

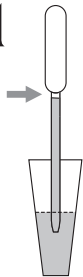


hCG
COMBO WITH OBC

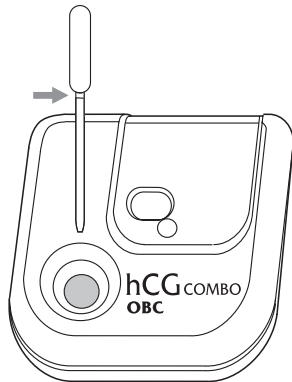
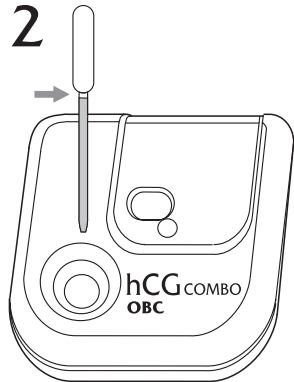
Inverness Medical

TEST PACK *+Plus*

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2



3





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INTENDED USE

INVERNESS MEDICAL TESTPACK PLUS hCG COMBO with On Board Controls (OBC) (TESTPACK hCG COMBO) is a rapid immunoassay for the qualitative detection of human Chorionic Gonadotropin (hCG) in serum and 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 and serum 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 and serum following conception makes it an excellent marker for pregnancy.

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

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

PRINCIPLE OF TEST PROCEDURE

In the test procedure, serum or 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. As the serum or 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 polyclonal antibody in the result window, providing a visual indication of the presence of hCG.

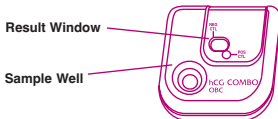
The test should be read at 5 minutes. If hCG is present in the urine or serum at levels of 25mIU/ml or greater, a Plus sign (+) appears in the result window. A Minus sign (-) indicates no hCG was detected.

TESTPACK hCG COMBO 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 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 [Goat], Anti hCG Antibody [Mouse], hCG Antigen, Goat IgG and Goat Antibodies.
- Pack of 20 transfer pipettes
- One package insert

**KIT STORAGE**

Store TESTPACK hCG COMBO 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

Urine Specimens: 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. Specimens should not be repeatedly frozen and thawed.

TESTPACK hCG COMBO has not been validated for use with urine 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.

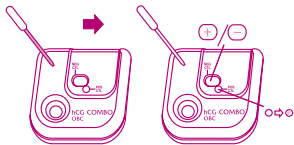
Serum Specimens: No special preparation of serum is required. Serum specimens not tested immediately must be stored refrigerated (2-8°C) for up to 48 hours or frozen **once** (-20°C) for up to 3 months. Specimens should not be repeatedly frozen and thawed.

TEST PROCEDURE

Reaction discs must be brought to 18-30°C for a minimum of 30 minutes 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. Allow the sample to migrate through the strip - you will see a light pink colour move through the window as the test begins to work. Read results 5 minutes after addition of sample to the sample well.

Ignore any results that appear 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.

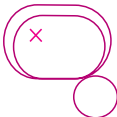
The following process is recommended for quality control for TESTPACK hCG COMBO. In addition, refer to your laboratory standard operating procedures and/or quality assurance plan for additional quality control requirements/documentation.

Internal Quality Control

TESTPACK hCG COMBO utilises an internal On Board Control system consisting of three 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 polyclonal 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-immune goat 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, the anti-hCG monoclonal Antibody colloid complex binds to the immobilised Goat anti-mouse 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.

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 COMBO 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.



Read test results 5 minutes after addition of sample to sample well, however, a positive result may appear earlier.



A **positive** result 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 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 COMBO 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.

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 25mIU/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 5 minutes after addition of sample.

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 conceptions⁸. It is recommended when using urine specimens with a sensitive pregnancy test such as TESTPACK hCG COMBO 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.
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 or serum 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 COMBO and produce misleading results.
9. False positive and false negative pregnancy tests have been 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. False results can occur with TESTPACK hCG COMBO due to non-specific protein binding^{11, 12, 13}.
12. Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with in vitro immunoassays^{14, 15}.
13. Grossly haemolysed, plasma, lipaemic specimens or specimens containing icterus are not suitable for testing with TESTPACK hCG COMBO, since they may give inaccurate and/or erratic results.
14. If the test result is not consistent with clinical evidence, further evaluation may be required.

EXPECTED VALUES

Urine and serum specimens from pre-menopausal females generally contain <5mIU/ml hCG; levels are generally <10mIU/ml in healthy males and post-menopausal females⁶. On the first day of the first missed period, the levels of maternal hCG are normally 50-250mIU/ml⁶.

PERFORMANCE CHARACTERISTICS

Sensitivity

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

Specificity

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

INTERFERING SUBSTANCES

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

Interfering Substances (in Urine)

