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TestLine results in External Quality Assessments

Q1-Q2 2024





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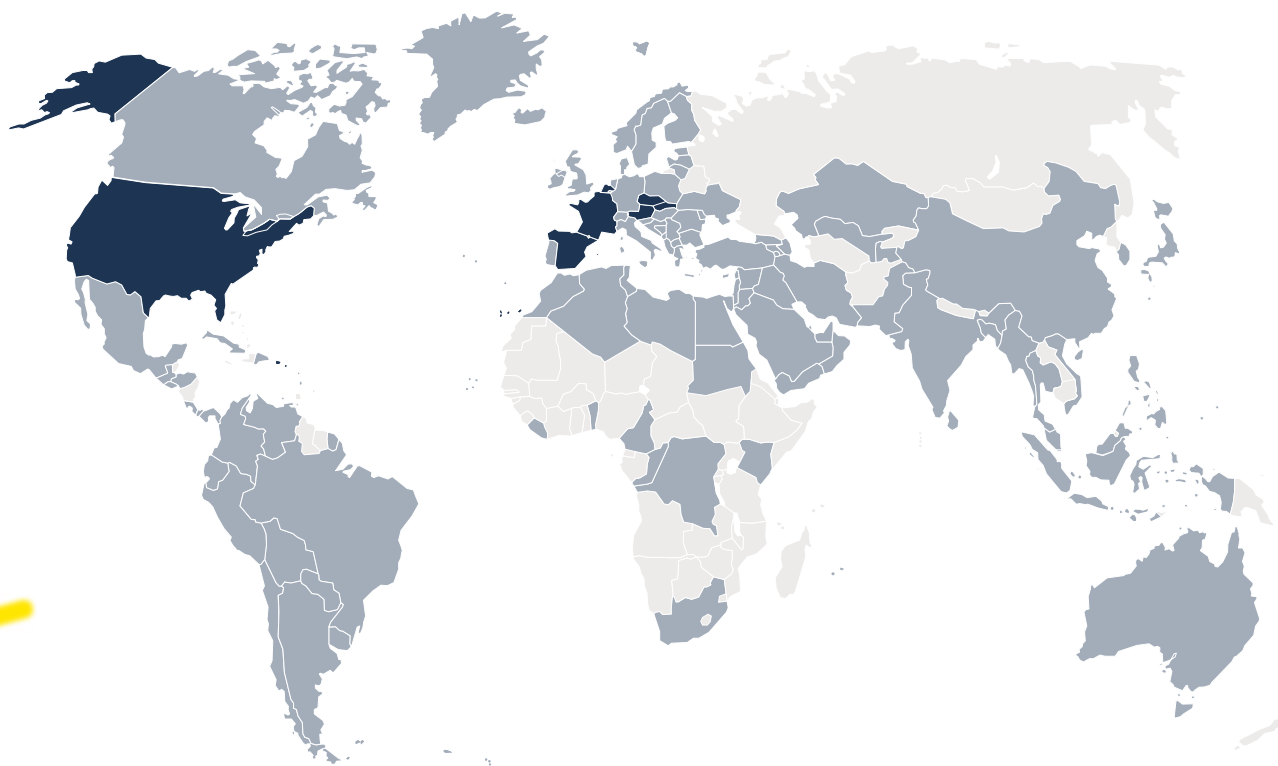
Company profile

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

- Companies and branches
- Distribution
- without representation



History

🏠 Foundation | 🤝 Acquisition



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

Our quality management system is certified according to ISO 9001:2015 and ISO 13485:2016 by the renowned company LRQA.



IVDR and Notified Body

Products placed on the market after May 26, 2022, are certified in accordance with Regulation (EU) 2017/746 of the European Parliament and Council on in vitro diagnostic medical devices (IVDR) with the involvement of the notified body 3EC International a.s. Other products are gradually being recertified during the transitional period.



Company highlights



150+
employees

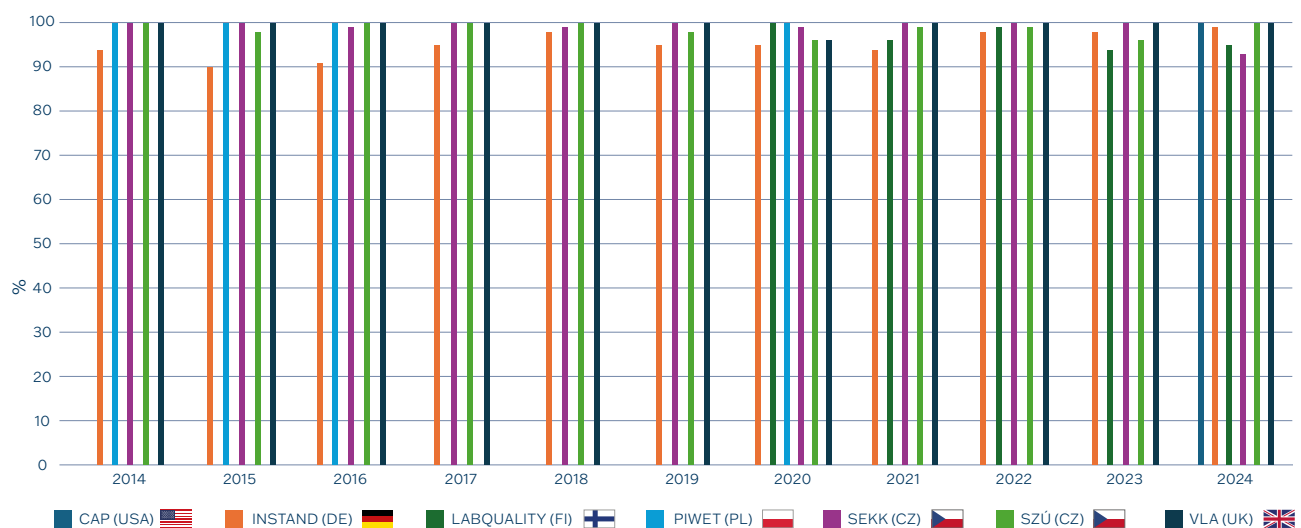


IVDR
certification



450+
products

TestLine overall success rate in EQA

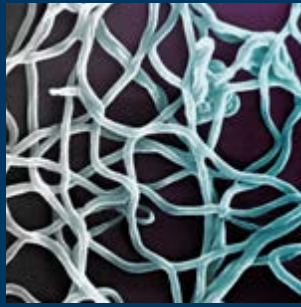




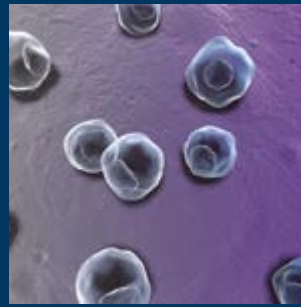
INFECTIOUS SEROLOGY – BACTERIA



BORDETELLA page 9



BORRELIA page 10



CHLAMYDIA page 13



HELICOBACTER page 15



TETANUS page 17

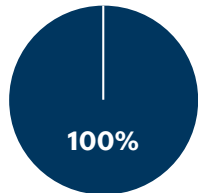


TREPONEMA page 18



YERSINIA page 19

Bordetella

[See related products on web](#)**LABQUALITY – 05.2024**

EIA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgA	negative	negative	+
IgA	negative	negative	+
IgG	negative	negative	+
IgG	negative	negative	+
IgM	negative	negative	+
IgM	negative	negative	+

Immunoblot

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgA	negative	negative	+
IgA	negative	negative	+
IgG	negative	negative	+
IgG	negative	negative	+
IgM	negative	negative	+
IgM	negative	negative	+

