

Datasheet for ABIN996984 **EBV VCA IgG ELISA Kit**



Overview

Quantity:	96 tests
Target:	EBV VCA IgG
Reactivity:	Epstein-Barr Virus (EBV)
Method Type:	Competition ELISA
Application:	ELISA
Product Details	
Sample Type:	Serum
Analytical Method:	Qualitative
Detection Method:	Colorimetric
Specificity:	98.1 %
Material not included:	1. ELISA microwell reader capable of reading at a wavelength of 450 nm.
	2. Pipettes capable of accurately delivering 10 to 200 μ L.
	3. Multichannel pipette capable of accurately delivering (50-200 μ K)
	4. Reagent reservoirs for multichannel pipettes.
	5. Wash bottle or microwell washing system.
	6. Distilled or deionized water.
	7. One liter graduated cylinder.
	8. Serological pipettes.
	9. Disposable pipette tips.
	10. Paper towels.
	11. Laboratory timer to monitor incubation steps.

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Target Details	
Target:	EBV VCA IgG
Abstract:	EBV VCA IgG Products
Target Type:	Antibody, Antibody
Application Details	
Comment:	Quality Control:
	1. Each time the assay is run the Calibrator must be run in triplicate. A reagent blank, Negative
	Control, and Positive Control must also be included in each assay.
	2. Calculate the mean of the three Calibrator wells. If any of the three values differ by more than
	15 % from the mean, discard that value and calculate the mean using the remaining two wells.
	3. The mean OD value for the Calibrator and the OD values for the Positive and Negative
	Controls should fall within the following ranges: OD Range Negative Control <0.250 Calibrator >
	0.300 Positive Control > 0.500 a. The OD of the Negative Control divided by the mean OD of the
	Calibrator should be < 0.9. b. The OD of the Positive Control divided by the mean OD of the
	Calibrator should be > 1.25. c. If the above conditions are not met the test should be considered
	invalid and should be repeated.
	4. The Positive Control and Negative Control are intended to monitor for substantial reagent
	failure and will not ensure precision at the assay cutoff.
	5. Additional controls may be tested according to guidelines or requirements of local, state,
	and/or federal regulations or accrediting organizations.
	6. Refer to NCCLS document C24: Statistical Quality Control for Quantitative Measurements for
	guidance on appropriate QC practices.
	Limitations of procedure:
	1. Most (80 %) of IM individuals have peak anti-VCA IgG titers before they consult a physician
	(4). Therefore, testing paired acute and convalescent sera for significant changes in antibody
	levels is not useful in most patients with IM (4).

2. The antibody titer of a single serum specimen cannot be used to determine recent infection. Test results for anti-VCA should be interpreted in conjunction with the clinical evaluation and results of antibody tests for other EBV antigens (i.e., EBNA, EA, and IgM-VCA).

Sample Volume:

10 µL

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Application Details

Assay Time:	1 h
Plate:	Pre-coated
Sample Preparation:	1. It is recommended that specimen collection be carried out in accordance with NCCLS
	document M29: Protection of Laboratory Workers from Infectious Disease.
	2. No known test method can offer complete assurance that human blood samples will not
	transmit infection. Therefore, all blood derivatives should be considered potentially infectious.
	3. Only freshly drawn and properly refrigerated sera obtained by approved aseptic venipuncture
	procedures should be used in this assay (27, 28). No anticoagulants or preservatives should be
	added. Avoid using hemolyzed, lipemic, or bacterially contaminated sera.
	4. Store sample at room temperature for no longer than 8 hours. If testing is not performed
	within 8 hours, sera may be stored between 2° and 8 °C for no longer than 48 hours. If delay in
	testing is anticipated, store test sera at -20 °C or lower. Avoid multiple freeze/thaw cycles that
	may cause loss of antibody activity and give erroneous results.
Assay Procedure:	1. Break off number of wells needed (four for calibrators plus number of samples) and place in
	strip holder.
	2. Add 100 μL of each calibrator to wells 1-4, then add 100 μL of the diluted test samples to the
	remaining wells. Note: Standards are supplied prediluted. Do not dilute further.
	3. Incubate at room temperature (15 to
	2. °C) for 10 minutes.
	4. Shake out contents and wash 3 times with the diluted wash buffer.
	5. Add 100 µL of Enzyme Conjugate to each well.
	6. Incubate at room temperature for 5 minutes.
	7. Shake out contents and wash 3 times with wash buffer, then rinse once with DI water. Slap
	wells against paper towels to remove excess moisture.
Calculation of Results:	A. Calculations:
	1. Correction Factor A cutoff OD value for positive samples has been determined by the
	manufacturer and correlated to the Calibrator. The correction factor (CF) will allow you to
	determine the cutoff value for positive samples and to correct for slight day-to-day variations in
	test results. The correction factor is determined for each lot of kit components and is printed o
	the Component List located in the kit box.
	2. CutoffOD Value To obtain the cutoff OD value, multiply the CF by the mean OD of the

