TestLine®

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Catalog 2025

Comprehensive diagnostic solutions for infectious serology and immunology

EN

BIOVENDOR.GROUP

CONTENT

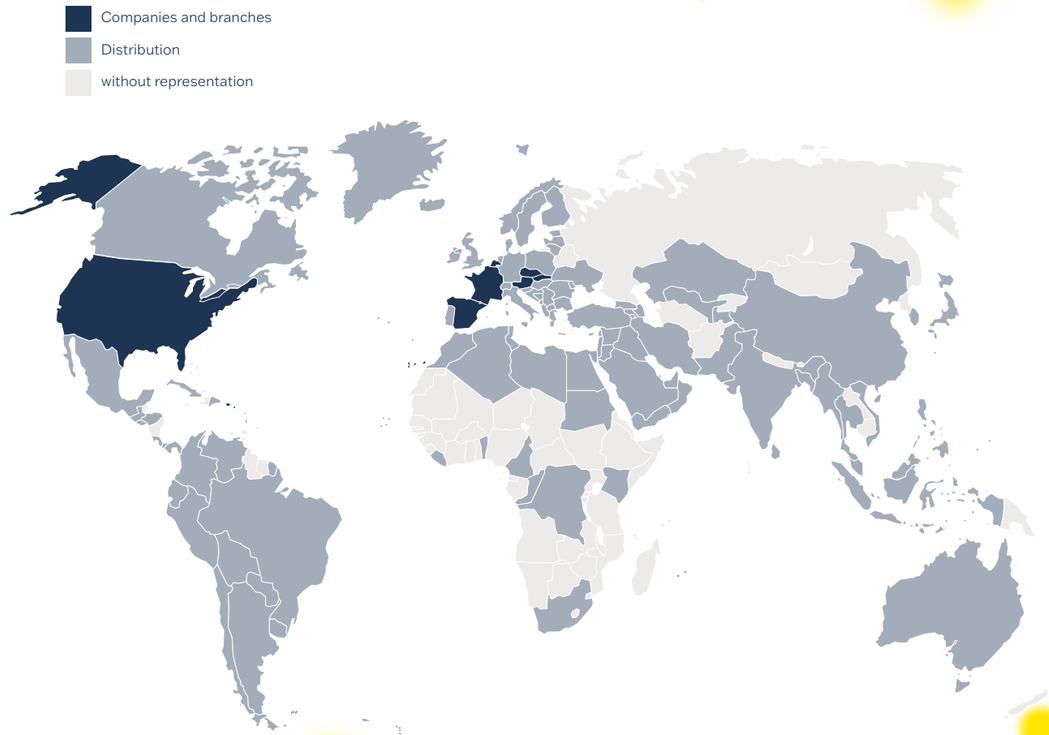
ABOUT THE COMPANY

Company profile

TestLine Clinical Diagnostics s.r.o. (TestLine) is a Czech company engaged in the development, production and distribution of human and veterinary laboratory diagnostics. Wide range of in vitro diagnostics and support in the field of laboratory automation allow to solve the individual needs of each microbiology or immunology laboratory. In 2012, TestLine became part of the BioVendor Group.

More than 30 years of experience in laboratory technology, consultation and cooperation with experts in the field guarantee high quality products. The new developments are based on innovative scientific knowledge, in addition to standard ELISA and BLOT methods, multiplex tests are coming to the fore. Also thanks to participation in international projects, unique test formats and complex solutions for laboratory diagnostics are created.

Representation of BioVendor Group



History

Foundation | Acquisition

- 1992 — **BioVendor LM**
- 1995 — **BioVendor R&D**
- 2012 — **TestLine**
- 2016 — **ViennaLab**
- 2017 — **DiaSource**

Quality management, customer satisfaction

TestLine Clinical Diagnostics s.r.o. is a certified company according to ISO 9001:2015 (Quality Management Systems) and ISO 13485:2016 (Requirements for Medical Devices).

The quality policy is designed to establish basic rules oriented towards customer satisfaction, professionalism of our employees and compliance with the established management systems.

Customer care

- The task of all company employees is to quickly and flawlessly implement the requirements of our customers leading to their satisfaction.
- Customer satisfaction reflects the quality of the services and products provided in the field of medical devices, because only satisfied customers return.
- We organize and support educational workshops and conferences to enhance the professional level of our customers.
- Our products meet the requirements prescribed by the valid legislation of the Czech Republic and the European Union countries. Our efforts are focused on ensuring high quality and maximum user comfort of our products, implementing automation of their processing or providing sophisticated evaluation programs.

Compliance with applicable laws and regulations is a matter of course, and we also require this of our employees and suppliers.
In accordance with Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data, we adhere to the following principles.

Certification and quality assurance

TestLine is a reliable partner in the field of diagnostic testing and therefore products are developed and manufactured with the highest standards of quality and safety in mind.

Good Manufacturing Practice (GMP)
We adhere to the principles of Good Manufacturing Practice (GMP), which ensures that our products meet the highest quality standards.

ISO 9001:2015 and ISO 13485:2016
We are certified according to ISO 9001:2015 and ISO 13485:2016 quality management system standards. This certification was awarded by the renowned British company Lloy- d's Register Quality Assurance, which means that our production processes are in compliance with internationally recognised standards.


LRQA
Certificate of Approval
TestLine Clinical Diagnostics s.r.o.
ISO 13485:2016, ISO 9001:2015

CERTIFIED
ISO 9001 · ISO 13485

ABOUT THE COMPANY

IVDR and Notified Person
We are actively working to implement the new regulatory directive for the manufacture and marketing of in vitro diagnostic medical devices (IVDRs) to ensure full compliance with the new European regulations.

Our Notified Body, 3EC, carries out performance assessments in accordance with the conformity assessment procedures under the relevant legislation.


3EC
CERTIFICATE
TestLine Clinical Diagnostics s.r.o.
EN ISO 13485:2016

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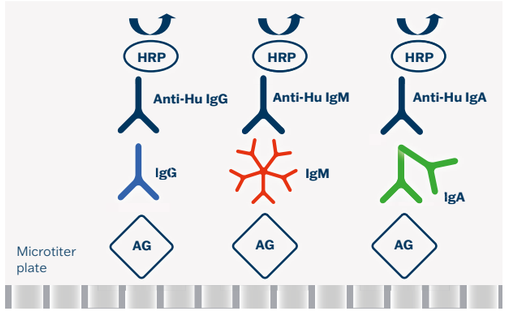
Technology

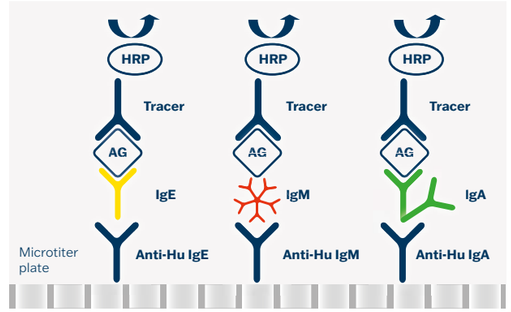
- ELISA
- CLIA
- Immunoblot
- Microblot-Array

ELISA

The principle of the sandwich test



The principle of the capture test



User comfort

- Components in working dilution
- Colour-coded reagents
- Interchangeability of components
- Colour coded strips with breakaway wells
- CUT-OFF control, Semi-quantitative evaluatio of results (Positivity Index-IP)
- Calibrators, quantitative evaluation of results (IU/ml, U/ml)

Advantages of kits

- High diagnostic efficiency, good reproducibility and high test dynamics
- Simple workflow, total examination time usually 1.5 hours
- Possibility of independent verification and comprehensive customer service
- IgG kits enable avidity testing (CMV, EBV VCA, HSV, Measles, TBEV, Toxocara, Toxoplasma, VZV)
- Dilution solution of IgM sample kits contains RF sorb (CMV, EBV, HSV, Measles, Mumps, Mycoplasma REC, TBEV, VZV)

Workflow

Step		Test steps
	1.	Sample dilution – serum/plasma 1:101 (10 µl + 1 ml)
	2.	Dosage of calibrators and diluted 100 µl samples – blank = empty hole
	3.	Incubation 30 min. at 37 °C
	4.	Draining and washing the wells 5 times
	5.	Dosage of Conjugate 100 µl – blank = empty hole
	6.	Incubation 30 min. at 37 °C
	7.	Drain and wash the wells 5 times
	8.	Substrate dosage 100 µl (TMB-Complete) – including the blank
	9.	Incubation 30 min. at 37 °C
	10.	Dosage of Stopping Solution 100 µl – including the blank
	11.	Photometric measurement at 450 nm

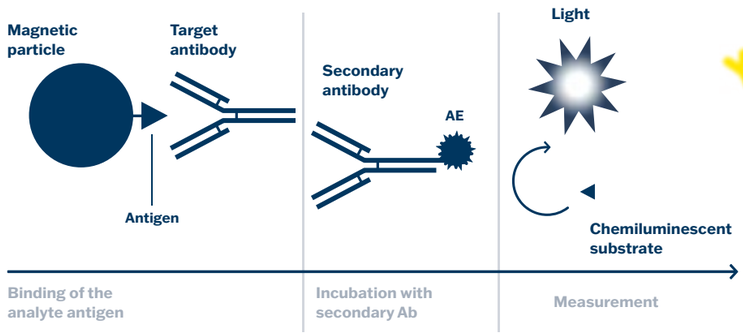
Note: The workflow can be modified in individual kits.

CLIA

The principle of the test

CLIA is a fully automated, very fast, specific and sensitive method. It combines the use of magnetic strips to separate the antigen-antibody immunocomplex with flash chemiluminescence for sensitive detection. The use of magnetic particle suspensions facilitates automation, significantly reduces reaction times and improves assay specificity.

Flash chemiluminescence of the acridinium ester provides an intense light signal even at very low concentrations, its intensity is measured in relative light units (RLU). CLIA kits are designed for the KleeYa® automated platform.



User comfort

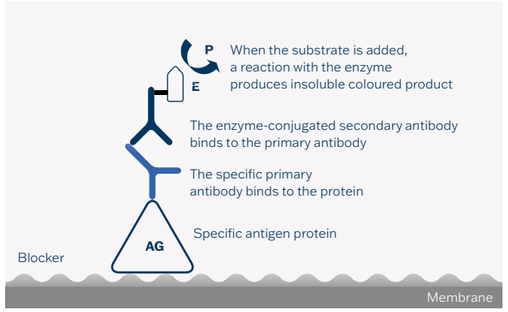
- Fully automatic method
- Kits contain all reagents, including calibrators
- Reagent cartridges with solutions in working dilution
- Control serums available in a separate set
- Results in U/ml

Benefits

- High diagnostic sensitivity and specificity ensured by the use of recombinant antigens
- Low consumption of samples (10 µl) and reagents
- Short test time (30 min)
- Wide dynamic range
- Reagents are tagged with RFID tags, and in addition to their identification, reagent consumption and the number of available assays are also recorded
- Connection to LIS
- Superior customer support
- Comprehensive diagnostic capability due to the availability of antibody tests against 3 dominant antigens, in clinically relevant antibody classes

IMMUNOBLOT

The principle of the test



User comfort

- Components in working dilution
- Colour-coded strips
- Interchangeability of components
- Negative and Positive Control
- Control lines on the strip
- Possibility of hardware evaluation

Advantages of the kits

- Identical workflow
- Easy interpretation and reproducibility of results
- Sophisticated evaluation software
- High diagnostic efficiency
- Suitable for automatic systems
- Comprehensive customer service

Evaluation of the test

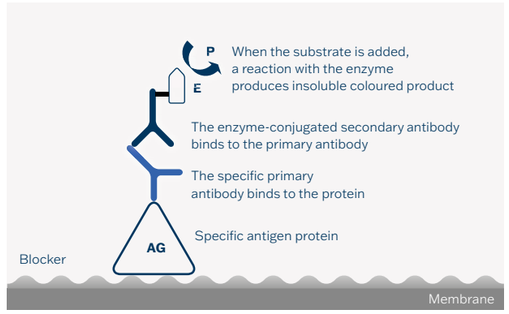
Visually using a template or by the Immunoblot Sohware

Workflow

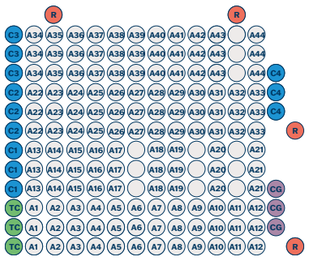
Step		Test steps
	1.	Dosage of Universal Solution 2 ml
	2.	Strip wetting 10 min. at laboratory temperature – shaker
	3.	Suction
	4.	Sample dilution – serum/plasma 1:51 (30 µl + 1,5 ml) – cerebrospinal fluid 1:2 (0,75 ml + 0,75 ml) – synovial fluid 1:17,5 (90 µl + 1,5 ml)
	5.	Dosage of controls and diluted samples 1.5 ml
	6.	Incubation 30 min. at lab. temperature – shaker
	7.	Draining and washing in Universal solution 3 times 1.5 ml after 5 min. – shaker
	8.	Dosage of Conjugate 1.5 ml
	9.	Incubation 30 min. at lab. temperature – shaker
	10.	Suction and washing in Universal solution 3 times 1.5 ml after 5 min. – shaker
	11.	Substrate dosage (BCIP/NBT) 1.5 ml
	12.	Incubation 15 min. at laboratory temperature – shaker
	13.	Aspiration and washing in distilled water 2 times 2 ml after 5 min. – shaker
	14.	Sticking and evaluation of strips

MICROBLOT-ARRAY

The principle of the test



Distribution of antigens and controls spots



Description of control spots

- **R** – Reference
- **TC** – Test control
- **CM** – IgM conjugate control
- **CG** – IgG conjugate control
- **CA** – IgA conjugate control
- **C1** – Calibrator 1
- **C2** – Calibrator 2
- **C3** – Calibrator 3
- **C4** – Calibrator 4
- **A1–A44** – Antigens

Workflow

Step		Test steps
	1.	Pipette Universal Solution – 150 µl
	2.	Wells soaking at room temperature for 10 min.
	3.	Aspirate off
	4.	Dilute samples serum/plasma 1:51 (10 µl + 500 µl) cerebrospinal fluid 1:3 (50 µl + 100 µl) synovial fluid 1:17.5 (10 µl + 165 µl)
	5.	Pipette control and diluted samples – 100 µl
	6.	Incubate at room temperature for 30 min.
	7.	Quick wash using the Universal Solution
	8.	Aspirate and wash 3 × 5 min. with 150 µl of Universal Solution
	9.	Pipette Conjugate – 100 µl
	10.	Incubate at room temperature for 30 min.
	11.	Quick wash using the Universal Solution
	12.	Aspirate and wash 3 × 5 min. with 150 µl of Universal Solution
	13.	Pipette Substrate Solution (BCIP/NBT) – 100 µl
	14.	Incubate at room temperature for 15 min.
	15.	Quick wash using the distilled water
	16.	Aspirate and wash 2 × 5 min. with 200 µl of distilled water
	17.	Dry and evaluate wells

User comfort

- Components in working dilution
- Fully automatic processing with ELISA analyzers
- Evaluation of results using sophisticated software
- Assessment of test validity through control spots

Advantages of kits

- Low sample consumption
- Antigens spotted in triplicate – minimizing processing error
- Parallel testing of multiple markers simultaneously
- High specificity

Evaluation of the test

Comprehensive evaluation of the tests is made possible by the Microblot-Array Sohware program, which is an integral part of the reader.

Microblot-Array Reader

- 96-well microtiter plate format
- High scanning speed, 2 minutes/full microtitration plate
- Option to scan selected wells or strips
- Automatic spot localization and spot capture
- 5 MPx CMOS camera, resolution 2592 x 1944 px

Microblot-Array Software

- Fully automatic evaluation
- Two-way communication with LIS
- Image centering and processing
- Spot localization with manual correction
- Image analysis and test evaluation based on the intensity of individual spots
- Assessment of test validity through control spots
- Clear display of results

Automation and software

ELISA, MICROBLOT-ARRAY
- Agility
- DS2 | DSX
- Gemini
- Freedom EVOlyzer
- HydroFlex
- Infinite F50 Plus
- MBA Reader

IMMUNOBLOT
- Roboblot

CLOSED SYSTEMS
- Kleeya
- BlueDiver

EVALUATION SOFTWARE
- Immunoblot Software
- Microblot-Array Software
- Antibody Index Software

AGILITY

The **AGILITY** instrument represents a completely new concept in the automation of ELISA methods, which enables the processing of all types of kits. The use of SmartEIA kits uniquely designed for the AGILITY system brings the maximum level of automation and user comfort.

- Fully open system, all types of ELISA and Microblot--Array kits can be used
- SmartEIA - automatic recognition of kit type, batch and expiry date
- 3 robotic arms (2 pipetting, 1 component transport) for maximum performance
- Simultaneous processing of up to 16 kits, capacity of up to 200 samples for high throughput
- Two-way communication with LIS, inventory of consumables and individual reagents
- Sample presence monitoring, barcode identification system, closed waste solution system
- Online help available during the test

DS2, DSX

DS2 – 2-plates, fully open analyzer (up to 24 parallel tests)

DSX – 4-plates, fully open analyzer (up to 48 parallel tests)

- Fully open system, all types of ELISA and Microblot--Array kits can be used
- Two-way communication interface, barcode operation
- Easy operation and optimised function settings
- Fast pipetting of samples and reagents, two-step sample predilution option
- Online help available during the test

GEMINI

Gemini – 3-plates, fully open system

- Fully open system, all types of ELISA and Microblot--Array kits can be used
- Highly flexible time manager with LIS connectivity
- Easy installation and maintenance, high pipetting safety ensured by triple checking
- Convenient programming of test protocols, simple operation
- Online support available during the test

FREEDOM EVOLYZER

EVOlyzer – automatic processing with modular and flexible design for all types of laboratories

- Modular design with open work surface layout for optimized layout of samples, reagents and pipetting station
- Walk-Away system for continuous loading saves time and increases throughput
- Capacitive liquid detection controls reagent volume and precipitate detection
- Freedom EVOlution™ software enables integration with LIMS systems via ASTM communication
- Increased security and control through electronic signatures for file security and barcode evaluation to ensure consistency of reagents and expiration date

HYDROFLEX

The **HydroFlex™ Plus** is a flexible and upgradeable platform for automatic strip washing, magnetic bead washing and vacuum filtration of wafers in a 96-well format. It is the ideal solution for a wide range of cell-, bead- and ELISA-based applications. The HydroFlex Plus washer is supplied with shaking microparticles and automatic buffer switching.

- Ready for automatic ELISA, cell washing and protein determination
- Magnetic bead washing with powerful neodymium magnets, two magnets per well for efficient bead settling (patented design)
- Automated system for vacuum filtration using vacuum sensor, individual vacuum setting for each filtration step within the protocol
- Wash head position and speed control for gentle cell washing
- Up to two aspiration points per well for minimum residual volumes
- Simultaneous aspiration and dispensing of ELISA buffers
- Automatic buffer switching option and shaking of the plates
- Two or four wash buffers
- Tested reliability to minimize maintenance and service costs
- IVDR (EU) 2017/746 certification and RoHS Directive 2011/65/EU

INFINITE® F50 PLUS

The ELISA microplate photometer provides accurate and fast photometric measurement of absorbance using innovative eight-channel optics and LED technology. Together with the Magellan™ data control and analysis software, these readers are ideal for a variety of ELISA method applications.

- Ideal for absorbance-based ELISAs, kinetic and multi-channel readings
- Ready for qualitative and quantitative data analysis using Magellan data analysis software
- All major curve shapes are supported, and Magellan‘s sample files and tutorials make it easy to get started
- 4 standard filters 405, 450, 492 and 620 nm, additional filters available
- Plate measurement speed within 15 seconds
- Eight-channel optics for fast reading
- Reference channel for optimised light intensity Longlife
- LED bulbs offer 10 times longer maintenance-free operation than conventional halogen bulbs
- Connection to LIS
- Two-year warranty and tested reliability >100,000 boards
- Linear plate shaking
- Certification of the device and software according to IVDR (EU) 2017/746 and RoHS Directive 2011/65/EU

MBA READER

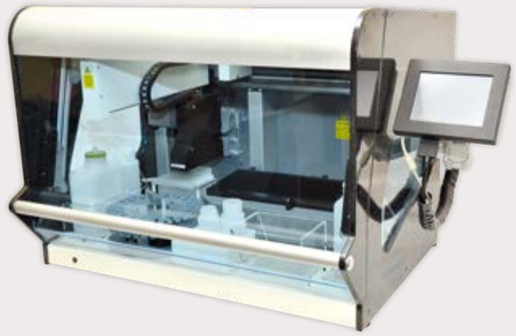
The **Array Reader C-series** is a high-quality instrument designed for efficient evaluation of Microblot-Arrays in microtiter format, optimized for advanced multiplex diagnostics.

- Designed for the analysis of multiplex Microblot-Array assays in individual wells of a microtiter plate
- High sample throughput
- Fast reading, approximately 2–5 minutes per plate
- Long life visible (white) LED lighting system
- Reading all or selected wells and/or strips
- Automatic grid layout, image analysis with manual control
- Intuitive and easy to use software

ROBOBLOT

RoboBlot is a new generation of fully automated analyzer for processing and evaluation of immunoblot kits.

- Full compatibility of RoboBlot, BLOT-LINE kits and Immunoblot Software (TestLine)
- Fully automatic test processing, minimizing manual handling and operator time
- Control of the entire process using Immunoblot Software and the analyzer's touch screen, two-way communication with LIS
- High performance and reliability, processing up to 50 strips and 5 different methods in one run
- Safe system, barcode reader for pipetting samples with disposable tips, level detection



KLEEYA

The KleeYa® platform is a fully European automatic random access analyzer solution with high sensitivity and large sample processing capacity.

- Fully automated walk-away system
- Broad application thanks to a comprehensive portfolio with unique parameters
- Flexible combination of single tests or groups of parameters for a comprehensive examination
- Up to 120 tes per hour
- Flexible insertion of tubes of different sizes to prioritize samples where speed of result plays a role
- Stackable square cuvettes ensure easy insertion, error-free separation and automatic handling

BLUEDIVER

BlueDiver provides a comprehensive solution for fast and accurate analysis and evaluation of immunoblots, multi-parametric diagnosis of infectious and autoimmune diseases in one device.

- Compact instrument with small dimensions
- No risk of contamination, works with disposable RTU cartridges
- High flexibility, up to 24 different tests can be analysed in one run
- Easy to use and minimal operator work, compatibility of strips and reagents is automatically checked by barcodes
- Extremely short analysis time, evaluation by scanning equipment without the need to glue strips, transfer of results to LIS

IMMUNOBLOT SOFTWARE

Immunoblot Software enables standard evaluation of TestLine immunoblots of BLOT, BLOT-LINE type with elimination of subjective error and contributes to the application of correct laboratory work at the workplace.

- It is user-friendly and intuitively guides you through the entire evaluation process
- Significantly increases the speed and accuracy of evaluation
- Connection to the laboratory information system
- It is independent of the type of office scanner used
- For kits offering differential diagnostics, it has the option to turn off/on individual determinations
- The program allows you to save and print two types of evaluation - cummulative (all analyzed strips) and individual (detailed information on 1 strip)

MICROBLOT-ARRAY SOFTWARE

Microblot-Array Software enables comprehensive evaluation of TestLine Microblot-Array kits, is an integral part of the Microblot-Array Reader.

- It is user-friendly and intuitively guides you through the entire evaluation process
- The evaluation process is fully automatic, the validity of the test is assessed through control spots
- Image centering and processing, spot localization with manual correction
- Image analysis and test evaluation based on spot intensity, results in U/ml
- Clear display of results, for kits offering differential diagnostics the option to turn off/on individual determinations
- Connection to the laboratory information system

INTRATHECAL ANTIBODY SYNTHESIS

ANTIBODY INDEX SOFTWARE

The **Antibody Index Software** allows the evaluation of the antibody index (AI), i.e. the ratio of specific antibodies in the cerebrospinal fluid and serum in relation to the state of the blood-lymphatic barrier and the concentration of total immunoglobulins in the cerebrospinal fluid and serum using TestLine ELISA kits.

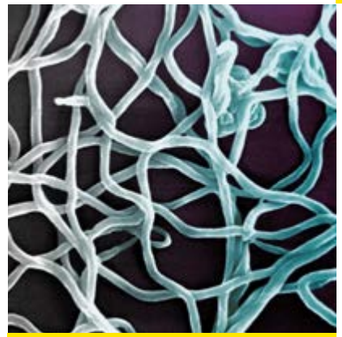
- It is user-friendly and intuitively guides you through the entire evaluation process
- Calibration curve incorporated into the program, without the need for calibrators in the analysis
- The program allows you to save and print two types of evaluations - aggregate and individual
- All results are archived in the program‘s database
- Enables connection to the laboratory information system

Infectious Serology – Bacteria

- Anaplasma
- Bordetella
- Borrelia
- Helicobacter
- Chlamydia
- Mycoplasma
- Pneumococcus
- Tetanus
- Treponema
- Yersinia

ANAPLASMA | p. 24

BORDETELLA | p. 26



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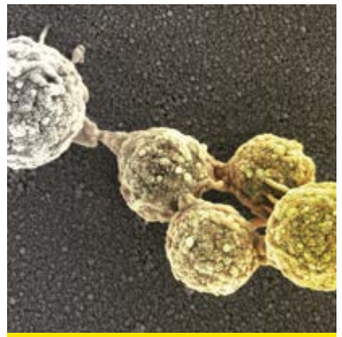
CHLAMYDIA | p. 34



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TREPONEMA | p. 42

YERSINIA | p. 44

Introduction

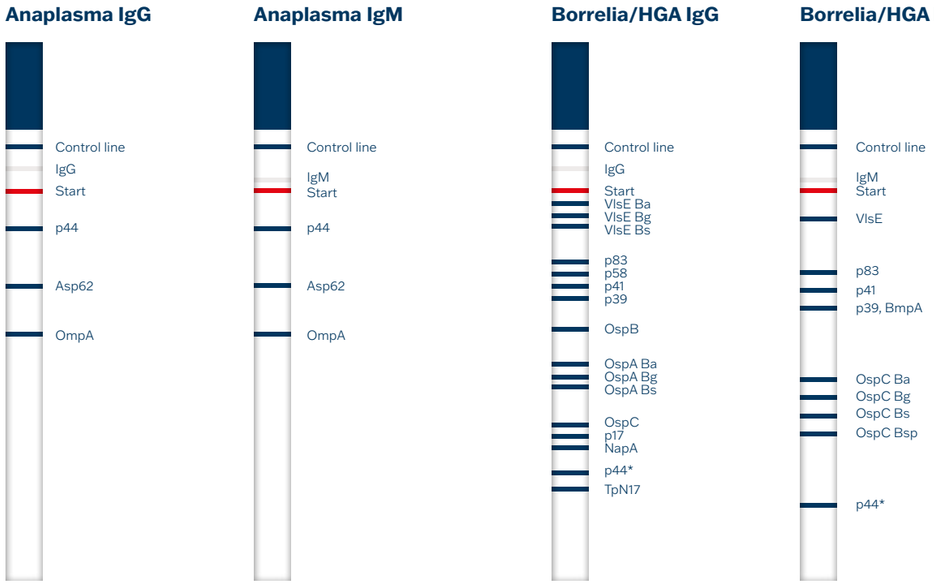
Human granulocytic anaplasmosis (HGA) is a disease caused by the bacterium Anaplasma phagocytophila. The bacteria spread by haematogenous and lymphatic routes after attachment to an infected tick, invading white blood cells where they grow in vacuoles

cytoplasmic membranes (forming morulae) and reduce their defensive function. Clinically, the disease can manifest from asymptomatic forms to severe forms with respiratory and gastrointestinal complications, renal, neurological, etc. Characteristic manifestations are fever, headache, muscle and joint pain, skin changes (erythema migrans similar to Lyme borreliosis, usually accompanied by maculopapular rash to haemorrhagia), hepatosplenomegaly and lymphadenopathy.

