Vitrotest ELISA kits & components	EC DECLARATION OF CONFORMITY		
	No DoC_Ascaris_lumbricoides_IgG_EL051-96	1st ed.	P. 1 of 1

MANUFACTURER:	**Vitrotest Europe Sp. z O.O.**
ADDRESS:	**Krakowska str., 139-155, 50-428, Wroclaw, Poland**
PRODUCT NAME:	**Vitrotest Ascaris lumbricoides IgG** ELISA test kit for the detection of IgG class antibodies to *Ascaris lumbricoides*
PRODUCT CATALOGUE NUMBER:	**EL051-96**
GMDN CODE:	**52133**

We hereby declare that the above mentioned product meet the provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

CLASSIFICATION:	In vitro medical device, other device (not applicable to list A or B of Annex II of Directive 98/79/EC, not a product for self-testing, not for performance evaluation).
CONFORMITY ROUTE:	Annex III of Directive 98/79/EC.
APPLICABLE STANDARDS:	EN ISO 13485:2016; EN ISO 14971:2019; EN 13612:2002; EN ISO 15223-1:2016; EN ISO 18113-1:2011; EN ISO 18113-2:2011; EN ISO 23640:2015.

This Declaration of conformity is issued under the responsibility of the manufacturer.

Edition 1

Wroclaw, Poland
Issued in

15.02.2022
Date

Vitrotest Europe Sp. z o.o.
ul. Krakowska 139-155, 50-428 Wrocław
NIP: 8992881308, REGON: 386329301
KRS: 0000844411

Galyna Rayevska, Ph.D.
Chief of the Board

Digitally signed by Monastîrschii Viorica
Date: 2022.09.07 15:35:39 EEST
Reason: MoldSign Signature
Location: Moldova

MANUFACTURER:	**Vitrotest Europe Sp. z O.O.**
ADDRESS:	**Krakowska str., 139-155, 50-428, Wroclaw, Poland**
PRODUCT NAME:	**Vitrotest EBV EBNA-1 IgG** ELISA test kit for the qualitative and semiquantitative determination of IgG class antibodies to nuclear antigen of Epstein-Barr Virus
PRODUCT CATALOGUE NUMBER:	**EL054-96**
GMDN CODE:	**49657**

We hereby declare that the above mentioned product meet the provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

CLASSIFICATION:	In vitro medical device, other device (not applicable to list A or B of Annex II of Directive 98/79/EC, not a product for self-testing, not for performance evaluation).
CONFORMITY ROUTE:	Annex III of Directive 98/79/EC.
APPLICABLE STANDARDS:	EN ISO 13485:2016; EN ISO 14971:2019; EN 13612:2002; EN ISO 15223-1:2016; EN ISO 18113-1:2011; EN ISO 18113-2:2011; EN ISO 23640:2015.

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Galyna Rayevska, Ph.D.
Chief of the Board

Vitrotest ELISA kits & components	EC DECLARATION OF CONFORMITY		
	No DoC_EBV_VCA_IgG_EL053-96	1st ed.	P. 1 of 1

MANUFACTURER:	**Vitrotest Europe Sp. z O.O.**
ADDRESS:	**Krakowska str., 139-155, 50-428, Wroclaw, Poland**
PRODUCT NAME:	**Vitrotest EBV VCA IgG** ELISA test kit for the qualitative and semiquantitative determination of IgG class antibodies to capsid antigen of Epstein-Barr Virus
PRODUCT CATALOGUE NUMBER:	**EL053-96**
GMDN CODE:	**49657**

We hereby declare that the above mentioned product meet the provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

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CONFORMITY ROUTE:	Annex III of Directive 98/79/EC.
APPLICABLE STANDARDS:	EN ISO 13485:2016; EN ISO 14971:2019; EN 13612:2002; EN ISO 15223-1:2016; EN ISO 18113-1:2011; EN ISO 18113-2:2011; EN ISO 23640:2015.