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2.2 Relative

1. Comparative Study A comparative study was conducted to compare the DAI ELISA EBV-VCA IgG Test System to another commercial ELISA for the detection of IgG antibodies against EBV-VCA. A total of 199 serum specimens were obtained from two plasma donor centers and a reference laboratory. Below is a results summary. Table 1: DAI ELISA EBV-VCA IgG Test System vs. Commercial EBV-VCA IgG ELISA DAI EBV-VCA IgG ELISA Test System Positive Negative Equivocal * Total Commercial EBV- IgG ELISA Positive 104 8* 3 115 Negative 10** 46 4 60 Equivocal * 11 12 1 24 T otals 125 66 8 199 Relative Specificity = 46/56 = 8

2.1 % Percent Agreement: 150/168 = 89.3 % *Equivocal samples not included in calculations ** Discrepant results. See Table 2 below for the results of the retesting of the discrepant samples using the DAI IFA EBV-VCA IgG Test System: Table 2: Analysis of Discrepant Results Sample ID DAI ELISA Commerical DAI IFA EBV- EBV- VCA IgG VCA- IgG VCA IgG Test Test System ELISA System 26 0.251

- 1.16 29 0.261
- 1.00 39 0.358
- 1.00 39 0.368
- 1.13 41 0.391
- 1.30 53 0.582
- 1.05 63 0.767
- 1.10 + 34 0.797
- 1.30 + 81
- 1.243 0.65 + 83
- 1.270 0.70 + 89
- 1.399 0.73 + 93
- 1.449 0.39 101
- 1.614 0.57 + 111
- 1.859 0.60 + 133
- 2.216 0.48 + 137
- 2.254 0.75 + 139
- 2.320 0.77 + 152
- 2.730 0.20 + Summary a. Eight samples were negative by DAI ELISA and positive by the

commercial VCA IgG ELISA. DAI IFA confirmed six of these eight samples to be negative. b. Ten

samples were positive by DAI ELISA and negative by the commercial VCA IgG ELISA. DAI IFA
confirmed nine of these ten samples to be positive. c. Recalculation of the relative sensitivity,
relative specificity, and percent agreement, based upons the resolution of the discrepant
samples by IFA, provided the results are shown in Table 3: Table 3 Recalculation of Relative
All immunocompetent persons infected with EBV produce antibodies to VCA (6). Both IgM and
IgG antibodies to VCA appear rapidly following infection and reach peak titers within three to
four weeks (4). IgG antibodies to VCA decline slowly after peaking but persist indefinitely (15).
Indications of a primary acute EBV infection are the presence of IgG antibodies to VCA, coupled
with anti-EA, and/or IgM anti-VCA antibodies, and the absence of antibodies to EBNA (4, 11).
The presence of IgG anti-VCA and anti-EBNA indicates the infection was not recent (4, 11). The
incidence of EBV infection varies with age and socioeconomic status (6). In the underdeveloped
countries, most persons acquire EBV in early childhood and the infection is usually unapparent
(2, 4). In one study in the United States, about 50 % of college freshmen were seropositive for
EBV (30). In a study conducted by DAI Scientific technicians using 135 normal samples from
the Southeastern United States, 134/135 samples were positive by both the DAI ELISA EBV-
VCA IgG Test System and the DAI IFA EBV-VCA IgG Test System. In another study consisting of
32 normal pediatric samples, 32/32 samples were negative using both the DAI ELISA EBV-VCA
IgG Test System, and the DAI IFA EBV-VCA IgG Test System. The number of individuals with
IgG antibody to EBV-VCA varies with age and socioeconomic status. DAI Scientific
recommends that each laboratory establish their expected values based upon the population
type typically tested. cc

Restrictions:

For Research Use only

Handling

Storage:

Expiry Date:

14 months

4 °C