Microblot-Array

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgA	negative	negative	+
IgA	negative	negative	+
IgG	negative	negative	+
IgG	negative	negative	+
IgM	negative	negative	+
IgM	negative	negative	+

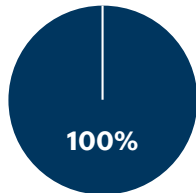
Clinical evaluation

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
Interpretation	no evidence of infection	no evidence of infection	+
Interpretation	no evidence of infection	no evidence of infection	+

Borrelia

[See related products on web](#)

LABQUALITY – 03.2024



CLIA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	positive	positive	+
IgG	positive	positive	+
IgM	positive, negative	negative	+
IgM	positive, borderline	positive	+

EIA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	positive	positive	+
IgG	positive	positive	+
IgM	positive, negative	positive	+
IgM	positive, borderline	positive	+

Microblot-Array

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	positive	positive	+
IgG	positive	positive	+
IgM	positive, negative	positive	+
IgM	positive, borderline	positive	+

Clinical evaluation

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
Interpretation	infection confirmed	infection confirmed	+
Interpretation	infection confirmed	infection confirmed	+

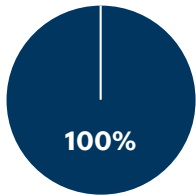
SZÚ – 05.2024EIA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	negative	negative	+
IgG	positive, borderline, negative	positive	+
IgG	positive, borderline	positive	+
IgM	negative	negative	+
IgM	positive	positive	+
IgM	negative	negative	+

Immunoblot

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	negative	negative	+
IgG	positive, borderline, negative	positive	+
IgG	positive, borderline, negative	positive	+
IgM	negative	negative	+
IgM	positive	positive	+
IgM	negative	negative	+

INSTAND – 06.2024



CLIA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	negative	negative	+
IgG	positive	positive	+
IgM	negative	negative	+
IgM	negative	negative	+

EIA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	negative	negative	+
IgG	positive	positive	+
IgM	negative	negative	+
IgM	negative	negative	+

Immunoblot

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	negative	negative	+
IgG	positive	positive	+
IgM	negative	negative	+
IgM	negative	negative	+

Clinical evaluation

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
Interpretation	no evidence of infection	no evidence of infection	+
Interpretation	late infection	late infection	+

Chlamydia

[See related products on web](#)**INSTAND – 06.2024**

CLIA

Chlamydia pneumoniae

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgA	negative, borderline, positive	negative	+
IgA	negative	negative	+
IgG	borderline, positive	positive	+
IgG	negative	negative	+
IgM	negative	negative	+
IgM	negative	negative	+

Chlamydia trachomatis

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgA	negative, borderline, positive	negative	+
IgA	negative	negative	+
IgG	borderline, positive	borderline	+
IgG	negative	negative	+
IgM	negative	negative	+
IgM	negative	negative	+

EIA

Chlamydia pneumoniae

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgA	negative, borderline, positive	positive	+
IgA	negative	negative	+
IgG	borderline, positive	positive	+
IgG	negative	negative	+
IgM	negative	negative	+
IgM	negative	negative	+

Chlamydia trachomatis

Category	Sample specification	TestLine result	Meets criteria
IgA	negative, borderline, positive	negative	+
IgA	negative	negative	+
IgG	borderline, positive	positive	+
IgG	negative	negative	+
IgM	negative	negative	+
IgM	negative	negative	+

Immunoblot

Chlamydia pneumoniae

Category	Sample specification	TestLine result	Meets criteria
IgG	positive	positive	+
IgG	negative	negative	+
IgA	negative, borderline, positive	negative	+
IgA	negative	negative	+

Chlamydia trachomatis

Category	Sample specification	TestLine result	Meets criteria
IgA	negative, borderline, positive	negative	+
IgA	negative	negative	+
IgG	borderline, positive	borderline	+
IgG	negative	negative	+

Clinical evaluation

Chlamydia pneumoniae

Category	Sample specification	TestLine result	Meets criteria
Interpretation	ongoing, late infection	late infection	+
Interpretation	no evidence of infection	no evidence of infection	+

Chlamydia trachomatis

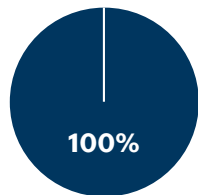
Category	Sample specification	TestLine result	Meets criteria
Interpretation	late infection	late infection	+
Interpretation*	the sample was not evaluated		

* The results for this sample were ambiguous (due to plasma pooling causing sample inhomogeneity, mixture of antigens in kits etc.) – therefore this sample was not included in the final evaluation of any manufacturer.

Helicobacter

[See related products on web](#)

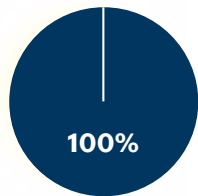
CAP – 03.2024



EIA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	positive	positive	+
IgM*	the sample was not evaluated		

LABQUALITY – 04.2024



CLIA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgA	negative	negative	+
IgA	positive	positive	+
IgG	negative	negative	+
IgG	positive	positive	+

EIA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgA	negative	negative	+
IgA	positive	positive	+
IgG	negative	negative	+
IgG	positive	positive	+

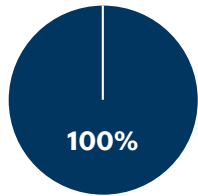
Immunoblot

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgA	negative	negative	+
IgA	positive	positive	+
IgG	negative	negative	+
IgG	positive	positive	+

Clinical evaluation

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
Interpretation	no evidence of infection	no evidence of infection	+
Interpretation	infection confirmed	infection confirmed	+

INSTAND – 06.2024



CLIA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgA	borderline, positive	positive	+
IgA	negative	negative	+
IgG	positive	positive	+
IgG	negative	negative	+

EIA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgA	borderline, positive	positive	+
IgA	negative	negative	+
IgG	positive	positive	+
IgG	negative	negative	+

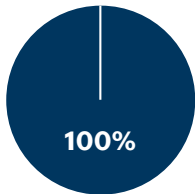
Immunoblot

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgA	negative, borderline, positive	positive	+
IgA	negative	negative	+
IgG	positive	positive	+
IgG	negative	negative	+

Clinical evaluation

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
Interpretation	infection confirmed	infection confirmed	+
Interpretation	no evidence of infection	no evidence of infection	+

Tetanus

[See related products on web](#)**INSTAND – 06.2024**

CLIA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	positive	positive	+
IgG	positive	positive	+

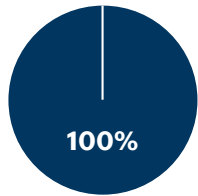
EIA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	positive	positive	+
IgG	positive	positive	+

Clinical evaluation

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
Interpretation	infection confirmed	infection confirmed	+
Interpretation	infection confirmed	infection confirmed	+

Treponema

[See related products on web](#)**INSTAND – 06.2024**

EIA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	negative	negative	+
IgG	positive	positive	+
IgM	negative	negative	+
IgM	negative	negative	+
Total	negative	negative	+
Total	positive	positive	+

Immunoblot

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	negative	negative	+
IgG	positive	positive	+
IgM	negative	negative	+
IgM	negative	negative	+

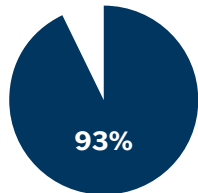
Clinical evaluation

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
Interpretation	no evidence of infection	no evidence of infection	+
Interpretation	late infection	late infection	+

Yersinia

[See related products on web](#)

INSTAND – 06.2024

EIA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgA	negative	positive	-
IgA*	the sample was not evaluated		
IgG	negative, borderline	negative	+
IgG*	the sample was not evaluated		
IgM	negative	negative	+
IgM	negative	negative	+

