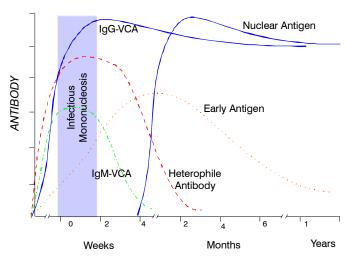
Epstein-Barr EBNA (IgG) Enzyme Immunoassay

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

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. There is wide variation in the peak titers of each antibody and the time to develop a full spectrum of antibodies among patients. Many asymptomatic individuals maintain high, unchanging titers. This variability, together with the false-positive and false-negative problems associated with IgM detection, precludes the use of simple IgG/IgM testing for the diagnosis of Infectious Mononucleosis (IM). During the acute phase of IM, IgG and IgM responses to viral capsid antigen complex (VCA) are rapid and occur almost simultaneously. 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.

The time course and the strength of EBNA IgG response often can yield valuable information as to the patient's underlying problems. EBNA antibodies are absent during the acute phase and 10-15% of IM patients have no detectable VCA-IgM response by the time of the first serum collection. The gradual appearance of EBNA antibodies begins during the first to second month after onset, persisting for life. Hence, VCA-IgG antibodies found with low titer or no anti-EBNA indicates acute IM phase serum, whereas VCA-IgG antibodies in the presence of peak titer anti-EBNA, indicates later infection.



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.

Product Description	Quantity	GenBio Product No.
ImmunoWELL EBV EBNA IgG Test	1 kit / 96 wells	3270

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 VCA IgM Test	1 kit / 96 wells	3260

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 μ L 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).
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- 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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