One Step HCG Urine Pregnancy Test

INV-FHC-101

Invitech One Step hCG Urine Pregnancy Test (25 mIU/ml) is a rapid, one step test for the qualitative detection of human chorionic gonadotropin (hCG) in urine.
Intended for professional in vitro diagnostic use only.

INTENDED USE

The Invitech One Step hCG Urine Pregnancy Test (25 mIU/ml) is a rapid, chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine. It detects the presence of hCG at a concentration of 25 mIU/ml or above, to aid in the early detection of pregnancy.

PRINCIPLE

Human chorionic gonadotropin (hCG) is one of the glycoproteins secreted by the placenta. It contains α and β subunits. The α subunit of hCG shows cross-reactivity with the structurally related glycoproteins hLH, hTSH and hFSH, however the β subunit does not. The Invitech One Step hCG Urine Pregnancy Test (25 mIU/ml) uses a monoclonal antibody directed against highly purified β hCG.
The Invitech One Step hCG Urine Pregnancy Test (25 mIU/ml) is a rapid qualitative immunoassay, based on the principle of a double antibody sandwich, for determination of hCG in urine. When a sample is added to the cassette, capillary action allows it to migrate along the membrane, where any hCG in the sample will be captured by an anti-hCG monoclonal antibody in the sample pad, which will then meet an anti-hCG monoclonal antibody in the test zone. The sample will continue to migrate and will meet anti-mouse IgG in the control zone.
If the level of hCG in the sample is at or above 25 mIU/ml, red lines will appear in both the test and control zones, indicating a positive result. If the level of hCG in the sample is below 25 mIU/ml, a red line will only appear in the control zone, suggesting a negative result. A red line will always appear in the control zone if the test has been performed correctly.

REQUIRED MATERIAL

MATERIAL PROVIDED

1. One pouch containing a reaction strip and a desiccant. The desiccant is for storage purposes only, and is not used in the test procedures.
2. Leaflet with instructions for use.
3. Pictorial, easy-to-follow instructions

MATERIAL NOT PROVIDED

1. Clean, dry plastic or glass specimen container
2. Timer

PRECAUTIONS

1. For professional in vitro diagnostic use only
2. Do not use after the expiry date
3. Discard after first use. Do not reuse
4. Do not use the test if the foil pouch is punctured or damaged
5. Do not use the test if the desiccant pouch is pink or is missing
6. Do not open the foil pouch until you are ready to perform the test
7. Dispose of the test in a biohazard container after testing

STORAGE AND STABILITY

1. Store at 4 - 30°C as packaged in the sealed pouch, up to the expiration date.
2. Keep away from direct sunlight, moisture and heat.
3. Open the foil pouch immediately before performing the test.
4. DO NOT FREEZE.

SPECIMEN COLLECTION AND PREPARATION

SPECIMEN COLLECTION

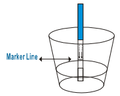
A urine sample must be collected in a clean, dry container. An early morning (first) urine sample is strongly recommended, as it will contain the highest concentration of hCG. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle, to obtain a clear specimen for testing.

SPECIMEN STORAGE

Urine specimens may be stored at 2 - 8°C for up to 48 hours prior to testing. For longer storage, specimens may be frozen and stored below -20°C. Frozen samples must be thawed and mixed before testing.

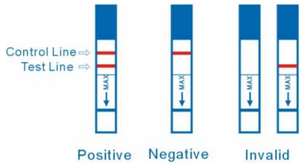
DIRECTIONS FOR USE

1. Allow the test dipstick and urine sample to equilibrate to room temperature (15 - 30°C) prior to testing
2. Remove the test dipstick from the foil pouch by tearing at the nick, immediately prior to testing Check that the desiccant pouch is present and not pink in colour
3. Insert the dipstick into the urine, with the arrow pointing towards the urine. Do not immerse past the MAX line
4. Hold the dipstick in the urine for 10 seconds, then remove and lay it on a clean, level surface (such as the mouth of the urine container)
5. Read the result at 5 minutes. Do not read before 5 minutes



INTERPRETATION OF RESULTS

1. **Negative:** One red line appears in the control zone. No line appears in the test zone.
2. **Positive:** Two red lines appear, one in the test zone and one in control zone. Any line in the test zone, however faint, should be interpreted as a positive result.
3. **Invalid:** No visible lines at all, or a visible line in the test zone but not in the control zone. The most likely cause of an invalid result is incorrect technique. Repeat using a new test dipstick. If the test still fails, discontinue using the kit and contact Invitech Ltd on 0845 313 3348.



NOTE: if the colour in the Test Zone is weak, it is recommended that the test be repeated in 48 hours.

QUALITY CONTROL

Internal procedural controls are included in the test. A red line in the control zone is the internal procedural control, confirming correct 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 very pale pink and should not interfere with the ability to read the test result. It is recommended that a positive hCG control (containing between 25 and 200 mIU/ml hCG) and a negative control (containing no hCG) should be used to verify test performance, as required by your laboratory.

