VIDIA

2023
2024

ELISA – MONO – LIA – RAPID – IF

DEVELOPMENT - PRODUCTION
DISTRIBUTION OF DIAGNOSTIC KITS
for human medicine

VIDIA spol. s r.o.
About us

We are a private Czech biotechnological company that has been involved in development, production and distribution of diagnostic kits for human medicine and the environmental monitoring for 31 years. Our company was founded in 1991 by researchers headed by a virologist Mr. RNDr. Jaroslav Roubal, CSc.

Recently our portfolio consists of more than 500 diagnostic kits. We have many years of experience in medical production and research, a professional team and modern laboratory equipment. As a result, we successfully implement all stages of the development and production proces of our **high-quality VIDITEST kits designed for the diagnosis of infectious viral, bacterial and parasitic diseases.**

High satisfaction of our users is the main goal of our company.

We provide an individual approach and we are constantly improving our products. Alternatively, we develop new ones, customized according to the requirements and needs of our users. Experienced and specialized team provides professional and technical support our with the interpretation of results and service of all equipment supplied by us. We work closely with scientific research institutes of the Academy of Sciences of the Czech Republic, universities and hospitals. We support scientific conferences and workshops for the professional public.

We focus on expanding our distribution network, **apart from the Czech and Slovak Republics, we now supply a wide range of VIDITEST kits to more than 30 countries in Europe, America and Asia.**

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PRODUCT PORTFOLIO

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Introduction
to portfolio

We place particular emphasis on the high quality and stability of our products, from the preparation of individual components to output quality control. The entire product portfolio undergoes strict multi-stage quality control process during the production process and kits are validated in the National Reference Laboratories. Since 2003 the company is certified according to ISO 9001 and ISO 13485. We participate in international quality assessment programs: External Quality Assurance, Labquality (Finland), INSTAND (Germany). Within the Czech Republic, we are involved in the ECE program.

Our portfolio includes a wide range of diagnostic tests for more than 60 infectious agents. For infectious serological diagnostics of viruses, bacteria, parasites and fungi we provide immunoenzymatic ELISA (Enzyme-Linked Immunosorbent Assay) kits - **ELISA-VIDITEST and MONO-VIDITEST**, enzymatic immuno-blot LIA (Line-ImunoAssay) kits - **LIA-VIDITEST** and IF (immunofluorescence) kits - **IF-VIDITEST**. Some kits are used in cerebrospinal fluid, serology, environmental toxicology or as educational tools for students. Immunochromatic rapid tests - **RAPID-VIDITEST** for rapid diagnosis, especially of gastrointestinal and respiratory infectious diseases, and detection of inflammatory or tumor markers.

Portfolio
according to the method of determination

ELISA-VIDITEST

- Immunoenzymatic kits (Enzyme-Linked Immunosorbent Assay)
- Quantitative, semiquantitative or qualitative evaluation of antibodies
- Determination of intrathecal antibodies synthesis
- Determination of avidity of antibodies
- ELISA break-away strips in the handling frame coated with the antigen
- High sensitivity and specificity
- High stability
- Color coded reagents in r. t. u. format
- Unified incubation times, temperatures, reagents for ELISA-VIDITEST and MONO-VIDITEST kits
- Manual or automatic processing of the test in our analyzer VIDIMAT

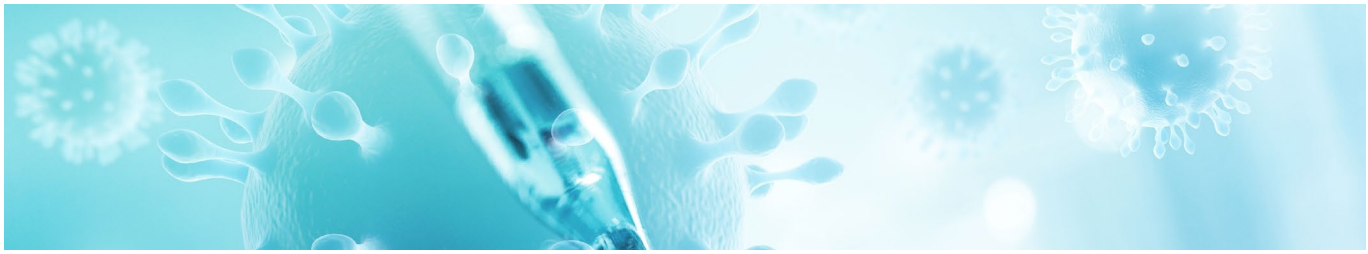
MONO-VIDITEST

- Innovative solution of ELISA-VIDITEST assays in the single-cassette-system format
- Simple and complex solution of automatization of infectious serology
- Semiquantitative or qualitative evaluation of antibodies
- Determination of intrathecal antibodies synthesis
- Determination of avidity of antibodies
- More simple and comfortable usage for one or more samples in one run
- High sensitivity and specificity
- High stability
- Reagents are part of the cassette
- Unified incubation times, temperatures, reagents for all ELISA-VIDITEST and MONO-VIDITEST
- Automatic processing of the test in our analyzer VIDIMAT

LIA-VIDITEST

- Enzymatic Line Immuno-Assay (LIA) on nitrocellulose membrane strips
- Qualitative evaluation of antibodies
- Focused on antigens of the various pathogens
- Unified incubation times, temperatures, reagents
- Evaluation using our VidiScan2 software
- Parallel testing of more samples for IgM and IgG in one run
- Confirmatory evaluation of test results of ELISA-VIDITEST and MONO-VIDITEST
- Validated for automatic or semiautomatic RoboBlot, BeeBlot, B20 analyzers

Portfolio
according to the method of determination



RAPID-VIDITEST

- Diagnostic rapid chromatographic immunoassay
- One-step test
- Qualitative determination of the presence of antigens of various viruses, bacteria, parasites
- Combined tests for differential diagnostics
- Easy to use and interpret
- Results in 10-15 minutes
- No need for additional laboratory equipment
- All components included in the test
- Storage temperature 2-30 °C

IF-VIDITEST

- Diagnostic immunofluorescence (IF) tests
- Indirect immunofluorescence method
- Application in serological diagnosis of many infections
- Qualitative evaluation
- Determination of the titer of specific antibodies
- High sensitivity and specificity
- Simple workflow
- The kits contain r.t.u. reagents
- Additional evaluation to the results of ELISA and MONO-VIDITEST

Portfolio
according to the pathogen and marker

VIROLOGY
Pathogen of the viral infection

	method					determination					
	ELISA-VIDITEST	MONO-VIDITEST	LIA-VIDITEST	RAPID-VIDITEST	IF-VIDITEST	IgA	IgG	IgG avidity	IgM	CSF	Antigen
Adenovirus				✓			■		■		■
Astrovirus				✓							■
Coronavirus SARS-CoV-2	✓	✓		✓		■	■		■		■
Cytomegalovirus (CMV)	✓	✓				■	■	■	■	■	■
Enterovirus				✓							■
Epstein-Barr Virus (EBV) EA-D	✓	✓			✓	■	■		■		
Epstein-Barr Virus (EBV) EBNA	✓	✓					■		■		
Epstein-Barr Virus (EBV) VCA	✓	✓			✓	■	■	■	■	■	
Human Herpesvirus 6 (HHV-6)	✓	✓			✓		■		■	■	
Herpes Simplex Virus (HSV-1 + HSV-2)	✓	✓			✓	■	■		■	■	
Influenza Virus A+B				✓			■		■		
Norovirus				✓							■
Polyomavirus BK (BKV)	✓						■				
Polyomavirus JC (JCV)	✓						■				
Rotavirus				✓							■
Respiratory Syncytial Virus (RSV)				✓							■
TBE Virus	✓	✓	✓				■	■	■	■	
Varicella zoster virus (VZV)	✓	✓			✓	■	■	■	■	■	

Portfolio
according to the pathogen and marker

	method					determination					
	ELISA-VIDITEST	MONO-VIDITEST	LIA-VIDITEST	RAPID-VIDITEST	IF-VIDITEST	IgA	IgG	IgG avidity	IgM	CSF	Antigen
BACTERIOLOGY											
Pathogen of the bacterial infection											
Borrelia	✓	✓	✓				▪		▪		
Campylobacter				✓							▪
Clostridium difficile (GDH+Toxin A, B)				✓							▪
Escherichia coli (E.coli)				✓							▪
Helicobacter pylori				✓							▪
Chlamydia pneumoniae	✓	✓				▪	▪		▪		
Chlamydia trachomatis	✓	✓				▪	▪				
Legionella pneumophila				✓							▪
Mycoplasma pneumoniae	✓	✓				▪	▪		▪		
Pseudomonas aeruginosa	✓	✓					▪				
Salmonella				✓							▪
Streptococcus pneumoniae				✓							▪
Yersinia enterocolitica				✓							▪
PARASITOLOGY											
Pathogen of the parasitic infection											
Cryptosporidium parvum				✓							▪
Entamoeba histolytica				✓							▪
Giardia lamblia				✓							▪
Toxoplasma gondii	✓					▪	▪	▪	▪		
MYCOLOGY											
Pathogen of the funcal infection											
Aspergillus fumigatus	✓	✓				▪	▪		▪		

Portfolio
according to the pathogen and marker

	method					determination					
SPECIALIZATION AND RESEARCH **Autoimmunity** **Cytoskeleton** **Cytokin** **Inflammatory and tumor marker**	ELISA-VIDITEST	MONO-VIDITEST	LIA-VIDITEST	RAPID-VIDITEST	IF-VIDITEST	IgA	IgG	IgG avidity	IgM	CSF	Antigen
Calprotectin				✓							■
Complement factor H	✓						■				
FOB				✓							■
Interferon γ	✓										■
Interleukin 2 IL-2	✓										■
Lactoferrin				✓							■
pNF-H	✓										■
Transferrin				✓							■
Vimentin	✓						■				
ENVIROMENTAL TOXICOLOGY **Toxic substances**											
Bisphenol A	✓										■
Microcystin-LR	✓										■
AUTOMATION **Analyzer**											
VIDIMAT	✓	✓				■	■	■	■	■	
Software											
VidiSoft2	✓	✓				■	■	■	■	■	
VidiScan2			✓			■	■		■	■	
E-Calculator	✓	✓				■	■	■	■	■	

VIROLOGY

RESPIRATORY INFECTIONS VIRUSES
GASTROINTESTINAL INFECTIONS VIRUSES
VIRUSES OF PRENATAL AND CONGENITA INFECTIONS
CHILDREN'S INFECTION VIRUSES
NEUROINFECTION VIRUSES
VIRUSES OF OTHER INFECTIONS

Coronavirus SARS-CoV-2

VIDITEST kits are used to diagnose an infectious acute respiratory disease called COVID-19, caused by the new coronavirus SARS-CoV-2 (Severe Acute Respiratory Syndrome-related Coronavirus 2). The epidemic is transformed into a global pandemic with high contagiousness and mortality rate. The main manifestations of COVID-19 are fever, fatigue and dry cough. In a few cases, nasal congestion, runny nose, sore throat, myalgia and diarrhea occur, especially in young children. The exact diagnose of COVID-19 is vital for identification of the infected persons, restriction) of the spreading of the virus and enabling of treatment to the infected persons in early phase of the infection. Development of efficient vaccines for prevention and medical countermeasures for treatment of SARS-CoV-2 infection is an urgent global priority.

ELISA-VIDITEST

Immunoenzymatic kits intended for the detection of IgA, IgG and IgM antibody response after an undergone infection by SARS-CoV-2 and for monitoring of post-vaccination protective antibodies.

VIDIA kits

CE IVD

REF	Product	Evaluation	Incubation	Sample	Number of tests	VIDIMAT
	ELISA-VIDITEST					
ODZ-500	anti-SARS-CoV-2 (NP) IgG quanti	quant.	30´/30´/15´	serum, plasma	96	✔
ODZ-471	anti-SARS-CoV-2 (NP) IgM	semiquant.	30´/30´/15´	serum, plasma	96	✔
ODZ-471/RF	anti-SARS-CoV-2 (NP) IgM	semiquant.	30´/30´/15´	serum, plasma	96	✔
ODZ-469	anti-SARS-CoV-2 (NP) IgA	semiquant.	30´/30´/15´	serum, plasma	96	✔
ODZ-488	anti-SARS-CoV-2 (S1) IgG quanti	semiquant, quant.	30´/30´/15´	serum, plasma	96	✔
ODZ-473/4ST	anti-SARS-CoV-2 (S1) IgG	semiquant., 4ST quant.	30´/30´/15´	serum, plasma	96	✔
ODZ-497/5ST	anti-SARS-CoV-2 (RBD) IgG quanti	semiquant., quant.	30´/30´/15´	serum, plasma	96	✔
ODZ-489	anti-SARS-CoV-2 (S1) IgM quanti	quant.	30´/30´/15´	serum, plasma	96	✔
ODZ-487	anti-SARS-CoV-2 (S1) IgA quanti	quant.	30´/30´/15´	serum, plasma	96	✔

MONO-VIDITEST

Immunoenzymatic kits in cartridge format intended for the diagnostics of IgA, IgG and IgM antibody response after an undergone infection by SARS-CoV-2 and for monitoring of post-vaccination protective antibodies.

VIDIA kits

CE IVD

REF	Product	Evaluation	Incubation	Sample	Number of tests	VIDIMAT
	MONO-VIDITEST					
KZ-520-12	anti-SARS-CoV-2 (NP) IgG	semiquant.	30´/30´/15´	serum, plasma	12	✔
KZ-521-12	anti-SARS-CoV-2 (NP) IgM	semiquant.	30´/30´/15´	serum, plasma	12	✔
KZ-522-12	anti-SARS-CoV-2 (NP) IgA	semiquant.	30´/30´/15´	serum, plasma	12	✔
KZ-533-12	anti-SARS-CoV-2 (S1) IgG quanti	quant.	30´/30´/15´	serum, plasma	12	✔
KZ-540-12	anti-SARS-CoV-2 (RBD) IgG quanti	semiquant., quant.	30´/30´/15´	serum, plasma	12	✔
KZ-535-12	anti-SARS-CoV-2 (S1) IgA quanti	quant.	30´/30´/15´	serum, plasma	12	✔
KZ-534-12	anti-SARS-CoV-2 (S1) IgM quanti	quant.	30´/30´/15´	serum, plasma	12	✔

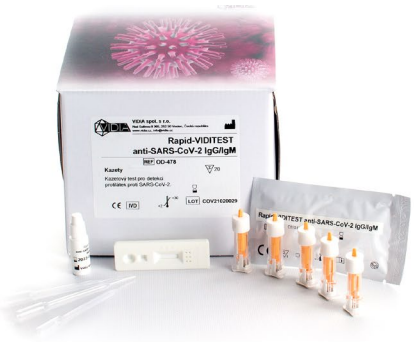
RAPID-VIDITEST

Immunochromatographic rapid tests intended as screening test for persons who are suspect to be infected by coronavirus (detection of antigen) and for the determination of the antibody response after an undergone infection and/or vaccination.

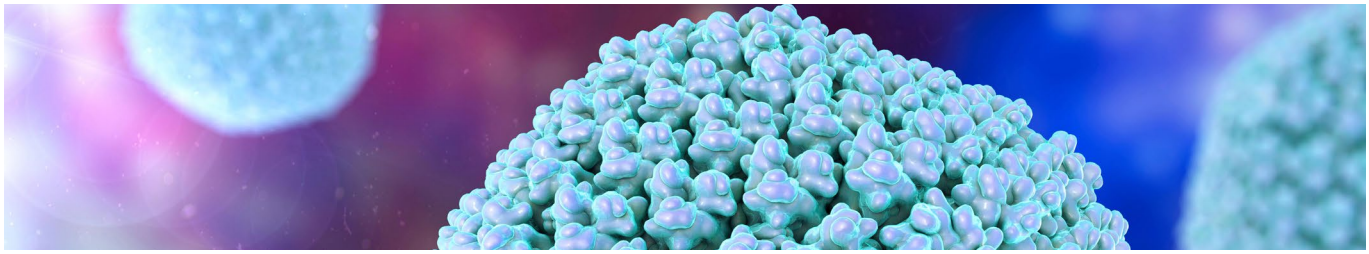
VIDIA kits

CE IVD

REF	Product	Incubation	Sample	Number of tests	Format
	RAPID-VIDITEST				
ODZ-475	SARS-CoV-2 Antigen	15 min	nasopharyngeal swab	20	card
ODZ-476	COVID-19 + Influenza A+B Antigen	15 min	nasopharyngeal swab	20	card
ODZ-478	anti-SARS-CoV-2 IgG/IgM	10 min	whole blood, serum, plasma	20	card
ODZ-496	anti-SARS-CoV-2 (RBD) IgG	10 min	whole blood, serum, plasma	20	card



Adenovirus, Respiratory syncytial virus (RSV)



The acute respiratory disease is caused by a wide range of viral pathogens, the most common of which are Adenovirus, Respiratory Syncytial Virus (RSV) and Influenza Virus A and B. RSV is generally considered to be the most common cause of pneumonia, nasopharyngitis, bronchiolitis and tracheobronchitis in infants and children. The infection is usually mild. Major complications occur in the elderly and patients with immunodeficiency. It causes pneumonia in the elderly in 14-27% of cases in the winter. Symptoms of respiratory disease caused by adenovirus range from symptoms of the common cold to pneumonia, laryngitis and bronchitis. Unlike other respiratory viruses, it is not seasonal, but is detected throughout the year.

