Hipro Hipro Biotechnology Co.,Ltd

EN
ENGLISH

β-HCG

β-Human Chorionic Gonadotropin Test Kit

(Fluorescence Immunoassay Method)

Instructions for Use

Version:A/2

REF HP-Palm-β-HCG-25

Manufacturer

Shijiazhuang Hipro Biotechnology Co.,Ltd.

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EC REP Lotus NL B.V.

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Product Name

General Name: β-Human Chorionic Gonadotropin Test Kit

(Fluorescence Immunoassay Method)

Package Specification

25 Tests/Kit.

Intended Use

The Hipro β-Human Chorionic Gonadotropin (β-HCG) Test Kit is an vitro diagnostic test for the quantitative measurement of β-Human Chorionic Gonadotropin (β-HCG) in human serum, plasma or whole blood.

Human chorionic gonadotropin (HCG) is a glycoprotein secreted by the trophoblastic cells of the placenta, consisting of α and β dimer glycoproteins. Normal pregnant women have a significant increase in β-HCG 9 to 13 days after conception, which is an important indicator for monitoring early pregnancy. The determination of β-HCG can also diagnose ectopic pregnancy, threatened abortion, mole and trophoblastic tumor, and is also an important indicator of post-treatment follow-up and prognosis observation.

Test Principle

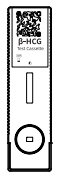
This test kits based on the double antibody sandwich method to determine the concentration of β-HCG in human serum, plasma or whole blood.

The β-HCG antigen in the sample binds to the mouse anti-human β-HCG antibody labeled with fluorescent microspheres on the binding pad to form an immune complex. Immune complex under the capillary action to move forward along the cellulose nitrate membrane, by testing area on nitrocellulose membrane (T) in advance of package is another plant resistance to capture beta HCG antibodies, extra marks antibodies are in quality control area (C) be wrapped up on the NC membrane sheep polyclonal antibody against rat IgG capture. After the reaction is complete, the fluorescence intensity on the T and C lines is detected by an immunofluorescence quantitative analyzer, and the concentration of β-HCG in the sample is calculated.

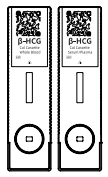
Material Provided

Component	25Kits
Sample Diluent	25
Calibration Cassette	2
Test Cassette	25
Instructions for Use	1
Capillary device with dropper	25

Test Cassette



Calibration Cassette

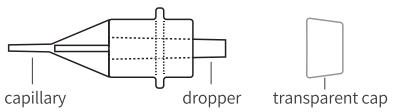


QR code is with built-in parameter for each assay.

Sample Diluent

Instructions for Use

Capillary device with dropper



Material Required But Not Provided

Timing device

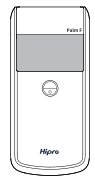
Storage&Validity

Store test kit at: 2°C-30°C until the expiration date indicated on the label.

Avoid exposure to direct sunlight. The test kit is stable for 18months when unopened.

Perform the test within 1 hour when opened.

Applicable Instrument



Palm F Fluorescence Immunoassay Analyzer

Specimen type

1. The specimen type of β-HCG test kit is human serum, plasma or whole blood.
2. EDTA and heparin anticoagulants recommended for plasma/whole blood.
3. After sample collection, please test as soon as possible.
4. Fresh collected specimen should be measured within 2 hours otherwise should be stored at 2° C~8° C up to 24 hours .

Storage

1.For long-term storage the whole blood should centrifuged into plasma and serum/plasma stored at -20 °C up to 3 months.

2.Avoid repeated freezing and thawing.

3.Avoid hemolysate.

Required volume

10μL is required for serum,plasma or whole blood, used for dilution.

80μL is required of diluted sample for each determination.

This volume does not include the dead volume(unusable volume in the sample container) or the additional volume required to make replicate test or other tests to be performed on the same sample.

