STATEMENT

We, ACON Laboratories, Inc., having a registered office at *5850 Oberlin Drive #340, San Diego, CA 92121* authorize SRL Sanmedico having a registered office at *A. Corobceanu street 7A, apt. 9, Chisinău, MD-2012, Moldova*

to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Date: January 3, 2023

Signature: _____

Qiyi Xie, Md, MPH
Sr. Officer, Regulatory & Clinical Affairs
ACON Laboratories, Inc.
Ph: 858-875-8011
Email: qxie@aconlabs.com

Digitally signed by Monastîrschii Viorica
Date: 2023.03.23 14:08:48 EET
Reason: MoldSign Signature
Location: Moldova

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 104507 0003 Rev. 06

Manufacturer: **ACON Laboratories, Inc.**
5850 Oberlin Drive, #340
San Diego CA 92121
USA

Product Category(ies): **Blood glucose measuring systems for self testing and self-testing devices for clinical chemistry, hematology and pregnancy and ovulation**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V1 104507 0003 Rev. 06

Report no.: SH22743EXT01

Valid from: 2022-05-04
Valid until: 2025-05-26

Date, 2022-05-04

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 104507 0003 Rev. 06

Model(s):

On Call Plus Blood Glucose Monitoring System,
On Call Plus Blood Glucose Test Strips,
On Call EZ II Blood Glucose Monitoring System,
On Call Advanced Blood Glucose Monitoring System,
On Call Advanced Blood Glucose Test Strips,
On Call Chosen Blood Glucose Test Strips,
On Call Vivid Blood Glucose Monitoring System (OGM-101),
On Call Vivid Blood Glucose Test Strips (OGS-101),
On Call Sharp Blood Glucose Monitoring System (OGM-121),
On Call Sharp Blood Glucose Test Strips (OGS-121)
On Call Plus II Blood Glucose Monitoring System (OGM-171),
On Call Plus II Blood Glucose Test Strips (OGS-171),
On Call Extra Blood Glucose Monitoring System (OGM-191),
On Call Extra Blood Glucose Test Strips (OGS-191),
On Call GK Dual Blood Glucose & Ketone Monitoring System (OGM-161),
On Call Blood Ketone Test Strips (OGS-161),
Urinalysis Reagent Strips (Urine),
UTI Urinary Tract Infection Test Strips,
Cholesterol Monitoring System (CCM-111),
CHOL Total Cholesterol Test Devices (CCS-111),
TRIG Triglycerides Test Devices (CCS-112),
HDL High Density Lipoprotein Test Devices (CCS-113),
3-1 Lipid Panel Test Devices (CCS-114),
Cholesterol CTRL Control Devices,
Cholesterol Monitoring System (CCM-101),
CHOL Total Cholesterol Test Strips (CCS-101),
PT/INR Monitoring System (CCM-151),
PT/INR Test Strips (CCS-151),
Hemoglobin Testing System (CCM-141),
Hemoglobin Test Strips (CCS-141),
hCG Pregnancy Rapid Test Cassette (Urine),
Pregnancy Rapid Test Midstream,
On Call Extra Mobile Blood Glucose Monitoring System (OGM-281),
On Call Sure Blood Glucose Monitoring System (OGM-211),
On Call Sure Sync Blood Glucose Monitoring System (OGM-212),
On Call Sure Blood Glucose Test Strips (OGS-211),
GIMA Blood Glucose Monitoring System,
GIMA Bluetooth Blood Glucose Monitoring System,
GIMA Blood Glucose Test Strips,
On Call GU Dual Blood Glucose & Uric Acid Monitoring

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Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 104507 0003 Rev. 06

System (OGM-201),
On Call Blood Uric Acid Test Strips (OGS-201),
LH Ovulation Rapid Test Cassette (Urine),
Ovulation Rapid Test Midstream,
Ovulation & Pregnancy Test Combo Pack,
On Call Extra Voice Blood Glucose Monitoring System (OGM-291),
Early Detection Pregnancy Test,
Digital Pregnancy Test,
Go-Keto Blood Glucose & Ketone Monitoring System (OGM-161),
Go-Keto Blood Ketone Test Strips (OGS-161),
Go-Keto Blood Glucose Test Strips,
On Call Extra GM Blood Glucose Monitoring System(OGM-191),
On Call Extra GM Blood Glucose Test Strips (OGS-191),
On Call Plus GM Blood Glucose Monitoring System,
On Call Plus GM Blood Glucose Test Strips,
Go-Keto Urinalysis Reagent Strips

Facility(ies):

ACON Laboratories, Inc.
5850 Oberlin Drive, #340, San Diego CA 92121, USA

ACON Laboratories, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

AZURE Institute, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

Acon Laboratories Inc.
Guerrero Negro 9942 Parque Industrial Pacifico IV, 22644 Tijuana B.C. CP, MEXICO

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TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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TÜV®

Declaration of Conformity

ACON Laboratories, Incorporated
5850 Oberlin Drive #340
San Diego, CA 92121, USA

We, the manufacturer, declare under our sole responsibility that the *in vitro* diagnostic device:

Mission® Urinalysis Reagent Strips (U031-XX1)

classified as Others in the directive 98/79/EC,

meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

The self-declaration is according to Annex III (excluding Section 6) of the Directive.

Authorized Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany

Signed this 11 day of February, 2020
in San Diego, CA USA

Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
Acon Laboratories, Inc.

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 104507 0001 Rev. 03

Holder of Certificate: **ACON Laboratories, Inc.**
5850 Oberlin Drive, #340
San Diego CA 92121
USA

Certification Mark:

Scope of Certificate: **Design and Development, Manufacture and distribution of In Vitro Diagnostic Test Kits and Reagents for the Determination of Infectious Diseases, Clinical Chemistry, Drugs of Abuse, Tumor/Cardiac Marker, Fertility/Pregnancy and Blood Glucose Monitoring System, Lancing Devices and Lancets**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 104507 0001 Rev. 03

Report No.: SH22743A01

Valid from: 2022-09-15
Valid until: 2025-09-06

Date, 2022-09-15

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 104507 0001 Rev. 03

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

ACON Laboratories, Inc.
5850 Oberlin Drive, #340, San Diego CA 92121, USA

Address holder for registration only

ACON Laboratories, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

Manufacture and distribution of
In Vitro Diagnostic Test Kits and Reagents for the Determination of Infectious Diseases, Clinical Chemistry, Drugs of Abuse, Tumor/Cardiac Marker, Fertility/Pregnancy and Blood Glucose Monitoring System, Lancing Devices and Lancets

ACON Laboratories, Inc.
6865 Flanders Dr., Suite B, San Diego CA 92121, USA

Storage of
In Vitro Diagnostic Test Kits and Reagents for the Determination of Infectious Diseases, Clinical Chemistry, Drugs of Abuse, Tumor/Cardiac Marker, Fertility/Pregnancy and Blood Glucose Monitoring System, Lancing Devices and Lancets

AZURE Institute, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

Design and Development of
In Vitro Diagnostic Test Kits and Reagents for the Determination of Infectious Diseases, Clinical Chemistry, Drugs of Abuse, Tumor/Cardiac Marker, Fertility/Pregnancy and Blood Glucose Monitoring System, Lancing Devices and Lancets

Acon Laboratories Inc.
Guerrero Negro 9942 Parque Industrial Pacifico IV, 22644
Tijuana B.C. CP, MEXICO

Manufacture of
blood glucose test strips, antigen rapid test and IgG/IgM antibody rapid test for infectious disease.

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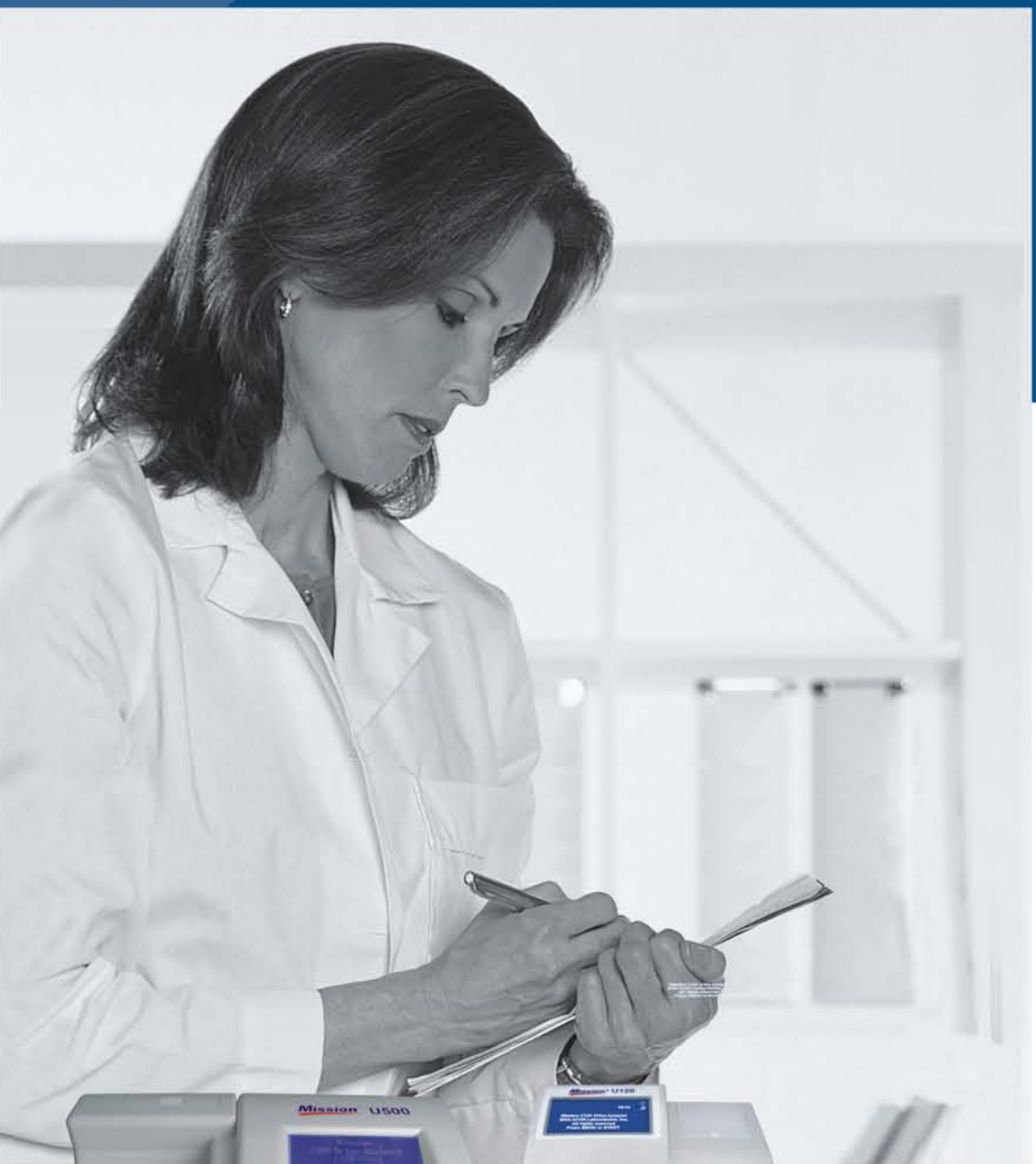
TÜV®

Mission® Urinalysis Reagent Strips and Urine Analyzers



Obtain reliable and cost-effective results with *Mission*® Urinalysis Reagent Strips and Urine Analyzers!

- *Accurate*
- *Reliable*
- *Convenient*

ACON®

Global Diagnostics for Local Markets™

Urinalysis Reagent Strips

Simple and Accurate

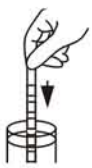
- Analytical sensitivity better than or comparable to market leaders
- High quality color chart ensures accurate visual reading

Flexible

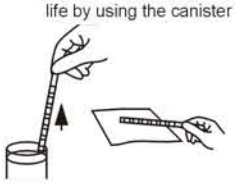
- Compatible for visual and analyzer reading
- More than 30 different combinations available

Multiple Packaging Options and Long Shelf Life

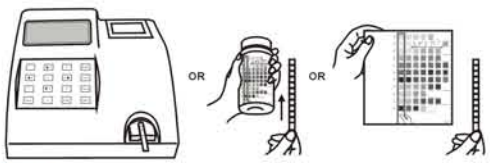
- Canister Packaging
  - Available in 25, 50, 100 and 150 strips per kit
  - 2 year shelf life for unopened canisters which offers cost savings and convenience for high volume testing
  - 3 month shelf life for strips in opened canisters
- Pouch Packaging ***New!***
  - Single-strip Pouch
    - Individually packaged strips with 1, 3, 6 and 20 strips and 1 color chart per kit for OTC or low volume testing
    - Unique packaging maintains 2 year shelf life for all strips in the kit compared to 3 months for remaining strips in an opened canister
  - Multi-strip Pouch
    - Canister Refill Kits with 25 strips/pouch uniquely packaged to save cost for low volume testing and extended shelf life by using the canister for refills



