CE

β-HCG Rapid Test Kit

Instructions for use | IVD For in vitro diagnostic use only.

REF A02025002 | Σ 25 Tests

【Product Name】

β-HCG Rapid Test Kit

【Intended Use】

The Anbio β-HCG Rapid Test Kit along with Anbio FIA Meter is a fluorescence immunoassay for quantitative measurement of Human chorionic gonadotropin (β-HCG) in human whole blood, serum or plasma. The test kit is used as an aid in the early detection of pregnancy.

⚠ ***For professional use only.***

【Summary】

Human chorionic gonadotropin (hCG) is a glycoprotein with a molecular weight of 38000, secreted by the placenta. Like other glycoprotein hormones (hLH, hTSH and hFSH), hCG contains two different subunits, an α- and a β-chain, linked by noncovalently bindings. The primary structures of the α subunits of these hormones are virtually identical, while their β subunits, responsible for the immunological and biological specificity, are different. Thus a specific determination of hCG can only be made by the determination of its β component. The measured hCG content results almost exclusively from intact hCG molecules but there can be a contribution, albeit a usually negligible fraction of the total, from the free β-HCG subunit. hCG appears in the serum of pregnant women five days after the implantation of blastocyst and its concentration continually increases until the third month of the pregnancy.

【Test Principle】

The Anbio β-HCG Rapid Test Kit is based on fluorescence immunoassay technology. The Anbio β-HCG Rapid Test Kit uses a sandwich immuno detection method. When sample is added to the sample well of the test, the fluorescence-labeled detector β-HCG antibody binds to β-HCG antigen in the specimen. As the sample mixture migrates on the nitrocellulose matrix of test strip by capillary action, the complexes of detector antibody and β-HCG are captured to anti-β-HCG antibody that has been immobilized on test strip. Thus the more β-HCG antigen is in the specimen, the more complexes are accumulated on test strip. Signal intensity of fluorescence of detector antibody reflects amount of β-HCG captured and Anbio FIA Meter shows β-HCG concentration in the specimen.

【Main Components】

The following components are included in the β-HCG Rapid Test Kit:

Supplied materials:

Component	Main Ingredients
Test Cartridge	1) T line: Mouse anti-β-HCG monoclonal antibody (coated) 2) C line: Goat anti-rabbit IgG polyclonal antibody 3) Binding pad: Fluorescent microsphere-labeled mouse anti- β -HCG monoclonal antibody (labeled) and fluorescent microsphere-labeled rabbit IgG polyclonal antibody
IC Card	/
Sample Diluent	10mmol/L PBS

Optional Materials:

1. Sterile lancets (for Fingerstick Whole Blood only)
2. Alcohol pads (for Fingerstick Whole Blood only)
3. Disposable pipettes (50μL)
4. β-HCG Quality control (LEVEL 1, LEVEL 2)

Materials Required but not Provided:

1. Transfer Pipette Set
2. Specimen Collection Containers
3. Timer
4. Centrifuge (for Plasma/Serum only)
5. Anbio FIA Meter (model number: AF-100, AF-100s, AF-1200, AF-100C)

【Storage Conditions and Shelf Life】

Component	Storage- Temperature limitation	Stability
Test Cartridge		The shelf life is up to 24 months. Please refer to use-by date on the label. Test Cartridge should be used within 1 hour after opening the pack.
IC Card		/
Sample Diluent		The diluent is stable up to 24 months. Please refer to use-by date on the label.

