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**(FOR RESEARCH USE ONLY. DO NOT USE IT IN CLINICAL DIAGNOSIS !)**

## **Human Parvovirus B19 (HP-B19) IgM Lateral Flow Assay Kit**

Catalog No: E-HD-C001

20T/40T

This manual must be read attentively and completely before using this product.

If you have any problems, please contact our Technical Service Center for help.

Toll-free: 1-888-852-8623   Tel: 1-832-243-6086   Fax: 1-832-243-6017

Email: [techsupport@elabscience.com](mailto:techsupport@elabscience.com)

Website: [www.vetassay-elab.com](http://www.vetassay-elab.com)

Please kindly provide us the lot number (on the outside of the box) of the kit for more efficient service.

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## Test principle

This kit applies the Capture-GICA (Gold Immunochromatography) method as its principle, and can be used for the qualitative detection of Human Parvovirus B19 (HP-B19) IgM in human serum. The quality control (C) line is pre-coated with HP-B19 polyclonal antibody, and the detection (T) line is pre-coated with anti-human IgM antibody. The gold pad is coated with gold-labeled HP-B19 antigen. HP-B19 IgM in sample will combine with gold-labeled HP-B19 antigen and form a gold-labeled antigen-antibody complex. The complex will then move along the detection card and react with the pre-coated anti-human IgM antibody on the detection line (T-line) and form the Anti-human IgM antibody- HP-B19 IgM antibody- HP-B19 antigen immunological complex, then a visible line will appear in the detection area. If there is no HP-B19 IgM antibody or HP-B19 IgM antibody content is lower than the detection limit, there will be no complex or precipitation line appeared. The quality control line is standard reference to determine whether the chromatography is normal and whether the detection system is effective. The HP-B19 IgM antibody- HP-B19 antigen immunological complex and color reaction will occur in the quality control area under all conditions, otherwise the detection result is considered invalid and re-test will be required.

## Kit components

Item	Specification
Detection Card	20T/40T
Sample Diluent	1 vial
Manual	1 copy

Note: All reagent bottle caps must be tightened to prevent evaporation and microbial pollution.

## Notes

1. Please read the manual carefully before use, changes of operation may result in unreliable results.
2. Do not use product out of date or in a broken aluminum foil, it is disposable and cannot be used repeatedly.
3. The detection card should be brought to room temperature before opening after take it out from the refrigerator. The opening detection card should be used as soon as possible.
4. Please do not use but not limited to the following liquids for negative control: water, PBS.
5. The tested sample should be fresh and clear. Avoid of using samples of turbidity, polluted, high hemolysis or abnormal viscous.
6. Avoid of touching the chromatography membrane of the sample well and test well.
7. The waste of experiment should be considered as contaminant, and must be properly handled according to the local regulations.
8. Each reagent is optimized for use in the E-HD-C001. Do not substitute reagents from any other manufacturer into the test kit. Do not combine reagents from other E-HD-C001 with different lot numbers.

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## Storage and expiry date

**Storage:** Store at 4-30°C. With cool and dry environment.

**Expiry date:** expiration date is on the packing box.

## Requirements of sample

1. The sample must be serum.
2. Whole blood should be used immediately after collecting, and the prepared serum samples can be stored at 2-8 °C temporally for detection, or at -20°C for long-term storage.
3. Avoid of samples with hemolysis, turbidity, lipidemia, bacterial or polluted and repeated frozen/thawed samples, which will cause false-positive results.
4. **Cross reaction:** This kit has no cross reaction with HBoV antibody, PARV4 antibody, anti-HIV antibody, Hepatitis B virus surface antigen, ANA, and Rheumatoid positive sample.
5. Hemolysis samples with  $\geq 500$  mg/mL hemoglobin, jaundice sample with  $\geq 1.8$  mmol/L bilirubin and high fat sample with  $\geq 180$  mmol/L glycerin trilaurate will interfere the detection of HP-B19 IgM antibody with this kit.

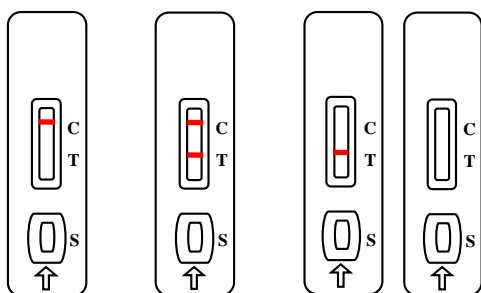
## Assay procedure

Read the manual carefully before detection. The reagent and sample should be adjusted to room temperature (15°C to 30°C) before use. The detection card cannot be opened before the experiment condition is ready.

1. Take the detection card out and put it on flat and clean table.
2. Add 10  $\mu$ L of serum to the sample well and then add 2 drops (or 100  $\mu$ L) of **Sample Diluent**.
3. Observe the result within 10-20 min. The result is invalid after 20 min.

## Judgment of result

1. **Positive:** Red line appears in both test line (T) and control line (C).
2. **Negative:** Red line only appears in control line (C).
3. **Invalid:** No color line appears in control line (C). It indicates that the operation is wrong or the detection card is invalid, please carry out another detection.



Negative

Positive

Invalid

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### **Interpretation of results**

1. **Positive result:** The sample contains HP-B19 IgM antibody, and clinical information needs to be combined to determine whether the patient has been infected with HP-B19.
2. **Negative result:** No HP-B19 IgM was detected in the sample, or the content is too low to the detection limit. The possibility of being infected cannot be completely excluded at this situation.

### **Limitations of this test method**

This product is for qualitative detection of HP-B19 IgM in human serum only, while the detection effect for whole blood samples, plasma samples or samples from other parts is still unclear.