BioVendor Group CLIA

EBV

Diagnosis of infectious mononucleosis

EBV EA-D IgG, IgM
EBV EBNA-1 IgG, IgM
EBV VCA IgA, IgG, IgM

Diagnostic panel:
Herpes viruses

CE IVD

The kits are CE-IVD certified and intended for professional use.

CLIA kits are optimized and validated for the determination of antibodies in human serum and plasma

Designed for the platform

Kleeya®

Introduction

Epstein-Barr virus (EBV) is a DNA virus from the group of herpes viruses. There are currently eight known herpes viruses in human pathology. The virus is transmitted by droplets, direct contact or through saliva. EBV infection leads to lymph node hyperplasia and reticuloendothelial cell proliferation in the lymph nodes. It also infiltrates the spleen and is found to a lesser extent in other organs (liver, kidneys, heart muscle, brain). The virus stimulates the production of antibodies against its antigens, but also against antigens of certain animal cells, nuclear antigens, and ampicillin. The most typical manifestation is infectious mononucleosis (IM); it is also related to Burkitt's lymphoma and nasopharyngeal carcinoma. 90% of cases of the disease occur in childhood. After an incubation period (1–2 months), IM develops with characteristic symptoms of fever, pharyngitis and generalized lymph node enlargement. Manifestations of IM are affected by age and the state of the body's immune system. Like other herpes viruses, after a primary infection, EBV is not completely eradicated from the body but remains latent and may be reactivated in the future.

Diagnosis of the disease

The determination of specific IgA, IgG and IgM antibodies against individual EBV antigens in serum or plasma by CLIA or ELISA method with confirmation by Immunoblot or Microblot-Array methods is a suitable method for the detection of EBV infection and the stage of the disease.

VCA

IgA and IgM class anti-VCA are markers of acute infection and can form both during primary infection and reactivation of EBV infection. IgM antibodies reach high levels in acute and the convalescent phase of the infectious mononucleosis. Both antibody classes may persist for several months. IgG class antibodies have an anamnestic character and persist in high titers for life in most of the infected persons. IgG seroconversion can be detected at an early stage of the primary infection, and a significant increase in IgG titer is characteristic of reinfection and reactivation.

EBNA-1

IgM class anti-EBNA-1 are detectable during the acute phase of primary infection and stay present for several weeks or months. They are also produced after reactivation. IgG class antibodies appear later and are detectable detectable for life. The long-term absence of IgG antibodies in infected individuals may indicate immunodeficiency.

EA-D

IgM and IgG class anti-EA-D are supplementary markers of the primary EBV infection. High titers of EA-D IgG antibodies are typical for late acute or convalescent phase of IM.

Clinical manifestations of EBV infection

Primary infection

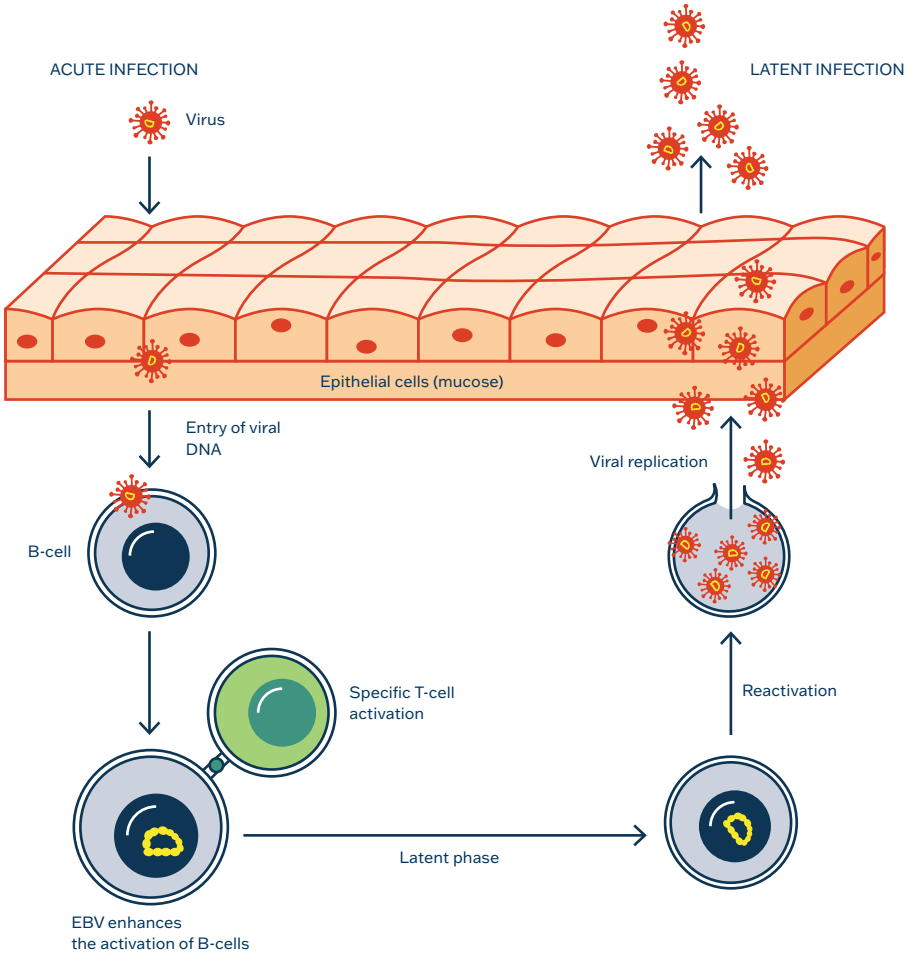
- Asymptomatic infection
- Non-specific fever
- Infectious mononucleosis (pharyngitis,lymphadenopathy, splenomegaly, fever)