Specific antibodies start to form 2 weeks after the onset of the disease, but in the acute phase of the disease they are detectable in only 30-60% of patients. During recovery, 70-90% of samples are positive.

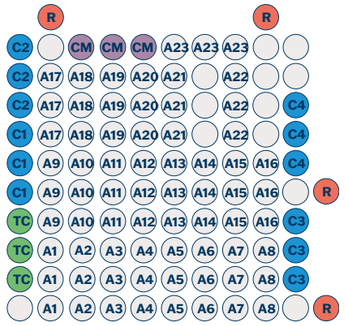
Antigens

IMMUNOBLOT



* In the case of a positive Anaplasma search test, further testing is advisable to rule out or confirm HGA.

MICROBLOT-ARRAY



A1 – VlsE Ba	A9 – OspB	A17 – NapA
A2 – VlsE Bg	A10 – OspA Ba	A18 – OspE
A3 – VlsE Bs	A11 – OspA Bg	A19 – p17
A4 – p83	A12 – OspA Bs	A20 – OmpA
A5 – p58	A13 – OspC Ba	A21 – p44
A6 – p41 Ba	A14 – OspC Bg	A22 – Asp62
A7 – p41 Bs	A15 – OspC Bs	A23 – VCA-p18
A8 – p39	A16 – OspC Bsp	

Product information

IMMUNOBLOT

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
BLOT-LINE Anaplasma IgG	S, P	10-30-30-15/RT	Viz, SwIm	91.7 %	99.9 %
BLOT-LINE Anaplasma IgM	S, P	10-30-30-15/RT	Viz, SwIm	91.4 %	99,9 %
BLOT-LINE Borrelia/HGA IgG	S, P, CSF, Syn	10-30-30-15/RT	Viz, SwIm	Borrelia 99.3 % Anaplasma 92.3 %	Borrelia 99.4 % Anaplasma 96.9 %
BLOT-LINE Borrelia/HGA IgM	S, P, CSF, Syn	10-30-30-15/RT	Viz, SwIm	Borrelia 99.2 % Anaplasma 94.7 %	Borrelia 99,31 % Anaplasma 97.14 %
BlueBLOT-LINE Borrelia IgG	S, P, CSF, Syn	30-20-10/RT	Viz, SwIm	Borrelia 97.44 % Anaplasma 83.33 %	Borrelia 99.9 % Anaplasma 99.9 %
BlueBLOT-LINE Borrelia IgM	S, P, CSF, Syn	30-20-10/RT	Viz, SwIm	Borrelia 98.3 % Anaplasma 91.7 %	Borrelia 99.9 % Anaplasma 95.8 %

MICROBLOT-ARRAY

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
Microblot-Array Borrelia IgG	S, P, CSF, Syn	10-30-30-15/RT	AU, IP, U/ml	Borrelia 98.7 % Anaplasma 92.0 %	Borrelia 98.9 % Anaplasma 99.99 %
Microblot-Array Borrelia IgM	S, P, CSF, Syn	10-30-30-15/RT	AU, IP, U/ml	Borrelia 94.6 % Anaplasma 95.0 %	Borrelia 99.9 % Anaplasma 99.9 %

S – serum | **P** – plasma | **CSF** – cerebrospinal fluid | **Syn** – synovial fluid | **RT** – laboratory temperature | **Viz** – visual evaluation | **SwIm** – software evaluation

Introduction

Pertuse (whooping cough, whooping cough) is a disease caused by the bacterium Bordetella pertussis and is still a significant cause of morbidity. The typical form of pertussis has stages:

Incubation (6–20 days)

Catarrhal (1–2 weeks): the initial symptoms (rhinorrhoea, subfebrile, mild dry irritating cough) correspond to a common cold, the dry irritating cough worsens and turns into a paroxysmal cough.

Paroxysmal (2–6 weeks): typically irritating, paroxysmal cough, increasing in number and severity, accompanied by gagging or vomiting.

Convalescent (1–3 weeks): there is a reduction in the number of seizures and a reduction in cough.

Pertussis has been growing significantly in recent years and is spreading to older age groups of children, adolescents and adults, often in a milder form (a prolonged dry irritating cough, but without the typical attacks). These patients may pose a risk to unvaccinated young children with potentially serious or fatal consequences.
Vaccination against pertussis is part of the regular vaccination in the Czech Republic and is a prerequisite for disease prevention. Post-vaccination immunity gradually decreases, so it is recommended to re-vaccinate parents of newborns, including health workers.
After an infection, immunity is developed, which is not lifelong. Antibodies to pertussis toxin (persisting into adulthood), filamentous haemagglutinin (gradually disappearing) and fimbriae can be detected in the serum.
Parapertussis usually has milder symptoms, without serious complications. The milder form is due to the absence of pertussis toxin. Post-vaccination and post-infection immunity following *B. pertussis* disease does not protect against disease caused by *B. parapertussis*.

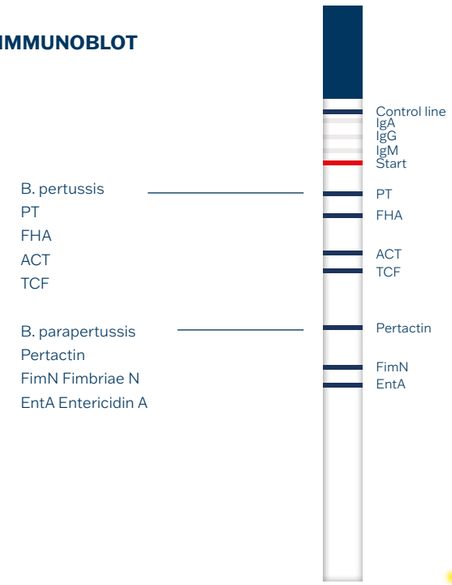
Antigens

ELISA

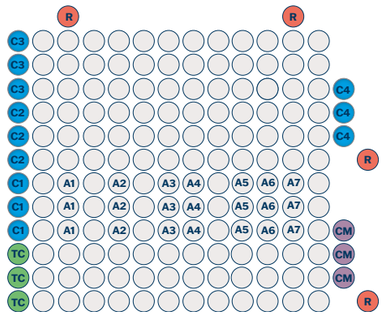
EIA Bordetella pertussis
Highly purified *Bordetella pertussis* toxin

EIA Bordetella parapertussis
Mixture of antigens specific for *Bordetella parapertussis*

IMMUNOBLOT



MICROBLOT-ARRAY



Description of antigens

A1 – PT
A2 – FHA
A3 – ACT
A4 – TCF
A5 – Pertactin
A6 – FimN
A7 – EntA

Pathogen	Antigen	Description
Bordetella pertussis	PT	Pertussis toxin (45 kDa) – essential virulence factor, specific only for *B. pertussis*, the most important pertussis antigen
	FHA	filamentous hemagglutinin of B. pertussis – adhesion protein, important immunogen, selected part of the sequence with high specificity
	ACT	adenylate cyclase toxin (CyaA) – an important virulence factor
	TCF	B. pertussis with antiphagocytic effect tracheal colonization factor – a protein produced only by *B. pertussis*; adhesin, ensuring the binding of the bacterium to the surface of the ciliated respiratory cells epithelial and phagocytic cells
Bordetella parapertussis	Pertactin	75 kDa, outer membrane protein of virulent strains *B. parapertussis*
	FimN	Fimbriae N – adhesin, not produced by *B. pertussis*
	EntA	Entericidin A – membrane lipoprotein

Product information

ELISA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
EIA Bordetella parapertussis IgA	S, P	30-30-30/37 °C	IP	98.0 %	99.0 %
EIA Bordetella parapertussis IgG	S, P	30-30-30/37 °C	IP	96.9 %	97.6 %
EIA Bordetella parapertussis IgM	S, P	30-30-30/37 °C	IP	98.0 %	98.3 %
EIA Bordetella pertussis Toxin IgA	S, P	30-30-30/37 °C	IU/ml	99.1 %	99.9 %
EIA Bordetella pertussis Toxin IgG	S, P	30-30-30/37 °C	IU/ml	98.2 %	98.9 %
EIA Bordetella pertussis Toxin IgM	S, P	30-30-30/37 °C	IP	97.9 %	98.3%

IMMUNOBLOT

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
BLOT-LINE Bordetella IgA	S, P	10-30-30-15/RT	Viz, SwIm	Bpp 99.9 % Bpe 95.5 %	Bpp 99.9 % Bpe 99.9 %
BLOT-LINE Bordetella IgG	S, P	10-30-30-15/RT	Viz, SwIm	Bpp 88.9 % Bpe 99.9 %	Bpp 99.9 % Bpe 99.9 %
BlueBLOT-LINE Bordetella IgA	S, P	30-20-10/RT	SwIm	Bpp 92.3 % Bpe 95.8 %	Bpp 99.9 % Bpe 99.9 %
BlueBLOT-LINE Bordetella IgG	S, P	30-20-10/RT	SwIm	Bpp 99.9 % Bpe 96.1 %	Bpp 99.9 % Bpe 99.9 %

MICROBLOT-ARRAY

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
Microblot-Array Bordetella IgA	S, P	10-30-30-15/RT	AU, IP, U/ml	Bpp 95.4 % Bpe 96.9 %	Bpp 99.9 % Bpe 99.9 %
Microblot-Array Bordetella IgG	S, P	10-30-30-15/RT	AU, IP, U/ml	Bpp 97.6 % Bpe 97.1 %	Bpp 99.9 % Bpe 99.9 %
Microblot-Array Bordetella IgM	S, P	10-30-30-15/RT	AU, IP, U/ml	Bpp 95.8 % Bpe 95.4 %	Bpp 99.9 % Bpe 99.9 %

S – serum | **P** – plasma | **CSF** – cerebrospinal fluid | **Syn** – synovial fluid | **RT** – laboratory temperature | **Viz** – visual evaluation | **SwIm** – software evaluation

Introduction

Lyme borreliosis is a multisystemic infectious disease caused by the spirochete *Borrelia burgdorferi* sensu lato. The infection is transmitted by ticks of the genus Ixodes. The clinical manifestations of Lyme borreliosis are divided into early and late.

Early localised phase – lasts from days to weeks

The characteristic manifestation is erythema migrans (EM), which develops in only 50% of cases. The disease usually presents initially with flu-like symptoms, headache, lymphadenitis.

Early disseminated phase – lasts approximately weeks to months

Haematogenous and lymphogenic dissemination of Borrelia occurs (CNS, joints, heart, eye, skin - secondary EM). Neuroborreliosis, paresa neurofacialis, Borrelia lymphocytoma (formed on earlobes, finger joints) and Bannwarth syndrome are most commonly diagnosed at this stage.

Late disseminated phase – lasts months to years

Immunopathological changes occur. Diagnostically typical are acrodermatitis chronica atrophicans (chronic skin lesions – ACA), chronic neuroborreliosis, borrelial arthritis.

The results of numerous studies show that all genospecies of *Borrelia burgdorferi* sensu lato are involved not only in the development of EM but also in a wide range of clinical manifestations. However, the frequency of isolations suggests that *B. burgdorferi* sensu stricto has mainly related to joint disorders, *B. garinii* is associated with neurological symptoms and *B. afzelii* with chronic skin manifestations, especially ACA

Antigens

ELISA

EIA Borrelia recombinant IgG
Combination of recombinant antigens VlsE (*B. afzelii*, *B. garinii*, *B. burg.* s.s.), p83, p58, internal flagellin p41i, p39, OspA (*B. afzelii*, *B. garinii*), OspB, OspC (*B. afzelii*, *B. garinii*), OspE, p17 and NapA

EIA Borrelia recombinant IgM
Combination of recombinant OspC antigens (*B. afzelii*, *B. garinii*, *B. burg.* s.s., *B. spielmanii*), VlsE, internal flagellin p41i, p39, p17 and OspE

EIA Borrelia afzelii VlsE IgG
Sonified whole cell antigen *B. afzelii* with high levels of p83, p41 (flagellin), p39, OspA, OspC, p18 and p14, additionally enriched with VlsE protein

EIA Borrelia afzelii IgM
Sonified whole cell antigen *B. afzelii* with high levels of p83, p41 (flagellin), p39, OspA, OspC, p18 and p14

EIA Borrelia garinii VlsE IgG
Sonified *B. garinii* whole-cell antigen with high levels of p83, p41 (flagellin), p39, OspA, OspC, p18, p14, additionally enriched in VlsE protein

EIA Borrelia garinii IgM
Sonified *B. garinii* whole cell antigen with high levels of p83, p41 (flagellin), p39, OspA, OspC, p18 and p14

EIA Borrelia b. senso stricto VlsE IgG
Sonified whole-cell antigen of *B. burgdorferi* sensu stricto with high content of p83, p41 (flagellin), p39, OspA, OspB, OspC, p28 and p21, additionally enriched with VlsE protein

EIA Borrelia b. sensu stricto IgM
Sonified B. burgdorferi sensu stricto whole cell antigen with high levels of p83, p41 (flagellin), p39, OspA, OspB, OspC, p28 and p21

EIA Borrelia VlsE IgG
Sonicated whole-cell antigen of *B. garinii* strains, *B. afzelii*, *B. burgdorferii* sensu stricto, containing heterogeneous isoforms of surface antigens OspA, OspC and outer extracellular antigen p83–100, additionally enriched in protein VlsE

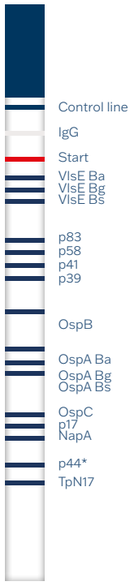
EIA Borrelia IgM
Sonicated whole-cell antigen of *B. garinii* strains, *B. afzelii*, *B. burgdorferii* sensu stricto, containing heterogeneous isoforms of surface antigens OspA, OspC and outer extracellular antigen p83–100

CLIA
CLIA Borrelia CSF IgG
CLIA Borrelia recombinant IgG
Combination of recombinant VlsE antigens (*B. afzelii*, *B. garinii*, *B. burgdorferi* sensu stricto), p83, p58, internal flagellin p41 (*B. afzelii*), OspA (*B. afzelii*), OspB, OspC (*B. afzelii*), p17 and NapA of *Borrelia burgdorferi* sensu lato species

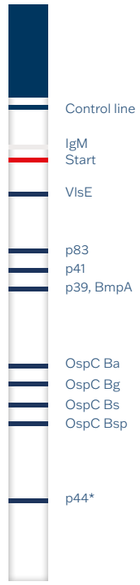
CLIA Borrelia CSF IgM
CLIA Borrelia recombinant IgM
Combination of recombinant antigens OspC (*B. afzelii*, *B. garinii*, *B. burgdorferi* sensu stricto, *B. spielmanii*), VlsE (*B. garinii*), internal flagelin p41 (*B. afzelii*), p39 of *Borrelia burgdorferi* sensu lato species

IMMUNOBLOT

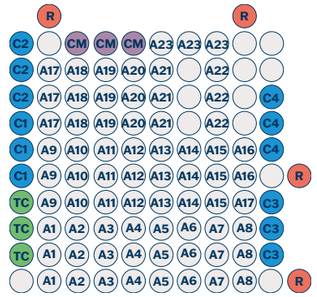
Borrelia/HGA IgG



Borrelia/HGA IgM



MICROBLOT-ARRAY



A1 – VlsE Ba
A2 – VlsE Bg
A3 – VlsE Bs
A4 – p83
A5 – p58
A6 – p41 Ba
A7 – p41 Bs
A8 – p39
A9 – OspB
A10 – OspA Ba
A11 – OspA Bg
A12 – OspA Bs
A13 – OspC Ba
A14 – OspC Bg
A15 – OspC Bs
A16 – OspC Bsp
A17 – NapA
A18 – OspE
A19 – p17
A20 – OmpA
A21 – p44
A22 – Asp62
A23 – VCA-p18

S – serum | **P** – plasma | **CSF** – cerebrospinal fluid | **Syn** – synovial fluid | **RT** – laboratory temperature | **Viz** – visual evaluation | **SwIm** – software evaluation

Pathogen	Antigen	Description
Borrelia spp.	VlsE Ba VlsE Bg VlsE Bs	Variable major protein-like sequence, expressed; significant for IgG antibody response, species-specific antigen
	p83	Major extracellular protein (p100 degradation product)
	p58	OppA-2 (Oligopeptide permease 2) – membrane transporter, is considered a marker of disseminated stage of Lyme borreliosis
	p41 Ba p41 Bs	The inner part of flagellin, a highly specific early antibody response antigen
	p39	BmpA (glycosaminopeptide receptor) - marker of late IgG antibody response
	OspB	Outer surface protein B, a marker of late phase infection, considered a marker of Lyme arthritis
	OspA Ba OspA Bg OspA Bs	Outer surface protein A, a highly specific marker of Borrelia infection in the IgG class
	OspC Ba OspC Bg OspC Bs OspC Bsp	Outer surface protein C, the major antigen of the early antibody response, immunodominant marker of IgM antibody response
	OspE	Outer surface protein E
	NapA	Neutrophil activating protein A – a potent immunogen, a major marker of Lyme arthritis pathogenesis
	p17	DbpA (decorin-binding protein A) – outer membrane protein
Anaplasma	p44	*Anaplasma phagocytophilium* – the main marker of HGA antibody response
	OmpA	Outer membrane protein A of *Anaplasma phagocytophilium*; lipoprotein associated with peptidoglycans, an important marker of virulence
	Asp62	Surface protein – membrane carrier
Treponema	TpN17	Highly specific membrane protein of *Treponema pallidum*.
EBV	VCA-p18	Capsid Antigen p18 – an important marker of EBV

(Ba – *B. afzelii*, Bg – *B. garinii*, Bs – *B. burgdorferi sensu stricto*, Bsp – *B. spielmanii*)

INFECTIOUS SEROLOGY – BACTERIA – **BORRELIA**

Product information

ELISA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
EIA Borrelia recombinant IgG (192)	S, P, CSF, Syn	30-30-15/37 °C	IP, U/ml	98.3 %	98.1 %
EIA Borrelia recombinant IgM (192)	S, P, CSF, Syn	30-30-15/37 °C	IP, U/ml	99.1 %	97.3 %
EIA Borrelia afzelii VlsE IgG (192)	S, P, CSF, Syn	30-30-15/37 °C	IP	95.7 %	98.9 %
EIA Borrelia afzelii IgM (192)	S, P, CSF, Syn	30-30-15/37 °C	IP	98.9 %	99.0 %
EIA Borrelia b. sensu stricto VlsE IgG	S, P, CSF, Syn	30-30-15/37 °C	IP	98.9 %	98.9 %
EIA Borrelia b. sensu stricto IgM	S, P, CSF, Syn	30-30-15/37 °C	IP	97.5 %	98.9 %
EIA Borrelia garinii VlsE IgG (192)	S, P, CSF, Syn	30-30-15/37 °C	IP	98.9 %	98.9 %
EIA Borrelia garinii IgM (192)	S, P, CSF, Syn	30-30-15/37 °C	IP	95.7 %	98.9 %

All EIA kits are available in SmartEIA for automatic processing on Agility

CLIA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
CLIA Borrelia recombinant IgG	S, P		max. 40 U/ml	98.99 %	98.92 %
CLIA Borrelia recombinant IgM	S, P		max. 40 U/ml	98.59 %	98.95 %
CLIA Borrelia CSF IgG	S, P		max. 40 U/ml	95.1 %	99.2 %
CLIA Borrelia CSF IgM	S, P		max. 40 U/ml	94.1 %	99.9 %

Control sera are available for all CLIA kits to verify functionality and accuracy of results.

IMUNOBLOT

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
BLOT-LINE Borrelia/HGA IgG	S, P, CSF, Syn	10-30-30-15/RT	Viz, SwIm	99.3 %	99.4 %
BLOT-LINE Borrelia/HGA IgM	S, P, CSF, Syn	10-30-30-15/RT	Viz, SwIm	99.2 %	99.3 %
BLOT-LINE Borrelia afzelii IgG	S, P	10-30-30-15/RT	Viz, SwIm	97.3 %	99.9 %
BLOT-LINE Borrelia afzelii IgM	S, P	10-30-30-15/RT	Viz, SwIm	96.6 %	97.9 %
BLOT-LINE Borrelia garinii IgG	S, P, CSF	10-30-30-15/RT	Viz, SwIm	97.1 %	99.9 %
BLOT-LINE Borrelia garinii IgM	S, P, CSF	10-30-30-15/RT	Viz, SwIm	97.6 %	99.9 %
BLOT-LINE Borrelia b.sensu stricto IgG	S, P, Syn	10-30-30-15/RT	Viz, SwIm	96.3 %	99.9 %
BLOT-LINE Borrelia b.sensu stricto IgM	S, P, Syn	10-30-30-15/RT	Viz, SwIm	97.4 %	99.9 %
BlueBLOT-LINE Borrelia IgG	S, P, CSF, Syn	30-20-10/RT	SwIm	97.4 %	99.9 %
BlueBLOT-LINE Borrelia IgM	S, P, CSF, Syn	30-20-10/RT	SwIm	98.3 %	99.9 %

MICROBLOT-ARRAY

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
Microblot-Array Borrelia IgG	S, P, CSF, Syn	10-30-30-15/RT	AU, IP, U/ml	98.7 %	98.9 %
Microblot-Array Borrelia IgM	S, P, CSF, Syn	10-30-30-15/RT	AU, IP, U/ml	98.5 %	99.9 %

S – serum | **P** – plasma | **CSF** – cerebrospinal fluid | **Syn** – synovial fluid | **RT** – laboratory temperature | **Viz** – visual evaluation | **SwIm** – software evaluation

Introduction

Helicobacter pylori belongs to the genus Helicobacter. Morphologically, they are gram-negative, aerobic microaerophilic rods. As a pathogen, it is implicated in infections of the gastric mucosa, especially in the antrum and duodenum. It is the causative agent of chronic type B gastritis, which may later develop ulcerative disease. In this disease, *H. pylori* is found in almost 100% of cases. *H. pylori* infection is often accompanied by dyspeptic disorders. Active chronic gastritis can develop into an atrophic form with a risk of gastric cancer.

The pathogenicity factors of *H. pylori* are based on the morphological structure of the bacterial cell (spiral shape, flagella) and the ability to produce extracellular enzymes and cytotoxins (e.g. urease, catalase, proteases, VacA, CagA).

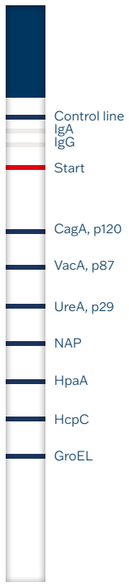
There are a number of pathogenic and facultatively pathogenic strains. Their virulence varies both in the presence of the aforementioned factors and in their abundance. The host response also contributes to the pathogenesis of the disease. Resistant strains are mainly isolated from unsuccessfully treated persons.

Antigens

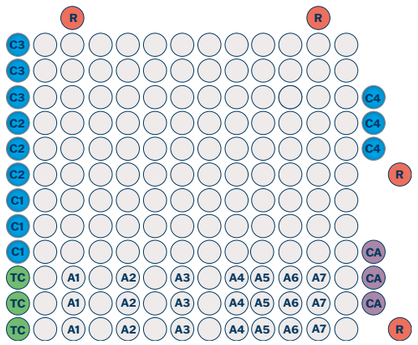
ELISA

Clinically significant *H. pylori* strain with high content of CagA (120 kDa) and VacA (87 kDa) proteins

IMMUNOBLOT



MICROBLOT-ARRAY



A1 – CagA
A2 – VacA
A3 – UreA
A4 – NAP
A5 – HpaA
A6 – HcpC
A7 – GroEL

CLIA

CLIA Helicobacter MONO IgA, IgG

Clinically significant *H.pylori* strain with high content of CagA (120 kDa) and VacA (87 kDa) proteins

Antigen	Description
CagA, p120	Cytotoxin associated gene A, highly specific, virulence factor
VacA, p87	Vacuolating cytotoxin A, highly specific, virulence factor
UreA, p29	light subunit of urease, specific, virulence factor
NAP	Neutrophil-activating protein, virulence factor, potential biomarker of gastritis
HpaA	Helicobacter pylori adhesin A, a surface lipoprotein, a potential marker of gastritis and stomach ulcers
HcpC	Helicobacter cysteine-rich protein, virulence factor
GroEL	Chaperonin, a heat shock protein (Hsp 60), a virulence factor, is considered a marker of chronic infections

Product information

ELISA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
EIA Helicobacter MONO IgA	S, P	30-30-15/37 °C	IP, U/ml	98.7 %	98.9%
EIA Helicobacter MONO IgG	S, P	30-30-15/37 °C	IP, U/ml	98.9 %	98.9 %
EIA Helicobacter MONO IgM	S, P	30-30-15/37 °C	IP, U/ml	97.5 %	97.7 %

All EIA kits are available in SmartEIA for automatic processing on Agility

CLIA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
CLIA Helicobacter MONO IgA	S, P	max. 40	U/ml	94.3 %	98.6 %
CLIA Helicobacter MONO IgG	S, P	max. 40	U/ml	99.9 %	98.4 %

Control sera are available for all CLIA kits to verify functionality and accuracy of results.

IMMUNOBLOT

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
BLOT-LINE Helicobacter IgA	S, P	10-30-30-15/RT	Viz, SwIm	95.2 %	99.9 %
BLOT-LINE Helicobacter IgG	S, P	10-30-30-15/RT	Viz, SwIm	96.9 %	99.9 %

MICROBLOT-ARRAY

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
Microblot-Array Helicobacter IgA	S, P	10-30-30-15/RT	AU, IP, U/ml	96.5 %	99.1 %
Microblot-Array Helicobacter IgG	S, P	10-30-30-15/RT	AU, IP, U/ml	97.4 %	99.0 %

S – serum | **P** – plasma | **CSF** – cerebrospinal fluid | **Syn** – synovial fluid | **RT** – laboratory temperature | **Viz** – visual evaluation | **SwIm** – software evaluation

Introduction

In human medicine, *Chlamydia trachomatis* and *Chlamydia pneumoniae*, which are human pathogens, are of major importance. *Chlamydia psittaci* is primarily an animal pathogen with the potential for transmission to humans.

Chlamydia trachomatis is the world's most common sexually transmitted bacterial pathogen and the causative agent of venereal disease. Young people are the most at risk, most in the 15–30 age group. Urogenital chlamydial infections often take the form of so-called postgonococcal inflammation. Cervical chlamydial infection is currently considered one of the risk factors for cervical cancer. *Chlamydia trachomatis* is the most common cause of infertility in both women and men.

Chlamydia pneumoniae is the most widespread of all chlamydial species in the human population. The number of acute and chronic diseases has increased during the last years. Primoinfection usually occurs between 5 and 18 years of age. The most common clinical manifestations of infection are: rhinitis, sinusitis, otitis media, pharyngitis, bronchitis, atypical pneumonia with non-productive cough and unremarkable hearing findings.

Chlamydia psittaci can cause human disease presenting as atypical pneumonia (avian strains) or placentitis (mammalian strains).

