Chuangxingwell

Heparin-Binding Protein (HBP) Rapid Test Kit (Fluorescence Immunochromatography) Package Insert

IVD

For professional in vitro diagnostic use only

INTENDED USE

This test kit is suitable for in vitro quantitative detection of the content of heparin binding protein in human plasma.

SUMMARY

Folic acid is a compound composed of pterinidine, p-aminobenzoic acid and glutamic acid. It is a water-soluble B vitamin. When folic acid is deficient, the forms of deoxy-thymidylate, purine nucleotides and amino acid interconversion are blocked, DNA syn-thesis in cells is reduced, cell division and maturation are hindered, and megaloblastic anemia occurs. At present, the methods commonly used to detect folic acid in clinics and laboratories include fluorescence immunochromatography, colloidal gold immuno-chromatography, chemiluminescence, and latex enhanced immunoturbidimetry.[1,2]

PRINCIPLE

Based on the principle of fluorescence immunochromatography, double antibody sandwich method was used for detection. The test line (T) of reagent nitrocellulose membrane is coated with anti HBP antibody, and the quality control line (c) is coated with Goat anti mouse IgG antibody and dnp-bsa. In the detection process, the HBP antigen in the sample first combines with the fluorescent labeled anti HBP antibody conjugate to form an immune complex. It moves to the nitrocellulose membrane through the chromatographic action of the membrane, reacts with the anti HBP antibody on the detection line (T), and is fixed on the detection line t to form a double antibody sandwich immune complex. At the same time, the fluorescent labeled Rabbit anti DNP and unreacted immune complex were combined with Goat anti mouse IgG antibody and dnp-bsa coated on the quality control line (c).

The fluorescence intensity of the reagent is detected by dry fluorescence immunoas-say analyzer to obtain the fluorescence intensity value. The fluorescence analyzer fits the fluorescence intensity value to the dose-response curve, and automatically converts the corresponding concentration values of heparin binding protein and pro-calcitonin (ng / mL).

KIT COMPONENTS

1.Test cassettes.
2.Diluent.
3.ID card.
4.Package Insert.

STORAGE CONDITIONS AND SHELF LIFE

1. Store as packaged in the sealed pouch at 2-40ºC, avoid hot and sunshine, dry place, valid for 24 months. DO NOT FREEZE. Some protective measures should be taken in hot summer and cold winter to avoid high temperature or freeze-thaw.
2. Once open the pouch, the test strip should be used within 1 hour. Prolonged exposure to ambient humidity will cause product deterioration.

SAMPLE REQUIREMENTS

1. For human plasma samples, only sodium citrate anticoagulated plasma is recommended;
2. After the clinical sample is collected, if it is tested within 24 hours, it can be temporarily stored at 2-8ºC for inspection; if it cannot be tested within 24 hours, it should be stored at -20ºC or below for 3 months;
3. The sample must be restored to room temperature before testing, and repeated freezing and thawing should not be avoided;
4. The sample is turbid or severely hemolyzed and cannot be used for testing;
5. Interfering substances: hemoglobin content ≤ 4 mg/mL, triglyceride content ≤ 6 mg/mL, bilirubin content ≤0.4 mg/L, cholesterol content ≤3 mg/mL, there is no significant impact on the test results.

TEST PROCEDURE

Before using this reagent, you must carefully read the reagent instructions and the accompanying instrument instructions, and operate in accordance with the instructions.

1. Return the kit and sample to room temperature (15-30°C) before testing;
2. Set the relevant parameters of the instrument according to the manual of the dry fluorescence immunoassay analyzer, insert the ID card and read the data;
3. Take out the reagent from the aluminum foil bag, place it flat on the workbench, add 80μL of the sample immediately, and perform the test after reacting for 15 minutes.

RESULTS ANALYSIS

1. The HBP level is less than 15ng/mL. Due to differences in geography, race, and age, it is recommended that each laboratory establish its own reference range;
2. If the detection concentration is HBP≤1ng/mL. It cannot be said that the content of the sample must be lower than the lower limit of detection of this reagent, and it does not rule out the presence of high levels of interfering substances in the sample, such as hemolytic samples, high blood lipid samples, and high bilirubin samples. This situation should be correctly judged based on the sample situation, the patient' s medical history, symptoms, etc.;

3. The increase in HBP levels in plasma should be combined with clinical symptoms and other test results;
4. The test results are for clinical reference only, and cannot be used alone as the basis for confirming or excluding cases. The final diagnosis result should be deter-mined by the physician in combination with clinical symptoms and other laboratory test indicators;
5. If the test result is abnormally high, there may be some interfering substances in the sample, causing cross-reaction. This situation should be tested with other reagents or experimental methods.

LIMITATIONS OF INSPECTION METHODS

1. This kit is only used for in vitro auxiliary diagnosis. The clinical diagnosis should be comprehensively judged by professionals based on the patient's clinical symptoms, past medical history, signs, and auxiliary examinations;
2. Samples with high hemolysis, high blood lipids, and jaundice may cause abnormal test results;
3. When the concentration of the test sample exceeds the range of the quantitative standard curve, the quantitative test result has a large deviation, and the sample needs to be diluted and tested again.

PERFORMANCE CHARACTERISTICS

- **The lowest detection limit**

HBP≤1 ng/mL.

- **Linear range**

The linear interval of HBP detection is [1, 200ng/mL]; the linear correlation coefficient r should be≥0.9900.

- **Accuracy**

relative deviation should be ≤15%;

- **Repeatability**

CV≤15%;

- **Difference between batches**

CV≤15%;

- **HOOK effect**

HBP antibody coating concentration is 1.8mg/mL, when the antigen concentration exceeds 1000ng/mL, hook effect may occur.

PRECAUTIONS

1. Read the instruction manual of this reagent before operation;
2. This reagent is a disposable test product, and it is strictly forbidden to reuse it;
3. Avoid using reagents with damaged single packages, unclear marks, and expired expiration dates;
4. After the test card is taken out of the aluminum foil bag, perform the test immediately to avoid leaving it in the air for too long, which may cause moisture;
5. The paper strips, sample liquid and used reagents in the reagent cartridge should be regarded as the source of infection and should be handled with gloves to avoid direct contact with the skin;
6. Please use a clean pipette tip and test tube for each sample. Each pipette tip and test tube can only be used for one sample. After use, please treat it as a biological product according to relevant regulations;
7. If the test reagents stored in the refrigerator are used, it is recommended that they should be taken out of the refrigerator before testing, placed at room temperature and then opened for use, otherwise the test results will be affected.

BIBLIOGRAPHY

1. Linder A et al, Heparin-binding protein measurement improves the prediction of severe infection with organ dysfucntion in the emergency department. Critical Care Medicine 2015;Vol 43, Number 11:2378-2386.
2. Linder A, Christensson B, Herwald H et al: Heparin-Binding Protein: An Early Marker of Circulatory Failure in Sepsis. Clin Inf Dis 2009; 49: 1044-50

THE MEANING OF THE SYMBOLS USED

	Caution	IVD	In Vitro Diagnostic Medical Device		Do Not Use if Package is Damaged
	Manufacturer	LOT	Batch Code		Contains Sufficient for <n> Tests
	CE Marking	REF	Catalogue Numbe	EC REP	Authorized representative in the European Community
	Keep Dry		Use-By Date		Keep Away From Sunlight
	Temperature Limit		Do Not Re-use		Date of Manufacture

Manufacturer
Jinan Chuangxingwell Biotech Co., Ltd.
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EC REP

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