect

TESTPACK hCG URINE has been shown to produce positive results with specimens containing up to and including 1,000,000 mIU/ml hCG, which is higher than the maximum level expected during typical pregnancy.

Specificity

TESTPACK hCG URINE has been evaluated for its cross-reactivity with a variety of substances, including other hormones found in urine. No cross-reactivity was detected when the following substances were added to both "positive" (containing 25 mIU/ml hCG) and "negative" urine specimens: LH (1000mIU/ml), FSH (1000mIU/ml), TSH (1000 μ IU/ml).

INTERFERING SUBSTANCES

The following substances were added to "negative" and "positive" (containing 25 mIU/ml hCG) specimens. The "negative" urine specimens tested negative in 100% of the determinations. The "positive" (containing 25 mIU/ml hCG) urine specimens tested positive in 100% of the determinations.

Acetaminophen	(20 mg/dL);	Biotin	(25 μ g/dL)
Acetoacetic Acid	(2000 mg/dL);	Bilirubin	(1 mg/dL);
Acetone	(1000 mg/dL)	Caffeine	(20 mg/dL);
Albumin (human serum)	(1200 mg/dL);	Creatinine	(200 mg/dL)
Acetosalicyclic Acid	(20 mg/dL);	Dextromethorphan	(20 mg/dL);
Ampicillin	(20 mg/dL)	Diphenhydramine	(20 mg/dL);
Ascorbic Acid	(200 mg/dL);	EDTA	(40 mg/dL);
Atrophine	(20 mg/dL);	Ephedrine	(20 mg/dL)

Ethanol	(1%);	Phenylpropranolamine	(4000 mg/dL);
Estrone β -D Glucuronide	(100 μ g/dL)	5 β -Pregnane-3 α , 20 α -diol	
Gentisic Acid	(20 mg/dL);	Glucuronide	(100 μ g/dL);
Glucose	(10000 mg/dL)	Ribovlavin	(2 mg/dL);
Haemoglobin	(360 mg/dL);	Salicylic Acid	(20 mg/dL);
Hydroxybutyric Acid	(100 mg/dL)	Sodium Carbonate	(800 mg/dL);
Human Serum Proteins	(2000mg/dL);	Sodium Chloride	(6800 mg/dL);
Ibuprofen	(40 mg/dL)	Tetracycline	(30 mg/dL);
Nicotine	(20 μ g/dL);	Urea	(2000 mg/dL);
Oxalic Acid	(60 mg/dL);	Uric Acid	(100 mg/dL)
Oxytetracycline	(30 mg/dL);		

In addition no pH effect in range pH 4.5 to pH 8.5.

ACCURACY

In a study, 300 urine specimens collected from women for the purpose of pregnancy testing, were evaluated with the Inverness Medical TESTPACK Plus + hCG URINE with OBC test (TESTPACK hCG URINE) and with the Clearview HCG Urine test.

Of the 300 urine specimens evaluated, 131 specimens tested positive by both methods and 169 specimens tested negative by both methods. An agreement of 100% (300/300) was determined for these specimens. Therefore the relative sensitivity and relative specificity were found to be 100%.

The study results are summarised below:

TESTPACK hCG URINE	Clearview HCG Urine	
	+	-
+	131	0
-	0	169











ADVICE LINE

For further information, please contact your distributor or call Inverness Medical Customer Service on;

UK : 08705 134 952

International : +44 1234 835 959

www.testpack.com

Key to symbols Erläuterung der Symbole	Symbolforklaring Leyenda de símbolos	Symbolien selitykset Clé des symboles	Επεξήγηση συμβόλων Legenda dei simboli	Betekenis van symbolen Nøgle til symboler	Chave dos símbolos Symbolförklaring	الرموز الرئيسية					
	CE Mark CE-Zeichen CE-mærke	Marca CE CE-merkintä Marque CE	Σήμανση CE Marchio CE CE-merk	CE-merke Marcação CE CE-märkning	علامة CE		Catalogue Number Katalognummer Katalognummer	Número de catálogo Luettelonumero Numéro de catalogue	Αριθμός καταλόγου Numero di catalogo Catalogusnummer	Katalognummer Número de catálogo Katalognummer	رقم النشرة
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	For professional in vitro diagnostic use only Der Test ist ausschließlich für professionelle In-Vitro- Diagnose vorgesehen Kun til professionel in vitro-diagnostisk brug	Uso exclusivo para diagnóstico in vitro profesional Ainoastaan ammatimaiseen in vitro -diagnosikäyttöön Pour utilisation diagnostique in vitro professionnelle uniquement	Μόνο για επαγγελματική in vitro διαγνωστική χρήση Unicamente per uso diagnostico professionale in vitro Alleen voor professioneel gebruik bij in vitro diagnostiek	Bare for profesjonelt in- vitro diagnostisk bruk Apenas para diagnostico profesional in vitro Endast för professionellt in vitro-diagnostiskt bruk للاستخدام التشخيصي من قبل المتخصصين فقط		Use By/Expiry Date Haltbarkeits-/ Ablaufdatum Anvendes for/Udløbsdato Utilizar antes de/ Fecha de caducidad	Käyt. ennen/ Viim. käyttö pvm Utiliser avant/ date de péremption Χρήση μέχρι/ Ημερομηνία λήξης	Utilizzare entro/ Data di scadenza Te gebruiken voor/Uiterste houdbaarheidsdatum Brukes innen/ utløpsdato	Usar até/ Prazo de Validade Utgångsdatum يستخدم قبل/ انتهاء الصلاحية		
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	Manufactured by Herstellt von Fremstillet af	Fabricado por Valmistanut Fabriqué par	Παρασκευάζεται από την Prodotto da	Geproduceerd door Tilverkt av Fabricado por	الشركة المصنعة		Consult instructions for use Siehe Gebrauchsanweisung Se bruger-vejledningen Consultar el prospecto	Ks. käyttöohjeet Lire les instructions d'utilisation Συμβουλευτείτε τις οδηγίες χρήσης	Consultare le istruzioni per l'uso Raadpleeg instructies voor gebruik Se bruks-anvisningen	Consulte as instruções de utilização Läs instruktionerna för användning ارجع إلى إرشادات الاستخدام	

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