Immunoblot

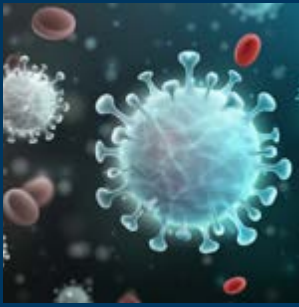
<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgA	negative	negative	+
IgA*	the sample was not evaluated		
IgG	negative, borderline	negative	+
IgG*	the sample was not evaluated		
IgM	negative	negative	+
IgM	negative	negative	+

Clinical evaluation

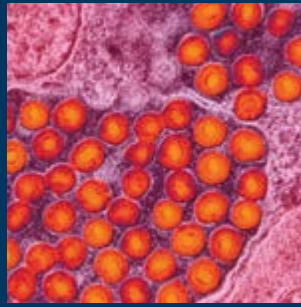
<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
Interpretation	no evidence of infection	no evidence of infection	+
Interpretation*	the sample was not evaluated		

* The results for this sample were ambiguous (due to plasma pooling causing sample inhomogeneity, mixture of antigens in kits etc.) – therefore this sample was not included in the final evaluation of any manufacturer.

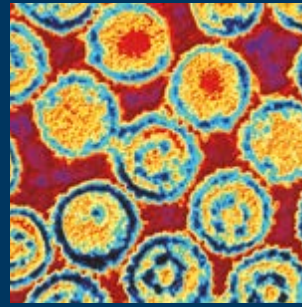
INFECTIOUS SEROLOGY – VIRUSES



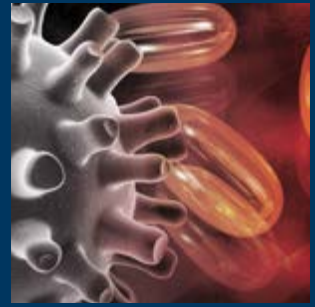
COVID-19 page 21



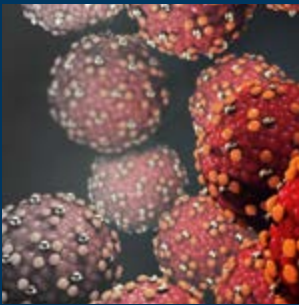
CMV page 22



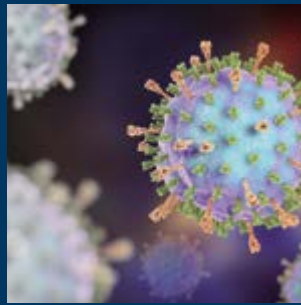
EBV page 24



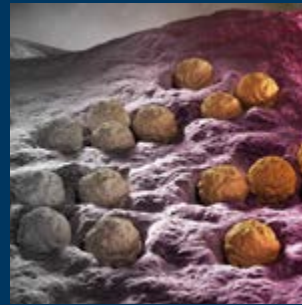
HSV page 27



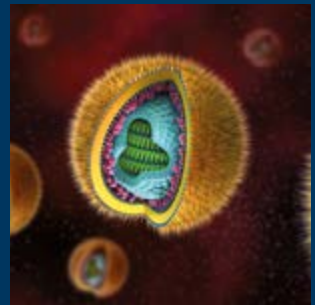
MEASLES page 28



MUMPS page 29



RUBELLA page 30



VZV page 31

Coronavirus (COVID-19)


[See related products on web](#)

LABQUALITY – 03.2024



CLIA

Category	Sample specification	TestLine result	Meets criteria
IgA	positive	positive	+
IgA	negative	negative	+
IgA	positive	positive	+
IgG	positive	positive	+
IgG	negative	negative	+
IgG	positive	positive	+
IgM	positive	positive	+
IgM	negative	negative	+
IgM*	the sample was not evaluated		

EIA

COVID-19 RBD

Category	Sample specification	TestLine result	Meets criteria
IgA	positive	positive	+
IgA	negative	negative	+
IgA	positive	positive	+
IgG	positive	positive	+
IgG	negative	negative	+
IgG	positive	positive	+
IgM	positive	positive	+
IgM	negative	negative	+
IgM*	the sample was not evaluated		

Microblot-Array

Category	Sample specification	TestLine result	Meets criteria
IgA	positive	positive	+
IgA	negative	negative	+
IgA	positive	positive	+
IgG	positive	positive	+
IgG	negative	negative	+
IgG	positive	positive	+
IgM	positive	positive	+
IgM	negative	negative	+
IgM*	the sample was not evaluated		

* The results for this sample were ambiguous (due to plasma pooling causing sample inhomogeneity, mixture of antigens in kits etc.)
– therefore this sample was not included in the final evaluation of any manufacturer.

Cytomegalovirus (CMV)


[See related products on web](#)

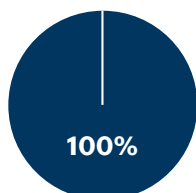
CAP – 03.2024



EIA

Category	Sample specification	TestLine result	Meets criteria
IgG	negative	negative	+
IgM	negative	negative	+

SZÚ – 05.2024



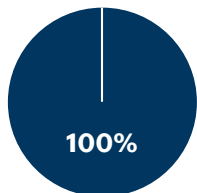
EIA

Category	Sample specification	TestLine result	Meets criteria
Avidity	high	high	+
IgG	positive	positive	+
IgG	negative	negative	+
IgM	positive	positive	+
IgM	negative	negative	+

Clinical evaluation

Category	Sample specification	TestLine result	Meets criteria
Interpretation	latent infection	latent infection	+
Interpretation	seronegative	seronegative	+

LABQUALITY – 06.2024



CLIA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	positive	positive	+
IgG	positive	positive	+
IgG	positive	positive	+
IgM	negative	negative	+
IgM	positive	positive	+
IgM	positive	positive	+

EIA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
Avidity	high	high	+
Avidity	low	low	+
Avidity	low	low	+
IgG	positive	positive	+
IgG	positive	positive	+
IgG	positive	positive	+
IgM	negative	negative	+
IgM	positive	positive	+
IgM	positive	positive	+

Immunoblot

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	positive	positive	+
IgG	positive	positive	+
IgG	positive	positive	+
IgM	negative	negative	+
IgM	positive	positive	+
IgM	positive	positive	+

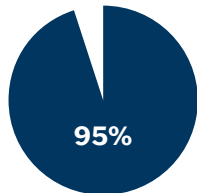
Clinical evaluation

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
Interpretation	late infection	late infection	+
Interpretation	acute infection	acute infection	+
Interpretation	acute infection	acute infection	+

Epstein-Barr virus (EBV)


[See related products on web](#)

LABQUALITY – 03.2024



CLIA

EBNA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	positive	positive	+
IgG	negative	negative	+
IgG	positive	positive	+

VCA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	positive	positive	+
IgG	negative	negative	+
IgG	positive	positive	+
IgM	negative	negative	+
IgM	negative	negative	+
IgM	negative	negative	+

EIA

EBNA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	positive	positive	+
IgG	negative	negative	+
IgG	positive	positive	+

VCA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
Avidity	high	high (47%)	+
Avidity	high	high (103%)	+
IgG	positive	positive	+
IgG	negative	negative	+
IgG	positive	positive	+
IgM	negative	negative	+
IgM	negative	negative	+
IgM	negative	negative	+

Microblot-Array

EBNA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	positive	positive	+
IgG	negative	negative	+
IgG	positive	positive	+

VCA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	positive	positive	+
IgG	negative	negative	+
IgG	positive	positive	+
IgM	negative	negative	+
IgM	negative	negative	+
IgM	negative	positive	-

