Platelia™ EBV-VCA IgG

1 plate - ☑ 96

ENZYME IMMUNOASSAY FOR QUALITATIVE DETERMINATION OF IgG ANTIBODIES TO EPSTEIN-BARR VIRUS (VIRAL CAPSID ANTIGEN) IN HUMAN SERUM

[IVD] CE

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1 - INTENDED USE
This immunoassay kit is for the qualitative determination of IgG antibodies to Epstein-Barr Virus-Viral Capsid Antigen (EBV-VCA) in human serum. The Platelia™ EBV-VCA IgG assay may be used in conjunction with other Epstein-Barr serology’s (Platelia™ EBV-VCA IgM, Platelia™ EBV-EA-D IgG and Platelia™ EB-NA-1 IgG) as an aid in the diagnosis of infectious mononucleosis.

2 - CLINICAL VALUE
Detection of the Epstein-Barr virus was first described in 1964 by Epstein, Achong, and Barr using electron microscopic studies of cultured lymphoblasts derived from patients with Burkitt’s lymphoma. EBV is classified as a member of the herpes-virus family based upon its characteristic morphology.
EBV infection may demonstrate a wide spectrum of clinical symptoms. The majority of primary EBV infections are transmitted via saliva, occur during childhood, and are subclinical. In the United States, 50% of the population demonstrate EBV antibodies before the age of 5 years; 80% by adulthood. Transfusion-associated EBV infections have also been reported.
In young adults, EBV infection may be clinically manifested as Infectious Mononucleosis (IM) with relatively atypical symptoms of fever pharyngitis, tonsilitis, lymphadenopathy, malaise, headache, myagia, spleno- and hepatomegaly, rash and leucocytosis. College students and military personnel are often cited as a high morbidity incidence population for IM.
Following primary EBV infection, it is postulated that the B lymphocyte may continue to harbor the EBV genome and establish a latent infection that may extend through life. Reactivation of EBV infection or enhanced EBV activation has been documented in immunodeficient or immuno-suppressed patients, i.e., organ transplant patients, individuals with malignancies, pregnant women, and persons of advanced age. Controversy persists regarding the definitive implication of EBV as the etiologic agent in the clinical state labeled «chronic EBV infection» or «chronic mononucleosis».
Epstein-Barr virus has also been associated in the pathogenesis of two human cancers, Burkitt’s lymphoma and nasopharyngeal carcinoma. Documentation by means of DNA hybridization studies demonstrates the presence of the EBV genome on biopsy specimens taken from individuals with these carcinomas.
Burkitt’s lymphoma is primarily observed in Sub-Sahara Africa, especially in African children, and in New Guinea. Malarial infections are usually diagnosed in Burkitt’s lymphoma patients and are suggested to be a co-factor. Nasopharyngeal carcinoma is observed in Asia, most notably in Southern China, and may have genetic or environmental influences as the co-factor.
B-cell lymphomas similar to the African Burkitt’s lymphoma have recently been reported in patients with Acquired Immunodeficiency Syndrome (AIDS). It is suggested that AIDS patients may be pre-disposed of EBV infection/ reactivation due to their general state of immunosuppression.

The heterophile antibody test is currently the most widely used procedure for the diagnosis of acute IM. However, up to 20 % of patients with primary EBV infection do not exhibit a positive heterophile antibody test. Additionally, false positive results up to 7 % have been reported using commercially available rapid slide heterophile antibody tests, due primarily to technique errors in the subjective reporting of red-cell agglutination.