RAPID-VIDITEST

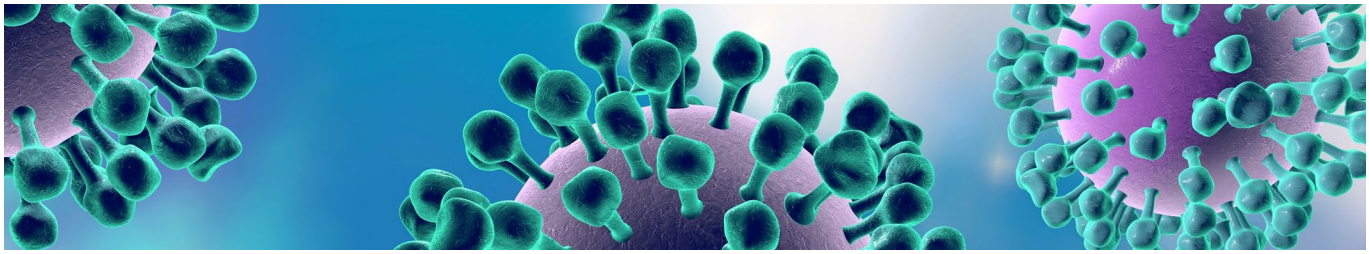
Rapid immunochromatographic immunoassay for qualitative and differential determination of adenovirus and RSV antigens.

VIDIA kits

CE IVD

REF	Product	Pathogen / Marker	Incubation	Sample	Number of tests	Format
	RAPID-VIDITEST					
ODZ-051	Adenovirus Resp.	Adenovirus	10 min	nasopharyngeal swab	20	card
ODZ-065	RSV	RSV	10 min	nasopharyngeal swab	20	card
ODZ-021	RSV	RSV	10 min	nasopharyngeal swab	20	blister
ODZ-062	RSV+Adeno Resp.	RSV, Adenovirus	10 min	nasopharyngeal swab	20	blister
ODZ-023	RSV+Adeno Resp.	RSV, Adenovirus	10 min	nasopharyngeal swab	20	card
ODZ-462	RSV+Influenza A+B	RSV, Influenza A+B	10 min	nasopharyngeal swab	20	card

Influenza



VIDITEST kits are intended to diagnose an acute, highly contagious, respiratory disease caused by the flu virus, or Influenza A and B. The virus is easily spread by coughing and sneezing. Influenza A viruses (subtypes H1N1 and H3N2) are usually more common than type B viruses and are associated with the most severe influenza epidemics (particularly subtypes H3N2). Type B infections are usually milder. Influenza A and B and RSV have similar clinical manifestations, seasonal prevalence, and infectious potential for high-risk patient populations (e.g., people of extremely old age, latent cardiopulmonary disease, and immunosuppression). Rapid identification of these viruses is very important for the administration of a suitable antiviral agent.

RAPID-VIDITEST

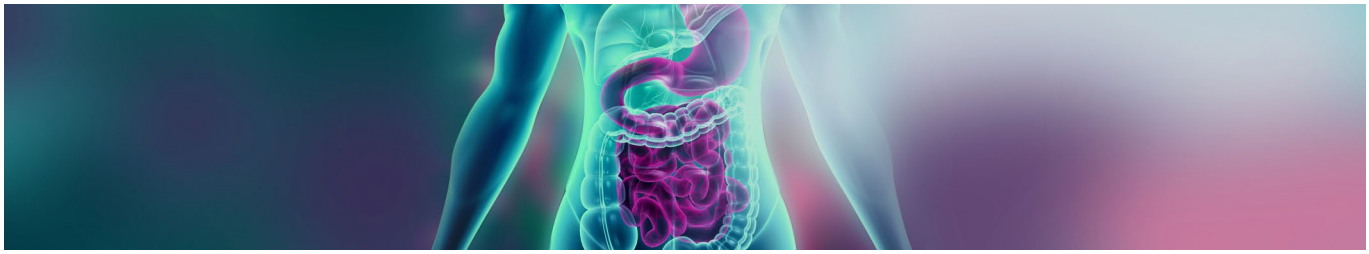
Rapid immunochromatographic immunoassays for the detection of Influenza type A (including A / H1N1, A / H3N2, A / H5N1) and type B antigens in nasopharyngeal samples. And rapid tests for differential detection of RSV and Influenza A + B virus.

VIDIA kits

CE IVD

REF	Product	Incubation	Sample	Number of tests	Format
	RAPID-VIDITEST				
ODZ-026	Influenza A+B	10 min	nasopharyngeal swab	20	card
ODZ-134	Influenza A+B	10 min	nasopharyngeal swab	20	blister
ODZ-462	RSV+Influenza A+B	10 min	nasopharyngeal swab	20	card

Adenovirus, Astrovirus, Enterovirus, Norovirus, Rotavirus



VIDITEST kits are intended for the diagnosis of viral gastroenteritis, inflammatory infectious diseases of the gastrointestinal tract, most often caused by viral agents - adenovirus, astrovirus, enterovirus, norovirus and rotavirus. The main symptoms of viral gastroenteritis are watery diarrhea and vomiting. The affected person may also have headache, fever, and abdominal cramps. The symptoms begin 1 to 2 days following infection with a virus that causes gastroenteritis and may last for 1 to 10 days, depending on which virus causes the illness. Astrovirus is the most common cause of gastroenteritis in children, adolescents and adults. Rotavirus is a more common cause of acute diarrhea in children under two years of age. Human enteroviruses are divided into polioviruses (polio, CNS disorders), coxsackie viruses (respiratory infections, gastroenteritis), echoviruses (rhinitis, respiratory infections) and other enteroviruses. Viruses are transmitted by the faecal-oral route.

RAPID-VIDITEST

Immunochromatographic immunoassays for qualitative detection of antigens of the most common viral agents causing gastroenteritis.

VIDIA kits

CE IVD

REF	Product	Pathogen / Marker	Incubation	Sample	Number of tests	Format
	RAPID-VIDITEST					
ODZ-285	Adenovirus	Adenovirus	10 min	stool	20	card
ODZ-186	Astrovirus	Astrovirus	10 min	stool	20	card
ODZ-187	Enterovirus	Coxsackieviruses, Echoviruses, Polioviruses, Enteroviruses	10 min	stool	20	card
ODZ-346	Norovirus	Norovirus	15 min	stool	20	card
ODZ-246	Rotavirus	Rotavirus	10 min	stool	20	card

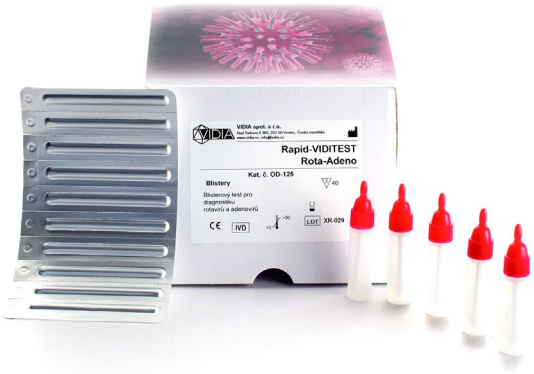
RAPID-VIDITEST

Rapid immunochromatographic immunoassay for qualitative and differential determination of antigens of the most common viral agents causing gastroenteritis.

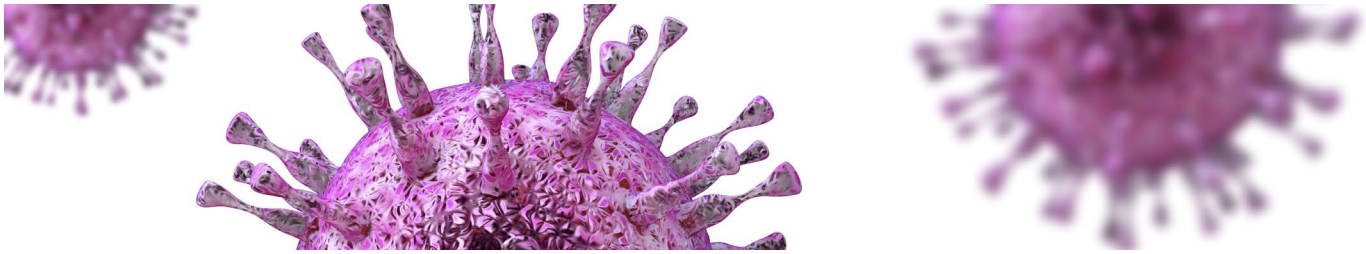
VIDIA kits

CE IVD

REF	Product	Pathogen / Marker	Incubation	Number of tests	Format
	RAPID-VIDITEST				
ODZ-123	Rota-Adeno	Rotavirus, Adenovirus	10 min	20	blister
ODZ-122	Rota-Adeno	Rotavirus, Adenovirus	10 min	20	card
ODZ-422	Rota-Adeno-Noro	Rotavirus, Adenovirus, Norovirus	15 min	20	card



Cytomegalovirus (CMV)



VIDITEST 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

Immunoenzymatic kits for the detection of specific IgA, IgG and IgM antibodies against CMV in serum, plasma and cerebrospinal fluid, and for avidity evaluation and for estimation of the intrathecal antibody production.

VIDIA kits

CE 1023 IVD

REF	Product	Evaluation	Incubation	Sample	Number of tests	VIDIMAT
	ELISA-VIDITEST					
ODZ-176	anti-CMV IgG	quant.	30´/30´/15´	serum, plasma	96	✔
ODZ-102/5ST	anti-CMV IgG (CSF)	semiquant., quant.	30´/30´/15´	serum, plasma, cerebrospinal fluid	96	-
ODZ-177	anti-CMV IgG a avidity IgG	semiquant.	30´/10´/30´/15´	serum, plasma	48	✔
ODZ-402	anti-CMV IgM	semiquant.	30´/30´/15´	serum, plasma	96	✔
ODZ-164	anti-CMV IgA	semiquant.	30´/30´/15´	serum, plasma	96	✔

Determination of specific cellular immunity

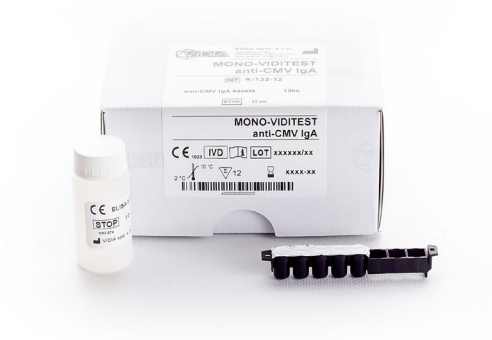
MONO-VIDITEST

Immunoenzymatic kits in cartridge format for the detection of specific IgA, IgG and IgM antibodies against CMV in serum and plasma, and for avidity evaluation of IgG antibodies.

VIDIA kits

CE 1023 IVD

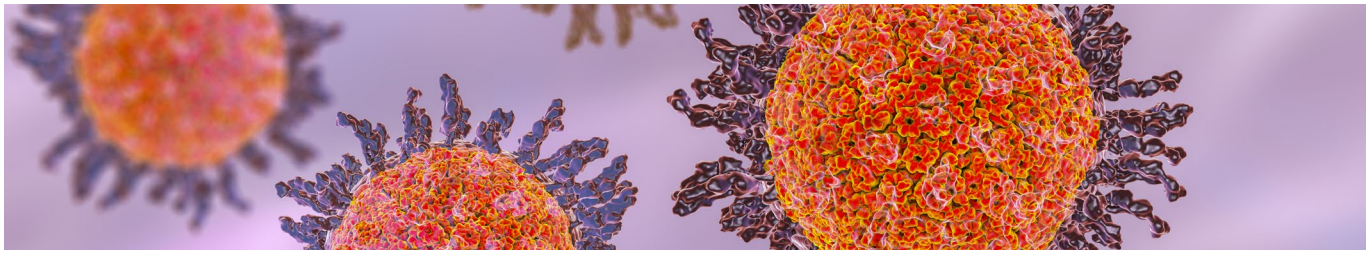
REF	Product	Evaluation	Incubation	Sample	Number of tests	VIDIMAT
	MONO-VIDITEST					
KZ-130-12	anti-CMV IgG	semiquant.	30´/30´/15´	serum, plasma	12	✔
KZ-131-12	anti-CMV IgM	semiquant.	30´/30´/15´	serum, plasma	12	✔
KZ-132-12	anti-CMV IgA	semiquant.	30´/30´/15´	serum, plasma	12	✔
KZ-133-12	anti-CMV IgG avidity	semiquant.	30´/10´/30´/15´	serum, plasma	12	✔



Benefits of kits for CMV

- Semiquantitative evaluation of IgA, IgG and IgM antibodies
- IgG quantification using 5 standards
- Automatic calculation of intrathecal synthesis of IgG antibodies by E-calculator
- Determination of avidity of IgG antibodies
- Compatible with other ELISA-VIDITESTs – posibility of whole herpesvirus panel antibody examination from one dilution of serum sample
- Unified incubation times, temperatures and reagents for all ELISA-VIDITEST and MONO-VIDITEST
- Manual or automatic processing of the test in our analyzer VIDIMAT
- Determination of specific cellular immunity

Herpes Simplex Virus (HSV)



VIDITEST 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). **Tests are the part of TORCH panel.** 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

Immunoenzymatic kits for the detection of specific IgA, IgG and IgM antibodies against HSV in serum and plasma.

VIDIA kits

CE IVD

REF	Product	Evaluation	Incubation	Sample	Number of tests	VIDIMAT
ODZ-169	anti-HSV1+2 IgG	semiquant.	30´/30´/15´	serum, plasma	96	✔
ODZ-234	anti-HSV1+2 IgM	semiquant.	30´/30´/15´	serum, plasma	96	✔
ODZ-283	anti-HSV1+2 IgA	semiquant.	30´/30´/15´	serum, plasma	96	✔

MONO-VIDITEST

Immunoenzymatic kits in cartridge format for the detection of specific IgA, IgG and IgM antibodies against HSV in serum, plasma and cerebrospinal fluid, and for estimation of the intrathecal IgG antibody production.

VIDIA kits CE IVD

REF	Product	Evaluation	Incubation	Sample	Number of tests	VIDIMAT
	MONO-VIDITEST					
KZ-140-12	anti-HSV1+2 IgG	semiquant., quant.	30´/30´/15´	serum, plasma cerebrospinal fluid	12	✔
KZ-141-12	anti-HSV1+2 IgM	semiquant.	30´/30´/15´	serum, plasma	12	✔
KZ-142-12	anti-HSV1+2 IgA	semiquant.	30´/30´/15´	serum, plasma	12	✔

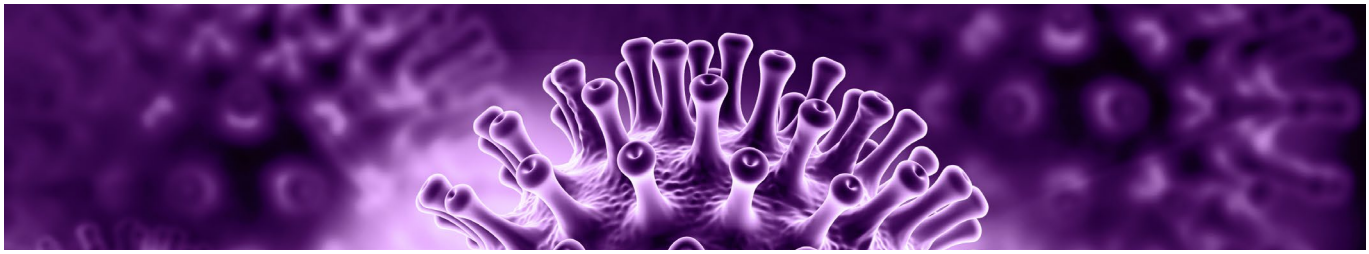
IF-VIDITEST

Immunofluorescence kits intended for the detection of specific anti-HSV antibodies in human serum and plasma.

VIDIA kits CE IVD

REF	Product	Evaluation	Sample	Number of tests
	IF-VIDITEST			
ODZ-059	anti-HSV	qualit.	serum, plasma	80

Human Herpesvirus 6 (HHV-6)



VIDITEST kits are intended for serological diagnosis of diseases associated with HHV-6 (Human Herpesvirus 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

Immunoenzymatic kits for the detection of specific IgG and IgM antibodies against HHV-6 in serum isolated from venous or capillary blood, plasma and cerebrospinal fluid, and for estimation of the intrathecal IgG antibody production.

VIDIA kits

CE IVD

REF	Product	Evaluation	Incubation	Sample	Number of tests	VIDIMAT
	ELISA-VIDITEST					
ODZ-235	anti-HHV-6 IgG	semiquant.	30´/30´´/15´	serum, plasma	96	✔
ODZ-344	anti-HHV-6 IgG (CSF)	semiquant., 5 ST quant.	30´/30´´/15´	serum, plasma, cerebrospinal fluid	96	-
ODZ-345	anti-HHV-6 IgM	semiquant.	30´/30´´/15´	serum	96	✔

MONO-VIDITEST

Immunoenzymatic kits in cartridge format for the detection of specific, IgG and IgM antibodies against HHV-6 in serum isolated from venous or capillary blood, plasma and cerebrospinal fluid, and for estimation of the intrathecal IgG antibody production.

VIDIA kits CE IVD

REF	Product	Evaluation	Incubation	Sample	Number of tests	VIDIMAT
	MONO-VIDITEST					
KZ-160-12	anti-HHV-6 IgG	semiquant., quant.	30´/30´/15´	serum, plasma, cerebrospinal fluid	12	✔
KZ-161-12	anti-HHV-6 IgM	semiquant.	30´/30´/15´	serum	12	✔

IF-VIDITEST

Immunofluorescence kits for the detection of specific anti-HHV-6 antibodies in human serum and plasma.

