β-HCG MONOSTEP TEST

For *in Vitro* **diagnostic use**

Membrane immunochromatographic test for the detection of the Chorionic Gonadotropin in urine

INTENDED USE
The β-HCG Monostep Test is an immunochromatographic, manual test designed for the qualitative determination of human chorionic gonadotropin (hCG) in urine for the early detection of pregnancy. It is intended for healthcare professional use.

SUMMARY
Human chorionic gonadotropin (hCG) is a glycopeptide hormone produced by the placenta during pregnancy. The appearance and rapid increase in the concentration of hCG in the mother's serum and urine makes it a good marker for confirming pregnancy. The concentration of hCG in urine increases steadily to a circulation peak of as much as 50,000 mIU/ml between the eighth and eleventh weeks. β-HCG Monostep Test is a immunochromatographic test which use specific antibodies to selectively identify hCG in urine with a high degree of sensitivity.

PRINCIPLE
Urine is added to the test kit and allowed to migrate through the absorbent device. The labeled antibody-dye conjugate binds to the hCG in the specimen forming an antibody-antigen complex. This complex binds to the anti-hCG antibody in the test zone and produces a coloured band when the hCG concentration is equal to or greater than 25 mIU/ml. In the absence of hCG, no band is formed in the test zone. The reaction mixture continues flowing through the absorbent device past the test and control zones. Unbound conjugate binds to the reagents in the control zone, producing a coloured band, demonstrating that the reagents and the test kit are functioning correctly.

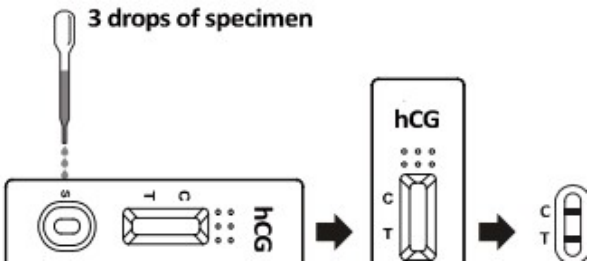
STORAGE AND STABILITY
The test kit must be stored at room temperature (+4°C - +30°C) for the duration of the shelf life.

REAGENTS AND MATERIALS PROVIDED
hCG monostep test (card): 100 items - Immunochromatographic test in a sealed pouch, containing a drying.
Plastic droppers: 100 items – plastic dropper for dispensing the sample
Instruction for use
MATERIAL REQUIRED BUT NOT PROVIDED
- Specimen collection container.
- Timer.

SPECIMEN COLLECTION AND STORAGE
Urine
1. The first morning urine typically contains the highest concentration of hCG and is therefore the best sample when performing the urine test. However, a randomly collected urine specimen may also be used.
2. Collect the urine specimen in a clean glass, plastic container. Do not use preservatives.
3. If the specimen is not used immediately following collection, but is to be used within 48 hours it should be refrigerated (2 to 8 ˚C), and brought back to room temperature (4 to 30 ºC) before testing. If specimen is not going to be used for more than 48 hours, it should be frozen at -20 °C. A frozen specimen should not be used if stored longer than 2 weeks. Prior to testing, the frozen specimen must be completely thawed, thoroughly mixed, and brought to room temperature.

ASSAY PROCEDURE
1. Take the test kit from the foil pouch.
2. Put the test kit on a flat and dry surface, use the sample dropper and add 2-3 drops (80-120 µl) of sample into the sample well S.
3. Read results at **3 minutes**. Note: a low hCG concentration might result in a weak line appearing in the test line region (T) after an extended period of time; therefore, do not interpret the result after 10 minutes.

INTERPRETATION OF RESULTS
Positive: If there are two coloured bands in the result window, this indicates that the specimen contains hCG and should be interpreted as positive result.
Negative: If there is only one coloured band in the result window, this indicates that the specimen doesn't contain a detectable level of hCG and should be interpreted as a negative result.
Invalid: If there is no coloured band in the result window, the test result is invalid. The control band will not appear if an insufficient volume of specimen is added into the test kit. Proper procedures may not have been followed in performing the test or deterioration of the test kit may have occurred. Repeat the test procedure using a new test kit.