3 - PRINCIPLE OF THE PROCEDURE

The Enzyme-Linked Immunosorbent Assays (ELISA) rely on the ability of biological materials, (i.e., antigens) to adsorb to plastic surfaces such as polystyrene (solid phase). The Platelia™ EBV-VCA IgG kit utilizes the ELISA technology in which an affinity purified VCA antigen is bound to the wells of a microplate. When antigens bound to the solid phase are brought into contact with a patient’s serum, antigen specific antibody, if present, will bind to the antigen on the solid phase forming antigen-antibody complexes. Excess antibody is removed by washing. This is followed by the addition of goat anti-human IgG conjugated with horseradish peroxidase which then binds to the antibody-antigen complexes. The excess conjugate is removed by washing, followed by the addition of Substrate, tetramethylbenzidine (TMB). If specific antibody to the antigen is present in the patient’s serum, a blue color develops. When the enzymatic reaction is stopped with 1N H₂SO₄, the contents of the wells turn yellow. The color, which is proportional to the concentration of antibody in the serum, can be read on a suitable spectrophotometer or ELISA microwell plate reader.

The Platelia™ EBV-VCA IgG kit is composed primarily of viral capsid antigen (VCA) to detect IgG antibodies specific for EBV infection. Antibodies are detectable in the absence of the heterophile antibodies. Rising early in the course of the disease, the EBV-VCA IgG levels peak after 3-4 weeks, then decline and persist at low levels for life. The sensitivity, specificity and reproducibility of enzyme-linked immunosorbent assays may be comparable to other serological tests for antibody, such as immunofluorescence, complement fixation, hemagglutination and radioimmunoassays.
4 - CONTENTS OF THE KIT

All reagents are exclusively for *in vitro* diagnostic use.

<table>
<thead>
<tr>
<th>Label</th>
<th>Nature of reagents</th>
<th>Presentation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>R1</strong></td>
<td>Microplate</td>
<td>12 Strips (8 wells each) coated with purified EBV-Viral Capsid Antigen (inactivated), stored in a foil pouch with desiccant/humidity indicator.</td>
</tr>
<tr>
<td><strong>R2</strong></td>
<td>Concentrated washing solution (20x)</td>
<td>1 x 50 ml</td>
</tr>
<tr>
<td><strong>R3</strong></td>
<td>Non reactive control</td>
<td>1 x 0.4 ml</td>
</tr>
<tr>
<td><strong>R4a</strong></td>
<td>Positive control I</td>
<td>1 x 0.4 ml</td>
</tr>
<tr>
<td><strong>R4b</strong></td>
<td>Positive control II</td>
<td>1 x 0.4 ml</td>
</tr>
<tr>
<td><strong>R5</strong></td>
<td>Calibrator</td>
<td>1 x 0.4 ml</td>
</tr>
<tr>
<td><strong>R6</strong></td>
<td>Conjugate</td>
<td>1 x 16 ml</td>
</tr>
<tr>
<td><strong>R7</strong></td>
<td>Diluent I</td>
<td>1 x 30 ml</td>
</tr>
</tbody>
</table>
5 - WARNING AND PRECAUTIONS

Precautions
The reliability of the results depends on correct implementation of the following Good Laboratory Practices:

- Do not use expired reagents.
- Do not mix reagents from different lots within a given test run.

REMARK: It is possible to use other lots than those contained in the kit, provided the same lot is used within a given test run: washing solution (R2), Chromogen/Substrate solution (R9) and stopping solution (R10); these reagents can be used with Platelia™ EBV-VCA IgM, Platelia™ EBV-EA-D IgG and Platelia™ EB-NA-1 IgG of our catalogue. Diluent I (R7) can be used with Platelia™ EBV-EA-D IgG and Platelia™ EB-NA-1 IgG. Contact our technical service for detailed information.

- Before use, it is necessary to wait 30 minutes for the reagents to stabilize to room temperature.
- Carefully reconstitute the reagents avoiding any contamination.
- Do not carry out the test in the presence of reactive vapors (acid alkaline, aldehyde vapors) or dust that could alter the enzyme activity of the conjugate.
- Use glassware thoroughly washed and rinsed with deionized water or preferably, disposable material.
- Do not allow the microplate to dry between the end of the washing operation and the reagent distribution.
- The enzyme reaction is very sensitive to metal ions. Consequently, do not allow any metal element to come into contact with the various conjugate or substrate solution.