Clinical evaluation

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
Interpretation	late infection	late infection	+
Interpretation	no evidence of infection	no evidence of infection	+
Interpretation	late infection	late infection	+

SZÚ – 04.2024



EIA

EA-D

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	negative	negative	+
IgG	negative	negative	+
IgM	negative	negative	+
IgM	negative	negative	+

EBNA-1

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	negative	negative	+
IgG	positive	positive	+
IgM	negative	negative	+
IgM	negative	negative	+

VCA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
Avidity	high	high	+
IgA	negative	negative	+
IgA	negative	negative	+
IgG	negative	negative	+
IgG	positive	positive	+
IgM	negative	negative	+
IgM	negative	negative	+

Immunoblot

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	negative	negative	+
IgG	positive	positive	+
IgM	negative	negative	+
IgM	negative	negative	+

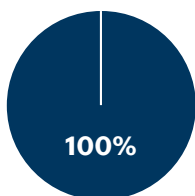
Clinical evaluation

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
Interpretation	seronegative	seronegative	+
Interpretation	anamnestic antibodies	anamnestic antibodies	+

Herpes simplex virus (HSV)


[See related products on web](#)

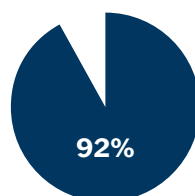
CAP – 03.2024



EIA

Category	Sample specification	TestLine result	Meets criteria
HSV IgG*	the sample was not evaluated		
HSV 1 IgG*	the sample was not evaluated		
HSV 2 IgG	negative	negative	+

LABQUALITY – 03.2024



EIA

HSV

Category	Sample specification	TestLine result	Meets criteria
IgG	negative	negative	+
IgG	positive	positive	+
IgG	positive	positive	+
IgM*	the sample was not evaluated		
IgM	positive	positive	+
IgM	negative	borderline	-

HSV-1

Category	Sample specification	TestLine result	Meets criteria
IgG	negative	negative	+
IgG	positive	positive	+
IgG	positive	positive	+

HSV-2

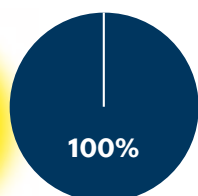
Category	Sample specification	TestLine result	Meets criteria
IgG	negative	negative	+
IgG	positive	positive	+
IgG	negative	negative	+

* The results for this sample were ambiguous (due to plasma pooling causing sample inhomogeneity, mixture of antigens in kits etc.)
– therefore this sample was not included in the final evaluation of any manufacturer.

Measles


[See related products on web](#)

LABQUALITY – 03.2024



EIA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	positive	positive	+
IgG	positive	positive	+
IgG*	the sample was not evaluated		
IgM	positive	positive	+
IgM	positive	positive	+
IgM	negative	negative	+

Clinical evaluation

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
Interpretation	acute infection	acute infection	+
Interpretation	acute infection	acute infection	+
Interpretation*	the sample was not evaluated		

* The results for this sample were ambiguous (due to plasma pooling causing sample inhomogeneity, mixture of antigens in kits etc.) – therefore this sample was not included in the final evaluation of any manufacturer.

Mumps

[See related products on web](#)

LABQUALITY – 03.2024



EIA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	positive	positive	+
IgG	positive	positive	+
IgG	negative	negative	+
IgM	positive	positive	+
IgM	negative	negative	+
IgM	negative	negative	+

Clinical evaluation

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
Interpretation	acute infection	acute infection	+
Interpretation	chronic infection	chronic infection	+
Interpretation	no evidence of infection	no evidence of infection	+

Rubella

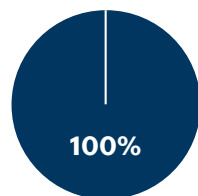
CAP – 03.2024



EIA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	negative	negative	+

LABQUALITY – 03.2024



CLIA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	positive	positive	+
IgG	negative	negative	+
IgG	positive	positive	+
IgM	negative	negative	+
IgM	negative	negative	+
IgM	positive	positive	+

EIA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
Avidity	high	high	+
Avidity	low	low	+
IgG	positive	positive	+
IgG	negative	negative	+
IgG	positive	positive	+
IgM	negative	negative	+
IgM	negative	negative	+
IgM	positive	positive	+

Clinical evaluation

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
Interpretation	chronic infection	chronic infection	+
Interpretation	no evidence of infection	no evidence of infection	+
Interpretation	acute infection	acute infection	+

Varicella zoster virus (VZV)



See related products on web

CAP – 03.2024



EIA

Category	Sample specification	TestLine result	Meets criteria
IgG	negative	negative	+

INFECTIOUS SEROLOGY – PARASITES



TOXOCARA page 33



TOXOPLASMA page 34

Toxocara

 [See related products on web](#)

SZÚ – 01.2024



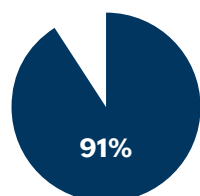
EIA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
Avidity	high	high	+
Avidity	high	high	+
IgG	negative	negative	+
IgG	positive	positive	+
IgG	positive	positive	+
IgG	negative	negative	+
IgG	negative	negative	+

Toxoplasma

[See related products on web](#)

LABQAULITY – 01.2024



EIA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
Avidity	low	low	+
Avidity	low	low	+
IgA	positive	positive	+
IgA	negative	negative	+
IgA	positive	positive	+
IgG	positive	positive	+
IgG	negative	negative	+
IgG	positive	positive	+
IgM	positive	positive	+
IgM	negative	negative	+
IgM	positive	positive	+

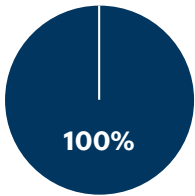
Immunoblot

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgA	positive	negative	-
IgA	negative	negative	+
IgA	positive	negative	-
IgG	positive	positive	+
IgG	negative	negative	+
IgG	positive	positive	+
IgM	positive	positive	+
IgM	negative	negative	+
IgM	positive	borderline	+

Clinical evaluation

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
Interpretation	acute infection	acute infection	+
Interpretation	no evidence of infection	no evidence of infection	+

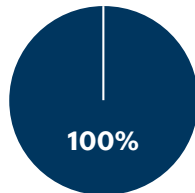
CAP – 03.2024



EIA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	positive	positive	+
IgM	negative	negative	+

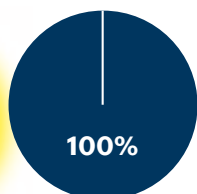
SZÚ – 05.2024



EIA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
Avidity	high	high	+
Avidity	high	high	+
Avidity	high	high	+
Avidity	high	high	+
Avidity	high	high	+
IgA	negative	negative	+
IgA	negative	negative	+
IgA	negative	negative	+
IgA	negative	negative	+
IgA	positive	positive	+
IgE	negative	negative	+
IgE	negative	negative	+
IgE	negative	negative	+
IgE	negative	negative	+
IgE	borderline	borderline	+
IgG	positive	positive	+
IgG	positive	positive	+
IgG	positive	positive	+
IgG	positive	positive	+
IgG	positive	positive	+
IgM	negative	negative	+
IgM	negative	negative	+
IgM	negative	negative	+
IgM	negative	negative	+
IgM	positive	positive	+

INSTAND – 06.2024



EIA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
Avidity	high	high	+
Avidity	low	low	+
IgA	negative	negative	+
IgA	positive	positive	+
IgG	positive	positive	+
IgG	positive	positive	+
IgM	negative	negative	+
IgM	positive	positive	+

Immunoblot

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgA	negative	negative	+
IgA	positive	positive	+
IgG	positive	positive	+
IgG	positive	positive	+
IgM	negative	negative	+
IgM	positive	positive	+

