

MANUFACTURER: **Vitrotest Europe Sp. z O.O.**

ADDRESS: **Krakowska str., 139-155, 50-428, Wrocław, 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 18113-1:2011;  
EN ISO 14971:2019; EN ISO 18113-2:2011;  
EN 13612:2002; EN ISO 23640:2015.  
EN ISO 15223-1:2016;

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

Edition 1

Wrocław, 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

MANUFACTURER: **Vitrotest Europe Sp. z O.O.**

ADDRESS: **Krakowska str., 139-155, 50-428, Wrocław, Poland**

PRODUCT NAME: **Vitrotest Borrelia IgG**  
ELISA test kit for the qualitative and semiquantitative determination of IgG class antibodies to *Borrelia burgdorferi sensu lato*

PRODUCT CATALOGUE NUMBER: **EL084-96**

GMDN CODE: **63901**

**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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EN ISO 15223-1:2016;

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Edition 1

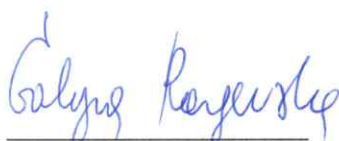
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21.02.2022

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ADDRESS:

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PRODUCT NAME:

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

PRODUCT CATALOGUE NUMBER:

**EL085-96**

GMDN CODE:

**63059**

**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:

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CONFORMITY ROUTE:

Annex III of Directive 98/79/EC.

APPLICABLE STANDARDS:

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EN ISO 14971:2019;  
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EN ISO 15223-1:2016;EN ISO 18113-1:2011;  
EN ISO 18113-2:2011;  
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MANUFACTURER:

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ADDRESS:

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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.**

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Annex III of Directive 98/79/EC.

APPLICABLE STANDARDS:

EN ISO 13485:2016;  
EN ISO 14971:2019;  
EN 13612:2002;  
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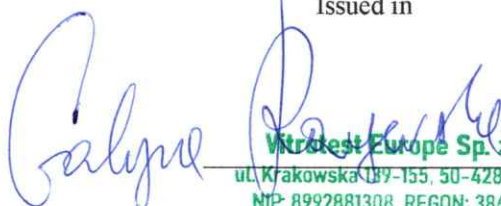
Edition 1

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Issued in

25.02.2022

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**Vitrotest Europe Sp. z o.o.**

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MANUFACTURER: **Vitrotest Europe Sp. z O.O.**

ADDRESS: **Krakowska str., 139-155, 50-428, Wrocław, Poland**

PRODUCT NAME: **Vitrotest Helicobacter pylori IgG**  
ELISA test kit for the qualitative and semiquantitative determination of IgG class antibodies to *Helicobacter pylori*

PRODUCT CATALOGUE NUMBER: **EL098-96**

GMDN CODE: **51008**

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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.**

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EN ISO 15223-1:2016;

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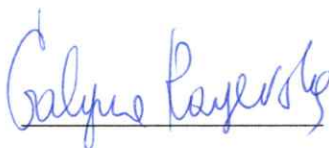
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# Vitrotest

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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[info@vitrotest.pl](mailto:info@vitrotest.pl)

## 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*

## Epstein-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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