<table>
<thead>
<tr>
<th>Label</th>
<th>Nature of reagents</th>
<th>Presentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>R9</td>
<td>Chromogen/Substrate solution (ready-to-use): Tetramethylbenzidine (TMB). The reagent should remain closed when not in use; otherwise, a precipitate may form in the reaction wells.</td>
<td>1 x 15 ml</td>
</tr>
<tr>
<td>R10</td>
<td>Stopping solution (ready-to-use): 1N Sulfuric acid</td>
<td>1 x 15 ml</td>
</tr>
</tbody>
</table>
• The Chromogen/Substrate solution must be colorless. The appearance of color indicates that the reagent cannot be used and must be replaced. Use a new pipette tip for each sample.

• Washing the microplate is a critical step in the procedure: respect the recommended number of washing cycles and make sure that all wells are completely filled and then completely emptied. Incorrect washing may lead to inaccurate results.

• Never use the same container to distribute conjugate and development solution.

• Check the pipettes and other equipment for accuracy and correct operation.

• Do not change the assay procedure.

Health and safety instructions

All the reagents provided are intended for in vitro diagnostic use.

• Wear disposable gloves when handling reagents.

• Do not pipette by mouth.

• Human origin material used in the preparation of the reagents has been tested and found non-reactive for hepatitis B surface antigen (HBs Ag), antibodies to hepatitis C (HCV) and to human immunodeficiency virus (anti-HIV1 and anti-HIV2). Because no method can absolutely guarantee the absence of infectious agents, handle reagents of human origin and patient samples as if capable of transmitting infectious disease.

• Consider any material directly in contact with samples and reagents of human origin, as well as washing solution, as infectious material.

• Avoid spilling samples or solutions containing samples.

• Spills must be rinsed with bleach diluted to 10 %. If the contaminating fluid is an acid, spills must be initially neutralized with sodium bicarbonate, then cleaned with bleach and dried with absorbent paper. The material used for cleaning must be discarded in a contaminated residue container.

• Samples, reagents of human origin, as well as contaminated material and products should be discarded after decontamination.
  - either by immersion in bleach at the final concentration of 5 % of sodium hypochloride for 30 minutes,
  - or by autoclaving at 121°C for 2 hours minimum.

Autoclaving for at least one hour at 121°C, is the best method to inactivate the HIV viruses and the HB virus.
CAUTION: DO NOT INTRODUCE SOLUTIONS CONTAINING SODIUM HYPOCHLORIDE INTO THE AUTOCLAVE.

- Chemicals should be handled and disposed of in accordance with Good Laboratory Practices.
- Avoid any contact of the substrate buffer, the chromogen and the stopping solution with the skin or mucosa (risk of toxicity, irritation or burn).
- For hazard and precaution recommendations related to some chemical components in this test kit, please refer to the pictogram(s) mentioned on the labels and the information supplied at the end of instruction for use. The Safety Data Sheet is available on www.bio-rad.com.

6 - MATERIAL REQUIRED BUT NOT PROVIDED

- Vortex mixer.
- Microplate reader equipped with 450 nm filters (*).
- Container for biohazard waste.
- Sodium hypochloride (bleach) and sodium bicarbonate.
- Distilled or deionized water.
- Graduated cylinders.
- Disposable latex gloves.
- Goggles or safety glasses.
- Absorbent paper.
- Automatic or semi-automatic, adjustable or preset, pipettes or multipipettes to measure and dispense 10, 100 and 1000 µl.
- Manual, semi-automatic or automatic microplate washer (*).
- Disposable tubes.

(*) Consult us for detailed information about the equipment recommended by our technical department.