Step 1: Immerse strip into urine



Step 2: Remove excess urine



Step 3: Obtain results by analyzer or visual reading

Catalog No.	No. of Parameters	Type of Strip♦		Strips per Canister◇	Pouch Packaging▲	Reading Method			Analyzer-Read Strips: Standard (S) or Additional (A)	Parameters												
		For Visual Reading	For Analyzer Reading (U120/U500)			Visual	U120	U500		ASC	GLU	BIL	KET	SG	BLO	pH	PRO	URO	NIT	LEU	ALB	CRE
U031-131	13	13C	NA	100■	✓	✓	NA	NA	A	*	*	*	*	*	*	*	*	*	*	*	*	*
U031-111	11	11A		100	✓	✓	✓	✓	S	*	*	*	*	*	*	*	*	*	*	*		
U031-101	10	10U		100	✓	✓	✓	✓	S		*	*	*	*	*	*	*	*	*	*		
		10A				✓	✓	✓	A	*	*	*	*	*	*	*	*	*	*			
		10C		100■		✓	✓	✓	S		*		*	*	*	*	*		*	*	*	*
U031-091	9	9U		100	✓	✓	✓	✓	S		*	*	*	*	*	*	*	*	*			
U031-081	8	8U		100	✓	✓	✓	✓	A		*	*	*		*	*	*	*	*			
		8N				✓	✓	✓	S		*		*	*	*	*	*		*	*		
		8S				✓	✓	✓	A		*			*	*	*	*	*	*	*		
U031-071	7	7N		100	✓	✓	✓	✓	A		*		*		*	*	*		*	*		
U031-061	6	6N	6NE	100	✓	✓	✓	✓	A		*				*	*	*		*	*		
		6U	6UE			✓	✓	✓				*		*	*		*	*	*			
U031-051	5	5B	5BE	100	✓	✓	✓		A		*		*		*	*	*					
		5N	5NE			✓	✓	✓			*				*		*		*	*		
		5S	5SE			✓	✓				*			*	*	*	*					
		5U	5UE			✓	✓					*			*			*	*	*		
U031-041	4	4S	4SE	100	✓	✓	✓	✓	A		*			*		*	*					
		4B	4BE			✓	✓				*				*	*	*					
		4K	4KE			✓	✓	✓			*		*			*	*					
		4G	4GE			✓	✓				*				*		*			*		
		4N	4NE			✓	✓	✓							*		*		*	*		
		4P	4PE			✓	✓	✓			*						*		*	*		
U031-031	3	3P	3PE	100	✓	✓	✓	✓	A		*					*	*					
		3K	3KE			✓	✓	✓			*		*				*					
		3G	3GE			✓	✓	✓			*		*			*						
		3N	3NE			✓	✓	✓							*				*	*		
U031-021	2	2G	2GE	100	✓	✓	✓	✓	A		*						*					
		2K	2KE			✓	✓	✓			*		*									
		2N	2NE			✓	✓	✓							*					*		
		2B	2BE			✓	✓	✓			*		*									
		2U	2UE			✓	✓	✓												*	*		
		2S	2SE			✓	✓	✓						*		*							
		2C	2CE	100■		✓	✓	✓														*	*
U031-011	1	1B	1BE	100	✓	✓	✓		A						*							
		1P	1PE			✓	✓	✓								*						
		1G	1GE			✓	✓	✓			*											
		1K	1KE			✓	✓	✓					*									
		1R	1RE			✓	✓	✓									*					

♦Type of Strip:
Visual Strip Size
1-6 Parameters: 5 mm x 80 mm; 7-11 Parameters: 5 mm x 108 mm;
12-13 Parameters: 5 mm x 121 mm
U120/U500 Strip Size
1-11 Parameters: 5 mm x 108 mm;
"E" means extended strip length for 1-6 Parameters

◇ Also available in canisters of 25, 50 and 150 strips
■ Not available in canisters of 150 strips
▲ Single-strip Pouch available in 1,3, 6 and 20 strip kit
Canister Refill Kit, with 25 strips per pouch or canister, available in 3-pouch and 1- canister kit, or 4-pouch kit

CE Marked for sale in the European Community
Cleared for US 510(k)

U120 Urine Analyzer

Accurate
- Up to 120 tests/hour in Continuous Test Option
- Capable of reading 1 strip at a time in Single Test Option
- Test modes include Routine, STAT and QC
- Automatic calibration for accurate results and easy operation

Reliable
- Can read up to 4 Strip combinations with 8, 9, 10, 11 parameters, additional strips with 1-11 parameters available upon request
- Minimal training required

Convenient Operation
- Saves and recalls the last 2,000 results automatically
- Audible beep signals operator to dip strips in urine
- Can print up to 3 copies per test for convenient reviewing and easy record keeping
- Option to print results on sticker paper for quick and simple record management

Easy Data Management
- Includes RS232C port for easy data transfer to an external computer or LIS
- Optional Barcode Reader to record patient ID

Unique Lockout Functions *new!*
- Strip Lockout
  - Prevents using strips of another brand on the U120 Urine Analyzer
  - Requires barcode reader scan or manual entry of the canister code
- User Lockout
  - Eliminates unapproved users from testing
  - Up to 10 lab operators can perform testing, but only the lab administrator can change analyzer settings
- QC Lockout
  - Prevents testing without passing QC
  - QC tests can be performed once every 8 hours, day, week or month
  - Analyzer will alert when to run QC test
  - If QC tests fail, analyzer will switch to STAT mode and list "E" at the end of each test number

Specifications

Feature	Specifications
Analyzer Type	Manual
Methodology	Reflectance Photometry
Detection	Photosensitive Diode
Throughput	Single Test Option: 60 tests/hour Continuous Test Option: 120 tests/hour
Test Modes	Routine, STAT and QC
Lockout Functions	Strip Lockout: Available Upon Request; User/QC Lockout: Included with option to turn ON/OFF
Memory	Last 2,000 results
Strip Incubation Time	1 Minute
Wavelength of Monochromatic LED	525 nm and 635 nm
Standard Strips	8, 9, 10, 11 Parameters (5 mm x 108 mm)
Additional Strips Available	1-11 Parameters (5 mm x 108 mm); see URS Parameters
Total Combinations Per Analyzer	4 Combinations
Analyzer Ports	Standard RS232C Port for Barcode Reader or Data Transfer USB Port for Data Transfer 25 Pin Parallel Port for External Printer
Capabilities	Internal Thermal Printer (included) RS232C Barcode Reader (optional) Optional External Printer (not included) USB or RS232C Data Transfer Cable (optional)
Major Readable Barcodes	Code 128, Code 39, Codabar (NW-7), Interleaved 25, UPC-A, UPC-E, EAN 8, EAN 13
Calibration	Automatic
Available Languages on the Screen	English and additional language(s)
Operating Conditions	0-40°C (32-104°F); ≤85% RH
Storage Conditions	-5-50°C (23-122°F); ≤90% RH
Power Source	100-240 VAC, 50-60 Hz
Dimensions (L x W x H)	27.2 cm x 26.9 cm x 14.6 cm (10.7" x 10.6" x 5.7")
Display Dimensions (L x W)	10.8 cm x 5.7 cm (4.2" x 2.2")
Weight	2.6 kg (5.7 lbs)

Ordering Information

Product Name	Catalog No.	Components		Kit Box Dimensions (L x W x H) & Weight	Carton Dimensions (L x W x H) & Weight	Number of Kits/Carton
U120 Urine Analyzer	U111-101√†	1 Urine Analyzer 1 Strip holder 2 Printer Paper Rolls	2 Fuses (2.0A) 1 Power Cord 1 Quick Start Guide 1 Instruction Manual	42.0 cm x 41.5 cm x 31 cm; 5.0 kg 16.4" x 16.2" x 12.1"; 176.4 oz		1
U120 Urine Analyzer with Barcode Reader	U111-111√†	1 Urine Analyzer 1 Strip holder 2 Printer Paper Rolls 1 Barcode Reader (RS232C)	2 Fuses (2.0A) 1 Power Cord 1 Serial Splitter Cable (RS232C) 1 Quick Start Guide 1 Instruction Manual	44.5cm x 44.5cm x 40.0cm; 5.5 kg 17.5" x 17.5" x 15.7"; 194 oz		1
Barcode Reader	U221-111√†	1 Barcode Reader (RS232C)	1 Serial Splitter Cable (RS232C)	23.6 cm x 10.8 cm x 7.8 cm; 0.482 kg 9.3" x 4.3" x 3.1"; 17.0 oz	63.0 cm x 37.0 cm x 30.0 cm; 12.0 kg 24.8" x 14.6" x 11.8"; 423.3 oz	22
Printer Paper Rolls	U121-101	4 Printer Paper Rolls	Thermal Paper (0.06 m x 20 m): 200 results/roll	12.0 cm x 12.0 cm x 6.5 cm; 0.36kg 4.7" x 4.7" x 2.6"; 12.7oz	63.0 cm x 37.0 cm x 30.0 cm; 19.4 kg 24.8" x 14.6" x 11.8"; 684.3 oz	50
			Sticker Paper (0.06 m x 9 m): 100 results/roll	12.0 cm x 12.0 cm x 6.5 cm; 0.4 kg 4.7" x 4.7" x 2.6"; 14.1 oz	63.0 cm x 37.0 cm x 30.0 cm; 21.4 kg 24.8" x 14.6" x 11.8"; 684.3 oz; 754.9 oz	
U120 Data Transfer Kit	U221-131√†	1 Data Transfer Cable (RS232C)	1 Package Insert	16.0 cm x 13.0 cm x 3.5 cm; 0.147 kg 6.3" x 5.1" x 1.4"; 5.2 oz	25.0 cm x 21.0 cm x 15.0 cm; 1.36 kg 9.8" x 8.3" x 5.9"; 48.0 oz	8

√CE Marked for sale in the European Community CE

† Cleared for US 510(k)

U500 Urine Analyzer

Accurate and Efficient
- Up to 500 tests/hour for medium/large volume sample testing
- Professional accuracy equivalent to market leader
- Automatic strip detection and alignment for better efficiency
- Test modes include Routine, STAT and QC

Easy to Operate
- Large touch screen LCD offers simple menu navigation
- Uniquely designed strip platform/waste tray unit for easy one-step cleaning

Convenient
- Automatic calibration and waste disposal reduce hands-on time
- Can read strips with 8, 9, 10, 11 parameters, additional strips with 1-11 parameters available upon request
- Strip selection of up to 4 combinations for analyzer reading
- Stores up to 2,000 records and automatically flags abnormal results
- Capable of printing results on sticker paper for quick and easy record management

Data Management Capability
- Includes RS232C port for easy data transfer to an external computer or LIS
- Optional Barcode Reader to record patient ID

Unique Lockout Functions *Coming Soon!*
- Strip Lockout
  - Prevents using strips of another brand on the U500 Urine Analyzer
  - Requires barcode reader scan or manual entry of the canister code
- User Lockout
  - Eliminates unapproved users from testing
  - Up to 10 lab operators can perform testing, but only the lab administrator can change analyzer settings
- QC Lockout
  - Prevents testing without passing QC
  - QC tests can be performed once every 8 hours, day, week or month
  - Analyzer will alert when to run QC test
  - If QC tests fail, analyzer will switch to STAT mode and list "E" at the end of each test number

Specifications

Feature	Specifications
Analyzer Type	Semi-Automatic
Methodology	Reflectance Photometry
Detection	Photosensitive Diode
Throughput	500 tests/hour (Measuring cycle: 7 seconds/test)
Test Modes	Routine, STAT and QC
Lockout Functions	Strip Lockout: Available Upon Request; User/QC Lockout: Included with option to turn ON/OFF
Memory	Last 2,000 Records
Strip Incubation Time	1 Minute
Wavelength	525 and 635 nm
Standard Strips	8, 9, 10, 11 Parameters (5 mm x 108 mm)
Additional Strips Available	1-11 Parameters (5 mm x 108 mm); see URS Parameters
Total Combinations Per Analyzer	4 Combinations
Waste Disposal Capacity	Up to 150 Strips
Analyzer Ports	Standard RS232C Port for Barcode Reader or Data Transfer 25 Pin Parallel Port for External Printer
Capabilities	Internal Thermal Printer (included) RS232C Barcode Reader (optional) Optional External Printer (not included) RS232C Data Transfer Cable (optional)
Major Readable Barcodes	Code 128, Code 39, Codabar (NW-7), Interleaved 25, UPC-A, UPC-E, EAN 8, EAN 13
Calibration	Automatic
Available Languages on the Screen	English and additional language(s)
Operating Conditions	0-40°C (32-104°F); ≤85% RH
Storage Conditions	-5-50°C (23-122°F); ≤90% RH
Power Source	100-240 VAC, 50-60 Hz
Dimensions (L x W x H)	36.6 cm x 28.3 cm x 19.5cm (14.4" x 11.1" x 7.7")
Display Dimensions (L x W)	11.5 cm x 9.0 cm (4.5" x 3.5")
Weight	4.0 kg (8.8 lbs)

Ordering Information

Product Name	Catalog No.	Components		Kit Box Dimensions (L x W x H) & Weight	Carton Dimensions (L x W x H) & Weight	Number of Kits/Carton
U500 Urine Analyzer	U211-101√	1 Urine Analyzer 1 Strip Platform/Waste Tray 2 Printer Paper Rolls	2 Fuses (2.0A) 1 Power Cord 1 Instruction Manual	51.0 cm x 42.0 cm x 38.5 cm; 7 kg 20.1" X 16.5" x 15.2"; 246.9 oz		1
U500 Urine Analyzer with Barcode Reader	U211-111√	1 Urine Analyzer 1 Strip Platform/Waste Tray 2 Printer Paper Rolls 1 Barcode Reader (RS232C)	2 Fuses (2.0A) 1 Power Cord 1 Serial Splitter Cable (RS232C) 1 Instruction Manual	55.0 cm x 55.0 cm x 55.0cm; 9.2 kg 21.7" x 21.7" x 21.7"; 324.5 oz		1
Barcode Reader	U221-111√†	1 Barcode Reader (RS232C)	1 Serial Splitter Cable (RS232C)	23.6 cm x10.8 cm x 7.8 cm; 0. 482 kg 9.3" x 4.3" x 3.1"; 17.0 oz	63.0 cm x 37.0 cm x 30.0 cm; 12 kg 24.8" x 14.6" x 11.8"; 423.3 oz	22
Printer Paper Rolls	U121-101	4 Printer Paper Rolls	Thermal Paper (0.06 m x 20 m): 200 results/roll	12.0 cm x 12.0 cm x 6.5 cm; 0.360 kg 4.7" x 4.7" x 2.6"; 12.7oz	63.0 cm x 37.0 cm x 30.0 cm; 19.4 kg 24.8" x 14.6" x 11.8"; 684.3 oz	50
			Sticker Paper (0.06 m x 9 m): 100 results/roll	12.0 cm x 12.0 cm x 6.5 cm; 0.40 kg 4.7" x 4.7" x 2.6"; 14.1oz	63.0 cm x 37.0 cm x 30.0 cm; 21.4 kg 24.8" x 14.6" x 11.8"; 684.3 oz; 754.9 oz	
U500 Data Transfer Kit	U221-131√	1 Data Transfer Cable (RS232C)	1 Package Insert	16.0 cm x 13.0 cm x 3.5 cm; 0.147kg 6.3" x 5.1" x 1.4"; 5.2 oz	25.0 cm x 21.0 cm x 15.0 cm; 1.36 kg 9.8" x 8.3" x 5.9"; 48.0 oz	8

We also offer other rapid diagnostic and medical products:

Blood Glucose Monitoring Systems, Immunoassay EIA/ELISA and more.