Antigens

ELISA

Clinically significant *H. pylori* strain with high content of CagA (120 kDa) and VacA (87 kDa) proteins

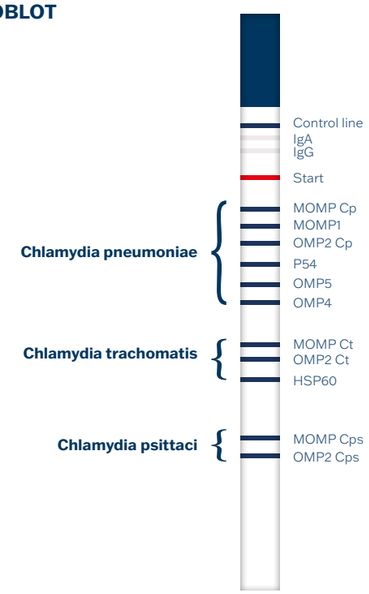
EIA Chlamydia IgA, IgG, IgM
Inactivated and highly purified LPS antigen from *Chlamydia sp.*

EIA Chlamydia pneumoniae IgA, IgG, IgM
Inactivated and purified antigen *Chlamydia pneumoniae*

EIA Chlamydia pneumoniae REC IgA, IgG
ombination of selected parts of specific antigens MOMP, OMP2, OMP4, OMP5 and p54

EIA Chlamydia trachomatis IgA, IgG, IgM
Inactivated and purified *Chlamydia trachomatis* antigen with high MOMP content

IMMUNOBLOT



CLIA

CLIA Chlamydia pneumoniae

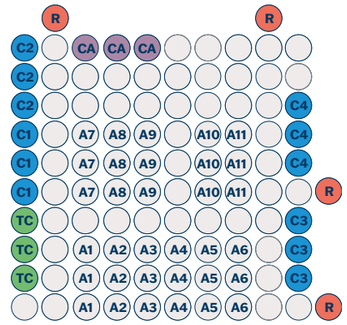
Purified and inactivated native antigen

CLIA Chlamydia trachomatis

Mixture of highly specific recombinant antigens

INFECTIOUS SEROLOGY – BACTERIA – **CHLAMYDIA**

MICROBLOT-ARRAY



A1 – MOMP Cp
A2 – MOMP1 Cp
A3 – OMP2 Cp
A4 – p54
A5 – OMP5 Cp
A6 – OMP4 Cp
A7 – MOMP Ct
A8 – OMP2 Ct
A9 – HSP60
A10 – MOMP Cps
A11 – OMP2 Cps

Pathogen	Antigen	Description
Chlamydia pneumoniae	MOMP Cp	dominant surface species-specific membrane protein - function structural protein; metabolic function
	MOMP1	isoform of MOMP antigen, resulting from post-translational modification
	OMP2 Cp	surface species-specific membrane protein - basic component the chlamydial surface membrane complex
	OMP4	outer membrane protein
	OMP5	outer membrane protein
	P54	immunodominant surface antigen, highly specific for *Ch. pneumoniae* – a sensitive marker for the diagnosis of acute infection
Chlamydia trachomatis	MOMP Ct	dominant surface species-specific membrane protein – function structural protein; metabolic function
	OMP2 Ct	Surface species-specific membrane protein – an essential component of the chlamydial surface membrane complex
	HSP60	temperature shock protein (GroEL); marker of chronic information
Chlamydia psittaci	MOMP Cps	indoflmaimnanmatt iosurnface species-specific membrane protein – function structural protein; metabolic function
	OMP2 Cps	surface species-specific membrane protein – basic component the chlamydial surface membrane complex

S – serum | **P** – plasma | **CSF** – cerebrospinal fluid | **Syn** – synovial fluid | **RT** – laboratory temperature | **Viz** – visual evaluation | **SwIm** – software evaluation

Product information

ELISA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
EIA Chlamydia IgA	S, P	30-30-30/37 °C	IP	98.8 %	96.6 %
EIA Chlamydia IgG	S, P	30-30-30/37 °C	IP	98.9 %	98.9 %
EIA Chlamydia IgM	S, P	30-30-30/37 °C	IP	95.9 %	95.2 %
EIA Chlamydia pneumoniae IgA	S, P	30-30-30/37 °C	IP, U/ml	98.8 %	99.0 %
EIA Chlamydia pneumoniae IgG	S, P	30-30-30/37 °C	IP, U/ml	98.9 %	94.4 %
EIA Chlamydia pneumoniae IgM	S, P	30-30-30/37 °C	IP	94.7 %	99.9 %
EIA Chlamydia pneumoniae REC IgA	S, P	30-30-30/37 °C	IP, U/ml	99.9 %	99.2 %
EIA Chlamydia pneumoniae REC IgG	S, P	30-30-30/37 °C	IP, U/ml	96.6 %	98.9 %
EIA Chlamydia trachomatis IgA	S, P	30-30-30/37 °C	IP, U/ml	97.2 %	97.7 %
EIA Chlamydia trachomatis IgG	S, P	30-30-30/37 °C	IP, U/ml	97.9 %	97.6 %
EIA Chlamydia trachomatis IgM	S, P	30-30-30/37 °C	IP	96.3 %	99.2 %

All EIA kits are available in SmartEIA for automatic processing on Agility

CLIA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
CLIA Chlamydia pneumoniae IgA	S, P	max. 40	U/ml	99.99 %	98.92 %
CLIA Chlamydia pneumoniae IgG	S, P	max. 40	U/ml	96.63 %	96.55 %
CLIA Chlamydia pneumoniae IgM	S, P	max. 40	U/ml	99.99 %	99.99 %
CLIA Chlamydia trachomatis IgA	S, P	max. 40	U/ml	94.87 %	99.30 %
CLIA Chlamydia trachomatis IgG	S, P	max. 40	U/ml	97.37 %	97.89 %
CLIA Chlamydia trachomatis IgM	S, P	max. 40	U/ml	92.31 %	99.99 %

Control sera are available for all CLIA kits to verify functionality and accuracy of results.

IMMUNOBLOT

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
BLOT-LINE Chlamydia IgA	S, P	10-30-30-15/RT	Viz, SwIm	Chpn 98.8 % Chtr 97.4 %	Chpn 99.9 % Chtr 98.2 %
BLOT-LINE Chlamydia IgG	S, P	10-30-30-15/RT	Viz, SwIm	Chpn 97.7 % Chtr 98.2 %	Chpn 98.8 % Chtr 98.0 %
BLOT-LINE Chlamydia pneumoniae IgA	S, P	10-30-30-15/RT	Viz, SwIm	98.8 %	99.9 %
BLOT-LINE Chlamydia pneumoniae IgG	S, P	10-30-30-15/RT	Viz, SwIm	97.7 %	98.8 %
BLOT-LINE Chlamydia pneumoniae IgM	S, P	10-30-30-15/RT	Viz, SwIm	95.0 %	99.9 %
BLOT-LINE Chlamydia trachomatis IgA	S, P	10-30-30-15/RT	Viz, SwIm	97.4 %	98.2 %
BLOT-LINE Chlamydia trachomatis IgG	S, P	10-30-30-15/RT	Viz, SwIm	98.2 %	98.0 %
BlueBLOT-LINE Chlamydia IgA	S, P	30-20-10/RT	SwIm	Chpn 99.9 % Chtr 98,2 %	Chpn 99.9 % Chtr 98.0 %
BlueBLOT-LINE Chlamydia IgG	S, P	30-20-10/RT	SwIm	Chpn 98.3 % Chtr 97.8 %	Chpn 99.9 % Chtr 98.3 %

MICROBLOT-ARRAY

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
MicroBlot-Array Chlamydia IgA	S, P	10-30-30-15/RT	AU, IP, U/ml	Chpn 98.7 % Chtr 98.2 %	Chpn 99.9 % Chtr 98.9 %
MicroBlot-Array Chlamydia IgG	S, P	10-30-30-15/RT	AU, IP, U/ml	Chpn 98.8 % Chtr 98.6 %	Chpn 99.0 % Chtr 99.0 %

S – serum | **P** – plasma | **CSF** – cerebrospinal fluid | **Syn** – synovial fluid | **RT** – laboratory temperature | **Viz** – visual evaluation | **SwIm** – software evaluation

Introduction

Mycoplasma pneumoniae is the primary pathogen of the respiratory tract. It causes pneumonia accompanied by fever, nausea, chills, cough and fatigue. The disease is protracted but well treated with antibiotics. The infection is airborne, by droplet infection. Epidemics usually occur in large groups, especially children, during the spring and autumn months.

Diagnosis of the disease is based on clinical picture, epidemiological history and laboratory tests.

Due to the difficulty in culturing *Mycoplasma pneumoniae*, the determination of specific IgA, IgG and IgM antibodies in serum or plasma by ELISA is a suitable option for routine diagnosis.

IgM: In primoinfection, the rise of IgM antibodies occurs in the 1st–2nd week after infection, peaks about 1 month after the onset of the disease and can persist for more than 1 year. The prevalence of specific IgM antibodies is 80 % in patients under 20 years of age and 40 % in patients over 20 years of age.

IgA: The rise in IgA antibodies usually occurs later than in IgM, but an earlier decline is common. They are particularly important in the absence of IgM in some patients and in reinfections.

IgG: The rise in IgG antibodies sometimes occurs as early as 2–3 weeks after the onset of symptoms, but they reach peak levels over a longer period of time, sometimes up to 6 months. They persist for more than 1 year, with cases known to persist for more than 4 years. In the case of reinfections, it is necessary to assess the dynamics of antibodies in paired samples taken 1–2 weeks apart.

For the evaluation of serological findings, testing of the sample in all 3 antibody classes or testing of paired samples is optimal.

Antigens

ELISA

EIA Mycoplasma

Purified and inactivated *M. pneumoniae* antigen enriched with highly specific immunodominant epitopes

EIA Mycoplasma REC

Mixture of highly specific recombinant antigens

CLIA

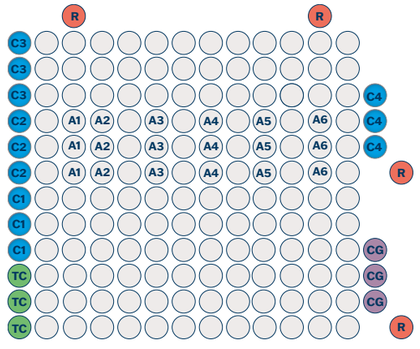
CLIA Mycoplasma pneumoniae IgA, IgG

Mixture of highly specific recombinant antigens

CLIA Mycoplasma pneumoniae IgM

Purified and inactivated Mycoplasma pneumoniae antigen enriched with highly specific inumodominant epitopes

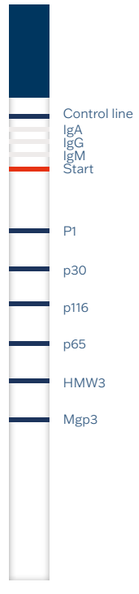
MICROBLOT-ARRAY



Description of antigens

A1 – P1
A2 – P30
A3 – P116
A4 – P65
A5 – HMW3
A6 – Mgp3

IMMUNOBLOT



Antigen	Description
P1	Adhesin; most important protein, major virulence factor
p30	Cytadhesin p30; the second most important protein, the main
p116	Adhesin, a major virulence factor
p65	virulence factor p65Surface protein; Proline-rich P65 protein
HMW3	Cytadherence high molecular weigh 3; adhesion-promoting protein
Mgp3	Adhesion-promoting protein

Product information

ELISA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
EIA Mycoplasma IgA	S, P	30-30-30/37 °C	IP, U/ml	98.8 %	97.6 %
EIA Mycoplasma IgG	S, P	30-30-30/37 °C	IP, U/ml	97.5 %	97.5 %
EIA Mycoplasma IgM	S, P	30-30-30/37 °C	IP, U/ml	96.7 %	98.8 %
EIA Mycoplasma REC IgA	S, P	30-30-30/37 °C	IP, U/ml	95.0 %	95.5 %
EIA Mycoplasma REC IgG	S, P	30-30-30/37 °C	IP, U/ml	95.5 %	95.5 %
EIA Mycoplasma REC IgM	S, P	30-30-30/37 °C	IP, U/ml	97.7 %	99.0 %

Všechny EIA soupravy jsou dostupné ve verzi SmartEIA pro automatické zpracování na Agility

CLIA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
CLIA Mycoplasma IgA	S, P	max. 40	U/ml	93.33 %	96.10 %
CLIA Mycoplasma IgG	S, P	max. 40	U/ml	90.00 %	93.45 %
CLIA Mycoplasma IgM	S, P	max. 40	U/ml	88.52 %	85.26 %

Ke všem CLIA soupravám jsou dostupná kontrolní séra k ověření funkčnosti a správnosti výsledků.

IMUNOBLOT

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
BLOT-LINE Mycoplasma IgA	S, P	10-30-30-15/RT	Viz, SwIm	96.3 %	99.5 %
BLOT-LINE Mycoplasma IgG	S, P	10-30-30-15/RT	Viz, SwIm	96.2 %	99.0 %
BLOT-LINE Mycoplasma IgM	S, P	10-30-30-15/RT	Viz, SwIm	96.7 %	99.2 %
BlueBLOT-LINE Mycoplasma IgA	S, P	30-20-10/RT °C	Viz, SwIm	96.8 %	98.2 %
BlueBLOT-LINE Mycoplasma IgG	S, P	30-20-10/RT °C	SwIm	96.4 %	98.2 %
BlueBLOT-LINE Mycoplasma IgM	S, P	30-20-10/RT °C	SwIm	97.8 %	98.1 %

MICROBLOT-ARRAY

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
Microblot-Array Mycoplasma IgA	S, P	10-30-30-15/RT °C	IP, U/ml, AU	97.1 %	99.3 %
Microblot-Array Mycoplasma IgG	S, P	10-30-30-15/RT °C	IP, U/ml, AU	95.7 %	99.0 %
Microblot-Array Mycoplasma IgM	S, P	10-30-30-15/RT °C	IP, U/ml, AU	98.9 %	99.3 %

S – serum | **P** – plasma | **CSF** – cerebrospinal fluid | **Syn** – synovial fluid | **RT** – laboratory temperature | **Viz** – visual evaluation | **SwIm** – software evaluation

Introduction

Pneumococcal disease is caused by ***Streptococcus pneumoniae***, of which there are more than 90 serotypes worldwide. Their common occurrence is limited to 20-23 types. Invasive pneumococcal disease, i.e. bacteraemia leading to pneumococcal pneumonia, meningitis, sepsis or arthritis, is a risk. Vaccination is an effective way to prevent the disease.

All *Streptococcus pneumoniae* serotypes have a unique cellular envelope consisting of a C-polysaccharide (CPS) composed of teichoic acid covalently bound to peptidoglycans. CPS induces the production of cross-reactive antibodies with all other streptococci in approximately 30% of individuals.

The specific response to vaccination is IgG class antibodies against PCP. Anti-CPS antibodies provide only limited protection against pneumococcal infection, and therefore absorption to CPS was included in the assay.

Antibody formation can be assessed by serological determination of IgG antibody levels to pneumococcal capsular polysaccharide (PCP) before and after vaccination, for which this immunoenzyme kit can be used. Reduced post-vaccination antibody production may indicate immune deficiency.

Antigens

ELISA

Pneumococcal capsular polysaccharide PCP
(1-5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F, 33F).

Produktové informace

ELISA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
EIA PCP IgG	S, P	30-30-30/37 °C	IP, U/ml	97.8 %	96.8 %

S – serum | **P** – plasma | **CSF** – cerebrospinal fluid | **Syn** – synovial fluid | **RT** – laboratory temperature | **Viz** – visual evaluation | **SwIm** – software evaluation

Introduction

Tetanus is a disease caused by a toxin produced by the bacterium *Clostridium tetani*. The incidence of the disease has been reduced worldwide through improved sanitation and widespread vaccination prophylaxis. However, between 400 000 and 800 000 people die each year from this infection. Most of these people live in developing countries. Protection through vaccination decreases with age, as tetanus antitoxin levels decline with age.

Sufficient antibody protection is achieved by vaccination in infancy and subsequent booster doses. Protection starts at 0.1 IU/ml of antitetanus toxoid.

The vaccine does not usually cause side effects, but it is recommended to detect the antibody titre before the booster dose. In this way, side effects in the patient such as local swelling, pain and fever can be avoided.

Sometimes an immune response failure can occur in patients with normal or elevated levels of all immunoglobulins and in patients with isolated immunodeficiencies. Therefore, normal immunoglobulin concentrations do not exclude a deficiency of antibodies and the response to antigenic stimulation should be tested.If antibody determinations are performed after primary and booster vaccination, abnormalities in cellular interactions and titres may occur.

Antigens

ELISA

Chemically inactivated tetanus toxin

CLIA

Recombinant tetanus toxoid fragment C

Product information

ELISA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
EIA Tetanus Toxoid IgG	S, P	30-30-30/37 °C	IP, U/ml	96.1 %	97.1 %

All EIA kits are available in SmartEIA for automatic processing on Agility

CLIA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
CLIA Tetanus Toxoid IgG	S, P	max. 40	IU/ml	95.08 %	88.89 %

Control sera are available for all CLIA kits to verify functionality and accuracy of results.

S – serum | **P** – plasma | **CSF** – cerebrospinal fluid | **Syn** – synovial fluid | **RT** – laboratory temperature | **Viz** – visual evaluation | **SwIm** – software evaluation

Introduction

Syphilis (lues) is a sexually transmitted disease caused by the spirochete *Treponema pallidum* subsp. *pallidum*.

Transmission occurs primarily through sexual contact with an infected person, with only 5–10% of cases occurring through other non-sexual routes (mother-to-child transmission, rarely through blood or skin contact).

Primary syphilis: a hard, painless ulcer develops at the site of infection after 2–4 weeks, which disappears spontaneously after 4–6 weeks.

Secondary syphilis: the infection spreads throughout the body, characterized mainly by skin manifestations - exanthema, highly infectious condylomata lata; swollen nodes occur. This stage is eventually followed by a symptomless period of several years (latency).

Tertiary syphilis: there is severe involvement of the skin, organs, heart and cardiovascular system, eyes and central nervous system.

Pregnant women with primary or secondary syphilis may transmit the infection to the fetus. A miscarriage occurs or the fetus becomes infected and affected to varying degrees (congenital syphilis).

Antigens

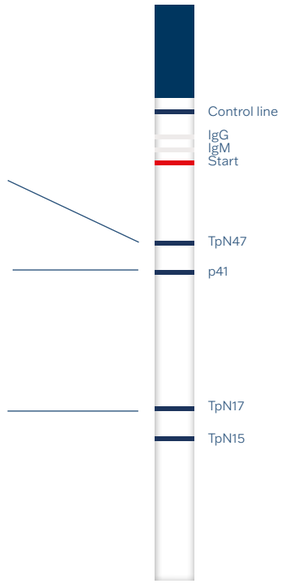
ELISA

Combination of selected parts of specific antigens *Treponema pallidum*, especially p17, p47, p41 and p15

Highly specific antigens:
TpN47
TpN17
TpN15

Specific antigen:
TpN41

IMMUNOBLOT



Antigen	Description
TpN15	Strong immunogenicity and a high antibody response No cross-reactivity with other spirochetes Common in secondary and early latent syphilis Higher incidence in patients with latent syphilis (both IgG and IgM)
TpN17	Highly specific marker for all phases of syphilis In late latent syphilis, IgG antibodies persist for the longest Strong immunogenicity and a high antibody response during syphilis infection No cross-reactivity with other spirochetal diseases
TpN47	Immunodominant antigen highly specific marker responsive in all phases of syphilis disease characteristic of IgG primary syphilis response
p41	the outer membrane protein one of the major immunogens of T. pallidum

Product information

ELISA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
EIA Treponema pallidum IgG	S, P	30-30-30/37 °C	IP	98.6 %	99.2 %
EIA Treponema pallidum IgM	S, P	30-30-30/37 °C	IP	95.7 %	95.2 %
EIA Treponema pallidum TOTAL	S, P	30-30/37 °C	IP	99.9 %	97.8 %

IMMUNOBLOT

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
BLOT-LINE Treponema IgG	S, P	10-30-30-15/RT	Viz, SwIm	98.0 %	99.9 %
BLOT-LINE Treponema IgM	S, P	10-30-30-15/RT	Viz, SwIm	97.6 %	99.9 %

S – serum | **P** – plasma | **CSF** – cerebrospinal fluid | **Syn** – synovial fluid | **RT** – laboratory temperature | **Viz** – visual evaluation | **SwIm** – software evaluation

Introduction

Yersinia are pathogenic gram-negative bacteria of the *Enterobacteriaceae* family and their representatives *Y. enterocolitica* and *Y. pseudotuberculosis* are known as human enteropathogens. Carriers are latently infected warm-blooded animals.

Infection occurs orally when contaminated water or food is ingested.

The clinical symptoms of *Y. enterocolitica* and *Y. pseudotuberculosis* infection are very similar. Differences are mostly seen in intestinal complaints, pseudoapendicitis and sepsis. The most common *Y. enterocolitica* in humans causes inflammation of the small, large or appendix accompanied by diarrhea. It can also cause inflammation joints and lymph node enlargement. Complications in the form of acute reactive arthritis, erythema nodosum, acute glomerulonephritis and myocarditis may occur during the course of infection.

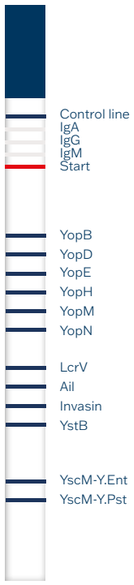
In some cases, arthritis can develop into a chronic and difficult-to-treat form. Reactive arthritis is often associated with erythema nodosum, especially in women. Symptoms on the skin appear about 1 to 6 weeks after infection. In some cases, *Yersinia enterocolitica* can also persist for years in the intestinal mucosa and in lymphoid tissues.

Antigens

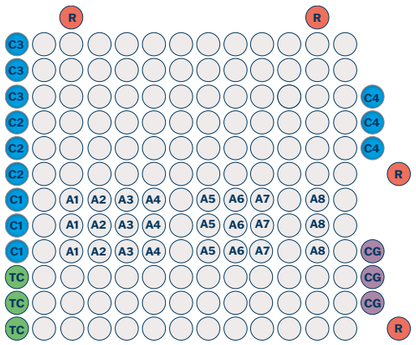
ELISA

Mixture of highly specific recombinant antigens

IMMUNOBLOT



MICROBLOT-ARRAY



Description of antigens

A1 – YopB
A2 – YopD
A3 – YopM
A4 – YopN
A5 – LcrV
A6 – Ail
A7 – Invasin
A8 – YscM

Antigen	Description
YopB	Yersinia outer protein, transmembrane protein
YopD	Yersinia outer protein, transmembrane protein
YopM	Yersinia outer protein
YopN	Yersinia outer protein
LcrV	Low calcium response Virulence, important for YopD and YopB secretion
Ail	attachment-invasion locus protein, early phase, involved in the process of adhesion and invasion and allows yersinia to survive outside the host cell, an important virulence factor
Invasin	surface adhesin, which binds to β1 integrins on the surface of target cells and exerts especially in the first phase of infection, virulence factor
YscM-Y.Ent	Yop proteins translocation protein M (specific for *Y. enterocolitica*)

Product information

ELISA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
EIA Yersinia IgA	S, P	30-30-30/37 °C	IP	98.2 %	98.1 %
EIA Yersinia IgG	S, P	30-30-30/37 °C	IP, U/ml	98.3 %	98.3 %
EIA Yersinia IgM	S, P	30-30-30/37 °C	IP	97.3 %	97.9 %

All EIA kits are available in SmartEIA for automatic processing on Agility

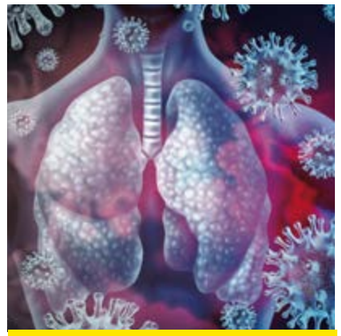
IMMUNOBLOT

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
BLOT-LINE Yersinia IgA	S, P	10-30-30-15/RT	Viz, SwIm	94.2 %	99.9 %
BLOT-LINE Yersinia IgG	S, P	10-30-30-15/RT	Viz, SwIm	97.8 %	99.9 %
BlueBLOT-LINE Yersinia IgA	S, P	30-20-10/RT	SwIm	96.4 %	99.9 %
BlueBLOT-LINE Yersinia IgG	S, P	30-20-10/RT	SwIm	96.9 %	99.9 %

S – serum | **P** – plasma | **CSF** – cerebrospinal fluid | **Syn** – synovial fluid | **RT** – laboratory temperature | **Viz** – visual evaluation | **SwIm** – software evaluation

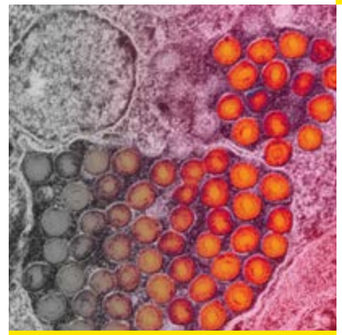
Infectious Serology – Viruses

- Adenovirus
- Covid-19
- CMV
- EBV
- HSV 1+2
- Influenza
- Measles
- Mumps
- Parainfluenza
- Parvovirus B
- RSV
- Rubella
- TBEV
- VZV

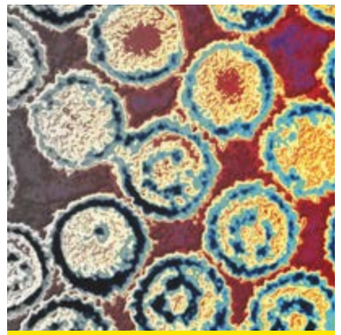


ADENOVIRUS | p. 49

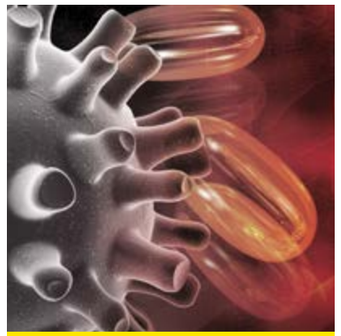
COVID-19 | p. 50



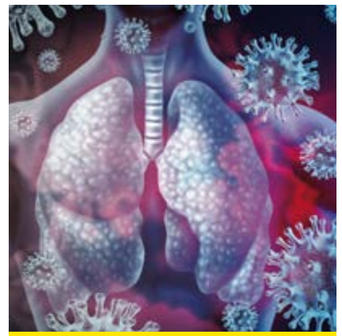
CMV | p. 54



EBV | p. 56



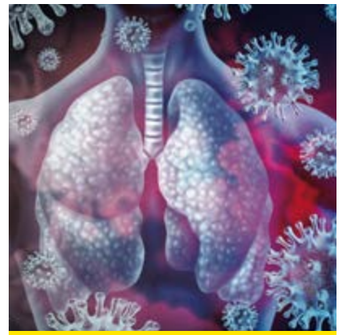
HSV 1+2 | p. 60



INFLUENZA | p. 62

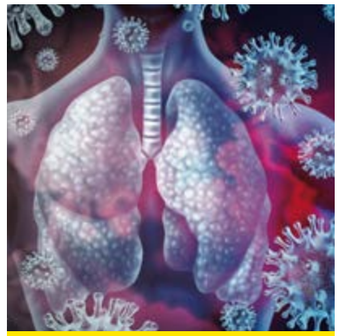
MEASLES | p. 63

MUMPS | p. 64



PARAINFLUENZA | p. 65

PARVOVIRUS | p. 66



RSV | p. 67

RUBELLA | p. 68

TBEV | p. 69

VZV | p. 70

Introduction

Adenoviruses are human and animal pathogens that are characterized by their marked stability to environmental influences and their associated complement fixation antigens. Acute adenovirus infections have an incubation period of 5 to 7 days and are spread by fecal-oral or fecal-oral transmission. Reinfections are frequent and the presence of anamnestic antibodies favours a more severe course of infection. The viruses predominantly infect the mucosa of the respiratory and digestive tracts, but also the conjunctiva and the cornea of the eye. They accumulate in epithelial cells and regional lymph nodes. Infection is most commonly manifested by respiratory tract disease (pharyngitis, tonsillitis, laryngitis, bronchitis, bronchiolitis or pneumonia). In summer, adenoviruses cause pharyngoconjunctival fevers, where the reservoir of viruses is located in the water of swimming pools, and epidemics of keratoconjunctivitis. The intestinal form of adenovirus infection occurs mainly in children under one year of age.