Clinical evaluation

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
Interpretation	late infection	late infection	+
Interpretation	acute infection	acute infection	+
Interpretation	acute infection	acute infection	+

LABQUALITY – 06.2024

EIA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
Avidity	high	high	+
Avidity	high	high	+
IgG	negative	negative	+
IgG	positive	positive	+
IgG	positive	positive	+
IgM	negative	negative	+
IgM	positive	positive	+
IgM	negative	negative	+

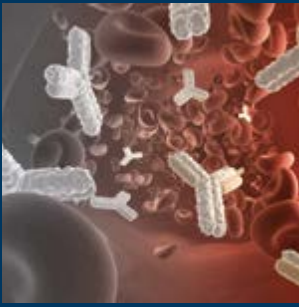
Immunoblot

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgG	negative	negative	+
IgG	positive	positive	+
IgG	positive	positive	+
IgM	negative	negative	+
IgM	positive	positive	+
IgM	negative	negative	+

Clinical evaluation

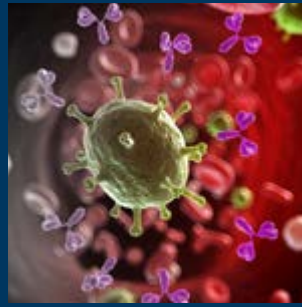
<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
Interpretation	no evidence of infection	no evidence of infection	+
Interpretation	acute infection	acute infection	+
Interpretation	late infection	late infection	+

IMMUNOLOGY – SYSTEMIC AUTOIMMUNE DISEASE



ANA

page 39



ANCA

page 44



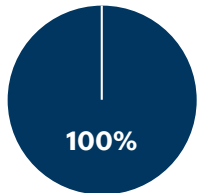
ENA

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Antinuclear antibodies (ANA)


[See related products on web](#)

CAP – 04.2024



Microblot-Array

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
Anti-Jo-1	negative	negative	+
Anti-Scl-70	positive	positive	+

SEKK – 04.2024



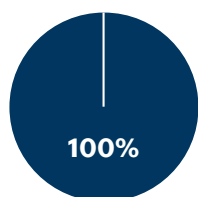
Immunoblot

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
Anti-ds-DNA	positive	positive	+
Anti-ds-DNA	negative	negative	+
Anti-ENA/centromere	negative	negative	+
Anti-ENA/centromere	negative	negative	+
Anti-ENA/Jo-1	negative	negative	+
Anti-ENA/Jo-1	negative	negative	+
Anti-ENA/RNP	negative	negative	+
Anti-ENA/RNP	negative	negative	+
Anti-ENA/Scl-70	negative	negative	+
Anti-ENA/Scl-70	negative	negative	+
Anti-ENA/SS-A/Ro	positive	positive	+
Anti-ENA/SS-A/Ro	negative	negative	+
Anti-ENA/SS-B/La	positive	positive	+
Anti-ENA/SS-B/La	negative	negative	+

Microblot-Array

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
Anti-ds-DNA	positive	positive	+
Anti-ds-DNA	negative	negative	+
Anti-ENA/centromere	negative	negative	+
Anti-ENA/centromere	negative	negative	+
Anti-ENA/Jo-1	negative	negative	+
Anti-ENA/Jo-1	negative	negative	+
Anti-ENA/RNP	negative	negative	+
Anti-ENA/RNP	negative	negative	+
Anti-ENA/Scl-70	negative	negative	+
Anti-ENA/Scl-70	negative	negative	+
Anti-ENA/SS-A/Ro	positive	positive	+
Anti-ENA/SS-A/Ro	negative	negative	+
Anti-ENA/SS-B/La	positive	positive	+
Anti-ENA/SS-B/La	negative	negative	+

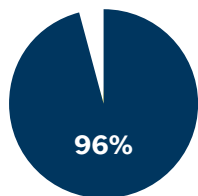
INSTAND – 05.2024



Microblot-Array

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
ANA	positive	positive	+
ANA	positive	positive	+
anti-dsDNA	negative	negative	+
anti-dsDNA	negative	negative	+

LABQUALITY – 05.2024

Immunoblot

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
Anti-CENP A	negative	negative	+
Anti-CENP A	negative	negative	+
Anti-CENP A	negative	negative	+
Anti-CENP B	negative	negative	+
Anti-CENP B	negative	negative	+
Anti-CENP B	negative	negative	+
Anti-dsDNA	positive	positive	+
Anti-dsDNA	negative	negative	+
Anti-dsDNA	negative	negative	+
Anti-ENA/Jo-1	negative	negative	+
Anti-ENA/Jo-1	negative	negative	+
Anti-ENA/Jo-1	negative	negative	+
Anti-ENA/RNP	positive	positive	+
Anti-ENA/RNP	positive	positive	+
Anti-ENA/RNP	positive	positive	+
Anti-ENA/Scl-70	negative	negative	+
Anti-ENA/Scl-70	negative	negative	+
Anti-ENA/Scl-70	negative	negative	+
Anti-ENA/SS-A/Ro 52kD	negative	negative	+
Anti-ENA/SS-A/Ro 52kD	positive	negative	-
Anti-ENA/SS-A/Ro 52kD	negative	negative	+
Anti-ENA/SS-A/Ro 60kD	negative	negative	+
Anti-ENA/SS-A/Ro 60kD	negative	negative	+
Anti-ENA/SS-A/Ro 60kD	positive	positive	+
Anti-ENA/SS-B/La	negative	negative	+
Anti-ENA/SS-B/La	negative	negative	+
Anti-ENA/SS-B/La	negative	negative	+
Anti-histones*	the sample was not evaluated		
Anti-histones	negative	negative	+

* The results for this sample were ambiguous (due to plasma pooling causing sample inhomogeneity, mixture of antigens in kits etc.)
– therefore this sample was not included in the final evaluation of any manufacturer.

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
Anti-histones	negative	negative	+
Anti-Rib-P	negative	negative	+
Anti-Rib-P	negative	negative	+
Anti-Rib-P	negative	negative	+
Anti-SmB	positive	positive	+
Anti-SmB	negative	negative	+
Anti-SmB	positive	positive	+
Anti-SmD	positive	positive	+
Anti-SmD	negative	negative	+
Anti-SmD	positive	positive	+

Microblot-Array

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
Anti-CENP A	negative	negative	+
Anti-CENP A	negative	negative	+
Anti-CENP A	negative	negative	+
Anti-CENP B	negative	negative	+
Anti-CENP B	negative	negative	+
Anti-CENP B	negative	negative	+
Anti-dsDNA	positive	positive	+
Anti-dsDNA	negative	negative	+
Anti-dsDNA	negative	negative	+
Anti-ENA/Jo-1	negative	negative	+
Anti-ENA/Jo-1	negative	negative	+
Anti-ENA/Jo-1	negative	negative	+
Anti-ENA/RNP	positive	positive	+
Anti-ENA/RNP	positive	positive	+
Anti-ENA/RNP	positive	positive	+
Anti-ENA/Scl-70	negative	negative	+
Anti-ENA/Scl-70	negative	negative	+
Anti-ENA/Scl-70	negative	negative	+

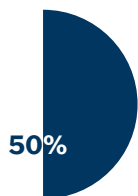
<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
Anti-ENA/SS-A/Ro 52kD	negative	negative	+
Anti-ENA/SS-A/Ro 52kD	positive	negative	-
Anti-ENA/SS-A/Ro 52kD	negative	negative	+
Anti-ENA/SS-A/Ro 60kD	negative	negative	+
Anti-ENA/SS-A/Ro 60kD	negative	negative	+
Anti-ENA/SS-A/Ro 60kD	positive	positive	+
Anti-ENA/SS-B/La	negative	negative	+
Anti-ENA/SS-B/La	negative	negative	+
Anti-ENA/SS-B/La	negative	negative	+
Anti-histones*	the sample was not evaluated		
Anti-histones	negative	negative	+
Anti-histones	negative	negative	+
Anti-Rib-P	negative	negative	+
Anti-Rib-P	negative	negative	+
Anti-Rib-P	negative	negative	+
Anti-SmB	positive	positive	+
Anti-SmB	negative	positive	-
Anti-SmB	positive	positive	+
Anti-SmD	positive	positive	+
Anti-SmD	negative	negative	+
Anti-SmD	positive	positive	+

* The results for this sample were ambiguous (due to plasma pooling causing sample inhomogeneity, mixture of antigens in kits etc.)
– therefore this sample was not included in the final evaluation of any manufacturer.

