FAMKA
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Hepatitis B Virus 5 in 1 Panel Rapid Test Card
H BsAg/HBsAb/HBeAg/HBeAb/HBcAb)
(Surface Antigen/Surface Antibody/E Antigen/E Antibody/
Core Antibody)
(Whole Blood/Serum/Plasma)

Product Name
The common name:D1agnost1c kit for HBV Infection Marker (surface antigen, surface antibody, core antibody, e antigen, e antibody) (Colloidal Gold)

Packing Specification
Card Type

Intended Use
Qualitative detection of the five hepatitis B markers HBsAg, HBsAb, HBeAg, HBeAb, HBcAb in human whole Blood, for clinical diagnosis

Detection Principle
The product uses the colloidal gold and membrane chromatography technology, and measures HBsAg, HBeAg in whole Blood with dual-antibody sandwich method, and measures HBsAb with dual-antigen sandwich method, and measures HBeAb and HBcAb with neutralization competitive inhibition method.

Major Component Ingredients
1. Individually sealed foil pouches containing

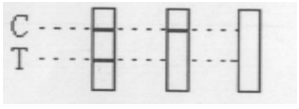
1. One Cassette Test Device
2. One Pipette
3. One Lancet
4. One Alcohol Wipe
5. One bottle of buffer
6. One package insert (instruction for use)

Sample Requirements
1.Collect venous blood samples in sterile conditions, and collect blood into a container with anticoagulant(EDTA or heparin).
2.When testing, you should make full use of fresh sample. If the sample can not be detected in time, it can be refrigerated for 3 days at 2-8 'C' Long-term preservation needs to be frozen at -20 "C, and it can't be repeatedly freezing and thawing.
3.The conventional anticoagulant does not affect the test results.
4.The hemolysis, viscous and high-fat blood samples do not apply to this reagent.
5.Adding 0.1 % NaN, in the samples does not affect the result.

Test Method
Please read the instructions for the test kit completely before carrying out test.
1.Revert the test board and the testing samples to room temperature (20-30C).
2.The right side of the test board should be kept horizontal from the original package. From left to right, respectively corresponding to HBsAg, HBsAb, HBeAg, HBeAb, HBcAb. With a small straw to take subjects' whole blood, and add into 5 sample wells of the test board by drops (one drop).
3.Then draw one drop of whole Blood buffer into 5 sample well of the test board as well.
4.Observe and record the experimental result within 15 minutes. Weakly positive samples
appear test line in 15-20 minutes Determination after 30 minutes is invalid

Note: Take out test paper from the original packaging, and it should be used within 1 hour as soon as possible, especially at room temperature above 30 'C' or in a highly humidenvironment.

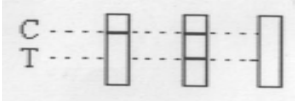
Results Determination
(1) HBsAg, HbsAb, HBeAg (Sandwich method)



Positive Negative Invalid

Negative: Only one purple bar (control line) in the control C zone. Positive: Detecting T zone There are two purple bars in the control C zone. Invalid: Detecting T zone There is no purple bar in the control C zone.

(2) HBeAb, HBcAb (Competition method)



Positive Negative Invalid

Negative: Detecting T zone There are two purple bars in the control C zone.
Positive: Only one purple bar (control line) in the control C zone. (Weakly positive sample may appear a very thin response line at the test line).
Invalid: Detecting T zone There is no purple bar in the control C zone.

The Interpretation of Test Results
1.The purple bands, which appear at the quality-control control lines. Isused as the internal control standards of the test paper strip
2.The purple bands appear gradation phenomenon at the testing line, when testing different specimens, and this is due to high and low concentrations of surface antigen.

The Limitations of the Testing Methods
This method is clinical auxiliary diagnostic product, any of the tested positive samples should be further confirmed by application of other methods (such as EIA).

Performance Indicators of Products
sAg 2.5ng eAg 2NCU sAb 30mlU eAb 4NCU cAb 2NCU

Instructions and Notes
1.This product is a disposable in vitro diagnostic products, and the same test card not be reused.
2.This product is a qualitative reagent screening the presence of hepatitis B markers, but it can not determine the surface antibody content of the samples. 3.This product is suitable for testing human whole blood.
4.Experimental environment should shelter from the wind and avoid making the experiment in too high temperature, high humidity or too dry conditions.
5.Operation according to infectious disease laboratory test procedures.
6.When a large number of samples tested, please mark well, to avoid confusion.
7.Experiments confirm that hepatitis A, hepatitis C, HIV, syphilis, HEV, HGV do not interfere with the results.
8. It should not be frozen or use after it is past due.

Storage Conditions and Valid Period
Preserve at 2-30C in sealed dark dry place, and the valid period is 24 months.

References
1.Control practical handbook for bio-products and their quality standards for raw and auxiliary materials, Volume 111, national audio-visual publishing house, Miao Yong, Zang Guangzhou editor in chief.
2.The preparation instructions for extrinsic diagnostic reagents guideline; State Food Drug Administration Device (2007) No. 240.

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