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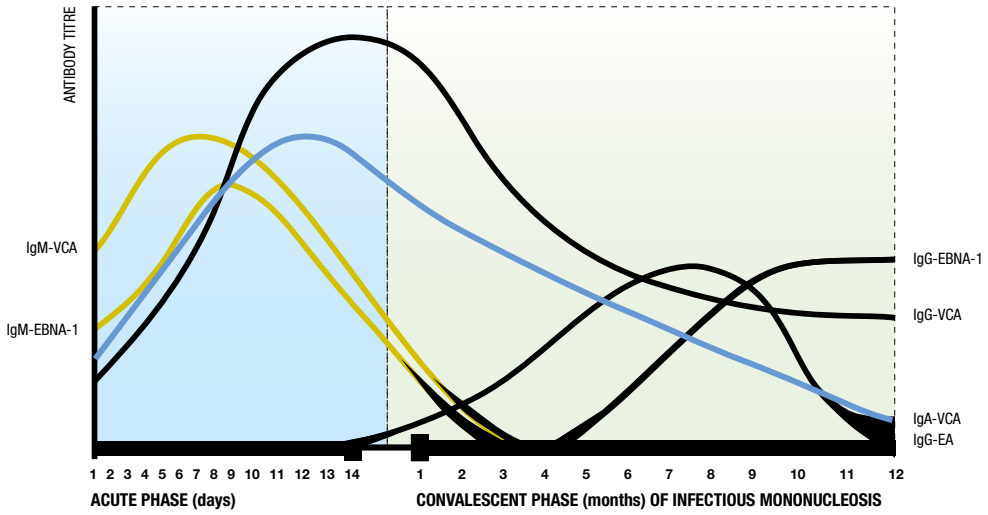
Epstein-Barr virus – EBV

ELISA-VIDITEST anti-EBV and IF-VIDITEST anti-EBV kits are intended for the diagnosis of EBV-associated diseases, i.e. infectious mononucleosis, chronic active EBV infection, EBV-related lymphoproliferative disorders and nasopharyngeal carcinoma. The tests can also contribute to laboratory examination of immune deficiency syndromes, chronic fatigue syndrome and other conditions when reactivation of latent EBV infection is common.

Markers of EBV infection:
Viral capsid antigen – VCA: structural protein or protein complex, the compound of the viral capsid
EB-viral nuclear antigen 1 – EBNA-1: nonstructural nuclear protein, present in latently infected cells
Early antigen – EA: nonstructural protein or protein complex, synthetized in early phase of viral replication cycle. Based on the structure and localization in the infected cells, two components of EA can be distinguished. EA-R (restricted) component is present in distinct regions of cytoplasm and methanol-resistant EA-D (diffuse) component is dispersed both in the cytoplasm and in the nucleus.

Antibody response against VCA, EA and EBNA-1 in the course of EBV infection display different dynamics.

SCHEME OF ANTIBODY SYNTHESIS AFTER PRIMOINFECTION WITH EBV



Different phases of EBV infection can be distinguished according to the characteristic pattern of IgG, IgM and IgA antibodies against VCA, EBNA-1 and/or EA:

Phase of EBV infection	IgG anti-VCA	IgM anti-VCA	IgA anti-VCA	IgG anti EBNA-1	IgM anti EBNA-1	IgG anti-EA	IgM anti-EA
Latency	++	-	-	+++	-	- (+) (20%, EA-R)	-
Primary infection	++	+/+++	+/+++	-	++	++ (EA-D)	+/+++
Reactivation	+++	+ (30%)	++	+++	- (+)	+++ (EA-R+D)	- (+)

Herpesviruses

VCA EBV

IgG antibodies have anamnestic character and persist in infected individual for a life. Seroconversion can be detected in early acute phase of the primary infection. Significant rise in IgG anti-VCA antibody indicate reinfection or reactivation. Avidity determination enables differentiation between primary and past infection or reactivation. IgM and IgA antibody response is typical for active infection. High levels of IgM anti-VCA are usually present in acute and convalescent phase of infectious mononucleosis (IM), while in EBV reactivation IgM response is low and often undetectable and IgA response is more pronounced. After recovery, both IgM and IgA may persist for several weeks or months.