Latent chronic infection

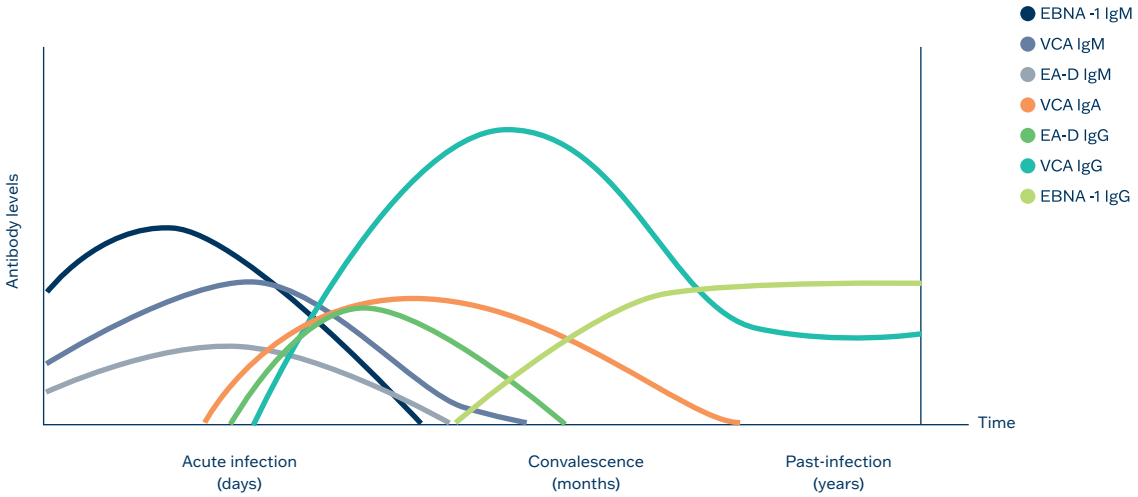
- Asymptomatic salivary excretion of the virus

Reactivation

- Asymptomatic in general
- In cases of immunodeficiency (e.g. malignant lymphoproliferative disorders, tongue leucoplasia, lymphoid pneumonia, etc.
- In certain geographic areas: Burkitt's lymphoma,nasopharyngeal carcinoma



Antibody response dynamics



Clinical applications

- Screening tests for the detection of infection with EBV in humans
- Confirmation of infectious mononuclosis
- Disease stage determination

Routine evaluation model for EBV serology

VCA			EA-D		EBNA-1		Evaluation
IgM	IgA	IgG	IgM	IgG	IgM	IgG	
–	–	–	–	–	–	–	Seronegativity
+	–	–	+	–	+	–	Primary infection
+	+	–	+	+	(+)	–	
+	+	+	+	+	(+)	–	
+	(+)	+	–	(+)	–	–	
–	(+)	+	–	(+)	–	+	Post-acute stage
–	–	+	–	–	–	+	Past infection
+	(+)	+	(+)	(+)	(+)	+	Reactivation

Antigens

CLIA EBV EA-D IgG and IgM	CLIA EBV EBNA-1 IgG and IgM
Recombinant EBV antigen EA-D	Recombinant EBV antigen EBNA-1

CLIA EBV VCA IgA and IgM	CLIA EBV VCA IgG
Recombinant EBV antigen p18	Mix of recombinant EBV antigens p18 and p23

