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11/18

EBV-VCA IgA ELISA Kit

(Catalog # E4687-100 ; 96 assays ; Storage at 4ºC)

I. Introduction:

Epstein-Barr virus (EBV) is a herpes virus known to cause infectious mononucleosis (IM). EBV infection may demonstrate a wide spectrum of clinical symptoms. The majorities of primary EBV infections are transmitted via saliva, occur during childhood, and are sub-clinical. In the U.S., 50% of the population demonstrate EBV antibodies before the age of 5 years; 80% by adulthood. Transfusion-associated EBV infections have also been reported. Epstein-Barr virus has also been associated in the pathogenisis of two human cancers, Burkitt's lymphoma and nasopharyngeal carcinoma. Burkitt's lymphoma is primarily observed in Sub-Sahara Africa, especially in African children, and in New Guinea. Nasopharyngeal carcinoma is observed in Asia, most notably in Southern China.

II. Applications:

- Detection of IgA antibody to EBV-VCA

III. Sample Type:

- Plasma
- Serum

IV. Kit Contents:

Components	E4687-100	Part Number
Microplate	12 strips x 8 wells	E4687-100-1
Sample Diluent	22 ml	E4687-100-2
Calibrator	1 ml	E4687-100-3
Positive Control	1 ml	E4687-100-4
Negative Control	1 ml	E4687-100-5
Enzyme conjugate	12 ml	E4687-100-6
TMB Substrate	12 ml	E4687-100-7
Stop Solution	12 ml	E4687-100-8
Wash Buffer (20X)	25 ml	E4687-100-9

V. User Supplied Reagents and Equipment:

- Microplate reader capable of measuring absorbance at 450 nm

VI. Storage Conditions and Reagent Preparation:

Store kit at 2-8°C. Keep microwells sealed in a dry bag with desiccants. Spin tubes briefly to bring down all components to the bottom of tubes. Reagents are stable until the expiration of the kit. Do not expose reagent to heat, sun, or strong light.

- Wash BufferPrepare 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 (18-26°C).

VII. Assay Protocol:

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

1. Place the desired no. of coated strips into the holder. Replace any unused microwell strips back into the aluminum bag, seal and store at 2-8°C.
2. Negative control, positive control, and calibrator are ready to use. Prepare 1:21 dilution of test samples, 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 100 µl 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.
10. **CALCULATION OF RESULTS**: 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. Calculate the cut-off value: Calibrator OD x Calibrator Factor (CF). Calculate the Ab (Antibody) Index of each determination by dividing the O.D. value of each sample by cut-off value

Example of typical results:
Calibrator mean OD = 0.8
Calibrator Factor (CF) = 0.5
Cut-off Value = 0.8 x 0.5= 0.400
Positive control O.D. = 1.2
Ab Index = 1.2 / 0.4 = 3
Patient sample O.D. = 1.6
Ab Index = 1.6 / 0.4 = 4.0

QUALITY CONTROL
The test run may be considered valid provided the following criteria are met:
1. The O.D. of the Calibrator should be greater than 0.250.
2. The Ab index for Negative control should be less than 0.9.

3. The Ab Index for Positive control should fall within the range specified on the COA/label.

INTERPRETATION

The following is intended as a guide to interpretation of this EBV-VCA IgA test results; each laboratory is encouraged to establish its own criteria for test interpretation based on sample populations encountered.

Antibody Index Interpretation

<0.9 No detectable antibody to EBV-VCA IgA by ELISA.
0.9-1.1 Borderline positive. Follow-up testing is recommended if clinically indicated.
>1.1 Detectable antibody to EBV-VCA IgA by ELISA

LIMITATIONS OF THE TEST

1. The test results obtained using this kit serve only as an aid to diagnosis and should be interpreted in relation to the patient's history, physical findings and other diagnostic procedures.
2. Lipemic or hemolyzed samples may cause erroneous results.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

98 sera from patients with suspected EBV infection were tested by this EBV-VCA IgA ELISA and a reference ELISA method. 14 sera were positive and 79 were negative by both methods (95% agreement). The results are summarized below:

		EBV-VCA IgA ELISA		
		+	–	Total
Reference ELISA Kit	+	14	2	16
	_	3	79	82
	Total	17	81	98

Intra-Assay Study

Serum	No. of Replicates	Mean	Standard Deviation	Coefficient of Variation %
1	16	1.78	0.090	5.05
2	16	1.12	0.067	5.90
3	16	0.24	0.017	7.08

Inter-Assay Study

Serum	No. of Replicates	Mean	Standard Deviation	Coefficient of Variation %
1	10	1.63	0.132	8.90
2	10	1.05	0.096	9.14
3	10	0.27	0.029	10.74

VIII. Related Products:

EBV-VCA IgM ELISA Kit (E4689)
QuickDetect™ IgA (Human) ELISA Kit (E4467)
EBV-VCA IgG ELISA Kit (E4688)
QuickDetect™ IgM (Human) ELISA Kit (E4479)
QuickDetect™ IgG (Human) ELISA Kit (E4475)

FOR RESEARCH USE ONLY! Not to be used on humans.