Antigens

ELISA

Native antigen

Product information

ELISA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
EIA Adenovirus IgA	S, P	30-30-30/37 °C	IP	96.0 %	94.9 %
EIA Adenovirus IgG	S, P	30-30-30/37 °C	IP, U/ml	97.4 %	92.3 %
EIA Adenovirus IgM	S, P	30-30-30/37 °C	IP	75.0 %	89.5 %

All EIA kits are available in SmartEIA for automatic processing on Agility

Introduction

Coronaviruses belong to the family of enveloped RNA viruses, were discovered in the 1960s and are zoonotic infections that cause respiratory and digestive tract diseases in humans and animals (birds, mammals). They cause a variety of clinical presentations, ranging from the common cold to severe respiratory syndromes (MERS, SARS and COVID-19). Most known coronaviruses circulate between animals. Alpha- and Beta-coronaviruses infect only mammals, Gamma- and Delta-coronaviruses infect both birds and mammals. Alpha- and Beta- coronaviruses are found in humans. In total, 7 species of human coronaviruses are known so far – 229E, NL63, OC43, HKU1, MERS, SARS, SARS – 2. Transmission from an infected person can occur 1–3 days before the onset of the disease. The new coronavirus is a respiratory virus; it is primarily transmitted to humans after close contact with an infected person, when infectious droplets are spread into the environment, especially when speaking, coughing and sneezing. Transmission is also possible by objects freshly contaminated with the secretions of an infected person. The virus has been isolated from samples taken from the lower respiratory tract (bronchoalveolar lavage), and viral DNA has been detected in nasopharyngeal and throat swabs, serum, blood, rectal swabs, saliva, urine and faeces.

The virus was found in respiratory samples 1–2 days before the onset of symptoms and up to 8 days after the onset in mild cases, longer in severe cases. Susceptibility appears to be universal; current information suggests that infection in children is as likely as in adults, but with milder clinical manifestations. Possible immunity to COVID-19 has not yet been established. The reported mortality rate varies from 2 to 3%.

Antigens

ELISA

EIA COVID-19 NP
Recombinant Nucleocapsid antigen (Nucleocapsid Protein)

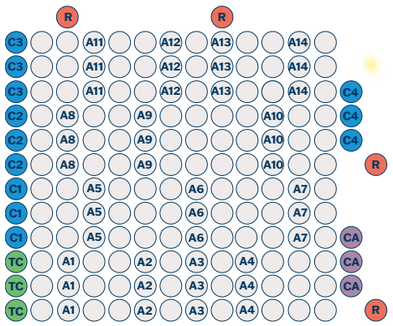
EIA COVID-19 RBD
Recombinant Receptor-binding domain (RBD) antigen and combination of S1 Spike relevant SARS-CoV-2 mutations

CLIA

CLIA COVID-19 NP IgA, IgG and IgM
Recombinant non-nucleocapsid protein (NP)

CLIA COVD-19 RBD IgA, IgG and IgM
Recombinant RBD domain of Spike S1 protein

MICROBLOT-ARRAY



Description of antigens

A1 – Nucleocapsid NCP
A2 – RBD
A3 – Spike S1
A4 – Spike S2
A5 – Spike S1 α-variant (UK)
A6 – Spike S1 γ-variant (Brazil)
A7 – Spike S1 δ-variant (Indian)
A8 – Envelope protein (E)
A9 – ACE2
A10 – PLPro protein
A11 – MERS-CoV
A12 – SARS – CoV
A13 – HCoV 229E Np
A14 – HCoV NL63 Np

Patogen	Antigen	Description
SARS-CoV-2	Nucleocapsid NP	A potent immunodominant coronavirus antigen that contains diagnostically relevant epitopes for the diagnosis of SARS-CoV-2 Sensitive detection of anti-SARS-CoV-2 IgG antibodies
	RBD	Receptor-binding domain S1 of the spike (S) subunit of the SARS-CoV-2 protein Anti-RBD SARS-CoV-2 antibodies are highly subtype specific and protective The presence of anti-RBD antibodies significantly correlates with the production of neutralizing antibodies IgA – to monitor the immune response after a positive PCR reaction; indicator of the beginning of the immune reaction IgM, IgG – detection of antibodies from 2 to 4 weeks after infection
	Spike S1	S1 subunit of the SARS-CoV-2 spike protein, contains a receptor-binding domain (RBD) through which the virus binds to the host cell surface Anti-S1 antibodies are highly subtype specific, show high sensitivity to SARS-CoV-2 and are protective
	Spike S2	S2 subunit of SARS-CoV-2 spike protein Plays an important role in the fusion of the virus with the cell membrane
	Spike S1 α-varianta	British mutation; Spike Glycoprotein S1 (B.1.1.7)
	Spike S1 γ-varianta	Brazilian mutation; Spike Glycoprotein S1 (P.1)
	Spike S1 δ-varianta	Indian mutation; Spike Glycoprotein S1 (B1.617.2)
	Envelope protein (E)	The smallest major structural protein Important for different stages of viral infection and replication, important role in the viral life cycle
Human receptor	ACE2	Angiotensin Converting Enzyme (transmembrane glycoprotein) Key component of the renin-angiotensin system Expressed in vascular endothelial cells in the heart, kidneys, but also testes, liver, intestines, lungs and brain Involved in the regulation of cardiovascular and renal
SARS-CoV-2	PLpro	functions Papain-like protease One of the basic proteins of SARS-CoV-2, essential for virus replication; deubiquitinating activity Essential for proteolysis of viral polyprotein
Other endemic coronavirues	MERS-CoV S1	Middle East Respiratory Syndrome Coronavirus S1 protein
	SARS-CoV Np	Severe Acute Respiratory Syndrome Coronavirus Nucleocapsid protein
	HCoV 229E Np	Human coronavirus 229E Nucleocapsid protein
	HCoV NL63 Np	Human coronavirus NL63 Nucleocapsid protein

Product information

ELISA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
EIA COVID-19 NP IgA	S, P	30-30-15/37 °C	IP	99.9 %	99.1 %
EIA COVID-19 NP IgG	S, P, DBS	30-30-15/37 °C	IP, U/ml	95.4 %	98.4 %
EIA COVID-19 NP IgM	S, P	30-30-15/37 °C	IP	99.9 %	95.4 %
EIA COVID-19 RBD IgA	S, P, DBS	30-30-15/37 °C	IP	98.7 %	98.7 %
EIA COVID-19 RBD IgG	S, P, DBS	30-30-15/37 °C	IP, U/ml	99.9 %	99.9 %
EIA COVID-19 RBD IgM	S, P, DBS	30-30-15/37 °C	IP	99.9 %	99.4 %

All EIA kits are available in SmartEIA for automatic processing on Agility

CLIA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
CLIA COVID-19 NP IgA	S, P	max. 40	U/ml	92.9 %	99.9 %
CLIA COVID-19 NP IgG	S, P	max. 40	U/ml	99.9 %	99.9 %
CLIA COVID-19 NP IgM	S, P	max. 40	U/ml	99.9 %	99.9 %
CLIA COVID-19 RBD IgA	S, P	max. 40	U/ml	92.9 %	99.9 %
CLIA COVID-19 RBD IgG	S, P	max. 40	U/ml	99.9 %	99.9 %
CLIA COVID-19 RBD IgM	S, P	max. 40	U/ml	96.5 %	99.9 %

Control sera are available for all CLIA kits to verify functionality and accuracy of results.

MICROBLOT-ARRAY

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
Microblot-Array COVID-19 IgA	S, P	0-30-30-15/RT °C	AU, IP, U/ml	98.3 %	99.8 %
Microblot-Array COVID-19 IgG	S, P	0-30-30-15/RT °C	AU, IP, U/ml	99.9 %	99.9 %
Microblot-Array COVID-19 IgM	S, P	0-30-30-15/RT °C	AU, IP, U/ml	97.7 %	99.3 %

S – serum | **P** – plasma | **CSF** – cerebrospinal fluid | **Syn** – synovial fluid | **RT** – laboratory temperature | **Viz** – visual evaluation | **SwIm** – software evaluation | **DBS** – dry blood spot

Introduction

Human cytomegalovirus (CMV, Human Herpesvirus 5, HHV 5) belongs to the group of herpesviruses. Primary infection with human CMV occurs most often in childhood or adolescence by various modes of transmission (respiratory, urogenital). The clinical course is usually asymptomatic or mild (fever, fatigue, symptoms of mononucleosis). After primary CMV infection, the virus enters a latent phase and subsequent reactivation (secondary infection) occurs depending on the changes in host-virus relationships (pregnancy, serious illness, stress, immunosuppressive treatment). Reinfection can occur with another strain of CMV. Primary CMV infection during pregnancy is a serious risk. Immunocompromised people (AIDS, transplant recipients, etc.) usually develop symptomatic disease with involvement of various organs, often with fatal consequences.

Antigens

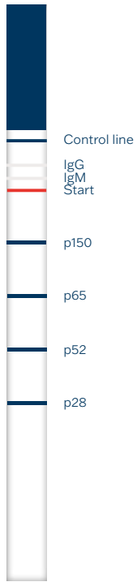
ELISA

Purified and inactivated antigen from strain AD 169 with a high content of specific immunodominant epitopes

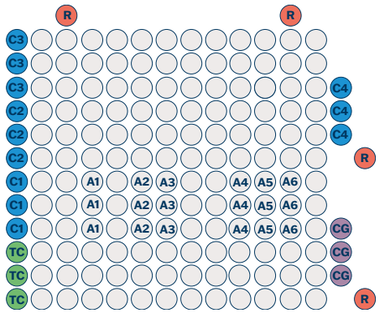
CLIA

Purified and inactivated antigen isolated from CMV strain AD 169 with high content of specific immunodominant epitopes

IMMUNOBLOT



MICROBLOT-ARRAY



Description of antigens

A1 – p150
A2 – IEA (p72)
A3 – p65
A4 – p52
A5 – p28
A6 – CMV gB

Antigen	Description
p150	Tegument protein UL32 A strong immunogen of the late phase of infection (late antigen), not present in the early phase. In the IgG class, detectable at higher titres even in reactivation.
IEA (p72)	Immediate early antigen, capsid protein UL123 Plays a role in the early phase of the human CMV replication cycle Important function in defence mechanisms against CMV infection
p65	Tegument protein UL83 In the IgM class – one of the markers of the early phase of infection In the IgG class – more typical of late stage or reactivation of infection
p52	CM2 protein; UL44 V IgM – an important marker of the early phase of primoinfection In the IgG class – reactivity rather in the late phase, possibly reactivation of infection
p28	Tegument protein UL99 Potent immunogen, may occur in late stages of infection
gB	Membrane glycoprotein B Antibody response in IgG class – about 50–100 days after primary infection.

Product information

ELISA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
EIA CMV IgA	S, P, CSF	30-30-30/37 °C	IP	94.7 %	95.8 %
EIA CMV IgG	S, P, CSF	30-30-30/37 °C	IP, U/ml	98.8 %	98.9 %
EIA CMV IgM	S, P, CSF	30-30-30/37 °C	IP	98.5 %	98.9 %

All EIA kits are available in SmartEIA for automatic processing on Agility

CLIA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
CLIA CMV IgA	S,P	max. 40	U/ml	93.8 %	94.2 %
CLIA CMV IgG	S,P	max. 40	U/ml	98.3 %	98.3 %
CLIA CMV IgM	S,P	max. 40	U/ml	93.3 %	99.3 %

Control sera are available for all CLIA kits to verify functionality and accuracy of results.

IMMUNOBLOT

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
BLOT-LINE CMV IgG	S, P	10-30-30-15/RT °C	Viz, SwIm	95.9 %	99.0 %
BLOT-LINE CMV IgM	S, P	10-30-30-15/RT °C	Viz, SwIm	96.5 %	99.0 %

MICROBLOT-ARRAY

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
Microblot-Array CMV IgG	S, P	10-30-30-15/RT °C	AU, IP, U/ml	98.1 %	99.9 %
Microblot-Array CMV IgM	S, P	10-30-30-15/RT °C	AU, IP, U/ml	96.9 %	99.1 %

S – serum | **P** – plasma | **CSF** – cerebrospinal fluid | **Syn** – synovial fluid | **RT** – laboratory temperature | **Viz** – visual evaluation | **SwIm** – software evaluation

Introduction

Epstein-Barr virus belongs to the group of herpes viruses (human herpesvirus 4, HHV4). The source of infection is an infected person, transmission occurs by droplet infection or direct contact. The incubation period is 1-2 months, 90% of infections occur in childhood. Infections caused by EB virus cause disease characterized by fever, pharyngitis, generalized lymph node enlargement. The manifestations of EB virosis are influenced by age and the state of the body's immune system. EBV does not completely disappear from the body, it persists in a latent state and can reactivate.

Antigens

ELISA

Recombinant antigens with highly specific immunodominant epitopes

CLIA

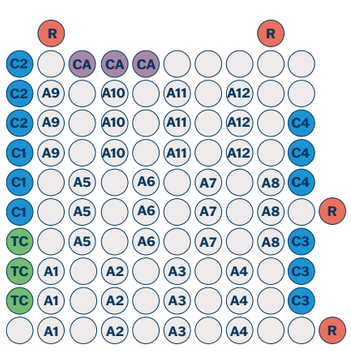
CLIA EBV EA-D IgG a IgM
Recombinant EBV antigen EA-D

CLIA EBV EBNA-1 IgG a IgM
Recombinant EBV antigen EBNA-1

CLIA EBV VCA IgA a IgM
Recombinant EBV antigen p18

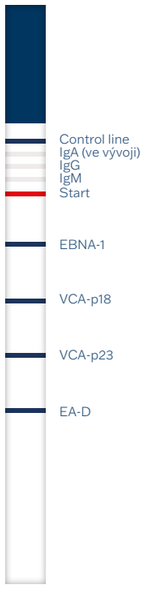
CLIA EBV VCA IgG
Combination of recombinant EBV antigens p18 and p23.

MICROBLOT-ARRAY



IMMUNOBLOT

BLOT-LINE
EBV



Description of antigens

A1 – EBNA-1
A2 – EBNA-2
A3 – VCA p18
A4 – VCA p23
A5 – EA-D p54
A6 – EA-D p138
A7 – EA-R
A8 – Rta
A9 – ZEBRA
A10 – gp85
A11 – gp350
A12 – LMP1

INFECTIOUS SEROLOGY – VIRUSES – **EBV**

Antigen	Description
EBNA-1	Epstein-Barr nuclear antigen 1 IgG: an important diagnostic marker of late phase or reactivation of infection; IgM: antibodies detectable 2-4 months after primary EBV infection, may also be present in reactivation
EBNA-2	Epstein-Barr nuclear antigen 2 IgG: high antibody titres in chronic infection or in the post-acute phase Absence of IgG anti-EBNA-2 antibodies and simultaneous presence of anti-EBNA-1 antibodies excludes primary infection
VCA p18	Viral Capsid Antigen p18; IgA: marker of primary infection; persists at high titres in patients with nasopharyngeal carcinoma IgM: indicator of primary infection; may be present during reactivation of infection IgG: Significant marker of late stage infection, antibodies are not present in primary infections
VCA p23	Viral Capsid Antigen p23 Antibodies to this antigen can be detected at all stages of infection (IgG and IgM) and persist in the body for a long time
EA-D p54	Early Antigen Diffuse p54; BMRF1 IgA: produced during primary infection; high titers in reactivation; persists at high titers in patients with nasopharyngeal carcinoma Complementary marker of acute EBV infection, detectable also in the latent phase of primary infection (IgG and IgM)
EA-D p138	Early Antigen Diffuse p138 IgA: produced during primary infection; high titers in reactivation; persists at high titers in patients with nasopharyngeal carcinoma Complementary marker of acute EBV infection, detectable also in the latent phase of primary infection (IgG and IgM)
EA-R	Early Antigen Restricted protein p85; IgG: antibodies are usually present in the later phase, virtually absent during the acute phase except in children; high levels in reactivated or immunocompromised patients
Rta	Replication and transcription Activator (BRLF1); Very early antigen IgG: a potential diagnostic marker of nasopharyngeal carcinoma
ZEBRA	From Epstein-Barr replication activator protein; Trans-activator protein BZLF1 IgM: a very early indicator of acute infection; IgG: early stage marker, but detectable in late stages of infection Serological marker of EBV reactivation, marker of EBV-associated diseases
gp85	Probable membrane antigen gp85 (BDLF3);
gp350	Epstein-Barr virus envelope glycoprotein gp350 (BLLF1); IgM: high titers in patients with infectious mononucleosis IgG: titer increase only after several months following primary infection Specific immune response for EBV-associated diseases
LMP1	Latent membrane protein 1 Commonly present in latent infections; Associated with EBV-related malignancies (nasopharyngeal carcinoma)

S – serum | **P** – plasma | **CSF** – cerebrospinal fluid | **Syn** – synovial fluid | **RT** – laboratory temperature | **Viz** – visual evaluation | **SwIm** – software evaluation

Product information

ELISA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
EIA EBV EA-D IgG	S, P	30-30-30/37 °C	IP	95.5 %	97.7 %
EIA EBV EA-D IgM	S, P	30-30-30/37 °C	IP	95.9 %	97.7 %
EIA EBV EBNA-1 IgG	S, P	30-30-30/37 °C	IP, U/ml	96.9 %	98.9 %
EIA EBV EBNA-1 IgM	S, P	10-30-30-30/37 °C	IP	97.8 %	97.7 %
EIA EBV VCA IgA	S, P, CSF	30-30-30/37 °C	IP	97.7 %	97.9 %
EIA EBV VCA IgG	S, P, CSF	30-30-30/37 °C	IP, U/ml	99.9 %	98.4 %
EIA EBV VCA IgM	S, P, CSF	10-30-30-30/37 °C	IP, U/ml	98.4 %	98.6 %

All EIA kits are available in SmartEIA for automatic processing on Agility.

CLIA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
CLIA EBV EA-D IgG	S, P	max. 40	U/ml	99.9 %	97.1 %
CLIA EBV EA-D IgM	S, P	max. 40	U/ml	96.4 %	99.9 %
CLIA EBV EBNA-1 IgG	S, P	max. 40	U/ml	99.3 %	97.9 %
CLIA EBV EBNA-1 IgM	S, P	max. 40	U/ml	95.8 %	98.4 %
CLIA EBV VCA IgA	S, P	max. 40	U/ml	99.0 %	99.0 %
CLIA EBV VCA IgG	S, P	max. 40	U/ml	99.9 %	96.8 %
CLIA EBV VCA IgM	S, P	max. 40	U/ml	99.9 %	98.4 %

Control sera are available for all CLIA kits to verify functionality and accuracy of results.

IMMUNOBLOT

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
BLOT-LINE EBV IgA	S, P	10-30-30-15/RT	Viz, SwIm	EBV 95.4 % VCA 96.4 %	EBV 98.2 % VCA 98.0 %
BLOT-LINE EBV IgG	S, P	10-30-30-15/RT	Viz, SwIm	EBV 99.9 % EBNA-1 93.8 % VCA 95.4 % EA-D 93.6 %	EBV 98.6 % EBNA-1 99.0 % VCA 99.0 % EA-D 97.9 %
BLOT-LINE EBV IgM	S, P	10-30-30-15/RT	Viz, SwIm	EBV 92.7% EBNA-1 91.3 % VCA 92.9 % EA-D 93.3 %	EBV 98.9 % EBNA-1 98.8 % VCA 98.6 % EA-D 97.4 %
BlueBLOT-LINE EBV IgG	S, P	30-20-10/RT	SwIm	EBV 98.1 % EBNA-1 93.7 % VCA 96.8 % EA-D 92.5 %	EBV 98.2 % EBNA-1 99.3 % VCA 99.9 % EA-D 99.4%
BlueBLOT-LINE EBV IgM	S, P	30-20-10/RT	SwIm	EBV 95.7 % EBNA-1 80.0 % VCA 94.6 % EA-D 91.7 %	EBV 97.5 % EBNA-1 99.9 % VCA 98.8 % EA-D 97.1 %

INFECTIOUS SEROLOGY – VIRUSES – **EBV**

MICROBLOT-ARRAY

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
Microblot-Array EBV IgA	S, P	10-30-30-15/RT °C	IP, U/ml	99.9 %	99.9 %
Microblot-Array EBV IgG	S, P	10-30-30-15/RT °C	AU, IP, U/ml	99.0 %	99.0 %
Microblot-Array EBV IgM	S, P	10-30-30-15/RT °C	IP, U/ml	99.3 %	99.9 %

S – serum | **P** – plasma | **CSF** – cerebrospinal fluid | **Syn** – synovial fluid | **RT** – laboratory temperature | **Viz** – visual evaluation | **SwIm** – software evaluation

Introduction

Herpes simplex virus comes in two types (HSV-1 and HSV-2) and belongs to the herpes virus group. Both types of viruses share common antigens and cross-react in serological tests. Only humans are the natural host of infection. Infection is spread by droplets or close personal contact. The primary sites of viral replication are the mucous membranes of the eye, mouth, nose or genitals. Primary HSV-1 infection usually occurs in childhood. HSV-1 usually infects the conjunctiva of the eye or the mucous membranes of the oral cavity. Infection is often asymptomatic or may lead to herpetic lesions. HSV-2 infection is one of the most common sexually transmitted infections in the form of genital mucosal lesions. Rarely, the fetus may be transplacentally infected; more commonly, the child is infected with cervical secretions during delivery.

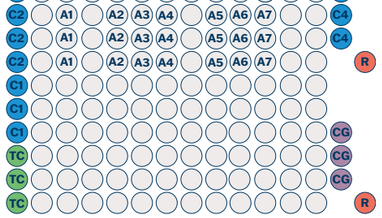
One of the most serious manifestations of HSV infection is herpetic encephalitis. A characteristic feature of HSV is its tendency to persist in the body. Under certain circumstances (stress, reduced immunity), reactivation of the virus may occur.

Antigens

ELISA/CLIA

Mixture of inactivated and purified HSV-1 and HSV-2 strains

MICROBLOT-ARRAY



Description of antigens

A1 – HSV 1+2
A2 – gC-1
A3 – gG-1
A4 – gD-1
A5 – gC-2
A6 – gG-2
A7 – gD-2

Antigen	Description
HSV 1+2	Native HSV-1 and HSV-2 antigen
gC-1 gC-2	Glycoprotein C-1 specific for Herpes simplex 1 virus; Glycoprotein C-2 specific for Herpes simplex 2 virus; Early antibody production
gD-1 gD-2	Glycoprotein D-1 specific for *Herpes simplex 1 virus*; Glycoprotein D-2 specific for *Herpes simplex 2 virus*; serves to capture and enter the virus into a potential host cell; stimulates high production of neutralizing antibodies, high similarity between HSV-1 and -2
gG-1 gG-2	Glycoprotein G-1 specific for *Herpes simplex 1 virus*; Glycoprotein G-2 specific for *Herpes simplex 2 virus*; Suitable for distinguishing HSV-1 and -2 infection; IgG: indication of ongoing or probably latent infection; antibodies are formed only in the convulsive phase, they have also been found in patients with reactivation of infection IgM: antibodies are formed only in the convulsive phase; no antibodies were found in patients with reactivation of infection

Product information

ELISA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
EIA HSV 1+2 IgG	S, P, CSF	30-30-30/37 °C	IP, U/ml	99.9 %	95.6 %
EIA HSV 1+2 IgM	S, P, CSF	10-30-30-30/37 °C	IP	96.7 %	98.8 %
EIA HSV 1 IgG	S, P	30-30-30/37°C	IP	99.9 %	96.3 %
EIA HSV 1 IgM	S, P	10-30-30-30/37°C	IP	94.6 %	96.9 %
EIA HSV 2 IgG	S, P	30-30-30/37°C	IP	95.5 %	98.2 %
EIA HSV 2 IgM	S, P	30-30-30/37°C	IP	92.3 %	98.1 %

All EIA kits are available in SmartEIA for automatic processing on Agility

CLIA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
CLIA HSV 1+2 IgG	S, P	max. 40	U/ml	89.2 %	97.5 %
CLIA HSV 1+2 IgM	S, P	max. 40	U/ml	94.6 %	87.4 %

Control sera are available for all CLIA kits to verify functionality and accuracy of results.

MICROBLOT-ARRAY

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
Microblot-Array HSV 1+2 IgG	S, P	10-30-30-15/RT °C	AU, IP, U/ml	99.9 %	97.5 %
Microblot-Array HSV 1+2 IgM	S, P	10-30-30-15/RT °C	AU, IP, U/ml	95.0 %	99.4 %

S – serum | **P** – plasma | **CSF** – cerebrospinal fluid | **Syn** – synovial fluid | **RT** – laboratory temperature | **Viz** – visual evaluation | **SwIm** – software evaluation

Introduction

Influenza A, Influenza B (influenza) is an acute respiratory viral disease with frequent epidemic occurrence in the population, especially in winter. Infection is transmitted by the droplet route. The virus spreads from the mucosa of the upper respiratory tract to the entire respiratory s y s t e m , where virulence factors allow the virus to multiply and cause inflammation of the respiratory mucosa. After an incubation period of usually 1 to 3 days, symptoms appear. The first symptoms of the disease include fever, often accompanied by chills, followed by a dry cough, sore throat, muscle and joint pain, severe fatigue and rhinitis. In the case of severe manifestations in at-risk groups, the disease may require hospitalisation.

Three types of influenza virus have been identified as causing disease in humans: A, B and C. Many antigenic variants are known. The surface antigens haemagglutinin and neuraminidase are essential for the immune response. Their antigenicity is constantly changing by mechanisms known as antigenic drift and shift. The occurrence of an epidemic or pandemic of a new influenza is particularly enhanced by antigenic variability, as new variants infect a population that is only partially immune or, in extreme cases, completely susceptible to the disease.

Determination of influenza type provides clinically and epidemiologically important data. Type B influenza is more likely to lead to a severe clinical course and epidemic spread of the virus, but unlike type A influenza, it does not lead to pandemics.

Antigens

ELISA

Influenza A – native nuclear antigen combined with recombinant haemagglutinins, updated annually (A/Brisbane/02/2018 (H1N1)-like virus, A/Kansas/14/2017/ (H3N2)-like virus)

Influenza B – native nuclear antigen combined with recombinant hemagglutinins, updated annually (B/Colorado/06/2017-like virus)

Product information

ELISA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
EIA Influenza A IgA	S, P	30-30-30/37 °C	IP	93.8 %	95.3 %
EIA Influenza A IgG	S, P	30-30-30/37 °C	IP	96.5 %	91.7 %
EIA Influenza A IgM	S, P	10-30-30-30/37 °C	IP	90.9 %	98.9 %
EIA Influenza B IgA	S, P	30-30-30/37 °C	IP	94.1 %	95.8 %
EIA Influenza B IgG	S, P	30-30-30/37 °C	IP	92.3 %	98.3 %
EIA Influenza B IgM	S, P	10-30-30-30/37 °C	IP	93.8 %	96.6 %

All EIA kits are available in SmartEIA for automatic processing on Agility

S – serum | **P** – plasma | **CSF** – cerebrospinal fluid | **Syn** – synovial fluid | **RT** – laboratory temperature | **Viz** – visual evaluation | **SwIm** – software evaluation

Introduction

Measles is a highly contagious viral infectious disease caused by measles virus, genus *Morbillivirus*, family *Paramyxoviridae*. The disease used to be one of the leading causes of death in children under 5 years of age worldwide; since the introduction of vaccination, the incidence of measles has decreased.

The only natural host of the measles virus is humans. Transmission occurs through droplet infection or direct contact with the patient. The incubation period is approximately 10 days and the first characteristic symptoms of measles include high fever, cough, conjunctivitis and rhinitis. After 3-5 days, a typical deep red rash appears in the area around the ears and gradually spreads over the face to the whole body. Characteristic white spots (Koplik spots) may appear on the inside of the cheeks. After a few days, the rash fades and gradually recedes. The most severe complications of measles include encephalitis, pneumoniae and otitis. After recovery, the patient usually acquires lifelong immunity to measles.

The main prevention of measles is universal vaccination of children with the MMR vaccine, which contains attenuated measles, mumps and rubella viruses.