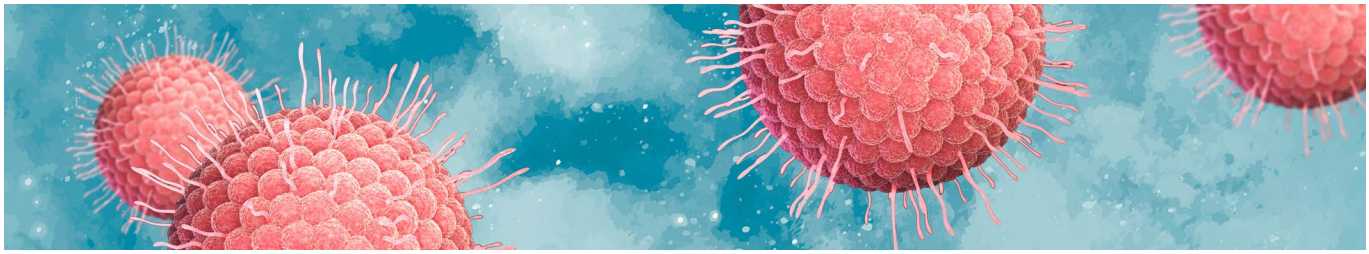
VIDIA kits CE IVD

REF	Product	Evaluation	Sample	Number of tests
	IF-VIDITEST			
ODZ-061	anti-HHV-6 IgG	qualit.	serum, plasma	80
ODZ-508	anti-HHV-6 IgM	qualit.	serum, plasma	80

Benefits of kits for HHV-6

- Semiquantitative determination of IgG and IgM antibodies in serum or plasma
- Quantitative determination of IgG in cerebrospinal fluid
- IgG quantification using 5 standards
- IgG quantification using 1 standard
- Automatic calculation of intrathecal synthesis of IgG antibodies by E-calculator
- Compatible with other ELISA-VIDITESTs – posibility of whole herpesvirus panel antibody examination from one dilution of serum sample
- Unified temperatures and reagents for all ELISA-VIDITEST and MONO-VIDITEST
- Color-coded r.t.u. reagents ready
- Additional qualitative evaluation by IF-VIDITEST to the results of ELISA and MONO-VIDITEST

Varicella Zoster Virus (VZV)



VIDITEST 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.

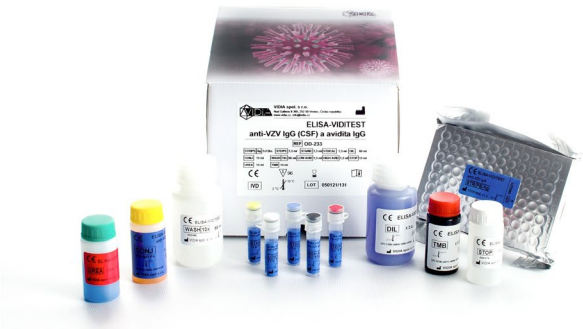
ELISA-VIDITEST

Immunoenzymatic kits for the detection of specific IgA, IgG and IgM antibodies against VZV in serum, plasma and cerebrospinal fluid, for avidity evaluation and for estimation of the intrathecal IgG antibody production.

VIDIA kits

CE IVD

REF	Product	Evaluation	Incubation	Sample	Number of tests	VIDIMAT
	ELISA-VIDITEST					
ODZ-087	anti-VZV IgG (CSF)	semiquant., 5ST quant.	30´/30´/15´	serum, plasma, cerebrospinal fluid	96	-
ODZ-168	anti-VZV IgG	semiquant.	30´/30´/15´	serum, plasma	96	✔
ODZ-197	anti-VZV IgM	semiquant.	30´/30´/15´	serum, plasma	96	✔
ODZ-233	anti-VZV IgG (CSF) a avidity IgG	semiquant., quant.	30´/10´/30´/15´	serum, plasma, cerebrospinal fluid	96	✔
ODZ-284	anti-VZV IgA	semiquant.	30´/30´/15´	serum, plasma	96	✔



MONO-VIDITEST

Immunoenzymatic kits in cartridge format for the detection of specific IgA, IgG and IgM antibodies against VZV in serum, plasma and cerebrospinal fluid, for avidity evaluation, and for estimation of the intrathecal IgG antibody production.

VIDIA kits CE IVD

REF	Product	Evaluation	Incubation	Sample	Number of tests	VIDIMAT
	MONO-VIDITEST					
KZ-150-12	anti-VZV IgG	semiquant., quant.	30´/30´/15´	serum, plasma, cerebrospinal fluid	12	✔
KZ-151-12	anti-VZV IgM	semiquant.	30´/30´/15´	serum, plasma	12	✔
KZ-152-12	anti-VZV IgA	semiquant.	30´/30´/15´	serum, plasma	12	✔
KZ-153-12	anti-VZV IgG avidity	semiquant.	30´/10´/30´/15´	serum, plasma	12	✔

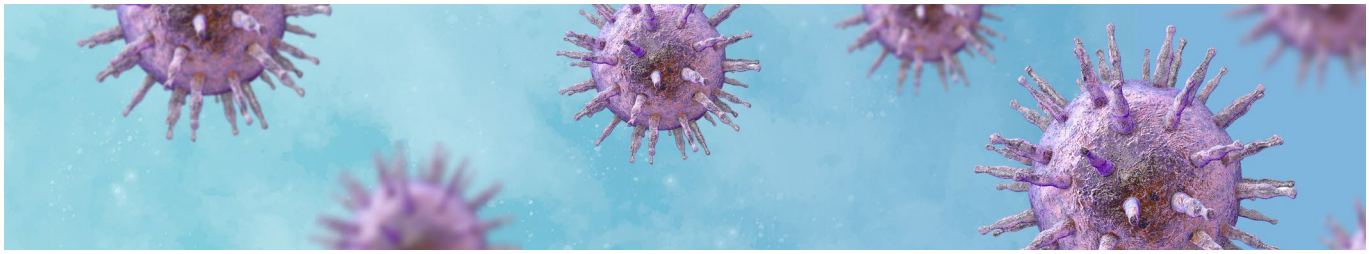
IF-VIDITEST

Immunofluorescence kits for the detection of specific anti-VZV antibodies in human serum and plasma.

VIDIA kits CE IVD

REF	Product	Evaluation	Sample	Number of tests
	IF-VIDITEST			
ODZ-119	anti-VZV	qualit.	serum, plasma	160

Epstein-Barr Virus (EBV)



VIDITEST 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.

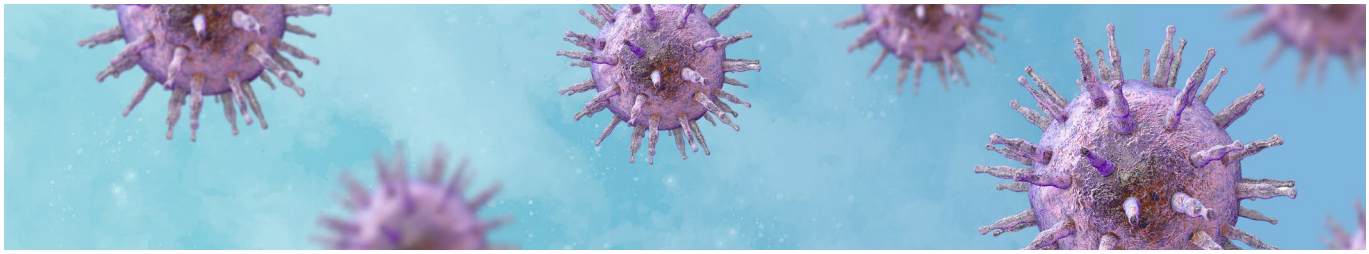
Markers of EBV infection:

- **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.

INTERPRETATION OF RESULTS - ANTIBODIES							
VCA EBV			EA(D) EBV		EBNA-1 EBV		
IgG	IgM	IgA	IgG	IgM	IgG	IgM	Phase of EBV infection
-	-	-	-	-	-	-	Seronegative
-	+	+	-	+ or -	-	+	Primary infection (early stage)
+ Low avidity	+	+	+ or -	+ or -	-	+	Primary infection
	+	-	+ or -	+ or -	-	+	
	-	+	+ or -	+ or -	-	-	
+ high avidity	+	-	+ or -	-	+	-	Suspicious reactivation
	-	+	+ or -	-	+	-	
	-	-	+	-	+	-	
+ high avidity	-	-	-	-	+	-	Seropositive without signs of active infection

Epstein-Barr Virus (EBV)
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

Immunoenzymatic kits for detection of specific IgG and IgM antibodies to Epstein-Barr virus (EBV) nuclear antigen-1 (EBNA-1) in human serum or plasma.

VIDIA kits CE IVD

REF	Product	Evaluation	Incubation	Sample	Number of tests	VIDIMAT
	ELISA-VIDITEST					
ODZ-001	anti-EBNA-1 EBV IgG	semiquant., 5 ST quant.	30´/30´/15´	serum, plasma	96	-
ODZ-002	anti-EBNA-1 EBV IgM	semiquant.	30´/30´/15´	serum, plasma	96	✔

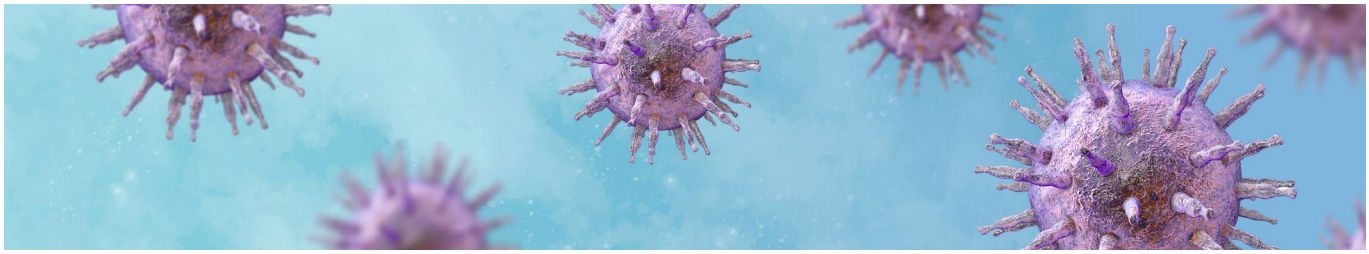
MONO-VIDITEST

Immunoenzymatic kits in cartridge format for the detection of specific IgG and IgM antibodies to Epstein-Barr virus (EBV) nuclear antigen-1 (EBNA-1) in human serum or plasma.

VIDIA kits CE IVD

REF	Product	Evaluation	Incubation	Sample	Number of tests	VIDIMAT
	MONO-VIDITEST					
KZ-110-12	anti-EBNA-1 EBV IgG	semiquant., quant	30´/30´/15´	serum, plasma	12	✔
KZ-111-12	anti-EBNA-1 EBV IgM	semiquant.	30´/30´/15´	serum, plasma	12	✔

Epstein-Barr Virus (EBV)
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

Immunoenzymatic kits for the detection of specific IgA, IgG and IgM antibodies to viral capsid antigen (VCA) of Epstein-Barr virus (EBV) in human serum, plasma and cerebrospinal fluid, for avidity evaluation and for estimation of the intrathecal IgG antibody production.

VIDIA kits

CE IVD

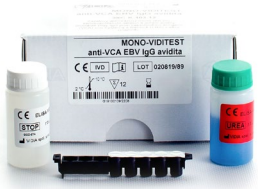
REF	Product	Evaluation	Incubation	Sample	Number of tests	VIDIMAT
	ELISA-VIDITEST					
ODZ-084/5ST	anti-VCA EBV IgG (CSF)	semiquant, 5 ST quant.	30´/30´/15´	serum, plasma, cerebrospinal fluid	96	-
ODZ-175	anti-VCA EBV IgG and IgG avidity	semiquant.	30´/10´/30´/15´	serum, plasma	96	✔
ODZ-265	anti-VCA EBV IgG	semiquant.	30´/30´/15´	serum, plasma	96	✔
ODZ-005	anti-VCA EBV IgM	semiquant.	30´/30´/15´	serum	96	✔
ODZ-096	anti VCA EBV IgA	semiquant.	30´/30´/15´	serum	96	✔

MONO-VIDITEST

Immunoenzymatic kits in cartridge format for the detection of specific IgA, IgG and IgM antibodies to viral capsid antigen (VCA) of Epstein-Barr virus (EBV) in human serum, plasma and cerebrospinal fluid and for avidity evaluation.

VIDIA kits CE IVD

REF	Product	Evaluation	Incubation	Sample	Number of tests	VIDIMAT
	MONO-VIDITEST					
KZ-100-12	anti-VCA EBV IgG	semiquant.	30´/30´/15´	serum, plasma, cerebrospinal fluid	12	✔
KZ-103-12	anti-VCA EBV IgG avidity	semiquant.	30´/10´/30´/15´	serum, plasma	12	✔
KZ-101-12	anti-VCA EBV IgM	semiquant.	30´/30´/15´	serum	12	✔
KZ-102-12	anti-VCA EBV IgA	semiquant.	30´/30´/15´	serum	12	✔



IF-VIDITEST

Immunofluorescence kits for the detection of specific anti-VCA EBV antibodies in human serum and plasma.

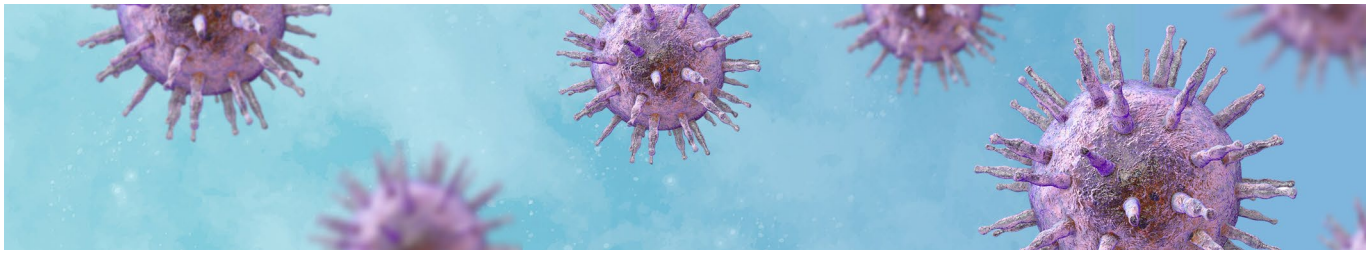
VIDIA kits CE IVD

REF	Product	Evaluation	Sample	Number of tests
	IF-VIDITEST			
ODZ-060	anti-VCA EBV	qualit.	serum, plasma	240

Benefits of kits for VCA EBV

- Complete panel of EBV serological markers in single dilution of serum sample
- Semiquantitative evaluation of IgA, IgG and IgM antibodies
- IgG quantification
- Automatic calculation of intrathecal synthesis of IgG antibodies by E-calculator
- Determination of avidity of antibodies
- ELISA-VIDITEST anti-EBNA-1 IgM contains high specific synthetic peptide antigen
- Color-coded reagents r. t. u.
- Unified incubation times, temperatures, reagents for all ELISA-VIDITEST and MONO-VIDITEST
- Manual or automatic processing of the test in our analyzer VIDIMAT
- Additional qualitative evaluation by IF-VIDITEST to the results of ELISA-VIDITEST and MONO-VIDITEST

Epstein-Barr Virus (EBV)
EA (D) 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 EBVassociated Burkitt lymphoma.

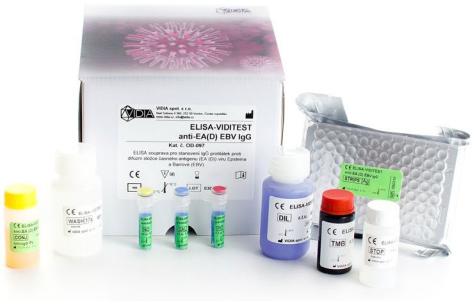
ELISA-VIDITEST

Immunoenzymatic kits for detection of specific IgA, IgG and IgM antibodies to diffusion component of an early antigen (EA (D)) Epstein-Barr virus (EBV) in human serum.

VIDIA kits

CE IVD

REF	Product	Evaluation	Incubation	Sample	Number of tests	VIDIMAT
	ELISA-VIDITEST					
ODZ-006	anti-EA (D) EBV IgG	semiquant.	30´/30´/15´	serum, plasma	96	✔
ODZ-007	anti-EA (D) EBV IgM	semiquant.	30´/30´/15´	serum	96	✔
ODZ-254	anti-EA (D) EBV IgA	semiquant.	30´/30´/15´	serum	96	✔



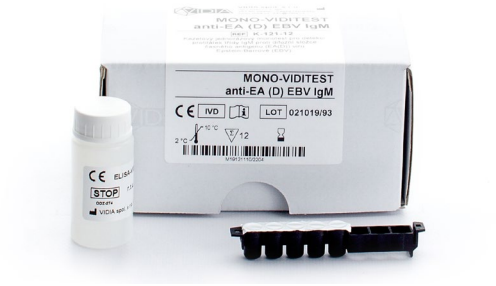
MONO-VIDITEST

Immunoenzymatic kits in cartridge format for detection of specific IgA, IgG and IgM antibodies to diffusion component of an early antigen (EA (D)) Epstein-Barr virus (EBV) in human serum.

