30 ANNIVERSARY 1991–2021
celebration

Development and production of unique diagnostic kits

ELISA | MONO | LIA | RAPID | IF | BI

...the way to the correct results

VIDIA

VIDIA

Company profile

VIDIA spol. s r.o. is a well-established private Czech biotechnological company that has developed, manufactured and sold IVD kits. Besides IVD kits for human medicine, VIDIA also produces the kits for environmental monitoring and educational purposes. VIDIA closely cooperates with academic institutes, universities and hospitals as well. VIDIA celebrates 30 years anniversary of the company founding by RNDr. Jaroslav Roubal, CSc.

› Customer service

Our experienced staff is ready to consult with you about ambiguous results, improve our kits according to your requirements as well as to develop new diagnostic kits.

› High quality for correct results

All VIDIA IVD products are CE certified and the kits are designed to be highly stable and have a long shelf life. The company has been certified since 2003 according to ISO 9001 and ISO 13485 standards.

› Reasonable pricing

VIDIA keeps a reasonable product-cost strategy with the intention of bringing profits to their customers.

30TH 1991 - 2021 ANNIVERSARY CELEBRATION

Products

VIDIA – THE WAY TO THE CORRECT RESULTS

Coronavirus

NEW

SARS-CoV-2

ELISA-VIDITEST anti-SARS-CoV-2 kits are intended for the diagnosis of the COVID-19 disease caused by the novel coronavirus SARS-CoV-2.

ELISA-VIDITEST anti-SARS-CoV-2 kits are solid-phase immunoanalytical tests using specific antigens fixed to the wells of the microtiterstrips working on the principle of bonding with specific antibodies present in patient's sample.

After infection of a human body with the SARS-CoV-2 virus, the antibodies to this virus appear in the patient's blood. Most persons infected with SARS-CoV-2 display an antibody response between day 10 and day 21 after infection. Based on the currently available data, the IgM and IgG antibodies to SARS-CoV-2 develop between 6–15 days post disease onset. The presence of antibodies was detected in <40% among patients within 1 week from onset, and rapidly increased to 100% (total antibodies), 94.3% (IgM) and 79.8% (IgG) from day-15 after onset.

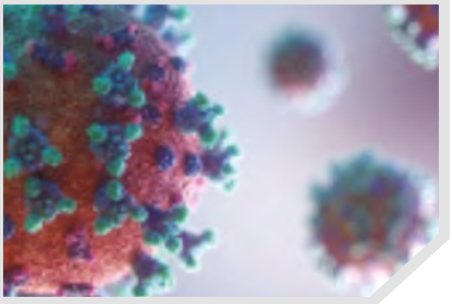
ELISA-VIDITEST

CE IVD

REF	Product	Method	Evaluation	Wells	Sample	Sensitivity/Specificity
ODZ-469	anti-SARS-CoV-2 (NP) IgA	ELISA	semiquant.	96	serum/plasma	94% / 96%
ODZ-470	anti-SARS-CoV-2 (NP) IgG	ELISA	semiquant.	96	serum/plasma	96% / 97%
ODZ-471	anti-SARS-CoV-2 (NP) IgM	ELISA	semiquant.	96	serum/plasma	93% / 97%
ODZ-472	anti-SARS-CoV-2 (S1) IgA	ELISA	semiquant.	96	serum/plasma	93% / 96%
ODZ-473	anti-SARS-CoV-2 (S1) IgG	ELISA	semiquant.	96	serum/plasma	94% / 97%
ODZ-474	anti-SARS-CoV-2 (S1) IgM	ELISA	semiquant.	96	serum/plasma	91% / 96%

Why using ELISA-VIDITEST:

- Qualitative and semiquantitative detection of anti-SARS-CoV-2 antibodies
- IgA, IgG and IgM determination
- Kits for the detection of both nucleocapsid protein (NP) and spike protein (S1) of coronavirus
- Antibody determination in serum and plasma
- Unified incubation times for IgA, IgG and IgM determination
- Guaranteed stability and high sensitivity
- Compatible with VIDIMAT



Herpesviruses

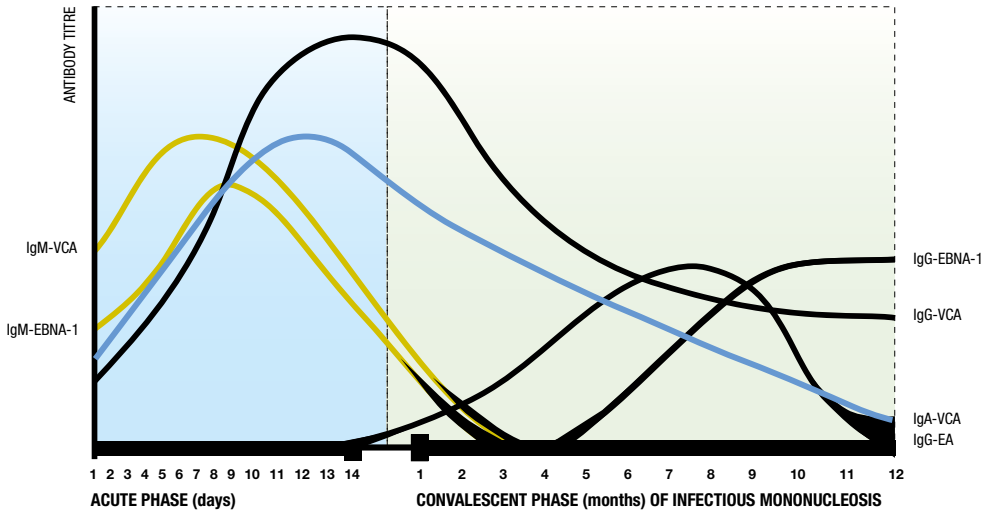
Epstein-Barr virus – EBV

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%

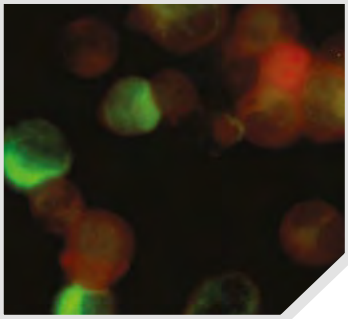
IF-VIDITEST

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:

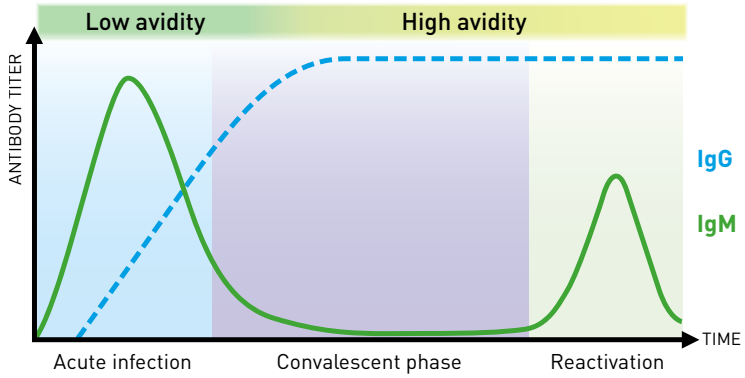
- Complete panel of EBV serological markers in single dilution of serum sample
- Ready to use HRP conjugate and controls
- IF assay enables differentiation of anti-EA(D) and anti-EA(R) antibody response and confirmation of the results in the alternative assay
- ELISA kits compatible with VIDIMAT
- Incubation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

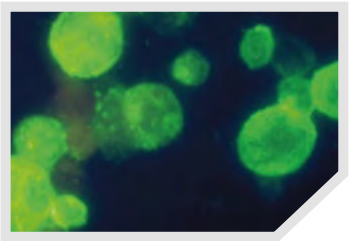
CE IVD

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

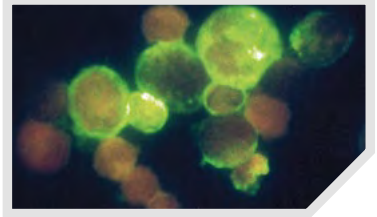
IF-VIDITEST

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

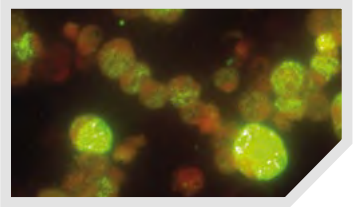
IF-VIDITEST

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



Rubella virus

IMPROVED KITS SOON

AVAILABLE DURING 2021

ELISA-VIDITEST anti-Rubella kits are intended for the diagnosis of rubella in children and adults including pregnant women and congenitally infected newborns. As a part of TORCH complex they are utilized for differential diagnosis of vertically transmissed infections from mother to fetus. They may be also used for differential diagnosis of exanthematous diseases and for monitoring of individual immune status.

IgG anti-Rubella antibodies have anamnestic character: appear in the first week of disease onset, reach a maximum level after few weeks and than persist in lower levels lifelong. IgM can be detected in early acute phase of the infection and disappear obviously after 3-5 months. In some patients, IgM anti-Rubella antibodies persist for several months. Following vaccination seroconversion in anti-Rubella IgG is significant, although the concentration of antibody is generally lower than in natural infection. Specific IgG can be detected up to 15 years, IgM on the average 8-12 weeks.

A single antibody positivity does not provide proof of recent infection and cannot necessarily be equated with immune protection status. To obtain a final diagnosis, the patient history and clinical symptoms should be taken into consideration.