√CE Marked for sale in the European Community CE

† Cleared for US 510(k)

ACON Laboratories, Inc., 10125 Mesa Rim Road, San Diego, CA 92121, U.S.A. • Tel: 1-858-875-8000 • Fax: 1-858-200-0729 • E-mail: info@aconlabs.com
Please visit our website for details: www.aconlabs.com

1150449703

Atlas Medical

Date: 05/Jan/2023

STATEMENT

We, Atlas Medical having a registered office at Ludwig-Erhard-Ring 3, 15827 Blankenfelde-Mahlow, Berlin, Germany assign SRL Sanmedico having a registered office at A. Corobceanu Street 7A, apt.9, Chisinau MD-2012, Moldova, as authorized representative in correspondence with the conditions of directive 98/79/EEC.

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.

On Behalf of Manufacturer:

General Manager

Haya Amawi

Signature: _____

Date: 05.01.2023

Atlas Medical GmbH
Ludwig - Erhard Ring 3
15827 Blankenfelde - Mahlow
Tel. (0049) 33708 - 355030

Atlas Medical: Ludwig-Erhard-Ring 3, 15827 Blankenfelde-Mahlow, Berlin, Germany,
Tel:+4933708355030

Regulatory Office: William James House, Cowley Rd, Cambridge, CB4 0WX, United Kingdom
Tel: +44 (0) 1223 858 910

Middle East Site: P.O Box 204, King Abdullah II Industrial Estate, Amman, 11512, Jordan
Tel: +962 6 4026468

Atlas Medical

Declaration Ref No: DC22-0015

Date : 13.05.2022

CE Declaration of Conformity

We,

Atlas Medical GmbH
Head office: Ludwig-Erhard-Ring 3
15827 Blankenefelde-Mahlow Germany
Tel: +49(0)33708355030
Email: info@atlas-site.com

Middle East Site: : Sahab Industrial Zone Area, King Abdullah II Industrial City
Amman 11512, Jordan
Tel.: +962 6 4026468
Fax: +962 6 4022588
Email: info@atlas-medical.com

Declare our responsibility that the following product:

Blood Grouping Reagents:

(Anti-A Monoclonal Reagent, Anti-B Monoclonal Reagent , Anti-AB Monoclonal Reagent and Anti-D IgG/IgG blend Reagent)

see the attached list of variants

That are classified as Annex II, list A

Is produced under Atlas quality system (ISO13485: 2016) supported by GMED certificate and complies with the essential requirements of

In Vitro Diagnostic Medical Devices Directive 98/79/EC

And

EN ISO 18113-1, -2 :2011, EN ISO 15223:2016
EN ISO 14971:2019, EN ISO 23640 :2015 , ISO 2859 :2017,
EN 13612:2002, EN 13641:2002 , EN 13975:2003,
EN ISO 13485:2016, EN 62366-1:2020

And

Intended for In-Vitro Professional use only.

Conformity Assessment Route:

Annex IV.3 –Approval full Quality Assurance System.
Annex IV.4-EC Design Examination (of the product)

Notified Body:

G-MED	CE	0459

GMED, Laboratoire national de métrologie et d'essais
1 rue Gaston Boissier 75015 Paris
Tél. : 01 40 43 37 00 , TVA:FR 28 839 022 522

EC Certificates No.:

- **CE Certificate of Approval full Quality Assurance System: 33540 rev4.**
- **CE Certificate Of EC Design Examination: 33544 rev3.**

Atlas Medical GmbH	Start of CE Marking	Date of expiry	Name & Position	Signature	MRXDO10F.11 21.10.2013
	09th october 2017	26th May 2025	Amani Al-habahbeh (RA Manager)	Amani	

Atlas Medical

Atlas Medical

Declaration Ref No: DC22-0015

Date : 13.05.2022

Product Code	Product Name	GMDN Code
8.02.00.0.0010	Anti-A Monoclonal Reagent (Titer: 1/512), 10ml/vial, 1 vial/Carton Box	52532
8.02.00.1.0100	Anti-A Monoclonal Reagent (Titer: 1/512), 10ml/vial. 10 vials / Plastic Pack	52532
8.02.00.1.0180	Anti-A Monoclonal Reagent (Titer: 1/512), 10ml/vial. 18 vials / Carton Box	52532
8.02.01.0.0010	Anti-B Monoclonal Reagent (Titer: 1/512), 10ml/vial, / Carton Box	52538
8.02.01.1.0100	Anti-B Monoclonal Reagent (Titer: 1/512), 10ml/vial, 10 vials / Plastic Pack	52538
8.02.01.1.0180	Anti-B Monoclonal Reagent (Titer: 1/512), 10ml/vial, 18 vials / Carton Box	52538
8.02.02.0.0010	Anti-AB Monoclonal Reagent (Titer: 1/512), 10ml/vial, 1 vial/ Carton Box	46442
8.02.02.1.0100	Anti-AB Monoclonal Reagent (Titer: 1/512), 10ml/vial, 10 vials/Plastic Pack	46442
8.02.02.1.0180	Anti-AB Monoclonal Reagent (Titer: 1/512), 10ml/vial, 18 vials/Carton Box	46442
8.02.03.0.0010	Anti-D IgG/IgM Blend Reagent (Titer: 1/128), 10ml/vial, 1 vial/ Carton Box	52647
8.02.03.1.0100	Anti-D IgG/IgM Blend Reagent (Titer: 1/128), 10ml/vial, 10 vials / Plastic Pack	52647
8.02.03.1.0180	Anti-D IgG/IgM Blend Reagent (Titer: 1/128), 10ml/vial, 18 vials / Carton Box	52647
8.02.04.0.0010	Anti-A Monoclonal Reagent (Titer: 1/256), 10ml/vial, 1 Vial/Carton Box	52532
8.02.04.0.0100	Anti-A Monoclonal Reagent (Titer: 1/256), 10ml/vial, 10 vials / Plastic Pack	52532
8.02.05.0.0010	Anti-B Monoclonal Reagent (Titer: 1/256), 10ml/vial, 1vial/Carton Box	52538
8.02.05.0.0100	Anti-B Monoclonal Reagent (Titer: 1/256), 10ml/vial, 10 vials /Plastic Pack	52538
8.02.05.6.0030	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-D (1/64)),3x10ml / plastic Pack	45308
8.02.05.7.0020	ABO Set: Anti-A (1/256), Anti-B (1/256), 2x10ml /Plastic Pack	52695
8.02.06.0.0010	Anti-AB Monoclonal Reagent (Titer: 1/256), 10ml/vial, 1vial/Carton Box	46442
8.02.06.1.0100	Anti-AB Monoclonal Reagent (Titer: 1/256), 10ml/vial,10 vials /Plastic Pack	46442
8.02.06.1.0180	Anti-AB Monoclonal Reagent (Titer: 1/256), 10ml/vial,18 vials / Carton Box	45308
8.02.07.0.0010	Anti-D IgG/IgM Blend Reagent (Titer: 1/64), 10ml/vial, 1Vial/ Carton Box	52647
8.02.07.1.0100	Anti-D IgG/IgM Blend Reagent (Titer: 1/64), 10ml/vial, 10 vials / Plastic Pack	52647

Atlas Medical GmbH	Start of CE Marking	Date of expiry	Name & Position	Signature	MRXDO10F.11 21.10.2013
	09th october 2017	26th May 2025	Amani Al-habahbeh (RA Manager)		

Atlas Medical
Quality Diagnostic Products

Atlas Medical

Declaration Ref No: DC22-0015

Date : 13.05.2022

8.02.47.0.0030	ABO Set (Anti-A (1/512), Anti-B (1/512), Anti-D (1/128)),3x10ml/Plastic Pack	45308
8.02.47.1.0030	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-D (1/64)), 3x10ml /Carton Box.	45308
8.02.47.3.0030	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-D (1/64)), 3x10ml /Plastic Pack	45308
8.02.47.5.0030	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-D (1/128)), 3x10ml/Plastic Pack	45308
8.02.49.0.0040	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-AB (1/256), Anti-D (1/64)), 4x10ml/Carton Box	45308
8.02.49.2.0040	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-AB (1/256), Anti-D (1/128)), 4 x 10ml, 4 vials/Plastic Pack	45308
8.02.53.0.0040	ABO Set (Anti-A (1/512), Anti-B (1/512), Anti-AB (1/512) Anti-D (1/128)), 4x10ml/Plastic Pack	45308
8.02.53.1.0040	ABO Set (Anti-A (1/512), Anti-B (1/512), Anti-AB (1/512) Anti-D (1/128)), 4x10ml, 4vials/Plastic Pack	45308
8.02.70.0.0010	Anti-A monoclonal reagent , Titer (1/1024), 10 ml/vial, 1Vial/ Carton Box	52532
8.02.71.0.0010	Anti-B Monoclonal reagent (Titer: 1/1024) , 10 ml/vial ,1Vial/ Carton Box	52538
8.02.72.0.0010	Anti-AB Monoclonal reagent (Titer: 1/1024) , 10 ml/vial , 1Vial/ Carton Box	45308
8.02.85.0.0010	Anti-D IgG/IgM Blend Reagent , Titer 1/256, 10ml/vial, 1Vial/ Carton Box	52647

Atlas Medical
Quality Diagnostic Products

Atlas Medical GmbH	Start of CE Marking	Date of expiry	Name & Position	Signature	MRXDO10F.11 21.10.2013
	09th october 2017	26th May 2025	Amani Al-habahbeh (RA Manager)		

CERTIFICAT
CERTIFICATE OF REGISTRATION
N° 36655 rev.1

GMED certifie que le système de management de la qualité développé par

GMED certifies that the quality management system developed by

ATLAS MEDICAL GmbH
Ludwig-Erhard-Ring 3
15827 Blankenfelde-Mahlow GERMANY

pour les activités
for the activities

Conception et développement, fabrication et vente de dispositifs médicaux de diagnostic in vitro .

Design and Development, Manufacturing and Sales of in vitro diagnostic medical devices.

réalisées sur le(s) site(s) de
performed on the location(s) of

Voir addendum

See addendum

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

ISO 13485: 2016

Début de validité */ Effective date* **October 9th, 2020 (included)**
Valable jusqu'au */ Expiry date :* **October 8th, 2023 (included)**
Etabli le */ Issued on :* **October 8th, 2020**

DocuSigned by:
Beatrice Lys
EE33BDA9BAA04A3...

GMED SAS GMED SAS GMED GROUPE LNE

On behalf of the President
Béatrice LYS
Technical Director

cofrac
CERTIFICATION DE SYSTEMES DE MANAGEMENT
Accréditation n°4-0608
Liste des sites accrédités et portée disponible sur www.cofrac.fr

GMED N° 36655–1
Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Renouvelle le certificat 36655-0

GMED_SQ_plus3sites-F-V0-07-2018

Addendum au certificat n° 36655 rev. 1 page 1/1
Addendum of the certificate n° 36655 rev. 1
Dossier / *File* N°P601408

Ce certificat couvre les activités et les sites suivants :
This certificate covers the following activities and sites:

French version :
Conception et développement, fabrication et vente de dispositifs médicaux de diagnostic *in vitro* à usage professionnel et/ ou d'autodiagnostic, dans les domaines du groupage sanguin, de la microbiologie, de la biochimie, de la toxicologie, de l'oncologie, de la cardiologie, de l'histologie, de l'endocrinologie et des maladies infectieuses, dans les techniques d'Agglutination/ ELISA/ Tests rapides/ Colorimétrie/ Disques antibiotiques.

English version:
Design and Development, Manufacturing and Sales of in vitro diagnostic medical devices for professional use and/or for self-testing, in the field of Immunohematology, Microbiology, Biochemistry, Toxicology, Oncology, Cardiology, Histology, Endocrinology Biosensors and Infectious diseases, in techniques of Agglutination/ ELISA/ Rapid tests/ Colorimetry/Antibiotic disks.

ATLAS MEDICAL GmbH
Ludwig-Erhard-Ring 3
15827 Blankenfelde-Mahlow
GERMANY

French version:
Siège social, responsable de la mise sur le marché
English version:
Headquarter, legal manufacturer

****

Sahab Industrial Zone Area
King Abdullah II Industrial City
Amman 11512
JORDAN

French version:
Conception, fabrication et contrôle final
English version:
Design, manufacture and final control

****

William James House
Cowley Road,
Cambridge, CB OWX
United Kingdom

French version:
Contact réglementaire
English version:
Regulatory Administration

****

3 sites / 3 *sites*

DocuSigned by:
Beatrice Lys
EF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director

Atlas Medical CE 0459

Blood Grouping Reagents: Anti-A Monoclonal Reagent, Anti-B Monoclonal Reagent, Anti-AB Monoclonal Reagent, Anti-D IgG/IgM blend Reagent, & Their variants SLIDE AND TUBE TESTS

IVD **For *In-Vitro* and professional use only**

Store at 2- 8°C

INTENDED USE

The blood grouping reagents are used to detect the presence or absence of A, B or Rhesus Antigens on the surface of human red blood cells based on hemaglutination using slide or tube test techniques in whole blood samples or anticoagulant blood samples collected in EDTA , citrate or heparin tubes.