VIDIA kits

CE IVD

REF	Product	Evaluation	Incubation	Sample	Number of tests	VIDIMAT
	MONO-VIDITEST					
KZ-120-12	anti-EA(D) EBV IgG	semiquant.	30´/30´/15´	serum, plasma	12	✔
KZ-121-12	anti-EA(D) EBV IgM	semiquant.	30´/30´/15´	serum	12	✔



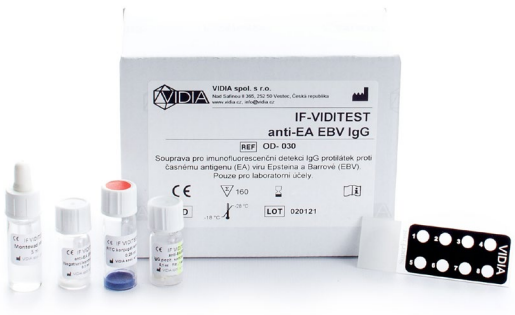
IF-VIDITEST

Immunofluorescence kits for the detection of specific anti-EA EBV antibodies in human serum and plasma.

VIDIA kits

CE IVD

REF	Product	Evaluation	Sample	Number of tests
	IF-VIDITEST			
ODZ-057	anti-EA EBV IgG	qualit.	serum, plasma	160
ODZ-058	anti-EA (D) EBV IgG	qualit.	serum, plasma	80



Benefits of kits for EA (D) EBV

- Complete panel of EBV serological markers in single dilution of serum sample
- Semiquantitative evaluation of IgA, IgG and IgM antibodies
- Specific recombinant antigen derived from the D-component of EA EBV
- Color-coded reagents r. t. u.
- Unified incubation times, temperatures, reagents for all ELISA-VIDITEST and MONO-VIDITEST
- Manual or automatic processing of the test in our analyzer VIDIMAT
- Additional qualitative evaluation by IF-VIDITEST to the results of ELISA-VIDITEST and MONO-VIDITEST

TBEV

VIDITEST kits are intended for serological diagnosis of TBEV (Tick-borne encephalitis virus) - associated diseases (encephalitis, meningoencephalitis). It can be also used for differential diagnosis of neuroinfections and for monitoring of the antibody response after vaccination against TBEV. ELISAVIDITEST anti-TBEV IgG and avidity IgG kit enables to determine low-avidity and high-avidity IgG antibodies, and therefore define primary and earlier underwent infections and condition after anti-TBEV vaccination. The basis of the encephalitis diagnostics is the determination of intrathecal synthesis of IgG specific antibodies in cerebrospinal fluid.

ELISA-VIDITEST

Immunoenzymatic kits for the detection of specific IgG and IgM antibodies against TBEV in human serum, plasma and cerebrospinal fluid, for avidity evaluation and for estimation of the intrathecal IgG antibody production.

VIDIA kits

CE IVD

REF	Product	Evaluation	Incubation	Sample	Number of tests	VIDIMAT
	ELISA-VIDITEST					
ODZ-170	anti-TBEV IgG and IgG avidity	semiquant.	30´/10´/30´/15´	serum, plasma, cerebrospinal fluid	96	✔
ODZ-192	anti-TBEV IgG (CSF)	semiquant., quant.	30´/30´/15´	serum, plasma, cerebrospinal fluid	96	✔
ODZ-194	anti-TBEV IgM	semiquant.	30´/30´/15´	serum, plasma, cerebrospinal fluid	96	✔

MONO-VIDITEST

Immunoenzymatic kits in cartridge format for the detection of specific IgG and IgM antibodies against TBEV in human serum, plasma and cerebrospinal fluid, for avidity evaluation and for estimation of the intrathecal IgG antibody production.

VIDIA kits

CE IVD

REF	Product	Evaluation	Incubation	Sample	Number of tests	VIDIMAT
	MONO-VIDITEST					
KZ-310-12	anti-TBEV IgG	semiquant., quant.	30´/30´/15´	serum, plasma, cerebrospinal fluid	12	✔
KZ-311-12	anti-TBEV IgM	semiquant.	30´/30´/15´	serum, plasma, cerebrospinal fluid	12	✔
KZ-313-12	anti-TBEV IgG avidity	semiquant.	30´/10´/30´/15´	serum, plasma	12	✔

LIA-VIDITEST

LIA-VIDITEST Multiplex Borrelia and TBEV, 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 TBEV.

VIDIA kits

CE IVD

REF	Product	Evaluation	Incubation	Sample	Number of tests
	LIA-VIDITEST				
ODZ-396	Multiplex Borrelia and TBEV IgG	qualit.	15´/30´/30´/10´	serum, plasma, cerebrospinal fluid, synovial fluid	16
ODZ-397	Multiplex Borrelia and TBEV IgM	qualit.	15´/30´/30´/10´	serum, plasma, cerebrospinal fluid, synovial fluid	16

Benefits of the kits for TBEV

- Semiquantitative evaluation of IgG and IgM antibodies
- Quantitative evaluation of IgG in Au/ml (VIEU/ml)
- Detection of post-infection and post-vaccine antibodies
- Determination of avidity of IgG antibodies
- Calculation of intrathecal antibodies synthesis using E-calculator
- Sample: serum, plasma and cerebrospinal fluid
- Unified incubation times, temperatures, reagents for all ELISA-VIDITEST and MONO-VIDITEST
- Manual or automatic test processing using VIDIMAT
- Confirmatory evaluation by LIA-VIDITEST for the test results from ELISA-VIDITEST and MONO-VIDITEST
- Multiplex kits for both Lyme disease (LD) and TBE diagnostics
- Evaluation of the results with our VidiScan2 software
- Validated for automatic or semi-automatic RoboBlot, BeeBlot, B20 analyzers

Polyomavirus BK, Polyomavirus JC

VIDITEST kits are intended for serological diagnosis of diseases caused by or associated with BKV and JCV polyomaviruses. From 50-60% 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).
Polyomavirus BK caused BK-viral nephropathy, haemorrhagic cystitis, urethral stenosis, infections of upper and lower respiratory tract mainly in immunodeficient patients. Anti-BKV antibodies are present in 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. 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

Immunoenzymatic kits for the detection of specific IgG antibodies against BKV or JCV in human serum and plasma.

VIDIA kits

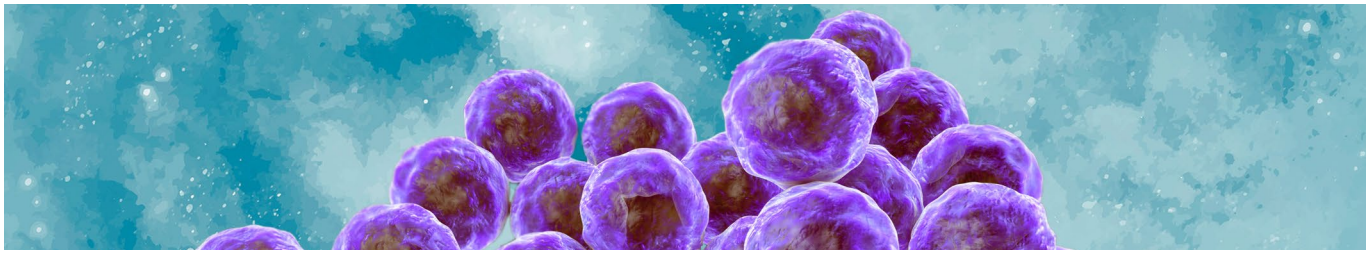
CE IVD

REF	Product	Evaluation	Incubation	Sample	Number of tests	VIDIMAT
	ELISA-VIDITEST					
ODZ-405	anti-BKV IgG	semiquant.	30´/30´/10´	serum, plasma	96	-
ODZ-450	anti-JCV IgG	semiquant., quant.	60´/60´/10´	serum, plasma	96	-

BACTERIOLOGY

RESPIRATORY INFECTIONS BACTERIA
GASTROINTESTINAL INFECTIONS BACTERIA
SEXUALLY TRANSMISSIBLE INFECTIONS BACTERIA
PRENATAL AND CONGENITAL INFECTIONS BACTERIA
NEUROINFECTIONS BACTERIA

Chlamydie pneumoniae



VIDITEST kits are intended for serological diagnosis of infections in lower respiratory tract and eye caused by bacteria *Chlamydia pneumoniae*. Primary chlamydial infection is characterized by the predominant IgM response within 2 - 4 weeks and the delayed IgG and IgA response within 6 - 8 weeks. After the acute infection IgM antibodies become undetectable in 2 - 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.

ELISA-VIDITEST

Immunoenzymatic kits for the detection of specific IgA, IgG and IgM antibodies against *Ch. pneumoniae.*

VIDIA kits

CE 1023 IVD

REF	Product	Evaluation	Incubation	Sample	Number of tests	VIDIMAT
	ELISA-VIDITEST					
ODZ-457	anti-Chlamydia pneumoniae IgG	semiquant.	30´/30´/15´	serum, plasma	96	✔
ODZ-458	anti-Chlamydia pneumoniae IgM	semiquant.	30´/30´/15´	serum, plasma	96	✔
ODZ-459	anti-Chlamydia pneumoniae IgA	semiquant.	30´/30´/15´	serum, plasma	96	✔

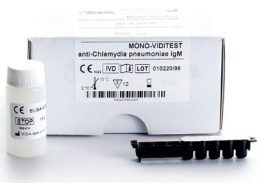
MONO-VIDITEST

Immunoenzymatic kits in cartridge format for the detection of specific IgA, IgG and IgM antibodies against *Ch. pneumoniae.*

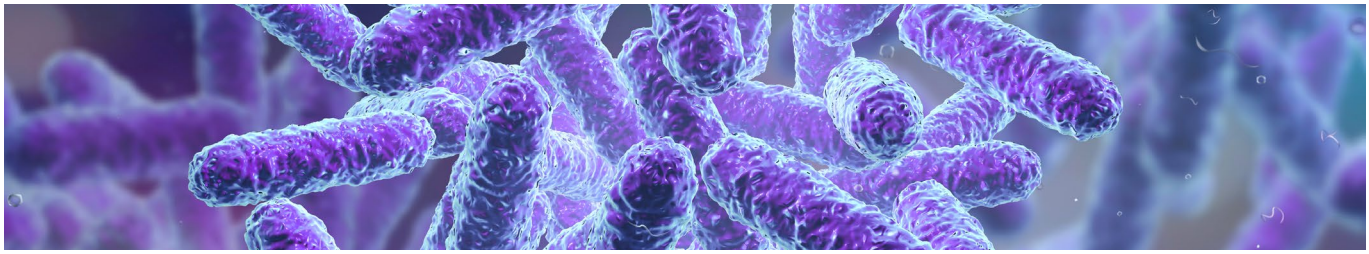
VIDIA kits

CE 1023 IVD

REF	Product	Evaluation	Incubation	Sample	Number of tests	VIDIMAT
	MONO-VIDITEST					
KZ-230-12	anti-Chlamydia pneumoniae IgG	semiquant.	30´/30´/15´	serum, plasma	12	✔
KZ-231-12	anti-Chlamydia pneumoniae IgM	semiquant.	30´/30´/15´	serum, plasma	12	✔
KZ-232-12	anti-Chlamydia pneumoniae IgA	semiquant.	30´/30´/15´	serum, plasma	12	✔



Legionella pneumophila



VIDITEST KITS are intended to aid in the presumptive diagnosis of legionella infection (Legionnaires' Disease) caused by Legionella pneumophila serogroup 1. Legionnaires' disease is a serious form of pneumonia that carries with it a mortality rate in the order of 10-15 %. Symptoms include a flu-like illness, followed by a dry cough and frequently progress to pneumonia. Approximately 30% of people infected may also present with diarrhoea and vomiting and around 50% may show signs of mental confusion. The incubation period normally ranges from 2-10 days with 3-6 days the typical illness onset time after exposure. The Rapid-VIDITEST *Legionella* allows early diagnosis of *Legionella pneumophila* serogroup 1 infection through detection of a specific soluble antigen present in the urine of patients with Legionnaires' Disease. *Legionella pneumophila* serogroup 1 antigen has been detected in urine as early as three days after the onset of symptoms.

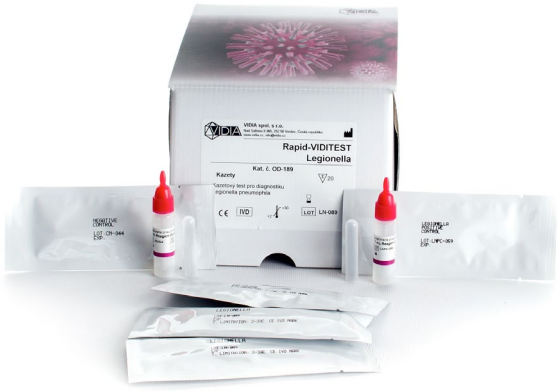
RAPID-VIDITEST

Rapid immunochromatographic immunoassays for the qualitative detection of *Legionella pneumophila* serogroup 1 antigen in urine specimens from patients with symptoms of pneumonia.

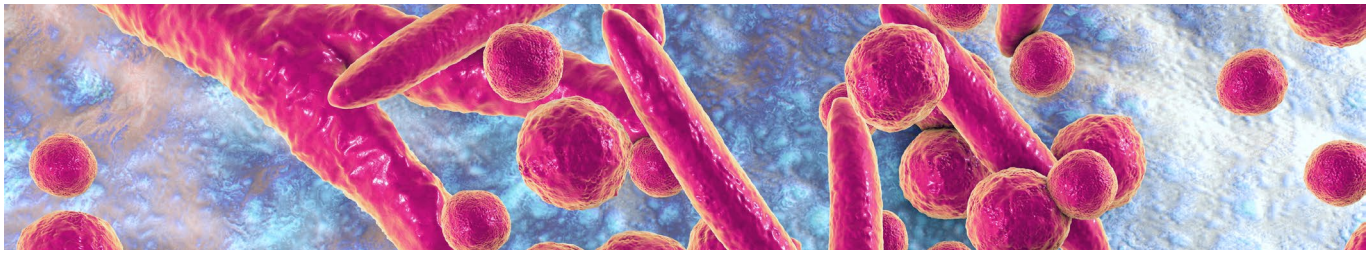
VIDIA kits

CE IVD

REF	Product	Evaluation	Incubation	Sample	Number of tests	Format
	RAPID-VIDITEST					
ODZ-189	Legionella	qualit.	15 min	urine	20	card



Mycoplasma pneumoniae



VIDITEST kits are intended for the serological 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 - IgA, IgG, IgM

ELISA-VIDITEST

Immunoenzymatic kits for the detection of specific IgA, IgG and IgM antibodies against *Mycoplasma pn.*

VIDIA kits

CE IVD

REF	Product	Evaluation	Incubation	Sample	Number of tests	VIDIMAT
	ELISA-VIDITEST					
ODZ-010	anti-Mycoplasma pneumoniae IgG	semiquant.	30´/30´/15´	serum, plasma	96	✔
ODZ-011	anti-Mycoplasma pneumoniae IgM	semiquant.	30´/30´/15´	serum, plasma	96	✔
ODZ-012	anti-Mycoplasma pneumoniae IgA	semiquant.	30´/30´/15´	serum, plasma	96	✔

MONO-VIDITEST

Immunoenzymatic kits in cartridge format for the detection of specific IgA, IgG and IgM antibodies against *Mycoplasma pn.*

VIDIA kits

CE IVD

REF	Product	Evaluation	Incubation	Sample	Number of tests	VIDIMAT
	MONO-VIDITEST					
KZ-400-12	anti-Mycoplasma pneumoniae IgG	semiquant.	30´/30´/15´	serum, plasma	12	✔
KZ-401-12	anti-Mycoplasma pneumoniae IgM	semiquant.	30´/30´/15´	serum, plasma	12	✔
KZ-402-12	anti-Mycoplasma pneumoniae IgA	semiquant.	30´/30´/15´	serum, plasma	12	✔

Pseudomonas aeruginosa

VIDITEST kits are intended for the serological diagnosis of respiratory infection caused by *Pseudomonas aeruginosa.* This opportunistic pathogen leads to acute and chronic types of infection in various organs. It is the most important bacterial pathogen in patients with cystic fibrosis, in whom chronic lung infection is responsible for most of the morbidity and mortality. Chronic Pseudomonas aeruginosa infection can be reliably distinguished from intermittent colonization by measuring serum IgG antibodies to Pseudomonas aeruginosa. Significant and increasing antibody response develops during chronic infection, whereas it is not observed in intermittently colonized patients. The level of antibody response in chronically infected patients correlates with the severity of the infection. Because the patients with cystic fibrosis may experience repeated colonization with Pseudomonas aeruginosa, they will be exposed to repeated courses of antibiotic therapy. Measurement of the antibody response in such cases may be useful in monitoring the patient's response to infection management and therapy.

ELISA-VIDITEST

Immunoenzymatic kits for the detection of specific IgG antibodies against Pseudomonas aeruginosa in serum or plasma.