Antigens

ELISA

Purified and inactivated native antigen with high content of specific immunodominant epitopes

Product information

ELISA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
EIA Measles IgG	S, P	30-30-30/37 °C	IP, IU/l	99.2 %	97.8 %
EIA Measles IgM	S, P	10-30-30-30/37 °C	IP	97.7 %	99.2 %

S – serum | **P** – plasma | **CSF** – cerebrospinal fluid | **Syn** – synovial fluid | **RT** – laboratory temperature | **Viz** – visual evaluation | **SwIm** – software evaluation

Introduction

Mumps (parotitis epidemica, mumps) is an acute viral disease caused by an RNA virus of the *Para- myxoviridae* group.

The infection is transmitted by droplets, less often by objects contaminated with saliva. The disease occurs seasonally, with the highest incidence in winter and spring, affecting mainly children aged 5–9 years and adolescents aged 15–19 years.

The incubation period of the disease is 2–3 weeks. The disease can be asymptomatic, with relatively mild non-specific symptoms (lack of appetite, increased temperature, headache) occurring mainly in children. The typical symptom of mumps is unilateral or bilateral painful swelling of the parotid salivary glands, and possibly of the sublingual or submandibular salivary glands. Complications of the disease are more common in adults, the most severe being aseptic meningitis, orchitis, oophoritis and otitis.

The main prevention of mumps is universal vaccination of children with the MMR vaccine, with the parotitic component of the vaccine inducing antibody production in about 90% of those vaccinated.

Antigens

ELISA

Purified and inactivated native antigen with high content of specific immunodominant epitopes

Product information

ELISA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
EIA Mumps IgA	S, P	30-30-30/37 °C	IP	84.0 %	99.9 %
EIA Mumps IgG	S, P	30-30-30/37 °C	IP, U/ml	98.7 %	95.7 %
EIA Mumps IgM	S, P	10-30-30-30/37 °C	IP	87.5 %	99.0 %

S – serum | **P** – plasma | **CSF** – cerebrospinal fluid | **Syn** – synovial fluid | **RT** – laboratory temperature | **Viz** – visual evaluation | **SwIm** – software evaluation

Introduction

Human parainfluenza viruses (HPIVs) belong to the subgroup of paramyxoviruses (*Respi- rovirus* and *Rubulavirus* genera) and cause infections mainly in young children, adolescents and people with weakened immune systems, but they can outbreak in anyone. Parainfluenza virus spreads in the population by airborne and droplet routes, compared to influenza virus, especially outside the winter season. They are characterised by frequent reinfections, with the vast majority of children over five years of age showing antibodies to HPIV type 3 and 75% of them also to types 1 and 2. There are four types of HPIV, termed types 1, 2, 3 and 4. Together with respiratory syncytial viruses (RS viruses), they are the main viral pathogens of respiratory tract disease. The disease is usually accompanied by severe clinical symptoms. In adults, parainfluenza virus causes febrile illness and laryngitis. The first signs include sudden headache, muscle and joint pain and fever. If the lower respiratory tract is affected, tracheobronchitis with signs of tachypnoea and dry cough develops.

HPIV type 1 causes severe pneumonia in newborns, which is characterised by high fever, dyspnoea and purulent sputum containing blood. Sometimes symptoms of meningitis also appear at the same time.

HPIV type 2 very often causes acute laryngotracheobronchitis with laryngitis (pseudocroup) in young and older children. Infection initially presents with symptoms of catarrh followed by tachypnoea, dry, barking cough and stridor.

HPIV type 3 is associated with bronchitis, bronchiolitis and pneumonia.

Antigens

ELISA

Parainfluenza mix – a combination of antigens from three individual types of parainfluenza virus (1, 2, 3)

Product information

ELISA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
EIA Parainfluenza mix IgA	S, P	30-30-30/37 °C	IP	93.8 %	94.1 %
EIA Parainfluenza mix IgG	S, P	30-30-30/37 °C	IP, U/ml	98.8 %	93.8 %
EIA Parainfluenza mix IgM	S, P	10-30-30-30/37 °C	IP	94.1 %	98.8 %

All EIA kits are available in SmartEIA for automatic processing on Agility

S – serum | **P** – plasma | **CSF** – cerebrospinal fluid | **Syn** – synovial fluid | **RT** – laboratory temperature | **Viz** – visual evaluation | **SwIm** – software evaluation

Introduction

Parvovirus B19 (Erythrovirus B19) belongs to the family *Parvoviridae*. It is a common human pathogen. Its exclusive host is humans. It is an uncoated virus with single-stranded DNA. It consists of two struc- tural proteins, VP1 and VP2, with VP2 being the major one and constituting approximately 96 % of the total viral particle. VP1 is targeted by the production of neutralising antibodies.

Infection occurs year-round with a slight increase in late spring. Transmission of infection is possible by direct contact with the patient (by droplets and orofecal route), blood derivatives or vertically from mother to fetus. In most immunocompetent individuals, infection proceeds asymptomatically or with nonspecific signs of mild upper respiratory tract infection. The virus multiplies in rapidly dividing haematopoietic cells of the bone marrow and a slight drop in haemoglobin levels may be a symptom.

Primary infection with parvovirus B19 occurs most often in childhood as the so-called fifth disease (erythema infectiosum). After an incubation period of 1-2 weeks, the first phase of infection occurs with non-specific symptoms (fever, chills, headache and muscle aches). After about two weeks, specific manifestations of the disease appear (skin exanthema, typical rash in the face, possibly joint pain). In adults, the disease may manifest as a febrile infection with marked arthralgias. In persons with haemolytic diseases, parvovirus B19 may cause aplastic crisis. Persistent infection with manifestations of chronic anaemia may occur in immunocompromised individuals. Primary infection during pregnancy is also a serious risk.

Transplacental transmission occurs in about 1/3 of infected pregnant women and can be fatal due to severe fetal anaemia (fetal hydrops, risk of fetal death).

The method of direct detection is the detection of viral DNA by PCR, while the determination of specific antibodies in human serum is used for indirect detection of the virus.

Antigens

ELISA

VP2 recombinant protein

CLIA

Recombinant protein VP2

Product information

ELISA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
EIA Parvovirus B19 IgG	S, P	30-30-30/37 °C	IP, U/ml	98.6 %	99.9 %
EIA Parvovirus B19 IgM	S, P	10-30-30-30/37 °C	IP	96.8 %	99.9 %

CLIA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
CLIA Parvovirus B19 IgG	S, P	max. 40	IU/ml	98.9 %	98.9 %
CLIA Parvovirus B19 IgM	S, P	max. 40	IU/ml	90.5 %	99.9 %

Control sera are available for all CLIA kits to verify functionality and accuracy of results.

S – serum | **P** – plasma | **CSF** – cerebrospinal fluid | **Syn** – synovial fluid | **RT** – laboratory temperature | **Viz** – visual evaluation | **SwIm** – software evaluation

Introduction

Human respiratory syncytial virus is a paramyxovirus that spreads during the winter months, especially in children and infants. The incubation period is 2 to 6 days and there is no long-term immunity after the disease. Studies in adult volunteers have shown that reinfection is possible. It is believed that anamnestic antibodies are responsible for the mild course of the disease in adults, in whom the disease mostly runs as a cold. In children, the immune system is not sufficiently mature and therefore a more severe course of infection (bronchitis, bronchiolitis, pneumonia) may occur, especially in infants. Based on antigenic variability, RS viruses are divided into two main groups (A and B). Viral surface glycoproteins (contact glycoprotein G and fusion glycoprotein F) induce the production of virusneutralizing antibodies.

G glycoproteins, unlike F glycoproteins, are highly variable.

Antigens

ELISA

RS virus – native antigen

Product information

ELISA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
EIA RSV IgA	S, P	30-30-30/37 °C	IP	95.0 %	97.2 %
EIA RSV IgG	S, P	30-30-30/37 °C	IP	97.5 %	87.5 %
EIA RSV IgM	S, P	10-30-30-30/37 °C	IP	75.0 %	95.8 %

All EIA kits are available in SmartEIA for automatic processing on Agility

S – serum | **P** – plasma | **CSF** – cerebrospinal fluid | **Syn** – synovial fluid | **RT** – laboratory temperature | **Viz** – visual evaluation | **SwIm** – software evaluation

Introduction

Rubella is an exanthematous viral disease of children and adolescents that is spread by droplet infection or transplacentally. It is usually a benign disease characterised by fever, mild signs of upper respiratory tract infection, maculopapular rash and swollen suboccipital and postauricular lymph nodes. Rubella can be very serious in the early stages of pregnancy because the virus crosses the placenta and in most cases leads to spontaneous abortion or birth defects. The fetus is most at risk when the mother becomes ill in the first trimester; the risk of damage decreases with the length of gestation.

Reinfections are more common in vaccinated than in naturally immune individuals, and most of these reinfections are asymptomatic. Rubella reinfections in pregnancy rarely result in transmission to the unborn child.

In rubella infection, specific antibodies are produced about 1 week after the viral phase of the infection has subsided. Acute infection induces the production of high levels of specific IgG and IgM antibodies. While IgM antibodies usually disappear after 2 months, IgG antibodies persist for a long time, usually for life. A significant rise in IgG antibody levels also occurs after vaccination, although the titres of these antibodies are generally lower than after natural infection.

Antigens

ELISA

Purified and inactivated antigen from HPV-77 strain with a high content of specific immunodominant epitopes

CLIA

Purified and inactivated antigen from HPV-77 strain with a high content of specific immunodominant epitopes

Product information

ELISA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
EIA Rubella IgG	S, P	30-30-30/37 °C	IP, IU/ml	97.7 %	97.3 %
EIA Rubella IgM	S, P	10-30-30-30/37 °C	IP	95.1 %	99.6 %

CLIA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
CLIA Rubella IgG	S, P	max. 40	U/ml	97.8 %	96.0 %
CLIA Rubella IgM	S, P	max. 40	U/ml	99.9 %	99.9 %

Control sera are available for all CLIA kits to verify functionality and accuracy of results.

S – serum | **P** – plasma | **CSF** – cerebrospinal fluid | **Syn** – synovial fluid | **RT** – laboratory temperature | **Viz** – visual evaluation | **SwIm** – software evaluation

Introduction

Tick-borne encephalitis is an infectious viral disease whose causative agents are arboviruses in the *Flaviviridae* family. It is a disease with a natural outbreak. The reservoir of the virus is small and larger forest animals and the vector is various developmental stages of ticks. Humans are most commonly infected after attachment (even short-term) to an infected tick, rarely by ingestion of uncooked infected milk. Most reported cases of tickborne encephalitis occur in summer and autumn. Manifest disease often has a biphasic course. After an incubation period (3-14 days), non-specific influenza-like symptoms (fever, headache and muscle aches, malaise) set in. This is followed by several days of improvement and then the development of the neural phase of the disease (severe headache, visual disturbances, vomiting, malaise, meningeal symptoms, cranial nerve involvement, limb paresis). The acute phase of tick-borne encephalitis lasts 1-3 weeks. A more severe course, often with permanent sequelae, is seen in the elderly.

Antigens

ELISA

Purified and inactivated native tick-borne encephalitis virus antigen

CLIA

TBE Virus IgG

Mixture of purified and inactivated native tick-borne encephalitis virus antigen and recombinant NS1 antigen

TBE Virus IgM

Mixture of recombinant tick-borne encephalitis virus antigens: Envelope and NS1 protei

Product information

ELISA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
EIA TBE Virus IgG	S, P, L	30-30-15/37 °C	IP, IU/ml	98.7 %	97.7 %
EIA TBE Virus IgM	S, P, L	10-30-30-15/37 °C	IP	96.6 %	98.9 %

All EIA kits are available in SmartEIA for automatic processing on Agility

CLIA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
CLIA TBE Virus IgG	S,P	max. 40	U/ml	96.0 %	99.0 %
CLIA TBE Virus IgM	S,P	max. 40	U/ml	98.0 %	97.9 %

Control sera are available for all CLIA kits to verify functionality and accuracy of results.

S – serum | **P** – plasma | **CSF** – cerebrospinal fluid | **Syn** – synovial fluid | **RT** – laboratory temperature | **Viz** – visual evaluation | **SwIm** – software evaluation

Introduction

Virus Varicella zoster (VZV, HHV-3) belongs to the group of herpes viruses and causes the infectious diseases chickenpox (primary infection) and shingles (reactivation).

Primary infection with VZV occurs most often in childhood by droplet infection. VZV is highly contagious; up to 90% of people without specific antibodies become ill after contact with an infected person. Symptoms of infection include fever, chills, stomach upset or diarrhoea, itching or skin pain at the site where the characteristic exanthema later appears. The disease usually resolves without sequelae. Primoinfections in adolescents and adults tend to be more severe, sometimes with serious complications (e.g. encephalitis, pneumonia and hepatitis), especially in immunocompromised individuals. The virus also crosses the placenta and subsequent infection of the foetus can lead to severe birth defects. If infection of a seronegative mother (without specific antibodies) occurs around the time of delivery, the newborn is at serious risk of death.

A characteristic feature of VZV is its tendency to persist in the body. When immunity is lowered, the virus may reactivate and develop shingles.

Antigens

ELISA

Purified and inactivated VZV antigen with high content of specific immunodominant epitopes

CLIA

Purified and inactivated VZV antigen with high content of specific immunodominant epitopes

Product information

ELISA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
EIA VZV IgA	S, P, L	30-30-30/37 °C	IP	99.9 %	99.9 %
EIA VZV IgG	S, P, L	30-30-30/37 °C	IP, IU/l	98.9 %	99.9 %
EIA VZV IgM	S, P, L	10-30-30-30/37 °C	IP	99.9 %	98.9 %

All EIA kits are available in SmartEIA for automatic processing on Agility

CLIA

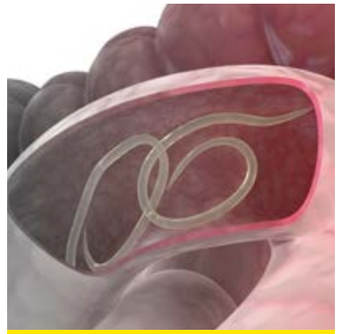
Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
CLIA VZV IgA	S, P	max. 40	U/ml	97.9 %	95.3 %
CLIA VZV IgG	S, P	max. 40	U/ml	96.6 %	97.6 %
CLIA VZV IgM	S, P	max. 40	U/ml	97.3 %	95.3 %

Control sera are available for all CLIA kits to verify functionality and accuracy of results.

S – serum | **P** – plasma | **CSF** – cerebrospinal fluid | **Syn** – synovial fluid | **RT** – laboratory temperature | **Viz** – visual evaluation | **SwIm** – software evaluation

Infectious Serology – Parasites

- Toxocara
- Toxoplasma



Toxocara | p. 74

Toxoplasma | p. 76

Introduction

Larval ***toxocariasis*** is a tissue helminthosis in which humans become paratenic (inadequate) hosts for roundworm larvae that otherwise mature in dogs (*Toxocara canis*) or cats (*Toxocara cati*).

Infection of humans occurs by ingestion of parasite eggs containing larvae. The larvae released from the eggs penetrate the mucous membrane of the digestive tract and enter the blood and lymphatic system of the host. Migrating larvae can cause severe damage to host tissues, especially the liver, kidneys, lungs, heart muscle and CNS tissues.

Visceral larva migrans (VLM) – non-specific and variable clinical signs (eosinophilia, leukocytosis, hepatomegaly, temperature, fatigue, muscle and joint pain, lymphadenopathy, abdominal pain, asthmatic symptoms, pulmonary infiltrates, skin exanthema).

Ocular larva migrans (OLM) – the presence of larvae in the eye can disrupt the retina and manifest as visual impairment, strabismus, uveitis, chorioretinitis, whitish vitreous haze, retinal ablation, etc. In some cases it can lead to blindness of one or both eyes.

Nervous larva migrans (NLM) – the presence of larvae in the peripheral or central nervous system is the cause of meningoencephalitis and other neurological manifestations (eosinophilic meningomyelitis, epileptiform conditions, cerebral vasculitis, radiculitis, paresis).

Antigeny

ELISA

Excretory-secretory antigen „ES“ prepared by incubation of *Toxocara canis* larvae

Product information

ELISA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
EIA Toxocara IgA	S, P	30-30-15/37°C	IP	95.2 %	95.8 %
EIA Toxocara IgG	S, P	30-30-15/37°C	IP	95.5 %	95.5 %

Všechny EIA soupravy jsou dostupné ve verzi SmartEIA pro automatické zpracování na Agility

S – serum | **P** – plasma | **CSF** – cerebrospinal fluid | **Syn** – synovial fluid | **RT** – laboratory temperature | **Viz** – visual evaluation | **SwIm** – software evaluation | **NTU** – NovaTec Units

Introduction

Toxoplasmosis is a parasitic disease caused by the protozoan *Toxoplasma gondii*. It is a parasite with a complex developmental cycle that o c c u r s in several morphologically distinct stages. The primary host is felids. Humans and other warm-blooded vertebrates can become infected either through primary infection of food (undercooked meat) or through ingestion of oocysts (contaminated fingers, objects, etc.).

Acquired toxoplasmosis usually occurs asymptomatically or with only mild symptoms (lymphadenopathy, subfebrile, fatigue) and without sequelae in immunocompetent individuals. More severe manifestations of the disease (encephalitis, hepatitis, myocarditis, generalised form) may occur in immunocompromised individuals who are also at risk of reactivation of latent infection.

Congenital toxoplasmosis is caused by transmission of infection from mother to fetus. Primoinfection of the mother shortly before pregnancy or during pregnancy can lead to miscarriage, stillbirth or delivery of a child with varying degrees of damage (brain calcification, hydrocephalus, visual disturbances, impaired mental development).

Antigens

ELISA

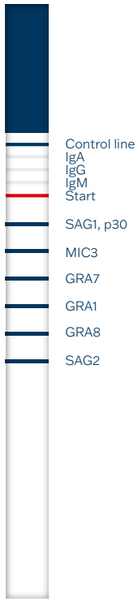
Purified and inactivated native *T. gondii* antigen (RH strain)

CLIA

Purified and inactivated native *Toxoplasma gondii* antigen (RH strain)

IMMUNOBLOT

An antigen with Mr = 30 kDa (p30) is considered specific.



SAG1 p30; a highly immunogenic surface antigen involved in the activation of a strong immune response in tachyzoites during the acute phase of toxoplasmosis. Good serological marker of anti-T. gondii antibodies in the acute and chronic phase of infection; high titres of IgG, IgM and IgA.

MIC3 p90; a potent adhesin and a major vaccine candidate. It is a dimeric 90 kDa micronemal protein rich in cysteine. It is expressed in tachyzoite, bradyzoite and sporozoite and has excellent immune properties.

GRA1 p24; a highly immunogenic protein whose reactivity is largely correlated with the chronic phase of the disease.

GRA7 p29; expressed in all infectious forms of toxoplasma. Evokes a strong antibody response in the acute phase of infection. It is considered an important diagnostic tool, also suitable for the chronic phase of infection.

GRA8 p35; highly immunogenic protein, more suitable for diagnosis of acute toxoplasmosis than chronic infection.

SAG2 p22; a major surface protein, known as the vas deferens ligand, which is characterized by good antigenicity and immunogenicity. Effective in detecting IgG antibodies in patients with acute toxoplasmosis.

Product information

ELISA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
EIA Toxoplasma IgA	S, P	60-60-20/37 °C	IP	98.3 %	99.9 %
EIA Toxoplasma IgE	S, P	60-60-20/37 °C	IP	97.5 %	99.9 %
EIA Toxoplasma IgG	S, P	60-60-20/37 °C	IP, IU/ml	98.9 %	99.9 %
EIA Toxoplasma IgM	S, P	60-60-20/37 °C	IP	94.3 %	99.9 %

All EIA kits are available in SmartEIA for automatic processing on Agility

CLIA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
CLIA Toxoplasma IgA	S, P	max. 40	IP		
CLIA Toxoplasma IgG	S, P	max. 40	IP		
CLIA Toxoplasma IgM	S, P	max. 40	IP		

Control sera are available for all CLIA kits to verify functionality and accuracy of results.

IMMUNOBLOT

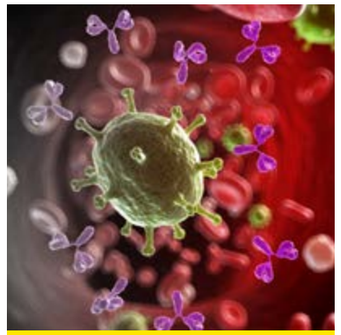
Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
BLOT-LINE Toxoplasma IgA	S, P	10-30-30-15/RT	Viz, SwIm	95.2 %	99.1 %
BLOT-LINE Toxoplasma IgG	S, P	10-30-30-15/RT	Viz, SwIm	95.6 %	98.0 %
BLOT-LINE Toxoplasma IgM	S, P	10-30-30-15/RT	Viz, SwIm	95.6 %	98.0 %

S – serum | **P** – plasma | **CSF** – cerebrospinal fluid | **Syn** – synovial fluid | **RT** – laboratory temperature | **Viz** – visual evaluation | **SwIm** – software evaluation | **NTU** – NovaTec Units

Immunology – Systemic autoimmune diseases

– ANA / ENA
– ANCA

ANA / ENA | p. 80



ANCA | p. 84

Introduction

The determination of antinuclear antibodies is important for the diagnosis of systemic autoimmune diseases. It is a group of autoantibodies directed against organ non-specific cellular antigens that are localized in the cell nucleus or cytoplasm. Their detection may indicate the presence of a systemic immunopathological process. In particular, the following diseases are involved: **systemic lupus erythematosus (SLE), Sjogren's syndrome (SjS), scleroderma, mixed connective tissue disease (MCTD), systemic sclerosis, polymyositis and dermatomyositis**.

An important separate group of antinuclear antibodies are antibodies against extractable nuclear antigens of ENA (SS-A/Ro, SS-B/La, Sm, RNP, Scl-70 and Jo-1), mainly ribonucleoproteins and nuclear enzymes.

The typing of specific autoantibodies is an important tool in the differential diagnosis of individual systemic autoimmune diseases.

Antibodies to SS-A/Ro and SS-B/La are frequently found in patients with SjS and SLE. Antibodies to Sm antigen are a highly specific marker and one of the diagnostic criteria for SLE. Antibodies to the RNP antigen (part of the Sm/RNP complex) are also frequently present in SLE patients. The presence of these antibodies is a highly specific diagnostic criterion for MCTD (especially in the absence of anti-Sm antibodies). Myositis is another group of organ-non-specific autoimmune diseases. The detection of antibodies to the Jo-1 antigen is used in their diagnosis.

Antibodies against Scl-70 and centromere B antigen are important for the diagnosis of systemic sclerosis (especially its progressive forms). Antinuclear antibodies also include antibodies against nucleic acids (ssDNA, dsDNA), nuclear protein complexes (DNP, RNP) and histones. Antibodies against double-stranded DNA (anti-dsDNA) belong to the group of antinuclear antibodies. It is a heterogeneous group of antibodies that target different epitopes on the native double-stranded DNA molecule. They are considered highly specific for systemic lupus erythematosus (SLE).

Antigens

ELISA

EIA ENA screen plus – mixture of native and recombinant antigens: Ro52/SS-A, Ro60/SS-A, La/SS-B, RNP--A, RNP-C, RNP 68, Sm, Scl 70, Jo-1 and centromere B

EIA SS-A – highly purified native SS-A/Ro60 antigen (60 kDa) and recombinant SS-A/Ro52 antigen (52 kDa)

EIA SS-A/Ro60 – highly purified native SS-A/Ro60 antigen (60 kDa)

EIA SS-A/Ro52 – recombinant SS-A/Ro52 antigen (52 kDa)

EIA SS-B – mixture of native and recombinant SS-B/La antigen

EIA Sm – native Sm antigen

EIA U1RNP – mixture of recombinant antigens RNP A, RNP C and RNP 68

EIA Scl-70 – mixture of native and recombinant Scl-70 antigen

EIA Centromere – mixture of recombinant CENP B and CENP A antigens

EIA Jo-1 – recombinant Jo-1 antigen

EIA dsDNA – purified native human dsDNA

CLIA

CLIA ENA screen plus
SS-A/Ro52, SS-A/Ro60, SS-B/La, RNP-A, RNPC, RNP68, Sm, Scl-70, Jo-1 and centromere B

CLIA dsDNA
native human dsDNA

CLIA Scl-70
mixture of native and recombinant Scl-70

CLIA SS-A
Native SS-A/Ro60 antigen (60kDa) and recombinant SS-A/Ro52 antigen (52 kDa)

CLIA SS-A/Ro60
highly purified native SS-A/Ro60 antigen (60 kDa)

CLIA U1RNP
a mixture of recombinant RNP-A, RNP-B and RNP68 antigens

CLIA Centromere
mixture of recombinant CENP B and CENP A antigens

CLIA Jo-1
recombinant Jo-1

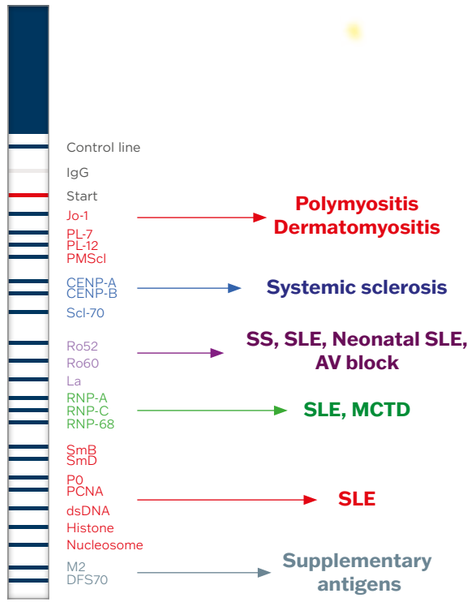
CLIA Sm
native Sm antigen

CLIA SS-A/Ro52
recombinant SS-A/Ro52 antigen (52 kDa)

CLIA SS-B
recombinant SS-B/La antigen

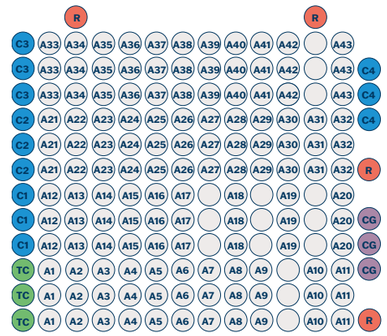
IMMUNOBLOT

BLOT-LINE ANA



MICROBLOT-ARRAY

A1 – Jo-1
A2 – PL-7
A3 – PL-12
A4 – EJ
A5 – OJ
A6 – KS
A7 – YARS (Ha)
A8 – ZoA
A9 – ZoB
A10 – HMGCR
A11 – SAE-1
A12 – SAE-2
A13 – SRP54
A14 – Mi-2
A15 – TIF1γ
A16 – MDA5
A17 – NXP2
A18 – PMScl 100
A19 – PMScl 75
A20 – M2
A21 – DFS70
A22 – Scl70
A23 – CENP A
A24 – CENP B
A25 – POLR3A
A26 – NOR90
A27 – Th/To (RPP25)
A28 – PDGFRβ
A29 – Fibrillarin
A30 – Ro52
A31 – Ro60 (SS-A)
A32 – La (SS-B)
A33 – PCNA
A34 – P0
A35 – SmB
A36 – SmD
A37 – Nucleolin
A38 – Nucleosome
A39 – Histone
A40 – RNP A
A41 – RNP 68/70
A42 – RNP C
A43 – Ku
A44 – dsDNA



