GP

CE IVD

HCG+β

Fast Test Kit

(Immunofluorescence Assay)

IF1013 for Getein1100
IF5013 for Getein1160
IF3013 for Getein1180
REF IF4013 for Getein1200
IF2013 for Getein1600

User Manual

INTENDED USE

HCG+β Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of human chorionic gonadotropin (HCG) in human serum or plasma samples. This test is used as an aid in pregnancy test.

SUMMARY

Human chorionic gonadotropin (HCG) is a glycoprotein hormone produced by the placenta, a component of the fertilized egg, after conception. The biologically active hormone (intact HCG) is composed of noncovalently linked α and β subunit. The alpha subunit is similar to hormone (LH), follicle-stimulating hormone (FSH), thyroid-stimulating hormone (TSH). whereas beta subunits is unique to HCG and confers its biological and immunological specificity. During a normal pregnancy, HCG level can be detected soon after conception. It will double every 72 hours and reach its peak in the first 8~11 weeks of pregnancy.
HCG measurement with blood or urine can be used as an aid in pregnancy test. Regular HCG has been known as a promoter of corpus luteal progesterone production, even though this function only explains 3 weeks of a full gestations production of regular HCG. HCG-positive indicates an implanted blastocyst and mammalian embryogenesis. Elevated values of HCG during pregnancy are indicative of chorionic carcinoma, hydatiform mole, or multiple pregnancy. HCG+β measurements can also be used in conjunction with other parameters during the second trimester of pregnancy to assess the risk of trisomy 21 (Down syndrome).

PRINCIPLE

The test based on the principle of sandwich immunoassay. The test uses two anti-human β-HCG monoclonal antibodies. One monoclonal antibody is coated on the sample pad, the other monoclonal antibody is coated on the detection zone. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human β-HCG monoclonal antibody binds with the HCG and β-HCG in sample and forms an antigen-antibody complex. The complex moves to the test card detection zone by capillary action. In the dection zone, marked antigen-antibody complex will be captured on the test line by another set of monoclonal antibody against human β-HCG.
Then insert test card into Getein1100/Getein1160/Getein-1180 Immunofluorescence Quantitative Analyzer/automatically inserted by Getein1200/Getein1600 Immunofluorescence Quantitative Analyzer (hereinafter referred to as Getein1100, Getein1160, Getein1180, Getein1200 and Getein1600), the concentration of HCG and β-HCG in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1160/Getein1180/Getein1200/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100/Getein1160/Getein1180 contains:
Package specifications: 25 tests/box, 10 tests/box
1) HCG+β test card in a sealed pouch with desiccant
2) Disposable pipet
3) Sample diluent
4) User manual: 1 piece/box
5) SD card: 1 piece/box
2. A kit for Getein1200/Getein1600 contains:
Package specifications: 2×24 tests/kit, 2×48 tests/kit
1) Sealed cartridge with 24/48 Getein HCG+β test cards
2) User manual: 1 piece/box
Materials required for Getein1200/Getein1600:
1) Sample diluent: 1 bottle/box
2) Box with pipette tips: 96 tips/box
3) Mixing plate: 1 piece/box
3. Sample diluent composition:
Phosphate buffered saline, proteins, detergent, preservative, stabilizer.
4. A test card consists of:
A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with a fluorescence latex-labelled anti-human β-HCG monoclonal antibody, the test line is coated with another anti-human β-HCG monoclonal antibody, and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.
Note: Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1180 Immunofluorescence Quantitative Analyzer
Getein1160 Immunofluorescence Quantitative Analyzer
Getein1200 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test card at 4~30℃ with a valid period of 24 months.
Use the test card for Getein1100/Getein1160/Getein1180 within 1 hour once the foil pouch is opened.
For test card of Getein1200/Getein1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Do not use the kit beyond the expiration date.
3. Do not use the test card if the foil pouch or the cartridge is damaged.
4. Do not open pouches or the cartridge until ready to perform the test.
5. Do not reuse the test card.
6. Do not reuse the pipet.
7. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
8. Carefully read and follow user manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***serum, plasma. Heparin and sodium citrate*** should be used as the anticoagulant for plasma. Samples should be free of hemolysis.
2. If testing is delayed, serum and plasma samples may be stored up to 5 days at 2~8℃ or stored at -20℃ for 6 months before testing.
3. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
4. Do not use heat-inactivated samples.
5. SAMPLE VOLUME***(for Getein1100): 100 μL***
(for Getein1160/Getein1180): 10 μL