7 - RECONSTITUTION AND STORAGE OF REAGENTS

The kit should be stored at +2-8°C until the expiry date mentioned on the package (except for specific instructions). Before use, allow reagents to reach room temperature (+21-25°C). Return all reagents to refrigerator promptly after use.
1) Ready-to-use reagents

- Reagent 1 (R1): microplate
  Each tray containing 12 trips is wrapped in a sealed foil lined bag. Cut the bag
  with scissors or a scalpel 0.5 - 1 cm above the line. Replace unused strips into
  the bag immediately. Reseal the bag carefully and replace it at +2-8°C. Then,
  the strips are stable for 1 month.
- Reagent 3 (R3): non-reactive control
- Reagent 4a (R4a): positive control I
- Reagent 4b (R4b): positive control II
- Reagent 5 (R5): calibrator
- Reagent 6 (R6): conjugate
- Reagent 7 (R7): diluent I
- Reagent 9 (R9): Chromogen/Substrate solution
- Reagent 10 (R10): stopping solution

2) Reagents to be reconstituted

- Reagent 2(R2): washing solution concentrated 20x
  Dilute 50 ml of the 20X washing solution to 1.0 l with distilled and/or deionized
  water to obtain the ready-for-use solution. Mix well. After dilution, store at +2-
  8°C for 5 days.

8 - SPECIMENS

Collect a blood sample according to the current practices. Test will be performed
with non diluted samples. Separate the serum from the clot or red cells as soon
as possible to avoid any haemolysis. Extensive haemolysis may affect test
performance. Specimens with aggregates should be clarified by centrifugation
prior testing. Suspended fibrin particles or aggregates may yield falsely positive
results.

The specimens can be stored at +2-8°C if screening is performed within 5 days
or they may be deep-frozen at -20°C for several months. Avoid repeated freeze/
thaw cycles. If the specimens are to be shipped, they must be packaged in
accordance with the regulations in force regarding the transport of etiological
agents.

DO NOT USE CONTAMINATED, HYPERLIPAEMIC, ICTERIC
HYPERHAEMOLYSED OR HEAT-INACTIVATED SERA.
9 - ASSAY PROCEDURE

Strictly follow the proposed procedure.

Use the calibrator and the controls for each series of determinations to validate the test results.

Follow the following Good Laboratory Practice:
1. Carefully establish the sample distribution and identification plan.
2. Prepare the diluted washing solution (R2) (refer to section 7).
3. Take the carrier tray and the strips (R1) out of the protective pouch. Place the desired number of antigen-coated strips into a microwell frame. Allow 1 well for the reagent blank, 3 wells for Calibrator, 1 well for each Negative, Positive I and Positive II Controls.

4. All samples, controls and calibrator should be vortexed before use. Dilute test samples, Calibrator, Negative and Positive Controls 1:21 (e.g. 10 µl + 200 µl) with Sample Diluent I (R7) within dilution tubes or dilution plate

5. Pipette 100 µl of each diluted Calibrator, Control or patient sample into each well. Pipette 100 µl of Sample Diluent I (R7) into the first well for the reagent blank.

6. Incubate the microplate for 20 minutes ± 2 minutes at room temperature (21-25°C).

7. Aspirate the contents of all wells into a container for biohazards waste (containing sodium hypochloride). Add immediately into each well, a minimum of 300 µl of washing solution. Aspirate again. Repeat this procedure at least 4 times (a total of a minimum of 5 washes). If necessary, dry the plate by turning it upside down on absorbent paper. If an automatic washer is used, follow the same procedure.
8. Distribute 100 µl of the ready-to-use Conjugate (R6) into all wells.
9. Incubate 20 minutes ± 2 minutes at room temperature (21-25°C).
10. Empty all wells by aspiration and wash 5 times as described above.
11. Quickly dispense 100 µl of Chromogen/Substrate Solution (R9) into each well.
12. Allow the reaction to develop in the dark for 10 minutes ± 2 minutes at room temperature (21-25°C). Do not use adhesive film during this incubation.
The Chromogen/Substrate Solution will turn blue in wells containing detectable levels of IgG antibodies.
13. Add 100 µl of Stopping Solution (R10) to each well. Mix by gently tapping the plate. Addition of the Stopping Solution (R10) will result in a color change from blue to yellow.
14. Wait for a minimum of 5 minutes and read. Carefully wipe the plate bottom. Using a wavelength of 450 nm, blank the reader on the reagent blank well and measure the optical density of each well. The plate should be read within 30 minutes of adding the Stopping Solution (the strips must always be kept away from light before reading).
15. Check all results for agreement between the reading and the plate and sample distribution and identification plan.