Test characteristics

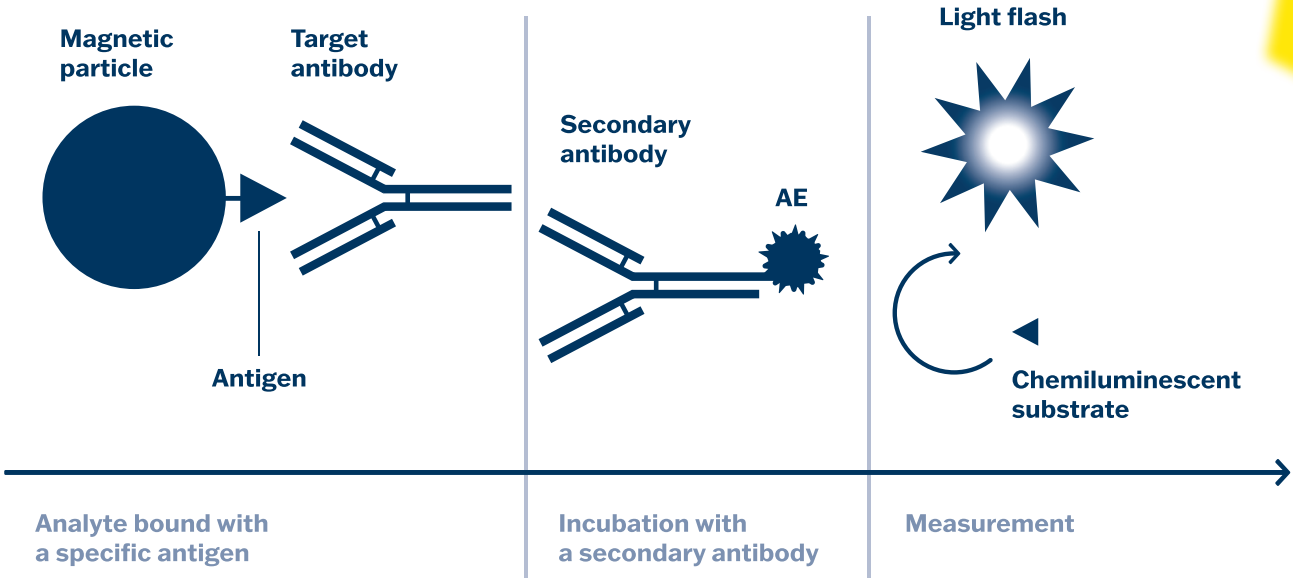
Kit	Calibration range	Diagnostic sensitivity	Diagnostic specificity
CLIA EBV EA-D IgG	5–160 U/ml	99,99 %	97,09 %
CLIA EBV EA-D IgM	3–160 U/ml	96,43 %	99,99 %
CLIA EBV EBNA-1 IgG	3–320 U/ml	99,29 %	97,96 %
CLIA EBV EBNA-1 IgM	3–160 U/ml	95,83 %	98,40 %
CLIA EBV VCA IgA	3–160 U/ml	99,99 %	99,99 %
CLIA EBV VCA IgG	3–320 U/ml	99,99 %	96,77 %
CLIA EBV VCA IgM	3–160 U/ml	99,99 %	98,36 %

Correlation of methods

CLIA kits were compared to established ELISA kits. 97–99% agreement was found among the compared methods.

How does CLIA method work?

CLIA is a fully automated, fast, specific and sensitive method. It combines the use of magnetic particles for immunocomplex separation of the antigen and flash chemiluminescence for sensitive detection. The use of magnetic particle suspension facilitates automation, significantly shortens reaction times and improves the specificity of the determination. Flash chemiluminescence of acridinium ester provides an intense light signal even at very low concentrations and its intensity is measured in relative units of light (RLU). CLIA kits are designed for use on the KleeYa® automated platform.



CLIA kits

Diagnostic CLIA kits are used to determine IgA, IgG and IgM antibodies against immunodominant antigens (EA-D, EBNA-1 and VCA) of Epstein-Barr virus in human serum or plasma on a KleeYa® analyzer. The results are reported in U/ml.

Control set CLIA

Control sera verify the accuracy of results obtained by the CLIA kits.

Ease of use

- Fully automated method
- Kits include all necessary reagents, incl. calibrators
- Working strength reagent solution
- Control sera available as independant sets
- Results in U/ml

Advantages

- High diagnostic sensitivity and specificity
- Low sample (10 µl) and reagent consumption
- Short test time (30 min)
- Wide measuring range
- Full traceability of reagent consumption and number of tests available using RFID tags
- LIS connectivity available
- Superior customer service

Ordering information

CLIA kits

CLIA diagnostic kits are used to determine IgA, IgG and IgM antibodies against EBV in patient serum or plasma on a KleeYa® analyzer.

Kit	Catalogue number	Number of tests
CLIA EBV EA-D IgG	CL-EAG100	100
CLIA EBV EA-D IgM	CL-EAM100	100
CLIA EBV EBNA-1 IgG	CL-EBG100	100
CLIA EBV EBNA-1 IgM	CL-EBM100	100
CLIA EBV VCA IgA	CL-VCA100	100
CLIA EBV VCA IgG	CL-VCG100	100
CLIA EBV VCA IgM	CL-VCM100	100

Control sets

Each set contains two vials of positive and two vials of negative control serum with the predetermined level of specific antibodies. They are designed to verify the accuracy of results obtained with CLIA kits.

Control set	Catalogue number	Number of tests
CLIA Control set EBV EA-D IgG	CL-EAGCON	2 x 20
CLIA Control set EBV EA-D IgM	CL-EAMCON	2 x 20
CLIA Control set EBV EBNA-1 IgG	CL-EBGCON	2 x 20
CLIA Control set EBV EBNA-1 IgM	CL-EBMCON	2 x 20
CLIA Control set EBV VCA IgA	CL-VCACON	2 x 20
CLIA Control set EBV VCA IgG	CL-VCGCON	2 x 20
CLIA Control set EBV VCA IgM	CL-VCMCON	2 x 20

Contact us at

clia@biovendor.group

or visit our website

clia.biovendor.group

DISTRIBUTED BY

Distributor logo to be inserted here.

Distributor contact details to be inserted here.

ENIP0201