INTRODUCTION & PRINCIPLES

Blood grouping reagents are prepared from In-Vitro culture supernatants of hybridized immunoglobulin-secreting mouse cell lines. The reagents are diluted with phosphate buffer containing sodium chloride, EDTA and bovine albumin to give reagents that are optimized for use in tube and slide procedures. **Anti-A monoclonal reagent is colored with acid blue (patent blue) dye, Anti-B monoclonal reagent is colored with acid yellow (tartrazine) dye, and Anti-AB monoclonal reagent is not colored.** The test procedure is based on hemaglutination principle, where red cells possessing the antigen agglutinate in the presence of the corresponding antibody indicating that the result is positive. The test is considered negative when no agglutination appears.

Anti-D IgG/IgM blend reagent is prepared from carefully blended human monoclonal IgM and IgG. Anti-D IgG/IgM blend reagent is suitable for slide and tube test procedures. The reagent will directly agglutinate Rh D positive cells, including majority of variants (but not D^{VI}) and a high proportion of weak D (Du) phenotypes. The reagent will agglutinate category D^{VI} and low grade weak D (D^{u}) phenotypes by the indirect anti-globulin techniques.

Anti-D IgG/IgM blend reagent is diluted with a sodium chloride solution, sodium phosphate solution and bovine albumin (sodium caprylate free). Anti-D IgG/IgM blend reagent is not colored. The procedure is based on hemaglutination principle, where red cells' possessing the antigen agglutinates in the presence of the corresponding antibody in the reagent indicating that the result is positive. The test is considered negative when no agglutination appears.

MATERIALS

MATERIALS PROVIDED

Blood Grouping Reagents:

- Anti-A monoclonal reagent (10 ml/vial), Clone: (9113D10).
- Anti-B monoclonal reagent (10 ml/vial), Clone: (9621A8).
- Anti-AB monoclonal reagent (10ml/vial), Clone: (152D12+9113D10).
- Anti-D IgG/IgM Blend reagent (10 ml/vial), Clone: (P3X61 + P3X21223B10 + P3X290 + P3X35).

MATERIALS NEEDED BUT NOT PROVIDED

- Plastic test tube or glass.
- Isotonic saline solution (% 0.9) NaCl).
- Applicator sticks.
- Centrifuge (100-1200 (g) for tube test).
- Timer.
- Incubator
- Anti-Human Globulin Reagent (can be ordered from Atlas Medical).
- White or transparent glass slide.

PRECAUTIONS

- The reagents are intended for in vitro diagnostic use only.
- The test is for well trained professional healthy user not for lay user.
- These reagents are derived from animal and human sources, thus, appropriate care must be taken in the use and disposal of these reagents, as there are no known test methods that can guarantee absence of infectious agents.
- Do not use reagents if it is turbid or contain particles as this may indicate reagent deterioration or contamination.
- Protective clothing should be worn when handling the reagents.
- **The reagents contain (0.1-0.2%) Sodium Azide and 0.02% sodium arseniate which is toxic and can be absorbed through the skin. When drained, the drains should be thoroughly flushed with water.**
- The reagents should be used as supplied and in accordance to the procedure mentioned below. Don't use beyond expiration date.
- Avoid cross contamination of reagents or specimens.
- Visible signs of microbial growth in any reagent may indicate degradation and the use of such reagent should be discontinued.
- Don't use these reagents if the label is not available or damaged.
- Do not use dark glass slide.
- Don't use the kit if damaged or the glass vials are broken or leaking and discard the contents immediately.
- Test materials and samples should be discarded properly in a biohazard container.
- Wash hands and the test table top with water and soap once the testing is done.
- Heamolysed blood sample should not be used for testing.
- The test should be performed at room temperature in a well let area with very good visibility.
- Failure to follow the procedure in this package insert may give false results or safety hazard.
- Close the vial tightly after each test.
- The reagent is considered toxic, so don't drink or eat beside it.
- If spillage of reagent occurs clean with disinfectant (disinfectant used could be irritable so handle with care).

STORAGE CONDITIONS

- The reagents should be stored refrigerated between 2 - 8°C.
- Never Freeze or expose to elevated temperature.
- The reagent is stable until the expiry date stated on the product label. Do not use the reagents past the expiry date.

REAGENT PREPRATION

- The reagents are intended for use as supplied, no prior preparation or dilution of the reagent is required.
- All reagents should be brought to room temperature before use.

SPECIMEN COLLECTION AND PREPARATION

- Blood collected with or without anticoagulant (EDTA, Heparin or Citrate) can be used for Antigen typing.

Note: Blood collected without anticoagulant should be tested immediately.

- The specimens should be tested as soon as possible after collection. If testing is delayed, the specimens should be stored at 2- 8 ºC, Sample must be retained to room temperature prior to analysis. (Testing should be carried out within five days of collections).
- Insure that there is no sign of hemolysis.
- At the time of the test, centrifuge the blood sample at 1200 RCF for 3 minutes.
- Blood collection is to be done with great care.

PROCEDURES

A. DIRECT TUBE METHOD AT ROOM TEMPERATURE

1. Prepare a 5% suspension of red blood cells in isotonic solution.
2. Using the vial dropper, transfer a drop (40±10µl) of each reagent into a separate and appropriately marked tube.
3. Add 50 µl of red blood cell suspension prepared in step 1.
4. Shake to homogenize the mixture, then centrifuge at 500g for **1 minute.**
5. Gently shake the tube in such a way to detach the cell pellet and macroscopically observe for any possible agglutination.
6. Read the reaction immediately.
7. For Anti-D tube, if the reaction is weak or negative, shake the tubes and incubate at 37°C for **15 minutes.**
8. Wash the red blood cells twice with isotonic saline solution (NaCl 0.9%) and discard the last washing liquid.
9. Add one drop (50µl) of the AHG reagent into the tube. Mix and centrifuge at 120g for **1 minute.**
10. Gently shake the tube in such a way to detach the cell pellet and macroscopically observe for any possible agglutination.
11. Read the reaction immediately.

B. ANTIGLOBULIN INDIRECT METHOD for ANTI-D

1. After immediately centrifuging and reading as above, if the reaction is weak or negative, shake the tubes and incubate at 37°C for 15 minutes.
2. Wash the red blood cells twice with isotonic saline solution (NaCl 0.9%) and discard the last washing liquid.
3. Add one drop (40 µl ± 10 µl) of ANTI-HUMAN GLOBULIN to the tube. Mix and centrifuge at 120 (g) for **1 minute**.
4. Gently shake the tube in such a way to detach the cell pellet and macroscopically observe for any possible agglutination.
5. Read the reaction immediately.

C. DIRECT SLIDE METHOD AT ROOM TEMPERATURE

1. Bring reagents and samples to room temperature (18-25°C).
2. Using the wax pen divide the slide into appropriate numbers of divisions.
3. Using the provided dropper, place one drop (40 µl ± 10 µl) of each reagent onto its correspondent division on the slide.
4. Add 25µl of the precipitated cells next to each drop of reagents.
5. Mix the reagent and the cells using a clean stirring stick over an area with a diameter of approximately 20-40mm.
6. Incubate the slide at room temperature (18-25°C) without stirring for **30 seconds**.
7. Hold the slide and gently rock the slide for **3 minutes** and observe macroscopically for any agglutination.
8. Read the reaction immediately.

READING THE RESULT

POSITIVE: If Agglutination appears.

NEGATIVE: If no agglutination is observed.

Use the below table to determine the blood group:

Result of each reaction				ABO Group
Anti-A monoclonal reagent	Anti-B monoclonal reagent	Anti-AB monoclonal reagent	Anti-D IgG/IgM blend reagent	
+	-	+	+	**A+**
+	-	+	-	**A-**
-	+	+	+	**B+**
-	+	+	-	**B-**
+	+	+	+	**AB+**
+	+	+	-	**AB-**
-	-	-	+	**O+**
-	-	-	-	**O-**

STABILITY OF THE REACTIONS

- ABO Blood Grouping Tube tests should be read immediately following centrifugation.
- Slide tests should be interpreted within three minutes to avoid the possibility that a negative result may be incorrectly interpreted as positive due to drying of reagents.
- Delay in reading and interpreting results may result in weekly positive or falsely negative reactions. Slide tests should be interpreted at the end of the three minutes.

PROCEDURE LIMITATION

1. False positive/ negative results may occur due to:
   - Contamination from test materials.
   - Improper storage, cells concentration, incubation time or temperature.
   - Improper or excessive centrifugation.
   - Deviation from the recommended technique.
   - Blood samples of weak A or B subgroups may give rise to false negative results or weak reactions when tested using slide test method. It is advisable to re-test weak subgroups using tube test method.
2. Weaker reactions may be observed with stored blood than with fresh blood.
3. ABO antigens are not fully developed at birth, weaker reactions may therefore occur with cord or neonatal red cells.
4. ABO blood grouping interpretation on individuals greater than 6 months old should be confirmed by testing serum or plasma of the individual against group A and group B red cells (reverse grouping). If the results obtained with the serum do not correlate with the red cell test, further investigation is required.
5. Return the kit to the agent if it does not function properly.
6. Anti-D IgG/IgM blend Reagent tests conducted on particular weak-D phenotypes, while satisfactory, cannot ensure recognition of all weak variants, due to the variability of antigen patterns.

DIAGNOSTIC PERFORMANCE CHARACTERISTICS

The following tables compare the results in slide and tube techniques of 3 lots of Atlas Medical reagents and the results of a CE marked device.

Slide Technique				
Group A				
Positive with anti-A monoclonal reagent and anti-AB monoclonal reagent Negative with anti-B and Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
232	232	232	232	100%
Tube Technique				
Group A				
Positive with anti-A monoclonal reagent and anti-AB monoclonal reagent Negative with anti-B and Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
212	212	212	212	100%

Slide Technique				
Group B				
Positive with anti-B monoclonal reagent and anti-AB monoclonal reagent Negative with anti-A and Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
61	61	61	61	100%
Tube Technique				
Group B				
Positive with anti-B monoclonal reagent and anti-AB monoclonal reagent Negative with anti-A and Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
61	61	61	61	100%

Slide Technique				
Group O				
Negative with anti-A monoclonal reagent, Anti-B monoclonal reagent and anti-AB monoclonal reagent Negative with Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
241	241	241	241	100%
Tube Technique				
Group O				
Negative with anti-A monoclonal reagent, Anti-B monoclonal reagent and anti-AB monoclonal reagent Negative with Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
243	243	243	243	100%

Slide Technique				
Group AB				
Positive with anti-A monoclonal reagent, Anti-B monoclonal reagent and anti-AB monoclonal reagent Negative with Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
33	33	33	33	100%
Tube Technique				
Group AB				
Positive with anti-A monoclonal reagent, Anti-B monoclonal reagent and anti-AB monoclonal reagent Negative with Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
24	24	24	24	100%

No inversion in diagnosis has been shown: from a qualitative point of view we have observed 100% compliance in direct group testing in slide and tube techniques for determination of A, B, AB and O groups for the three lots of Atlas Medical.

QUALITY CONTROL

The reactivity of all blood grouping reagents should be confirmed by testing known positive and negative red blood cells on each day of use.

To confirm the specificity and sensitivity, Blood grouping reagents should be tested with antigen-positive and antigen-negative red blood cells.

REFERENCES

1. BCSH Blood Transfusion Task Force. Guidlines for microplate techniques in liquid-phase blood grouping and antibody screening. Clin. Lab. Haem 1990: 12, 437-460.
2. Issitt P. D. Applied Blood Group Serology, 3rd ed. Miami: Montgomery Scientific, 1985.
3. Kholer G., Milstein C. Continuous culture of fused cells secreting antibody of predefined specificity, 256, 495-497, 1975
4. Messeter L. et. al. Mouse monoclonal antibodies with anti-A, anti-B and anti-A,B specificities, some superior to human polyclonal ABO reagents, Vox Sang 46, 185-194, 1984
5. Race R.R. and Sanger R. Blood groups in man, 6th ed., Oxford: Blackwell Scientific, 1975.
6. Voak D. ET. al., Monoclonal anti-A and anti-B development as cost effective reagents. Med. Lab. Sci 39, 109-122. 1982.

7. Standards for Blood Banks d Transfusion Service. 11th Ed., Washington D.C., AABB 1984:25.
8. Widmann F.K.ed Technical Manual, 9th Ed., Wahington D.C.: AABB 1985:9.