VIDIA kits

CE IVD

REF	Product	Pathogen Marker	Evaluation	Incubation	Sample	Number of tests	VIDIMAT	
	ELISA-VIDITEST							
ODZ-511	anti-Pseudomonas aeruginosa IgG	*P. aeruginosa*	quant.	60´/60´/10´	serum, plasma	12	✔	NEW

MONO-VIDITEST

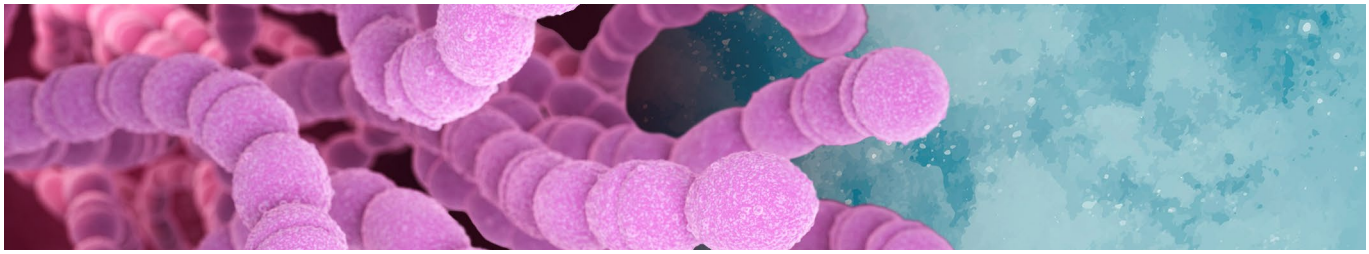
Immunoenzymatic kits in cartridge format for the detection of specific IgG antibodies against *Pseudomonas aeruginosa* in serum or plasma.

VIDIA kits

CE IVD

REF	Product	Pathogen Marker	Evaluation	Incubation	Sample	Number of tests	VIDIMAT	
	MONO-VIDITEST							
KZ-430-12	anti-Pseudomonas aeruginosa IgG	*P. aeruginosa*	quant.	60´/60´/10´	serum, plasma	12	✔	NEW

Streptococcus pneumoniae



VIDITEST kits are intended to diagnose serious diseases, pneumonia or meningitis caused by *Streptococcus pneumoniae* bacteria. *Streptococcus pneumoniae* colonizes upper respiratory tract tissues causing severe pneumonia and mild/acute earache or otitis. Pneumococci cause 13 % -19 % of all cases of bacterial meningitis. One-fourth of patients with pneumococcal meningitis also have pneumonia. Clinical symptoms are generally similar to those of other forms of purulent bacterial meningitis and include headache, lethargy, vomiting, irritability, fever, nuchal rigidity, cranial signs, seizures and coma. The case-fatality of pneumococcal meningitis is about 30 % but can be as high as 80 % among the elderly. Bacterial pneumonia accounts for 12 - 15 % of invasive pneumococcal disease among children aged 2 years and younger and bacterial meningitis among children younger than 5 years of age. Several vaccines are available with variable efficiency depending on patient age or whether patients are developing some chronic illness or immunodeficiency. Nevertheless, vaccines have been demonstrated to provide protection against pneumococcal pneumonia. RAPID-VIDITEST assays for the detection of soluble antigens of *Streptococcus pn.* a *Legionella pn.* serogoup 1 to provide early and differential diagnosis of both diseases and the use of the most suitable antibiotic treatment during the early stages of both diseases.

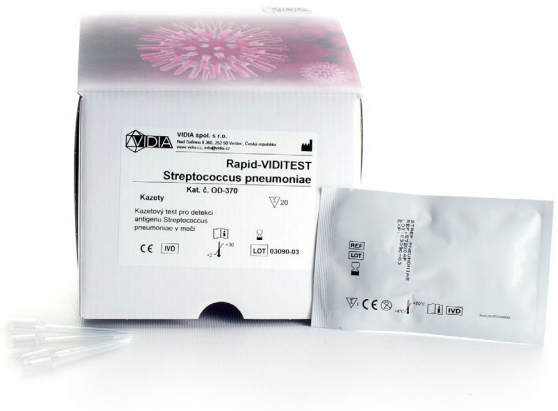
RAPID-VIDITEST

Rapid immunochromatographic immunoassays for qualitative and differential determination of *Streptococcus pneumoniae* and *Legionella pneumophila* antigens in urine.

VIDIA kits

CE IVD

REF	Product	Evaluation	Incubation	Sample	Number of tests	Format
	RAPID-VIDITEST					
ODZ-370	Streptococcus pneumoniae	qualit.	10 min	urine	20	card



Escherichia coli

VIDITEST kits are intended to diagnose diseases caused by bacteria *Escherichia coli* **O157:H7** (Enterohemorrhagic *Escherichia coli*). Infection presents with a wide spectrum of clinical manifestations, including asymptomatic carriage, nonbloody diarrhea, hemorrhagic colitis, the hemolytic-uremic syndrome, and thrombotic thrombocytopenic purpura. Not only is *E. coli* O157:H7 an important agent for hemorrhagic colitis, it is also one of the leading causes of bacterial diarrhea. Transmission of *E. coli* O157:H7 is primarily food-borne. Undercooked meat is the most common culprit, dairy products and secondary person-to-person spread are also important. The organism produces at least two Shiga-like toxins. These toxins are thought to have direct pathogenic significance in *E. coli* O157:H7 infection. Timely collection (within 7 days of illness onset) of a stool sample for culture is imperative for a high recovery rate.

RAPID-VIDITEST

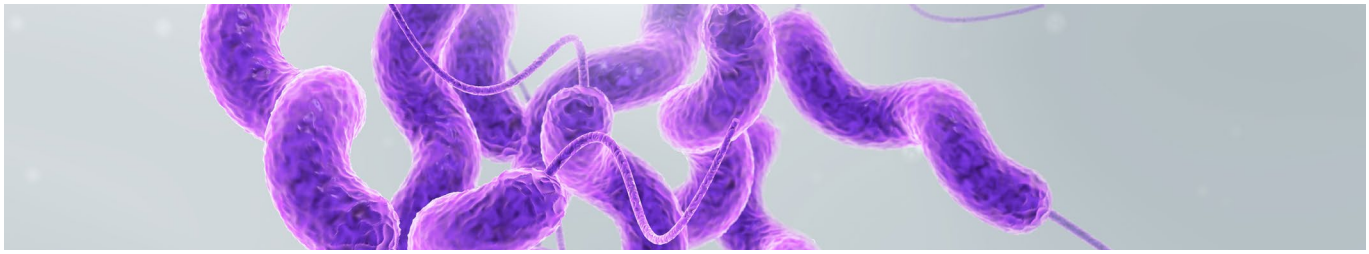
Rapid immunochromatographic immunoassays for qualitative detection of *Escherichia coli* O157 antigens in stool samples.

VIDIA kits

CE IVD

REF	Product	Pathogen / Marker	Incubation	Sample	Number of tests	Format
	RAPID-VIDITEST					
ODZ-028	E. coli	*E. coli*	10 min	stool	20	card

Campylobacter



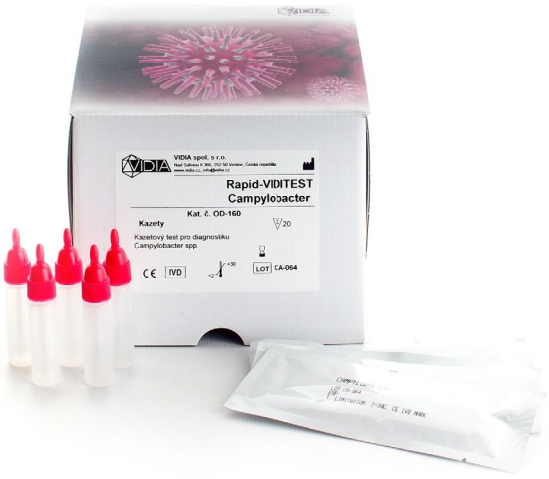
VIDITEST kits are intended to diagnose infectious campylobacteriosis caused by bacteria of the genus *Camplycobacter.* Bacteria cause foodborne illness. It most often occurs in raw meat and poultry, unpasteurized milk and water. Most people who become ill with campylobacteriosis get diarrhoea, cramping, abdominal pain, and fever within two to five days after exposure to the organism. The diarrhoea may be bloody and can be accompanied by nausea and vomiting. The illness typically lasts one week. Some infected persons do not have any symptoms. In persons with compromised immune systems, *Campylobacter* occasionally spreads to the bloodstream and causes a serious life-threatening infection.

RAPID-VIDITEST

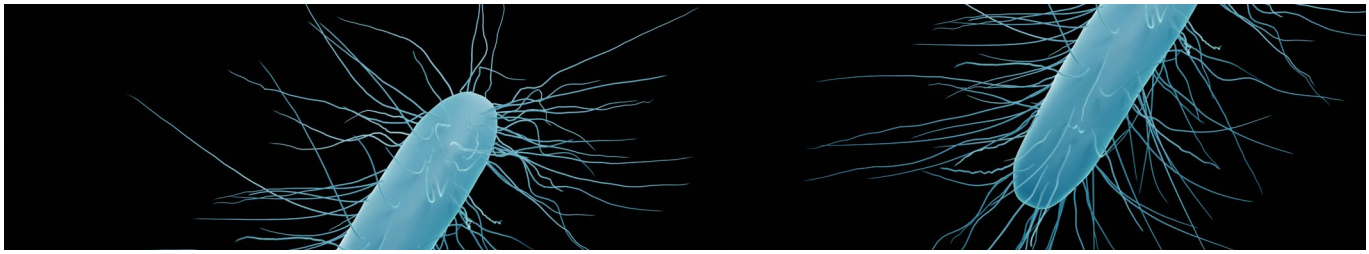
Rapid chromatographic immunoassays for the qualitative detection of *Campylobacter* in feces specimens.

VIDIA kits CE IVD

REF	Product	Pathogen / Marker	Incubation	Sample	Number of tests	Format
	RAPID-VIDITEST					
ODZ-160	Campylobacter	*Campylobacter*	10 min	stool	20	card



Clostridium difficile



VIDITEST kits are intended for early diagnosis of infections caused by bacteria *Clostridium difficile*, **the most serious cause of diarrhea and / or pseudomembranous colitis in hospitalized patients.** *Clostridium difficile* is an anaerobic gram-positive spore-forming bacillus. The key feature in enabling it to persist in patients and the physical environment for long periods and thereby facilitating its transmission, is the ability of *C. difficile* to form spores. Mature colonic bacterial flora in a healthy adult is generally resistant to *C. difficile* colonization. However, if the normal colonic flora is altered, resistance to colonization is lost. Thus, any factor associated with alteration of the normal enteric flora increases the risk of *C. difficile* colonization after exposure to antibiotics, especially those with broad-spectrum activity such as penicillins, cephalosporins and clindamycin. *C. difficile* can release two high-molecular-weight toxins, toxin A and toxin B, which are responsible for the clinical manifestations, which range from mild, self-limited watery diarrhea to fulminant pseudomembranous colitis, toxic megacolon, and death. *C. difficile* Glutamate Dehydrogenase (GDH) is an enzyme produced in large quantities by all toxigenic and non-toxigenic strains, making it an excellent marker for the organism. A positive signal in the GDH strip of RAPID-VIDITEST kit indicates the presence of *C. difficile* in the stool. The following analysis of the sample with the Toxins strip, that detects both toxin A and B from *C. difficile*, confirms if the strain is toxigenic and in consequence pathogenic causing the disease.

RAPID-VIDITEST

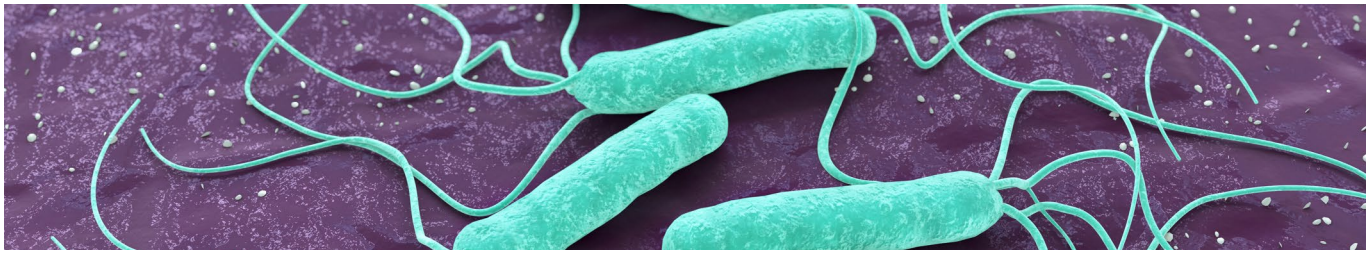
Rapid immunochromatographic immunoassays for qualitative and differential detection of the glutamate dehydrogenase (GDH) and the toxins A and B from *Clostridium difficile* in human faeces.

VIDIA kits

CE IVD

REF	Product	Pathogen / Marker	Incubation	Sample	Number of tests	Format
	RAPID-VIDITEST					
ODZ-330	Clostridium difficile Ag (GDH)	glutamate dehydrogenase *Clostridium difficile*	10 min	stool	20	card
ODZ-332	Clostridium difficile toxin A+B	toxin A and B *Clostridium difficile*	15 min	stool	20	card
ODZ-449	Clostridium difficile GDH-Toxin A+B	glutamate dehydrogenase toxin A and B *Clostridium difficile*	15 min	stool	20	card

Helicobacter pylori



VIDITEST kits are intended for diagnosis of infections caused by bacteria *Helicobacter pylori*. Bacteria is responsible for 80-90% of B-gastritis cases and is suspected to be a major cofactor for the development of gastric and duodenal ulcers. The colonisation of the gastric and duodenal mucous membranes by Helicobacter pylori can also be detected serologically. Patients with confirmed exposition to *H. pylori* often show a positive serological result. Since antibodies persist for a longer time after a infection, seropositive individuals are also found among symptom-free patients. The ratio of seropositive values rises with age. Invasive and non-invasive methods are used to diagnosis *H. pylori* infection in patients with symptoms of gastrointestinal disease.

RAPID-VIDITEST

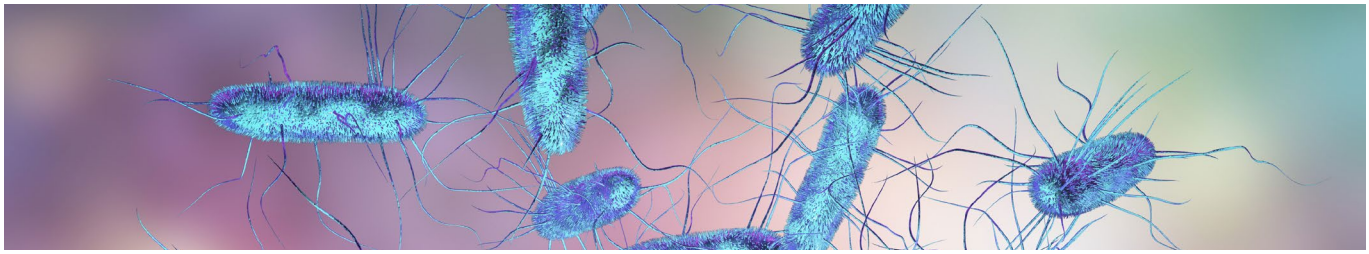
Rapid chromatographic immunoassays for the qualitative detection of *Helicobacter pylori* in feces specimens.

VIDIA kits

CE IVD

REF	Product	Pathogen / Marker	Incubation	Sample	Number of tests	Format
	RAPID-VIDITEST					
ODZ-128	H. pylori	*Helicobacter pylori*	10 min	stool	20	card
ODZ-129	H. pylori	*Helicobacter pylori*	10 min	stool	20	blister

Salmonella



VIDITEST kits are intended to diagnose salmonellosis caused by bacteria of the genus *Salmonella.* Clinical syndromes in humans caused by infection with Salmonella enterica are divided into typhoid fever, caused by *Salmonella* enterica serovars typhi and Salmonella paratyphi, and a range of clinical syndromes, including diarrhoeal disease, caused by the non-typhoid salmonellae (NTS) of which there are around 2,500 serovars. Typhoid fever is a human-restricted and highly adapted invasive systemic disease of adults and children that shows little association with immunosuppression. In contrast, NTS have a broad vertebrate host range and epidemiology that often involves food animals, at least in industrialised countries where it usually presents as gastroenteritis. Severe, invasive disease due to NTS is usually associated with the immunocompromised state common in HIV-infected adults. Invasive NTS disease is also common in young African children with co-morbidities such as severe anaemia, malnutrition and HIV infection.

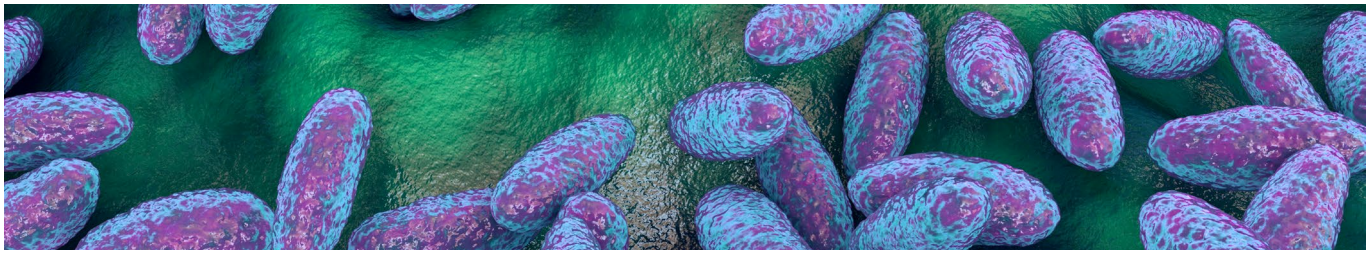
RAPID-VIDITEST

Rapid chromatographic immunoassays for the qualitative detection of *Salmonella* antigen in human feces specimens in order to detect salmonellosis.