10- CALCULATION AND INTERPRETATION OF THE RESULTS

1) Calculate the mean absorbance
1. Mean Cut-off Calibrator O.D. (Optical Density) - Calculate the mean O.D. value for the Cut-off Calibrator from the three Calibrator (R5) determinations. If any of the three calibrators Values differ by more than 15 % from the mean, discard that value and calculate the average of the two remaining values.
2. Correction Factor - To account for day-to-day fluctuations in assay activities due to room temperature and timing, a Correction Factor is determined for each lot of kits. The Correction Factor is printed on the Calibrator vial.
3. Cut-off Calibrator Value - The Cut-off Calibrator value for each assay is determined by multiplying the Correction Factor by the mean Cut-off Calibrator O.D. determined in step 1.
4. ISR Value - Calculate an Immune Status Ratio (ISR) for each specimen by dividing the specimen O.D. Value by the Cut-off Calibrator Value determined in Step 3.
Example: O.D.’s obtained for Calibrator (R5) = 0.380, 0.400, 0.420
Mean O.D. for Calibrator (R5) = 0.400
Correction factor = 0.5
Cut-off Calibrator Value = 0.5 x 0.400 = 0.200
O.D. obtained for patient sera = 0.600
ISR Value = 0.600/0.200 = 3.00

2) Assay validation
1. Reagent Blank (when read against blank air) must be < 0.150 at 450 nm: OD (RB) < 0.150
2. Negative control (R5) must be ≤ 0.250 at 450 nm (when read against reagent blank): OD (R3) ≤ 0.250
3. Each calibrator (R5) must be ≥ 0.250 at 450 nm (when read against reagent blank): OD (R5) ≥ 0.250
4. Positive control (R4b) must be ≥ 0.500 at 450 nm (when read against reagent blank): OD (R4b) ≥ 0.500
5. The ISR (Immune Status Ratio) Values for negative, positive I and positive II controls (R3, R4a, R4b) should be in their respective ranges printed on the vials.

If those criteria are not within their respective ranges, the test should be considered invalid and should be repeated.

3) Interpretation of the results
The patients’ ISR (Immune Status Ratio) Values are interpreted as follows:

<table>
<thead>
<tr>
<th>ISR Value</th>
<th>Results</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 0.90</td>
<td>Negative</td>
<td>No significant level of detectable EBV-VCA IgG antibody. Such individuals are presumed to be uninfected with EBV and to be susceptible to primary infection.</td>
</tr>
<tr>
<td>0.91-1.09</td>
<td>Equivocal</td>
<td>Samples should be retested</td>
</tr>
<tr>
<td>≥ 1.10</td>
<td>Positive</td>
<td>Significant level of detectable EBV-VCA IgG antibody. Indicative of current or previous infection. The individuals may be at risk of transmitting EBV infection, but is not necessarily currently contagious.</td>
</tr>
</tbody>
</table>

1. The following is a recommended method for reporting the results obtained; «The following results were obtained with the Platelia™ EBV-VCA IgG test. Values obtained with different methods may not be used interchangeably. The magnitude of the reported IgG level cannot be correlated to an endpoint titer». 
2. Four distinctive EBV antibodies are used to provide a comprehensive picture of EBV infection; these are EBV-VCA IgM, EBV-VCA IgG, EBV-EA IgG and EB-NA IgG. Accurate interpretation of EBV infection is based on the results from all these antibodies, and usually should not rely on single test results for a diagnosis.

3. Samples that remain equivocal after repeat testing should be retested by an alternate method, e.g., immunofluorescence assay (IFA). If results remain equivocal upon further testing, an additional sample should be taken.

4. The performance characteristics for this product have been established using one calibrator. If a linear dose response curve with the assay is desired, the customer should establish a minimum of two additional calibrators.