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PPI861A01
Rev.L (19.02.2022)

CE 0459

LIST OF VARIENTS:

Product Code	Product Name
8.02.00.0.0010	Anti-A Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 1 vial/Carton Box
8.02.00.1.0100	Anti-A Monoclonal Reagent (Titer: 1 /512), 10ml/vial. 10 vials / Plastic Pack
8.02.00.1.0180	Anti-A Monoclonal Reagent (Titer: 1 /512), 10ml/vial. 18 vials / Carton Box
8.02.01.0.0010	Anti-B Monoclonal Reagent (Titer: 1 /512), 10ml/vial, / Carton Box
8.02.01.1.0100	Anti-B Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 10 vials / Plastic Pack
8.02.01.1.0180	Anti-B Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 18 vials / Carton Box
8.02.02.0.0010	Anti-AB Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 1 vial/ Carton Box
8.02.02.1.0100	Anti-AB Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 10 vials/Plastic Pack
8.02.02.1.0180	Anti-AB Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 18 vials/Carton Box
8.02.03.0.0010	Anti-D IgG/IgM Blend Reagent (Titer: 1 /128), 10ml/vial, 1 vial/ Carton Box
8.02.03.1.0100	Anti-D IgG/IgM Blend Reagent (Titer: 1 /128), 10ml/vial, 10 vials / Plastic Pack
8.02.03.1.0180	Anti-D IgG/IgM Blend Reagent (Titer: 1 /128), 10ml/vial, 18 vials / Carton Box
8.02.04.0.0010	Anti-A Monoclonal Reagent (Titer: 1 /256), 10ml/vial, 1 Vial/Carton Box
8.02.04.0.0100	Anti-A Monoclonal Reagent (Titer: 1 /256), 10ml/vial, 10 vials / Plastic Pack
8.02.05.0.0010	Anti-B Monoclonal Reagent (Titer: 1 /256), 10ml/vial, 1vial/Carton Box
8.02.05.0.0100	Anti-B Monoclonal Reagent (Titer: 1 /256), 10ml/vial, 10 vials /Plastic Pack
8.02.05.6.0030	ABO Set (Anti-A (1/256), Anti-B (1 /256), Anti-D (1/64)),3x10ml / plastic Pack
8.02.05.7.0020	ABO Set: Anti-A (1/256), Anti-B (1 /256), 2x10ml /Plastic Pack
8.02.06.0.0010	Anti-AB Monoclonal Reagent (Titer: 1 /256), 10ml/vial, 1vial/Carton Box
8.02.06.1.0100	Anti-AB Monoclonal Reagent (Titer: 1 /256), 10ml/vial,10 vials /Plastic Pack
8.02.06.1.0180	Anti-AB Monoclonal Reagent (Titer: 1 /256), 10ml/vial,18 vials / Carton Box
8.02.07.0.0010	Anti-D IgG/IgM Blend Reagent (Titer: 1 /64), 10ml/vial, 1Vial/ Carton Box
8.02.07.1.0100	Anti-D IgG/IgM Blend Reagent (Titer: 1 /64), 10ml/vial, 10 vials / Plastic Pack
8.02.47.0.0030	ABO Set (Anti-A (1 /512), Anti-B (1 /512), Anti-D (1 /128)),3x10ml/Plastic Pack
8.02.47.1.0030	ABO Set (Anti-A (1 /256), Anti-B (1 /256), Anti-D (1 /64)), 3x10ml /Carton Box.
8.02.47.3.0030	ABO Set (Anti-A (1 /256), Anti-B (1 /256), Anti-D (1 /64)), 3x10ml /Plastic Pack
8.02.47.5.0030	ABO Set (Anti-A (1 /256), Anti-B (1 /256), Anti-D (1 /128)), 3x10ml/Plastic Pack
8.02.49.0.0040	ABO Set (Anti-A (1 /256), Anti-B (1 /256), Anti-AB (1 /256), Anti-D (1 /64)), 4x10ml/Carton Box
8.02.49.2.0040	ABO Set (Anti-A (1 /256), Anti-B (1 /256), Anti-AB (1 /256), Anti-D (1 /128)), 4 x 10ml, 4 vials/Plastic Pack
8.02.53.0.0040	ABO Set (Anti-A (1 /512), Anti-B (1 /512), Anti-AB (1 /512) Anti-D (1 /128)), 4x10ml/Plastic Pack
8.02.53.1.0040	ABO Set (Anti-A (1 /512), Anti-B (1 /512), Anti-AB (1 /512) Anti-D (1 /128)), 4x10ml, 4vials/Plastic Pack
8.02.70.0.0010	Anti-A monoclonal reagent , Titer (1/1024), 10 ml/vial, 1Vial/ Carton Box
8.02.71.0.0010	Anti-B Monoclonal reagent (Titer: 1 /1024) , 10 ml/vial ,1Vial/ Carton Box
8.02.72.0.0010	Anti-AB Monoclonal reagent (Titer: 1 /1024) , 10 ml/vial , 1Vial/ Carton Box
8.02.85.0.0010	Anti-D IgG/IgM Blend reagent (Titer 1 /256), 10ml/vial, 1Vial/ Carton Box

REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry

Science Park CREALYS
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http://www.corisbio.com

STATEMENT

We, **CORIS BIOCONCEPT** having a registered office at SCIENCE PARK CREALYS, Rue Jean Sonet 4A, 5032 Gembloux, BELGIUM assign SRL Sanmedico, having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova, as authorized representative in correspondence with the conditions of directive 98/79/EC.

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.

Gembloux, December 03rd, 2021

Rimma DOLOTKAZINA
Sales Director

CORIS BIOCONCEPT
RUE JEAN SONET 4A
BE-5032 GEMBLOUX

Certificate BE21/819944231.00

The management system of

Coris BioConcept

Science Park CREALYS - Rue Jean Sonet 4A
5032 Gembloux, Belgium

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design, development, manufacture and distribution of in vitro diagnostic tests for the detection of pathogens in the diagnosis of respiratory, gastric, enteric and parasitic diseases, the detection of resistance to antibiotics and the detection in urine of therapeutics, used for the treatment of these infectious diseases.
Distribution of instrument for electrochemical detection to be used with Coris' kit.

This certificate is valid from 21 August 2021 until 20 August 2024
and remains valid subject to satisfactory surveillance audits.
Issue 3. Certified since 7 April 2021.
Recertification audit due before 20 July 2024.

Multiple certificates have been issued for this scope.
The main certificate is numbered BE21/819944231.00.

This is a multi-site certification.
Additional site details are listed on subsequent pages.

Authorised by

Pieter Weterings
Certification Manager

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Accreditation Number
005-QMS
EN ISO/IEC 17021-1:2015

Coris BioConcept

ISO 13485:2016
EN ISO 13485:2016

Issue 3

Detailed scope

Design, development, manufacture and distribution of in vitro diagnostic tests for the detection of pathogens in the diagnosis of respiratory, gastric, enteric and parasitic diseases, the detection of resistance to antibiotics and the detection in urine of therapeutics, used for the treatment of these infectious diseases.

Distribution of instrument for electrochemical detection to be used with Coris' kit.

Additional facilities

Science Park CREALYS - Rue Jean Sonet 29, 5032 Gembloux, Belgium

Accreditation Number

005-QMS
EN ISO/IEC 17021-1:2015

CORIS BioConcept

EC Declaration of Conformity according to Annex III of the IVDD

This is to certify that following IVD products:

- **Rota-Strip (C-1001)**
- **Adeno-Strip (C-1002)**
- **40/41 Adeno-Strip (C-1003)**
- **Combi-Strip & Combi K-SeT (C-1004; K-1204; K-1504)**
- **Crypto-Strip (C-1005)**
- **RSV Respi-Strip & RSV K-SeT (C-1006; K-1206; K-1506)**
- **Adeno Respi-Strip & Adeno Respi K-SeT (C-1009; K-1209; K-1509)**
- **Influ A+B K-SeT (K-1212; K-1512)**
- **Giardia-Strip & Giardia K-SeT (C-1013; K-1213; K-1513)**
- **Legionella *K*-SeT (K-1215; K-1515)**
- **GastroVir-Strip & GastroVir K-SeT (C-1016; K-1216; K-1516)**
- **Crypto/Giardia Duo-Strip (C-1018)**
- **Pylori-Strip & Pylori K-SeT (C-1019; K-1219; K-1519)**
- **C.diff-Strip & Clostridium K-SeT (C-1020; K-1220; K-1520)**
- **Strep-A Respi-Strip (C-1022)**
- **P. aeruginosa mexQ-TesT (C-3806)**
- **Proguanil / Malarone™-Strip; Proguanil-Strip (C-10T1; C-40T1)**
- **Mefloquine / Lariam™-Strip; Mefloquine-Strip (C-10T2; C-40T2)**
- **HAT Sero K-SeT (K-12S2; K-15S2)**
- **OXA-48 K-SeT (K-15R1)**
- **KPC K-SeT (K-15R2)**
- **RESIST-3 O.O.K. K-SeT (K-15R4)**
- **RESIST-3 O.K.N. K-SeT (K-15R5)**
- **RESIST-4 O.K.N.V. (K-15R8)**
- **OXA-23 K-SeT (K-15R7)**
- **RESIST-5 O.O.K.N.V. (K-15R9)**
- **IMP *K*-SeT (K-15R10)**
- **BL-RED 25 (RED-0001)**
- **Adenovirus Positive Control (C-1082)**
- **RSV Positive Control (C-1086)**
- **Influenza A Positive Control (C-1090)**
- **Influ A&B Control Test (C-1092)**
- **Giardia Lamblia Control Test (C-1093)**
- **Pylori Positive Control (C-1099)**
- **Strep-A Positive Control (P-1022)**
- **Negative Control (CTR-1000)**

are manufactured and sold by **Coris BioConcept**
Science Park CREALYS
Rue Jean Sonet 4A - 5032 Gembloux - BELGIUM

These products:

1. Belong to the Class "Others/General" as they are not for self-testing and do not belong to List A or List B of Annex II of IVDD (98/79 EC).
2. Comply with all Essential Requirements (Annex I) of the IVDD (98/79 EC)
3. This compliance has been properly documented using a checklist created from Annex I and III of the IVDD, linked to all supporting Technical Documentation. This documentation included both product specific and process (Quality System) specific documents.
4. Have a Quality System in place based ISO 13485
5. This Declaration is issued by Coris BioConcept and has unlimited time validity.
6. This Declaration of Conformity is signed below, certifying these requirements have been met and documented.

For Coris BioConcept, made in Gembloux the 2sd of October, 2019

T. Leclipteux
C.E.O

C. Misson
QA Manager

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ИНН: 5035025076, КПП: 503501001
Банк получателя: ПАО Сбербанк России г. Москва
в Орехово-Зуевском ОСБ № 1556/063
р/с 40702810040310124002
к/с 30101810400000000225
БИК 044525225

17.06.2020

АВТОРИЗАЦИЯ ДИСТРИБЬЮТОРА

Закрытое акционерное общество «ЭКОлаб» (Россия, 142530, Московская обл., г.Электрогорск, ул.Буденного, д.1) настоящим подтверждаем , что "SANMEDICO"SRL (ул. Коробчяну 7А, кв. 9, г. Кишинёв, Республика Молдова) является нашим эксклюзивным дистрибьютором и представителем в Республике Молдова и осуществляет участие с продукцией ЗАО «ЭКОлаб» в процедурах государственных закупок товаров на территории Республики Молдова, от своего имени ведет переговоры, представляет коммерческие предложения, заключает соответствующие договоры, а также осуществляет поставки указанной продукции на территории Республики Молдова.

Полномочия по настоящему авторизационному письму не могут быть переданы другим лицам.

Настоящее письмо действительно с момента подписания и до 31 декабря 2022г.

Генеральный директор  Борисов В.Ю.

CEpartner4U

Certificate number: 2017-IVD/193

Certificate of CE-Notification

This is to certify that, in accordance with the *In Vitro* Diagnostic Medical Device Directive 98/79/EC, **CEpartner4U BV** agrees to perform all duties and responsibilities as the Authorized Representative for

CJSC EKOlab

1 Budennogo Str., Elektrogorsk, Moscow region, 142530, Russia

as stipulated and demanded by the aforementioned Directive. The Dutch Competent Authorities have accepted the manufacturer's medical device registrations by CEpartner4U as listed on the product list attached to the manufacturer's Declaration of Conformity:

Device group: Rabbit plasma

IVD devices were registered under number:

Registration number Rabbit plasma: NL-CA002-2017-43242

with Dutch Competent Authorities as a consequently this IVD devices were entered in EUDAMED by Dutch Competent Authorities

The manufacturer has provided CEpartner4U with all necessary documentation, together with an appropriate Declaration of Conformity that the IVD medical devices fulfil the essential requirements of Directive 98/79/EC.

2017-12-18

Olga Teirlinck
Consultant CEpartner4U BV

CEpartner4U
Esdoornlaan13
3951 DB Maarn NL
tel: +31 (0)343 442 524
www.cepartner4u.nl

DECLARATION OF CONFORMITY

1) **Manufacturer** *(Name, department)*: **CJSC EKOlab**

Address: 1 Budennogo Str., Elektrogorsk, Moscow region, 142530, Russia

2) **European authorized representative: CEpartner4U BV,**

Address: **ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS**;
(on product labels printed as:
CEpartner4U , ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS. www.cepartner4u.com)

3) **Product(s)** *(name, type or model/batch number, etc.)*:

- Rabbit plasma

4) **The product(s) described above is in conformity with:**

Title	Document No.
In vitro Diagnostic Medical Devices Directive	98/79/EC

5) **Additional information** *(conformity procedure, Notified Body, CE certificate, etc.)*:

Conformity assessment procedure for CE marking: *In vitro* Diagnostic Medical Device Directive, Annex III

Registration nr. : pending

Elektrogorsk, Russia; 2017-11-03

(Place & date of issue (yyyy-mm-dd))

V.Y. Borisov, General Director, CJSC EKOlab

(name; function and signature of manufacturer)

Appendix

Date: 2017-11-08

List of devices.

Device name	Type/ model/ref number	Risk class / rule[1]	Code: EMDS/GMDN	First date of CE-compliance
Rabbit plasma		Low risk	15011290/0	2017-11-08

[1] See EDMS codes: http://www.edma-ivd.be/ (products classification)/Preference GMDN code

RESIST-4 O.K.N.V.