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KRS: 0000844411

Galyna Rayevska, Ph.D.
Chief of the Board

Vitrotest ELISA kits & components	EC DECLARATION OF CONFORMITY		
	No DoC_EBV_VCA_IgM_EL052-96	1st ed.	P. 1 of 1

MANUFACTURER:	**Vitrotest Europe Sp. z O.O.**
ADDRESS:	**Krakowska str., 139-155, 50-428, Wroclaw, Poland**
PRODUCT NAME:	**Vitrotest EBV VCA IgM** ELISA test kit for the qualitative and semiquantitative determination of IgM class antibodies to capsid antigen of Epstein-Barr Virus
PRODUCT CATALOGUE NUMBER:	**EL052-96**
GMDN CODE:	**49662**

We hereby declare that the above mentioned product meet the provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

CLASSIFICATION:	In vitro medical device, other device (not applicable to list A or B of Annex II of Directive 98/79/EC, not a product for self-testing, not for performance evaluation).
CONFORMITY ROUTE:	Annex III of Directive 98/79/EC.
APPLICABLE STANDARDS:	EN ISO 13485:2016; EN ISO 14971:2019; EN 13612:2002; EN ISO 15223-1:2016; EN ISO 18113-1:2011; EN ISO 18113-2:2011; EN ISO 23640:2015.

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Galyna Rayevska, Ph.D.
Chief of the Board

Vitrotest ELISA kits & components	EC DECLARATION OF CONFORMITY		
	No DoC_Helicobacter_pylori_IgA_EL099-96	1st ed.	P. 1 of 1

MANUFACTURER:	**Vitrotest Europe Sp. z O.O.**
ADDRESS:	**Krakowska str., 139-155, 50-428, Wroclaw, Poland**
PRODUCT NAME:	**Vitrotest Helicobacter pylori IgA** ELISA test kit for the qualitative and semiquantitative determination of IgA class antibodies to *Helicobacter pylori*
PRODUCT CATALOGUE NUMBER:	**EL099-96**
GMDN CODE:	**51004**

We hereby declare that the above mentioned product meet the provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

CLASSIFICATION:	In vitro medical device, other device (not applicable to list A or B of Annex II of Directive 98/79/EC, not a product for self-testing, not for performance evaluation).
CONFORMITY ROUTE:	Annex III of Directive 98/79/EC.
APPLICABLE STANDARDS:	EN ISO 13485:2016; EN ISO 14971:2019; EN 13612:2002; EN ISO 15223-1:2016; EN ISO 18113-1:2011; EN ISO 18113-2:2011; EN ISO 23640:2015.

This Declaration of conformity is issued under the responsibility of the manufacturer.

Edition 1

Wroclaw, Poland
Issued in

25.02.2022
Date

Vitrotest Europe Sp. z o.o.
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NIP: 8992881308, REGON: 386329301
KRS: 0000844411

Galyna Rayevska, Ph.D.
Chief of the Board

Vitrotest ELISA kits & components	EC DECLARATION OF CONFORMITY		
	No DoC_Toxocara_canis_IgG_EL058-96	1st ed.	P. 1 of 1

MANUFACTURER:	**Vitrotest Europe Sp. z O.O.**
ADDRESS:	**Krakowska str., 139-155, 50-428, Wroclaw, Poland**
PRODUCT NAME:	**Vitrotest Toxocara canis IgG** ELISA test kit for the detection of IgG class antibodies to *Toxocara canis*
PRODUCT CATALOGUE NUMBER:	**EL058-96**
GMDN CODE:	**52418**

We hereby declare that the above mentioned product meet the provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

CLASSIFICATION:	In vitro medical device, other device (not applicable to list A or B of Annex II of Directive 98/79/EC, not a product for self-testing, not for performance evaluation).
CONFORMITY ROUTE:	Annex III of Directive 98/79/EC.
APPLICABLE STANDARDS:	EN ISO 13485:2016; EN ISO 14971:2019; EN 13612:2002; EN ISO 15223-1:2016; EN ISO 18113-1:2011; EN ISO 18113-2:2011; EN ISO 23640:2015.

This Declaration of conformity is issued under the responsibility of the manufacturer.

Edition 1

Wroclaw, Poland
Issued in

15.02.2022
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NIP: 8992881308, REGON: 386329301
KRS: 0000844411

Galyna Rayevska, Ph.D.
Chief of the Board

Vitrotest ELISA kits & components	EC DECLARATION OF CONFORMITY		
	No DoC_Trichinella_spiralis_IgG_EL067-96	1st ed.	P. 1 of 1

MANUFACTURER:	**Vitrotest Europe Sp. z O.O.**
ADDRESS:	**Krakowska str., 139-155, 50-428, Wroclaw, Poland**
PRODUCT NAME:	**Vitrotest Trichinella spiralis IgG** ELISA test kit for the detection of IgG class antibodies to *Trichinella spiralis*
PRODUCT CATALOGUE NUMBER:	**EL067-96**
GMDN CODE:	**52459**