ELISA-VIDITEST

CE 1023 IVD

REF	Product	Method	Evaluation	Wells	Sample	Sensitivity/Specificity
TORCH	anti-Rubella IgG	ELISA	quant.	96	serum, plasma	100% / 100%
TORCH	anti-Rubella IgM	ELISA	qualit.	96	serum, plasma	100% / 100%

IgG	IgM	Interpretation	Recommendation
-	-	No specific antibody detectable	By suspect of active infection control test with second serum sample taken after 7 days is recommended
-	+	Possible primary infection Polyclonal response as a result of other infection cannot be excluded	Monitoring of IgG and IgM antibodies in second serum sample collected within 10-14 days to determine seroconversion
+	+	Probable acute infection Recent vaccination	Monitoring of IgG and IgM antibodies in second serum sample collected within 10-14 days to follow dynamics of antibody response, supplementary tests: determination of anti- Rubella IgG avidity (IFA, CF, HAH)
+	-	Possible past infection (re-infection, vaccination)	By suspect of active infection – supplementary tests and monitoring (see above)

Why using ELISA-VIDITEST anti-Rubella:

- Quantitative evaluation of IgG in International units / mL
- Semiquantitative evaluation of IgM antibodies
- Ready to use HRP conjugate and controls
- Compatible with VIDIMAT

Toxoplasma gondii

IMPROVED KITS SOON

AVAILABLE DURING 2021

ELISA-VIDITEST anti-Toxo kits are intended for the diagnosis of toxoplasmosis in immunocompetent and immunodeficient individuals, pregnant women and children including congenitally infected newborns. As a part of TORCH complex they are utilized for differential diagnosis of vertically transmitted infections from mother to fetus. They may be also used for differential diagnosis of lymphadenopathies.

IgG anti-toxo antibodies appear in 1 – 2 weeks after onset of acute infection, reach a maximum level after few weeks and than fall down, generally remaining at low level lifelong. IgM can be detected in early acute phase of the infection and disappear obviously after 3-5 months. In some patients, IgM anti-toxo antibodies persist for several months or years after infection, so further tests are necessary to clarify the stage of infection. IgA rise somewhat later than IgM and clear off in 3-6 months after infection resolution.

ELISA-VIDITEST

CE 1023 IVD

REF	Product	Method	Evaluation	Wells	Sample	Sensitivity/Specificity
TORCH	anti-Toxo IgG	ELISA	quant.	96	serum, plasma	
TORCH	anti-Toxo IgM	ELISA	qualit.	96	serum, plasma	
	anti-Toxo IgA	ELISA	qualit.	96	serum, plasma	

IgG	IgM	Interpretation	Recommendation
-	-	No specific antibody detectable	In pregnant women check in the 2nd and 3rd trimester
-	+	Possible early phase of infection	Monitoring of IgG and IgM antibodies in second serum sample collected within 10-14 days to determine seroconversion
+	+	Probable recent infection, re-infection or latent infection may also be possible	Supplementary tests: determination of anti-Toxo IgG avidity, anti-Toxo IgA (IFA,CF), monitoring of IgG and IgM antibodies in second serum sample collected within 10 – 14 days to follow dynamics of antibody response
+	-	Possible past infection or re-infection In newborns, possible congenital infection	By suspect of active infection – supplementary tests and monitoring (see above)

Why using ELISA-VIDITEST anti-Toxo:

- Quantitative evaluation of IgG in International units/mL
- Semiquantitative evaluation of IgM and IgA antibodies
- Ready to use HRP conjugate and controls
- Compatible with VIDIMAT

Mycoplasma pneumoniae

INNOVATION

ELISA-VIDITEST anti-*Mycoplasma pneumoniae* kits are intended for the diagnosis of *Mycoplasma pneumoniae* related diseases. The use of these tests is to support the diagnosis of acute or chronic respiratory diseases including complications such as pericarditis, meningoencefalitis, otitis, erythema nodosum. It is recommended to estimate the changes of antibody titres through analysis of paired sera collected 1 – 2 weeks apart.

The first sample is taken during the acute phase of disease and the second sample is confirmatory and should be taken not earlier than 10 – 15 days after the first one. The antibody titer should rise during this period. There are differences in antibody kinetic profiles with regard to the immunoglobulin classes and therefore we strongly recommend using parallel detection in all three available Ig classes (IgG/IgM/IgA).

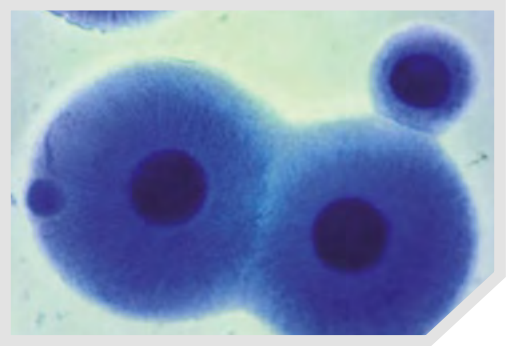
ELISA-VIDITEST

CE IVD

REF	Product	Method	Evaluation	Wells	Sample	Sensitivity/Specificity
ODZ-010	anti-Mycoplasma pn. IgG	ELISA	semiquant.	96	serum	91.8% / 85.7%
ODZ-011	anti-Mycoplasma pn. IgM	ELISA	semiquant.	96	serum	98% / 100%
ODZ-012	anti-Mycoplasma pn. IgA	ELISA	semiquant.	96	serum	96% / 83%

Result interpretation

	IgG	IgM	IgA
Seronegativity	-	-	-
Early phase of acute infection	-	+	+
Early acute infection without appearance IgM	-	-	+
Late acute phase of infection	+	+	+
Post-acute phase of infection	+	(+)	(+)
Anamnestic antibodies (infection in patient's history)	+	-	(+)
Reinfection	+	-	(+)



Why using ELISA-VIDITEST anti-Mycoplasma pn.:

- IgG, IgM and IgA determination
- Ready to use HRP conjugate and controls
- Same incubation times for IgG, IgM and IgA determination
- Compatible with VIDIMAT
- Incubation times 30'/30'/15'

Chlamydia

INNOVATION

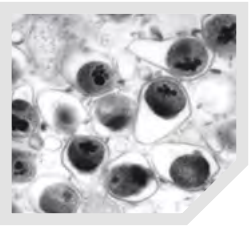
CHLAMYDIA TRACHOMATIS AVAILABLE DURING 2021

Chlamydia trachomatis and Chlamydia pneumoniae

ELISA-VIDITEST anti-*Chlamydia trachomatis* kits are intended for the diagnosis of acute and chronic infections caused by *Chlamydia trachomatis*, i.e. inflammatory diseases of genitourinary tract in women and men, including their complications (arthritis, conjunctivitis). Anti-*C.trachomatis* antibody testing contributes to differential dignosis of sexually transmitted diseases and eye infections in infants.

ELISA-VIDITEST anti-*Chlamydia pneumoniae* kits are intended for diagnosis of infections in lower respiratory tract and eye.

Primary chlamydial infection is characterized by the predominant IgM response within 2 to 4 weeks and the delayed IgG and IgA response within 6 to 8 weeks. After the acute *C. pneumoniae / C. trachomatis* infection IgM antibodies usually decrease and become undetectable in 2 to 6 months. IgG antibody titres decrease slowly and may persist for years. IgA antibodies tend to disappear in several weeks, but in some cases they can persist for months or years. When primary chlamydia infection is suspected, the detection of IgM is highly diagnostic. However, in recurrent or chronic infections the prevalence of IgM is low and therefore the absence of IgM does not necessarily exclude an on-going infection. For diagnosis of reinfection IgG and IgA levels rise in paired serum samples is indicative. The long time persistence of the elevated IgA antibody titres may indicate chronic infection.



ELISA-VIDITEST

CE 1023 IVD

REF	Product	Method	Evaluation	Wells	Sample	Sensitivity/Specificity
	anti-Chlamydia trachomatis IgG	ELISA	quant.	96	serum, plasma	
	anti-Chlamydia trachomatis IgA	ELISA	qualit.	96	serum, plasma	
NEW ODZ-457	anti-Chlamydia pneumoniae IgG	ELISA	semiquant.	96	serum, plasma	96.4% / 90.4%
NEW ODZ-458	anti-Chlamydia pneumoniae IgM	ELISA	semiquant.	96	serum, plasma	91.7% / 98.3%
NEW ODZ-459	anti-Chlamydia pneumoniae IgA	ELISA	semiquant.	96	serum, plasma	94.6% / 95.1%

Why using ELISA-VIDITEST anti-Chlamydia trachomatis and anti-Chlamydia pneumoniae:

- Determination of type- specific antibodies (differentiation between *C.trachomatis* and *C. pneumoniae*)
- Simultaneous detection of several markers of chlamydial infection in one dilution of the sample
- Semiquantitative evalutation of IgG, IgM and IgA antibodies
- Ready to use HRP conjugate and controls
- Dilution buffer is the same for IgG, IgA and IgM determination
- RF sorbent included for rheumatoid factor elimination (kits for IgM determination)
- Compatible with VIDIMAT

Borrelia

ELISA-VIDITEST anti-*Borrelia recombinant* kits are intended for the detection of IgG and IgM antibodies to the pathogenic Borrelia strains (*B.afzelii, B. garinii and B. burgdorferi sensu stricto*) in human serum, plasma, cerebrospinal fluid and synovial fluid. The detection of antibodies is one of the laboratory tests that help to diagnose Lyme disease (LD).
Anti-Borrelia IgM antibodies are detectable 3 weeks after infection with its maximum during the sixth week. Subsequently, the titre of IgM antibodies decreases and the IgG antibodies prevail. The detection of anti-Borrelia antibodies is very important at the early stage of the disease since the typical symptoms are present only in a certain proportion of patients (e.g. erythema migrans is present in 50% of patients). The clinical symptoms of LD are similar to the symptoms in other diseases, therefore the serology is also of use in differential diagnosis of neuroinfections, arthropathies, carditis and skin diseases.