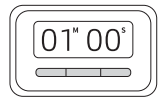
β-HCG Test Kit Instruction Guide

Before You Begin

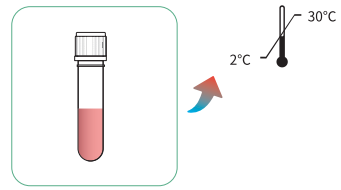
1a Please read the β-HCG IFU and applicable instrument User Manual carefully before operation. Please follow the instructions strictly.

Before You Begin

1b A timing device (phone, clock or timer) is required but not provided.

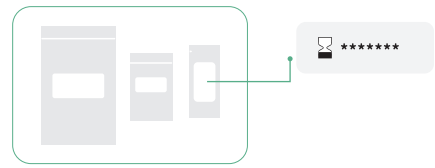


1c Allow the sample back to room temperature.



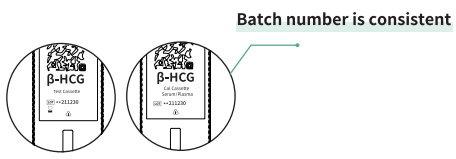
1d Ensure the test kit is at room temperature for at least 30 minutes prior to use.

1e Check on the expiration date on labels of different component.



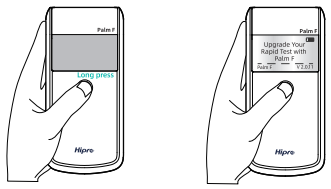
1f Make sure the lot number on calibration cassette and test cassette are same.

Do not misuse the cassettes with different lot.



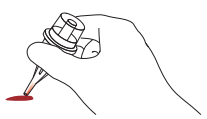
Test Procedures

2a Turn on the applicable instrument according to the User Manual.

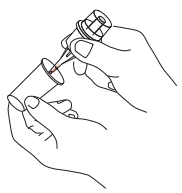


2b Insert the calibration cassette into the analyzer as the direction shows, to let the built-in parameter be read.

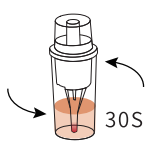
3a Use the quantitative capillary to collect the specimen (whole blood/serum/plasma.) Make sure the transparent cap is screwed tightly onto the dropper part.



3b Insert the capillary(with collected sample) into the tube.



3c Make sure the tube and the capillary device are tightly screwed and shake from left to right for 30seconds; During shake, make sure the transparent cap tightly covers the dropper and screws with the device and make sure the capillary is down toward.

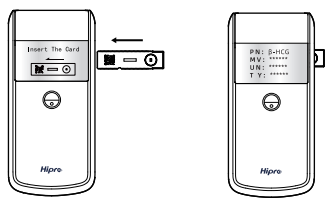


Test Procedures

3d Add 2 drops of mixed liquid from the sample diluent tube onto the sample well of test cassette.

4a Wait for 15 minutes before reading results.

4b Insert the test cassette into the analyzer and the analyzer will display the results automatically.



! Avoid bubbles when collecting samples.

Reference Value

153 healthy male, 153 healthy female and 153 pregnant woman(2-4weeksk,5-6weeks, 6-8weeks, 8-10weeks and 10-12weeks) and the results (95%) meet the linearity range:

The normal reference range for healthy male and female is <5mIU/mL.

Pregnant woman:

2-4 weeks (5.4-708.0) mIU/mL

5-6 weeks (217.0-32177.0) mIU/mL

6-8 weeks (4059.0-149094.0) mIU/mL

8-10 weeks (31366.0-170409.0) mIU/mL

10-12 weeks (44186.0-201615.0) mIU/mL

Recommended that each laboratory establish its own reference range.

Interpretation

1.For diagnostic purposes, the results obtained from this assay should always be used in combination with the clinical examination, patient medical history, and other findings.

2.If the test results are different from clinical symptoms, retesting is recommended.