We hereby declare that the above mentioned product meet the provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

CLASSIFICATION:	In vitro medical device, other device (not applicable to list A or B of Annex II of Directive 98/79/EC, not a product for self-testing, not for performance evaluation).
CONFORMITY ROUTE:	Annex III of Directive 98/79/EC.
APPLICABLE STANDARDS:	EN ISO 13485:2016; EN ISO 14971:2019; EN 13612:2002; EN ISO 15223-1:2016; EN ISO 18113-1:2011; EN ISO 18113-2:2011; EN ISO 23640:2015.

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Galyna Rayevska, Ph.D.
Chief of the Board

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Krakowska str 139-155,
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тел:+48 882 950 379
info@vitrotest.pl
NIP: 8992881308

Wrocław, 02.06.2022

To whom it may concern

STATEMENT

Herewith we, Vitrotest Europe Sp. z O.O. with registered address at Krakowska str., 139-155, 50-428, Wroclaw, Poland, acting as a manufacturer, hereby assign SRL SANMEDICO having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova , as authorized representative in Republic Moldova.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

June 2, 2022

Galyna Rayevska, Chief of the board

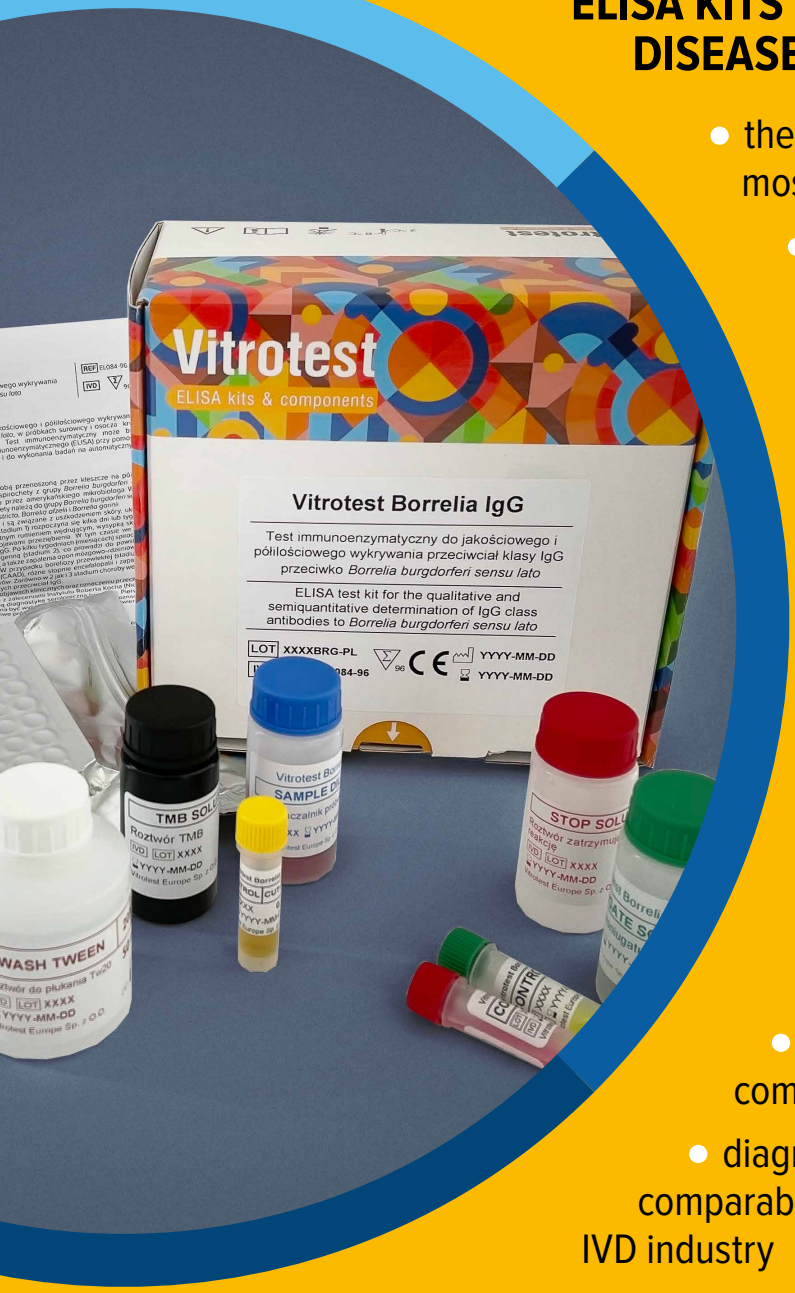
Vitrotest Europe Sp. z O.O.