ELISA-VIDITEST anti-C6 is an ELISA kit for the detection of anti-C6 antibodies in human serum. C6 is a highly specific conserved immunodominant 26 aminoacid peptide derived from VlsE – outher surface lipoprotein of *Borrelia burgdorferi*.

ELISA-VIDITEST

CE IVD

REF	Product	Method	Evaluation	Wells	Sample	Sensitivity/Specificity
ODZ-398	anti-Borrelia recomb. IgG + VlsE (CSF)	ELISA	semiquant. quant.	96	serum, plasma, cerebrospinal fluid, synovial fluid	95% / 99%
ODZ-399	anti-Borrelia recomb. IgM (CSF)	ELISA	semiquant. quant.	96	serum, plasma, cerebrospinal fluid, synovial fluid	99% / 97%
ODZ-398/5ST	anti-Borrelia recomb. IgG + VlsE (CSF)*/**	ELISA	semiquant. quant.	96	serum, plasma, cerebrospinal fluid, synovial fluid	95% / 99%
ODZ-399/5ST	anti-Borrelia recomb. IgM (CSF)*/**	ELISA	semiquant. quant.	96	serum, plasma, cerebrospinal fluid, synovial fluid	99% / 97%

*5-point calibration **kits are made-to-order

ELISA-VIDITEST

REF	Product	Method	Evaluation	Wells	Sample	Sensitivity/Specificity
ODZ-407	anti-C6	ELISA	semiquant.	96	serum	- / -

Why using ELISA-VIDITEST anti-Borrelia recom.:

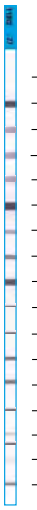
- Highly specific recombinant antigens
- High purity of antigens excludes cross-reactivity with antibodies to other spirochetes
- Quantitative and qualitative evaluation of the data
- Intrathecal IgG, IgM synthesis determination
- Antibody determination in serum, cerebrospinal fluid and synovial fluid
- ELISA kits compatible with VIDIMAT (except the kits with 5-point calibration)
- Incubations 30‘/30‘/15‘
- Ready to use HRP conjugate and controls

Borrelia

INNOVATION

LIA-VIDITEST anti-*Borrelia* kits are line immunoassays intended for qualitative detection of specific IgG and IgM antibodies to antigens of major pathogenic Borrelia stains (*B. afzelii, B. garinii, B. burgdorferi sensu stricto and B. spielmanii*) and *Anaplasma phagocytophilum* in human serum, plasma, cerebrospinal fluid and synovial fluid. The kits are used to confirm the ELISA results during the serological diagnostics of Lyme disease. The kits can be also used to an indicative diagnostics of Human granulocytic anaplasmosis (HGA). HGA is caused by bacterium *Anaplasma phagocytophilum*, which attacks white blood cells (granulocytes). Anaplasma infection can result in death for immunodeficient, post-splenectomy or post-transplant patients. Anaplasma-specific antibodies are detected in human serum by high-specific antigen p44.

› IgG



› IgM

› IgM

LIA-VIDITEST

CE IVD

REF	Product	Method	Evaluation	No. of tests	Sample	Sensitivity/Specificity
ODZ-316	anti-Borrelia IgG	LIA	qualit.	16	serum, plasma, cerebrospinal fluid, synovial fluid	100% / 98%
ODZ-317	anti-Borrelia IgM	LIA	qualit.	16	serum, plasma, cerebrospinal fluid, synovial fluid	97% / 98%
ODZ-317SP	anti-Borrelia IgM sp.	LIA	qualit.	16	serum, plasma, cerebrospinal fluid, synovial fluid	97% / 98%

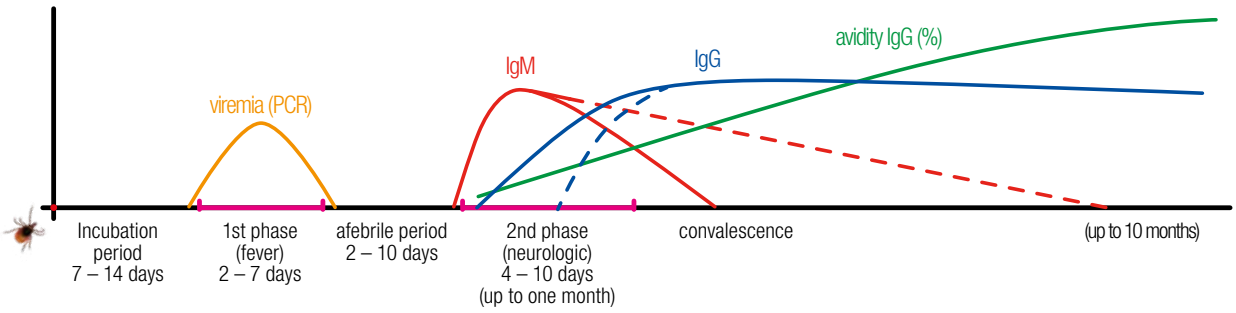
Why using LIA-VIDITEST anti-*Borrelia*:

- Detection of specific IgM and IgG antibodies to wide spectrum of major *Borrelia* strains antigens and p44 *Anaplasma* antigen
- Differentiation of specific antibodies of *B. afzelii*, *B. garinii, B. burgdorferi sensu stricto and B. spielmanii*
- Antigen specific lines evaluation using cut-off line
- Possibility of software data processing
- The software uses a common scanner
- Ready to use HRP conjugate and Universal buffer for sample dilution and washing
- Adhesive foils, evaluation protocol supplied with the kit
- Validated for Dynablot, RoboBlot, BeeBlot and B20 analyzers

Tick borne encephalitis virus – TBEV

ELISA-VIDITEST anti-TBEV kits are intended for diagnosis of the infection caused by Tick borne encephalitis virus (TBEV), e.g. encephalitis or meningoencephalitis. Kits can be also used for differential diagnosis of neuroinfections and follow-up of the protective antibody titres in immunized persons.

Dynamics of the diagnostic markers



ELISA-VIDITEST

CE IVD

REF	Product	Method	Evaluation	Wells	Sample	Sensitivity/Specificity
ODZ-192	anti-TBEV IgG	ELISA	semiquant.	96	serum, cerebrospinal fluid	98.1% / 100%
ODZ-170	anti-TBEV IgG and IgG avidity	ELISA	semiquant.	96	serum	98.5% / 100%
ODZ-194	anti-TBEV IgM	ELISA	semiquant.	96	serum, cerebrospinal fluid	100% / 97.9%

Why using ELISA-VIDITEST anti-TBEV:

- Determination of IgG and IgM in serum/plasma and cerebrospinal fluid
- Software for quantitative data processing in Vienna units included
- Only one sample dilution process due to the same dilution buffer for different versions
- Anti-TBEV IgG avidity determination
- Ready to use HRP conjugate and controls
- Compatible with VIDIMAT
- Incubation times 30‘/30‘/15‘

Multiplex assays

Lyme disease + Tick borne encephalitis

LIA-VIDITEST Multiplex Borrelia and TBEV IgG and IgM kits are line-immunoassay kits, which are intended for the simultaneous detection of antibodies to Borrelias and Tick borne encephalitis virus. The kits contain strips, on which are coated specific Borrelia recombinant antigens and native antigens from Tick Borne encephalitis virus.

IgG	
IgM conjugate control	negative control
IgG conjugate control	positive control
cut-off control	cut-off control
BOR-BmpA (p39) (Borrelia membrane protein A)	membrane protein A, glykosaminopeptide receptor, mixture of antigens BmpA *B.afzelii, garinii a burgdorferi sensu stricto*, late antigen for IgM and IgG antibody response, stage of infection II.- III.
BOR-DbpA (Osp17, p17) (decorin- binding protein A)	decorin- binding host cell protein, mixture of antigens DbpA *B.afzelii, garinii a burgdorferi sensu stricto*, early and late antigen, highly specific for IgM and IgG antibody response, stage of infection II. and III.
BOR-p83	major extracellular protein (degradation product of p100), mixture of antigens p83 *B.afzelii, garinii a burgdorferi sensu stricto*, late antigen for IgG antibody response (especially III. stage of infection), highly specific
BOR-VlsE (variable major protein--like equence)	variable surface antigen, species conserved antigen, especially late antigen (II. a III. stage of infection), highly specific for IgG antibody response, Borrelia expresses VlsE antigen only in the host organism
TBEV	native Tick born encephalitis virus antigen (viral particles)

IgM	
IgM conjugatove control	positive control
IgG conjugatove control	negative control
cut-off control	cut-off control
BOR-OspC (p25) (outer surface protein C)	outer surface protein C, mixture of antigens OspC *B.afzelii, garinii and burgdorferi sensu stricto*, IgM marker, major early antigen (stage of infection I., rarely II.)
BOR-FlaB (p41) (Flagellin B)	Flagellin (internal fragment), outer surface flagella protein, mixture of antigens FlaB *B.afzelii, garinii a burgdorferi sensu stricto*, early antigen for the IgM antibody response (stage of infection I.), may be non-specific (cross-reactivity with other spirochetes and flagellated bacteria)
BOR-OspA (p31), (outer surface protein A)	Mixture of antigens OspA *B.afzelii* and *garinii*, outer surface membrane lipoprotein, early antigen for the IgM antibody response
TBEV	native Tick born encephalitis virus antigen (viral particles)

REF	Product	No. of tests	Sample
ODZ-396	LIA-VIDITEST Multiplex Borrelia and TBEV IgG	16	serum, plasma, cerebrospinal fluid, synovial fluid
ODZ-397	LIA-VIDITEST Multiplex Borrelia and TBEV IgM	16	serum, plasma, cerebrospinal fluid, synovial fluid

Polyomavirus JC

INNOVATION

ELISA-VIDITEST anti-JVC IgG kit is intended for the detection of anti-polyomavirus JC specific IgG antibodies in human serum and plasma.