Manufacturer:

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Produced in BELGIUM

www.corisbio.com
IFU- 58R8/EN/02

***In vitro* rapid diagnostic test for the detection of OXA-48, KPC, NDM and VIM carbapenemases in bacterial culture**

FOR IN VITRO DIAGNOSTIC USE **EN**
FOR PROFESSIONAL USE ONLY
References: K-15R8, 2x20 cassettes, buffer, 20 tubes and droppers

I. INTRODUCTION

Carbapenemase-producing organisms (CPO) and more particularly carbapenem-resistant Enterobacteriaceae (CRE) represent a major public health concern worldwide due to their broad spectrum of resistance to antibiotics including, besides carbapenems, most classes of antimicrobial agents, and thus leaving very few options for the management of infected patients. Besides CREs, CPOs also include nonfermenting gram-negative bacilli (NFGNB), such as *Pseudomonas aeruginosa* and *Acinetobacter baumannii* that exhibit resistance not only to beta lactam and other groups of antibiotics, but also to carbapenems. The rapid spread of CPOs or of the genes encoding these resistances has led to nosocomial outbreaks and endemic situations in several countries in Europe and elsewhere worldwide.
Development of new rapid diagnostic tests to track antimicrobial resistance patterns is considered as one of the priority core action by international experts and health authorities. NDM and KPC represent two of the most increasing and prevalent carbapenemases in many countries. On the other hand, class D OXA-48 type carbapenemases represent the most challenging resistance mechanism to detect for clinical laboratories. VIM is not only present in Enterobacteriaceae but is also highly prevalent in non-fermenter bacteria. Rapid identification of those carbapenemases is of upmost importance to improve both patient therapy and control of the spread of such antibiotic resistance in hospitals.
Confirmatory phenotypic tests using combination disks with specific inhibitors already exist for detection of selected types of carbapenemases including class A (KPC) and class B (VIM, IMP, NDM) carbapenemases; however, these tests are time-consuming and require an extra additional day following antimicrobial susceptibility testing results. Moreover, phenotypic colorimetric assays are in some instances not sensitive enough for the detection of low-activity carbapenemases such as OXA-48. Several molecular assays based on different formats also allow detection of carbapenemases. These tests are expensive, time-consuming and can only be performed in dedicated environment and by skilled personnel, hence limiting their generalized use.

II. PRINCIPLE OF THE TESTS

These tests are ready to use and are based on a membrane technology with colloidal gold nanoparticles. Our kit is aimed to the detection of carbapenemases from a single bacterial colony isolate of Enterobacteriaceae or NFGNB growing on agar plate.
Each pouch contains 2 lateral-flow cassettes for the identification of (i) KPC and OXA-48 and (ii) NDM and VIM. These two devices are aimed at the detection of KPC, OXA-48, NDM and VIM carbapenemases on a single colony of bacterial isolates growing on agar plate resuspended in the provided buffer.
Identification of KPC and OXA-48. A nitrocellulose membrane is sensitized with:
(1) a monoclonal antibody directed against the KPC carbapenemase (bottom K line)
(2) a monoclonal antibody directed against the OXA-48 carbapenemase (middle O line)
(3) a control capture reagent (upper C line).
Three different colloidal gold nanoparticles conjugates are dried on a membrane: a conjugate directed against the KPC carbapenemase, a conjugate directed against the OXA-48 carbapenemase, and a control conjugate.

Identification of NDM and VIM. A nitrocellulose membrane is sensitized with:
(1) a monoclonal antibody directed against the NDM carbapenemase (bottom N line),
(2) a monoclonal antibody directed against the VIM carbapenemase (middle V line),
(3) a control capture reagent (upper C line).
Three different colloidal gold nanoparticles conjugates are dried on a membrane: a conjugate directed against the NDM carbapenemase, a conjugate directed against the VIM carbapenemase, and a control conjugate.

When the provided buffer containing the resuspended bacteria comes into contact with the strip, the solubilised conjugates migrate with the sample by passive diffusion and conjugates and sample material come into contact with the immobilized respective antibodies that are adsorbed onto the nitrocellulose strip. If the sample contains a KPC, OXA-48, NDM or VIM carbapenemase, the respective complexes made of the conjugates and either KPC, or OXA-48, or NDM or VIM will remain bound to their respectives specific lines (KPC, K line; OXA-48, O line; NDM, N line, VIM, V line). The migration continues by passive diffusion and both conjugates and sample material come into contact with the (upper) line control reagent that binds a control conjugate (line C), thereby producing a red line.
The result is visible within 15 minutes in the form of red lines on the strip.

III. REAGENTS AND MATERIALS

1. RESIST-4 O.K.N.V. (2x20 cassettes)
20 sealed pouches containing two lateral-flow cassettes and one desiccant.
Each device contains one sensitized strip.
2. LY-A buffer vial (15 mL)
Saline solution buffered to pH 7.5 containing TRIS, NaN_3 (<0,1%) and a detergent.
3. Instruction for use (1)
4. Semi-rigid disposable collection tubes with droppers (20)

IV. SPECIAL PRECAUTIONS

- All operations linked to the use of the test must be performed in accordance with Good Laboratory Practices (GLP).
- All reagents are for *in vitro* diagnostic use only.
- Pouch must be opened with care:
- Avoid touching nitrocellulose with your fingers.
- Wear gloves when handling samples.
- Never use reagents from another kit.
- Green lines indicate immunoreagents adsorption sites. Green colour disappears during the test.
- Reagents' quality cannot be guaranteed beyond their shelf-life dates or if reagents are not stored under required conditions as indicated in the insert.

V. WASTE DISPOSAL

- Dispose of gloves, swabs, test tubes and used devices in accordance with GLP.
- Each user is responsible for the management of any waste produced, and must ensure that it is disposed of in accordance with the applicable legislation.

VI. STORAGE

- An unopened pouch may be kept at between 4 and 30°C and used until the shelf-life date indicated on the packaging. Once the pouch is opened, run the test immediately.
- Avoid freezing devices and buffer.

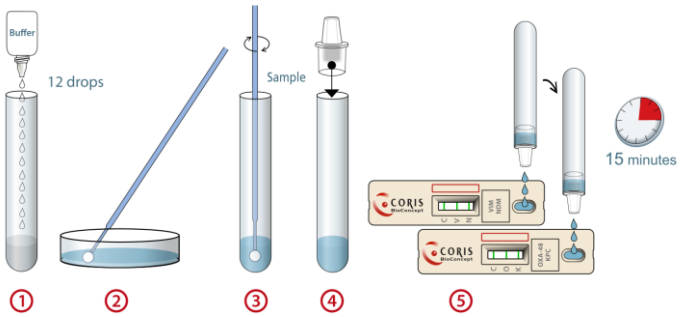
VII. SPECIMEN HANDLING AND COLLECTION

Specimens to be tested should be obtained and handled by standard microbiological methods.
Make sure that the specimens are not treated with solutions containing formaldehyde or its derivatives.
Culture media tested and validated with Coris BioConcept RESIT kits are listed on the website: https://www.corisbio.com/Products/Human-Field/RESIST-4-OKNV.php

VIII. PROCEDURE

PREPARATIONS OF THE TEST:
Allow kit components, in unopened packaging, and specimens (in case the plate containing colony to be tested was kept at 4°C) to reach room temperature (15-30°C) before performing a test.
Open the pouch and remove the device. Once opened, run the test immediately. Indicate the patient's name or specimen number on the device (one device per sample).
SPECIMEN PREPARATION PROCEDURE:
Performance claims with regard to samples types other than bacterial colonies have not been established. We recommend the use of fresh bacterial colonies for optimal test performance.

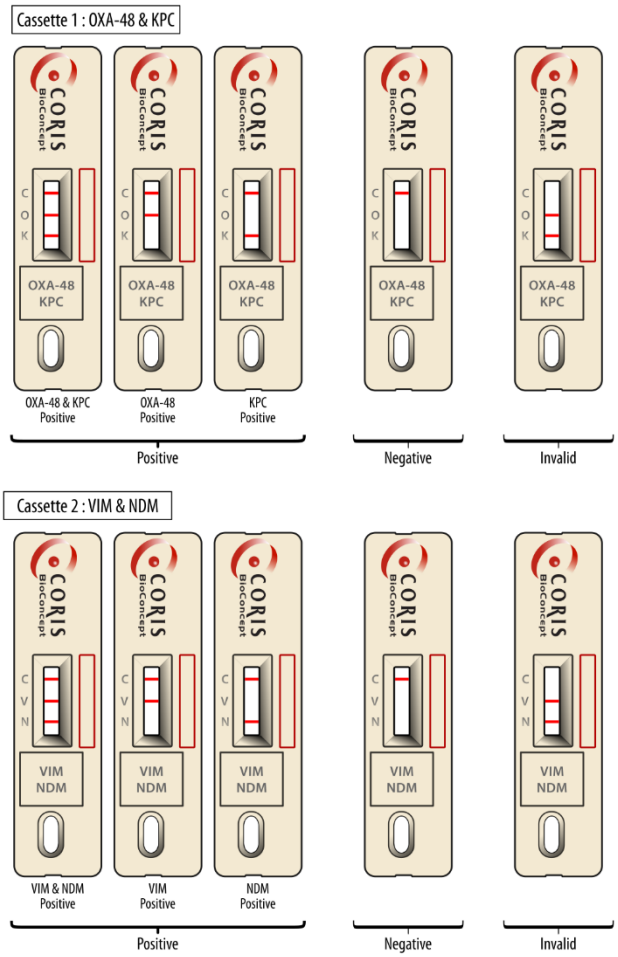
1. Prepare one semi-rigid tube and add **12** drops of LY-A buffer in the tube.
2. Harvest bacteria by taking one colony with a disposable bacteriological loop and dip the loop in the bottom of the semi-rigid tube containing the buffer.
3. Stir thoroughly before removing the loop
4. Insert tightly the dropper on the semi-rigid tube.
5. Vortex the preparation to homogenize. The entire bacterial colony must be suspended into the buffer.
6. Invert the test tube and add slowly **3** drops of diluted sample into the sample well of each of the two cassettes labeled (i) KPC and OXA-48 and (ii) NDM and VIM. Alternatively, add 100µl with a micropipette to both cassettes
7. Allow to react for 15 min max and read the result.



Positive results may be reported as soon as the test and control lines become visible.
Do not take the appearance of new lines into account after the reaction time is passed.
The result must be read on still wet strip.

IX. INTERPRETING RESULTS

The results are to be interpreted as follows for each of the two cassettes:
Negative test result: a reddish-purple line appears across the central reading window at the Control line (C) position. No other band is present.
Positive test result: in addition to a reddish-purple band at the Control line (C), a visible reddish-purple band appears at one of the Test lines position (OXA-48 or KPC) on cassette labelled (i) KPC and OXA-48, or at one of the Test lines position (VIM or NDM) on cassette labelled (ii) NDM and VIM. Intensity of the test line may vary according to the quantity of antigens as well as of the variant type present in the sample. Any reddish-purple Test line (OXA-48, KPC, NDM and VIM), even weak, should be considered as a positive result.
If a positive test line appears beside of the O mark, the sample contains OXA-48 or OXA-48-like variant, beside of K mark, the sample contains KPC, beside of N mark , the sample contains NDM and beside of V mark, VIM is present in the sample. Combinations of positive test lines can occur. In this case the sample contains the combination of several carbapenemases.
Invalid test result: The absence of a Control line indicates a failure in the test procedure. Repeat invalid tests with a new test device.
Note: during the drying process, a very faint shadow may appear at the Test line positions (O, K, N, V). It should not be regarded as a positive result.



X. PERFORMANCE

A. Detection Limit

The detection limit determined with purified recombinant proteins of OXA-48, KPC, NDM and VIM have been evaluated at 0.125 ng/ml, 0.625 ng/ml, 0,25 ng/ml and 0.23 ng/ml, respectively.

B. Prospective study (based on RESIST-3 O.K.N. *K*-SeT kit)

The OXA-48 and KPC cassette test was validated by comparison with reference molecular method (validated multiplex PCR including sequencing) in the National Reference Laboratory for Multidrug-Resistant Gram Negative Bacilli (Belgium) in a prospective study performed on 173 non duplicated, consecutive suspected CPE clinical isolates referred from July to September 2016.

Molecular method OXA-48 test	Positive	Negative	Total
Positive	69	0	69
Negative	0	104	104
Total	69	104	173

		95 % Confidence Interval [1]
Sensitivity:	100 %	(95.7 to 100 %)
Specificity:	100 %	(97.2 to 100 %)
Positive Predictive value:	100 %	(95.7 to 100 %)
Negative predictive value:	100 %	(97.2 to 100 %)
Agreement:	100 %	(173/173)

Molecular method KPC test	Positive	Negative	Total
Positive	9	0	9
Negative	0	164	164
Total	9	164	173

		95 % Confidence Interval [1]
Sensitivity:	100 %	(68.4 to 100 %)
Specificity:	100 %	(98.2 to 100 %)
Positive Predictive value:	100 %	(68.4 to 100 %)
Negative predictive value:	100 %	(98.2 to 100 %)
Agreement:	100 %	(173/173)

C. Validation on collection of reference strains

The VIM and NDM cassette test was validated by comparison with reference molecular method in the National Reference Laboratory for Multidrug-Resistant Gram Negative *Bacilli* (Belgium) in a retrospective study.

Molecular method NDM test	Positive	Negative	Total
Positive	24	0	24
Negative	0	95	95
Total	24	95	119

		95 % Confidence Interval [1]
Sensitivity:	100 %	(82.8 to 100 %)
Specificity:	100 %	(95.2 to 100 %)
Positive Predictive value:	100 %	(82.8 to 100 %)
Negative predictive value:	100 %	(95.2 to 100 %)
Agreement:	100 %	(119/119)

[1] Newcombe, Robert G. "Two-Sided Confidence Intervals for the Single Proportion: Comparison of Seven Methods," *Statistics in Medicine,* **17**, 857-872 (1998).

