CE

PRL Rapid Test Kit

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

REF A02028002 | Σ 25 Tests

【Product Name】

PRL Rapid Test Kit

【Intended Use】

The Anbio PRL Rapid Test Kit along with Anbio FIA Meter is a fluorescence immunoassay for quantitative measurement of Prolactin (PRL) in human whole blood, serum or plasma. This test is used as an aid to evaluate the function of hypothalamic-pituitary and diagnose the hypothalamic diseases.

⚠ ***For professional use only.***

【Summary】

The main physiological function of prolactin is to provoke and maintain female lactation. Pregnancy, sexual intercourse, breast stimulation, sleep, exercise, stress, estrogen, progesterone and some psychiatric drugs taking can also make elevated prolactin levels; Taking bromine hidden pavilion, VitB6, levodopa drug make prolactin levels lower. High level of prolactin inhibits ovulation and is the main cause of male and female infertility and reproductive disorders.

【Test Principle】

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

【Main Components】

The following components are included in the PRL Rapid Test Kit:

Supplied Materials:

Specification / Component	25Tests	Main Ingredients
Test Cartridge	25	1) T line: Mouse anti-PRL monoclonal antibody (coated) 2) C line: Goat anti-rabbit IgG polyclonal antibody 3) Binding pad: Fluorescent microsphere-labeled mouse anti-PRL monoclonal antibody (labeled) and fluorescent microsphere-labeled rabbit IgG polyclonal antibody
IC Card	1	/
Whole Blood Buffer	1	10mmol/L PBS
Tube	25	/
Instructions For Use	1	/

Optional Materials:

1. Sterile lancets (for Fingerstick Whole Blood only)
2. Alcohol pads (for Fingerstick Whole Blood only)
3. Disposable pipettes (50μL)
4. PRL Quality control

Materials Required but not Provided:

1. Transfer Pipette Set
2. Sample 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		/
Whole Blood Buffer		The buffer 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 PRL 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 buffer tubes for different samples.
9. Blood samples, used Test Cartridges, pipette tips and detector buffer 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.

【Sample 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 samples have been collected. Do not leave the samples at room temperature for prolonged periods. Samples may be stored at 2℃～8℃ for up to 3 days. For long-term storage, samples should be kept below -20℃.

For Whole Blood Collected by Venipuncture:

1.Using standard phlebotomy procedure, collect a venipuncture whole blood sample using a blood collection tube with suitable anticoagulant.
2.It is recommended that samples should be tested immediately. Do not leave the samples at room temperature for prolonged periods. If the samples 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 samples 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.

Whole blood: Take 50 μL of whole blood buffer into the empty centrifuge tube by transfer pipette.

Caution: When the sample is serum/plasma, proceed to step 4.

Step2:Sampling

Whole blood: Take 50μL of whole blood sample with a transfer pipette, and add it to the centrifuge tube.

Step3: Mixing

Whole blood: Close the lid of centrifuge tube and mix the sample by shaking or tapping 6-8 times, until the sample completely mixed.

Step4: Loading

Serum / plasma: Take 50μL of serum or plasma samples with a transfer pipette, load it into the sample well of the Test Cartridge.
Whole blood: Take 50μL of sample mixture with a transfer pipette and load it into the sample well of the Test Cartridge.
Step5:Testing
Timing 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 sample.
2. The results of Anbio PRL Rapid Test Kit should be evaluated with all clinical and laboratory data available. If PRL 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 PRL Rapid Test Kit and may cause erroneous results. These include technical or procedural errors, as well as additional substances in the samples.

【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 PRL Control is recommended for Anbio PRL 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 PRL 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 PRL Control for detailed operation.

【Interpretation of Results】

The Anbio FIA Meter calculate the test result automatically and displays PRL concentration of the test sample in terms of ng/ml.
1. The Reference Value

Gender	Reference value (ng/mL)
Male	3.45~17.42
Female (non-pregnant)	4.60~25.07

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

【Performance Characteristics】

Limits and Range
Limit of Detectiont: 0.5 ng/mL;
Limit of Quantitation: 1.0 ng/mL;
Measuring range: 1.0~200.0 ng/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).

ng/mL	Intra-batch						Inter-batch	
	Batch 1		Batch 2		Batch 3			
	SD	CV	SD	CV	SD	CV	SD	CV
9.72	0.974	10.33%	1.108	11.17%	0.888	9.04%	0.984	10.12%
97.88	10.129	9.72%	8.648	9.01%	7.953	8.51%	9.817	10.03%

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

ng/mL	Repeatability		Intra laboratory precision		Inter laboratory precision	
	SD	CV	SD	CV	SD	CV
9.97	0.883	8.86%	0.914	9.17%	0.914	9.17%
100.94	9.412	9.32%	9.412	9.32%	9.412	9.32%

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 PRL test results at the indicated concentrations.

Cross material	Concentration
TSH	200 mIU/L
LH	200 mIU/mL
FSH	200 mIU/mL
HCG	100000 mIU/L

【Bibliography of Suggested Reading】

1.Li Hongjun. Male hyperprolactinemia and infertility and sexual dysfunction [J]. Obstetrics and Gynecology, 2008, 43(4):313-315.
2.Niall HD. The Chemistry of the Human Lactogenic Hormones. In: Boyns AR, Griffiths K, editors Prolactin and Carcinogenesis: Proceeding of the Fourth Tenovus Workshop; March 1972; Cardiff, Wales. Cardiff: Alpha Omega Alpha, 1972: 13-20.

【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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