From 50% to 60% of population is infected by polyomavirus JC (JCV) during childhood. Infection is without any symptoms and later continues to the latent phase, which is characterised by long-term persistence of anamnestic IgG antibodies in serum. Virus can repeatedly reactivate in latently infected people or the reinfection by other serotype can occur. Reactivation/reinfection can be accompanied by temporary viremia or asymptomatic excretion in urine, in rare cases of immunocompromised patients it can cause infection of central nervous system – progressive multifocal leukoencephalopathy (PML). The presence of anti-JCV antibodies is one of the risk factors of PML outbreak in patients treated with natalizumab. Significant increase or high anti-JCV antibody level can indicate reinfection or reactivation in these patients.

ELISA-VIDITEST CE IVD

REF	Product	Method	Evaluation	Wells	Sample	Sensitivity/Specificity
ODZ-450	anti-JCV IgG	ELISA	quant., semiquant.	96	serum, plasma	95% / 95%

Why using ELISA-VIDITEST anti-JCV IgG:

- Recombinant antigens do not cross-react with the other polyomaviruses
- Qualitative data evaluation
- Quantitative data evaluation using e-calculator – monitoring of antibody concentration
- High sensitivity and specificity
- Ready to use HRP conjugate and controls

Polyomavirus BK

ELISA-VIDITEST anti-BKV IgG kit is intended for the detection of specific IgG antibodies to polyomavirus BK (BKV) in human serum and plasma. Recombinant antigens used in the kit do not cross-react with other polyomaviruses (polyomavirus JC, Merkel cell polyomavirus). The kit is used for the serological diagnostics of diseases caused or associated with BKV (e.g. BK-viral nephropathy, haemorrhagic cystitis, urethral stenosis, infections of upper and lower respiratory tract mainly in immunodeficient patients) and for the risk assessment of infection transmission and subsequent complications in graft acceptors.

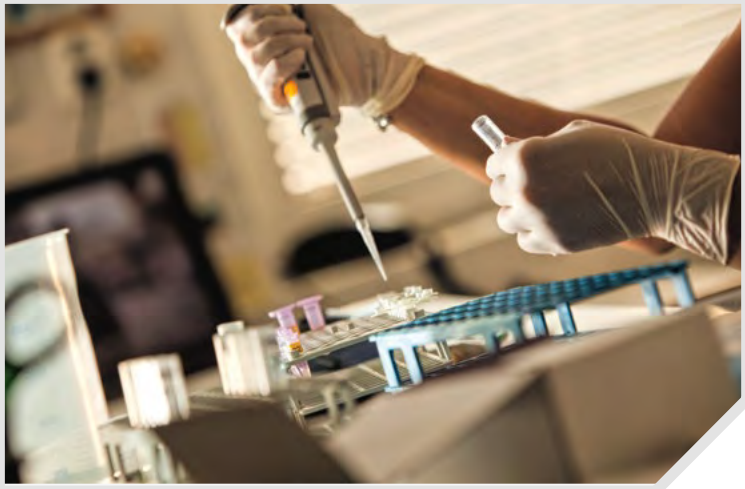
Anti-BKV antibodies are present in 50% to 80% of adult population. Primoinfection occurs mostly during childhood and in most of the cases it is asymptomatic or brings on an acute respiratory disease and then continues to the latent phase, which is characterised by long-term presence of anamnestic IgG antibodies in serum. In latently infected persons the virus can repeatedly reactivate or they can be re-infected by other BKV serotype. Reactivation/reinfection can be accompanied by temporary viremia or viruria; and in immunodeficient persons it can cause various diseases of urinary tract (haemorrhagic cystitis, urethral stenosis), kidneys (BK-viral nephropathy), central nervous system (encephalitis, polyradiculoneuritis), lungs (intersticial pneumonitis) or vasculitis. Absence of anti-BKV antibodies may indicate patient's susceptibility to primoinfection, which is connected with increased complication risk. Primoinfection can be diagnosed using anti-BKV IgG seroconversion. Significant increase of antibody level in paired serum/plasma samples can be a sign of reinfection or virus reactivation.

ELISA-VIDITEST CE IVD

REF	Product	Method	Evaluation	Wells	Sample
ODZ-405	anti-BKV IgG	ELISA	semiquant.	96	serum, plasma

Why using ELISA-VIDITEST anti-BKV IgG:

- Microtitrate plate contains a mixture of highly specific antigens – no cross-reactivities with other polyomaviruses
- Semiquantitative data evaluation
- High sensitivity and specificity
- Ready to use HRP conjugate and controls



Vimentin

INNOVATION

ELISA-VIDITEST anti-VIMENTIN kit is intended for the detection of IgG to vimenting in human serum.

Vimentin, desmin, glial fibrillary acidic protein and peripherin are four proteins classified as type III intermediate filaments. Among the four proteins vimentin is the most widely distributed, it is a cytoskeletal part in leukocytes, blood vessel endothelial cells, in some epithelial cells and in cell of mesenchymal origin (fibroblasts).
Serum autoantibodies against vimentin were found elevated in patients with neurofibromatosis type I (1), in patients with graft rejections of transplanted organs (2) and in patients with interstitial lung fibrosis (3).

ELISA-VIDITEST

RUO

REF	Product	Method	Evaluation	Wells	Sample
ODZ-403	anti-VIMENTIN IgG	ELISA	semiquant.	96	serum

References:
1) Kotaska K, Petrak B, Kukacka J, Kraus J, Prusa R. Anti–vimentin antibodies and neuron– specific enolase in children with neurofibromatosis type–1. Neuro Endocrinol Lett. 2007 Dec;28(6):761–4.
2) Jonker M, Danskine A, Haanstra K, Wubben J, Kondova I, Kuhn EM, Rose M. The autoimmune response to vimentin after renal transplantation in nonhuman primates is immunosuppression dependent. Transplantation. 2005 Aug 15;80(3):385–93.
3) Yang Y, Fujita J, Bandoh S, Ohtsuki Y, Yamadori I, Yoshinouchi T, Ishida T. Detection of antivimentin antibody in sera of patients with idiopathic pulmonary fibrosis and non–specific interstitial pneumonia. Clin Exp Immunol. 2002 Apr;128(1):169–74.

Complement factor H

BESTSELLER

ELISA-VIDITEST anti-complement factor H is intended for the quantitative detection of IgG antibodies against human complement factor H in human serum or plasma.

Factor H is a complement regulatory glycoprotein that is found in human plasma in concentrations of 300 – 800 mg/L. Autoantibodies that inhibit factor H function cause complement dysregulation and they have been detected in about 10% of patients with atypical hemolytic uremic syndrome (aHUS). Atypical HUS is a clinical syndrom that is characterised by microangiopatic hemolytic anemia, thrombocytopenia and renal failure.

ELISA-VIDITEST

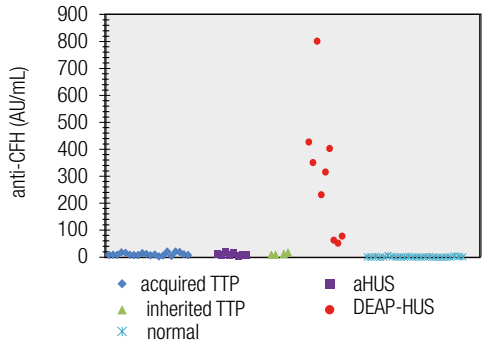
CE IVD

REF	Product	Method	Evaluation	Wells	Sample	Sensitivity/ Specificity
ODZ-166	anti-complement factor H	ELISA	quant.	48	serum, plasma	100% / 98,5%

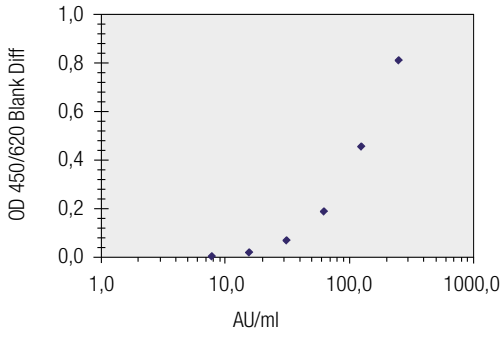
Why using ELISA-VIDITEST anti-complement factor H:

- The first commercially available CE IVD certified ELISA
- High sensitivity/specificity
- Quantitative evaluation of the data

anti-CFH IgG titres in aHUS, inherited and aquired TTP



Standard anti-CFH IgG



References:

- Anti-factor H autoantibody-associated hemolytic uremic syndrome: review of literature of the autoimmune form of HUS. Dragon-Durey MA, Blanc C, Garnier A, Hofer J, Sethi SK, Zimmerhackl LB. Semin Thromb Hemost. 2010 Sep;36(6):633-40.
- Anti-Factor H autoantibodies associated with atypical hemolytic uremic syndrome. Dragon-Durey MA, Loirat C, Cloarec S, Macher MA, Blouin J, Nivet H, Weiss L, Fridman WH, Frémeaux-Bacchi V. J Am Soc Nephrol. 2005 Feb;16(2):555-63.
- Factor H autoantibodies in atypical hemolytic uremic syndrome correlate with CFHR1/CFHR3 deficiency. Józsi M, Licht C, Strobel S, Zipfel SL, Richter H, Heinen S, Zipfel PF, Skerka C.Blood. 2008 Feb 1;111(3):1512-4.