⚠【Warnings and Precautions】

1.This kit is for in vitro diagnostic use only.
2. Do not mix components from different kit lots.
3. Do not use test kit beyond the expiration date.
4. Do not use Test Cartridge if its lot # does not match with IC Card # that is inserted onto the equipment.
5. The Anbio β-HCG Rapid Test Kit is only operational in the Anbio FIA Meter.
6. Do not use the Test Cartridge if the pouch is punctured or not well sealed.
7. The Test Cartridge and Meter should be used away from vibration and magnetic field. During normal usage, the Meter itself may cause vibration, which should be regarded as normal.
8. Use separate clean pipette tips and detector diluent tubes for different specimens.
9. Blood specimens, used Test Cartridges, pipette tips and detector diluent tubes should be handled and disposed in accordance with standard procedures and relevant regulations of microbiological hazard materials.
10. The results should be interpreted by the physician along with clinical findings and other laboratory test results.

【Specimen Collection and Preparation】

The test can be performed with serum or plasma or whole blood.The plasma and whole blood samples are recommended to use EDTA, heparin or sodium citrate for anticoagulation. Other body fluids and samples may not get accurate results.

For Serum and Plasma:

1. Separate the serum/plasma from blood as soon as possible to avoid hemolysis.
2. Test should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2℃～8℃ for up to 3 days. For long-term storage, specimens should be kept below -20℃.

For Whole Blood Collected by Venipuncture:

1.Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube with suitable anticoagulant.
2.It is recommended that specimens should be tested immediately. Do not leave the specimens at room temperature for prolonged periods. If the specimens are not tested immediately, they may be stored at 2℃～8℃.
3.It's not suitable to test the whole blood samples storing at 2℃～8℃ for more than 2 days.

For Fingertip Whole Blood Samples:

1.Clean the puncture site with the alcohol pad.
2.After the alcohol is dried, the fingertips are punctured with safety Lancet to form blood droplets.
3.Lay the disposable pipettes, do not squeeze, automatically collect fingertip whole blood for 50μL.
4. It is recommended that specimens should be tested immediately.

【Test Procedure】

Refer to Anbio FIA Meter Operation Manual (attached to Anbio FIA Meter) for the complete instructions on use of the Test. The test should be operated in room temperature.

Step1:Preparation

Check/ Swipe the IC Card information to the equipment.
Make sure the sample diluent is at the bottom of the tube by tapping or flicking before using.

Step2:Sampling

Draw 50 μL of serum/plasma/whole blood with a transfer pipette and add it to the diluent tube.

Step3: Mixing

Close the lid of diluent tube and mix the specimen by shaking or tapping 6-8 times, until the specimen completely mixed. Let it stand 1 minute.

Step4: Loading

Take 50μL of sample mixture with a transfer pipette and load it into the sample well of the Test Cartridge.

Step5:Testing

Standard test: Insert the Test Cartridge onto the Test Cartridge Holder and click "Timing Test". 15 minutes later, the result will show in the display and print out when click "Print".

Quick test: Put the Test Cartridge on the operation platform.15 minutes later, insert the Test Cartridge onto the Test Cartridge Holder and click "Quick Test". The result will show in the display and print out when click "Print".

【Limitations of Procedure】

1. This test has been developed for testing human whole blood, serum and plasma specimen.
2. The results of Anbio β-HCG Rapid Test Kit should be evaluated with all clinical and laboratory data available. If β-HCG test results do not agree with the clinical evaluation, additional tests should be performed.
3. Incorrect results can be caused by interference from some similar substance in the sample.
4. Other factors may interfere with Anbio β-HCG Rapid Test Kit and may cause erroneous results. These include technical or procedural errors, as well as additional substances in blood specimens.

【Quality Control】

- Internal procedural controls are included in the test. When testing, the quality control line (C line) will show a certain luminescence intensity, which is an internal procedural control. It confirms that a sufficient volume of samples has been added and that the correct procedure has been performed.
- Anbio β-HCG Control is recommended for Anbio β-HCG Rapid Test Kit and can be used in the following cases: When a box of a new lot is opened; When the Anbio FIA Meter or Anbio β-HCG Rapid Test Kit are not working properly; When the result and the symptoms are not consistent or if there are doubts about their accuracy.

Note: Please refer to the Instructions For Use of Anbio β-HCG Control for detailed operation.