Acetaminophen	(20 mg/dL)	Ethanol	(1%)
Acetoacetic acid	(2000 mg/dL)	Estrone β-D	(100 µg/dL)
Acetone	(1000 mg/dL)	glucuronide (E3G)	
Acetylsalicylic acid	(20 mg/dL)	Gentisic acid	(20 mg/dL)
Albumin (human serum)	(1200 mg/dL)	Glucose	(1000mg/dL)
Ampicillin	(20 mg/dL)	Haemoglobin	(360 mg/dL)
Ascorbic acid	(200 mg/dL)	Human serum proteins	(2000 mg/dL)
Atrophine	(20 mg/dL)	Hydroxybutyric acid	(100 mg/dL)
Biotin	(25 µg/dL)	Ibuprofen	(40 mg/dL)
Bilirubin	(1 mg/dL)	Nicotine	(20 µg/dL)
Caffeine	(20 mg/dL)	Oxalic acid	(60 mg/dL)
Creatinine	(200 mg/dL)	Oxytetracycline	(30 mg/dL)
Dextromethorphan	(20 mg/dL)	Phenylpropranolamine	(4000 mg/dL)
Diphenhydramine	(20 mg/dL)	5β-pregnane-3α,	(100 µg/dL)
EDTA	(40 mg/dL)	20α-diol glucuronide (P3G)	
Ephedrine	(20 mg/dL)	Riboflavin	(2 mg/dL)

Salicylic acid	(20 mg/dL)	Tetracycline	(30 mg/dL)
Sodium Carbonate	(800 mg/dL)	Urea	(2000 mg/dL)
Sodium Chloride	(6800 mg/dL)	Uric acid	(100 mg/dL)

Interfering Substances (in Serum)

Bilirubin	(40mg/dL)
Estrone β-D glucuronide (E3G)	(1 µg/mL)
Hemoglobin	(1000 mg/dL)
5β-pregnane-3α, 20α-diol glucuronide (P3G)	(1 µg/mL)
Triglycerides	(1395 mg/dL)

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

ACCURACY

In a study, 295 urine and 186 serum specimens collected from women for the purpose of pregnancy testing, were evaluated with the INVERNESS MEDICAL TESTPACK Plus hCG COMBO with OBC test (TESTPACK hCG COMBO) and with the Quidel QuickVue® One Step hCG Combo test (QuickVue® hCG Combo).

Of the 295 urine specimens evaluated, 126 specimens tested positive by both methods and 168 specimens tested negative by both methods. One specimen, which tested less than 5 mIU hCG/ml on a quantitative test, tested negative on the INVERNESS MEDICAL TESTPACK Plus hCG COMBO with OBC test but positive on the Quidel QuickVue® One Step hCG Combo test (QuickVue® hCG Combo).

An agreement of over 99% was determined for these urine specimens. The relative sensitivity and relative specificity were found to be greater than 99% for these specimens.

Of the 186 serum specimens evaluated, 110 specimens tested positive by both methods and 76 specimens tested negative by both methods. An agreement of over 99% was determined for these serum specimens. The relative sensitivity and relative specificity were found to be greater than 99% for these specimens.

The study results are summarised below:

Urine

TESTPACK hCG COMBO	QuickVue® hCG Combo	
	+	-
+	126	0
-	1	168

Serum

TESTPACK hCG COMBO	QuickVue® hCG Combo	
	+	-
+	110	0
-	0	76

ADVICE LINE

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

UK: 08705 134 952

International +44 (0)1234 835 959

www.testpack.com

*QuickVue® is a registered trademark of Quidel Corporation.

Key to symbols
Erläuterung der Symbole

Symbolforklaring
Leyenda de símbolos

Symbolien selitykset
Clé des symboles

Εξήγηση 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



Do Not Reuse
KIT Components
Der Packungsinhalt darf
nur einmal verwendet
Sættets komponenter
må ikke genbruges

Los componentes de este
kit no son reutilizables
Alä käytä testipaketin
osia uudelleen
Ne pas réutiliser les
composants du KIT

Να μην χρησιμοποιηθούν
ξανά τα συστατικά του kit
Non riutilizzare i
componenti del KIT
KITcomponenten niet
opnieuw gebruiken

SETT-komponenter
bare for engangsbruk
Não reutilizar
Componentes do kit
Delarna i paketet får
ej återanvändas



Store at 2-30°C
Lagerung bei
2° bis 30°C
Opbevares ved 2-30°C

Almacenar a 2-30°C
Säilytettävä 2-30°C
Conserver entre
2 et 30 °C

Φυλάσσεται στους
2-30°C
Conservare a 2 - 30 °C
Opstaan bij 2-30°C

Oppbevares ved
2-30°C
Conservar a 2°C-30°C
Förvaras vid 2-30° C

يُحفظ عند
30°c 2-

يحظر إعادة استخدام مكونات طقم الجهاز



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



Contains sufficient
for <n> tests
Inhalt ausreichend
für <n> Tests
Indeholder materiale
til <n> test

Contiene lo necesario
para <n> ensayos
Sisältää tarvittavat välineet
<n> määrään testejä
Quantité suffisante
pour <n> tests

To περιεχόμενο επαρκεί
για <n> εξετάσεις
Contenuto sufficiente
per <n> test
Bevat voldoende
voor <n> tests

Inneholder nok
til <n> tester
Contém o suficiente
para <n> testes
Inhålltet räcker
till <n> test

يحتوي على كافة المتطلبات اللازمة لإجراء اختبارات <n>



Lot number
Chargennummer
Produktionsserienummer
(Lot)

Número de lote
Eränumero
Numéro de lot

Αριθμός παρτίδας
Numero di lotto
Lotnummer

Lot nummer
Número de lote
Parti nr.

رقم التشغيل



Manufactured by
Hergestellt von
Fremstillet af

Fabricado por
Valmistanut
Fabriqué par

Παρασκευάζεται
από την
Prodotto da

Geproduceerd door
Tilvirket av
Fabricado por

Tillverkad av
الشركة المصنعة



Consult instructions
for use
Lire les instructions
Siehe Gebrauchs-anweisung
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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