Neurofilaments

Neurofilaments are the main cytoskeletal constituents in neuronal cells. They are important for maintaining the structural integrity and caliber of axons and dendrites thereby influencing the conduction velocity of nerve impulses. The neurofilament chains are divided into three groups according to their molecular size, neurofilament light (NF-L), neurofilament medium (NF-M), neurofilament heavy (NF-H). NF-L is the quantitatively most common filament with a molar ratio of 4:2:1 (NF-L : NF-M : NF-H). Phosphorylation of the C-terminal part of heavy and medium neurofilaments shows topological dependence, neurofilaments in axons are heavily phosphorylated, crosslinked and spatially organized, whereas neurofilaments found in neuronal body and in dendrites posse low degree of phosphorylation, the crosslinking level is low and their orientation is random.

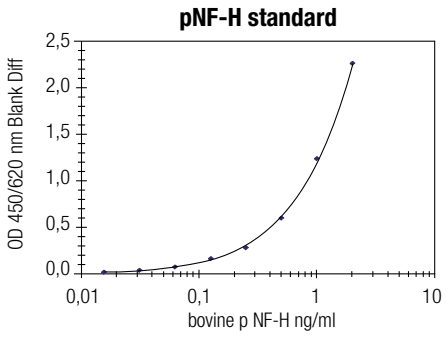
ELISA-VIDITEST pNF-H is intended to measure the concentration of phosphorylated forms of heavy neurofilaments in peripheral blood and cerebrospinal fluid. The ELISA uses sandwich of the mouse monoclonal antibody NF01 that binds to the phosphorylated epitopes on heavy neurofilaments and of mouse monoclonal antibody NF05 that reacts equally with phosphorylated and non-phosphorylated forms of heavy neurofilaments. Phosphorylated heavy neurofilaments were detected in higher concentrations in diseases that involve central nervous system damage (Shaw et al. 2005). The kit except the human pNF-H detects porcine, bovine and rat pNFH, but not mouse pNF-H.

ELISA-VIDITEST RUO

REF	Product	Method	Evaluation	Wells	Sample	Limit of detection
ODZ-437	pNF-H	ELISA	quant.	96	serum, plasma, cerebrospinal fluid	23 pg / mL

Why using ELISA-VIDITEST pNF-H:

- Sensitive and precise
- Quantitative data evaluation
- One-step ELISA - minimal hands-on time requirements
- No sample predilution before assay
- Incubation buffer that minimizes heterophile antibody interference



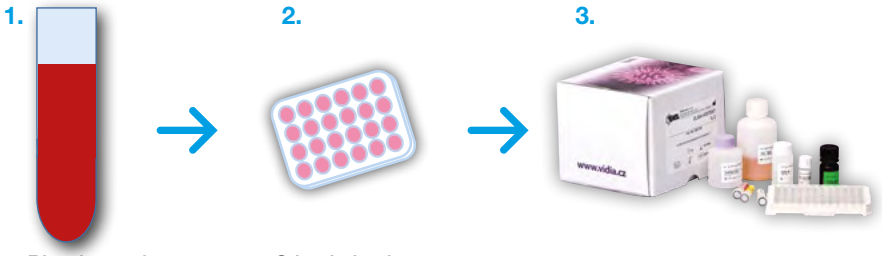
References:

- Shaw G, Yang C, Ellis R, Anderson K, Parker Mickle J, Scheff S, Pike B,Anderson DK, Howland DR. Hyperphosphorylated neurofilament NF-H is a serum biomarker of axonal injury. Biochem Biophys Res Commun. 2005 Nov 4;336(4):1268-77.
- Porchet R, Probst A, Draberova E, Draber P, Riederer IM, Riederer BM.: Differential subcellular localization of phosphorylated neurofilament and tau proteins in degenerating neurons of the human entorhinal cortex. Neuroreport. 2003 May 23;14(7):929-33.

Antigens for cellular immunity testing

Cellular immunity (CI) plays a dominant role in host control of herpesvirus infection. Its impairment may result in the development of chronic recurrent forms of the infections with poor prognosis for the patient. Virus-specific cellular immunity examination is important especially in the patients treated with immunosuppressive therapy (transplant recipients, oncological or autoimmune disease patients). It is beneficial also for vaccination or immunotherapy planning and efficiency monitoring.

Cellular immunity testing procedure:



REF	Product	Format	No. of tests/Amount
ODZ-264	CMV – CI combi r.t.u.	lyophilized	10 / 1 mL
ODZ-289	VZV – CI combi r.t.u.	lyophilized	10 / 1 mL
ODZ-314	HSV-1 – CI nativ r.t.u.	lyophilized	10 / 1 mL
ODZ-315	HSV-2 – CI nativ r.t.u.	lyophilized	10 / 1 mL
ODZ-319-05	CMV – CI nativ conc.	lyophilized	250 / 0.5 mg
ODZ-320	VZV – CI nativ conc.	lyophilized	50 / 0.1 mg
ODZ-321	HSV-1 – CI nativ conc.	lyophilized	50 / 0.1 mg
ODZ-322	HSV-2 – CI nativ conc.	lyophilized	50 / 0.1 mg
ODZ-365	Control – CI r.t.u. (for CMV, VZV)	lyophilized	10 / 1 mL
ODZ-366	Control – CI r.t.u. (for HSV-1, HSV-2)	lyophilized	10 / 1 mL

The development of the antigens was supported by grant TA-03010331 from Technology Agency of the Czech Republic.

Antigens specification:

CMV – CI combi r.t.u. antigen contains native CMV proteins (lysate from human cells infected by the virus) and a mixture of immunoactive peptides derived from immunodominant CMV proteins pp65 and IE1. It is intended for the specific stimulation of CD4+ and CD8+ T-lymphocytes.

VZV – CI combi r.t.u. antigen contains native VZV proteins (extract from human embryonal fibroblasts infected with wild type VZV (strain M)) and a mixture of immunoactive peptides derived from immunodominant VZV proteins IE62 and IE63. It is intended for the specific stimulation of CD4+ and CD8+ T-lymphocytes.

Native antigens HSV-1, HSV-2 – CI nativ r.t.u. are intended for virus-specific T-lymphocytes stimulation in tests of adoptive cellular immunity. The antigens r.t.u. are lyophilized in working concentration of the lymphocyte cultivation medium. After dissolving in the appropriate volume of sterile distilled water they can be directly mixed 1:1 with blood or the lymphocyte suspension and then cultivated.

Native antigens CMV, VZV, HSV-1 a HSV-2 – CI nativ conc. are intended for virus-specific T-lymphocytes stimulation. The antigens are supplied as concentrated.

Native CMV antigen: extract from human embryonal fibroblasts infected with CMV (strain AD169).

Native VZV antigen: extract from human embryonal fibroblasts infected with wild type VZV (strain M).

Native HSV-1 and HSV-2 antigens: extracts from VERO cells infected with HSV-1 (strain Prague) or HSV-2 (strain 610)

Control – CI r.t.u.: extract from uninfected human or monkey cells. The antigens serve as controls for the stimulation test.

Interferon γ and Interleukin 2

ELISA-VIDITEST Interferon γ is intended for the quantitative detection of Interferon γ (IFNγ) in samples.

ELISA-VIDITEST IL-2 is intended for the quantitative detection of Interleukin 2 (IL-2) in samples.

IFNγ is a dimerized soluble cytokine, which is important in innate and adaptive immunity against viral, bacterial and protozoal pathogens. IFNγ is predominantly produced by natural killer cells (innate immunity response) and CD4+ and CD8+ lymphocyte (once the antigen-specificic immunity develps).

IL-2 is a key signal molecule in adaptive immune response which is important for priming of immune response, T-cell expansion and differentiation. It is produced mainly by activated dendritic cells a T-lymphocytes .

ELISA-VIDITEST RUO

REF	Product	Method	Evaluation	Wells	Detection limit
ODZ-326	Interferon γ	ELISA	quant.	96	0.2 IU/ml (WHO)
ODZ-361	IL-2	ELISA	quant.	96	0.08 IU/ml (WHO)

Why using ELISA-VIDITEST Interferon γ a ELISA-VIDITEST IL-2:

- High sensitivity
- Quantification based on WHO standards
- Lyophilized standards for better stability
- Incubation at laboratory temperature

The development of the kits was supported by grant TA-03010331 from Technology Agency of the Czech Republic.

Influenza

Antigens used for complement fixation (CF) antibody assays are intended to detect specific antibodies of class IgM/IgG in mixture. The test can not discriminate between the antibody classes. The complement fixation test is performed in two stages. First, serum and antigen are mixed in presence of known amount of complement. If the serum antibodies and antigen react, the complement is bound to antigen–antibody complexes and depleted from the mixture. In the second stage erythrocytes with bound antibodies are added to the reaction mixture, and if complement remains from the first stage, the erythrocytes will be lysed. The highest serum dilution that prevents haemolysis is proportional to the concentration of antigen specific antibodies in the serum sample.

Influenza CF antigens are intended for the detection of class IgG and IgM antibodies to Influenza virus type A/H1N1 (A/H3N2, B or A and B) via complement fixation assay. Serum antibodies to Influenza type A CF antigen (B CF antigen or A and B CF antigen) are indicative of previous contact with the virus or with the Influenza antigens. Kits contain partially purified mixtures of formaldehyde inactivated Influenza virus type A (B) in allantoic fluid of chicken embryo in glycerol solution.

