

INTEX®-Pregnancy Test

GRAVI-HCG

Instructions for use

Rapid cassette test for the qualitative detection of hCG in urine

1. INTENDED USE

The INTEX®-Pregnancy Test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine, as an aid for the early detection of pregnancy.

This device is showing a visual qualitative result and is developed for professional use only.

2. 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 serum and urine as early as 7 to 10 days after conception (1-4). hCG level continues to rise very rapidly, frequently exceeding 100 mIU/ml by the first missed menstrual period (2-4), and peaking in the 30'000 – 100'000 mIU/ml range by 10-12 weeks into pregnancy.

The appearance of hCG in both the 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 INTEX®-Pregnancy Test is a rapid urine test to qualitatively detect the presence of hCG in urine specimens at the sensitivity of more than 20 mIU/ml.

The test utilizes monoclonal antibodies to selectively detect elevated levels of hCG in urine. At the level of claimed sensitivity, hCG Pregnancy Test shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at physiological levels.

3. PRINCIPLE

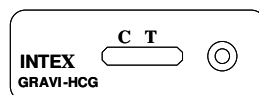
The INTEX®-Pregnancy Test is a qualitative, solid phase, two-site sandwich immunoassay (5-6) for the detection of human chorionic gonadotropin (hCG) in urine. The membrane is pre-coated at the test line region with anti-hCG antibodies directed against the α -chain of hCG and at the control line region with goat anti-mouse antibodies.

During testing, the sample reacts with the dye coupled monoclonal antibody (mouse anti-hCG antibody-colloidal gold conjugate) directed against the β -chain of hCG, which has been pre-coated in the test device. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-hCG antibodies on the membrane and generate a red line. Presence of this red line indicates a positive result, while its absence indicates a negative result.

Regardless of the presence of hCG, as the mixture continues to migrate across the membrane to the immobilized goat anti-mouse region, a red line at the control line region will always appear. The presence of this red line serves as verification for sufficient sample volume and proper flow and as a control for the reagents.

4. REAGENTS AND MATERIALS SUPPLIED

- 10 / 30 Individually wrapped test devices
- 1 disposable pipette
- 1 instruction sheet



5. MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection container.
- Timer

6. STABILITY AND STORAGE

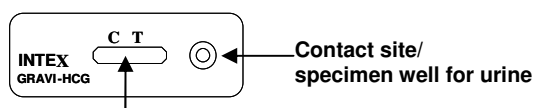
Store as packaged in the sealed pouch refrigerated (2-8°C) or at room temperature (not above 30°C). The kit is stable within the expiration date printed on the label. DO NOT FREEZE or use beyond the expiration date.

7. WARNINGS AND PRECAUTIONS

- *For in vitro diagnostic use only.*
- *For professional use only*
- *For single use only.*
- *Do not use after the expiration date.*
- *Do not eat, drink or smoke in the area where the specimens or kits are handled.*
- *Do not use test if pouch is damaged.*
- *Do not use more than the required amount of liquid.*
- *Bring all reagents to room temperature (15-30 °C) before use.*
- *Do not spill the samples into the reaction zone.*
- *Do not touch the reaction zone of the device to avoid contamination.*
- *Avoid cross-contamination of samples by using a new specimen collection container and specimen pipette for each sample.*
- *Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens.*
- *Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.*
- *The test device should remain in the sealed pouch until use.*
- *Evaluate the test result within 2 to 5 minutes.*
- *Store and transport the test device always at 2-30 °C (36 °-86 °F)*
- *Humidity and high temperature can adversely affect results.*

8. SET-UP FOR THE TEST DEVICE

The plastic case of the test cassette encloses one test strip and at the right end of the strip there is the sample well and at the left part there is the opening of the reaction zone. At the reaction zone you find the test (T) and the control (C) zone where bands indicate the presence or absence of the hormone after performing the test procedure. Because the strip encloses in a plastic case you can only imagine its position by the openings in the case (sample well and reaction zone).



Reaction zone with the test- (T) and the control- (C) zone (with ellipses marked)

9. SPECIMEN COLLECTION AND STORAGE

The urine specimen must be collected in a clean and dry plastic or glass container without any preservatives. The first morning urine is preferred since it generally contains the highest concentration of hCG. However, urine collected at any time of day may be used.

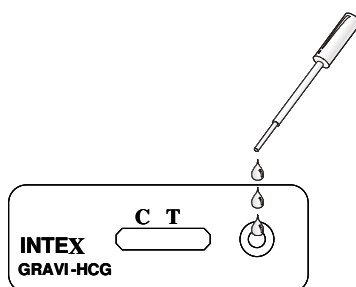
Urine samples exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain clear supernatant for testing.

Urine containing excessive bacterial contamination should not be used, as may cause spurious results.

Urine specimens may be stored at 2-8°C for up to 48 hours prior to assay. For prolonged storage, specimens may be frozen and stored below -20°C up to 5 days.