【Interpretation of Results】

The Anbio FIA Meter calculate the test result automatically and displays β-HCG concentration of the test sample in terms of mIU/mL.

1. The Reference Value

<5mIU/mL

The β-HCG quantitative test results indicate whether test targets are pregnant or not. If test concentration result is less than 5 mIU/ml it will illustrates that sample is negative. If test concentration result is higher than 25 mIU/mL, it will illustrates that sample is positive. Test concentration results between 5 and 25 mIU/mL will be reported with concentrations only. No interpretation will be reported for these results.

Weeks of Pregnancy	Range mIU/mL	Weeks of Pregnancy	Range mIU/mL
3	6.4-71.9	10	47402-198989
4	10.8-789.9	12	28621-223361
5	237-7817	14	13977-65333
6	189-34660	15	12247-74451
7	3785-175283	16	9136-61802
8	32451-156069	17	8224-60665
9	64091-152690	18	8156-63531

Note: Individual reference range is suggested to be established for each laboratory.

【Performance Characteristics】

Limits and Range

Limit of Detection: 2.00 mIU/mL ;
Limit of Quantitation: 2.00 mIU/mL;
Measuring range: 2-200,000.00 mIU/mL

Precision

Precision was determined with Anbio test kits, samples, and controls according to the CLSI (clinical and Laboratory Standards Institute) protocol (EP05- A3):

(1) 3 batches of test kits, repeated 10 times per batch (n=30).

mIU/mL	Intra-batch						Inter-batch	
	Batch 1		Batch 2		Batch 3			
	SD	CV	SD	CV	SD	CV	SD	CV
9.99	0.886	8.69%	1.100	11.07%	0.905	9.22%	0.948	9.49%
495.45	48.502	9.92%	60.036	11.90%	51.552	10.46%	52.121	10.52%
9922.76	804.029	8.32%	1070.991	10.70%	1103.467	10.94%	984.414	9.92%

(2) 3 laboratories with duplicate testing 5 times a day for 5 days (n = 75).

mIU/mL	Repeatability		Intra laboratory precision		Inter laboratory precision	
	SD	CV	SD	CV	SD	CV
10.11	0.96	9.50%	0.96	9.50%	0.972	9.61%
501.97	40.472	8.06%	41.42	8.25%	41.42	8.25%
10067.05	933.504	9.27%	933.504	9.27%	933.504	9.27%

Limitations-Interference

Detection of the effects of the following endogenous substances on assay performance. Interfering substances detected in the listed concentration range had no effect on the results.

Compound	Concentration
Bilirubin	350μmol/L
Triglycerides	40mmol/L
Hemoglobin	2g/L
RF	1500IU/mL
HAMA	1000ng/mL
Antinuclear antibody	1:640

Limitations-Cross-Reactivity

The following substances do not interfere with the β-HCG test results at the indicated concentrations

Cross material	Concentration
LH	200 mIU/mL
TSH	200 mIU/L
FSH	200 mIU/L

【Bibliography of Suggested Reading】

1.Ross GT. Clinical relevance of research on the structure of human chorionic gonadotropin[J]. Am J ObstetGynecol，1977，129(7)：795-808.
2.Kadar N，DeVore G，Romero R. Discriminatory hCG Zone: Its Use in the Sonographic Evaluation for Ectopic Pregnancy[J]. ObstetGynecol 1981，58：156-161.

【Index of Symbols】

IVD	In vitro diagnostic medical device		Do not re-use
EC REP	Authorized representative in the European Community/ European Union		Consult instructions for use or consult electronic instructions for use
	Caution		Manufacturer
30°C 2°C	Temperature limit	LOT	Batch code
	Use-by date		Keep dry
	Keep away from sunlight	REF	Catalog number
	Date of manufacture	Σ	Contains sufficient for <n> tests
CE	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		Do not use if package is damaged and consult instructions for use

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