Version 13-01/25

User's Manual

Human Parvovirus B19 IgG Antibody ELISA Kit

REF **DEIA-JY24112**

Σ **96T**

RUO

This product is for research use only and is not intended for diagnostic use.

For illustrative purposes only. To perform the assay the instructions for use provided with the kit have to be used.

Creative Diagnostics

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PRODUCT INFORMATION

Intended Use

This kit is used for qualitative detection of parvovirus B19 IgG antibody in serum or plasma from pregnant women and pregnant women. Human parvovirus B19 is transmitted through the respiratory tract, pregnant women susceptible to up to 23%~45%, if pregnancy women infected with B19, the fetus infection rate is 33% through the placenta, the incidence of stillbirth 6.5%, the incidence of non immune fetal edema 8%~10%. Specific IgM and IgG antibodies are tested to diagnose whether pregnant women are infected with B19 virus. The appearance of IgG antibodies indicates previous infection, IgG antibodies remain positive all their lives and generally obtain lifelong immunity. If pregnant women have a certain level of anti-b19 virus specific IgG, it can protect the fetus, reduce the damage of B19 virus infection. Serological test to detect specific IgG and IgM antibodies is the basis for the diagnosis of B19 infection. Antibody detection methods mainly include radioimmunoassay (RIA) enzyme (ELISA) immunofluorescence assay (IF) and immunoblot assay (WB). This kit assists the detection of parvovirus B19 in pregnant women.

Reagents And Materials Provided

1. Microtiter Well 1
2. Negative Control 1 ml
3. Positive Control 1 ml
4. Sample Diluent 12 ml
5. Conjugate 12 ml
6. Washing Buffer (20×) 30 ml
7. Substrate Solution A 6 ml
8. Substrate Solution B 6 ml
9. Stop Solution 6 ml
10. Plate Cover 3 pieces
11. Insert 1 copy

Materials Required But Not Supplied

1. Micropipettes: 0.02, 0.05, 0.10, 0.15, 0.20, and 1.0 ml.
2. Disposable pipette tips.
3. Distilled or deionized water.
4. Humidified Box capable of maintaining 37°C
5. Absorbent paper or paper towel.
6. Microtiter plate or strip-well washer
7. Microtiter plate reader with 450 nm (or 450 nm/630 nm) wavelength
8. Timer

Storage

Unopened test kits should be stored at 2-8°C. DO NOT FREEZE KIT COMPONNETS. The microtiter plate should be kept in a sealed bag to minimize exposure to damp air. Use up the reagents as soon as possible after the kit is unpacked.

Specimen Collection And Preparation

Serum should be prepared from a whole blood specimen obtained by acceptable medical techniques. Either serum or plasma can be used in this test. Remove serum or plasma from the clot or blood cells as soon as possible to avoid hemolysis. Specimen with extensive particulate should be clarified by centrifugation prior to use. Specimen frozen at -20°C or colder may be used. Avoid repeated freeze thaw.

Assay Procedure

1. Bring ELISA Kit (all reagents), and samples to room temperature before use (approximately 30 minutes)
2. Dilute concentrated wash buffer 1:19 with ddH_2O.
3. For each test, set one blank, two positive and three negative controls. Add 100 µl positive and negative control serum into positive and negative control wells respectively.
4. Add 100 µl sample diluent into test wells, then add 10 µl specimen in each well
5. Cover wells with seal paper, then incubate 30 minutes at 37°C.
6. Wash each well 5 times by filling each well with diluted wash buffer, then inverting the plate vigorously to get all water out and blocking the rim of wells on absorbent paper for a few seconds.
7. Add 100 µl Enzyme Conjugant to each well except the blank well.
8. Incubate: Cover the Microplate with plate cover and incubate the Coated Microplate in a thermostat-controlled water-bath or microplate incubator at 37°C for 60 minutes.
9. Wash the Plate as step 6.
10. Add Substrate: Add 50 µL of Substrate Solution A and 50 µL of Substrate Solution B to each well, include blank. mix well. Cover and incubate at 37°C for 15 minutes.
11. Stop reaction: Add 50 µL Stop Solution to each well, include blank mix well.
12. Read the absorbance at 450 nm. If a dual wavelength measurement is used, the reference wavelength should be selected from 620 nm to 690 nm.

Note:

1. Allow all kit components to reach room temperature before use.
2. Follow the direction insert to control the reaction temperature and time strictly.
3. Do not mix components of different lot numbers to use.
4. The kit should be store at 2-8°C. Do not use kit components beyond their expiration date.

Quality Control

If the OD of positive controls is not below 1.0, OD of negative is not higher than 0.1, the assay result is

validated. Otherwise, repeat the test.

Interpretation Of Results

1. Colorimetric Method
2. Cut off Value calculation:
3. COV = 0.10 + the average OD of negative controls (If the absorbance of negative controls is below 0.05, calculate it as 0.05. If the absorbance of negative controls is above 0.05; calculate it as its original value.)
4. Positive OD450 of sample ≥ COV HPVB19- IgG
5. Negative OD450 of sample < COV. HPVB19- IgG

Precautions

1. For research use only.
2. Do not use kit beyond expiration date.
3. Do not mix components from kits with different lot number.
4. Avoid microbial contamination of reagents.
5. Do not pipet reagent by mouth and no smoking or eating while performing assays.
6. Wear gloves during the whole process and avoid reagents or specimen spilling-out.
7. Wipe up the spills using 5% hypochlorite solution.
8. Decontaminate all liquids or solid wastes before deposing.