Antigen	Description	Probable disease association (evaluated by SW)			
		ANA	Myositida	Scleroderma	SLE and other connective tissue diseases
Jo-1	Hystidyl tRNA synthetase	●	●		
PL-7	Threonyl tRNA synthetase	●	●		
PL-12	Alanyl tRNA synthetase	●	●		
EJ	Glycyl tRNA Synthetase	●	●		
OJ	Isoleucyl tRNA synthetase	●	●		
KS	Asparaginyl tRNA synthetase	●	●		
YARS	Tyrosyl tRNA synthetase (Ha)	●	●		
ZoA	Phenylalanyl tRNA synthetase	●	●		
ZoB	Phenylalanyl tRNA synthetase	●	●		
HMGCR	3-hydroxy-3methylglutaryl-coenzyme A reductase	●	●		
SAE-1	Small ubiquitin-like modifier activating enzyme	●	●		
SAE-2	Small ubiquitin-like modifier activating enzyme	●	●		
SRP54	Signal recognition particle	●	●		
Mi-2	Helicase protein-nuclear transcription	●	●		
TIF1γ	Transcription Intermediary Factor 1	●	●		
MDA5	Melanoma differentiation associated protein 5 (CADM-140)	●	●		
NXP2	Nuclear matrix protein 2 (p140, MJ)	●	●		
PMScl 100	Human exosome complex	●	●	●	
PMScl 75	Human exosome complex	●	●	●	
Scl70	DNA-topoisomerase I	●		●	
CENP A	Centromere A	●		●	
CENP B	Centromere B	●		●	
POLR3A	RNA polymerase III	●		●	
NOR90	Nucleolar transcription factor 1 (Ubtf1)	●		●	●
Th/To	Ribonuclease P protein subunit 25 (Rpp25)	●		●	
PDGFR-β	Platelet-derived growth factor receptor beta	●		●	
Fibrillarin	U3 RNP – fibrillarin	●		●	
Ro52	TRIM21	●	●	●	●
Ro60	Sjögren's-syndrome-related antigen A (SS-A)	●			●
La	Sjögren's-syndrome-related antigen B (SS-B)	●			●
RNP A	U1 small nuclear ribonucleoprotein A	●		●	●
RNP 68/70	U1 small nuclear ribonucleoprotein 68/70 kDa	●		●	●
RNP C	U1 small nuclear ribonucleoprotein C	●		●	●
SmB	Smith antigen B	●			●
SmD	Smith antigen D	●			●
PCNA	Proliferating cell nuclear antigen	●			●
P0	Ribosomal protein P0	●			●
Ku	Ku (p70/p80)	●	●	●	●
Nucleolin	Nucleolin	●			●
Histons	Histone	●			●
Nucleosome	Nucleosome	●			●
dsDNA	Double-stranded DNA	●			●
M2	Mitochondrial M2 (AMA-M2)	●		●	
DFS70	Dense fine speckled 70 antigen	●			

Product information

ELISA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
EIA dsDNA	S, P	30-30-15/37 °C	IP, IU/ml	97.8 %	98.7 %
EIA ENA screen plus	S, P	30-30-15/37 °C	IP	96.2 %	97.7 %
EIA ENA profile	S, P	30-30-15/37 °C	IP	97.4 %	98.6 %
EIA ENA profile plus	S, P	30-30-15/37 °C	IP	95.3 %	98.9 %
EIA SS-A	S, P	30-30-15/37 °C	IP, U/ml	95.8 %	97.5 %
EIA SS-B	S, P	30-30-15/37 °C	IP, U/ml	97.9 %	97.9 %
EIA Sm	S, P	30-30-15/37 °C	IP, U/ml	95.7 %	98.2 %
EIA U1RNP	S, P	30-30-15/37 °C	IP, U/ml	97.7 %	98.2 %
EIA Scl-70	S, P	30-30-15/37 °C	IP, U/ml	97.9 %	97.9 %
EIA Centromere	S, P	30-30-15/37 °C	IP, U/ml	96.4 %	97.9 %
EIA Jo-1	S, P	30-30-15/37 °C	IP, U/ml	95.5 %	97.9 %

CLIA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
CLIA Centromere	S, P	max. 40	U/ml	99.9 %	99.9 %
CLIA dsDNA	S, P	max. 40	U/ml	95.9 %	99.9 %
CLIA ENA Screen plus	S, P	max. 40	U/ml	95.4 %	99.3 %
CLIA Jo-1	S, P	max. 40	U/ml	99.9 %	99.9 %
CLIA Scl-70	S, P	max. 40	U/ml	99.9 %	99.9 %
CLIA Sm	S, P	max. 40	U/ml	92.7 %	99.9 %
CLIA SS-A	S, P	max. 40	U/ml	97.8 %	99.9 %
CLIA SS-A/Ro52	S, P	max. 40	U/ml	96.0 %	99.9 %
CLIA SS-A/Ro60	S, P	max. 40	U/ml	99.9 %	99.9 %
CLIA SS-B	S, P	max. 40	U/ml	91.4 %	99.9 %
CLIA U1RNP	S, P	max. 40	U/ml	99.9 %	99.0 %
CLIA Sm	S, P	max. 40	U/ml	99.9 %	99.0 %

Control sera are available for all CLIA kits to verify functionality and accuracy of results.

IMMUNOBLOT

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
BLOT-LINE ANA	S, P	10-30-30-15/RT	Viz, SwIm	97.2 %	99.1 %

MICROBLOT-ARRAY

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
Microblot-Array ANA plus	S, P	10-30-30-15/RT	AU, IP, U/ml	ANA 98.9 % Myositis 92.5 % Scleroderma 92.2 % SLE 94.6 %	ANA 99.2 % Myositis 94.4 % Scleroderma 92.3 % SLE 90.1 %

S – serum | **P** – plasma | **CSF** – cerebrospinal fluid | **Syn** – synovial fluid | **RT** – laboratory temperature | **Viz** – visual evaluation | **SwIm** – software evaluation

Introduction

Antineutrophil cytoplasmic antibodies (ANCA) are a group of antibodies directed against antigens of thecytoplasm of neutrophil granulocytes and monocytes.

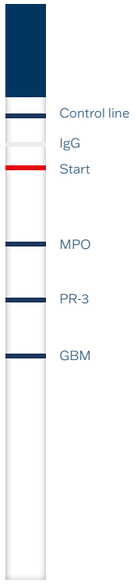
ANCA antibody testing is one of the basic tests in immunology laboratories. The determination of ANCA antibodies is of great importance, especially in suspected acute small-vessel vasculitis with severe pulmonary damage or renal failure, but also in some non-vasculitic clinical syndromes such as inflammatory bowel diseases, for example ulcerative colitis.

The most common target antigens of ANCA-associated vasculitis are myeloperoxidase and proteinase 3.

Antigens

IMMUNOBLOT

BLOT-LINE
ANCA



Antigen	Description
MPO	They are referred to as the p-ANCA subtype because they form a perinuclear fluorescent image. This fluorescent subtype of ANCA antibodies includes other antibodies such as lactoferrin, cathepsin MIT G or elastase. However, in at least 60% of p-ANCA reactivities, MPO is the main antigen. Anti-MPO antibodies are considered an important marker especially for progressive nephritis, is found to a large extent in patients with severe renal impairment. They are also important for the diagnosis of Churg-Strauss syndrome or microscopic polyangiitis.
PR3	Fluorescent subtype c-ANCA, i.e. cytoplasmic antibody (granular cytoplasmic fluorescence). PR3 is a neutral serine proteinase 3, also called Wegener's autoantigen. Antibodies to PR3 are a highly specific marker in the diagnosis of Wegener's granulomatosis. The presence or absence of antibodies to MPO and PR3 in the presence of antinuclear antibody positivity may be considered as a differential marker between ANCA-associated vasculitis and SLE-induced vasculitis.
GBM	Antibodies to GBM (glomerular basement membrane; Goodpasture's antigen) are important for the diagnosis of glomerulonephritis, which may be accompanied by pulmonary haemorrhage (Goodpasture's pulmonary syndrome). Because of similar clinical features with systemic vasculitis, it is advisable to perform anti-GBM antibody and ANCA antibody testing simultaneously. In all these cases, the activity and severity of the disease is closely correlated with the antibody concentration. Therefore, information on the antibody levels found can also be used to monitor disease progression.

Product information

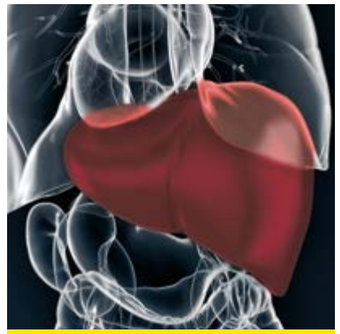
IMMUNOBLOT

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
BLOT-LINE ANCA-3	S, P	10-30-30-15/RT	Viz, SwIm	MPO 91.1 % PR3 93.5 % GBM 100.0 %	MPO 91.9 % PR3 96.7 % GBM 95.5 %

S – serum | **P** – plasma | **CSF** – cerebrospinal fluid | **Syn** – synovial fluid | **RT** – laboratory temperature | **Viz** – visual evaluation | **SwIm** – software evaluation

Immunology – Autoimmune liver diseases

- AIH
- PBC
- PSC



AIH – PBC – PSC | str. 88

Introduction

Autoimmune liver disease (ALD) is a chronic disease caused by an immune-mediated inflammatory response in genetically susceptible individuals. It is a group of complex and serious diseases affecting the immune system that lead to inflammation and damage to liver tissue. It is common that ALDs are accompanied by other autoimmune diseases affecting other organs in susceptible individuals. The ALD group includes autoimmune hepatitis types 1 and 2 (AIH1 and AIH2), along with the less common autoimmune hepatitis type 3 (AIH3), primary biliary cirrhosis (PBC), and primary sclerosing cholangitis (PSC).

Autoimmune hepatitis (AIH)

AIH type 1 is an autoimmune disease characterised by chronic inflammation of the liver. It is the predominant type of AIH and most commonly affects women between the ages of 15 and 40 but can also occur in men and other age groups. In addition to antinuclear antibodies (ANA), the main antigenic markers include anti-SLA/LP or anti-SMA antibodies.

AIH type 2 is a less common form, occurring mainly in children and adolescents, the main markers are anti-LKM-1 and anti-LC-1 antibodies.

AIH type 3 is a rare form, characterized by the presence of antibodies to SLA/LP. Clinically and therapeutically, it does not differ much from AIH1.

Primary biliary cirrhosis (PBC)

PBC is characterized by autoimmune-mediated destruction of inflamed bile ducts, predominantly affecting the small intrahepatic bile ducts. PBC primarily affects middle-aged women.

Key antigenic markers include anti-mitochondrial antibodies (AMA), particularly M2 and 3E (BPO) antibodies. In cases where patients test negative for AMA autoantibodies, positivity for autoantibodies targeting antinuclear antibodies (ANA) such as anti-gp210, anit-Sp100 or anti-Ro52 antibodies.

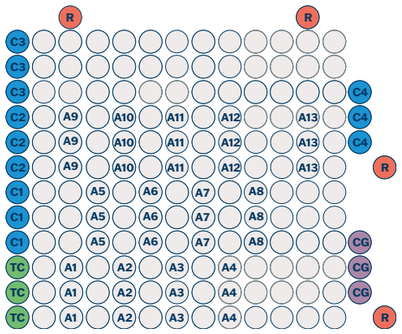
Primary sclerosing cholangitis (PSC)

PSC is autoimmune inflammation of the intrahepatic and extrahepatic bile ducts. A similar course of the disease without the autoantibodies can be induced by viruses, termed secondary cholangitis. The disease affects mostly men, especially under the age of 40. In addition to ANA and p-ANCA antibodies, anti-gp210 antibodies are important markers.

Most PSC patients are at risk of AIH and up to 30% of patients have autoimmune gastrointestinal diseases (ulcerative colitis or Crohn's disease).

Antigens

MICROBLOT-ARRAY



Description of antigens

A1 – LKM-1
A2 – LC-1
A3 – SLA/LP
A4 – ASGPR
A5 – gp210
A6 – Sp100
A7 – PML
A8 – Nup62
A9 – M2
A10 – 3E (BPO)
A11 – OGDC-E2
A12 – PDC-E2
A13 – Ro52

Product information

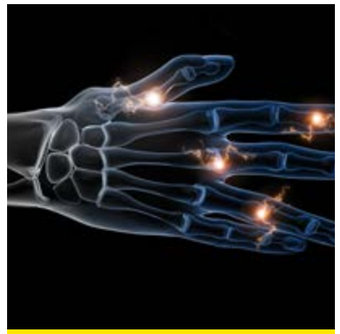
MICROBLOT-ARRAY

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
MBA Liver profile	S, P	10-30-30-15/RT	AU, IP, U/ml	99.9%	99.9%

S – serum | **P** – plasma | **CSF** – cerebrospinal fluid | **Syn** – synovial fluid | **RT** – laboratory temperature | **Viz** – visual evaluation | **SwIm** – software evaluation

Immunology – Rheumatology

- CPP
- RF



CCP – RF | p. 92

Introduction

Rheumatoid arthritis (RA) is an autoimmune disease characterized by chronic inflammation of the synovial lining in the joints eroding cartilage and bone with subsequent destruction of the joints. It affects more than 5 million people worldwide, usually occurring between the ages of 30 and 50, with up to three-quarters of all cases in women. The cause of rheumatoid arthritis is not yet fully understood. It is a multifactorial disease i n v o l v i n g interactions between a number of genes and environmental factors.

Determination of antibodies against **cyclic citrullinated peptides (CCP)** is a highly specific test allowing early diagnosis of rheumatoid arthritis. Anti-CCP antibodies can be detected several years before the clinical manifestation of the disease, their presence means a greater risk of an adverse disease course.

The most commonly used laboratory test is the determination of rheumatoid factor (RF).

Rheumatoid factors are immunoglobulins with antibody activity to the C-terminal part of the constant region of the heavy chain of human IgG, the Fc fragment. They are found in the serum of patients with rheumatoid arthritis, and with less frequency in other diseases such as Sjogren's syndrome, SLE or bacterial endocarditis. Methods based on agglutination, turbidimetry, nephelometry or ELISA are used to screen for rheumatoid factors (RF). These methods are semi-quantitative and detect mainly IgM class RFs. RFs of other classes (IgA, IgG) are not identified.

Detection of **RF of individual IgA, IgG and IgM classes** by ELISA methods allows quantitative determination with high sensitivity and specificity. RF may be present singly or in various combinations depending on clinical parameters and disease activity. A correlation between the level of RF IgA, IgG and disease prognosis has been demonstrated.

Determination of antibodies against **cyclic citrullinated peptides (CCP)** is a highly specific test allowing early diagnosis of rheumatoid arthritis. Anti-CCP antibodies can be detected several years before the clinical manifestation of the disease, and their presence implies a higher risk of an adverse disease course.

Antigens

ELISA

CCP
synthetic cyclic citrullinated peptides of the 2nd generation

RF
purified human immunoglobulin IgG

Product information

ELISA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
EIA CCP IgA	S, P	30-30-30/37 °C	IP, U/ml	98.7 %	98.9 %
EIA CCP IgG	S, P	30-30-30/37 °C	IP, U/ml	98.6 %	98.6 %
EIA RF IgA	S, P	30-30-30/37 °C	IP, U/ml	93.6 %	96.6 %
EIA RF IgG	S, P	30-30-30/37 °C	IP, U/ml	93.5 %	93.9 %
EIA RF IgM	S, P	30-30-30/37 °C	IP, U/ml	95.1 %	97.7 %

All EIA kits are available in SmartEIA for automatic processing on Agility

S – serum | **P** – plasma | **CSF** – cerebrospinal fluid | **Syn** – synovial fluid | **RT** – laboratory temperature | **Viz** – visual evaluation | **SwIm** – software evaluation

Immunology – Gastrointestinal immunology

- Celiac disease
- Gluten intolerance
- IBD (Crohn´s disease, ulcerative colitis)
- Pernicious anemia
- Milk

Celiac disease – Gluten – IBD – Pernicious anemia – Milk | p. 96

Introduction

Celiac disease (celiac sprue) is a common name for a worldwide disease affecting children and adults. It is a hereditary autoimmune disease caused by gluten intolerance. The main manifestation is inflammatory changes in the mucosa of the small intestine with diarrhoea, anaemia, weight loss and general impaired somatic and psychological development. If gluten is not permanently and completely eliminated from the diet, the immune system is depleted over time, and the disease affects other organs with the development of associated autoimmune diseases and numerous complications, most of which are life-threatening.

Gluten intolerance should not be confused with celiac disease. It may parallel cow's milk intolerance and changes in the intestinal mucosa, but without transglutaminase activation. The development of celiac disease does not occur in this case.

Cow's milk intolerance is a disease occurring in children and adults caused by intolerance to the protein components of cow's milk (casein, α-lactalbumin, β-lactoglobulin). The main manifestations are vomiting, diarrhoea, abdominal pain and possibly malabsorption syndrome.

Inflammatory Bowel Disease (IBD)

IBD includes Crohn's disease and ulcerative colitis, both causing chronic inflammation of the gastrointestinal (GI) tract with diarrhoea, abdominal pain, fatigue, weight loss, and rectal bleeding.

Crohn's disease can affect any part of the GI tract, most often the ileum and colon, involving all layers of the intestinal wall and leading to fistulas and abscesses.

Ulcerative colitis is limited to the colon and rectum, with inflammation confined to the inner lining.

Diagnosis involves clinical, laboratory, endoscopic, histological, and imaging methods. Blood antibody tests help differentiate the two: ASCA (anti Saccharomyces cerevisiae antibodies) is linked to Crohn's disease, and pANCA (MPO) to ulcerative colitis.

Autoimmune gastritis (AIG) and pernicious anemia (PA)

AIG is a chronic autoimmune disease causing destruction of gastric parietal cells, leading to gastric mucosal atrophy, low stomach acid, and intrinsic factor deficiency. This reduces vitamin B12 absorption and can result in pernicious anemia.

Diagnosis includes blood tests showing megaloblastic anemia, low B12, high homocysteine, and methylmalonic acid. Antibodies to parietal cells and intrinsic factor confirm the autoimmune cause.

Antigens

ELISA

EIA Transglutaminase
recombinant antigen (h-tTG)

EIA Gliadin DA
deamidated gliadin peptide DGPx1

EIA Gliadin
antigenic gluten extract rich in specific protein antigens, especially α-gliadin

EIA Milk
full delipidated antigen prepared from cow's milk and rich in casein, α-lactalbumin and β-lactoglobulin proteins

EIA ASCA
highly purified mannan from Saccharomyces cerevisiae

CLIA

CLIA Transglutaminase IgA, IgG
Recombinant antigen (h-tTG)

CLIA Gliadin DA IgA, IgG
Deamidated gliadin peptide DGPx1

Product information

ELISA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
EIA ASCA IgA	S, P	30-15-15/37 °C	IP, U/ml	98.5 %	98.1 %
EIA ASCA IgG	S, P	30-15-15/37 °C	IP, U/ml	98.7 %	99.1 %
EIA Gliadin IgA	S, P	30-30-15/37 °C	IP, U/ml	95.5 %	95.5 %
EIA Gliadin IgG	S, P	30-30-15/37 °C	IP, U/ml	95.5 %	95.5 %
EIA Gliadin DA IgA	S, P	30-30-15/37 °C	IP, U/ml	97.7 %	97.7 %
EIA Gliadin DA IgG	S, P	30-30-15/37 °C	IP, U/ml	97.7 %	97.7 %
EIA Milk IgA	S, P	30-30-15/37 °C	IP, U/ml	95.2 %	95.5 %
EIA Milk IgG	S, P	30-30-15/37 °C	IP, U/ml	95.0 %	95.2 %
EIA Milk IgM	S, P	30-30-15/37 °C	IP, U/ml	95.2 %	95.5 %
EIA Transglutaminase IgA	S, P	30-30-15/37 °C	IP, U/ml	97.7 %	97.7 %
EIA Transglutaminase IgG	S, P	30-30-15/37 °C	IP, U/ml	97.7 %	97.7 %

All EIA kits are available in SmartEIA for automatic processing on Agility

CLIA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
CLIA Gliadin DA IgA	S, P	max. 40	U/ml	99.9 %	99.9 %
CLIA Gliadin DA IgG	S, P	max. 40	U/ml	99.9 %	99.9 %
CLIA Transglutaminase IgA	S, P	max. 40	U/ml	99.9 %	99.9 %
CLIA Transglutaminase IgG	S, P	max. 40	U/ml	99.9 %	99.9 %

Control sera are available for all CLIA kits to verify functionality and accuracy of results.

MICROBLOT-ARRAY

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
Microblot-Array Autoimmune gastroenteritis IgA	S, P	10-30-30-15/RT	AU, IP, U/ml	??	??
Microblot-Array Autoimmune gastroenteritis IgM	S, P	10-30-30-15/RT	AU, IP, U/ml	??	??

S – serum | **P** – plasma | **CSF** – cerebrospinal fluid | **Syn** – synovial fluid | **RT** – laboratory temperature | **Viz** – visual evaluation | **SwIm** – software evaluation

Veterinary infections – Large animals

- AD
- IBR
- BVD-MD
- EBLV
- PTB

AD | p. 100

IBR | p. 101

BVD-MD | p. 102

EBLV | p. 103

PTB | p. 104

Introduction

Aujeszky's disease (Aujeszky's disease-AD) is an infectious disease of pigs caused by swine herpesvirus type 1 (SHV-1) of the family *Herpesviridae*. The disease is characterised by a biphasic course. In the acute stage, the nervous system and respiratory system are affected, and the disease is usually fatal in piglets. The pig, as the natural host and reservoir of the virus, is the vector of the virus to other susceptible animals during the latent stage of infection, in which the disease is usually fatal.

The kit is suitable for the detection of infection in breeding herds, for monitoring the effectiveness of protective vaccination and for certification of infection-free herds. The kit detects antibodies to the complete set of viral antigens (not suitable for distinguishing infected animals from animals vaccinated with the gE-vaccine). The sensitivity of the kit is set to International Standard Serum ADV-1 at a dilution of 1:8.

Antigens

ELISA

Purified and inactivated antigen
(porcine herpesvirus type 1)

Product information

ELISA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
AD Ab ELISA (Aujeszky's disease)	S	30-30-15/37 °C	S/P	99.4 %	99.0 %

S – serum | **P** – plasma | **M –** Milk | **Syn** – synovial fluid | **RT** – laboratory temperature | **Viz** – visual evaluation | **SwIm** – software evaluation

Introduction

Infectious bovine rhinotracheitis (IBR) is a disease of cattle caused by bovine herpes virus 1 (BHV 1) of the family *Herpesviridae*. Only cattle are susceptible to infection. The infectious process is either completely inapparent or manifests itself in different clinical forms. The disease is most commonly manifested as rhinotracheitis and vulvovaginitis, and reproductive disorders and abortions are also common. In infected animals, the virus induces a state of latent infection and persists in their organism without any clinical signs for life. Latent infection is accompanied by an adequate immunological response with the production of specific antibodies and irregular, intermittent shedding of virus into the external environment.

Infected animals thus become a permanent source of infection and a decisive factor in the spread of the disease. Reliable identification of these animals is an essential starting point for disease control and the implementation of a recovery programme.

Diagnosis of the disease, due to the absence of clinical signs in latently infected animals, is possible only serologically based on the positive detection of antiviral antibodies in blood serum, plasma or milk. In addition to this basic indication, i.e. searching for latently infected animals, the kit can be used to confirm clinical suspicion of disease, to verify virus circulation in livestock and to check the effectiveness of vaccination. The IBR-gB-ELISA (192) based on the blocking ELISA method is used for this purpose.

Antigens

ELISA

Purified and inactivated BHV-1 antigen

Product information

ELISA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
BHV-1 Ab ELISA (infectious bovine rhinotracheitis – IBR)	S, M	60-30-15/37 °C	S/P	99.4 %	99.2 %
IBR-gB ELISA (192) (infectious bovine rhinotracheitis)	S, P, M	720- 60-15/37 °C	% blokace	100.0 %	99.6 %

S – serum | **P** – plasma | **M –** Milk | **Syn** – synovial fluid | **RT** – laboratory temperature | **Viz** – visual evaluation | **SwIm** – software evaluation

Introduction

Bovine viral diarrhoea is a mucosal disease caused by the bovine viral diarrhoea virus (B V D V), a member of the genus *Pestivirus* in the family *Flaviviridae*. BVDV is one of the most important viral pathogens of cattle. Typical symptoms of the disease include diarrhoea and fever. A serious consequence of BVDV infection is the weakening of immunity (immunosuppression), which is a predisposing factor for the application of other pathogens with manifestations of respiratory infections, reproductive disorders, mastitis, or other intestinal diseases. The virus has the ability to cross the placenta and induces immunotolerance in fetuses infected in the first third of gestation.

Immunotolerance results in a persistent form of BVDV infection, during which animals shed the virus and are the main source of infection in the herd (persistently infected animals). These animals are serologically negative (immunotolerant). Any solution to BVDV infections is based on tracking down and removing these animals, resulting in large economic losses in cattle farms.

Diagnosis is based on the detection of specific antibodies to BVDV in bovine blood sera. The kit is used to find serologically negative (‚at risk') animals in farms with active BVDV infection. These serologically negative animals are then examined virologically to confirm persistent infection. In addition to this basic indication, i.e. searching for persistently infected animals, the TestLine BVD-MD IgG ELISA kit can be used to confirm clinical suspicion of infection, to verify the circulation of the virus in breeding stock, or to check the effectiveness of vaccination.

Antigens

ELISA

Purified and inactivated BVDV antigen

Product information

ELISA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
BVD-MD IgG ELISA (bovinní virová diarrhea – slizniční choroba)	S, M	60-30-15/37 °C	S/P	99.2 %	99.3 %

S – serum | **P** – plasma | **M –** Milk | **Syn** – synovial fluid | **RT** – laboratory temperature | **Viz** – visual evaluation | **SwIm** – software evaluation

Introduction

Enzootic bovine leukosis virus (EBLV) belongs to the family *Retroviridae*. Enzootic bovine leukosis (EBL) is an infectious disease of cattle. The virus primarily infects B lymphocytes and induces a sustained antibody response against five viral proteins. The strongest antibody response is induced against the surface glycoprotein gp-51 and the internal protein p-24. Only about 11 % of infected animals show signs of persistent lymphocytosis and lymphosarcomatosis.

Current diagnostic methods are based on the detection of specific antibodies. Among the methods routinely used are the agar gel precipitation test (AGPT) for the determination of antibodies in blood serum, ELISA or RIA methods. ELISA allows, due to its high sensitivity and specificity, the determination of antiviral antibodies in blood sera determined as negative by AGPT. The method also meets the requirements for testing mixed samples of these materials with sensitivity corresponding to the requirements of the O.I.E. (EU Directive 88/406). The kit is standardised according to international standards, including E05. The kit detects the standard O.I.E. serum labelled E05 at a dilution of 1:100, allowing the testing of ten mixed samples.

Antigens

ELISA

Purified and inactivated EBLV antigen containing p24
(internal protein)

Product information

ELISA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
EBLV Ag ELISA (enzootic bovine leukosis)	S, P	60-30-15/37 °C	S/P	99.9 %	99.8 %

S – serum | **P** – plasma | **M –** Milk | **Syn** – synovial fluid | **RT** – laboratory temperature | **Viz** – visual evaluation | **SwIm** – software evaluation

Introduction

Paratuberculosis (Johne's disease) is an economically costly disease of domestic ruminants (caused by *Mycobacterium avium* subspecies *paratuberculosis*; MAP) The causative agent causes an incurable disease in cattle with a very long incubation period of 2 years or more. The main clinical sign is watery diarrhoea with intense weight loss while maintaining food intake. The animal dies of exhaustion at an advanced stage of the disease.

During the secretion of MAP in the clinical stage of the disease, animals begin to form antibodies against the causative agent. However, these antibodies cross-react with other mycobacteria. These cross-reacting antibodies must be removed by absorption of serum/plasma and milk with M. phlei before the test is performed.