VIDIA kits CE IVD

REF	Product	Pathogen / Marker	Incubation	Sample	Number of tests	Format
	RAPID-VIDITEST					
ODZ-174	Salmonella	*Salmonella enteritis* *Salmonella typhimurium* *Salmonella typhi*	10 min	stool	20	card
ODZ-275	Salmonella typhi	*Salmonella typhi*	10 min	stool	20	card

Yersinia enterocolitica



VIDITEST kits are intended to diagnose gastrointestinal yersiniosis caused by bacteria *Yersinia enterocolitida.* The infection presents as an invasive diarrhea characterized by fever, abdominal pain, mucus- and blood-containing stool cultures. The incubation period for intestinal yersiniosis is about 3 to 7 days, and patients shed organisms in feces and remain infectious during the symptomatic period of about 2 to 3 weeks. Convalescent carriage of Yersinia in stool of untreated individuals may uncommonly extend for weeks to months in a small percentage of patients. In addition, intestinal yersiniosis may mimic acute appendicitis. The majority of human pathogenic strains are found in distinct serogroups (e.g. O:3, O:5, O:8 and O:9).

RAPID-VIDITEST

Rapid immunochromatographic immunoassays for qualitative detection of *Yersinia enterocolitida* antigens in human feces specimens .

VIDIA kits

CE IVD

REF	Product	Pathogen / Marker	Incubation	Sample	Number of tests	Format
	RAPID-VIDITEST					
ODZ-258	Yersinia enterocolitica O:3	*Yersinia enterocolitica 0:3*	10 min	stool	20	card
ODZ-260	Yersinia enterocolitica O:9	*Yersinia enterocolitica 0:9*	10 min	stool	20	card

Chlamydia trachomatis

VIDITEST kits are intended for serological diagnosis of acute and chronic infections caused by ***Chlamydia trachomatis*****, such as inflammatory diseases of the urogenital tract, as well as their complications (arthritis, conjunctivitis).** Antibody testing against *Chlamydia trachomatis* contributes to the differential diagnosis of sexually transmitted diseases and eye infections in infants. Primary chlamydial infection is characterized by the predominant IgM response after 2 to 4 weeks from infection and the delayed IgG and IgA response after 6 to 8 weeks. After the acute infection IgM antibodies usually decrease and become undetectable in 2 - 6 months. IgG antibody titres decrease slowly, whereas IgA antibodies tend to disappear rapidly. 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. In reinfections, IgG and IgA levels rise quickly. IgA antibodies have shown to be a reliable immunological marker of primary, chronic and recurrent infections. These antibodies usually decline rapidly to baseline levels following treatment and eradication of the chlamydia infection, however may persist for several months. The persistence of the elevated antibody titres is generally considered as the sign of chronic infection.

ELISA-VIDITEST

Immunoenzymatic kits for the detection of specific IgA and IgG antibodies against *Chlamydia trachomatis.*

VIDIA kits

CE 1023 IVD

REF	Product	Evaluation	Incubation	Sample	Number of tests	VIDIMAT
	ELISA-VIDITEST					
ODZ-464	anti-Chlamydia trachomatis IgG	semiquant.	30´/30´/15´	serum, plasma	96	✔
ODZ-465	anti-Chlamydia trachomatis IgA	semiquant.	30´/30´/15´	serum, plasma	96	✔

MONO-VIDITEST

Immunoenzymatic kits in cartridge format for the detection of specific IgA and IgG antibodies against *Chlamydia trachomatis.*

VIDIA kits

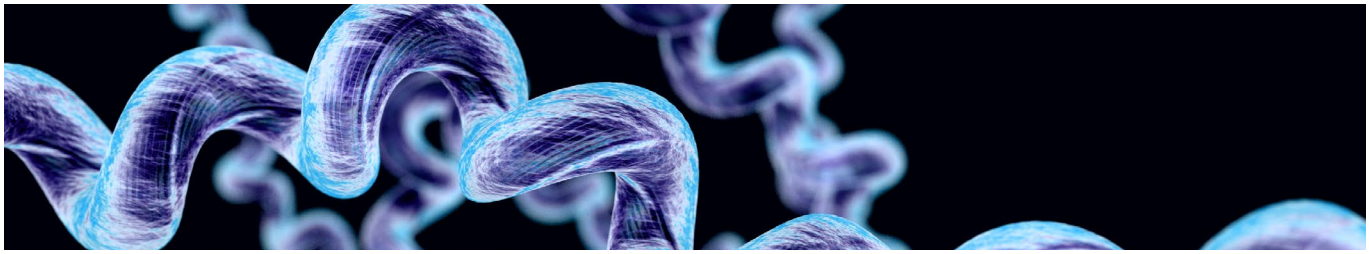
CE 1023 IVD

REF	Product	Evaluation	Incubation	Sample	Number of tests	VIDIMAT
	MONO-VIDITEST					
KZ-220-12	anti-Chlamydia trachomatis IgG	semiquant.	30´/30´/15´	serum, plasma	12	✔
KZ-222-12	anti-Chlamydia trachomatis IgA	semiquant.	30´/30´/15´	serum, plasma	12	✔

Benefits of kits for Chlamydia trachomatis

- Semiquantitative evaluation of IgA and IgG antibodies
- High sensitivity and specificity
- Color-coded reagents r.t.u.
- Unified gray zone
- Unified incubation times, temperatures, reagents for all ELISA-VIDITEST and MONO-VIDITEST
- Manual or automatic processing of the test in our analyzer VIDIMAT

Borrelia



VIDITEST kits are intended for the serological diagnosis of Lyme disease (LD) induced by human pathogenic strains of borrelia (*B. afzelii, B. garinii , B. burgdorferi sensu stricto, B. spielmanii*). The diagnosis of LD is based on the combination of clinical examination and laboratory testing. 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

Immunoenzymatic kits for the detection of specific IgG and IgM antibodies against main pathogenic borrelia strains and determination of intrathecal antibody synthesis.

VIDIA kits

CE IVD

REF	Product	Evaluation	Incubation	Sample	Number of tests	VIDIMAT
	ELISA-VIDITEST					
ODZ-398	anti-Borrelia recomb. IgG + VlsE (CSF)	semiquant., quant.	30´/30´/15´	serum, plasma, synovial fluid, cerebrospinal fluid	96	✔
ODZ-398/5ST	anti-Borrelia recomb. IgG + VlsE (CSF)	semiquant., 5 ST quant.	30´/30´/15´	serum, plasma, synovial fluid, cerebrospinal fluid	96	-
ODZ-399	anti-Borrelia recomb. IgM (CSF)	semiquant., quant.	30´/30´/15´	serum, plasma, synovial fluid, cerebrospinal fluid	96	✔
ODZ-399/5ST	anti-Borrelia recomb. IgM (CSF)	semiquant., 5 ST quant.	30´/30´/15´	serum, plasma, synovial fluid, cerebrospinal fluid	96	-

MONO-VIDITEST

Immunoenzymatic kits in cartridge format for the detection of specific IgG and IgM antibodies against main pathogenic borrelia strains and determination of intrathecal antibody synthesis.

VIDIA kits

CE IVD

REF	Product	Evaluation	Incubation	Sample	Number of tests	VIDIMAT
	MONO-VIDITEST					
KZ-300-12	anti-Borrelia recomb. IgG + VlsE	semiquant., quant.	30´/30´/15´	serum, cerebrospinal fluid, synovial fluid	12	✔
KZ-301-12	anti-Borrelia recomb. IgM	quant.	30´/30´/15´	serum, cerebrospinal fluid, synovial fluid	12	✔

LIA-VIDITEST

LIA-VIDITEST kits for the detection of specific IgG and IgM antibodies against main pathogenic borrelia strains (*B. afzelii, B. garinii, B. burgdorferi sensu stricto a B. spielmanii*) and *Anaplasma phagocytophila*. 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).

VIDIA kits

CE IVD

REF	Product	Evaluation	Incubation	Sample	Number of tests
	LIA-VIDITEST				
ODZ-316	anti-Borrelia IgG	qualit.	15´/30´/30´/10´	serum, plasma, cerebrospinal fluid, synovial fluid	16
ODZ-317	anti-Borrelia IgM	qualit.	15´/30´/30´/10´	serum, plasma, cerebrospinal fluid, synovial fluid	16
ODZ-317SP	anti-Borrelia IgM sp (+ spielmanii)	qualit.	15´/30´/30´/10´	serum, plasma, cerebrospinal fluid, synovial fluid	16

LIA-VIDITEST

LIA-VIDITEST test kit for detection of specific IgG and IgM antibodies against antigens of Borrelia afzelii, garinii a burgdorferi sensu stricto.

VIDIA kits

CE IVD

REF	Product	Evaluation	Incubation	Sample	Number of tests
	LIA-VIDITEST				
ODZ-490	anti-Borrelia IgG afzelii	qualit.	15´/30´/30´/10´	serum, plasma, cerebrospinal fluid, synovial fluid	16
ODZ-491	anti-Borrelia IgM afzelii	qualit.	15´/30´/30´/10´	serum, plasma, cerebrospinal fluid, synovial fluid	16
ODZ-492	anti-Borrelia IgG garinii	qualit.	15´/30´/30´/10´	serum, plasma, cerebrospinal fluid, synovial fluid	16
ODZ-493	anti-Borrelia IgM garinii	qualit.	15´/30´/30´/10´	serum, plasma, cerebrospinal fluid, synovial fluid	16
ODZ-494	anti-Borrelia IgG burgdorferi sensu stricto	qualit.	15´/30´/30´/10´	serum, plasma, cerebrospinal fluid, synovial fluid	16
ODZ-495	anti-Borrelia IgM burgdorferi sensu stricto	qualit.	15´/30´/30´/10´	serum, plasma, cerebrospinal fluid, synovial fluid	16

LIA-VIDITEST

LIA-VIDITEST test kit for detection of specific IgG and IgM antibodies against antigens of Borrelia afzelii, garinii a burgdorferi sensu stricto and tick-borne encephalitis virus. The test allows simultaneous detection of two infectious agents important in the diagnosis of serous neuroinfections. Due to the selection of the antigen group also containing highly specific and sensitive recombinant antigens, the test can be used in both stages of serological diagnosis, at first stage for baseline screening, in the second as a confirmation test.

VIDIA kits

CE IVD

REF	Product	Evaluation	Incubation	Sample	Number of tests
	LIA-VIDITEST				
ODZ-396	Multiplex Borrelia and TBEV IgG	qualit.	15´/30´/30´/10´	serum, plasma, cerebrospinal fluid, synovial fluid	16
ODZ-397	Multiplex Borrelia and TBEV IgM	qualit.	15´/30´/30´/10´	serum, plasma, cerebrospinal fluid, synovial fluid	16

Benefits of the Borrelia kits

- Quantitative and semiquantitative evaluation of IgG and IgM antibodies
- One kit for all sample types: human serum, plasma cerebrospinal fluid, synovial fluid
- Quantification using 5 standards or 1 standard
- Recombinant antigens of pathogenic borrelia strains
- Calculation of intrathecal antibodies synthesis using E-calculator
- Unified incubation times, temperatures, reagents for all ELISA-VIDITEST and MONO-VIDITEST
- Manual or automatic test evaluation by analyzers VIDIMAT
- Confirmatory evaluation by LIA-VIDITEST for the test results from ELISA-VIDITEST and MONO-VIDITEST
- Multiplex kits for both Lyme disease (LD) and TBE diagnostics
- Evaluation of the results with our VidiScan2 software
- Validated for automatic or semi-automatic RoboBlot, BeeBlot, B20 analyzers

CXCL13

VIDITEST kits are intended for the serological diagnosis of Lyme neuroborreliosis (LNB) caused by an infection with *Borrelia burgdorferi sensu lato* due to a tick bite. **CXCL13 is a key modulator of CNS inflammation. It appears to be of important clinical importance for the diagnosis and monitoring of LNB and other neuroinfections. CXCL13 is expressed at high levels in the** cerebrospinal fluid **(CSF) of patients with early-stage LNB.** Chemokine ligand 13, also known as B-cell attracting chemokine 1 (BAC-1) or B lymphocyte chemoattractant (BAC), is a member of the CXC chemokine family encoded by the CXCL13 gene located on chromosome 4 (4q21). CXCL13 in humans is mostly produced by dendritic cells, monocytes, and mature macrophages. The chemokine plays an important role in inflammation, infections, and immune response. After binding to the G-protein receptor CXCR5 on neutrophils and mast cells, CXCL13 elicits chemotaxis and migration of B lymphocytes from lymphoid tissues to the site of inflammation. Importantly, it has been suggested that CXCL13 is involved in neurological damage through promoting B cell migration to the CSF and activating them, subsequently leading to CSF pleocytosis with characteristic B cell elevation.

ELISA-VIDITEST

Immunoenzymatic kits for the quantitative detection of CXCL13 chemokine in human cerebrospinal fluid.

VIDIA kits CE IVD

REF	Product	Pathogen Marker	Evaluation	Incubation	Sample	Number of tests	VIDIMAT	
	ELISA-VIDITEST							
ODZ-510	CXCL13	Chemokine ligand 13	quant.	60´/60´/60´/15´	cerebrospinal fluid	96	✔	NEW

MONO-VIDITEST

Immunoenzymatic kits in cartridge format for the quantitative detection of CXCL13 chemokine in human cerebrospinal fluid.

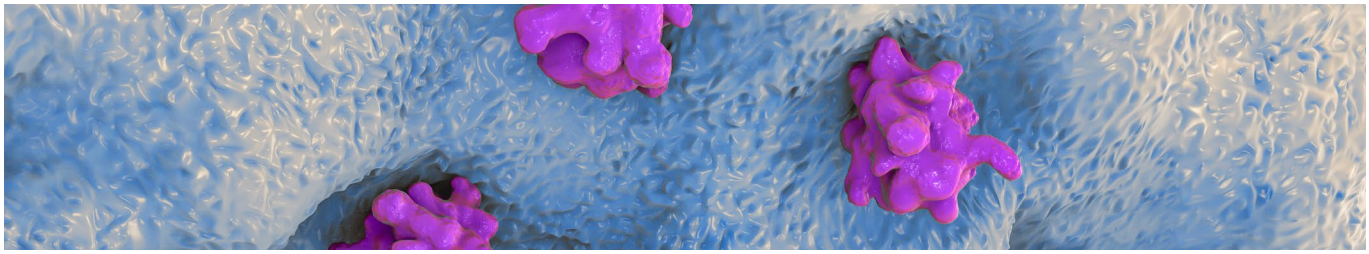
VIDIA kits CE IVD

REF	Product	Pathogen Marker	Evaluation	Incubation	Sample	Number of tests	VIDIMAT	
	MONO-VIDITEST							
KZ- 634-12	CXCL13	Chemokine ligand 13	quant.	60´/60´/60´/15´	cerebrospinal fluid	12	✔	NEW

PARASITOLOGY

GASTROINTESTINAL INFECTIONS PARASITES
PRENATAL AND CONGENITAL INFECTIONS PARASITES

Entamoeba



VIDITEST kits are intended for diagnosis of infectious amoebiasis and dysentery caused by parasitic protozoa of the genus Entamoeba. Amoebiasis is the infection of the human gastrointestinal tract. It is estimated to cause 50 000 - 100 000 deaths each year. The disease can manifest itself as an acute, chronic or asymptomatic infection. *Entamoeba histolytica* is pathogenic, causing all invasive diseases. It attacks the intestinal mucosa and thus spreads to other organs, especially the liver. *Entamoeba dispar*, a morphologically identical parasite, is non-pathogenic. Different techniques are required to detect specific antigens of each species in order to determine the exact diagnosis and prevent unnecessary or inappropriate chemotherapy.

RAPID-VIDITEST

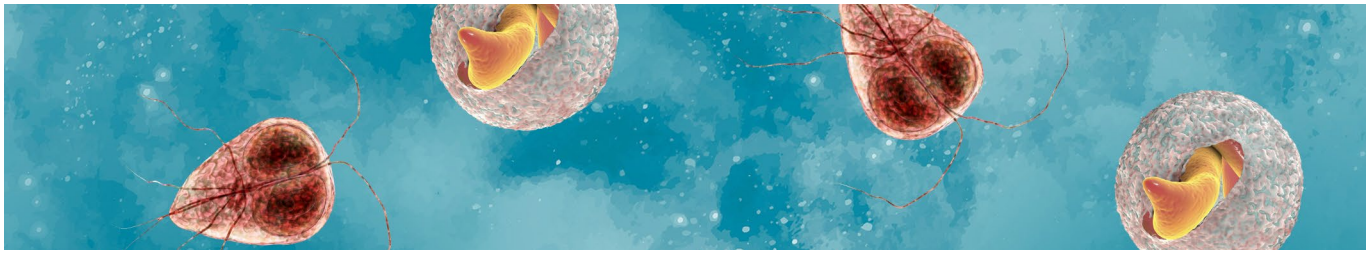
Rapid chromatographic immunoassays for the qualitative detection of *Entamoeba histolytica* and *Entamoeba dispar* antigens and for differential detection of parasite antigens *Cryptosporidia parvum, Giardia lamblia, Entamoeba histolytica* a *Entamoeba dispar* in human fecal specimens.