Molecular method VIM test	Positive	Negative	Total
Positive	38	0	38
Negative	1*	80	81
Total	39	80	119

*: the false-negative result is a ***P. aeruginosa*** colony harboring VIM-5 and NDM-1 genes. This colony was detected as NDM-positive but VIM-negative. The production of VIM-5 was not assessed.

		95 % Confidence Interval [1]
Sensitivity:	97.4 %	(84.9 to 99.9 %)
Specificity:	100 %	(94.3 to 100 %)
Positive Predictive value:	100 %	(88.6 to 100 %)
Negative predictive value:	98.8 %	(92.4 to 99.9 %)
Agreement:	99.2 %	(118/119)

D. Repeatability and reproducibility

To check intra-batch accuracy (repeatability), the same positive samples and a buffer solution were processed 15 times on kits of the same production batch in the same experimental conditions. All observed results were confirmed as expected.

To check inter-batch accuracy (reproducibility), some samples (positive and buffer) were processed on kits from three different production batches. All results were confirmed as expected.

XI. LIMITS OF THE KIT

The test is qualitative and cannot predict the quantity of antigens present in the sample. Clinical presentation and other test results must be taken into consideration to establish diagnosis.

A positive test does not rule out the possibility that other antibiotic resistance mechanisms may be present.

XII. TECHNICAL PROBLEMS / COMPLAINTS

If you encounter a technical problem or if performances do not correspond with those indicated in this package insert:

1. Write the lot number of the kit concerned
2. If possible, keep the sample in the appropriate storage condition during the complaint management
3. Contact Coris BioConcept (client.care@corisbio.com) or your local distributor

XIII. BIBLIOGRAPHIC REFERENCES

A. Y. Glupczynski, A. Jousset, S. Evrard, R. Bonnin, T. Huang, L. Dortet, P. Bogaerts and T. Naas. Prospective evaluation of the OKN K-SeT assay, a new multiplex immunochromatographic test for the rapid detection of OXA-48-like, KPC and NDM carbapenemases. J Antimicrob Chemother. 2017 Mar (7):1955-1960

B. DW. Wareham and MH. Abdul Momin Rapid Detection of Carbapenemases in Enterobacteriaceae: 1 Evaluation of the RESIST-3 O.K.N (OXA-48, KPC, NDM) Multiplexed Lateral Flow Assay. J Clin Microbiol. 2017 Feb (4):1223-1225

C. F Pasteran, L Denorme, I Ote, S Gomez, D De Belder, Y Glupczynski, P Bogaerts, B Ghiglione, P Power,

D. P Mertens, A Corso. Rapid identification of OXA-48 and OXA-163 subfamily in carbapenem resistant gram-negative bacilli with a novel immunochromatographic lateral flow assay. J Clin Microbiol. 2016 Aug 17. pii: JCM.01175-16

E. D. Meunier, A. Vickers, R. Pike, R.L. Hill, N. Woodford and K.L. Hopkins. Evaluation of the K-SeT R.E.S.I.S.T. immunochromatographic assay for the rapid detection of KPC and OXA-48-like carbapenemases. J Antimicrob Chemother. 2016 Aug; 71 (8):2357-9

F. Wareham DW, Shah R, Betts JW, Phee LM, Abdul Momin MH. Evaluation of an Immunochromatographic Lateral Flow Assay (OXA-48 K-SeT) for the Rapid Detection of OXA-48-like Carbapenemases in Enterobacteriaceae. . J Clin Microbiol. 2016 Feb;54 (2):471-3

G. Fernández J, Fleites A, Rodcio MR, Vazquez F. Evaluation of OXA-48 K-Se T: an immunochromatographic assay for rapid detection of OXA-48-producing Enterobacteriaceae.

H. Diagn Microbiol Infect Dis. 2016 May;85 (1):12-5

I. Dortet L, Jousset A, Sainte-Rose V, Cuzon G, Naas T. Prospective evaluation of the OXA-48 K-SeT assay, an immunochromatographic test for the rapid detection of OXA-48-type carbapenemases. J Antimicrob Chemother. 2016 Jul;71 (7):1834-40

J. Glupczynski Y, Evrard S, Ote I, Mertens P, Huang TD, Leclipteux T, Bogaerts P. Evaluation of two new commercial immunochromatographic assays for the rapid detection of OXA-48 and KPC carbapenemases from cultured bacteria. J Antimicrob Chemother. 2016 May;71(5):1217-22

K. B.M. Willey, X. Trimi, R. Ioboni, D.A. Boyd, G. Ricci, D.N. Grohn, D. Terenzi, A. Mazzulli, L. Mataseje, M. Mulvey, P. Lo, T. Mazzulli, S.M. Poutanen. The Coris BioConcept OXA48 K-SeT Immuno-Chromatographic Assay Detects OXA48-type Carbapenemases with High Sensitivity and Specificity. 26th European Congress of Clinical Microbiology and Infectious Diseases, Amsterdam April 9-12, 2016

L. A. Abulaila, F. Erdem, Z. Aktas and O. Oncul Evaluation Comparison of a novel OXA-48 K-Set test and blue-carba test in detection of carbapenemase-producing enterobacteriaceae with using PCR as reference method. 26th European Congress of Clinical Microbiology and Infectious Diseases, Amsterdam April 09 – 12, 2016

M. O. Karatuna, M. Kaya, I. Akyar Evaluation of the performance of OXA-48 K-SeT immunochromatographic test for rapid identification of OXA-48 carbapenemase-producing Enterobacteriaceae. 26th European Congress of Clinical Microbiology and Infectious Diseases, Amsterdam April 09 – 12, 2016

N. C.S. Nodari, A. Barth, C. Magagnin, A. Zavascki, A. Gales, C. Carvalhaes OXA-370 is rapidly detected from different culture media using OXA-48 K-SeT®

O. immunochromatography. 26th European Congress of Clinical Microbiology and Infectious Diseases, Amsterdam April 09 – 12, 2016

P. P. Bogaerts, S. Evrard, G. Cuzon, TD. Huang, T. Naas and Y. Glupczynski Specificity of the OXA-48 immunochromatographic K-SeT for the detection of OXA-48 like in Shewanella spp. 26th European Congress of Clinical Microbiology and Infectious Diseases, Infectious Amsterdam April 09 – 12, 2016

Q. A. Sarria, R. Gomez-Gil, G. Ruiz, MP. Romero, J. García- Rodríguez Preliminay study of the OXA-48 card letitest method for the direct detection of OXA-48 carbapenemase in blood and plates culture. 26th European Congress of Clinical Microbiology and Infectious Diseases, Amsterdam April 09 – 12, 2016

Last update: 02 AUGUST 2019

REF	Catalogue number		Manufacturer
IVD	In vitro diagnostic medical device		Temperature limits
Σ	Contains sufficient for <n> tests	LOT	Batch code
	Consult instructions for use	②	Do not reuse
	Keep dry		Use by
DIL SPE	Diluent specimen	CONT NaN_3	Contains Sodium azide

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Плазма кроличья цитратная сухая

(для реакции плазмокоагуляции)

Назначение

Плазма кроличья цитратная сухая используются для качественного определения патогенности стафилококков с помощью с помощью реакции плазмокоагуляции в пробирке

КРАТКИЙ ОБЗОР И ОПИСАНИЕ

Идентификация стафилококков основана на микроскопическом исследовании, морфологии колоний, а также характеристиках культуры и биохимических характеристиках. Стафилококки, связанные с острой инфекцией *(Staphylococcus aureus* — у людей; S. *intermedius* и S. *hyicus* — у животных) способны вызывать свертывание плазмы. Наиболее широко используемый и общепринятый критерий идентификации данных патогенных микроорганизмов основан на присутствии фермента коагулазы. Способность микроорганизмов *Staphylococcus* вырабатывать коагулазу была впервые открыта Лёбом (Loeb) в 1903 г.

Коагулаза связывает фибриноген плазмы, вызывая агглютинацию микроорганизмов или свертывание плазмы. Возможно образование двух видов коагулазы: свободная и связанная. Свободная коагулаза — это внеклеточный фермент, образуемый при культивировании микроорганизма в бульоне. Связанная коагулаза, известная также как фактор слипания, остается прикрепленной к клеточной стенке микроорганизма. Тест в пробирке позволяет обнаружить присутствие как связанной, так и свободной коагулазы. Культуры, не вырабатывающие фактор слипания, должны быть протестированы на способность вырабатывать внеклеточную (свободную) коагулазу.

Плазма кроличья цитратная для реакции плазмокоагуляции рекомендуется для выполнения прямого теста в пробирке. Посев, используемый для тестирования, должен быть чистым, поскольку примеси могут привести к ложным результатам после продолжительной инкубации.

ПРИНЦИПЫ МЕТОДИКИ

Метод основан на образовании (коагуляции) фибринового сгустка из фибриногена цитратной плазмы под действием фермента плазмокоагулазы патогенных стафилококков.

Тест в пробирке выполняется путем добавления суточной культуры в пробирку с цитратной плазмой, разведенной 0,9% раствором натрия хлорида 1:5 с перемешиванием. Пробирка инкубируется при температуре 37 °С. Формирование сгустка плазмы указывает на выработку коагулазы.

РЕАГЕНТЫ

Плазма кроличья цитратная сухая

— это лиофилизированная кроличья плазма, стерильная, содержащая 5% водный раствор цитрата натрия в соотношении 5:1.

ПРЕДУПРЕЖДЕНИЯ И МЕРЫ ПРЕДОСТОРОЖНОСТИ

Для диагностики *in vitro.*

Продукт содержит лиофильно высушенные компоненты крови.

При выполнении любых процедур соблюдайте правила асептики и установленные меры биологической безопасности. После использования обеззараживайте образцы, контейнеры, стекла, пробирки и другие загрязненные материалы в автоклаве.

Необходимо тщательно выполнять указания по применению

ХРАНЕНИЕ

Храните невскрытые упаковки с лиофилизированной плазмой кроличьей цитратной для реакции плазмокоагуляции при температуре от 2 до 8 °С.

Разведенную 0,9% раствором натрия хлорида плазму храните при температуре 2 до 8 °С не более 2 дней либо отберите аликвоты, немедленно заморозьте и храните при температуре -20 °С не более 30 дней. Разморозка и повторная заморозка не допускаются. Указанный срок хранения действителен только для продукта, хранящегося в запечатанном контейнере при соблюдении условий хранения. Не используйте продукт в случае его затвердевания, обесцвечивания или других признаков разложения. Проверьте восстановленные реагенты на наличие признаков загрязнения, испарения или других признаков разложения, например помутнения или частичного свертывания.

СБОР И ПРИГОТОВЛЕНИЕ ОБРАЦОВ

Образцы следует собирать в стерильные контейнеры или с помощью стерильного тампона и немедленно передавать в лабораторию в соответствии с требованиям и рекомендациями применимым местным, региональным и/или федеральным законодательством.

Обрабатывайте каждый образец в соответствии с методиками контроля качества, принятыми в лаборатории

В реакции используется суточная бульонная или агаровая культура стафилококка. Описанная далее методика требует использования чистой культуры.

Используйте изолированные колонии из чистой суточной агаровой или бульонной культуры, выращенной при 35-37 °С и исследованной морфологически (на типичность

морфологии колоний) и микроскопически (в окрашенном по Граму препарате-мазке должны наблюдаться грамположительные кокки).

МЕТОДИКА

Поставляемые материалы. Плазма кроличья цитратная сухая

Необходимые, но непоставляемые материалы: Бактериологическая петля для посева, пипетки, пробирки стерильные(10 х 75 мм),, стерильный 0,9% раствор натрия хлорида, пробирки с культурами малые (10 х 75 мм), водяная баня или термостат (37 °С), питательная среда для культивирования микроорганизмов.

Приготовление реагента

Растворите в асептических условиях плазму кроличью цитратную в 5 мл стерильного 0,9% раствора натрия хлорида, что соответствует разведению 1:5. Тщательно перемешайте.

Объем реагента	Стерильный 0,9% раствор натрия хлорида	Приблизительное количество тестов
1 мл	5 мл	10

МЕТОДИКА ТЕСТИРОВАНИЯ

1.С помощью стерильной пипетки емкостью 1 мл добавьте 0,5 мл плазмы кроличьей цитратной для реакции плазмокоагуляции, разведенной в стерильную пробирку 10 х 75 мм, установленную в штатив.

2.С помощью серологической пипетки емкостью 1 мл добавьте приблизительно 0,05 мл суточной бульонной культуры тестируемого микроорганизма в пробирку с плазмой. Можно также с помощью стерильной бактериологической петли тщательно эмульгировать 2 - 4 колонии (1 полную петлю) из чашки с питательным агаром в пробирке с плазмой.

3. Аккуратно перемешайте.

4.Инкубируйте при температуре 37 °С в течение 24 часов.

5.Периодически осматривайте пробирки, слегка наклоняя их. Не трясите и не взбалтывайте пробирки. Это может вызвать разрушение сгустка и привести к сомнительным или ложным отрицательным результатам теста. Свертывание любой степени, произошедшее за 4 часа, считается положительным результатом. Многие штаммы, слабо вырабатывающие ферменты, вызовут коагуляцию плазмы только через 24 ч инкубации. Окончательный учет результатов проводится через 24 часа.

6.Запишите результаты.

КОНТРОЛЬ КАЧЕСТВА

Во время использования проверьте эффективность плазмы кроличьей цитратной для реакции плазмокоагуляции, методику и методологию с помощью положительной и отрицательной контрольных культур. Далее приведен минимальный список культур, которые необходимо использовать для проверки эффективности.

Микроорганизмы	**АТСС**	**Реакция**
Staphylococcus aureus	6538	Сгусток в пробирке
Staphylococcus epidermidis	14990	Отсутствие сгустка в пробирке

Следуйте требованиям контроля качества в соответствии с применимым местным, региональным и/или федеральным законодательством, требованиями аккредитации и методиками контроля качества, принятыми в лаборатории.