5. To evaluate paired sera for significant change in antibody level, both samples must be tested in duplicate in the same assay. The mean ISR of both (acute and convalescent) must be greater than 1.00 to evaluate the paired sera for a significant rise in antibody level.

4) Prevalence

Approximately 80-90% of the adult population in the USA is seropositive for EBV-VCA IgG. Their titers may vary depending upon the assay method used. Antibody to EBV IgG develops early in IM and peaks in 3-4 weeks after the initial onset. The titer will decline gradually to the titer that one will maintain throughout one’s life. Elevated levels of antibody to EBV may occur in patients with nasopharyngeal carcinoma, Burkitt’s lymphoma, Hodgkin’s disease, sarcoidosis and systemic lupus erythematosus.

5) Limitations of use

1. Kit procedures or practices outside those in this package insert may yield questionable results.
   - Non repeatable reactions are often caused by:
     - Inadequate microplate washing,
     - Inadequate timing of the incubation steps,
     - Contamination of negative samples by serum or plasma with a high antibody titre,
     - Contamination of the development solution by oxidizing agents (bleach, metal ions...),
     - Contamination of the stopping solution.
   - Contaminated, icteric, lipemic, hemolyzed or heat inactivated sera may cause erroneous results and should be avoided.
   - The performance characteristics have not been established for any matrices other than serum.
2. The physician in the light of other clinical findings and diagnostic procedures should interpret results of this test.

- This kit is designed to measure IgG antibody in patient samples.
- Positive results in neonates must be interpreted with caution, since maternal IgG is transferred passively from the mother to the fetus before birth. IgM assays are generally more useful indicators of infection in children below 6 months of age. The values obtained from this assay are intended to be an aid to diagnosis only. Each physician must interpret the results in light of the patient’s history, physical findings and other diagnostic procedures. The performance characteristics have not been established for patients with nasopharyngeal carcinoma, Burkitt’s lymphoma, other EBV associated lymphadenopathies, and other EBV associated diseases other than EBV related mononucleosis. The results of Platelia™ EBV-VCA IgG performed on serum from immunosuppressed patients must be interpreted with caution. The performance characteristics for this assay have not been established for pediatric specimens.

- A significant rise in antibody level indicates recent antigenic stimulation. Lack of a significant rise in antibody does not exclude the possibility of an EBV infection. Samples collected very early in the course of an infection may not have detectable levels of IgG. In such cases, it is recommended that an IgM assay be performed, or a second serum sample be obtained at 10 - 21 days later to be tested in parallel with the original sample to determine seroconversion which is indicative of a primary infection.

- The presence of EBV IgG antibody may not assure protection from disease. The ISR of a single specimen antibody determination does not correlate with severity of clinical symptoms of IM.

11- PERFORMANCES

1 - Relative Sensitivity and Specificity Based on Serum Characterization

A total of 205 random samples from two separate populations were assayed with the Platelia™ EBV-VCA IgG test and with commercially available IFA test kit. The study population was composed of sera collected from normal ambulatory donors from a large University of California and from a state department of Health in the Eastern United States. The results are summarized in the table below.

<table>
<thead>
<tr>
<th>Platelia™ EBV-VCA IgG</th>
<th>1st commercial IFA test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Results</td>
</tr>
<tr>
<td>Positive</td>
<td>193</td>
</tr>
<tr>
<td>Doubtful</td>
<td>1</td>
</tr>
<tr>
<td>Negative</td>
<td>2</td>
</tr>
</tbody>
</table>
A second commercially available IFA test for EBV-VCA IgG was used to resolve 2 results which were false-positive by the first commercial IFA test. The doubtful result by the Platelia™ EBV-VCA IgG test is considered indeterminate and that result (1 total) was omitted from the following calculations for relative specificity and sensitivity:
Specificity: 100 % (11/11)
Sensitivity: 100 % (193/193)

2 - Repeatability (Intra-Assay Precision)
The Platelia™ EBV-VCA IgG test was evaluated for precision by testing three sera (one negative, one low positive and one positive) ten times each on the same plate. The results are summarized in the Table below.

