Diagnostic Kit for β-HCG

A test for the diagnosis of β-human chorionic gonadotropin (β-hCG) to detect β-human horionic gonadotropin (β-hCG) in human whole blood, serum or plasma with the use of Immunofluorescence Analyzer.

English

- For *in-vitro* diagnostic use

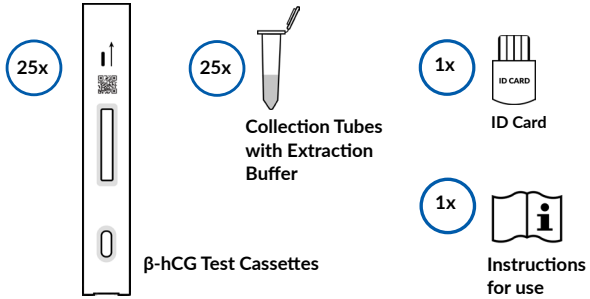
PACKING SPECIFICATION
25 Tests/ Kit (07HCG5025)

INTENDED USE
The β-hCG Test Cassette (Whole Blood/Serum/Plasma) is intended for quantitative determination of β-human chorionic gonadotropin (β-hCG) in human Whole Blood Serum or Plasma as an aid in the diagnosis of pregnancy. The test is intended for healthcare professionals use.

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 or plasma as early as 7 to 10 days after conception.[1,2,3,4] It is heterodimeric, with an α (alpha) subunit identical to that of luteinizing hormone (LH), follicle-stimulating hormone (FSH), thyroid-stimulating hormone (TSH), and β (beta) subunit that is unique to hCG. This procedure is employed to ensure that tests do not make false positives by confusing hCG with LH and FSH. (The latter two are always present at varying levels in the body, whereas the presence of hCG almost always indicates pregnancy.)
Human chorionic gonadotropin (hCG) is a hormone produced by the placenta after implantation.[5,6] The presence of hCG is detected in some pregnancy tests (HCG pregnancy strip tests). Some cancerous tumors produce this hormone; therefore, elevated levels measured when the patient is not pregnant may lead to a cancer diagnosis and, if high enough, paraneoplastic syndromes, however, it is not known whether this production is a contributing cause, or an effect of carcinogenesis. The pituitary analog of hCG, known as luteinizing hormone (LH), is produced in the pituitary gland of males and females of all ages.[5,7] This tests employ a monoclonal antibody, which is specific to the β-subunit of hCG (β-hCG).
The β-hCG Test cassette is a test that quantitatively detects the β-hCG level in Whole Blood/Serum/Plasma specimen. The test utilizes a combination of antibodies including a monoclonal anti-β-HCG antibody to selectively detect elevated levels of β-hCG. The minimum detection level is 2mIU/mL.

PRINCIPLE
The β-hCG Test Cassette (Whole Blood/Serum/Plasma) is based on Fluorescence Immunoassay for the detection of β-human chorionic gonadotropin in whole blood, serum or plasma to evaluate the pregnant in women. The specimen moves from specimen pad to absorbent pad. If the specimen contains β-hCG, it attaches to the fluorescent microspheres-conjugated anti-β-hCG antibodies. Then the complex will be captured by the capture antibodies coated on the nitrocellulose membrane (Test line). The concentration of β-hCG in the Specimen correlates linearly with the fluorescence signal intensity captured on the T line. According to the fluorescence intensity of the test and standard curve, the concentration of β-hCG in the Specimen can be calculated by Analyzer to show β-hCG concentration in specimen.

REAGENTS
The test contains anti-β-hCG antibody conjugated fluorophores and capture reagents coated on the membrane.

MATERIALS PROVIDED


MATERIALS REQUIRED BUT NOT PROVIDED
- Immunofluorescence Analyzer MPQuanti® (07IMA001)
- Pipette
- Centrifuge
- Timer

PRECAUTIONS
1. For professional *in-vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Do not interchange or mix reagents from different lots.
6. Humidity and temperature can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Read the entire procedure carefully prior to any testing.
9. The β-hCG Test Cassette should only be used with the Analyzer by approved medical professionals.