Antigens

ELISA

Purified and inactivated secretory antigen of *M. avium spp. paratuberculosis*

Product information

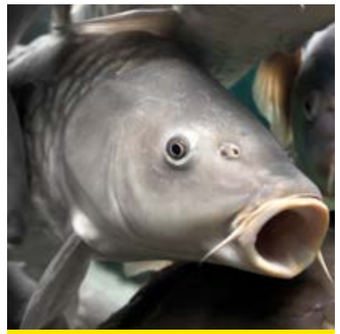
ELISA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
PTB Ab ELISA 480 (paratuberkulosis)	S, P, M	20-30-30-15/37 °C	S/P	99.3 %	99.4 %

S – serum | **P** – plasma | **M –** Milk | **Syn** – synovial fluid | **RT** – laboratory temperature | **Viz** – visual evaluation | **SwIm** – software evaluation

Veterinary infections – Fish

– IPNV / SVCV / VHSV



IPNV / SVCV / VHSV | p. 108

Introduction

IPNV – Infectious pancreatic necrosis virus (IPNV) of salmonids belongs to the family *Birnaviridae*. Salmonids, but also other marine fish and crustacean species are susceptible to the disease.

Clinical signs include: exophtalmus, enlargement of the abdominal cavity, lesions and ulcers on the pancreas, hemorrhagic changes on the skin, stomach and intestines containing milky cloudy mucus. Fish have darkly pigmented skin, swimming disorders (lying on the side near the bottom) and loss of reflexes appear.

Diagnosis is based on the detection of IPNV antigen in organ homogenates and in culture media of infected cell cultures. The sensitivity of the ELISA method (102 TCID50 per 0.1 ml of fluid examined) is sufficient for routine examination of field samples.

SVCV – The causative agent of spring viraemia disease in carp is *Rhabdovirus carpio* (SVCV), family *Rhabdoviridae*. The species is related to infectious haematopoietic necrosis virus and haemorrhagic septicaemia virus. SVCV mainly affects 1– to 2–year-old carpids. Other species of freshwater fish are also susceptible to infection. The disease is mainly widespread in Europe, but recently the virus has also appeared in Asia and America.

Spring viraemia has a wide range of clinical signs including exophtalmus, ascites (fluid in the abdominal cavity), and petechial haemorrhage into muscle and adipose tissue. Haemorrhagic changes are also present on the skin, gills, abdominal cavity. Fish have a deformed gas bladder. Further badly observed apathy, loss of reflexes, swimming and coordination disorders.

The ELISA method, based on the detection of SVCV antigen in organ homogenates and in culture media of infected cell cultures, is used for diagnosis. The sensitivity of the ELISA method (102.8-103.5 TCID50 per 0.1 ml of fluid tested) is sufficient for routine testing of field samples.

VHSV – Viral haemorrhagic septicaemia virus (VHSV) belongs to the family *Rhabdoviridae*. The species is related to infectious haematopoietic necrosis virus and carp spring viraemia virus. The virus affects more than 50 species of freshwater and marine fish. The occurrence of each strain varies geographically.

The disease may be inapparent or have a wide range of symptoms including petechial or massive bleeding on internal organs, muscles, gills and skin, exophtalmus, ascites (fluid in the abdominal cavity) and nervous system involvement.

The ELISA method based on the detection of VHSV in organ homogenates and in culture media of infected cell cultures is used in diagnostics. The sensitivity of the ELISA method (103 TCID50 per 0.1 ml of fluid tested) is sufficient for routine testing of field samples.

Product information

ELISA

Product name	Sample type	Workflow	Evaluation	Sensitivity	Specificity
IPNV Ag ELISA (infectious pancreatic necrosis virus)	HOM	60-60-10/37 °C	Abs. > 0.200	10^2TCID$_{50}$ per 1 ml investigated fluids	100.0 %
SVCV Ag ELISA (Spring Viraemia of Carp Virus)	HOM	60-60-10/37 °C	Abs. > 0.200	10^3TCID$_{50}$ per 1 ml investigated fluids	100.0 %
VHSV Ag ELISA (Viral haemorrhagic septicaemia virus)	HOM	60-60-10/37 °C	Abs. > 0.200	10^2TCID$_{50}$ per 3 ml investigated fluids	100.0 %

S – serum | **P** – plasma | **CSF** – cerebrospinal fluid | **Syn** – synovial fluid | **RT** – laboratory temperature | **Viz** – visual evaluation | **SwIm** – software evaluation

Infectious diseases

INFECTIOUS DISEASES – ELISA

Catalog number	Product name	Quantity	Type sample	Workflow	Evaluation	Other
AdA096	EIA Adenovirus IgA	96 wells	S, P	30-30-30/37 °C	IP	
AdG096	EIA Adenovirus IgG	96 wells	S, P	30-30-30/37 °C	IP	
AdM096	EIA Adenovirus IgM	96 wells	S, P	30-30-30/37 °C	IP	
BrG192	EIA Borrelia recombinant IgG (192)	192 wells	S, P, CSF, Syn	30-30-15/37 °C	IP, U/ml	AI
BrM192	EIA Borrelia recombinant IgM (192)	192 wells	S, P, CSF, Syn	30-30-15/37 °C	IP, U/ml	AI
BaGVD2	EIA Borrelia afzelii VlsE IgG (192)	192 wells	S, P, CSF, Syn	30-30-15/37 °C	IP	
BaM192	EIA Borrelia afzelii IgM (192)	192 wells	S, P, CSF, Syn	30-30-15/37 °C	IP	
BgGVD2	EIA Borrelia garinii VlsE IgG (192)	192 wells	S, P, CSF, Syn	30-30-15/37 °C	IP	AI
BgM192	EIA Borrelia garinii IgM (192)	192 wells	S, P, CSF, Syn	30-30-15/37 °C	IP	AI
BppA96	EIA Bordetella parapertussis IgA	96 wells	S, P	30-30-15/37 °C	IP	
BppG96	EIA Bordetella parapertussis IgG	96 wells	S, P	30-30-30/37°C	IP	
BppM96	EIA Bordetella parapertussis IgM	96 wells	S, P	30-30-30/37°C	IP	
BpAT96	EIA Bordetella pertussis Toxin IgA	96 wells	S, P	30-30-30/37°C	IU/ml	
BpGT96	EIA Bordetella pertussis Toxin IgG	96 wells	S, P	30-30-30/ 37°C	IU/ml	
BpMT96	EIA Bordetella pertussis Toxin IgM	96 wells	S, P	30-30-30/37°C	IP	
CoNA96	EIA COVID-19 NP IgA	96 wells	S, P	30-30-15/37°C	IP	
CoNG96	EIA COVID-19 NP IgG	96 wells	S, P, DBS	30-30-15/37°C	IP, U/ml	
CoNM96	EIA COVID-19 NP IgM	96 wells	S, P	30-30-15/37°C	IP	
CoRA96	EIA COVID-19 RBD IgA	96 wells	S, P, DBS	30-30-15/37°C	IP	
CoRG96	EIA COVID-19 RBD IgG	96 wells	S, P, DBS	30-30-15/37°C	IP, U/ml	
CoRM96	EIA COVID-19 RBD IgM	96 wells	S, P, DBS	30-30-15/37°C	IP	
CMA096	EIA CMV IgA	96 wells	S, P, CSF	30-30-30/37°C	IP	
CMG096	EIA CMV IgG	96 wells	S, P, CSF	30-30-30/37°C	IP, U/ml	Av
CMM096	EIA CMV IgM	96 wells	S, P, CSF	30-30-30/37°C	IP	RF
EAG096	EIA EBV EA-D IgG	96 wells	S, P	30-30-30/37°C	IP	
EAM096	EIA EBV EA-D IgM	96 wells	S, P	30-30-30/37°C	IP	RF
EBG096	EIA EBV EBNA-1 IgG	96 wells	S, P	30-30-30/37°C	IP, U/ml	
EBM096	EIA EBV EBNA-1 IgM	96 wells	S, P	10-30-30-30/37°C	IP	RF
VCA096	EIA EBV VCA IgA	96 wells	S, P, CSF	30-30-30/37°C	IP	
VCG096	EIA EBV VCA IgG	96 wells	S, P, CSF	30-30-30/37°C	IP, U/ml	Av
VCM096	EIA EBV VCA IgM	96 wells	S, P, CSF	10-30-30-30/37°C	IP, U/ml	RF
HSVG96	EIA HSV 1+2 IgG	96 wells	S, P, CSF	30-30-30/37°C	IP, U/ml	Av
HSVM96	EIA HSV 1+2 IgM	96 wells	S, P, CSF	10-30-30-30/37°C	IP	RF
HS1G96	EIA HSV 1 IgG	96 wells	S, P	30-30-30/37°C	IP	
HS1M96	EIA HSV 1 IgM	96 wells	S, P	10-30-30-30/37°C	IP	
HS2G96	EIA HSV 2 IgG	96 wells	S, P	30-30-30/37°C	IP	
HS2M96	EIA HSV 2 IgM	96 wells	S, P	10-30-30-30/37°C	IP	
HMA096	EIA Helicobacter MONO IgA	96 wells	S, P	30-30-15/37 °C	IP, U/ml	
HMG096	EIA Helicobacter MONO IgG	96 wells	S, P	30-30-15/37 °C	IP, U/ml	
HMM096	EIA Helicobacter MONO IgM	96 wells	S, P	30-30-15/37 °C	IP	
ChA096	EIA Chlamydia IgA	96 wells	S, P	30-30-30/37 °C	IP	
ChG096	EIA Chlamydia IgG	96 wells	S, P	30-30-30/37 °C	IP	
ChM096	EIA Chlamydia IgM	96 wells	S, P	30-30-30/37 °C	IP	
ChpA96	EIA Chlamydia pneumoniae IgA	96 wells	S, P	30-30-30/37 °C	IP, U/ml	
ChpG96	EIA Chlamydia pneumoniae IgG	96 wells	S, P	30-30-30/37 °C	IP, U/ml	
ChpM96	EIA Chlamydia pneumoniae IgM	96 wells	S, P	30-30-30/37 °C	IP	
CpAR96	EIA Chlamydia pneumoniae REC IgA	96 wells	S, P	30-30-30/37 °C	IP, U/ml	
CpGR96	EIA Chlamydia pneumoniae REC IgG	96 wells	S, P	30-30-30/37 °C	IP, U/ml	
ChtA96	EIA Chlamydia trachomatis IgA	96 wells	S, P	30-30-30/37 °C	IP, U/ml	
ChtG96	EIA Chlamydia trachomatis IgG	96 wells	S, P	30-30-30/37 °C	IP, U/ml	
ChtM96	EIA Chlamydia trachomatis IgM	96 wells	S, P	30-30-30/37 °C	IP	
InAA96	EIA Influenza A IgA	96 wells	S, P	30-30-30/37 °C	IP	
InAG96	EIA Influenza A IgG	96 wells	S, P	30-30-30/37 °C	IP	
InAM96	EIA Influenza A IgM	96 wells	S, P	10-30-30-30/37°C	IP	
InBA96	EIA Influenza B IgA	96 wells	S, P	30-30-30/37 °C	IP	
InBG96	EIA Influenza B IgG	96 wells	S, P	30-30-30/37 °C	IP	
InBM96	EIA Influenza B IgM	96 wells	S, P	10-30-30-30/37°C	IP	
MeG096	EIA Measles IgG	96 wells	S, P	30-30-30/37 °C	IP, IU/l	Av
MeM096	EIA Measles IgM	96 wells	S, P	10-30-30-30/37 °C	IP	RF
MuA096	EIA Mumps IgA	96 wells	S, P	30-30-30/37 °C	IP	
MuG096	EIA Mumps IgG	96 wells	S, P	30-30-30/37 °C	IP, U/ml	
MuM096	EIA Mumps IgM	96 wells	S, P	10-30-30-30/37 °C	IP	RF
MyA096	EIA Mycoplasma IgA	96 wells	S, P	30-30-30/37 °C	IP, U/ml	
MyG096	EIA Mycoplasma IgG	96 wells	S, P	30-30-30/37 °C	IP, U/ml	
MyM096	EIA Mycoplasma IgM	96 wells	S, P	30-30-30/37 °C	IP, U/ml	
MyAR96	EIA Mycoplasma REC IgA	96 wells	S, P	30-30-30/37 °C	IP, U/ml	
MyGR96	EIA Mycoplasma REC IgG	96 wells	S, P	30-30-30/37 °C	IP, U/ml	
MyMR96	EIA Mycoplasma REC IgM	96 wells	S, P	30-30-30/37 °C	IP, U/ml	RF
PaiA96	EIA Parainfluenza mix IgA	96 wells	S, P	30-30-30/37 °C	IP	
PaiG96	EIA Parainfluenza mix IgG	96 wells	S, P	30-30-30/37 °C	IP	
PaiM96	EIA Parainfluenza mix IgM	96 wells	S, P	10-30-30-30/37°C	IP	
PVG096	EIA Parvovirus B19 IgG	96 wells	S, P	30-30-30/37 °C	IP, IU/ml	
PVM096	EIA Parvovirus B19 IgM	96 wells	S, P	10-30-30-30/37°C	IP	
PCG096	EIA PCP IgG	96 wells	S, P	30-30-30/37 °C	IP, U/ml	
RSA096	EIA RSV IgA	96 wells	S, P	30-30-30/37 °C	IP	
RSG096	EIA RSV IgG	96 wells	S, P	30-30-30/37 °C	IP	
RSM096	EIA RSV IgM	96 wells	S, P	10-30-30-30/37°C	IP	

PRODUCT OVERVIEW

Catalog number	Product name	Quantity	Type sample	Workflow	Evaluation	Other
RubG96	EIA Rubella IgG	96 wells	S, P	30-30-30/37 °C	IP, IU/ml	Av
RubM96	EIA Rubella IgM	96 wells	S, P	10-30-30-30/37 °C	IP	RF
TBG096	EIA TBE Virus IgG	96 wells	S, P, CSF	30-30-15/37 °C	IP, U/ml	Av
TBM096	EIA TBE Virus IgM	96 wells	S, P, CSF	10-30-30-15/37 °C	IP	RF
TeTG96	EIA Tetanus Toxoid IgG	96 wells	S, P	30-30-30/37 °C	IU/ml	
TcA096	EIA Toxocara IgA	96 wells	S, P	30-30-15/37 °C	IP	Av
TcG096	EIA Toxocara IgG	96 wells	S, P	30-30-15/37 °C	IP	Av
TgA096	EIA Toxoplasma IgA	96 wells	S, P	60-60-20/37 °C	IP	Capture
TgE096	EIA Toxoplasma IgE	96 wells	S, P	60-60-20/37 °C	IP	Capture
TgG096	EIA Toxoplasma IgG	96 wells	S, P	60-60-20/37 °C	IP, IU/ml	Av
TgM096	EIA Toxoplasma IgM	96 wells	S, P	60-60-20/37 °C	IP	Capture
TpG096	EIA Treponema pallidum IgG	96 wells	S, P	30-30-30/37 °C	IP	
TpM096	EIA Treponema pallidum IgM	96 wells	S, P	30-30-30/37 °C	IP	Capture
Tp0096	EIA Treponema pallidum TOTAL	96 wells	S, P	30-30/37 °C	IP	Capture
VZVA96	EIA VZV IgA	96 wells	S, P, CSF	30-30-30/37 °C	IP	
VZVG96	EIA VZV IgG	96 wells	S, P, CSF	30-30-30/37 °C	IP, IU/l	Av
VZVM96	EIA VZV IgM	96 wells	S, P, CSF	10-30-30-30/37 °C	IP	RF
YA0096	EIA Yersinia IgA	96 wells	S, P	30-30-30/37 °C	IP	
YG0096	EIA Yersinia IgG	96 wells	S, P	30-30-30/37 °C	IP, U/ml	
YM0096	EIA Yersinia IgM	96 wells	S, P	30-30-30/37 °C	IP	

INFECTIOUS DISEASES – ELISA – SmartEIA pro Agility

Catalog number	Product name	Quantity	Type sample	Workflow	Evaluation	Other
SK-AdA096	SmartEIA Adenovirus IgA	96 wells	S, P	30-30-30/37°C	IP	
SK-AdG096	SmartEIA Adenovirus IgG	96 wells	S, P	30-30-30/37°C	IP	
SK-AdM096	SmartEIA Adenovirus IgM	96 wells	S, P	10-30-30-30/37°C	IP	
SK-BrG096	SmartEIA Borrelia recombinant IgG	96 wells	S, P, CSF, Syn	30-30-15/37 °C	IP, U/ml	AI
SK-BrM096	SmartEIA Borrelia recombinant IgM	96 wells	S, P, CSF, Syn	30-30-15/37 °C	IP, U/ml	AI
SK-BaGV96	SmartEIA Borrelia afzelii VlsE IgG	96 wells	S, P, CSF, Syn	30-30-15/37 °C	IP	
SK-BaM096	SmartEIA Borrelia afzelii IgM	96 wells	S, P, CSF, Syn	30-30-15/37 °C	IP	
SK-BsGV96	SmartEIA Borrelia b. sensu stricto VlsE IgG	96 wells	S, P, CSF, Syn	30-30-15/37 °C	IP	
SK-BsM096	SmartEIA Borrelia b. sensu stricto IgM	96 wells	S, P, CSF, Syn	30-30-15/37 °C	IP	
SK-BgGV96	SmartEIA Borrelia garinii VlsE IgG	96 wells	S, P, CSF, Syn	30-30-15/37 °C	IP	AI
SK-BgM096	SmartEIA Borrelia garinii IgM	96 wells	S, P, CSF, Syn	30-30-15/37 °C	IP	AI
SK-BppA96	SmartEIA Bordetella parapertussis IgA	96 wells	S, P	30-30-30/37 °C	IP	
SK-BppG96	SmartEIA Bordetella parapertussis IgG	96 wells	S, P	30-30-30/37 °C	IP	
SK-BppM96	SmartEIA Bordetella parapertussis IgM	96 wells	S, P	30-30-30/37 °C	IP	
SK-BpAT96	SmartEIA Bordetella pertussis Toxin IgA	96 wells	S, P	30-30-30/37 °C	IU/ml	
SK-BpGT96	SmartEIA Bordetella pertussis Toxin IgG	96 wells	S, P	30-30-30/37 °C	IU/ml	
SK-BpMT96	SmartEIA Bordetella pertussis Toxin IgM	96 wells	S, P	30-30-30/37 °C	IP	

Catalog number	Product name	Quantity	Type sample	Workflow	Evaluation	Other
SK-CMA096	SmartEIA CMV IgA	96 wells	S, P, CSF	30-30-30/37 °C	IP	
SK-CMG096	SmartEIA CMV IgG	96 wells	S, P, CSF	30-30-30/37 °C	IP, U/ml	Av
SK-CMM096	SmartEIA CMV IgM	96 wells	S, P, CSF	30-30-30/37 °C	IP	RF
SK-EAG096	SmartEIA EBV EA-D IgG	96 wells	S, P	30-30-30/37 °C	IP	
SK-EAM096	SmartEIA EBV EA-D IgM	96 wells	S, P	30-30-30/37 °C	IP	RF
SK-EBG096	SmartEIA EBV EBNA-1 IgG	96 wells	S, P	30-30-30/37 °C	IP, U/ml	
SK-EBM096	SmartEIA EBV EBNA-1 IgM	96 wells	S, P	30-30-30/37 °C	IP	RF
SK-VCA096	SmartEIA EBV VCA IgA	96 wells	S, P, CSF	30-30-30/37 °C	IP	
SK-VCG096	SmartEIA EBV VCA IgG	96 wells	S, P, CSF	30-30-30/37 °C	IP, U/ml	Av
SK-VCM096	SmartEIA EBV VCA IgM	96 wells	S, P, CSF	30-30-30/37 °C	IP	RF
SK-HSVG96	SmartEIA HSV 1+2 IgG	96 wells	S, P, CSF	30-30-30/37 °C	IP, U/ml	Av
SK-HSVM96	SmartEIA HSV 1+2 IgM	96 wells	S, P, CSF	30-30-30/37 °C	IP	RF
SK-HS1G96	SmartEIA HSV 1 IgG	96 wells	S, P	30-30-30/37 °C	IP	
SK-HS1M96	SmartEIA HSV 1 IgM	96 wells	S, P	10-30-30-30/37°C	IP	
SK-HS2G96	SmartEIA HSV 2 IgG	96 wells	S, P	30-30-30/37 °C	IP	
SK-HS2M96	SmartEIA HSV 2 IgM	96 wells	S, P	10-30-30-30/37°C	IP	
SK-HMA096	SmartEIA Helicobacter MONO IgA	96 wells	S, P	30-30-15/37 °C	IP, U/ml	
SK-HMG096	SmartEIA Helicobacter MONO IgG	96 wells	S, P	30-30-15/37 °C	IP, U/ml	
SK-ChA096	SmartEIA Chlamydia IgA	96 wells	S, P	30-30-30/37 °C	IP	
SK-ChG096	SmartEIA Chlamydia IgG	96 wells	S, P	30-30-30/37 °C	IP	
SK-ChM096	SmartEIA Chlamydia IgM	96 wells	S, P	30-30-30/37 °C	IP	
SK-ChpA96	SmartEIA Chlamydia pneumoniae IgA	96 wells	S, P	30-30-30/37 °C	IP, U/ml	
SK-ChpG96	SmartEIA Chlamydia pneumoniae IgG	96 wells	S, P	30-30-30/37 °C	IP, U/ml	
SK-ChpM96	SmartEIA Chlamydia pneumoniae IgM	96 wells	S, P	30-30-30/37 °C	IP	
SK-CpAR96	SmartEIA Chlamydia pneumoniae REC IgA	96 wells	S, P	30-30-30/37 °C	IP, U/ml	
SK-CpGR96	SmartEIA Chlamydia pneumoniae REC IgG	96 wells	S, P	30-30-30/37 °C	IP, U/ml	
SK-ChtA96	SmartEIA Chlamydia trachomatis IgA	96 wells	S, P	30-30-30/37 °C	IP, U/ml	
SK-ChtG96	SmartEIA Chlamydia trachomatis IgG	96 wells	S, P	30-30-30/37 °C	IP, U/ml	
SK-ChtM96	SmartEIA Chlamydia trachomatis IgM	96 wells	S, P	30-30-30/37 °C	IP	
SK-InAA96	SmartEIA Influenza A IgA	96 wells	S, P	30-30-30/37°C		
SK-InAG96	SmartEIA Influenza A IgG	96 wells	S, P	30-30-30/37°C		
SK-InAM96	SmartEIA Influenza A IgM	96 wells	S, P	10-30-30-30/37°C		
SK-InBA96	SmartEIA Influenza B IgA	96 wells	S, P	30-30-30/37°C		
SK-InBG96	SmartEIA Influenza B IgG	96 wells	S, P	30-30-30/37°C		
SK-InBM96	SmartEIA Influenza B IgM	96 wells	S, P	10-30-30-30/37°C		
SK-MeG096	SmartEIA Measles IgG	96 wells	S, P	30-30-30/37 °C	IP, IU/l	Av
SK-MeM096	SmartEIA Measles IgM	96 wells	S, P	30-30-30/37 °C	IP	RF
SK-MuA096	SmartEIA Mumps IgA	96 wells	S, P	30-30-30/37 °C	IP	
SK-MuG096	SmartEIA Mumps IgG	96 wells	S, P	30-30-30/37 °C	IP, U/ml	
SK-MuM096	SmartEIA Mumps IgM	96 wells	S, P	10-30-30-30/37 °C	IP	RF
SK-MyA096	SmartEIA Mycoplasma IgA	96 wells	S, P	30-30-30/37 °C	IP, U/ml	

PRODUCT OVERVIEW

Catalog number	Product name	Quantity	Type sample	Workflow	Evaluation	Other
SK-MyG096	SmartEIA Mycoplasma IgG	96 wells	S, P	30-30-30/37 °C	IP, U/ml	
SK-MyM096	SmartEIA Mycoplasma IgM	96 wells	S, P	30-30-30/37 °C	IP, U/ml	
SK-MyAR96	SmartEIA Mycoplasma REC IgA	96 wells	S, P	30-30-30/37 °C	IP, U/ml	
SK-MyGR96	SmartEIA Mycoplasma REC IgG	96 wells	S, P	30-30-30/37 °C	IP, U/ml	
SK-MyMR96	SmartEIA Mycoplasma REC IgM	96 wells	S, P	30-30-30/37 °C	IP, U/ml	RF
SK-PaiA96	SmartEIA Parainfluenza mix IgA	96 wells	S, P	30-30-30/37°C	IP	
SK-PaiG96	SmartEIA Parainfluenza mix IgG	96 wells	S, P	30-30-30/37°C	IP	
SK-PaiM96	SmartEIA Parainfluenza mix IgM	96 wells	S, P	10-30-30-30/37°C	IP	
SK-PCG096	SmartEIA PCP IgG	96 wells	S, P	30-30-30/37 °C	IP, U/ml	
SK-RSA096	SmartEIA RSV IgA	96 wells	S, P	30-30-30/37°C	IP	
SK-RSG096	SmartEIA RSV IgG	96 wells	S, P	30-30-30/37°C	IP	
SK-RSM096	SmartEIA RSV IgM	96 wells	S, P	10-30-30-30/37°C	IP	
SK-RubG96	SmartEIA Rubella IgG	96 wells	S, P	30-30-30/37 °C	IP, IU/ml	Av
SK-RubM96	SmartEIA Rubella IgM	96 wells	S, P	30-30-30/37 °C	IP	RF
SK-TBG096	SmartEIA TBE Virus IgG	96 wells	S, P, CSF	30-30-15/37 °C	IP, U/ml	Av
SK-TBM096	SmartEIA TBE Virus IgM	96 wells	S, P, CSF	30-30-15/37 °C	IP	RF
SK-TeTG96	SmartEIA Tetanus Toxoid IgG	96 wells	S, P	30-30-30/37 °C	IU/ml	
SK-TcA096	SmartEIA Toxocara IgA	96 wells	S, P	30-30-15/37 °C	IP	
SK-TcG096	SmartEIA Toxocara IgG	96 wells	S, P	30-30-15/37 °C	IP	Av
SK-TgA096	SmartEIA Toxoplasma IgA	96 wells	S, P	60-60-20/37 °C	IP	Capture
SK-TgE096	SmartEIA Toxoplasma IgE	96 wells	S, P	60-60-20/37 °C	IP	Capture
SK-TgG096	SmartEIA Toxoplasma IgG	96 wells	S, P	60-60-20/37 °C	IP, IU/ml	Av
SK-TgM096	SmartEIA Toxoplasma IgM	96 wells	S, P	60-60-20/37 °C	IP	Capture
SK-TpG096	SmartEIA Treponema pallidum IgG	96 wells	S, P	30-30-30/37 °C	IP	
SK-TpM096	SmartEIA Treponema pallidum IgM	96 wells	S, P	30-30-30/37 °C	IP	Capture
SK-Tp0096	SmartEIA Treponema pallidum TOTAL	96 wells	S, P	30-30/37 °C	IP	Capture
SK-VZVA96	SmartEIA VZV IgA	96 wells	S, P, CSF	30-30-30/37 °C	IP	
SK-VZVG96	SmartEIA VZV IgG	96 wells	S, P, CSF	30-30-30/37 °C	IP, IU/l	Av
SK-VZVM96	SmartEIA VZV IgM	96 wells	S, P, CSF	30-30-30/37 °C	IP	RF
SK-YeA096	SmartEIA Yersinia IgA	96 wells	S, P	30-30-30/37 °C	IP	
SK-YeG096	SmartEIA Yersinia IgG	96 wells	S, P	30-30-30/37 °C	IP, U/ml	
SK-YeM096	SmartEIA Yersinia IgM	96 wells	S, P	30-30-30/37 °C	IP	