<table>
<thead>
<tr>
<th>Serum</th>
<th>n</th>
<th>X</th>
<th>S.D.</th>
<th>CV %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
<td>10</td>
<td>0.392</td>
<td>0.047</td>
<td>12</td>
</tr>
<tr>
<td>Low positive</td>
<td>10</td>
<td>1.195</td>
<td>0.038</td>
<td>3.2</td>
</tr>
<tr>
<td>Positive</td>
<td>10</td>
<td>2.252</td>
<td>0.097</td>
<td>4.3</td>
</tr>
</tbody>
</table>

X = Mean ISR Value
S.D. = Standard Deviation
C.V. = Coefficient of Variation

3 - Reproducibility (Inter-Assay Precision)
The Platelia™ EBV-VCA IgG test was evaluated for precision by testing three sera (one negative, one low positive and one positive) ten times each on three different days. The results are summarized in the Table below.

<table>
<thead>
<tr>
<th>Serum</th>
<th>n</th>
<th>X</th>
<th>S.D.</th>
<th>CV %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
<td>30</td>
<td>0.42</td>
<td>0.064</td>
<td>15</td>
</tr>
<tr>
<td>Low positive</td>
<td>30</td>
<td>1.02</td>
<td>0.054</td>
<td>4.2</td>
</tr>
<tr>
<td>Positive</td>
<td>30</td>
<td>2.44</td>
<td>0.149</td>
<td>6.1</td>
</tr>
</tbody>
</table>

The C.V. on the positive samples are below 10 %.

4 - Cross-reactivity
The following 8 serum samples were assayed and were found negative with the Platelia™ EBV-VCA IgG.


<table>
<thead>
<tr>
<th>Sample</th>
<th>EBV</th>
<th>ANA</th>
<th>CMV</th>
<th>VZV</th>
<th>HSV 1</th>
<th>HSV 2</th>
<th>Platelia™ EBV-VCA IgG</th>
</tr>
</thead>
<tbody>
<tr>
<td>472</td>
<td>–</td>
<td>–</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>–</td>
<td>Negative</td>
</tr>
<tr>
<td>595</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>+</td>
<td>+</td>
<td>–</td>
<td>Negative</td>
</tr>
<tr>
<td>617</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>+</td>
<td>+</td>
<td>–</td>
<td>Negative</td>
</tr>
<tr>
<td>616</td>
<td>–</td>
<td>+</td>
<td>–</td>
<td>+</td>
<td>+</td>
<td>–</td>
<td>Negative</td>
</tr>
<tr>
<td>631</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>+</td>
<td>–</td>
<td>–</td>
<td>Negative</td>
</tr>
<tr>
<td>632</td>
<td>–</td>
<td>–</td>
<td>+</td>
<td>+</td>
<td>–</td>
<td>–</td>
<td>Negative</td>
</tr>
<tr>
<td>638</td>
<td>–</td>
<td>–</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>–</td>
<td>Negative</td>
</tr>
<tr>
<td>660</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>+</td>
<td>–</td>
<td>–</td>
<td>Negative</td>
</tr>
</tbody>
</table>

- EBV: Epstein-Barr Virus
- ANA: Antinuclear Antibody
- CMV: Cytomegalovirus
- VZV: Varicella-Zoster Virus
- HSV 1: Herpes Simplex Virus Type 1
- HSV 2: Herpes Simplex Virus Type 2


Този продукт съдържа човешки или животински компоненти. Бъдете внимателни при работа с него.
H314-H317  P280-
P301+P330+P331-
P305+P351+P338-
P303+P361+P353-
P333+P313-
P305+P351+P338-
P501
(BG) опасно
Причинява тежки изгаряния на кожата и сериозно увреждане на очите. Може да причини алергична кожна реакция.
Изолпзвайте предпазни ръкавици/предпазно облекло/предпазни очила/предпазна маска за лице. ПРИ ПОПЪТЪНЦЕ: изплатете устата. НЕ предизвиквайте повръщане. ПРИ КОНТАКТ С ОЧИТЕ: Промивайте внимателно с вода в продължение на няколко минути.

