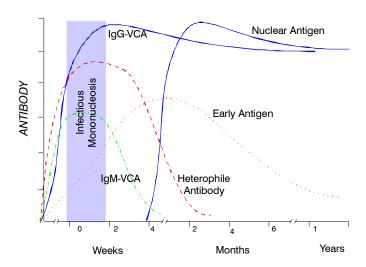
Epstein-Barr Virus VCA (IgM) Enzyme Immunoassay

ImmunoWELL VCA IgM Test is an ELISA method for the qualitative detection of IgM antibody to Epstein-Barr Virus Viral Capsid Antigen (VCA) in human serum. When the VCA IgM test is used in conjunction with other testing such as the EBV nuclear antigen (EBNA-1), VCA IgG, and EBV early antigen tests and/or heterophile tests, the results can serve as an aid in the diagnosis of infectious mononucleosis (IM).

Expected Results

Interpretations of EBV serologies, unlike standard viral serologies on paired sera, are based on the differential profiles of antibodies in a single serum against multiple antigens. During the acute phase of Infectious Mononucleosis (IM), IgG and IgM responses to viral capsid antigen complex (VCA) are rapid and occur almost simultaneously. VCA-IgM antibodies are reliably detectable only during primary infections. Due to the variable incubation period and intensity of symptoms, by the time patients consult their physicians, nearly all have reached peak titers of IgG. In general, both IgG and IgM become detectable within 2–3 weeks of onset and peak at 4–6 weeks. VCA-IgM disappears rapidly thereafter, while IgG wanes slightly and then varies little for life.

VCA-IgM is present in approximately 85 to 90% of sera from IM patients. The presence of VCA-IgM antibody is very useful in diagnosing acute or recent infection since it is difficult to demonstrate a significant VCA-IgG antibody rise in titer using paired sera. Because 10 to 15% of patients have no detectable VCA-IgM response, additional evaluation of antibodies for VCA-IgG, Early Antigen (EA) and EBNA in acute-phase serum are indicated to determine either current or reactivated infections.



Performance Characteristics

To assure consistent performance, lots are tested using internationally recognized standards (Boston Biomedical Inc, BBI). This serum panel consists of twenty-five samples representing all disease stages and has been validated by independent, third party organizations. These data are available on request.

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Ordering Information

Product Description	Quantity	GenBio Product No.
ImmunoWELL EBV VCA IgM Test	1 kit / 96 wells	3260
Also available from GenBio		
ImmunoWELL EBV EA (D) IgG Test	1 kit / 96 wells	3240
ImmunoWELL EBV VCA IgG Test	1 kit / 96 wells	3250
ImmunoWELL EBV EBNA IgG Test	1 kit / 96 wells	3270

Principle

The *ImmunoWELL* Test utilizes an EIA microtiter plate technique for the detection of antibodies. Serum is added to antigen coated microtiter wells and allowed to react. After removal of unbound antibodies, horseradish peroxidase-conjugated antihuman IgG antibodies are allowed to react with bound antibodies. The bound peroxidase reacts with tetramethylbenzidine (TMB), the chromogenic substrate, developing a color. Finally, the substrate reaction is stopped and the optical density is read with a microwell spectrophotometer.

Procedural Summary

- 1. Prepare Wash Buffer from Wash Buffer Concentrate
- 2. Dilute each control and specimen 1:100 in Specimen Diluent
- 3. Add 100 μ L of Specimen Diluent into the first well as a substrate blank.
- 4. Add 100 μ L of prediluted Calibrators, diluted Controls and Specimens to coated microwells and incubate 60 min at room temperature
- 5. Aspirate wells and wash microwells three times with Wash Buffer
- 6. Add 100 µL of Conjugate to wells and incubate 30 minutes at room temperature
- 7. Aspirate microwells and wash wells three times with Wash Buffer
- 8. Add 100 μ L of Substrate to wells and incubate 30 minutes at room temperature
- 9. Add 100 μ L Stop Solution to wells and read results at 450nm

References

- 1. Evans, A.S., Niederman, J.C., *Epstein-Barr Virus*, pp.253-281, In A.S. Evans (ed.), Viral Infections of Humans: Epidemiology and Control, Plenum Publishing, New York (1982).
- 2. Lennette, E.T., *Diagnosis of Epstein-Barr Virus Infections*, pp.257-271, In E.H. Lennette (ed.), Laboratory Diagnosis of Viral Infections, Dekker Publishing, New York (1985).
- 3. Lennette, E.T., *Epstein-Barr Virus*, pp.905-910, In P.R. Murray (ed.), Manual of Clinical Microbiology, ASM Press Publishing, Washington, D.C. (1995).
- 4. Sumaya, C.V., Jenson, H.B., *Epstein-Barr Virus*, pp.568-575, In N.R. Rose (ed.), Manual of Clinical Laboratory Immunology, ASM Press Publishing, Washington, D. C. (1992).



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