CF Ag

CE IVD

REF	Product	Method	Sample	Format
ODZ-107	Influenza A/H1N1	CFAg	serum	1 ml
ODZ-108	Influenza A/H1N1	CFAg	serum	6 x 1 ml
ODZ-109	Influenza A/H3N2	CFAg	serum	1 ml
ODZ-110	Influenza A/H3N2	CFAg	serum	6 x 1 ml
ODZ-111	Influenza B	CFAg	serum	1 ml
ODZ-112	Influenza B	CFAg	serum	6 x 1 ml
ODZ-113	Influenza – comb. kit.	CFAg	serum	3 x 6 ml

Why using Antigens for complemet fixation assay:

- Cost-effective test
- Differentiation between type A/H1N1 and A/H3N2
- Antigens are inactivated
- Test performance does not need any special laboratory devices
- Parallel different antigens testing of the sample from one patient

Adenovirus

CF Ag Adenovirus is intended for complement fixation test to detect antibodies against the Adenovirus group specific (mainly hexon) antigens in serum samples. A single positive antibody titre to CF antigens indicates a contact with the virus but it does not allow a conclusion as to the time of contact (recent or past).
A seroconversion or a four–fold rise in titre between serum samples taken during the acute and the convalescent phase of the disease is suggestive of a recent Adenovirus infection. CF Ag Adenovirus contains a mixture of the most common Adenovirus serotypes (1–7 and 14).

CF Ag CE IVD

REF	Product	Method	Sample	Format
ODZ-114	Adenovirus	CFAg	serum	1 ml lyof.
ODZ-115	Adenovirus	CFAg	serum	6 x 1 ml lyof.

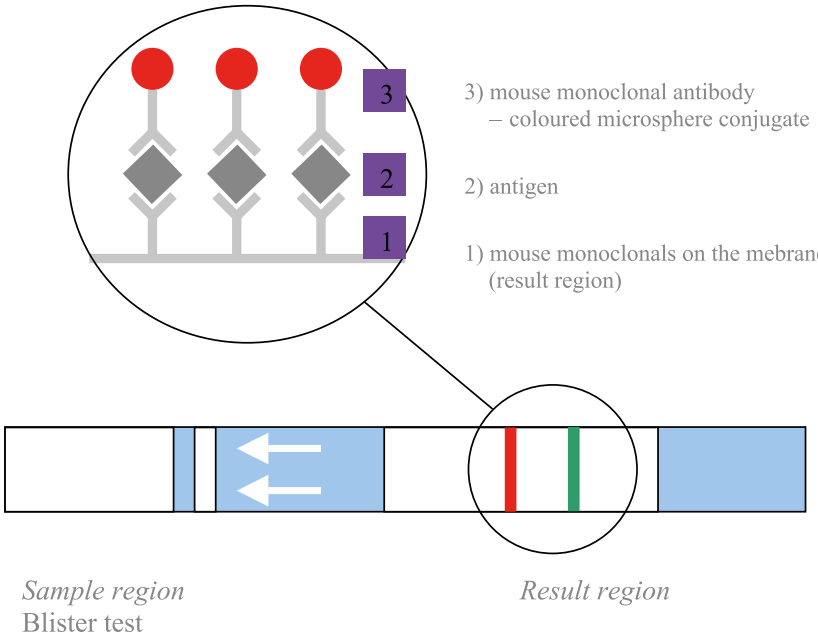
Why using Antigens for complemet fixation assay:

- Cost-effective test
- Long stability
- Test performance does not need any special laboratory devices
- Parallel different antigens testing of the sample from one patient
- Antigens are inactivated and lyofilized

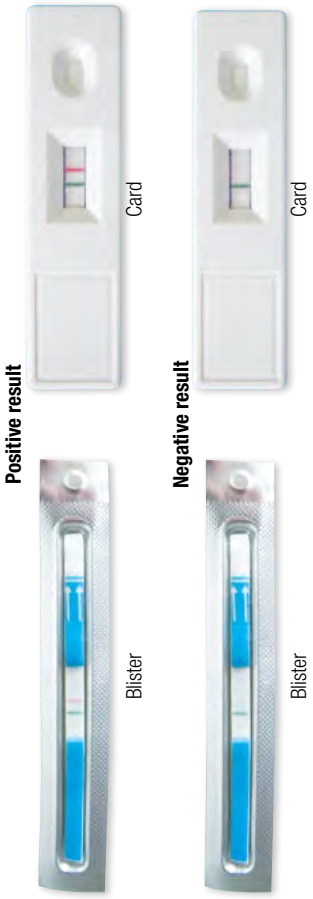
Principle

Rapid-VIDITEST tests are one step immunochromatographic assays for qualitative detection of a variety of viral and bacterial antigens in human samples. Depending on the specified antigen the specimens are taken as nose/throat swabs, lavages, aspirations, urine and stool samples.

- Simple use
- Result within 15 minutes
- Easy interpretation
- Laboratory equipment not needed



Blister test



Rapid-VIDITEST Mononucleosis is a rapid immunochromatograpic test for qualitative detection of heterophile anti-EBV antibodies from human serum, plasma and whole blood.

Rapid-VIDITEST CE IVD

REF	Product	Format	Marker	Disease	No. of tests	Sample	Sensitivity/ Specificity
ODZ-410	Mononucleosis	Card	heterophile anti-EBV antibodies	infectious mononucleosis	20	whole blood, serum, plasma	> 99.9% / 98.6%

Diagnosis of gastro-intestinal infections

Rapid-VIDITEST tests are one step immunochromatographic assays for qualitative detection of viral and bacterial pathogens which cause various gastro-intestinal infections.

Rapid-VIDITEST CE IVD **Sample: stool**

REF	Product	Format	Pathogen/Marker	Disease	No. of tests	Sensitivity/ Specificity
ODZ-285	Adenovirus	Card	Adenovirus	gastroenteritis	20	> 99% / > 99%
ODZ-186	Astrovirus	Card	Astrovirus	gastroenteritis	20	94% / 99%
ODZ-160	Campylobacter	Card	*Campylobacter spp*	campylobacteriosis	20	> 99% / > 98%
ODZ-330	C.difficile Ag (GDH)	Card	glutamate dehydrogenase *Clostridium difficile*	diarrhoea, pseudomembranous enterocolitis	20	> 99% / > 99%
ODZ-332	C.difficile toxin A+B	Card	toxin A and B *Clostridium difficile*	diarrhoea, pseudomembranous enterocolitis	20	76.7% / 94.8%*
ODZ-449	C. difficile GDH-Toxin A+B	Card	glumatate dehydrogenase, toxin A and B *Clostridium difficile*	diarrhoea, pseudomembranous enterocolitis	20	GDH 95% / 99%, toxins 94.6% / > 99.9%
ODZ-028	E.coli	Card	*E.coli*	diarrhea, hemorragic colitis, haemolytic-uremic syndrom	20	100% / 85%
ODZ-223	Entamoeba	Card	*Entamoeba histolytica, Entamoeba dispar*	amoebiasis	20	> 99% / > 99%
ODZ-187	Enterovirus	Card	Coxsackievirus, Echovirus, Polioviruses, Enteroviruses 68-71	gastroenteritis, bronchiolitis, meningitis, conjunctivitis, paralysis resembling poliomyelitis	20	> 99% / > 99%
ODZ-128	H.pylori	Card	*Helicobacter pylori*	chronic gastritis, gastric and duodenal ulcer	20	95% / 99%
ODZ-129	H.pylori	Blister	*Helicobacter pylori*	chronic gastritis, gastric and duodenal ulcer	20	95% / 99%
ODZ-346	Norovirus	Card	Norovirus GI, GII	gastroenteritis	20	85% / 96%
ODZ-246	Rotavirus	Card	Rotavirus	gastroenteritis	20	> 99% / > 98%
ODZ-122	Rota-Adeno	Card	Rotavirus, Adenovirus	gastroenteritis	20	Rota 98% / 99%, Adeno 99% / 99%
ODZ-123	Rota-Adeno	Blister	Rotavirus, Adenovirus	gastroenteritis	20	Rota 98% / 99%, Adeno 99% / 99%
ODZ-422	Rota-Adeno-Noro	Card	Rotavirus, Adenovirus, Norovirus GI, GII	gastroenteritis	20	Rota >99%/ 98.8%, Adeno >99%/ 97.6%, Noro GI 87.5%/ >98.9% Noro GII 95%/ >96.6%

Diagnosis of gastro-intestinal infections

Rapid-VIDITEST tests are one step immunochromatographic assays for qualitative detection of bacteria and parasites which cause various gastro-intestinal infections.

Rapid-VIDITEST

CE IVD **Sample: stool**

REF	Product	Format	Pathogen/Marker	Disease	No. of tests	Sensitivity/ Specificity
ODZ-174	Salmonella	Card	*Salmonella enteritis, Salmonella typhimurium Salmonella typhi*	salmonelosis, typhoid and paratyphoid fever	20	99% / 97%
ODZ-275	Salmonella typhi	Card	*Salmonella typhi*	typhoid fever	20	> 99% / > 99%
ODZ-016	Giardia	Card	*Giardia lamblia*	giardiasis	20	> 99% / > 99%
ODZ-257	Giardia	Blister	*Giardia lamblia*	giardiasis	20	> 99% / > 99%
ODZ-278	Crypto	Card	*Cryptosporidium parvum*	cryptosporidiosis	20	> 99% / > 99%
ODZ-055	Crypto-Giardia	Card	*Cryptosporidium parvum, Giardia lamblia*	cryptosporidiosis, giardiasis	20	> 99% / > 99%
ODZ-255	Crypto-Giardia	Blister	*Cryptosporidium parvum, Giardia lamblia*	cryptosporidiosis, giardiasis	20	> 99% / > 99%
ODZ-451	Crypto-Giardia-Entamoeba	Card	*Cryptosporiddium parvum, Giardia lamblia, Entntamoeba histolytica, Entamoeba dispar*	cryptosporidiosis, giardiasis, amoebiasis	20	Crypto 79,3% / 99,5% Giardia 93,8% / 98,9% Entamoeba 82,4% / 96,4%
ODZ-258	Yersinia enterocolitica O:3	Card	*Yersinia enterocolitica O:3*	yersiniosis	20	> 99% / > 99%
ODZ-260	Yersinia enterocolitica O:9	Card	*Yersinia enterocolitica O:9*	yersiniosis	20	> 99% / > 99%

Diagnosis of respiratory infections

Rapid-VIDITEST tests are one step immunochromatographic assays for qualitative detection of viruses and bacteria which cause respiratory infections.