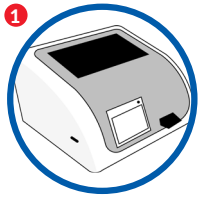
STORAGE AND STABILITY
1. The kit should be stored at 4 - 30 °C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. Do not freeze.
4. Care should be taken to protect the components of the kit from contamination.
5. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SAMPLE COLLECTION AND PREPARATION
Preparation
1. Before performing the test, please make sure that all components are brought to room temperature (15 - 30 °C). Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.
2. Take a tube with buffer solution out of the kit. Document patients name or ID on it.

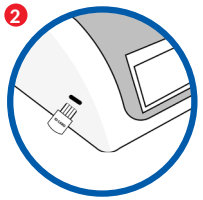
Specimen Handling
1. Collect the specimen according to standard procedures.
2. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2 - 8 °C for up to 1 day, for long term storage, specimens should be kept below -20 °C. Whole blood collected by venipuncture should be stored at 2 - 8 °C if the test is to be used within 1 day of collection. Do not freeze whole blood specimens.
3. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
4. EDTA K2, Heparin sodium, Citrate sodium and Oxalate potassium can be used as the anticoagulant tube for collecting the blood specimen.

Sample Dilution / Sample Stability
1. The specimen (**15 µL of whole blood/serum/plasma**) can be added directly with the pipette into the buffer.
2. Close the tube and shake the specimen by hand for approximately **10 seconds** so specimen and dilution buffer mix well.
3. Let the diluted Specimen homogenize for approximately **1 minute**.
4. It is best to place the diluted specimen on an ice pack and leave the specimen at room temperature for no more than 8 hours.

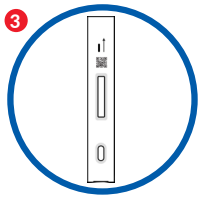
TEST PROCEDURE
Refer to Immunofluorescence Analyzer User Manual for the complete instructions for use of the Test. The test should be in room temperature.
Allow the test cassette, specimen and buffer to reach room temperature (15 - 30 °C) prior to testing.



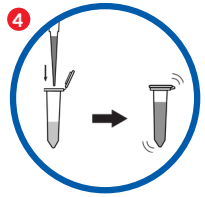
Turn on the Analyzer power.



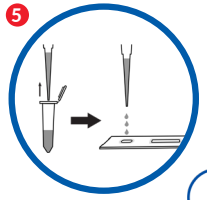
Take out the ID card and insert it into the Analyzer ID Card Slot. Choose test mode and/or sample type according to needs.



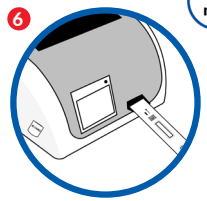
Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch. Place the test on a flat and clean surface.



Squeeze **15 µL of Whole Blood/Serum/Plasma** into the buffer tube by pipette; mix the specimen and the buffer well.



Add diluted specimen with a Pipette: Pipette **75 µL of diluted specimen** into the Specimen well of the test cassette. Start the timer at the same time.



Test results should be interpreted at **15 minutes** with the use of Immunofluorescence Analyzer.

Caution: There are different test modes of the Immunofluorescence Analyzer. The difference between them is incubation of the test cassette is outside or inside the analyzer. Choose test mode accordingly and confirm sample type. Consult the user manual of the analyzer for detailed operation information.
Operator must consult the Immunofluorescence Analyzer User Manual prior to use and become familiar with the processes and quality control procedures.

INTERPRETATION OF TEST RESULTS

Results read by Immunofluorescence Analyzer.
The result of test for β-hCG is calculated by Immunofluorescence Analyzer and display the result on the screen. For additional information, please refer to the user manual of Immunofluorescence Analyzer Analyzer.
Linearity range of β-hCG Test is 2 - 200,000 mIU/mL.