Antineutrophil cytoplasmic antibodies (ANCA)


[See related products on web](#)

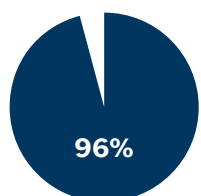
SEKK – 04.2024



Immunoblot

Category	Sample specification	TestLine result	Meets criteria
IgG	positive	negative	-
IgG	positive	positive	+

LABQUALITY – 04.2024



EIA

Category	Sample specification	TestLine result	Meets criteria
Anti-CENP A+B	negative	negative	+
Anti-CENP A+B	negative	negative	+
Anti-CENP A+B	negative	negative	+
Anti-dsDNA	positive	positive	+
Anti-dsDNA	negative	negative	+
Anti-dsDNA	negative	negative	+
Anti-ENA/Jo-1	negative	negative	+
Anti-ENA/Jo-1	negative	negative	+
Anti-ENA/Jo-1	negative	negative	+
Anti-ENA/RNP	positive	positive	+
Anti-ENA/RNP	positive	positive	+
Anti-ENA/RNP	positive	positive	+
Anti-ENA/Scl-70	negative	negative	+
Anti-ENA/Scl-70	negative	negative	+
Anti-ENA/Scl-70	negative	negative	+
Anti-ENA/SS-B/La	negative	negative	+
Anti-ENA/SS-B/La	negative	negative	+
Anti-ENA/SS-B/La	negative	negative	+
Anti-Sm	positive	positive	+
Anti-Sm	negative	weakly positive	-
Anti-Sm	positive	positive	+

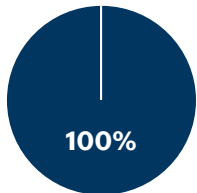
<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
Anti-SS-A/Ro	negative	negative	+
Anti-SS-A/Ro*	the sample was not evaluated		
Anti-SS-A/Ro	positive	positive	+

* The results for this sample were ambiguous (due to plasma pooling causing sample inhomogeneity, mixture of antigens in kits etc.)
– therefore this sample was not included in the final evaluation of any manufacturer.

Extractable nuclear antigens (ENA)


[See related products on web](#)

SEKK – 04.2024



EIA

Category	Sample specification	TestLine result	Meets criteria
Anti-ENA/centromere	negative	negative	+
Anti-ENA/centromere	negative	negative	+
Anti-ENA/Jo-1	negative	negative	+
Anti-ENA/Jo-1	negative	negative	+
Anti-ENA/RNP	negative	negative	+
Anti-ENA/RNP	negative	negative	+
Anti-ENA/Scl-70	negative	negative	+
Anti-ENA/Scl-70	negative	negative	+
Anti-ENA/SS-A/Ro	positive	positive	+
Anti-ENA/SS-A/Ro	negative	negative	+
Anti-ENA/SS-B/La	positive	positive	+
Anti-ENA/SS-B/La	negative	negative	+



IMMUNOLOGY – RHEUMATOLOGY



CPP

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RF

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Cyclic citrullinated peptides (CCP)



SEKK – 04.2024



Immunoblot

Category	Sample specification	TestLine result	Meets criteria
IgG	negative	negative	+
IgG	positive	positive	+

Rheumatoid Factor (RF)

 [See related products on web](#)

SEKK – 04.2024



EIA

Category	Sample specification	TestLine result	Meets criteria
IgA	negative	negative	+
IgA	positive	positive	+
IgG	negative	negative	+
IgG	positive	positive	+
IgM	negative	negative	+
IgM	positive	positive	+



IMMUNOLOGY – GASTROINTESTINAL IMMUNOLOGY



ASCA	page 53
Gliadin DA	page 54
TA	page 55

Antibodies to *Saccharomyces cerevisiae* (ASCA)

 [See related products on web](#)

SEKK – 03.2024



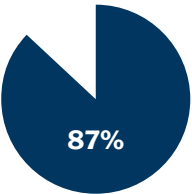
EIA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgA	positive	positive	+
IgA	negative	negative	+
IgG	positive	positive	+
IgG	negative	negative	+

Deamidated gliadin (Gliadin DA)



LABQUALITY – 03.2024



CLIA

Category	Sample specification	TestLine result	Meets criteria
IgA	positive, borderline	borderline	+
IgA	positive	positive	+
IgG	positive	positive	+
IgG	positive	positive	+

EIA

Category	Sample specification	TestLine result	Meets criteria
IgA	positive, borderline	negative	-
IgA	positive	positive	+
IgG	positive	positive	+
IgG	positive	positive	+

SEKK – 03.2024



CLIA

Category	Sample specification	TestLine result	Meets criteria
IgA	negative	negative	+
IgA	positive	positive	+
IgG	negative	negative	+
IgG	positive	positive	+

EIA

Category	Sample specification	TestLine result	Meets criteria
IgA	negative	negative	+
IgA	positive	positive	+
IgG	negative	negative	+
IgG	positive	positive	+

Transglutaminase (TA)

 [See related products on web](#)

LABQUALITY – 03.2024



CLIA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgA	positive	positive	+
IgA	positive	positive	+
IgG	negative	negative	+
IgG	positive	positive	+

EIA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgA	positive	positive	+
IgA	positive	positive	+
IgG	negative	negative	+
IgG	positive	positive	+

SEKK – 03.2024



CLIA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgA	negative	negative	+
IgA	positive	positive	+

EIA

<u>Category</u>	<u>Sample specification</u>	<u>TestLine result</u>	<u>Meets criteria</u>
IgA	negative	negative	+
IgA	positive	positive	+

CLIA KITS FOR DIAGNOSIS OF INFECTIOUS DISEASES

<u>Cat. No.</u>	<u>Product</u>	<u>Number</u>	<u>Units</u>
CL-BRG100	CLIA Borrelia recombinant IgG	100	tests
CL-BRM100	CLIA Borrelia recombinant IgM	100	tests
CL-ChtA100	CLIA Chlamydia trachomatis IgA	100	tests
CL-ChtG100	CLIA Chlamydia trachomatis IgG	100	tests
CL-ChtM100	CLIA Chlamydia trachomatis IgM	100	tests
CL-CPA100	CLIA Chlamydia pneumoniae IgA	100	tests
CL-CPG100	CLIA Chlamydia pneumoniae IgG	100	tests
CL-CPM100	CLIA Chlamydia pneumoniae IgM	100	tests
CL-CMA100	CLIA CMV IgA	100	tests
CL-CMG100	CLIA CMV IgG	100	tests
CL-CMM100	CLIA CMV IgM	100	tests
CL-CoNA100	CLIA COVID-19 NP IgA	100	tests
CL-CoNG100	CLIA COVID-19 NP IgG	100	tests
CL-CoNM100	CLIA COVID-19 NP IgM	100	tests
CL-CoRA100	CLIA COVID-19 RBD IgA	100	tests
CL-CoRG100	CLIA COVID-19 RBD IgG	100	tests
CL-CoRM100	CLIA COVID-19 RBD IgM	100	tests
CL-VCA100	CLIA EBV VCA IgA	100	tests
CL-VCG100	CLIA EBV VCA IgG	100	tests
CL-VCM100	CLIA EBV VCA IgM	100	tests
CL-EBG100	CLIA EBV EBNA-1 IgG	100	tests
CL-EBM100	CLIA EBV EBNA-1 IgM	100	tests
CL-EAG100	CLIA EBV EA-D IgG	100	tests
CL-EAM100	CLIA EBV EA-D IgM	100	tests
CL-HMG100	CLIA Helicobacter MONO IgG	100	tests
CL-HMA100	CLIA Helicobacter MONO IgM	100	tests