ELISA-VIDITEST

CE IVD

REF	Product	Method	Evaluation	Wells	Sample	Sensitivity/Specificity
ODZ-265	anti-VCA EBV IgG	ELISA	semiquant.	96	serum, plasma	98.1% / 97.1%
ODZ-084	anti-VCA EBV IgG (CSF)*	ELISA	quant.	96	serum, plasma, cerebrospinal fluid	98.1% / 97.1%
ODZ-175	anti-VCA EBV IgG and IgG avidity	ELISA	semiquant.	96	serum, plasma	-
ODZ-005	anti-VCA EBV IgM	ELISA	semiquant.	96	serum	94.7% / 96.1%
ODZ-096	anti-VCA EBV IgA	ELISA	semiquant.	96	serum	85% (92%$^{+}$) / 100%

$^{+}$ determined from the positive IM diagnosis patients data *5-point calibration

IF-VIDITEST

CE IVD

REF	Product	Method	Evaluation	No. of tests	Sample
ODZ-060	anti-VCA EBV	IFA	semiquant.	30 x 8	serum

Why using ELISA-VIDITEST or IF-VIDITEST anti-VCA EBV:

- Complete panel of EBV serological markers can be examined in single dilution of serum sample
- Qualitative screening or quantitative determination
- Validated for serum and cerebrospinal fluid (CSF) samples
- Supplied with software for intrathecal IgG antibody synthesis calculation
- ELISA-VIDITEST anti-VCA IgM contains RF sorbent for elimination of interfering IgG antibodies
- IF test available for confirmation of the results
- ELISA kits compatible with VIDIMAT (except the kits with 5-point calibration)
- Incubation times 30‘/30‘/15‘

Herpesviruses

EBNA-1 EBV

In acute phase of primary infection IgM antibody is present, while IgG antibody response is delayed. Absence of IgG anti-EBNA with concomitant presence of IgG and IgM anti-VCA is a diagnostic marker of infectious mononucleosis. Long term absence of IgG anti-EBNA-1 antibody may indicate immune deficiency.

ELISA-VIDITEST CE IVD

REF	Product	Method	Evaluation	Wells	Sample	Sensitivity/ Specificity
ODZ-001	anti-EBNA-1 EBV IgG*	ELISA	semiquant. quant.	96	serum, plasma	100% / 96.4%
ODZ-412	anti-EBNA-1 EBV IgG	ELISA	semiquant. quant.	96	serum	100% / 96.4%
ODZ-002	anti-EBNA-1 EBV IgM	ELISA	semiquant.	96	serum	95.5% / 95.5%

*5-point calibration

Why using ELISA-VIDITEST anti-EBNA-1 EBV:

- Complete panel of EBV serological markers in single dilution of serum sample
- Recombinant antigen guarantees high sensitivity and specificity (IgG det.)
- Quantitative determination of IgG
- ELISA-VIDITEST anti-EBNA-1 IgM contains high specific synthetic peptide antigen
- Ready to use HRP conjugate and controls
- ELISA kits compatible with VIDIMAT (except the kits with 5-point calibration)
- Incubation times 30‘/30‘/15‘

Herpesviruses

EA EBV

Anti-EA IgG and IgM is a supplemental marker of EBV activation (both primary infection and reactivation). High titers of anti-EA(D) are typical for late acute and convalescence phase of infectious mononucleosis, while anti-EA(R) is more frequent marker of EBV reactivation. In chronic reactivation and chronic active EBV infection antibody response against both the components can be found. High titers of IgG and IgA anti-EA(D) are observed in patients with nasopharyngeal carcinoma, the latter having prognostic significance. High levels of anti- EA(R) are characteristic for patients with EBV-associated Burkitt lymphoma.