10. TEST PROCEDURE

1. Read the entire procedure carefully prior to performing any tests. Allow test devices and urine sample to equilibrate to room temperature (15-30°C) prior testing.
2. Remove the hCG test device from foil pouch (bring the test to room temperature before opening the pouch). Use device as soon as possible within 1 hour after removal from pouch especially if the room temperature is more than 30°C or in high humidity environment. Mark the device with the patient's identification mark.
3. Place the test device on a clean and level surface. Holding the dropper vertically, dispense three full drops of specimen (~120 µl) without air bubbles into the sample well of the test device.



4. Wait for red lines to appear. The test should be read in approximately 2-5 minutes. It is significant that the background is clear before reading the test, especially when samples have low hCG concentration, and only a weak line appears in the test region (T). Do not interpret results after 5 minutes.
5. If the test is interpreted after 15 minutes the sensitivity is as low as 10 mIU/mL hCG. This increase risks to get apparently false positive results due to natural abortions, elevated physiological hCG levels of non-pregnant women and drugs comprising hCG. Thus, we recommend to interpret the test after 5 minutes reaction time for routine purposes.

11. QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is considered an internal positive procedural control.

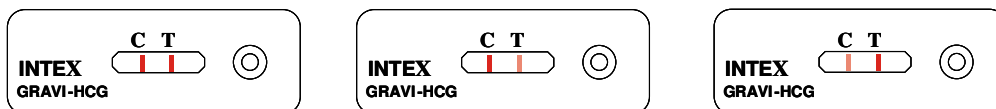
A clear background in the results window is considered an internal negative procedural control.

It is recommended that a positive hCG control (containing 25-250 mIU/ml hCG) and a negative hCG control (containing "0" mIU/ml hCG) be included in each day testing to verify proper test performance.

12. INTERPRETATION OF RESULTS

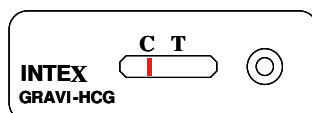
POSITIVE: Pregnant

Two distinct red bands will appear, one in the test region (T) and another in the control region (C).



NEGATIVE: Non-pregnant

Only a single 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 which means improper testing procedures or deterioration of reagents probably has occurred. In any event, repeat the test. If the problem persists, discontinue using the lot immediately and contact your local distributor.



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

13. LIMITATION OF THE PROCEDURE

Very dilute urine specimens as indicated by low specific gravity, may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine sample should be obtained 48-72 hours later and tested.

Very low levels of hCG (less than 50 mIU/ml) are present in urine or serum shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons (7), a test result that is weakly positive should be interpreted in conjunction with other clinical and laboratory data.

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 (>10 mIU/mL) (8-9). Therefore, the presence of hCG in urine as determined by using hCG Pregnancy Test should not be used to diagnose pregnancy unless these conditions have been ruled out.

Like with all diagnostic tests, a confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

14. EXPECTED VALUES

Urine hCG concentration of pregnant women rise very rapidly after implantation, reaching a peak concentration in excess of 200 mIU/ml about 2-3 months after the last menstrual period (3). hCG Test has a sensitivity of 20 mIU/ml for urine and is capable of detecting pregnancy as early as 1 day after the first missed menses.

Reportedly, a level of 25 mIU/ml or more, is present 7-10 days after conception or 4-5 days prior to the first missed menses (3). Test results which appear as very light line in the test region are not definitive for the diagnosis of pregnancy. It is strongly recommended that an additional urine specimen be obtained after 48-72 hours and tested again. Negative test results in patients suspected to be pregnant should be re-tested with the first morning specimen obtained 48-72 hours later.

15. PERFORMANCE CHARACTERISTICS

The test device can be evaluated 2 to 5 minutes after the addition of specimen to the test device.

Sensitivity

The analytical sensitivity of INTEX[®]-Pregnancy Test is 20 mIU/mL (based on the 4th IRP of HCG). The sensitivity was established by repetitive testing of samples containing 20 mIU/mL hCG during a period of several weeks.

The INTEX[®]-Pregnancy Tests do not show a “high dose Hook” or “Prozone Effect” up to the maximal observed physiological concentration (600 IU/mL). Thus, the working range is 20 mIU/mL up to 600 IU/mL.

Specificity

The specificity of the INTEX[®]-Pregnancy Test was determined from cross-reactivity studies with known amounts of Luteinizing Hormone (hLH), Follicle Stimulating Hormone (hFSH), and Thyroid Stimulating Hormone (hTSH). Negative results were obtained from all tests conducted with 300 mIU/ml hLH, 1000 mIU/ml hFSH and 1000 µIU/ml hTSH.









Precision/Urine Assay



Studies were performed which consisted of testing 130 positive and 178 negative urine specimens using the INTEX[®]-Pregnancy Test versus a reference hCG immunoassay. Both of these studies demonstrate 100% (relative) correlation.

16. LITERATURE

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17. SYMBOLS

 REF	Article number		For single use only
 LOT	Lot number		Expiry date
	Storage		Content
 IVD	Only for in vitro diagnostics		Instruction sheet

INTEX®-Pregnancy Test GRAVI-HCG		 REF
	10 Test cassettes	GH3310
	30 Test cassettes	GH3330



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