Precautions and limitations

1.The Hipro β-Human Chorionic Gonadotropin (β-HCG) test kit is an vitro diagnostic test for the quantitative measurement of β-Human Chorionic Gonadotropin in human serum, plasma or whole blood.

2.For terminal purposes, the results obtained from this assay should always be used in combination with the clinical examination, patient medical history, and other findings

3.Testing the same sample with test kits from different manufacturers may result in different test results due to methodological or antibody specificity reasons, so results from testing with different test kits should not be directly compared with each other to avoid incorrect medical interpretation.

4.Some drugs and structural analogues of β-HCG such as acetaminophen (20mg/dL), acetylsalicylic acid (65mg/dL), heparin (7,200 IU/dL), human serum albumin (6mg/dL), and ibuprofen (3,000 mg/dL) may be cross-reactive.

Performance Characteristics

1. **Appearance**

   The inside package should be sealed tightly and no air leakage; the information on label is complete and clear. The surface of the test cassette should be smooth.

2. **Strip width**

   The width of strip should be ⩾2.5mm.

3. **Liquid flow speed**

   The speed should be ⩾10mm/min.

4. **Linearity**

   Within range 1mIU/mL-10000mIU/mL, the correlation coefficient (r) should be ⩾0.990.

5. **Within-lot precision**

   The coefficient of variation (CV) should be ⩽15%.

6. **Between-lot precision**

   The coefficient of variation (CV) should be ⩽15%.

7. **Accuracy**

   The relative deviation should be ⩽15%.

8. **Limit of detection(LoD)**

   The LoD should be ⩽1mIU/mL.

9. **Specificity**

   The FSH test result of 200IU/L should be < 2.5IU/L.

   The LH test result of 200IU/L should be < 2.5IU/L.

   The TSH test result of 100IU/L should be < 2.5IU/L.

Precautions

1.For in vitro diagnostic us, do not reuse, do not use expired product.

2.All samples should be considered potentially infectious and suitable protective measures should be taken. Laboratory gloves should be worn while handling patient' sample,disposal of waste, storage, mixing and testing. Disposal of all wast material should be in accordance with local guidelines.

3.Do not use damaged test kits, or expired test cassette.

4.Make sure the lot number on ID card and test cassette are same. Do not misuse the reagents with different lot.

5.The desiccant inside the package not to be used for other purposes.

6.The test cassette and the components are only match with the suitable fluorescence immunoassay analyzer.

7.Avoid electromagnetic or vibration environment for analyzer; The vibration of the instrument is normal when it working.

8.Do not insert the polluted cassette into analyzer. Please dispose the used test cassette properly.

9.Any questions or suggestions about the test kits, please contact the manufacturer.

Symbols used on labels

Symbol	Usage	Symbol	Usage
	Use-By date		Do not freeze
LOT	Batch code		Biological risks
	Manufacturer		Do Not Reuse
	Temperature Limit		Date of manufacture
	Contains sufficient for <n> tests		
	Do not use if package is damaged		
	Consult Instructions for use		
	Keep Away from Sunlight		
IVD	In Vitro Diagnostic Medical device		
EC REP	Authorized Representative in the European Community		
CE	CE Mark		

Reference

1. Xie Xing, Gou Wenli, Lin Zhongqiu, et al. Gynecology and Obstetrics [M]. 9th Ed. Beijing: People's Medical Publishing House, 2018:35.

2. PEKTEZEL M Y, BAS D F, TOPCUOGLU M A, et al. Paradoxical consequence of human chorionic gonadotropin misuse [J]. J Stroke Cerebrovasc Dis, 2015, 24(1): 17 — 19.

Approval Date &Revision Date

Approval Date: Jul 10, 2023

Revision Date: Aug 3, 2023

Revision Date: Dec 22, 2023

CE IVD

工艺：70g双胶纸，双面印刷，横向4折页，竖向对折　展开尺寸：32*25cm，第一页的左上角项目名称为封面