(CZ) Nebezpečí
Způsobuje těžké poleptání kůže a poškození očí. Může vyvolat alergickou kožní reakci.

(DK) Fare
Forårsager svære forbrændinger af huden og øjenkader. Kan forårsage allergisk hudreaktion.

(EN) Danger
Causes severe skin burns and eye damage. May cause an allergic skin reaction.

(ES) Peligro
Provoca quemaduras graves en la piel y lesiones oculares graves. Puede provocar una reacción alérgica en la piel.


(CZ) Nebezpečí
Způsobuje těžké poleptání kůže a poškození očí. Může vyvolat alergickou kožní reakci.

(P) Koužel/předpadebná ruka

(IF) PÅVIRKEN: Ustetem fruktfkostnede skade.

(PL) Opiekuj się, gdy skóra jest wrażliwa.

It is important to remember that GLP is a legal framework for the management of laboratory animals and should be adhered to in order to ensure the ethical treatment and well-being of animals used in research. The regulations and guidelines are intended to ensure that the animals are treated with care and respect, and that their health and well-being are protected. GLP also aims to ensure that the results of experiments and studies conducted under GLP are accurate and reliable, which is essential for the development of new drugs and treatments.

There is no information provided about the therapeutic or research uses of this compound, so it is not possible to provide a complete and accurate description of its properties and effects. However, it is clear that the compound is potentially hazardous and should be handled with care to prevent injury to humans and the environment. It is important to follow the appropriate safety procedures and guidelines when handling or working with this compound in order to minimize the risk of exposure and injury.
protección. EN CASO DE INGESTIÓN: Enjuagarse la boca. NO provocar el vómito. EN CASO DE CONTACTO CON LOS OJOS: Aclarar cuidadosamente con agua durante varios minutos. Quitar las lentes de contacto, si lleva y resulta fácil. Seguir aclarando. EN CASO DE CONTACTO CON LA PIEL (o el pelo): Quitarse inmediatamente las prendas contaminadas. Aclararse la piel con agua o ducharse. En caso de irritación o erupción cutánea: Consultar a un médico. Eliminar el contenido o el recipiente conforme a la reglamentación local/ regional/nacional/internacional.

(FI)
Vaara

(FR)
Danger

(IT)
Pericolo
(LT)
Pavojinga
Smarkiai nudegina odą ir pažeidžia akis. Gali sukelti alerginę odos reakciją.
Mūvėti apsaugines pirštines/dėvėti apsauginius drabužius/naudoti akių (veido) apsaugos priemones.
PRARIJUS: išskalauti burną. NESKATINTI vėmimo.
PATEKUS Į AKIS: Kelias minutes atsargiai plauti vandeniu. Išimti kontaktinius lęšius, jeigu jie yra ir jeigu lengvai galima tai padaryti. Toliau plauti akis.

(NL)
Gevaar
Veroorzaakt ernstige brandwonden en oogletsel. Kan een allergische huidreactie veroorzaken.

(NO)
Fare
Forårsaker alvorlige hudforbrenninger og øyeskader. Kan forårsake allergiske hudreaksjoner.

(PL)
Niebezpieczeństwo
Powoduje poważne oparzenia skóry oraz uszkodzenia oczu. Może powodować reakcję alergiczną skóry.

(PT)
Perigo
Provoca queimaduras na pele e lesões oculares graves. Pode provocar uma reação alérgica cutânea.

(RO)
Pericol
Provoacă arsuri grave ale pielii și lezarea ochilor. Poate provoca o reacție alergică a pielii.

(SE)
Fara
Orsaker allvarliga frätskador på hud och ögon. Kan orsaka allergisk hudreaktion.
(SI)
Nevarno
Povzroča hude opekline kože in poškodbe oči.
Lahko povzroči alergijski odziv kože.

(SK)
Nebezpečenstvo
Provoacă arsuri grave ale pielii şi lezarea ochilor.
Môže vyvoláť alergickú kožnú reakciu.