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample should be brought to room temperature before testing.
For Getein1100:
3. Confirm SD card lot No. in accordance with test kit lot No.. Perform “SD card” calibration when necessary.
4. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
5. Put the test card on a clean table, horizontally placed.
6. Using sample transfer pipette, deliver ***100 μL*** of sample into one tube of sample diluent, mix gently and thoroughly. Then drop ***100 μL*** of sample mixture into the sample port on the test card.
7. ***Reaction time: 10 minutes.*** Insert the test card into Getein1100 and press "ENT" button or click on “Start” icon (for Android Getein1100) after reaction time is elapsed. The result will be shown on the screen and printed automatically.
For Getein1160/Getein1180:
8. Confirm SD card lot No. in accordance with test kit lot No.. Perform “SD card” calibration when necessary.
9. Enter testing interface of Getein1160/Getein1180.
10. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
11. Put the test card on a clean table,horizontally placed.
12. Using sample transfer pipette, deliver ***10 μL*** of sample into one tube of sample diluent, mix gently and thoroughly. Then drop ***100 μL*** of sample mixture into the sample port on the test card.
13. ***Reaction time: 10 minutes.*** Insert the test card into Getein1160/Getein1180 immediately after sample loading. The analyzer will count down the reaction time and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.
For Getein1200/Getein1600:
14. Each cartridge for Getein1200/Getein1600 contains a specific RFID card which can calibrate automatically.
15. Place the sample diluent at the correct position in Getein1200/Getein1600.
16. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1200/Getein1600 will do the testing and print the result automatically.

Notes:
1. It is required to perform “SD card” calibration when using a new batch of kits for Getein1100/Getein1160/Getein1180.
2. It is suggested to calibrate once for one batch of kits for Getein1100/Getein1160/Getein1180.
3. Make sure the test card and the sample insertion is correct and complete.

TEST RESULTS

Getein1100/Getein1160/Getein1180/Getein1200/Getein1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/Getein1160/Getein-1180/Getein1200/Getein1600.

EXPECTED VALUE

The expected normal value for HCG was determined by testing samples from 315 healthy, non-pregnant individuals. The 97.5th percentile of the concentration for HCG is 5.1 mIU/ml. According to the literature, HCG results greater than or equal to 25.0 mIU/mL (IU/L) are considered positive. Representative HCG ranges during normal pregnancy are shown in the table below. Because other clinical reference citations may show different values, it is recommended that each laboratory establish its expected values for the population it serves.

Serum HCG Levels During Normal Pregnancy	
Gestational weeks	HCG (IU/L)
0.2-1 week	5-50
1-2 week	50-500
2-3 week	100-5,000
3-4 week	500-10,000
4-5 week	1,000-50,000
5-6 week	10,000-100,000
6-8 week	15,000-200,000

PERFORMANCE CHARACTERISTICS

Measuring Range	5.0~100000.0 mIU/ml
Lower Detection Limit	≤ 5.0 mIU/ml
Within-Run Precision	≤10%
Between-Run Precision	≤15%

LIMITATIONS

1. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
2. Samples containing interferents may influence the results. The table below listed the maximum allowance of these potential interferents.

Interferent	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	5 g/L	25 g/L	0.1 g/L
Interferent	RF	Human anti-mouse antibody	Biotin
Concentration (Max)	3000 IU/mL	120 g/L	80 ng/mL

REFERENCES

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3. Cole LA. New discoveries on the biology and detection of human chorionic gonadotropin. Reprod. Biol. Endocrinol. 7: . doi:10.1186/1477-7827-7-8.
4. Hoermann R, Spoettl G, Moncayo R, etal. Evidence for the presence of human chorionic gonadotropin (hCG) and free beta-subunit of hCG in the human pituitary. J. Clin. Endocrinol. Metab. 71 (1):179-186.
5. EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
6. EN ISO 18113-2:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on HCG+β Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more detail in the European Standard EN ISO 15223-1:2021.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult *instructions for use* or consult electronic *instructions for use*	LOT	Batch code
	Temperature limit	IVD	*In vitro* diagnostic medical device
	Contains sufficient for <n> tests	EC REP	Authorized representative in the European Community/European Union
CE	CE mark		Do not use if package is damaged and consult *instructions for use*
REF	Catalogue number		

Thank you for purchasing HCG+β Fast Test Kit (Immunofluorescence Assay). Please read this user manual carefully before operating to ensure proper use.

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