<u>Cat. No.</u>	<u>Product</u>	<u>Number</u>	<u>Units</u>
CL-HSVG100	CLIA HSV 1+2 IgG	100	tests
CL-HSVM100	CLIA HSV 1+2 IgM	100	tests
CL-RubG100	CLIA Rubella IgG	100	tests
CL-RubM100	CLIA Rubella IgM	100	tests
CL-TeTG100	CLIA Tetanus Toxoid IgG	100	tests
CL-TgA050	CLIA Toxoplasma IgA	100	tests
CL-TgG100	CLIA Toxoplasma IgG	100	tests
CL-TgM100	CLIA Toxoplasma IgM	100	tests
CL-VZVA100	CLIA VZV IgA	100	tests
CL-VZVG100	CLIA VZV IgG	100	tests
CL-VZVM100	CLIA VZV IgM	100	tests

ELISA KITS FOR DIAGNOSTIC OF INFECTIOUS DISEASES

(Kits are also available as SmartKits® for Agility®)

<u>Cat. No.</u>	<u>Product</u>	<u>Number</u>	<u>Units</u>
BrG192	EIA Borrelia recombinant IgG (192)	192	wells
BrG096	EIA Borrelia recombinant IgG (on request)	96	wells
BrM192	EIA Borrelia recombinant IgM (192)	192	wells
BrM096	EIA Borrelia recombinant IgM (on request)	96	wells
BaGVD2	EIA Borrelia afzelii VlsE IgG (192)	192	wells
BaM192	EIA Borrelia afzelii IgM (192)	192	wells
BsGV96	EIA Borrelia b. sensu stricto VlsE IgG	96	wells
BsM096	EIA Borrelia b. sensu stricto IgM	96	wells
BgGVD2	EIA Borrelia garinii VlsE IgG (192)	192	wells
BgM192	EIA Borrelia garinii IgM (192)	192	wells
BppA96	EIA Bordetella parapertussis IgA	96	wells
BppG96	EIA Bordetella parapertussis IgG	96	wells
BppM96	EIA Bordetella parapertussis IgM	96	wells
BpAT96	EIA Bordetella pertussis Toxin IgA	96	wells

<u>Cat. No.</u>	<u>Product</u>	<u>Number</u>	<u>Units</u>
BpGT96	EIA Bordetella pertussis Toxin IgG	96	wells
BpMT96	EIA Bordetella pertussis Toxin IgM	96	wells
ChA096	EIA Chlamydia IgA	96	wells
ChG096	EIA Chlamydia IgG	96	wells
ChM096	EIA Chlamydia IgM	96	wells
ChpA96	EIA Chlamydia pneumoniae IgA	96	wells
ChpG96	EIA Chlamydia pneumoniae IgG	96	wells
ChpM96	EIA Chlamydia pneumoniae IgM	96	wells
CpAR96	EIA Chlamydia pneumoniae REC IgA	96	wells
CpGR96	EIA Chlamydia pneumoniae REC IgG	96	wells
ChtA96	EIA Chlamydia trachomatis IgA	96	wells
ChtG96	EIA Chlamydia trachomatis IgG	96	wells
ChtM96	EIA Chlamydia trachomatis IgM	96	wells
CMA096	EIA CMV IgA	96	wells
CMG096	EIA CMV IgG	96	wells
CMM096	EIA CMV IgM	96	wells
CoNA96	EIA COVID-19 NP IgA	96	wells
CoNG96	EIA COVID-19 NP IgG	96	wells
CoNM96	EIA COVID-19 NP IgM	96	wells
CoRG96	EIA COVID-19 RBD IgG	96	wells
CoRM96	EIA COVID-19 RBD IgM	96	wells
EAG096	EIA EBV EA-D IgG	96	wells
EAM096	EIA EBV EA-D IgM	96	wells
EBG096	EIA EBV EBNA-1 IgG	96	wells
EBM096	EIA EBV EBNA-1 IgM	96	wells
VCA096	EIA EBV VCA IgA	96	wells
VCG096	EIA EBV VCA IgG	96	wells

<u>Cat. No.</u>	<u>Product</u>	<u>Number</u>	<u>Units</u>
VCM096	EIA EBV VCA IgM	96	wells
HMA096	EIA Helicobacter MONO IgA	96	wells
HMG096	EIA Helicobacter MONO IgG	96	wells
HMM096	EIA Helicobacter MONO IgM	96	wells
HSV96	EIA HSV 1+2 IgG	96	wells
HS1G96	EIA HSV 1 IgG	96	wells
HS2G96	EIA HSV 2 IgG	96	wells
HSVM96	EIA HSV 1+2 IgM	96	wells
HS1M96	EIA HSV 1 IgM	96	wells
HS2M96	EIA HSV 2 IgM	96	wells
MeG096	EIA Measles IgG	96	wells
MeM096	EIA Measles IgM	96	wells
MuG096	EIA Mumps IgG	96	wells
MuA096	EIA Mumps IgA	96	wells
MuM096	EIA Mumps IgM	96	wells
RubG96	EIA Rubella IgG	96	wells
RubM96	EIA Rubella IgM	96	wells
TeTG96	EIA Tetanus Toxoid IgG	96	wells
TgA096	EIA Toxoplasma IgA (capture)	96	wells
TgE096	EIA Toxoplasma IgE (capture)	96	wells
TgG096	EIA Toxoplasma IgG	96	wells
TgM096	EIA Toxoplasma IgM (capture)	96	wells
TpG096	EIA Treponema pallidum IgG	96	wells
TpM096	EIA Treponema pallidum IgM	96	wells
Tp0096	EIA Treponema pallidum TOTAL	96	wells
VZVA96	EIA VZV IgA	96	wells
VZVG96	EIA VZV IgG	96	wells

<u>Cat. No.</u>	<u>Product</u>	<u>Number</u>	<u>Units</u>
VZVM96	EIA VZV IgM	96	wells
YeA096	EIA Yersinia IgA	96	wells
YeG096	EIA Yersinia IgG	96	wells
YeM096	EIA Yersinia IgM	96	wells