Note: The instructions provided must be strictly followed in order to achieve optimal test reactivity with the urine specimens

LIMITATIONS OF THE PROCEDURE
1. The β-HCG Monostep Test is for in vitro diagnostic use only.
2. In addition to pregnancy, hCG has been found in patients with both gestation and non-gestation trophoblastic diseases. These conditions should be ruled out when interpreting hCG levels to establish a pregnancy diagnosis.
3. Although the test is very accurate in detecting pregnancy a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained. Consult with a physician if unexpected or inconsistent results are obtained.
4. A normal pregnancy cannot be distinguished from an ectopic pregnancy based solely on hCG levels. Also, a spontaneous miscarriage may cause confusion in interpreting test results.
5. Very low levels of hCG (less than 50mIU/ml) are present in urine specimens shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons, a test result that is weakly positive should be confirmed by retesting with a first morning urine specimen collected 48 hours later.

6. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
7. A negative result obtained from a urine specimen collected from a mother in very early pregnancy may be due to an extremely low concentration of hCG. In such cases, the test should be repeated on a fresh specimen obtained two days later.
8. If a urine sample is too dilute (i.e. low specific gravity), it may not contain a representative urinary hCG concentration. If a negative result is obtained with a low specific gravity specimen and pregnancy is still suspected, obtain a first morning urine specimen and retest.

EXPECTED VALUES

Urine hCG levels are estimated to be:

20 – 100 mIU/ml	7-20 days post conception.
37,000 – 50,000 mIU/ml	8-11 weeks after last menstrual period
< 5 mIU/ml	Healthy men or non-pregnant women

STANDARDIZATION

β-HCG Monostep Test will detect urine at concentrations of 25 mIU/ml or greater (referenced to the World Health Organization International Standard).

TEST CHARACTERISTICS

Sensitivity

β-HCG Monostep Test will detect hCG in urine at concentrations of **25 mIU/ml** or greater. This sensitivity level has been confirmed with internal hCG standards in urine, calibrated against the World Health Organization International Standard.

Specificity

The ability of β-HCG Monostep Test to specifically detect hCG was challenged through cross-reaction studies on urine samples containing known quantities of structurally and physiologically related hormones. Urine and samples spiked with 300 mIU/ml LH (human Luteinizing Hormone), 1000 mIU/ml (Follicle Stimulating Hormone) and 1000 mIU/ml TSH (Thyroid Stimulating Hormone) show negative results only.

Accuracy

A multi-center clinical evaluation was conducted comparing the results obtained using the β-HCG Monostep Test to another commercially available urine hCG Rapid test. The study included 608 urine specimens, and both assays identified 377 negative and 231 positive results. The results demonstrated >99% overall accuracy of the β-HCG Monostep Test when compared to the other hCG Rapid Test.

		A commercial hCG urine test		
		Negative	Positive	Total
β-HCG Monostep Test	Negative	377	0	377
	Positive	0	231	231
	Total	377	231	608

Sensitivity: >99.9% (98.7-100)* Specificity: >99.9% (99.2-100)*
Accuracy: >99.9% (99.5-100)* *95% Confidence Intervals

Interference

Potentially interfering drugs, protein and glucose were supplemented to normal urine specimens and positive to hCG. Baseline urine level, as well as 20 mIU/ml hCG standards were then analyzed in parallel with all samples containing a specific concentration of an interfering substance.

Acetaminophen, 20 mg/dl	Caffeine, 20 mg/dl
Acetylsalicylic acid, 20 mg/dl	Gentistic acid, 20 mg/dl
Ascorbic acid, 20 mg/dl	Glucose, 2000 mg/dl
Atropine, 20 mg/dl	Haemoglobin, 1000 mg/dl
Bilirubin, 2 mg/dl	

REFERENCE

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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

IVD	In Vitro Diagnostic Medical Device		Temperature limitation	LOT	Batch code (EXXX)		Manufacturer		Keep dry	NON STERILE	Non-sterile
	Consult Instructions for use		Use by (year/month)	REF	Catalogue number		Do not reuse		Fragile, handle with care		Keep away from heat

CONTENT (100 tests) **REF VP80417**

HCG MONOSTEP TEST	100 items
DROPPERS	100 items
INSTRUCTIONS FOR USE	1 item

EDMA CODE 12 70 05 02 00 IVD