ELISA-VIDITEST

CE IVD

REF	Product	Method	Evaluation	Wells	Sample	Sensitivity/Specificity
ODZ-006	anti-EA(D) EBV IgG	ELISA	semiquant.	96	serum	95.9% / 94.1%
ODZ-007	anti-EA(D) EBV IgM	ELISA	semiquant.	96	serum	85.7% / 82.6%
ODZ-254	anti-EA(D) EBV IgA	ELISA	semiquant.	96	serum	100% / 100%

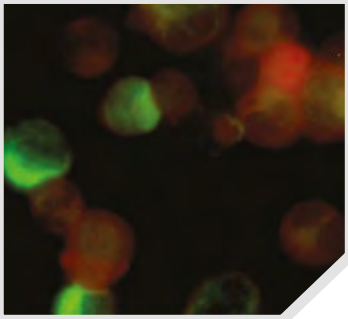
IF-VIDITEST

CE IVD

REF	Product	Method	Evaluation	No. of tests	Sample
ODZ-057	anti-EA EBV IgG	IFA	semiquant.	20 x 8	serum
ODZ-058	anti-EA(D) EBV IgG	IFA	semiquant.	10 x 8	serum

Why using ELISA-VIDITEST or IF-VIDITEST anti-EA EBV:

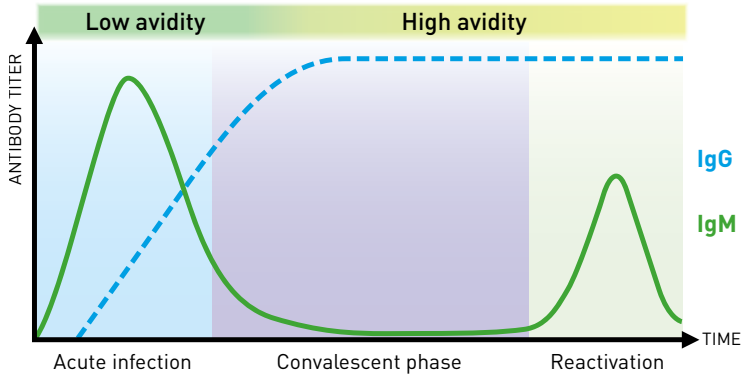
- Complete panel of EBV serological markers in single dilution of serum sample
- Ready to use HRP conjugate and controls
- IF assay enables differentiation of anti-EA(D) and anti-EA(R) antibody response and confirmation of the results in the alternative assay
- ELISA kits compatible with VIDIMAT
- Incubation times 30‘/30‘/15‘



Herpesviruses

Human Cytomegalovirus – CMV

ELISA-VIDITEST anti-CMV kits are intended for the diagnosis of diseases associated with CMV infection, e.g. CMV mononucleosis, CMV syndrome, acute and chronic infections in immunocompromised patients. The tests can also be a part of the laboratory work–up for chronic fatigue syndrome or for the estimation of serological status in blood donors, organ donors or patients during pre–transplantation laboratory check–up. Tests are the part of TORCH panel and can be used for the screening and follow–up of women during pregnancy in order to detect and manage the possible congenital CMV infections in newborns.



ELISA-VIDITEST

CE 1023 IVD

REF	Product	Method	Evaluation	Wells	Sample	Sensitivity/Specificity
TORCH ODZ-176	anti-CMV IgG	ELISA	semiquant.	96	serum, plasma	100% / 97%
ODZ-102	anti-CMV IgG (CSF)	ELISA	quant., semiquant.	96	serum, cerebrospinal fluid, plasma	100% / 97%
ODZ-102 5ST	anti-CMV IgG (CSF)*	ELISA	quant., semiquant.	96	serum, cerebrospinal fluid, plasma	100% / 97%
ODZ-177	anti-CMV IgG and IgG avidity	ELISA	semiquant.	96	serum, plasma	100% / 97%
TORCH ODZ-402	anti-CMV IgM	ELISA	semiquant.	96	serum, plasma	98% / 96%
ODZ-164	anti-CMV IgA	ELISA	semiquant.	96	serum, plasma	93% / 100%