LIMITATIONS

1. As with any diagnostic test, a confirmed pregnancy diagnosis should only be made by a physician, after evaluating all clinical and laboratory findings.
2. Dilute urine samples (i.e. with a low specific gravity) may not contain a representative level of hCG, potentially leading to a false negative result. If pregnancy is suspected, an early morning (first) urine sample should be collected and retested. Alternatively, perform a serum hCG test.
3. In very early pregnancy, false negative results may occur when the level of hCG is below the sensitivity level of the test. If pregnancy is suspected, an early morning (first) urine sample should be collected and retested 48 hours later.
4. Very low levels of hCG are present in urine shortly after implantation. However, a significant number of first trimester pregnancies terminate for natural reasons. It is recommended that weakly positive test results are confirmed by retesting an early morning (first) urine sample 48 hours later, or by performing serum hCG tests on consecutive days.
5. Elevated levels of hCG can be caused by a number of conditions other than pregnancy, including trophoblastic disease and some non-trophoblastic neoplasms such as testicular tumours, seminoma, choriocarcinoma, germ cell tumours, hydatidiform mole formation, teratoma with elements of choriocarcinoma, and islet cell tumour. Therefore, the presence of hCG in urine should not be used to diagnose pregnancy unless these conditions have been ruled out.
6. Serious urinary tract infections (with high levels of WBC, RBC and nitrite) can occasionally cause a false positive pregnancy test result. If a urinary tract infection is suspected, perform a serum hCG test.
7. Ectopic pregnancies typically produce lower levels of hCG than normal pregnancies. As this will be accentuated by the dilution effect in urine, use a serum hCG test when ectopic pregnancy is suspected.
8. Fertility treatments based on hCG may cause false positive results.
9. This test detects intact hCG up to 200,000 mIU/ml. Levels above this may give false negative results due to hook effect. If hook effect is suspected, dilute the urine by adding 1 drop of urine to 9 drops of water and retest.
10. This test does not reliably detect hCG degradation products, such as free-β hCG and β core fragments. Therefore quantitative hCG assays that do detect hCG degradation products may disagree with the results of this test.

EXPECTED RESULTS

Negative results are expected in healthy non-pregnant women and healthy men. Although hCG levels in normal early pregnancy are variable, One Step hCG Urine Pregnancy Test is capable of detecting pregnancy as early as 1 day after the first missed menses.

PERFORMANCE CHARACTERISTICS

ACCURACY

The results from the Invitech One Step hCG Urine Pregnancy Test (25 mIU/ml) were compared with those from another commercially available urine membrane hCG test. The study included 619 urine specimens. Both assays identified 374 negative and 243 positive results. The results demonstrated that the Invitech One Step hCG Urine Pregnancy Test (25 mIU/ml) showed >99.5% agreement when compared to the other urine membrane hCG test.

REFERENCE HCG METHOD

		Evaluation device		
		+	−	Total
Comparison reagent	+	243	1	244
	−	1	374	375
	Total	244	375	619

Agreement of the positive with comparison reagent: >99.5 %
Agreement of the negative with comparison reagent : >99.5%
Total agreement with comparison reagent: > 99.5%

SENSITIVITY AND SPECIFICITY

The Invitech One Step hCG Urine Pregnancy Test (25 mIU/ml) detects hCG at a concentration of 25 mIU/ml or greater. The test has been standardised to the W.H.O. Standard hCG IS 75/537. No cross reaction was observed when LH (300 mIU/ml), FSH (300 mIU/ml) and TSH (1,000 μIU/ml) were added to a sample containing 0 mIU/ml hCG and a sample containing 25mIU/mL hCG.

Results / Concentration(mIU/mL)	Positive results	Negative results	Total number of standard
	+	−	
0	0	5	5
12.5	0	5	5
18.75	0	5	5
25	29	1	30
50	10	0	10
100	5	0	5

INTERFERING SUBSTANCE

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

Acetaminophen	20mg/dl	Centesic acid	20mg/dl
Acetylsalicylic acid	20mg/dl	Glucose	2mg/dl
Ascorbic acid	20mg/dl	Hemoglobin	20mg/dl
Atropine	20mg/dl	Tetracycline	20mg/dl
Caffeine	20mg/dl	Ampicilline	20mg/d
Albumin	20mg/ml		

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

LINEARITY/ASSAY REPORTABLE RANGE

To investigate hook effect in the test, negative urine was spiked with hCG at concentrations ranging from 10 mIU/ml to 500,000 mIU/ml and each sample was tested repeatedly.

HCG concentration	Test result
HCG 10 mIU/ml	-
HCG 15mIU/ml	-
HCG 20 mIU/ml	-/+
HCG 25mIU/ml	+
HCG100mIU/ml	+
HCG500mIU/ml	+++
HCG1000mIU/ml	+++
HCG5IU/ml	++
HCG25IU/ml	+
HCG100IU/ml	+
HCG200IU/ml	-/+
HCG500IU/ml	-

The results indicated that the test can detect hCG at a range between 25 mIU/ml and 200,000 mIU/ml, although the results were weaker above levels of 100,000 mIU/ml.

BIBLIOGRAPHY

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MEANING OF SYMBOLS ON PACKAGE

Keep away from Sunlight
Store between 4 And 30°C
Keep dry
Do not re-use

CE EC REP
Qarad b.v.b.a.
Cipalstraat 3
B-2440 Geel, Belgium

Distributor

Invitech Ltd.
4a/4b Molesworth Business Estate
Molesworth Cambs PE28 0QG
TEL: 0845 313 3348
E-mail:sales@invitech.co.uk

Manufacturer : **Guangzhou Wondfo Biotech Co., Ltd.**
No. 8 Lizhishan Road, Scientific City, Luogang District, Guangzhou, Guangdong, P.R. China 510663
Tel: 86-20-32296086 Fax: 86-20-32296063
Website: www.wondfo.com.cn E-mail: sales@wondfo.com.cn

Version: 10/02/2015

Wondfo 万孚

物料编码： 02.032.001.0151-1 说明书(英国Invitech HCG条25mIU)

许广添
2015.02.12

尺寸规格： 254×180mm

颜色： PANTONE 350C PANTONE 485C

备注：