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Calbiotech Inc.,

CALBIOTECH
A life science company

VZV IgG ELISA

Catalog No.: VZ081G (96 Tests)

INTENDED USE

The Calbiotech VZV IgG ELISA Kit is intended for the detection of IgG antibody to VZV in human serum or plasma. For Research Use Only. Not for use in diagnostic procedures.

SUMMARY AND EXPLANATION

Varicella zoster virus causes chickenpox a highly contagious disease acquired by touching the blisters or respiratory secretions, or through the air. A person is usually infectious 1-2 days before the rash to 4-5 days after the start of the rash, or until the blisters have formed crusts. Symptoms start about 2-3 weeks after exposure and include fever, tiredness, and an itchy rash with small blisters that dry up and form scabs in 2-4 days. More severe but rare problems or complications that could occur are pneumonia (especially in adults), skin infection, blood infection and encephalitis. Approximately 90% of chickenpox cases are in children 1-14 years of age, and 90% of people have had chickenpox by their early 20's. The reactivated form (herpes zoster: shingles) of VZV infection generally occurs in older adults whose immunity has waned, in infants or children exposed to VZV in the perinatal period or in the immunocompromised. VZV infection during pregnancy infrequently leads to maternal pneumonia. Chickenpox can occur during pregnancy in women seropositive for VZV, especially when seropositive at low titer, with low-avidity, largely IgG3 antibodies. Maternal VZV infection during pregnancy (especially between 13-20 weeks gestation) can be associated with outcomes ranging from skin scarring or limb hypoplasia to multi system involvement and death. Because VZV and herpes simplex virus (HSV) can cross-react, viral culture can be used to detect and differentiate HSV from VZV, but PCR testing may prove the most valuable for diagnosing and differentiating active infection. IgG antibodies can be detected 9 days after the onset of rash in varicella, 10 days in zoster; immunoreactivity peaks at an average 66 and 27 days, respectively. The IgM response to varicella is detected at 6-7 days post-onset and peaks at an average 14 days; IgM response to zoster is detectable at 8-10 days and peaks at 18-19 days.

PRINCIPLE OF THE TEST

Diluted patient serum is added to wells coated with purified antigen. IgG specific antibody, if present, binds to the antigen. All unbound materials are washed away and the enzyme conjugate is added to bind to the antibody-antigen complex, if present. Excess enzyme conjugate is washed off and substrate is added. The plate is incubated to allow the hydrolysis of the substrate by the enzyme. The intensity of the color generated is proportional to the amount of IgG specific antibody in the sample

MATERIALS PROVIDED	96 Tests
1. Microwells coated with VZV antigen	12x8x1
2. Sample Diluent: 1 bottle (ready to use)	22 ml
3. Calibrator: 1 Vial (ready to use)	1ml
4. Positive Control: 1 vial (ready to use)	1ml
5. Negative Control: 1 vial (ready to use)	1ml
6. Enzyme conjugate: 1 bottle (ready to use)	12ml
7. TMB Substrate: 1 bottle (ready to use)	12ml
8. Stop Solution: 1 bottle (ready to use)	12ml
9. Wash concentrate 20X: 1 bottle	25ml

MATERIALS NOT PROVIDED

1. Distilled or deionized water
2. Precision pipettes, Disposable pipette tips
3. ELISA reader capable of reading absorbance at 450nm
4. Absorbance paper or paper towel
5. Graph paper

STORAGE AND STABILITY

1. Store the kit at 2-8° C.
2. Keep microwells sealed in a dry bag with desiccants.
3. The reagents are stable until expiration of the kit.
4. Do not expose test reagents to heat, sun or strong light.

WARNINGS AND PRECAUTIONS

1. For Research Use Only. Not for use in diagnostic procedures.
2. For Laboratory Use.
3. Potential biohazardous materials:
   The calibrator and controls contain human source components which have been tested and found non-reactive for hepatitis B surface antigen as well as HIV antibody with FDA licensed reagents. However, there is no test method that can offer complete assurance that HIV, Hepatitis B virus or other infectious agents are absent. These reagents should be handled at the Biosafety Level 2, as recommended in the Centers for Disease Control/National Institutes of Health manual, "Biosafety in Microbiological and Biomedical Laboratories." 1984.
4. Optimal results will be obtained by strict adherence to the test protocol. Precise pipetting as well as following the exact time and temperature requirements is essential.
5. Do not pipette by mouth. Do not smoke, eat, or drink in the areas in which specimens or kit reagents are handled.
6. The components in this kit are intended for use as an integral unit. The components of different lots should not be mixed.
7. Control sera and sample diluent contain preserved with sodium azide. Sodium azide may react with lead and copper plumbing to form explosive metal azide. On disposal, flush with a large volume of water.

SPECIMEN COLLECTION AND HANDLING

1. Collect blood specimens and separate the serum.
2. Typically, specimens may be refrigerated at 2–8 °C for up to seven days or frozen for up to six months. Avoid repetitive freezing and thawing.

REAGENT PREPARATION

Prepare 1X Wash buffer by adding the contents of the bottle (25 ml, 20X) to 475 ml of distilled or deionized water. Store at room temperature (20-25°C).

ASSAY PROCEDURE

Bring all specimens and kit reagents to room temperature (20-25°C) and gently mix.

1. Place the desired number of coated strips into the holder.
2. Negative control, positive control, and calibrator are ready to use. Prepare 1:21 dilution of specimens, by adding 10 µl of the sample to 200 µl of sample diluent. Mix well.
3. Dispense 100 µl of diluted sera, calibrator and controls into the appropriate wells. For the reagent blank, dispense 100µl sample diluent in 1A well position. Tap the holder to remove air bubbles from the liquid and mix well. Incubate for 20 minutes at room temperature.
4. Remove liquid from all wells. Wash wells three times with 300 µl of 1X wash buffer. Blot on absorbance paper or paper towel.
5. Dispense 100 µl of enzyme conjugate to each well and incubate for 20 minutes at room temperature.
6. Remove enzyme conjugate from all wells. Wash wells three times with 300 µl of 1X wash buffer. Blot on absorbance paper or paper towel
7. Dispense 100 µl of TMB substrate and incubate for 10 minutes at room temperature.
8. Add 100 µl of stop solution.
9. Read O.D. at 450 nm using ELISA reader within 15 min. A dual wavelength is recommended with reference filter of 600-650 nm.

CALCULATION OF RESULTS

1. Check Calibrator Factor (CF) value on the calibrator bottle. This value might vary from lot to lot. Make sure you check the value on every kit.
2. Calculate the cut-off value: Calibrator OD x Calibrator Factor (CF).
3. Calculate the Ab (Antibody) Index of each determination by dividing the O.D. value of each sample by cut-off value.

LIMITATIONS OF THE TEST

1. Lipemic or hemolyzed samples may cause erroneous results.