Vitrotest Europe Sp. z o.o.
ul. Krakowska 139-155, 50-428 Wrocław
NIP: 8992881308, REGON: 386329301
KRS: 0000844411

Vitrotest

ELISA kits & components

Vitrotest Europe Sp. z o.o. is Polish manufacturer of medical enzyme-linked immunosorbent assays for in vitro diagnostics. Our products contain a significant intellectual and innovative component.



ELISA KITS FOR INFECTIOUS DISEASES TESTING

- the analysis time is standardized for most kits
- all kits contain microplates with easily detachable wells
- clear and precise colored solutions facilitate analysis and reduce inaccuracy
- interchangeable TMB, Washing and STOP solutions for all Vitrotest kits
- unique positive and cut-off controls are synthesized according to the original technique
- absence of human origin components makes the use of kits safer
- the kits are verified on commercial panels of sera
- diagnostic characteristics of tests are comparable with the kits of leaders in the IVD industry

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Helminthiasis

EL051-96	**Vitrotest Ascaris lumbricoides IgG** ELISA test kit for the detection of IgG class antibodies to *Ascaris lumbricoides*
EL066-96	**Vitrotest Echinococcus granulosus IgG** ELISA test kit for the detection of IgG class antibodies to *Echinococcus granulosus*
EL058-96	**Vitrotest Toxocara canis IgG** ELISA test kit for the detection of IgG class antibodies to *Toxocara canis*
EL067-96	**Vitrotest Trichinella spiralis IgG** ELISA test kit for the detection of IgG class antibodies to *Trichinella spiralis*

Borreliosis

EL084-96	**Vitrotest Borrelia IgG** ELISA test kit for the qualitative and semiquantitative determination of IgG class antibodies to *Borrelia burgdorferi sensu lato*
EL085-96	**Vitrotest Borrelia IgM** ELISA test kit for the qualitative and semiquantitative determination of IgM class antibodies to *Borrelia burgdorferi sensu lato*

COVID-19

EL039-96	**Vitrotest SARS-CoV-2 IgG** ELISA test kit for the qualitative and semiquantitative determination of IgG class antibodies to coronavirus SARS-CoV-2
EL034-96	**Vitrotest SARS-CoV-2 IgM** ELISA test kit for the qualitative determination of IgM class antibodies to coronavirus SARS-CoV-2
EL038-96	**Vitrotest SARS-CoV-2 Total Ab** ELISA test kit for the qualitative determination of total antibodies to coronavirus SARS-CoV-2
EL040-96	**Vitrotest SARS-CoV-2 IgG QuantiSpike** ELISA test kit for the quantitative determination of IgG class antibodies to coronavirus SARS-CoV-2 Spike protein

Helicobacter pylori infection

EL098-96	**Vitrotest Helicobacter pylori IgG** ELISA test kit for the qualitative and semiquantitative determination of IgG class antibodies to *Helicobacter pylori*
EL099-96	**Vitrotest Helicobacter pylori IgA** ELISA test kit for the qualitative and semiquantitative determination of IgA class antibodies to *Helicobacter pylori*
EL046-96	**Vitrotest Helicobacter pylori CagA IgG** ELISA test kit for the quantitative and semiquantitative determination of IgG class antibodies to CagA protein of *Helicobacter pylori*
EL047-96	**Vitrotest Helicobacter pylori CagA IgA** ELISA test kit for the qualitative and semiquantitative determination of IgA class antibodies to CagA protein of *Helicobacter pylori*

Epstain-Barr Virus infection

EL053-96	**Vitrotest EBV VCA IgG** ELISA test kit for the qualitative and semiquantitative determination of IgG class antibodies to capsid antigen of Epstein-Barr Virus
EL052-96	**Vitrotest EBV VCA IgM** ELISA test kit for the qualitative and semiquantitative determination of IgM class antibodies to capsid antigen of Epstein-Barr Virus
EL054-96	**Vitrotest EBV EBNA-1 IgG** ELISA test kit for the qualitative and semiquantitative determination of IgG class antibodies to nuclear antigen of Epstein-Barr Virus

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