VIDIA kits

CE IVD

REF	Product	Pathogen / Marker	Incubation	Sample	Number of tests	Format
	RAPID-VIDITEST					
ODZ-223	Entamoeba	*Entamoeba histolytica, Entamoeba dispar*	10 min	stool	20	card
ODZ-451	Crypto-Giardia-Entamoeba	*Cryptosporidium parvum* *Giardia lamblia* *Entamoeba histolytica, Entamoeba dispar*	10 min	stool	20	card

Cryptosporidium parvum, Giardia lamblia



VIDITESTS kits are intended for some infectious of diarrheal cryptosporidiosis caused by the parasite *Cryptosporidium parvum* **and for parasites of diarrheal parasitosis caused by the flagellate protozoan** *Giardia lamblia.* Cryptosporidiosis is a protozoal acute short-term infection that can be severe in untreated children and in immunocompromised individuals, such as AIDS patients. It can also be asymptomatic. In tropical developing countries, the parasite is often endemic and has an epidemic of diarrhea in children. In immunocompetent patients, the disease manifests as self-medicated gastroenteritis. The incubation period is usually 2-10 days. The parasite colonizes the intestine and passes through the stool. Giardiasis is a common protozoal gastrointestinal infection lasting 2-6 weeks. It can also be asymptomatic. *Giardia lamblia* has become an important cause of chronic diarrhea, especially when it comes to travel medicine. In developing countries, where there is a shortage of clean water and a lack of basic hygiene measures, there are many more patients and carriers. The incidence of Giardia in young children in these areas can be up to 10-30%.

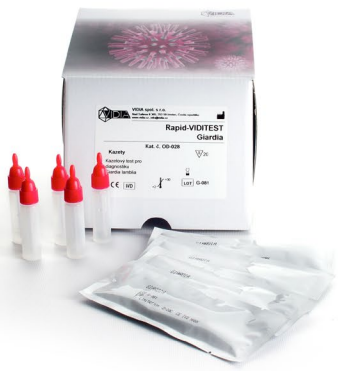
RAPID-VIDITEST

Rapid chromatographic immunoassays for the qualitative and differential detection of *Cryptosporidium parvum, Giardia lamblia* and *Entamoeba histolytica* antigens in human stool samples.

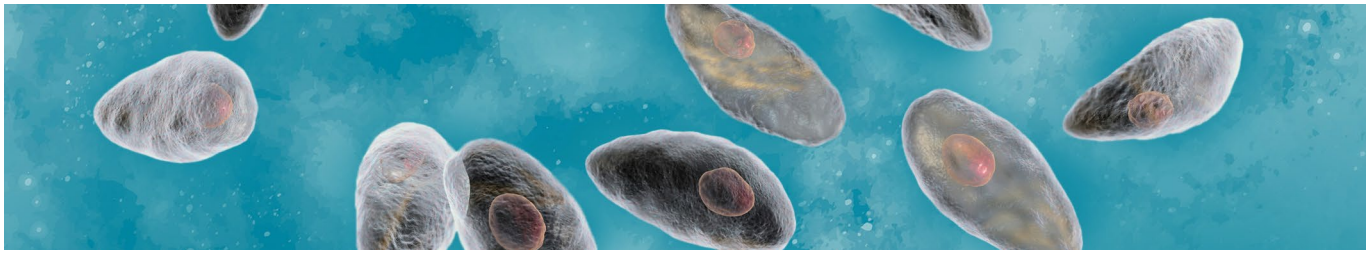
VIDIA kits

CE IVD

REF	Product	Pathogen / Marker	Incubation	Sample	Number of tests	Format
	RAPID-VIDITEST					
ODZ-016	Giardia	*Giardia lamblia*	10 min	stool	20	card
ODZ-257	Giardia	*Giardia lamblia*	10 min	stool	20	blister
ODZ-278	Crypto	*Cryptosporidium parvum*	10 min	stool	20	card
ODZ-055	Crypto-Giardia	*Cryptosporidium parvum* *Giardia lamblia*	10 min	stool	20	card
ODZ-255	Crypto-Giardia	*Cryptosporidium parvum* *Giardia lamblia*	10 min	stool	20	blister
ODZ-451	Crypto-Giardia-Entamoeba	*Cryptosporidium parvum* *Giardia lamblia* *Entamoeba histolytica,* *Entamoeba dispar*	10 min	stool	20	card



Toxoplasma gondii



VIDITEST kits are intended for the serological diagnosis of toxoplasmosis caused by *Toxoplasma gondii* **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

Immunoenzymatic kits for the detection of specific IgA, IgG and IgM antibodies against *Toxoplasma gondii* in serum and plasma and for avidity evaluation.

VIDIA kits

CE 1023 IVD

REF	Product	Evaluation	Incubation	Sample	Number of tests	VIDIMAT
	ELISA-VIDITEST					
ODZ-481	anti-Toxoplasma gondii IgG	semiquant.	30´/30´/15´	serum, plasma	96	✔
ODZ-482	anti-Toxoplasma gondii IgG and avidity IgG	semiquant.	30´/15´/30´/15´	serum, plasma	96	✔
ODZ-483	anti-Toxoplasma gondii IgM	semiquant.	30´/30´/15´	serum, plasma	96	✔
ODZ-480	anti-Toxoplasma gondii IgA	semiquant.	30´/30´/15´	serum, plasma	96	✔

MONO-VIDITEST

Immunoenzymatic kits for the detection of specific IgA, IgG and IgM antibodies against *Toxoplasma gondii* in serum and plasma and for avidity evaluation.

VIDIA kits

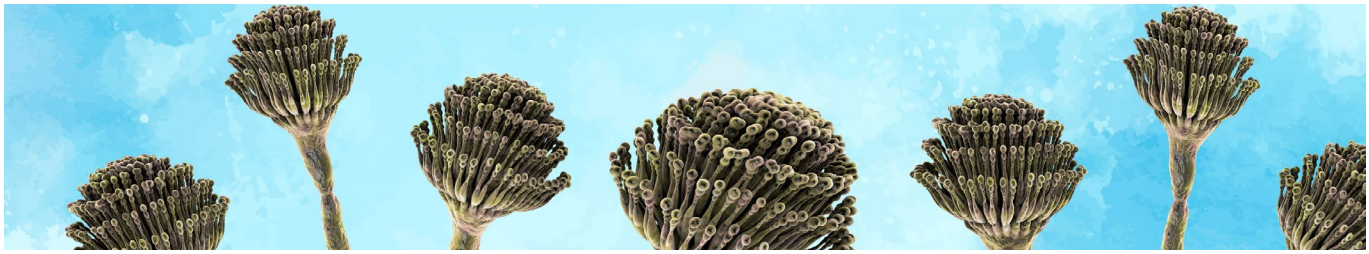
CE 1023 IVD

REF	Product	Evaluation	Incubation	Sample	Number of tests	VIDIMAT
	MONO-VIDITEST					
KZ-210-12	anti-Toxoplasma gondii IgG	semiquant.	30´/30´/15´	serum, plasma	12	✔
KZ-213-12	anti-Toxoplasma gondii IgG avidity	semiquant.	30´/15´/30´/15´	serum, plasma	12	✔
KZ-211-12	anti-Toxoplasma gondii IgM	semiquant.	30´/30´/15´	serum, plasma	12	✔
KZ-212-12	anti-Toxoplasma gondii IgA	semiquant.	30´/30´/15´	serum, plasma	12	✔

MYCOLOGY

FUNGI OF RESPIRATORY INFECTIONS

Aspergillus fumigatus



VIDITEST kits are intended for the serological diagnosis of fungal infections and other diseases caused by *Aspergillus fumigatus. A. fumigatus* is the most common cause of invasive fungal infection in immunosuppressed individuals, including patients receiving immunosuppressive therapy for autoimmune or neoplastic disease, organ transplant recipients, and patients with AIDS. *A. fumigatus* primarily causes invasive infection in the lungs and is a major cause of morbidity and mortality in these individuals. In addition, A. fumigatus can cause chronic lung infections, allergic bronchopulmonary aspergillosis, or allergic disease in immunocompetent hosts.

ELISA-VIDITEST

Immunoenzymatic kits for the detection of specific IgA, IgG and IgM antibodies against Aspergillus fumigatus in serum or plasma.

VIDIA kits

CE IVD

REF	Product	Evaluation	Incubation	Sample	Number of tests	VIDIMAT	
	ELISA-VIDITEST						
ODZ-512	anti-Aspergillus fumigatus IgG	semiquant., quant.	30´/30´/15´	serum, plasma	96	✔	NEW
ODZ-513	anti-Aspergillus fumigatus IgM	semiquant., quant.	30´/30´/15´	serum, plasma	96	✔	NEW
ODZ-514	anti-Aspergillus fumigatus IgA	semiquant., quant.	30´/30´/15´	serum, plasma	96	✔	NEW

MONO-VIDITEST

Immunoenzymatic kits in cartridge format for the detection of specific IgA, IgG and IgM antibodies against *Aspergillus fumigatus* in serum or plasma.

VIDIA kits

CE IVD

REF	Product	Evaluation	Incubation	Sample	Number of tests	VIDIMAT	
	MONO-VIDITEST						
KZ-700-12	anti-Aspergillus fumigatus IgG	semiquant., quant.	30´/30´/15´	serum, plasma	12	✔	NEW
KZ-701-12	anti-Aspergillus fumigatus IgM	semiquant., quant.	30´/30´/15´	serum, plasma	12	✔	NEW
KZ-702-12	anti-Aspergillus fumigatus IgA	semiquant., quant.	30´/30´/15´	serum, plasma	12	✔	NEW

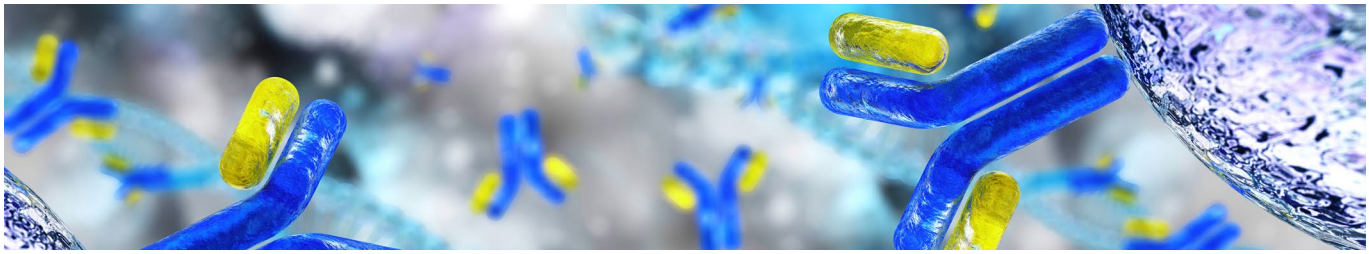

ELISA-VIDITEST
anti-Aspergillus fumigatus IgG


MONO-VIDITEST
anti-Aspergillus fumigatus IgG
IVD
LOT 010522/42

SPECIALIZATIONS AND RESEARCH

AUTOIMMUNITY
CYTOKINES
CYTOSKELETON
INFLAMMATORY AND TUMOR MARKERS

Complement factor H



VIDITEST kits are intended for serological diagnosis of atypical hemolytic-uremic syndrome (AI-HUS). Factor H is a complement regulatory glycoprotein that is found in human plasma in concentrations about 500 μg/mL. Its main function is the regulation of complement activation. Inhibitory autoantibodies against complement factor H resulting from an immunopathological reaction, dysregulate complement system. Such autoimmune dysregulation of complement is associated with a specific form of atypical haemolytic uremic syndrome (AI-HUS). It is recommended testing anti-complement factor H autoantibodies in all cases of HUS at the onset of the disease. Approximately 30% of AI-HUS patients had diarrhoea as prodromal syndromes, which in turn are the typical sign in the classic form of HUS which is caused by Shigga toxin positive species of *E. coli*. Removal of anti-factor H antibodies from the bloodstream by plasmapheresis or the use of immune suppressive drugs to eliminate the antibody production is beneficial for the outcome of the disease.

ELISA-VIDITEST

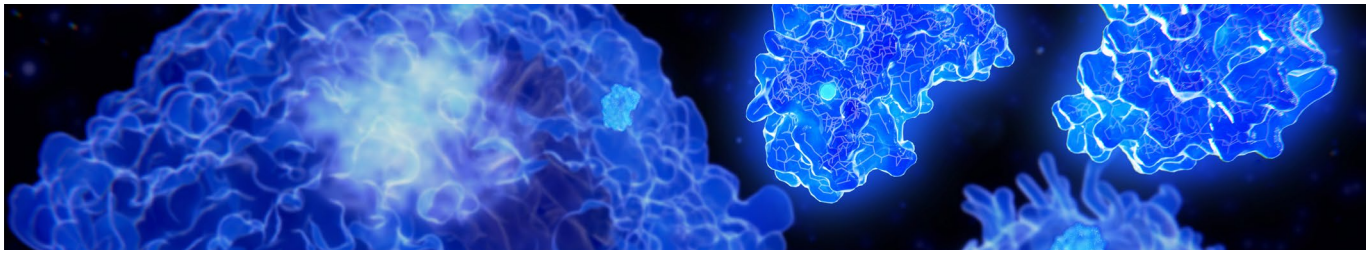
Immunoenzymatic kits for the quantitative detection of IgG antibodies against human complement factor H in human serum and plasma.

VIDIA kits

CE IVD

REF	Product	Evaluation	Incubation	Sample	Number of tests	VIDIMAT
ODZ-166	anti-complement factor H	quant.	60´/60´/20´	serum, plasma	48	-

Interferon γ (IFNγ), Interleukin 2 (IL-2)



VIDITEST kits are intended to demonstrate total or specific cellular immunity. 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

Immunoenzymatic kits for detection of the concentration of Interferon γ in the culture medium of lymphocytes stimulated with antigen or mitogen *in vitro*. **Kits are intended only for research purposes**.

VIDIA kits

RUO

REF	Product	Evaluation	Incubation	Number of tests	VIDIMAT
ODZ-326	Interferon γ	quant.	120´/30´/10´	96	-

Immunoenzymatic kits for detection of the concentration of Interleukin 2 in the test sample. **Kits are intended only for research purposes.**

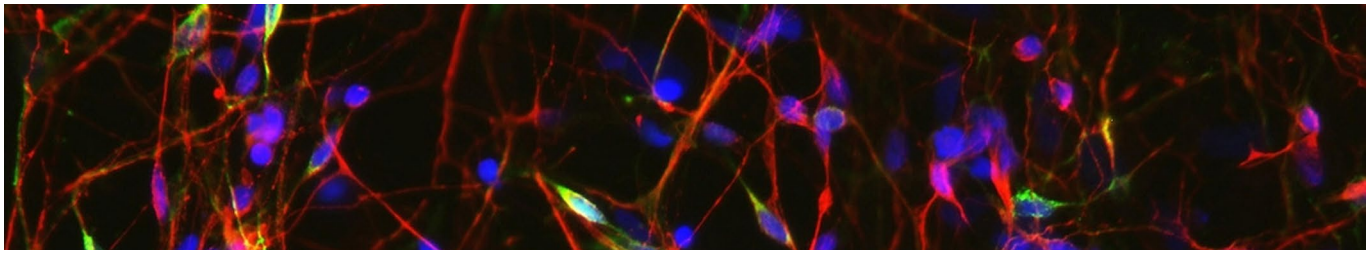
VIDIA kits

RUO

REF	Product	Evaluation	Incubation	Number of tests	VIDIMAT
ODZ-361	IL-2	quant.	120´/30´/10´	96	-

The kits were developed as part of the TA-03010331 project with the financial support of the Technology Agency of the Academy of Sciences of the Czech Republic.

Neurofilament pNF-H, Vimentin



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, light (NF-L), medium (NF-M) and heavy (NF-H) neurofilament. 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. Phosphorylated heavy neurofilaments were detected in higher concentrations in diseases that involve central nervous system damage.

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 in patients with graft rejections of transplanted organs and in patients with interstitial lung fibrosis.

ELISA-VIDITEST

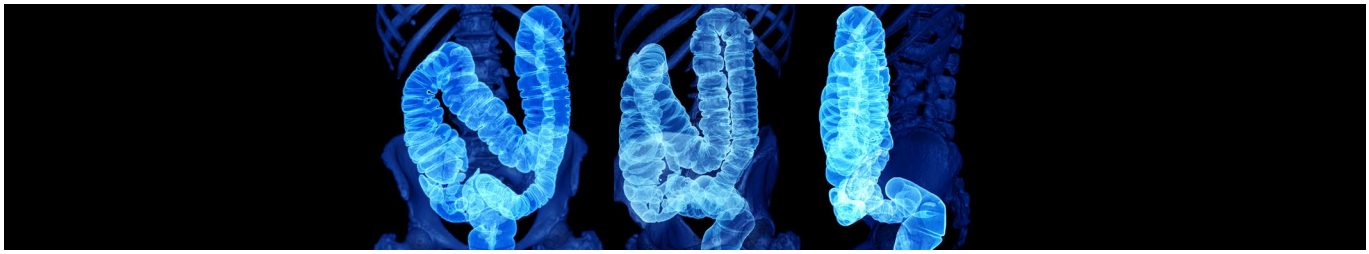
Immunoenzymatic kits for detection of the concentration of phosphorylated forms of heavy neurofilaments (pNF-H) in peripheral blood and cerebrospinal fluid and for the detection of IgG antibodies to the intermediate filament protein vimentin in human serum.