Rapid-VIDITEST

CE IVD

REF	Product	Format	Pathogen/ Marker	Disease	No. of tests	Sample	Sensitivity/Specificity
ODZ-051	Adenovirus Resp	Card	Adenovirus	various respiratory illnesses gastroenteritis, conjunctivitis, cystitis	20	nasal swabs, washes, aspirates	> 99% / > 99%
ODZ-026	Influenza A+B	Card	Influenza A, B	influenza	20	nasal swabs, washes, aspirates	> 99% / > 99%
ODZ-134	Influenza A+B	Blister	Influenza A, B	influenza	20	nasal swabs, washes, aspirates	> 99% / > 99%
ODZ-189	Legionella	Card	*Legionella pneumophila*	Legionnaires' disease	20	urine	> 99% / > 99%
ODZ-065	RSV	Card	Respiratory syncytial virus	bronchitis, pneumonia	20	nasal swabs, washes, aspirates	95% / 99%
ODZ-021	RSV	Blister	Respiratory syncytial virus	bronchitis, pneumonia	20	nasal swabs, washes, aspirates	95% / 99%
ODZ-023	RSV+Adeno Resp	Card	Respiratory syncytial Virus, Adenovirus	various respiratory illnesses gastroenteritis, conjunctivitis, cystitis	20	nasal swabs, washes, aspirates	RSV > 95% / > 99% Adeno 99% / > 99%
ODZ-062	RSV+Adeno Resp	Blister	Respiratory syncytial Virus, Adenovirus	various respiratory illnesses gastroenteritis, conjunctivitis, cystitis	20	nasal swabs, washes, aspirates	RSV > 95% / > 99% Adeno 99% / > 99%
ODZ-462	RSV-Influenza A+B	Card	Respiratory syncytial Virus, Influenza A,B	various respiratory illnesses, influenza	20	nasal swabs, washes, aspirates	RSV >96% / >97% Influenza A+B >99% / >95%
ODZ-068	Strep A	Card	*Streptococcus A*	tonsilitis/pharyngitis, scarlet fever, dermatitis	20	nasal swabs, washes, aspirates	> 99% / > 99%
ODZ-370	Streptococcus pneumoniae	Card	*Streptococcus pneumonieae*	pneumonia, meningitis, otitis	20	urine	99% / 92.9%
ODZ-463	Strep. pneumoniae-Legionella Card	Card	*Streptococcus pneumoniae, Legionella*	pneumophilla, meningitis, otitis, Legionnaires' disease	20	urine	*Strep. pneumonieae* >99% / >99% *Legionella* >99% >99%
NEW ODZ-475	SARS-CoV-2 Antigen	Card	Coronavirus	pneumonia	20	nasal swabs, washes aspirates	96.4 % / 99,2 %
NEW ODZ-476	SARS-CoV-2 + Influenza A+B Antigen	Card	Coronavirus, Influenza	pneumonia	20	nasal swabs, washes, aspirates	COVID-19 96.4 % / 99.2 % Flu A 94.1 % / 98.4 % Flu B 91.7 % / 100 %
NEW ODZ-478	anti-SARS-CoV-2 IgG/IgM	Card	Coronavirus	pneumonia	20	capillary blood	IgG: 96,3% / 98,6% , IgM: 95.0% / 98.0%

Inflammatory and tumor markers

Rapid-VIDITEST tests are one step immunochromatographic assays for qualitative detection of inflammatory and tumor markers – hemoglobin, transferrin, lactoferrin, calprotectin – in stool samples. FOB test does not require any dietary restrictions comparing to guaiac based tests.

Rapid-VIDITEST

CE IVD

REF	Product	Format	Marker	Disease	No. of tests	Sample	Sensitivity/ Specificity
ODZ-085	Lactoferrin	Card	lactoferrin	intestinal inflamation, Crohn disease, ulcerative colitis	20	stool	> 99% / > 99%
ODZ-248	Calprotectin	Card	calprotectin	intestinal inflamation, Crohn disease, ulcerative colitis	20	stool	> 94% / > 93%
ODZ-270	Calprotectin - Lactoferrin	Card	calprotectin, lactoferrin	intestinal inflamation, Crohn disease, ulcerative colitis	20	stool	Calprotectin > 94% / > 99% Lactoferrin > 93% / 99%
ODZ-250	FOB	Card	hemoglobin	gastrointestinal bleeding, colon cancer	20	stool	> 99% / > 99%
ODZ-101	FOB+Tf	Card	hemoglobin, transferrin	upper and lower gastrointestinal bleeding, colon cancer	20	stool	>99% / >99%

Pollutants

Bisphenol A

Bisphenol A (BPA) is well known toxicant whose estrogenic activity has been known for a long time. BPA interferes with the normal function of endocrine system, recently was found that it has a negative effect on in vivo fertility on animals, it can probably have a similar effect on the increase of human infertility.

ELISA-VIDTEST Bisphenol A kits are intended for detection of bisphenol A in environmental samples.

ELISA-VIDITEST

REF	Product	Method	Evaluation	Wells	Sample	Sample extraction	Limit of detection
ODZ-041	Bisphenol A	ELISA	quant.	96	soil, water	Yes	10 ng/mL

Why using ELISA-VIDITEST Bisphenol A:

- Possible new screening method
- Pollution monitoring without using HPLC
- Incubations at laboratory temperature
- Many tested samples in one test run
- Ready to use standards

Pollutants

Microcystin-LR

Microcystin-LR is a toxic compound produced by cyanobacterial genera *Microcystis, Anabaena, Nostoc* and *Plantothrix*, which are part of algal blooms that appear during vegetational season due to the eutrophication.
Eutrophication is often the result of anthropogenic pollution of water.

Microcystin-LR acts primarily as a hepatotoxin. Long-term exposure to MC-LR can cause chronic liver injury and death. MC-LR has toxic effect also on kidney, lungs and intestine, therefore WHO recommends rigorous monitoring of drinking water resources. WHO provisional guideline value for drinking water is 1,0 µg/L.

Microcystin-LR can cause also allergic reactions such as eczema, or else immunodeficiency, which may result in an increase of virus infections during the summer. Microcystin-LR should be regularly monitored also in recreational bathing waters.

ELISA-VIDITEST Microcystin-LR kit is intended for the detection of microcystin in water samples.

ELISA-VIDITEST

REF	Product	Method	Evaluation	Wells	Sample	Limit of detection
ODZ-165	Microcystin-LR	ELISA	quant.	96	water	1,0 µg/L

Why using ELISA-VIDITEST Microcystin-LR:

- Possible screening method
- High sensitivity
- Limit of detection 1,0 µg/L
- Ready to use standards and HRP conjugate
- Incubations at laboratory temperature
- Easy sample pretreatment – only filtration is recommended

ELISA kits for educational purposes

ELISA-VIDITEST EDUCO kits provide a safe demonstration of ELISA for educational purposes. The kits are designed for school laboratory classes: simple, cheap and with non–hazardous, non–infectious components.
Plastic droppers are included for suitable reagent handling. Kit demonstrates positivity and/or negativity in several unknown samples. Kits contain a detailed and straightforward user guide with troubleshooting section.

ELISA-VIDITEST EDUCO Diagnostic is ELISA kit for school use, intended to the demonstration of the analyte detection in unknown samples by ELISA. The students will learn how to prepare samples, calibration and process the result the same way as it is performed in a serology laboratory.

ELISA-VIDITEST

REF	Product	Method	Format
ODZ-191	EDUCO Diagnostic	ELISA	6 doublestrips

Why using ELISA-VIDITEST EDUCO:

- ELISA kits as tools to enhance laboratory lessons in schools
- Practical demonstration of an enzyme immunoassay (ELISA)
- Testing at room temperature, without any special equipment
- No hazardous substances or infectious material

VIDIMAT

VIDIMAT is a fully automatic small benchtop analyser, which is suitable for ELISA microtitrate plate and MONO-VIDITEST monotests processing. The analyser contains 2 positions for 2 microtitrate plates or for 24 monotests and one for pre-dilution plate.

The analyser is easy to operate, also software is very user-friendly. As a part of the analyser, there is a small netbook placed on the raised pad. It allows effective utilization of working place around the analyser. The samples are loaded into the sliding sample tray, analyser automatically detect the sample position. They can be identified using a barcode or manually.

VIDIMAT is able to process ELISA microtitrate plates along with the monotests in one run. It can be very useful for big laboratories and can serve as a complementary device to high-throughput analysers. On the other hand, MONO-VIDITEST kits are suitable also for those laboratories, which have the smaller sample turnover or they provide very special tests and therefore they cannot use whole 96-well mirotitrate plate.

