CE IVD

# One Step Test for HCG+β

(Colloidal Gold)

User Manual Cat.# CG1013

## INTENDED USE

One Step Test for HCG+β (Colloidal Gold) is intended for *in vitro* quantitative determination of human chorionic gonadotropin (HCG) in serum. 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 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, 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 and competitive immunoassay together. The test uses two anti-human β-HCG monoclonal antibodies and a β-HCG recombinant antigen. One monoclonal antibody is coated on the sample pad, the other monoclonal antibody and β-HCG recombinant antigen are coated on the detection zone. After the sample has been applied to the test strip, the gold-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, meanwhile, HCG and β-HCG in the sample will compete with β-HCG recombinant antigen on nitrocellulose matrix for gold-labelled anti-human β-HCG monoclonal antibody.

Then insert test card into FIA8000 Quantitative Immunoassay Analyzer (hereinafter referred to as FIA8000), the concentration of HCG and β-HCG in sample will be measured and displayed on the screen. The value will be stored in FIA8000 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

## CONTENTS

A kit contains:

1. Getein HCG+β test card in a sealed pouch with desiccant ..... 25
2. Disposable pipet ..... 25
3. User manual ..... 1
4. SD card ..... 1
5. Whole blood buffer ..... 1

A test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (a gold-labelled anti-human β-HCG monoclonal antibody is coated at the border of the nitrocellulose membrane and sample pad, the detection zone is coated with another anti-human β-HCG monoclonal antibody and β-HCG recombinant antigen, and the control zone is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

**Note: Do not mix or interchange different batches of kits.**

## APPLICABLE DEVICE

FIA8000 Quantitative Immunoassay Analyzer

## STORAGE AND STABILITY

Store the test card at 4~30℃ with a valid period of 24 months. Use the test card within 1 hour once the foil pouch is opened.

## PRECAUTIONS

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

## SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***serum, plasma, whole blood. Heparin and sodium citrate*** should be used as the anticoagulant for plasma and whole blood sample. Samples should be free of hemolysis.
2. If testing will be 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: ***100 μl***.

## TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample should be brought to room temperature before testing.
3. Confirm SD card lot No. in accordance with test kit lot No.. Perform “QC (SD)” calibration when necessary (Details refer to 8.2.1 of FIA8000 User Manual).
4. On the main interface of FIA8000, press "ENT" button to enter testing interface.
5. Remove the test card from the sealed pouch immediately

before use. Label the test card with patient or control identification.
6. Put the test card on a clean table, horizontally placed.
7. Using sample transfer pipette, deliver ***100 µl*** of sample (or 4 drops of sample when using disposable pipet) into the sample port on the test card.
8. ***Reaction time: 10 minutes.*** Insert the test card into FIA8000 and press "ENT" button after reaction time is elapsed. The results will be shown on the screen and printed automatically.

**Notes:**
1. It is required to perform "QC (SD)" calibration when using a new batch of kits.
2. It is suggested to calibrate once for one batch of kits.
3. Make sure the test card insertion is correct and complete.

## TEST RESULTS

**Valid:** When a purplish-red band appears at the control area (C), use FIA8000 to analyze the test card and get the result.
**Invalid:** If no colored band appears in the control area (C), the test result is invalid. The test should be repeated and if the same situation happened again, please stop using this batch of products and contact your supplier.

## EXPECTED VALUE

The expected normal value for HCG was determined by testing samples from 315 healthy, non-pregnant individuals. The 97.5$^{th}$ percentile of the concentration for HCG is 5.1 mIU/ml. According to the literature, HCG results greater than or equal to 25 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 | 5~10000 mIU/ml |
| Lower Detection Limit | ≤ 5 mIU/ml |
| Within-Run Precision | ≤10% |
| Between-Run Precision | ≤15% |

Method Comparison:
The assay was compared with Roche Cobas E601 Immunology Analyzer and its matching HCG+β test kits with 200 serum samples (75 positive samples and 125 negative samples). The correlation coefficient (r) for HCG+β is 0.989.

## 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


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: 8. 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 18113-1:2009 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
6. EN ISO 18113-2:2009 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009).


## DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on One Step Test for HCG+β (Colloidal Gold) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 980:2008 and International Standard ISO 15223-1:2007.

| Key to symbols used | | | |
|---|---|---|---|
|  | Manufacturer |  | Expiration date |
|  | Do not reuse |  | Date of manufacture |
|  | Consult instructions for use | LOT | Batch code |
|  | Temperature limitation | IVD | *In vitro* diagnostic medical device |
|  | Sufficient for | EC REP | Authorized representative in the European Community |
| CE | CE mark |  | Do not use if package is damaged |

Thank you for purchasing One Step Test for HCG+β (Colloidal Gold). Please read this user manual carefully before operating to ensure proper use.

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