*5-point calibration

Why using ELISA-VIDITEST anti-CMV:

- Compatible with other ELISA-VIDITESTs – posibility of whole herpesvirus panel antibody examination from one dilution of serum sample
- Quantitative and qualitative evaluation of the data
- ELISA-VIDITEST anti-CMV IgG (CSF) validated for serum and CSF samples
- Supplied with software for intrathecal IgG antibody synthesis determination
- Ready to use HRP conjugate and controls
- ELISA kits compatible with VIDIMAT (except the kits with 5-point calibration)
- Incubation times 30‘/30‘/15‘

Herpesviruses

Herpes simplex virus – HSV

ELISA-VIDITEST and IF-VIDITEST anti-HSV1+2 kits are intended for in vitro diagnosis of HSV type 1 or 2 associated diseases, i.e. herpes labialis, herpes genitalis, herpesvirus gingivostomatitis, keratoconjunctivitis and herpesvirus-induced neurological complications (encephalitis, meningitis, inflammatory mono- and polyneuropathies). The diagnostic kits can be also utilized for differential diagnosis of neuroinfections, infections of eye and skin and exanthematous diseases. The tests do not distinguish between HSV1 and HSV2.

ELISA-VIDITEST

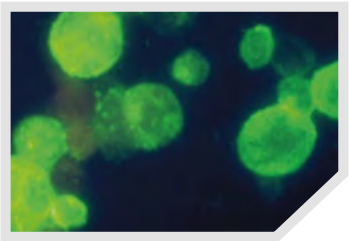
CE IVD

REF	Product	Method	Evaluation	Wells	Sample	Sensitivity/Specificity
TORCH ODZ-169	anti-HSV 1+2 IgG	ELISA	semiquant.	96	serum	98.8% / 97%
TORCH ODZ-234	anti-HSV 1+2 IgM	ELISA	semiquant.	96	serum	99% / 100%
ODZ-283	anti-HSV 1+2 IgA	ELISA	semiquant.	96	serum	96.1% / 98.4%

IF-VIDITEST

CE IVD

REF	Product	Method	Evaluation	No. of tests	Sample
ODZ-059	anti-HSV	IFA	semiquant.	10 x 8	serum



Why using ELISA-VIDITEST or IF-VIDITEST anti-HSV:

- Simultaneous detection of anti-HSV1 and anti-HSV2 antibodies
- Qualitative ELISA for IgG screening and quantitative version for determination of antibody concentration
- ELISA-VIDITEST anti-HSV1+2 IgM contains RF-sorbent for elimination of interfering IgG antibodies
- IF assays available for confirmation of the results
- Ready to use HRP conjugate and controls
- ELISA kits compatible with VIDIMAT
- Incubation times 30'/30'/15'

Herpesviruses

Varicella zoster virus – VZV

ELISA-VIDITEST and IF-VIDITEST anti-VZV kits are intended for the diagnosis of diseases induced or associated with VZV infection, such as varicella (chickenpox), herpes zoster (shingles) and the disease complications (pareses, neuropathies, encephalitis, myelitis, cerebellitis, pneumoniae, uveitis) and generalized infections in immunocompromised patients. The kits can also be utilized for differential diagnosis of neuroinfections, infections of eye and skin and exanthematous diseases.
VZV-specific IgG antibodies have anamnestic character, can be utilized for determination of individual immune status. Their significant increase in paired serum samples may indicate active infection. VZV-specific IgM and IgA rise in the course of active infection (both primary infection and reactivation) and disappear in convalescence phase. In some cases, they may persist in patient´s serum several weeks or months. Determination of VZV IgG avidity is useful to distinguish between primary and past infection or VZV reactivation.