VIDIMAT

Specification and technical details

Capacity

- 2 microtitrate plates
- 12 MONOTESTS, 1 microtitrate plate
- 24 MONOTESTS
- 1 pre-dilution plate

Data evaluation

- semiquantitative (qualitative)
- quantitative (AU/mL, IU/mL)

Incubations

- 30'/30'/15'
- 37 °C

(most of the kits)

Precise pipetting

- Analyzer uses high precision micro-syringe
- Aspiration of 1 µl with less than 3% CV
- Sample dilutions directly in the reaction wells - eliminates the need for extra pre-dilution steps
- The same level of Precision as other instruments in its class, but at much lower volumes

Real-time process monitoring

- The probe-mounted camera allows to monitor internal operations in real-time
- The camera and system logs allow technicians to remotely resolve most problems

Intelligent racks

- Intelligent racks sense each individual sample' s position during loading and record the position
- The VIDIMAT's further streamlines setup with a slide-out tray, that provides easy access to the intelligent racks for patient samples

Samples shaking

- Fully-integrated and automated orbital shaker
- Orbital shaker keeps fluids in wells while shaking up to 900 RPM
- Repeatable and accurate results

Quick and uniform heating

- Eliminates "edge effects"
- The forced convention incubator quickly and uniformly heats each individual reaction well
- Consistent results

Why using VIDIMAT :

- Fully automatic analyzer
- ELISA microtitrate plates and MONOTEST processing **in one run**
- Reliability
- Precision
- Easy to use

Monotests

MONO-VIDITEST kits are intended for the detection of antibodies to various pathogens in serum, plasma, cerebrospinal fluid and synovial fluid (where applicable). MONO-VIDITEST allows testing of one patient sample per one test. They have unified incubation and washing steps, so they can be tested in one run, which allows to combine various type of tests to very efficiently characterize a patient sample.
MONO-VIDITEST kits contain interchangeable VIDIA buffers and cartridges with all lot-specific reagents.

REF	MONO-VIDITEST	Sample	Tests in kit
KZ-100-12	anti-VCA EBV IgG	serum, cerebrospinal fluid	12
KZ-101-12	anti-VCA EBV IgM	serum	12
KZ-102-12	anti-VCA EBV IgA	serum	12
KZ-103-12	anti-VCA EBV IgG avidity	serum	12
KZ-110-12	anti-EBNA-1 EBV IgG	serum	12
KZ-111-12	anti-EBNA-1 EBV IgM	serum	12
KZ-120-12	anti-EA(D) EBV IgG	serum	12
KZ-121-12	anti-EA(D) EBV IgM	serum	12
KZ-122-12	anti-EA(D) EBV IgA	serum	12
KZ-150-12	anti-VZV IgG	serum, cerebrospinal fluid	12
KZ-151-12	anti-VZV gM	serum	12
KZ-152-12	anti-VZV IgA	serum	12
KZ-153-12	anti-VZV IgG avidity	serum	12
KZ-140-12	anti-HSV1+2 IgG	serum, cerebrospinal fluid	12
KZ-141-12	anti-HSV1+2 IgM	serum	12
KZ-142-12	anti-HSV1+2 IgA	serum	12
KZ-160-12	anti-HHV-6 IgG	serum, cerebrospinal fluid	12
KZ-161-12	anti-HHV-6 IgM	serum	12
KZ-300-12	anti-Borrelia recomb. IgG + VlsE	serum, cerebrospinal fluid, synovial fluid	12
KZ-301-12	anti-Borrelia recomb. IgM	serum, cerebrospinal fluid, synovial fluid	12
KZ-310-12	anti-TBEV IgG	serum, cerebrospinal fluid	12
KZ-311-12	anti-TBEV IgM	serum	12
KZ-313-12	anti-TBEV IgG avidity	serum	12
KZ-400-12	anti-Mycoplasma pn. IgG*	serum	12
KZ-401-12	anti-Mycoplasma pn. IgM*	serum	12
KZ-402-12	anti-Mycoplasma pn. IgA*	serum	12
KZ-130-12	anti-CMV IgG	serum	12
KZ-133-12	anti-CMV IgG avidity	serum	12
KZ-131-12	anti-CMV IgM	serum, plasma	12
KZ-132-12	anti-CMV IgA	serum	12
KZ-230-12	anti-Chlamydia pneumoniae IgG	serum, plasma	12
KZ-231-12	anti-Chlamydia pneumoniae IgM	serum, plasma	12
KZ-232-12	anti-Chlamydia pneumoniae IgA	serum, plasma	12

Monotests

AVAILABLE DURING 2021

REF	MONO-VIDITEST	Sample	Tests in kit
	anti-Chlamydia trachomatis IgG	serum, plasma	12
	anti-Chlamydia trachomatis IgA	serum, plasma	12
	anti-Toxo IgG	serum, plasma	12
	anti-Toxo IgM	serum, plasma	12
	anti-Toxo IgA	serum, plasma	12
	anti-Rubella IgG	serum, plasma	12
	anti-Rubella IgM	serum, plasma	12
NEW	anti-SARS-CoV-2 (NP) IgA	serum, plasma	12
NEW	anti-SARS-CoV-2 (NP) IgG	serum, plasma	12
NEW	anti-SARS-CoV-2 (NP) IgM	serum, plasma	12
NEW	anti-SARS-CoV-2 (S1) IgA	serum, plasma	12
NEW	anti-SARS-CoV-2 (S1) IgG	serum, plasma	12
NEW	anti-SARS-CoV-2 (S1) IgM	serum, plasma	12

Why using MONO-VIDITEST kits:

- 1 sample per one test
- Easy to use
- Various independent tests processed in one run
- Unified incubation times

Certificates

CQS z.s.
Prosecká 412/74, 190 00 Praha 9 - Prosek
Czech Republic

CQS is the Certification Body No 3029 accredited according to Standard EN ISO/IEC 17021-1:2015 by the Czech Accreditation Institute for the Certification of Management Systems.

CERTIFICATE
No.: CQS 2165/2018

CQS certifies that the Quality Management System of

VIDIA spol. s r.o.
Nad Safinou II 365, 252 50 Vestec, Czech Republic

has been assessed and found to be in conformity with the requirements of

EN ISO 9001:2015

with respect to the following processes

- Production of diagnostic kits, production of chemical substances and preparations, research and development in life sciences

Expiry date: 01. 09. 2021
Certification decision: 26. 07. 2018
Date of issue: 02. 09. 2018
The first certification: 10. 08. 2006

Jana Olšanská
Managing Director

CQS Members*:
Elektrotechnický zkušební ústav, s.p., Fyzikálně technický zkušební ústav, s.p., Institut pro testování a certifikaci, a.s., Strojírenský zkušební ústav, s.p., Technický a zkušební ústav stavební Praha, s.p., Textilní zkušební ústav, s.p.
* A CQS member list valid at the time of issue of the certificate. Current list is available at www.cqs.cz

CQS z.s.
Prosecká 412/74, 190 00 Praha 9 - Prosek
Czech Republic

CQS is the Certification Body No 3029 accredited according to Standard EN ISO/IEC 17021-1:2015 by the Czech Accreditation Institute for the Certification of Management Systems.

CERTIFICATE
No.: CQS 146/2018

CQS certifies that the Quality Management System of

VIDIA spol. s r.o.
Nad Safinou II 365, 252 50 Vestec, Czech Republic

has been assessed and found to be in conformity with the requirements of

EN ISO 13485:2016

with respect to the following processes; technical areas are presented in the audit report dated 26.07.2018

- Research, development and production of in vitro diagnostic medical devices
- Sales, storage and purchasing of in vitro diagnostic medical devices
- Installation and service of in vitro diagnostic medical devices

Expiry date: 01. 09. 2021
Certification decision: 26. 07. 2018
Date of issue: 02. 09. 2018
The first certification: 10. 08. 2006

Jana Olšanská
Managing Director

CQS Members*:
Elektrotechnický zkušební ústav, s.p., Fyzikálně technický zkušební ústav, s.p., Institut pro testování a certifikaci, a.s., Strojírenský zkušební ústav, s.p., Technický a zkušební ústav stavební Praha, s.p., Textilní zkušební ústav, s.p.
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Management Systems Certification Body
Institut pro testování a certifikaci, a.s.
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic
www.tcz.cz

CERTIFICATE
No. 18 0072 SJ

We confirm on the basis of a performed audit that company

VIDIA spol. s r. o.
Nad Safinou II 365, 252 50 Vestec, Czech Republic
Company Reg. No.: 16556267

has implemented and documented a functional quality management system in compliance with the requirements of the standard

ČSN EN ISO 9001:2016

Covering the following activities:

Production of diagnostic kits, production of chemical substances and preparations, research and development in life sciences

The Certificate is issued on the basis of the results mentioned in Audit Report No. 2334/4700/2018. The Certificate validity is conditioned by positive results of surveillance audits, which the certified company committed to undergo.
During use of the Certificate the Certificate Holder undertakes to follow the Rules of Use of the Certificate. This document is publicly available on www.tcz.cz

S 3002

Date of issue: 16. 07. 2018
Valid until: 15. 07. 2021
Date of the first certification awarding: 04. 08. 2006

Ing. Pavel Vašek
Head of Certification Body

Management Systems Certification Body
Institut pro testování a certifikaci, a.s.
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic
www.tcz.cz

CERTIFICATE
No. 18 0073 SJ

We confirm on the basis of a performed audit that company

VIDIA spol. s r. o.
Nad Safinou II 365, 252 50 Vestec, Czech Republic
Company Reg. No.: 16556267

has implemented and documented a functional quality management system in compliance with the requirements of the standard

ČSN EN ISO 13485 ed.2:2016

Covering the following activities:

- Research, development and production of *in vitro* diagnostic medical devices
- Purchasing, storage and sales of *in vitro* diagnostic medical devices
- Installation and service of *in vitro* diagnostic medical devices

The Certificate is issued on the basis of the results mentioned in Audit Report No. 2334/4701/2018. The Certificate validity is conditioned by positive results of surveillance audits, which the certified company committed to undergo.
During use of the Certificate the Certificate Holder undertakes to follow the Rules of Use of the Certificate. This document is publicly available on www.tcz.cz

S 3002

Date of issue: 16. 07. 2018
Valid until: 15. 07. 2021
Date of the first certification awarding: 04. 08. 2006

Ing. Pavel Vašek
Head of Certification Body

Distributor:

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