QUALITY CONTROL

Each β-hCG Test Cassette contains internal control that satisfies routine quality control requirements. This internal control is performed each time a specimen is tested. This control indicates that the test cassette was inserted and read properly by Immunofluorescence Analyzer Analyzer. An invalid result from the internal control causes an error message on Immunofluorescence Analyzer indicating that the test should be repeated. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1. The β-hCG Test Cassette (Whole Blood/Serum/Plasma) is for professional *in-vitro* diagnostic use, and should only be used for the quantitative detection of β-hCG. The test works only when the test procedures are precisely followed.
2. This test may produce false positive results. A number of conditions other than pregnancy, including testicular tumors, prostate cancer, breast cancer, and lung cancer, cause elevated levels of β-hCG.[8] Therefore, the presence of β-hCG in Specimen should not be used to diagnose pregnancy unless these conditions have been ruled out.
3. The results of β-hCG Tests are based on measuring the levels of β-hCG in a specimen. It should not be used as the sole criterion for treatment decisions. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.

EXPECTED VALUES

Normal values for males or non-pregnant females <5 mIU/mL in Serum/plasma.

Gestational weeks	Serum / Plasma β-hCG reference values (mIU/mL)
0.2 - 1	5 - 50
1 - 2	50 - 500
2 - 3	100 - 5,000
3 - 4	500 - 10,000
4 - 5	1,000 - 50,000
5 - 6	10,000 - 100,000
6 - 8	15,000 - 200,000
8 - 12	10,000 - 100,000

Note: Whether you have high or low levels of the hormone is not the key indicator of a healthy pregnancy. This is because many factors can influence hCG levels, including maternal smoking, body mass index (BMI), ethnicity, parity (the number of times a woman has given birth), and hyperemesis gravidarum (severe morning sickness) and so on.

PERFORMANCE CHARACTERISTICS

1. Accuracy
The test deviation is ≤±15%.

2. Sensitivity
The β-hCG Test Cassette (Whole Blood/Serum/Plasma) can detect levels of β-hCG as low as 2 mIU/mL in Whole Blood/Serum/Plasma.

3. Detection range
2 - 200,000 mIU/mL

4. Linearity range
2 - 200,000 mIU/mL, R≥0.990

5. Cross-reactivity
The β-hCG Test Cassette (Whole Blood/Serum/Plasma) reference range level is 5mIU/mL. The addition of LH (300 mIU/mL), FSH (1,000 mIU/mL), and TSH (1,000 µIU/mL) to negative (0 mIU/mL HCG) and positive (5 mIU/mL HCG) specimens showed no cross-reactivity.

6. Interfering Substances
The following potentially interfering substances were added to β-hCG negative and positive specimens, respectively.

Acetaminophen: 20 mg/dL
Acetylsalicylic Acid: 20 mg/dL
Ascorbic Acid: 20 mg/dL
Atropine: 20 g/dL
Bilirubin: 2 mg/dL
Caffeine: 20 mg/dL
Gentisic Acid: 20 mg/dL
Glucose: 2 g/dL
Hemoglobin: 500 mg/dL

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

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8. Dawood MY, BB Saxena, R Landesman Human chorionic gonadotropin and its subunits inhydatidiform mole and choriocarcinoma, Obstet. Gynecol. 1977; 50(2): 172-181.

SYMBOLS

	Consult Instructions For Use	REF	Catalogue Number
IVD	For *In-vitro* Diagnostic use	EC REP	Authorized Representative
30 °C 4 °C	Store at 4 °C ~ 30 °C		Do Not Reuse
	Keep away from Sunlight		Do Not Use if Package is Damaged
LOT	Lot Number	CE	European Conformity
	Manufacturer		Date of Manufacture
	Expiration Date	Σ	Tests per Kit
UDI	Unique Device Identifier		

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