ELISA-VIDITEST

CE IVD

REF	Product	Method	Evaluation	Wells	Sample	Sensitivity/Specificity
ODZ-168	anti-VZV IgG	ELISA	semiquant.	96	serum	98.6% / 98,6%
ODZ-087	anti-VZV IgG (CSF)*	ELISA	quant., semiquant.	96	serum, cerebrospinal fluid	98.6% / 98.6%
ODZ-233	anti-VZV IgG and IgG avidity	ELISA	semiquant.	96	serum	98.6% / 98.6%
ODZ-197	anti-VZV IgM	ELISA	semiquant.	96	serum	100% / 98.2%
ODZ-284	anti-VZV IgA	ELISA	semiquant.	96	serum	94% / 100%

*5-point calibration

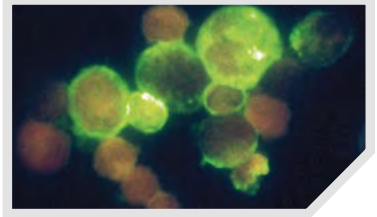
IF-VIDITEST

CE IVD

REF	Product	Method	Evaluation	No. of tests	Sample
ODZ-119	anti-VZV	IFA	semiquant.	20 x 8	serum

Why using ELISA-VIDITEST or IF-VIDITEST anti-VZV:

- Quantitative version for determination of IgG antibody concentration in International WHO units (IU/mL)
- ELISA-VIDITEST anti-VZV IgG (CSF) validated for antibody determination in sera and cerebrospinal fluids (CSF)
- Supplied with software for intrathecal IgG antibody synthesis determination
- ELISA-VIDITEST anti-VZV IgM contains RF sorbent for elimination of interfering IgG antibodies
- IF assays for confirmation of the results
- Ready to use HRP conjugate and controls
- ELISA kits compatible with VIDIMAT (except the kits with 5-point calibration)
- Incubation times 30‘/30‘/15‘



Herpesviruses

BESTSELLER

Human herpesvirus 6 – HHV-6

ELISA-VIDITEST and IF-VIDITEST anti-HHV-6 kits are intended for serological diagnosis of diseases associated with HHV–6 infection, such as exanthema subitum, acute respiratory illnesses, diarrhoea with fever and febrile seizures in infants, heterophile antibody-negative infectious mononucleosis in children, also interstitial pneumonia, encephalitis, meningitis, hepatitis and aplastic anemia in immunodeficient patients.
The presence of IgG anti-HHV-6 antibody reveals the immune status of the patient. Seroconversion or 4–fold rise in antibody titre in paired serum samples, taken in acute and convalescent phase of the infection, is indicative of the active infection.
ELISA-VIDITEST anti-HHV-6 IgG (CSF) can be used for the calculation of anti-HHV-6 intrathecal antibodies synthesis.

ELISA-VIDITEST

CE IVD

REF	Product	Method	Evaluation	Wells	Sample	Sensitivity/Specificity
ODZ-235	anti-HHV-6 IgG	ELISA	semiquant.	96	serum	99% / 95%
ODZ-344	anti-HHV-6 IgG (CSF)*	ELISA	quant., semiquant.	96	serum, cerebrospinal fluid	99% / 95%
ODZ-345	anti-HHV-6 IgM	ELISA	semiquant.	96	serum	93% / 94%

*5-point calibration

IF-VIDITEST

CE IVD

REF	Product	Method	Evaluation	No. of tests	Sample
ODZ-061	anti-HHV-6 IgG	IFA	semiquant.	10 x 8	serum

Why using ELISA-VIDITEST or IF-VIDITEST anti-HHV-6:

- IgG and IgM determination
- Supplied with software for intrathecal IgG antibody synthesis determination
- Unified incubation times for IgG and IgM determination
- ELISA-VIDITEST anti-HHV-6 IgM contains RF sorbent for elimination of interfering IgG antibodies
- Ready to use HRP conjugate and controls
- IgG determination in serum and cerebrospinal fluid
- IF assays available for confirmation of the results