GP

CE IVD

HCG+β

Fast Test Kit

(Immunofluorescence Assay)

IF1013 for Getein1100
IF4013 for Getein1200
IF2013 for Getein1600

Instructions for Use REF

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. This test is used as an aid in pregnancy test. For professional and laboratory use.
This test can NOT be used to guide the diagnosis of pair trisomy 21.

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 non-covalently linked α and β subunit. The alpha subunit is similar to luteinizing hormone (LH), follicle-stimulating hormone (FSH) and thyroid-stimulating hormone (TSH). whereas the beta subunit 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, hydatidiform mole, or multiple pregnancy.

PRINCIPLE

HCG+β Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay based on the double antibody sandwich principle. The test uses two HCG monoclonal antibodies. One HCG monoclonal antibody conjugated with fluorescence latex and another HCG monoclonal antibody is coated on the detection zone. After the sample has been applied to the test strip, the fluorescence -labelled 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 detection zone, marked antigen-antibody complex will be captured by another HCG monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of HCG and β-HCG in sample. Fluorescent signals intensity can be analyzed by applicable device thus the HCG and β-HCG in sample be detected quantitatively.

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1200 Immunofluorescence Quantitative Analyzer
Getein 1600 Immunofluorescence Quantitative Analyzer

CONTENTS

Materials provided	Getein 1100		Getein 1200/Getein 1600	
	10 T/kit	25 T/kit	2×24 T/kit	2×48 T/kit
HCG+β test card	10 pcs	25 pcs	24 test cards in 1 cartridge, and 2 cartridges in 1 box	48 test cards in 1 cartridge, and 2 cartridges in 1 box
Disposable pipet	10 pcs	25 pcs	/	/
Sample diluent	10*0.4 mL/tube	25*0.4 mL/tube	1 box	1 box
Instructions for use	1 pc	1 pc	1 pc	1 pc
SD card	1 pc	1 pc	1 pc in each cartridge	1 pc in each cartridge

HCG+β test card
A test card mainly consists of: Fluorescence -labelled HCG monoclonal antibody, HCG monoclonal antibody.
Sample diluent
(1) Sample diluent for Getein 1100 is 0.4 mL contained in each tube mainly consists of:
- Sample diluent main contains phosphate buffer (20 mmol/L), NaN3 (＜0.1%).

(2) Sample diluent for Getein 1200/ Getein 1600 is an independent packing box mainly consists of:
- Phosphate buffer (20 mmol/L), NaN3 (＜0.1%) (25 mL/ bottle for Getein 1200, 30 mL/bottle for Getein 1600),
- Box with pipette tips (96 tips/box),
- Mixing plate (1 piece/box).

Note:
1. The standard curve data can be written to RFID card in the kit. According to the function of RFID card, we define it as "Standard Curve Data Card", short for "SD Card".
2. Do not mix or interchange different batches of kits.

STORAGE AND STABILITY

Store the test kit at 4~30°C with a valid period of 24 months.
Use the test card for Getein 1100 within 1 hour once the foil pouch is opened.
For test card of Getein 1200/Getein 1600: 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. Handle all specimens as potentially infectious. The foil bag is nondegradable. Proper handling and disposal methods should be followed in accordance with local regulations.
7. Carefully read and follow the instructions for use to ensure proper test performance.
8. Sample diluent contains NaN_3(<0.1%) as a preservative. NaN_3 can react with copper or lead pipes in drain lines to form explosive compounds. Dispose properly in accordance with local regulation.

SPECIMEN COLLECTION AND PREPARATION

1. Serum and plasma can be used for this assay. Heparin and sodium citrate should be used as the anticoagulant for plasma.
2. If testing is delayed, serum and plasma samples may be stored up to 7 days at 2~8°C or stored at -20°C for 6 months before testing.
3. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.

TEST PROCEDURE

1. User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.
2. Test kit and sample should be brought to room temperature before testing.

For Getein 1100:
1. Confirm SD card lot No. in accordance with the test kit lot No., perform “SD card” calibration when necessary.
2. Select the corresponding model on the analyzer according to the sample type (see the user manual of analyzer for details).
3. Remove test card and disposable pipet from the sealed pouch immediately before use and put them on a clean table, horizontally placed.
4. Using disposable pipet or 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.
5. ***Reaction time: 10 minutes***. Insert the test card into Getein 1100 and press "ENT" button or click on “Start” icon (for Android Getein 1100) after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein 1200/Getein 1600:
1. Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card which can calibrate automatically.
2. Place the sample diluent at the correct position in Getein 1200/Getein 1600.
3. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein 1200/Getein 1600 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 Getein 1100.
2. It is suggested to calibrate once for one batch of kits for

Getein 1100.

3. Make sure the test card and the sample insertion is correct and complete.

TEST RESULTS

Getein 1100/Getein 1200/Getein 1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein 1100/Getein 1200/Getein 1600.

EXPECTED VALUE

The expected normal value for HCG is determined by testing samples from 315 healthy, non-pregnant individuals. The 97.5th percentile of the concentration for HCG is 5.1 mIU/ml (IU/L). 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
Limit of detection	≤ 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. Interferents in samples may influence the results. The table below listed the maximum allowance of these potential interference:

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

1. Tietz NW, Clinical Guide to Laboratory Tests, 3rd Ed. 1995. p. 134-136.
2. Hohnadel DC, Kaplan LA. Beta-hCG. Methods in clinical chemistry. Edited by Pesc, AJ and Kaplan LA. St. Louis, MO: The C.V. Mosby Company, 1987.
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		Caution

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

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