INFECTIOUS DISEASES – CLIA

Catalog number	Product name	Quantity	Type sample	Workflow	Evaluation
CL-BCSFG50	CLIA Borrelia CSF IgG	50 tests	S, P, L	max. 40	AU/ml
CL-BCSFM50	CLIA Borrelia CSF IgM	50 tests	S, P, L	max. 40	AU/ml
CL-BRG100	CLIA Borrelia recombinant IgG	100 tests	S, P	max. 40	U/ml
CL-BRM100	CLIA Borrelia recombinant IgM	100 tests	S, P	max. 40	U/ml
CL-CMA100	CLIA CMV IgA	100 tests	S, P	max. 40	U/ml
CL-CMG100	CLIA CMV IgG	100 tests	S, P	max. 40	U/ml
CL-CMM100	CLIA CMV IgM	100 tests	S, P	max. 40	U/ml
CL-CoNA100	CLIA COVID-19 NP IgA	100 tests	S, P	max. 40	U/ml
CL-CoNG100	CLIA COVID-19 NP IgG	100 tests	S, P	max. 40	U/ml
CL-CoNM100	CLIA COVID-19 NP IgM	100 tests	S, P	max. 40	U/ml
CL-CoRA100	CLIA COVID-19 RBD IgA	100 tests	S, P	max. 40	U/ml
CL-CoRG100	CLIA COVID-19 RBD IgG	100 tests	S, P	max. 40	U/ml
CL-CoRM100	CLIA COVID-19 RBD IgM	100 tests	S, P	max. 40	U/ml
CL-EAG100	CLIA EBV EA-D IgG	100 tests	S, P	max. 40	U/ml
CL-EAM100	CLIA EBV EA-D IgM	100 tests	S, P	max. 40	U/ml
CL-EBG100	CLIA EBV EBNA-1 IgG	100 tests	S, P	max. 40	U/ml
CL-EBM100	CLIA EBV EBNA-1 IgM	100 tests	S, P	max. 40	U/ml
CL-VCA100	CLIA EBV VCA IgA	100 tests	S, P	max. 40	U/ml
CL-VCG100	CLIA EBV VCA IgG	100 tests	S, P	max. 40	U/ml
CL-VCM100	CLIA EBV VCA IgM	100 tests	S, P	max. 40	U/ml
CL-HMA100	CLIA Helicobacter MONO IgA	100 tests	S, P	max. 40	U/ml
CL-HMG100	CLIA Helicobacter MONO IgG	100 tests	S, P	max. 40	U/ml
CL-HSVG100	CLIA HSV 1+2 IgG	100 tests	S, P	max. 40	U/ml
CL-HSVM100	CLIA HSV 1+2 IgM	100 tests	S, P	max. 40	U/ml
CL-CPA100	CLIA Chlamydia pneumoniae IgA	100 tests	S, P	max. 40	U/ml
CL-CPG100	CLIA Chlamydia pneumoniae IgG	100 tests	S, P	max. 40	U/ml
CL-CPM100	CLIA Chlamydia pneumoniae IgM	100 tests	S, P	max. 40	U/ml
CL-ChtA100	CLIA Chlamydia trachomatis IgA	100 tests	S, P	max. 40	U/ml
CL-ChtG100	CLIA Chlamydia trachomatis IgG	100 tests	S, P	max. 40	U/ml
CL-ChtM100	CLIA Chlamydia trachomatis IgM	100 tests	S, P	max. 40	U/ml
CL-MyA100	CLIA Mycoplasma IgA	100 tests	S, P	max. 40	U/ml
CL-MyG100	CLIA Mycoplasma IgG	100 tests	S, P	max. 40	U/ml
CL-MyM100	CLIA Mycoplasma IgM	100 tests	S, P	max. 40	U/ml
CL-PVG050	CLIA Parvovirus B19 IgG	50 tests	S, P	max. 40	IU/ml
CL-PVM050	CLIA Parvovirus B19 IgM	50 tests	S, P	max. 40	IU/ml
CL-RubG100	CLIA Rubella IgG	100 tests	S, P	max. 40	U/ml
CL-RubM100	CLIA Rubella IgM	100 tests	S, P	max. 40	U/ml
CL-TBG100	CLIA TBE Virus IgG	100 tests	S, P	max. 40	U/ml
CL-TBM050	CLIA TBE Virus IgM	50 tests	S, P	max. 40	U/ml
CL-TeTG100	CLIA Tetanus Toxoid IgG	100 tests	S, P	max. 40	IU/ml
CL-TgA100	CLIA Toxoplasma IgA	100 tests	S, P	max. 40	IU/ml
CL-TgG100	CLIA Toxoplasma IgG	100 tests	S, P	max. 40	IU/ml
CL-TgM100	CLIA Toxoplasma IgM	100 tests	S, P	max. 40	IU/ml
CL-VZVA100	CLIA VZV IgA	100 tests	S, P	max. 40	U/ml
CL-VZVG100	CLIA VZV IgG	100 tests	S, P	max. 40	IU/ml
CL-VZVM100	CLIA VZV IgM	100 tests	S, P	max. 40	U/ml

PRODUCT OVERVIEW

INFECTIOUS DISEASES – IMMUNOBLOT

Catalog number	Product name	Quantity	Type sample	Workflow	Evaluation
ApGL10	BLOT-LINE Anaplasma IgG	10 tests	S, P	10-30-30-15/RT	Viz, SwIm
ApML10	BLOT-LINE Anaplasma IgM	10 tests	S, P	10-30-30-15/RT	Viz, SwIm
BGL020	BLOT-LINE Borrelia/HGA IgG	20 tests	S, P, CSF, Syn	10-30-30-15/RT	Viz, SwIm
BML020	BLOT-LINE Borrelia/HGA IgM	20 tests	S, P, CSF, Syn	10-30-30-15/RT	Viz, SwIm
BaGL20	BLOT-LINE Borrelia afzelii IgG	20 tests	S, P	10-30-30-15/RT	Viz, SwIm
BaML20	BLOT-LINE Borrelia afzelii IgM	20 tests	S, P	10-30-30-15/RT	Viz, SwIm
BgGL20	BLOT-LINE Borrelia garinii IgG	20 tests	S, P, CSF	10-30-30-15/RT	Viz, SwIm
BgML20	BLOT-LINE Borrelia garinii IgM	20 tests	S, P, CSF	10-30-30-15/RT	Viz, SwIm
BsGL20	BLOT-LINE Borrelia b.sensu stricto IgG	20 tests	S, P, Syn	10-30-30-15/RT	Viz, SwIm
BsML20	BLOT-LINE Borrelia b.sensu stricto IgM	20 tests	S, P, Syn	10-30-30-15/RT	Viz, SwIm
BpAL20	BLOT-LINE Bordetella IgA	20 tests	S, P	10-30-30-15/RT	Viz, SwIm
BpGL20	BLOT-LINE Bordetella IgG	20 tests	S, P	10-30-30-15/RT	Viz, SwIm
CMGL20	BLOT-LINE CMV IgG	20 tests	S, P	10-30-30-15/RT	Viz, SwIm
CMML20	BLOT-LINE CMV IgM	20 tests	S, P	10-30-30-15/RT	Viz, SwIm
EBAL20	BLOT-LINE EBV IgA	20 tests	S, P	10-30-30-15/RT	Viz, SwIm
EBGL20	BLOT-LINE EBV IgG	20 tests	S, P	10-30-30-15/RT	Viz, SwIm
EBML20	BLOT-LINE EBV IgM	20 tests	S, P	10-30-30-15/RT	Viz, SwIm
HpAL20	BLOT-LINE Helicobacter IgA	20 tests	S, P	10-30-30-15/RT	Viz, SwIm
HpGL20	BLOT-LINE Helicobacter IgG	20 tests	S, P	10-30-30-15/RT	Viz, SwIm
CAL020	BLOT-LINE Chlamydia IgA	20 tests	S, P	10-30-30-15/RT	Viz, SwIm
CGL020	BLOT-LINE Chlamydia IgG	20 tests	S, P	10-30-30-15/RT	Viz, SwIm
CpAL20	BLOT-LINE Chlamydia pneumoniae IgA	20 tests	S, P	10-30-30-15/RT	Viz, SwIm
CpGL20	BLOT-LINE Chlamydia pneumoniae IgG	20 tests	S, P	10-30-30-15/RT	Viz, SwIm
CpML20	BLOT-LINE Chlamydia pneumoniae IgM	20 tests	S, P	10-30-30-15/RT	Viz, SwIm
CtAL20	BLOT-LINE Chlamydia trachomatis IgA	20 tests	S, P	10-30-30-15/RT	Viz, SwIm
CtGL20	BLOT-LINE Chlamydia trachomatis IgG	20 tests	S, P	10-30-30-15/RT	Viz, SwIm
MyAL20	BLOT-LINE Mycoplasma IgA	20 tests	S, P	10-30-30-15/RT	Viz, SwIm
MyGL20	BLOT-LINE Mycoplasma IgG	20 tests	S, P	10-30-30-15/RT	Viz, SwIm
MyML20	BLOT-LINE Mycoplasma IgM	20 tests	S, P	10-30-30-15/RT	Viz, SwIm
TcGB16	BLOT-LINE Toxocara IgG	16 tests	S, P	10-60-60-10/RT	Viz, SwIm
TgAB16	BLOT-LINE Toxoplasma IgA	16 tests	S, P	10-60-60-10/RT	Viz, SwIm
TgGB16	BLOT-LINE Toxoplasma IgG	16 tests	S, P	10-60-60-10/RT	Viz, SwIm
TgMB16	BLOT-LINE Toxoplasma IgM	16 tests	S, P	10-60-60-10/RT	Viz, SwIm
TpGL20	BLOT-LINE Treponema IgG	20 tests	S, P	10-30-30-15/RT	Viz, SwIm
TpML20	BLOT-LINE Treponema IgM	20 tests	S, P	10-30-30-15/RT	Viz, SwIm
YAL020	BLOT-LINE Yersinia IgA	20 tests	S, P	10-30-30-15/RT	Viz, SwIm
YGL020	BLOT-LINE Yersinia IgG	20 tests	S, P	10-30-30-15/RT	Viz, SwIm

INFECTIOUS DISEASES – IMMUNOBLOT FOR BLUEDIVER

Catalog number	Product name	Quantity	Type sample	Workflow	Evaluation
BD- BGL024	BlueBLOT-LINE Borrelia IgG	24 tests	S, P, CSF, Syn	30-20-10/RT	SwIm
BD- BML024	BlueBLOT-LINE Borrelia IgM	24 tests	S, P, CSF, Syn	30-20-10/RT	SwIm
BD-BpAL24	BlueBLOT-LINE Bordetella IgA	24 tests	S, P	30-20-10/RT	SwIm
BD-BpGL24	BlueBLOT-LINE Bordetella IgG	24 tests	S, P	30-20-10/RT	SwIm
BD-BpML24	BlueBLOT-LINE Bordetella IgM	24 tests	S, P	30-20-10/RT	SwIm
BD-EBGL24	BlueBLOT-LINE EBV IgG	24 tests	S, P	30-20-10/RT	SwIm
BD-EBML24	BlueBLOT-LINE EBV IgM	24 tests	S, P	30-20-10/RT	SwIm
BD-CAL024	BlueBLOT-LINE Chlamydia IgA	24 tests	S, P	30-20-10/RT	SwIm
BD-CGL024	BlueBLOT-LINE Chlamydia IgG	24 tests	S, P	30-20-10/RT	SwIm
BD-YAL024	BlueBLOT-LINE Yersinia IgA	24 tests	S, P	30-20-10/RT	SwIm
BD-YGL024	BlueBLOT-LINE Yersinia IgG	24 tests	S, P	30-20-10/RT	SwIm

INFECTIOUS DISEASES – MICROBLOT-ARRAY

Catalog number	Product name	Quantity	Type sample	Workflow	Evaluation
BpAMA48	Microblot-Array Bordetella IgA	96 tests	S, P	10-30-30-15/RT	AU, IP, U/ml
BpGMA48	Microblot-Array Bordetella IgG	96 tests	S, P	10-30-30-15/RT	AU, IP, U/ml
BpMMA48	Microblot-Array Bordetella IgM	96 tests	S, P	10-30-30-15/RT	AU, IP, U/ml
BGMA096	Microblot-Array Borrelia IgG	96 tests	S, P, CSF, Syn	10-30-30-15/RT	AU, IP, U/ml
BMMA096	Microblot-Array Borrelia IgM	96 tests	S, P, CSF, Syn	10-30-30-15/RT	AU, IP, U/ml
CMGMA48	Microblot-Array CMV IgG	96 tests	S, P	10-30-30-15/RT	AU, IP, U/ml
CMMMA48	Microblot-Array CMV IgM	96 tests	S, P	10-30-30-15/RT	AU, IP, U/ml
CoVAMA96	Microblot-Array COVID-19 IgA	96 tests	S, P	10-30-30-15/RT	AU, IP, U/ml
CoVGMA96	Microblot-Array COVID-19 IgG	96 tests	S, P	10-30-30-15/RT	AU, IP, U/ml
CoVMMA96	Microblot-Array COVID-19 IgM	96 tests	S, P	10-30-30-15/RT	AU, IP, U/ml
EBAMA96	Microblot-Array EBV IgA	96 tests	S, P	10-30-30-15/RT	AU, IP, U/ml
EBGMA96	Microblot-Array EBV IgG	96 tests	S, P	10-30-30-15/RT	AU, IP, U/ml
EBMMA96	Microblot-Array EBV IgM	96 tests	S, P	10-30-30-15/RT	AU, IP, U/ml
HpAMA48	Microblot-Array Helicobacter IgA	48 tests	S, P	10-30-30-15/RT	AU, IP, U/ml
HpGMA48	Microblot-Array Helicobacter IgG	48 tests	S, P	10-30-30-15/RT	AU, IP, U/ml
HSGMA48	Microblot-Array HSV 1+2 IgG	48 tests	S, P	10-30-30-15/RT	AU, IP, U/ml
HSMMA48	Microblot-Array HSV 1+2 IgM	48 tests	S, P	10-30-30-15/RT	AU, IP, U/ml
CAMA096	MicroBlot-Array Chlamydia IgA	96 tests	S, P	10-30-30-15/RT	AU, IP, U/ml
CGMA096	MicroBlot-Array Chlamydia IgG	96 tests	S, P	10-30-30-15/RT	AU, IP, U/ml
MyAMA48	Microblot-Array Mycoplasma IgA	48 tests	S, P	10-30-30-15/RT	AU, IP, U/ml
MyGMA48	Microblot-Array Mycoplasma IgG	48 tests	S, P	10-30-30-15/RT	AU, IP, U/ml
MyMMA48	Microblot-Array Mycoplasma IgM	48 tests	S, P	10-30-30-15/RT	AU, IP, U/ml
YAMA048	Microblot-Array Yersinia IgA	48 tests	S, P	10-30-30-15/RT	AU, IP, U/ml
YGMA048	Microblot-Array Yersinia IgG	48 tests	S, P	10-30-30-15/RT	AU, IP, U/ml

Immunology

IMMUNOLOGY – ELISA

Catalog number	Product name	Quantity	Type sample	Workflow	Evaluation
ScA096	EIA ASCA IgA	96 wells	S,P	30-15-15/37 °C	IP, U/ml
ScG096	EIA ASCA IgG	96 wells	S,P	30-15-15/37 °C	IP, U/ml
CCPA96	EIA CCP IgA	96 wells	S,P	30-30-30/37 °C	IP, U/ml
CCPG96	EIA CCP IgG	96 wells	S,P	30-30-30/37 °C	IP, U/ml
DNA096	EIA dsDNA	96 wells	S,P	30-30-15/37 °C	IP, IU/ml
ENAp12	EIA ENA profile plus	96 wells	S,P	30-30-15/37 °C	IP
ENA096	EIA ENA screen plus	96 wells	S,P	30-30-15/37 °C	IP
GDA096	EIA Gliadin DA IgA	96 wells	S,P	30-30-15/37 °C	IP, U/ml
GDG096	EIA Gliadin DA IgG	96 wells	S,P	30-30-15/37 °C	IP, U/ml
GlA096	EIA Gliadin IgA	96 wells	S,P	30-30-15/37 °C	IP, U/ml
GlG096	EIA Gliadin IgG	96 wells	S,P	30-30-15/37 °C	IP, U/ml
Jo1096	EIA Jo-1	96 wells	S,P	30-30-15/37 °C	IP, U/ml
MiA096	EIA Milk IgA	96 wells	S,P	30-30-15/37 °C	IP, U/ml
MiG096	EIA Milk IgG	96 wells	S,P	30-30-15/37 °C	IP, U/ml
MiM096	EIA Milk IgM	96 wells	S,P	30-30-15/37 °C	IP, U/ml
PCG096	EIA PCP IgG	96 wells	S,P	30-30-15/37 °C	IP, U/ml
RFA096	EIA RF IgA	96 wells	S,P	30-30-15/37 °C	IP, U/ml
RFG096	EIA RF IgG	96 wells	S,P	30-30-15/37 °C	IP, U/ml
RFM096	EIA RF IgM	96 wells	S,P	30-30-15/37 °C	IP, U/ml
Scl096	EIA Scl-70	96 wells	S,P	30-30-15/37 °C	IP, U/ml
Sm0096	EIA Sm	96 wells	S,P	30-30-15/37 °C	IP, U/ml
SSA096	EIA SS-A	96 wells	S,P	30-30-15/37 °C	IP, U/ml
SSB096	EIA SS-B	96 wells	S,P	30-30-15/37 °C	IP, U/ml
tTA096	EIA Transglutaminase IgA	96 wells	S,P	30-30-15/37 °C	IP, U/ml
tTG096	EIA Transglutaminase IgG	96 wells	S,P	30-30-15/37 °C	IP, U/ml
RNP096	EIA U1RNP	96 wells	S,P	30-30-15/37 °C	IP, U/ml

IMMUNOLOGY – ELISA – SmartEIA FOR AGILITY

Catalog number	Product name	Quantity	Type sample	Workflow	Evaluation
SK-ScA096	SmartEIA ASCA IgA	96 wells	S,P	30-30-15/37 °C	IP, U/ml
SK-ScG096	SmartEIA ASCA IgG	96 wells	S,P	30-30-15/37 °C	IP, U/ml
SK-CCPA96	SmartEIA CCP IgA	96 wells	S,P	30-30-30/37 °C	IP, U/ml
SK-CCPG96	SmartEIA CCP IgG	96 wells	S,P	30-30-30/37 °C	IP, U/ml
SK-DNA096	SmartEIA dsDNA	96 wells	S,P	30-30-15/37 °C	IP, IU/ml
SK-ENAp12	SmartEIA ENA profile plus	96 wells	S,P	30-30-15/37 °C	IP
SK-ENA096	SmartEIA ENA screen plus	96 wells	S,P	30-30-15/37 °C	IP
SK-GDA096	SmartEIA Gliadin DA IgA	96 wells	S,P	30-30-15/37 °C	IP, U/ml
SK-GDG096	SmartEIA Gliadin DA IgG	96 wells	S,P	30-30-15/37 °C	IP, U/ml
SK-GlA096	SmartEIA Gliadin IgA	96 wells	S,P	30-30-15/37 °C	IP, U/ml
SK-GlG096	SmartEIA Gliadin IgG	96 wells	S,P	30-30-15/37 °C	IP, U/ml
SK-Jo1096	SmartEIA Jo-1	96 wells	S,P	30-30-15/37 °C	IP, U/ml
SK-MiA096	SmartEIA Milk IgA	96 wells	S,P	30-30-15/37 °C	IP, U/ml
SK-MiG096	SmartEIA Milk IgG	96 wells	S,P	30-30-15/37 °C	IP, U/ml
SK-MiM096	SmartEIA Milk IgM	96 wells	S,P	30-30-15/37 °C	IP, U/ml
SK-PCG096	SmartEIA PCP IgG	96 wells	S,P	30-30-15/37 °C	IP, U/ml
SK-RFA096	SmartEIA RF IgA	96 wells	S,P	30-30-15/37 °C	IP, U/ml
SK-RFG096	SmartEIA RF IgG	96 wells	S,P	30-30-15/37 °C	IP, U/ml
SK-RFM096	SmartEIA RF IgM	96 wells	S,P	30-30-15/37 °C	IP, U/ml
SK-Scl096	SmartEIA Scl-70	96 wells	S,P	30-30-15/37 °C	IP, U/ml
SK-Sm0096	SmartEIA Sm	96 wells	S,P	30-30-15/37 °C	IP, U/ml
SK-SSA096	SmartEIA SS-A	96 wells	S,P	30-30-15/37 °C	IP, U/ml
SK-SSB096	SmartEIA SS-B	96 wells	S,P	30-30-15/37 °C	IP, U/ml
SK-tTA096	SmartEIA Transglutaminase IgA	96 wells	S,P	30-30-15/37 °C	IP, U/ml
SK-tTG096	SmartEIA Transglutaminase IgG	96 wells	S,P	30-30-15/37 °C	IP, U/ml
SK-RNP096	SmartEIA U1RNP	96 wells	S,P	30-30-15/37 °C	IP, U/ml

IMMUNOLOGY – CERTIFIED CONTROL SERA FOR ELISA

Catalog number	Product name	Quantity
XXXTLN	CKS TLN as listed at www.testlinecd.cz	3,5 ml
XXXTLP	CKS TLP as listed at www.testlinecd.cz	3,5 ml

IMMUNOLOGY – CLIA

Catalog number	Product name	Quantity	Type sample	Workflow	Evaluation
CL-CEN050	CLIA Centromere	50 tests	S, P	max. 40	U/ml
CL-DNA050	CLIA dsDNA	50 tests	S, P	max. 40	U/ml
CL-ENA100	CLIA ENA Screen plus	100 tests	S, P	max. 40	U/ml
CL-GDA100	CLIA Gliadin DA IgA	100 tests	S, P	max. 40	U/ml
CL-GDG100	CLIA Gliadin DA IgG	100 tests	S, P	max. 40	U/ml
CL-Jo1050	CLIA Jo-1	50 tests	S, P	max. 40	U/ml
CL-Scl050	CLIA Scl-70	50 tests	S, P	max. 40	U/ml
CL-Sm0050	CLIA Sm	50 tests	S, P	max. 40	U/ml
CL-SSA050	CLIA SS-A	50 tests	S, P	max. 40	U/ml
CL-Ro5250	CLIA SS-A/Ro52	50 tests	S, P	max. 40	U/ml
CL-Ro6050	CLIA SS-A/Ro60	50 tests	S, P	max. 40	U/ml
CL-SSB050	CLIA SS-B	50 tests	S, P	max. 40	U/ml

PRODUCT OVERVIEW

CL-tTA100	CLIA Transglutaminase IgA 100	100 tests	S, P	max. 40	U/ml
CL-tTG100 CLIA	Transglutaminase IgG 100	100 tests	S, P	max. 40	U/ml
CL-RNP050	CLIA U1RNP	50 tests	S, P	max. 40	U/ml

IMMUNOLOGY – IMMUNOBLOT

Catalog number	Product name	Quantity	Type sample	Workflow	Evaluation
ANAL20	BLOT-LINE ANA	20 tests	S,P	10-30-30-15/RT	Viz,SwIm
ANC3L20	BLOT-LINE ANCA-3	20 tests	S,P	10-30-30-15/RT	Viz,SwIm

IMMUNOLOGY – MICROBLOT-ARRAY

Catalog number	Product name	Quantity	Type sample	Workflow	Evaluation
ANApMA96	Microblot-Array ANA plus	96 tests	S, P	10-30-30-15/RT	AU, IP, U/ml
LKMMA48	Microblot-Array Liver profile	48 tests	S, P	10-30-30-15/RT	AU, IP, U/ml
AIGAMA48	Microblot-Array Autoimmune gastroenteritis IgA	48 tests	S, P	10-30-30-15/RT	AU, IP, U/ml
	Microblot-Array Autoimmune gastroenteritis IgG	48 tests	S, P	10-30-30-15/RT	AU, IP, U/ml

Veterinary infectious diseases

VETERINARY INFECTIOUS DISEASES – ELISA

Catalog number		Quantity	Type sample	Workflow	Evaluation
AD0480	AD Ab ELISA (Aujeszky's disease)	480 wells	S	30-30-15	S/P
BHd480	BHV-1 Ab ELISA (infectious bovine rhinotracheitis – IBR)	480 wells	S, M	60-30-15	S/P
IBR192	IBR-gB ELISA (192) (infectious bovine rhinotracheitis)	192 wells	S, P, M	720- 60-15	% blocking
BVD480	BVD-MD IgG ELISA (bovine viral diarrhoea – mucosal disease)	480 wells	S, M	60-30-15	S/P
EBL480	EBLV Ag ELISA (enzootic bovine leukosis)	480 wells	S	60-30-15	S/P
PTB480	PTB Ab ELISA 480 (bovine paratuberculosis)	480 wells	S, P, M	20-30-30-15	S/P
IPN096	IPNV Ag ELISA (infectious salmonid pancreatic necrosis)	96 wells	HOM	60-60-10	Abs. > 0,200
SVC096	SVCV Ag ELISA (spring viraemia of carp)	96 wells	HOM	60-60-10	Abs. > 0,200
VHS096	VHSV Ag ELISA (viral haemorrhagic septicaemia in trout)	96 wells	HOM	60-60-10	Abs. > 0,200
DBGM96	Dog EIA Borrelia IgG/IgM (canine borreliosis)	48/48 wells	S	30-30-10	IP

Instruments

INSTRUMENTS – ELISA, MICROBLOT-ARRAY

Catalog number	Product name
67000	Agility
62010	DS2
65400	DSX
9162800000	Gemini
WR-302-02	Ledetect 96
30203095	Freedom EVOlyzer
HydroFlex Plus	Hydroflex
30183570	Infinite F50
ARCXIX096	MBA reader

INSTRUMENTS – IMMUNOBLOT

Catalogue number	Product name
BLUEDIVER 1.0	BlueDiver
RBT-001	RoboBlot

INSTRUMENTS – CONSUMABLES – ELISA, MICROBLOT-ARRAY

Catalog number	Product name	Quantity
vp0025	Tray for pipetting with 8 and 12 channel pipette	25 pcs
62910	Strip for dilution of 8 samples for Agility, DSX, DS2 (250)	250 pcs

PRODUCT OVERVIEW

Catalog number	Product name	Quantity
67910	Agility Sample Tip (896)	896 pcs
67920	Agility reagent tip (490)	490 pcs
67960	Bronze SmartKit Agililty – Vessel for Sample Dilution Solution	50 pcs
65940	Bronze SmartKit Agility – control bottle	33 pcs
65950	Bronze SmartKit Agility – reagent bottle	24 pcs
65910	DSX/DS2 sample tips	4 x 108 pcs
65920	DSX/DS2 reagent tips	4 x 108 pcs

INSTRUMENTS – CONSUMABLES – IMMUNOBLOT

Catalog number	Product name	Quantity
vb1010	Tray for westernblots (for 10 WB strips)	10 pcs
vb2025	Tray for AutoBlot 3000 (for 20 WB strips)	25 pcs
vb4805	Tray for ProfiBlot 48 (for 48 WB strips)	5 pcs
RB-s05024	Reagent tip for RoboBlot, 5 ml	24 pcs
RB-s01192	Sample tip for RoboBlot, 1 ml	192 pcs
RB-vb5010	Tray for RoboBlot (50 strips)	10 pcs

Other

OTHER – BACTERIOLOGICAL DIAGNOSTICS

Catalog number	Product name	Quantity
Ps0050	PYRstrip (Dg. test for pyrrolidonyl peptidase activity of S. pyogenes)	50 tests
Ts0300	TRIBUstrip (Dg. test to distinguish Moraxella from Neisseria)	300 tests
Ut0050	UREASAtest 50 (Dg. medium for determination of urease activity of H.pylori)	50 tests
Utb100	UREASAtest bulk (Dg. medium for determination of urease activity of H.pylori)	100 tests
LM0020	LEPTOSPIRA – MEDIUM (liquid Korthof medium)	20 x 3 ml
LMm020	LEPTOSPIRA-MEDICATED MEDIUM (Korthof's medium for the recovery of contaminated cultures)*	20 x 3 ml

Explanation:
S – serum, **P** – plasma, **L** – liquor, **Syn** – synovial fluid, **M** – milk, **HOM** – tissue homogenate, **RT** – laboratory temperature, **Viz** – visual assessment, **SwIm** – software evaluation, **IP** – Positivity Index, **AI** – Antibody Index, **Av** – Avidity,, **RF** – saturation RF

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