IMMUNOBLOT KITS FOR DIAGNOSIS OF INFECTIOUS DISEASES

<u>Cat. No.</u>	<u>Product</u>	<u>Number</u>	<u>Units</u>
BGL020	BLOT-LINE Borrelia/HGA IgG	20	tests
BML020	BLOT-LINE Borrelia/HGA IgM	20	tests
BaGL20	BLOT-LINE Borrelia afzelii IgG	20	tests
BaML20	BLOT-LINE Borrelia afzelii IgM	20	tests
BgGL20	BLOT-LINE Borrelia garinii IgG	20	tests
BgML20	BLOT-LINE Borrelia garinii IgM	20	tests
BsGL20	BLOT-LINE Borrelia b. sensu stricto IgG	20	tests
BsML20	BLOT-LINE Borrelia b. sensu stricto IgM	20	tests
BpAL20	BLOT-LINE Bordetella IgA	20	tests
BpGL20	BLOT-LINE Bordetella IgG	20	tests
BpML20	BLOT-LINE Bordetella IgM	20	tests
CAL020	BLOT-LINE Chlamydia IgA	20	tests
CGL020	BLOT-LINE Chlamydia IgG	20	tests
CpAL20	BLOT-LINE Chlamydia pneumoniae IgA	20	tests
CpGL20	BLOT-LINE Chlamydia pneumoniae IgG	20	tests
CtAL20	BLOT-LINE Chlamydia trachomatis IgA	20	tests
CtGL20	BLOT-LINE Chlamydia trachomatis IgG	20	tests
CMGL20	BLOT-LINE CMV IgG	20	tests
CMML20	BLOT-LINE CMV IgM	20	tests
EBAL20	BLOT-LINE EBV IgA	20	tests
EBGL20	BLOT-LINE EBV IgG	20	tests

<u>Cat. No.</u>	<u>Product</u>	<u>Number</u>	<u>Units</u>
EBML20	BLOT-LINE EBV IgM	20	tests
HpAL20	BLOT-LINE Helicobacter IgA	20	tests
HpGL20	BLOT-LINE Helicobacter IgG	20	tests
TgAL20	BLOT-LINE Toxoplasma IgA	20	tests
TgGL20	BLOT-LINE Toxoplasma IgG	20	tests
TgML20	BLOT-LINE Toxoplasma IgM	20	tests
TpGL20	BLOT-LINE Treponema IgG	20	tests
TpML20	BLOT-LINE Treponema IgM	20	tests
YAL020	BLOT-LINE Yersinia IgA	20	tests
YGL020	BLOT-LINE Yersinia IgG	20	tests
YML020	BLOT-LINE Yersinia IgM	20	tests

BLUEBLOT-LINE KITS FOR DIAGNOSTICS OF INFECTIOUS DISEASES USING THE BLUEDIVER INSTRUMENT

<u>Cat. No.</u>	<u>Product</u>	<u>Number</u>	<u>Units</u>
BD-BGL024	BlueBLOT-LINE Borrelia IgG	24	tests
BD-BML024	BlueBLOT-LINE Borrelia IgM	24	tests
BD-BpAL24	BlueBLOT-LINE Bordetella IgA	24	tests
BD-BpGL24	BlueBLOT-LINE Bordetella IgG	24	tests
BD-CAL024	BlueBLOT-LINE Chlamydia IgA	24	tests
BD-CGL024	BlueBLOT-LINE Chlamydia IgG	24	tests
BD-EBGL24	BlueBLOT-LINE EBV IgG	24	tests
BD-EBML24	BlueBLOT-LINE EBV IgM	24	tests
BD-HpAL24	BlueBLOT-LINE Helicobacter IgA	24	tests
BD-HpGL24	BlueBLOT-LINE Helicobacter IgG	24	tests
BD-TpGL24	BlueBLOT-LINE Treponema IgG	24	tests
BD-TpML24	BlueBLOT-LINE Treponema IgM	24	tests
BD-YAL024	BlueBLOT-LINE Yersinia IgA	24	tests
BD-YGL024	BlueBLOT-LINE Yersinia IgG	24	tests

MICROBLOT ARRAY KITS FOR DIAGNOSTICS OF INFECTIOUS DISEASES

<u>Cat. No.</u>	<u>Product</u>	<u>Number</u>	<u>Units</u>
BPAMA48	Microblot-Array Bordetella IgA	48	tests
BPGMA48	Microblot-Array Bordetella IgG	48	tests
BPMMA48	Microblot-Array Bordetella IgM	48	tests
BGMA096	Microblot-Array Borrelia IgG	96	tests
BMMA096	Microblot-Array Borrelia IgM	96	tests
CAMA096	Microblot-Array Chlamydia IgA	96	tests
CGMA096	Microblot-Array Chlamydia IgG	96	tests
CMGMA48	Microblot-Array CMV IgG	48	tests
CMMMA48	Microblot-Array CMV IgM	48	tests
CoVAMA96	Microblot-Array COVID-19 IgA	96	tests
CoVGMA96	Microblot-Array COVID-19 IgG	96	tests
CoVMA96	Microblot-Array COVID-19 IgM	96	tests
EBAMA96	Microblot-Array EBV IgA	96	tests
EBGMA96	Microblot-Array EBV IgG	96	tests
EBMMA96	Microblot-Array EBV IgM	96	tests
HpAMA48	Microblot-Array Helicobacter IgA	96	tests
HpGMA48	Microblot-Array Helicobacter IgG	96	tests
HSGMA48	Microblot-Array HSV 1+2 IgG	48	tests
HSMMA48	Microblot-Array HSV 1+2 IgM	48	tests
YAMA048	Microblot-Array Yersinia IgA	48	tests
YGMA048	Microblot-Array Yersinia IgG	48	tests

CLIA KITS FOR IMMUNOLOGY

<u>Cat. No.</u>	<u>Product</u>	<u>Number</u>	<u>Units</u>
CL-ENA100	CLIA ENA screen plus	100	tests
CL-GDA100	CLIA Gliadin DA IgA	100	tests
CL-GDG100	CLIA Gliadin DA IgG	100	tests

<u>Cat. No.</u>	<u>Product</u>	<u>Number</u>	<u>Units</u>
CL-tTA100	CLIA Transglutaminase IgA	100	tests
CL-tTG100	CLIA Transglutaminase IgG	100	tests

ELISA KITS FOR IMMUNOLOGY

(All ELISA kits are also available as SmartKits® for Agility®)

<u>Cat. No.</u>	<u>Product</u>	<u>Number</u>	<u>Units</u>
ScA096	EIA ASCA IgA	96	wells
ScG096	EIA ASCA IgG	96	wells
ENA096	EIA ENA screen plus	96	wells
ENA012	EIA ENA profile	12	wells
ENAp12	EIA ENA profile plus	12	wells
CCPA96	EIA CCP IgA	96	wells
CCPG96	EIA CCP IgG	96	wells
GDA096	EIA Gliadin DA IgA	96	wells
GDG096	EIA Gliadin DA IgG	96	wells
RFA096	EIA RF IgA	96	wells
RFG096	EIA RF IgG	96	wells
RFM096	EIA RF IgM	96	wells
SSA096	EIA SS-A (on request)	96	wells
SSB096	EIA SS-B (on request)	96	wells
Sm0096	EIA Sm (on request)	96	wells
RNP096	EIA U1RNP (on request)	96	wells
Sci096	EIA Scl-70 (on request)	96	wells
DNA096	EIA dsDNA	96	wells
Jo1096	EIA Jo-1 (on request)	96	wells
tTA096	EIA Transglutaminase IgA	96	wells
tTG096	EIA Transglutaminase IgG	96	wells

IMMUNOBLOT KITS FOR IMMUNOLOGY

<u>Cat. No.</u>	<u>Product</u>	<u>Number</u>	<u>Units</u>
ANAL20	BLOT-LINE ANA	20	tests
AnC3I20	BLOT-LINE ANCA-3	20	tests

MICROBLOT ARRAY KITS FOR IMMUNOLOGY

<u>Cat. No.</u>	<u>Product</u>	<u>Number</u>	<u>Units</u>
ANAMA96	Microblot-Array ANA	96	tests
ANApMA96	Microblot-Array ANA plus (check availability in your country)	96	tests





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