VIDIA kits

CE IVD

REF	Product	Evaluation	Incubation	Sample	Number of tests	VIDIMAT
	ELISA-VIDITEST					
ODZ-403	anti-Vimentin IgG	semiquant.	30´/30´/10´	serum	96	-
ODZ-437	pNF-H	quant.	120´/60´/60´/20´	serum, plasma, cerebrospinal fluid	96	-

Calprotectin, FOB, Lactoferrin, Transferrin



VIDITEST kits are intended for the diagnosis of inflammatory gastrointestinal disorders and colorectal tumors. Calprotectin is a calcium-containing protein of neutrophil with bacteriostatic and fungistatic properties. Lactoferrin (Lf) is a glycoprotein that is produced by neutrophils, mononuclear phagocytes and epithelial cells and is contained in the secretory fluids such as saliva and breast milk. Its function is to block bacterial growth by limiting the availability of iron and this effect is enhanced by the presence of specific secretory IgA antibodies directed against bacteria. When inflammation develops in the gastrointestinal tract, neutrophils and phagocytic cells migrate to the inflammatory focus and release the granules containing Lf. The determination of these biomarkers in faeces is a suitable indicator in the diagnosis of Inflammatory bowel disease (IBD), including Crohn disease and ulcerative colitis. Human haemoglobin (hHb) and human transferrin (hTf) in human feces specimens might be indicators of colorectal cancer, gastric cancer or peptic ulcers. Detection of fecal transferrin, which is more stable in stool than haemoglobin, provides an alternative way of diagnosing the disease in the upper digestive tract.

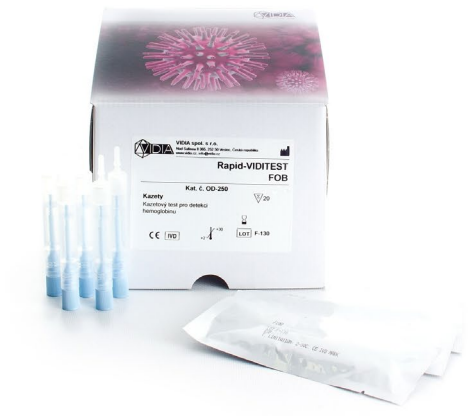
RAPID-VIDITEST

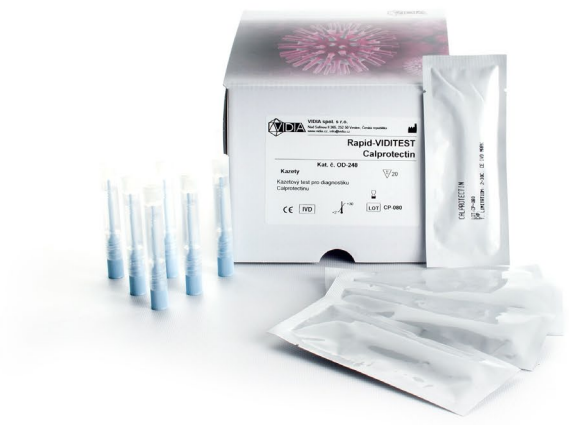
Rapid chromatographic immunoassays for the qualitative detection of inflammatory and tumor markers – calprotectin, hemoglobin (FOB), lactoferrin, transferrin in human feces specimens.

VIDIA kits

CE IVD

REF	Product	Pathogen / Marker	Incubation	Sample	Number of tests	Format
	RAPID-VIDITEST					
ODZ-085	Lactoferrin	Lactoferrin	10 min	stool	20	card
ODZ-248	Calprotectin	Calprotectin	10 min	stool	20	card
ODZ-250	FOB	FOB	10 min	stool	20	card
ODZ-270	Calprotectin - Lactoferrin	Calprotectin Lactoferrin	10 min	stool	20	card
ODZ-101	FOB+Tf	FOB Transferrin	10 min	stool	20	card





ENVIRONMENTAL TOXICOLOGY

TOXIC SUBSTANCES

Bisfenol A

VIDITEST kits are intended for monitoring the state of environmental pollution by plastic. Bisphenol A (BPA) is well known toxicant whose estrogenic activity has been known for a long time. BPA can be released from polycarbonate bottles. 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. The measuring range of the test is from 0.01 mg/ml to 1 mg/ml (**detection limit is 10 ng /ml**).

ELISA-VIDITEST

Immunoenzymatic kits for detection of bisphenol A (BPA) in environmental samples.

VIDIA kits

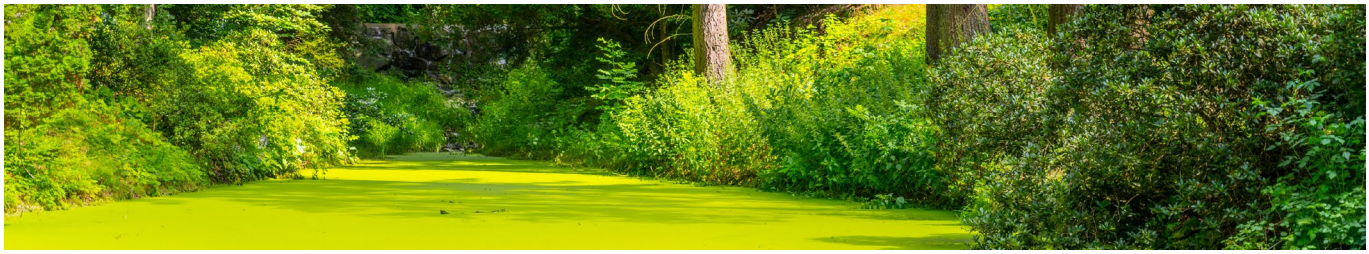
CE IVD

REF	Product	Evaluation	Incubation	Sample	Number of tests	VIDIMAT
	ELISA-VIDITEST					
ODZ-041	Bisphenol A	quant.	60´/60´/10´	water, soil	96	-

Benefits of kits Bisphenol A

- Possible new screening method
- Detection limit 10 ng /ml
- Pollution monitoring without the need for demanding instrumental methods (HPLC)
- Incubations at laboratory temperature
- Many tested samples in one test run
- Color-coded reagents in r.t.u.

Mikrocystin-LR



VIDITEST kits are intended for the detection of Microcystin-LR in water samples. 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. Microcystin-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

Immunoenzymatic kits for detection of Microcystin-LR in water samples.

VIDIA kits

REF	Product	Evaluation	Incubation	Sample	Number of tests	VIDIMAT
	ELISA-VIDITEST					
ODZ-165	Microcystin-LR	quant.	45´/15´/20´	water	96	-

Benefits of kits Mikrocystin-LR

- Possible new screening method
- High sensitivity
- Detection limit 100 ng/l
- Easy sample pretreatment – only filtration is recommended
- Color-coded reagents in r.t.u.

EDUCATION

DIDACTIC KITS

Demonstration of ELISA metod

VIDITEST kits provide a safe demonstration of ELISA for educational purposes. The kit is designed for school laboratory classes: simple, cheap and with non-hazardous, non-infectious components. Plastic droppers are included for suitable reagent handling. The kit contain three unknown samples. By comparison of these samples with a standard calibration curve the content of specific antibodies is determined and the positivity/negativity of the samples is defined. Results can be evaluated without any special laboratory equipment (reader/spectrophotometer). The kit contain a detailed and straightforward user guide with troubleshooting section. ELISA-VIDITEST EDUCO Diagnostic is ELISA kit for school use, intended for 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

The kit for school use to illustrate the principle of ELISA for the determination of specific antibodies.

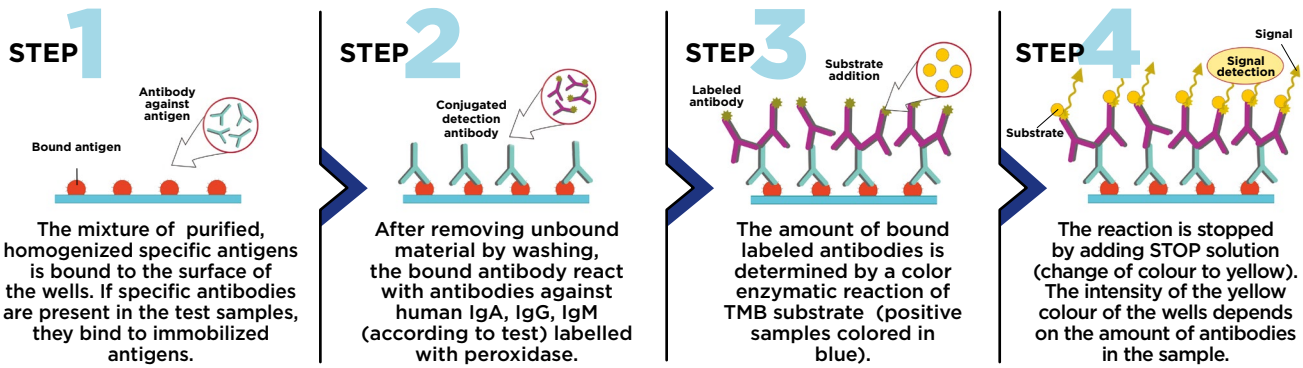
VIDIA kits

CE IVD

REF	Product	Evaluation	Incubation	Sample	Formát	VIDIMAT
ODZ-191	EDUCO Diagnostic	quant.	15´/15´/10´		6 doublestrips	-

Benefits of kits for education

- ELISA kits as tools to enhance laboratory lessons in schools
- Practical demonstration of ELISA method
- Testing at room temperature, without any special equipment
- No hazardous substances
- No infectious material
- One set divisible into several working groups
- Simple procedure


STEP 1
Antibody against antigen
Bound antigen
The mixture of purified, homogenized specific antigens is bound to the surface of the wells. If specific antibodies are present in the test samples, they bind to immobilized antigens.
STEP 2
Conjugated detection antibody
After removing unbound material by washing, the bound antibody react with antibodies against human IgA, IgG, IgM (according to test) labelled with peroxidase.
STEP 3
Substrate addition
Labeled antibody
The amount of bound labeled antibodies is determined by a color enzymatic reaction of TMB substrate (positive samples colored in blue).
STEP 4
Signal
Signal detection
Substrate
The reaction is stopped by adding STOP solution (change of colour to yellow). The intensity of the yellow colour of the wells depends on the amount of antibodies in the sample.

AUTOMATION

AUTOMATIC ELISA ANALYZER
ANALYTICAL AND INTERPRETATION SOFTWARE

VIDIMAT

VIDIMAT® is a fully automatic desktop analyzer, designed for multiparametric processing of enzymatic immunoassays without the need for disposable tips.

It provides complete compatibility of all offered types of immunoenzymatic kits. It offers processing of our VIDITEST kits in the format of 96 microtiter plates with flexible division ELISA-VIDITEST. It works also in the format of unique single-strip cassettes for individual tests MONO-VIDITEST, uniquely designed for the VIDIMAT® system. Each cassette contains all necessary r.t.u. reagents.

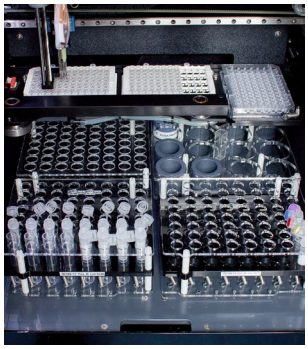
The VIDIMAT® analyzer is able to process ELISA-VIDITEST and MONO-VIDITEST kits simultaneously. It supports fully automatic processes from dilution and pipeting of samples and reagents through incubation, shaking, washing, photometric measurement and test evaluation to final printable protocols.

Operation of the device and SW STORM ® software is very user friendly. The analyzer includes a small netbook on a raised surface, which allows you to use the space around the device very efficiently. The samples are placed in the drawer in the analyzer and the position of the sample is automatically detected by placing the tube. The sample can be identified manually or by scanning a barcode.

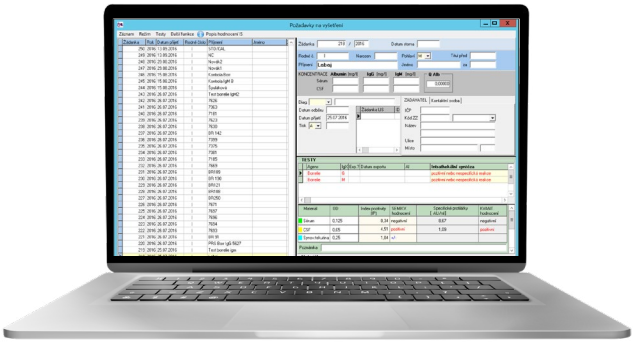
Benefits of the VIDIMAT analyzer

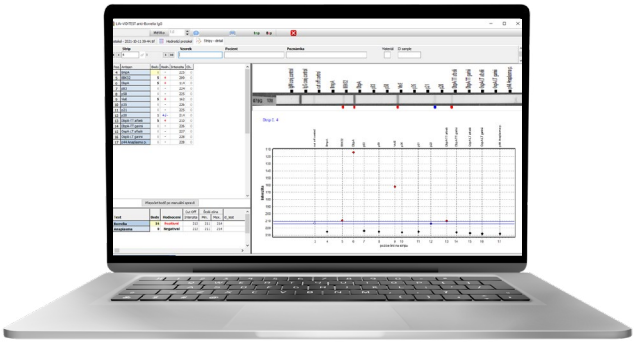
- Fully automatic, robust, desktop analyzer
- Parallel testing of ELISA-VIDITEST and MONO-VIDITEST kits
- 192 positions for tested samples + pre-dilution plate
- Precision pipette system
- Real-time monitoring
- Uniform heating
- Integrated barcode reader
- LIS connection
- No need to use disposable tips
- Automatic evaluation allows all types of analyzes
- Incubation: 30 min/30 min/15 min
- Total working hours 105 min

VIDIMAT is uniquely quiet and, thanks to its compact desktop design, is suitable for all types of clinical and research laboratories.



VIDISOFT2, VIDISCAN2, E-CALCULATOR



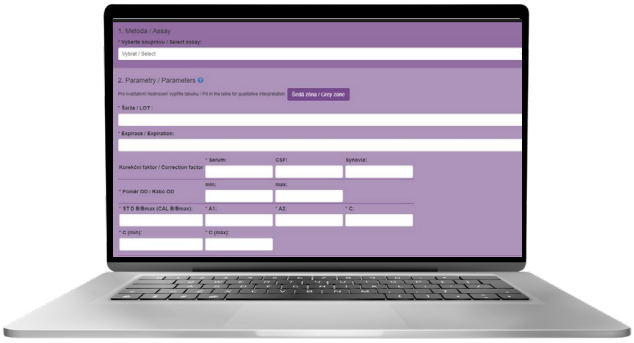


VIDISOFT2 software

- Complex solution for the evaluation of ELISA tests
- Calculation of specific antibodies and determination of quantitative evaluation
- Calculation of positivity index (IP) and determination of semi-quantitative evaluation
- Antibody index calculation
- Automatic calculation of intrathecal antibody synthesis
- Two-way communication with LIS
- Patient database
- Evidence of requests
- Record all amendments
- Creation of a working protocol and communication file for the VIDIMAT analyzer
- Automatic receipt of measured data (OD) from VIDIMAT
- Flexible to user needs

VIDISCAN2 software

- Automatic evaluation of LIA-VIDITEST test strips
- Simple, intuitive and standardized use
- Scans the form with attached strips
- Evaluation of strips according to the intensity of the cut-off line
- Point evaluation of individual antigens for the current strip
- Graphic representation of the measured intensity within the strip
- Communication between RoboBlot and LIS
- Editing input and output data and sorting samples
- Import and export of work protocols



E-CALCULATOR

- Convenient, fast and standardized use
- Web application at www.vidia.cz
- Compatible with all ELISA-VIDITEST
- Calculation of Positivity Index (IP) and semi-quantitative evaluation
- Calculation of specific antibodies (AU/mL, mIU/mL, VIEU/mL) and determination of quantitative evaluation
- Determination of test validity (OD ratio)
- Calculation of Intrathecal antibody synthesis according to Reiber
- Import of measured values from VIDIMAT
- Export of calculated reports
- Flexible to user needs

CERTIFICATES

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

CERTIFICATE
No. 21 0054 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. 233404993/2021. 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.itczlin.cz

S 3002

Date of Issue: 16. 07. 2021
Valid until: 15. 07. 2024
Date of the first certification awarding: 04. 08. 2006

Ing. Pavel Vaněk
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.itczlin.cz

CERTIFICATE
No. 21 0055 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. 233404994/2021. 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.itczlin.cz

S 3002

Date of Issue: 16. 07. 2021
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Ing. Pavel Vaněk
Head of Certification Body

CQS z.s.
Prosecká 412/74, 190 00 Praha 9 - Prosek
Česká republika

CQS je certifikačním orgánem č. 3029 akreditovaným podle normy ČSN EN ISO/IEC 17021-1:2016 Českým institutem pro akreditaci, o.p.s. pro certifikaci systémů managementu

CERTIFIKÁT
číslo: CQS 2141/2021

CQS na základě kladného výsledku certifikačního auditu prohlašuje, že systém managementu kvality

VIDIA spol. s r.o.
Nad Safinou II 365, 252 50 Vestec, Česká republika

byl prověřen a shledán v souladu s požadavky

ČSN EN ISO 9001:2016

Tento certifikát platí pro procesy:

- **Výroba diagnostických souprav, výroba chemických látek a chemických přípravků**

••••••

Platnost do: 01. 09. 2024
Rozhodnutí o certifikaci: 27. 07. 2021
Datum vydání: 02. 09. 2021
Datum změny: 27. 06. 2022
První certifikace udělena: 10. 08. 2006

Ing. Jana Olšanská
Vedoucí certifikačního orgánu

Členové CQS*:
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.
* Seznam členů CQS platný v době vydání certifikátu. Aktuální seznam je k dispozici na www.cqs.cz.

NOTES

Distributor:

...the way
to the correct
results

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T A
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EVROPSKÁ UNIE
Evropský fond pro regionální rozvoj
Operační program Podnikání
a inovace pro konkurenceschopnost