РЕЗУЛЬТАТЫ

Любое свертывание плазмы кроличьей цитратной считается положительным

результатом теста. При интерпретации реакций можно руководствоваться следующими указаниями:

Отрицательный	Отсутствие признаков свертывания плазмы
Положительный 1+	Небольшие несвязанные сгустки
Положительный 2+	Небольшой сгусток
Положительный 3+	Большой сгусток
Положительный 4+	Все содержимое пробирки сворачивается и не вытекает при при переворачивании пробирки

ОГРАНИЧЕНИЯ ПРИМЕНЕНИЯ МЕТОДИКИ

1.Некоторые виды микроорганизмов используют цитраты в своем метаболизме и дают ложные положительные реакции на активность коагулазы. Обычно это не вызывает проблем, поскольку тест на коагулазу выполняется практически исключительно для стафилококков. Однако возможно, что бактерии, использующие цитрат, могут являться примесями в культурах *Staphylococcus,* для которых выполняется тест на коагулазу. Эти зараженные культуры при продолжительной инкубации могут дать ложные положительные результаты из-за использования цитрата,[4] поэтому в реакции необходимо использовать только чистую культуру

2. Некоторые штаммы S. *aureus* вырабатывают стафилокиназу, которая может лизировать сгустки. Если результаты для пробирок не будут зафиксированы в течение 24 ч инкубации, возможно проявление ложных отрицательных результатов.[1]

3. Не используйте плазму, если перед постановкой реакции в ней образовался осадок или сгусток.

НАЛИЧИЕ

№ по каталогу	**Описание**
52.01	**Плазма кроличья цитратная сухая 10х1**

Набор рассчитан на исследование 100 образцов, включая контрольные

СПРАВОЧНЫЕ МАТЕРИАЛЫ

1. Об унификации микробиологических (бактериологических) методов исследования, применяемых в клинико-диагностических лабораториях лечебно-профилактических учреждений. «Приказ Министерства здравоохранения СССР, № 535 от 22 апреля 1985 г, Москва.

2. J. Vandepitte, K. Engbaek, P Piot, C.C. Heuck. 1991. Basic laboratory procedures in clinical bacteriology. World Health Organization, Geneva

3. Kloos, W. E., and T. L. Bannerman. 1999. *Staphylococcus* and *Micrococcus,* p. 264-282. *In* P.R. Murray, P.R., E.J. Baron, M.A. Pfaller, F.C. Tenover and R.H. Yolken, Manual of clinical microbiology, 7th ed. American Society for Microbiology, Washington, D.C.

4. Loeb, L. 1903. The influence of certain bacteria on the coagulation of the blood. J. Med. Res.

10:407-419.
5. Bayliss, B.G. and E.R. Hall. 1965. Plasma coagulation by organisms other than *Staphylococcus aureus*. J. Bacteriol. 89:101-104.
6. Pezzlo, M. (ed.). 1994. Aerobic bacteriology, p. 1.0.0.-1.20.47. *In* H. D. Isenberg (ed.), Clinical microbiology procedures handbook, vol. 1. American Society for Microbiology, Washington, D.C.
7. Association of Official Analytical Chemists. 2000. Official methods of analysis of AOAC International, 17th ed. AOAC International, Arlington, VA.

По вопросам, касающимся качества препарата, следует обращаться по адресу Россия, 142530 Московская обл, г. Электрогорск, ул Буденного , д.1, ЗАО «ЭКОлаб», тел.(49643)3-23-11, факс (49643) 3-30-93-отдел сбыта, (49643)3-37-30 - ОБТК

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REF	Catalog number / Номер по каталогу
SN	Serial number/Номер серии
IVD	*In vitro* Diagnostic Medical Device / Медицинский прибор для диагностики *in vitro*
STERILE	Sterile /Стерильно
8 °C 2 °C	Temperature limitation / Ограничение температуры
Σ 100	Contains sufficient for <n> tests/ Достаточно для проведения 100-тестов
	Consult Instructions for Use / См. инструкцию по применению

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СЕРТИФИКАТ СООТВЕТСТВИЯ

Регистрационный номер РОСС RU.04ИБФ1.ОС23.0000308

Срок действия с 30.06.2022 по 29.06.2025

ОРГАН ПО СЕРТИФИКАЦИИ
№ РОСС RU.32001.04ИБФ1.ОС23
Общество с ограниченной ответственностью «ЕВРАЗИЙСКИЙ СОЮЗ СЕРТИФИКАЦИИ»
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ВЫДАН

Закрытому акционерному обществу «ЭКОлаб»
ИНН 5035025076 ОГРН 1035007106958
Адрес: 142530, РФ, Московская область, г. Электрогорск, ул. Буденного, д. 1

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО СИСТЕМА МЕНЕДЖМЕНТА КАЧЕСТВА МЕДИЦИНСКИХ ИЗДЕЛИЙ

применительно к работам согласно приложению № 1 к настоящему сертификату

СООТВЕТСТВУЕТ ТРЕБОВАНИЯМ ГОСТ ISO 13485-2017 (ISO 13485:2016)

Выдан на основании решения экспертной комиссии,
протокол № РОСС RU.04ИБФ1.ОС23.0000308П от 30.06.2022

Орган по сертификации ООО "Евразийский Союз Сертификации" ДЛЯ СЕРТИФИКАТОВ СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ ПромТех Стандарт РОСС RU.32001.04ИБФ1.ОС23

Руководитель органа _____ (подпись) А.В. Арендарь (инициалы, фамилия)

Председатель комиссии _____ (подпись) А.А. Акимов (инициалы, фамилия)

Настоящий сертификат соответствия обязывает организацию поддерживать состояние выполняемых работ в соответствие с вышеуказанным стандартом, что будет находиться под контролем органа по сертификации системы добровольной сертификации «ПромТехСтандарт» и подтверждаться при прохождении ежегодного инспекционного контроля

АО «ОПЦИОН», Москва, 2021 г., «В», ТЗ № 1130.

E.A.R.-CERTIFICATE

(ART 10.3 of the Directive 98/79/EC on In Vitro Diagnostic)

REF. NO. : RP 2901-2021

ORDER NO. : DK 2491-2021

DATE: 11/01/2022

MANUFACTURER:

EKVITESTLAB LLC
Velyka Vasylkivska street, 114
03150, Kyiv, Ukraine

FACILITIES:

EKVITESTLAB LLC
Peremohy Avenue, 60/2
03057, Kyiv, Ukraine

PRODUCT CATEGORIES:

Please See Annex A - List of Devices (13 Devices, 2 Pages)

MODELS:

Please See Annex A - List of Devices (13 Devices, 2 Pages)

The European Authorized Representative Center Obelis s.a. declares that the aforementioned manufacturer has fulfilled the essential requirement of appointing a European Authorized Representative in accordance with article 10.3 of the Directive 98/79/EC and to the terms and conditions set out in the agreement entered into force on 1st May 2021.*

G.ELKAYAM C.E.O.

Obelis s.a. - O.E.A.R.C.
Registered Address :
Bld Général Wahis 53
1030 Bruxelles
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03

Mr. G. Elkayam CEO
Obelis sa

Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001 : 2015 and ISO 13485 : 2016 certified in accordance to the profession of a European Authorized Representative.

*This certificate is not a confirmation of product notification nor an approval to place products on the market.
**This certificate will become void automatically upon termination of the EAR agreement.

* This is not a CE mark and is only provided as a template for informational purposes.

ANNEX to IVDD EAR Certificate

Order No.: DK 2491-2021

Reference No.: RP 2901-2021

Manufacturer: Ekvitestlab LLC

Country: Ukraine

#	EMDN	Generic device name (including BASIC UDI)	Commercial Name of device	Intended use	Class
1	52133	EQUI Ascaris lumbricoides IgG	EI-601	ELISA kit for the qualitative detection of IgG antibodies to Ascaris lumbricoides	Class I (Others)
2	63005	EQUI Opisthorchis felineus IgG	EI-602	ELISA kit for the qualitative detection of IgG antibodies to Opisthorchis felineus	Class I (Others)
3	52418	EQUI Toxocara canis IgG	EI-603	ELISA kit for the qualitative detection of IgG antibodies to Toxocara canis	Class I (Others)
4	52464	EQUI anti-Trichinella spiralis	EI-605	ELISA kit for the qualitative detection of antibodies to Trichinella spiralis	Class I (Others)
5	52464	EQUI anti-Trichinella spiralis	EI-605	ELISA kit for the qualitative detection of antibodies to Trichinella spiralis	Class I (Others)
6	62915	EQUI anti-Lamblia	EI-606	ELISA kit for the qualitative detection of antibodies to Giardia lamblia (intestinalis)	Class I (Others)
7	48281	EQUI HAV IgM	EI-031	ELISA kit for the qualitative detection of IgM antibodies to hepatitis A virus	Class I (Others)
8	51021	EQUI anti-Helicobacter	EI-501	ELISA kit for the qualitative detection of total antibodies to Helicobacter pylori	Class I (Others)
9	51008	EQUI Helicobacter IgG	EI-502	ELISA kit for the qualitative and semiquantitative detection of IgG antibodies to CagA protein of Helicobacter pylori	Class I (Others)
10	51012	EQUI Helicobacter	EI-504	ELISA kit for the qualitative detection of IgM	Class I (Others)

Attachments - ANNEX to IVDR EAR Certificate –V1 19/05/2021 – ID: 00331821

		IgM		antibodies to CagA protein of Helicobacter pylori	
11	64800	EQUI SARS-CoV-2 IgM swift	EI-165	ELISA kit for the qualitative detection of IgM antibodies to nucleoprotein and spike antigens of SARS-CoV-2 virus	Class I (Others)
12	64830	EQUI SARS-CoV-2 IgA swift	EI-166	ELISA kit for the qualitative detection of IgA antibodies to nucleoprotein and spike antigens of SARS-CoV-2 virus	Class I (Others)
13	64824	EQUI SARS-CoV-2 IgG swift	EI-167	ELISA kit for the qualitative detection of IgG antibodies to nucleoprotein and spike antigens of SARS-CoV-2 virus	Class I (Others)

Date: 11 January 2022

CEO Of Obelis

Gideon Elkayam

G. ELKAYAM C.E.O.

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Registered Address :
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Attachments - ANNEX to IVDR EAR Certificate –V1 19/05/2021 – ID: 00331821

Declaration of Conformity

According to annex III of the Council Directive 98/79/EC on in vitro diagnostic medical device We,

EKVITESTLAB LLC

Velyka Vasylkivska St. 114, Kyiv, Ukraine, 03150, tel. 0(800)31-89-87; +38 (044)334-89-87

e-mail: info@equitest.com.ua, web-site: www.equitest.com.ua

Declare under our sole responsibility that the following in vitro diagnostic medical devices other than those covered by annex II and devices for performance evaluation

EQUI anti-Lamblia - ELISA kit for the qualitative detection of antibodies to *Giardia lamblia (intestinalis)*, REF EI-606

Meet the provisions of the Council Directive 98/79/EC concerning medical devices which apply to them.

Undersigned declares to fulfill the obligations imposed by Annex III section 2 to 5:

- availability of the technical documentation set in Annex III (section 3), allowing the assessment of conformity of the product with the requirements of the Directive.
- the manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).
- the manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).

Conformity assessment was performed according to Article 9 (7) and Annex III, section 3.

Our current Quality System is formatted to international standards:

- **ISO 13485:2016 «Medical devices — Quality management systems — Requirements for regulatory purposes»**

Corporate Contact Information

EKVITESTLAB LLC
Velyka Vasylkivska St. 114, Kyiv, Ukraine, 03150
tel. 0(800)31-89-87; +38 (044)334-89-87
e-mail: info@equitest.com.ua
RESPONSIBLE PERSON'S name: Anna Yurchuk
Position: Director

SIGNATURE : 

Date : October 25, 2021
Stamp

European Authorized Representative:
Registered Address:
Obelis s.a.
Bd. Général Wahis 53
B-1030 Brussels, Belgium
Phone: 32.2.732.59.54
Fax: 32.2.732.60.03
E-mail: mail@obelis.net
Representative: Mr. Gideon ELKAYAM (CEO)

Declaration of Conformity

According to annex III of the Council Directive 98/79/EC on in vitro diagnostic medical device We,

EKVITESTLAB LLC

Velyka Vasylkivska St. 114, Kyiv, Ukraine, 03150, tel. 0(800)31-89-87; +38 (044)334-89-87

e-mail: info@equitest.com.ua, web-site: www.equitest.com.ua

Declare under our sole responsibility that the following in vitro diagnostic medical devices other than those covered by annex II and devices for performance evaluation

EQUI Toxocara canis IgG - ELISA kit for the qualitative detection of IgG antibodies to *Toxocara canis*, REF EI-603

Meet the provisions of the Council Directive 98/79/EC concerning medical devices which apply to them.

Undersigned declares to fulfill the obligations imposed by Annex III section 2 to 5:

- availability of the technical documentation set in Annex III (section 3), allowing the assessment of conformity of the product with the requirements of the Directive.
- the manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).
- the manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).

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e-mail: info@equitest.com.ua
RESPONSIBLE PERSON'S name: Anna Yurchuk
Position: Director

SIGNATURE : 

Date : October 25, 2021
Stamp

European Authorized Representative:
Registered Address:
Obelis s.a.
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B-1030 Brussels, Belgium
Phone: 32.2.732.59.54
Fax: 32.2.732.60.03
E-mail: mail@obelis.net
Representative: Mr. Gideon ELKAYAM (CEO)

ПРОМСТАНДАРТ ■ PROMSTANDART ■ ПРОМСТАНДАРТ ■ PROMSTANDART ■ ПРОМСТАНДАРТ

CERTIFICATE

MANAGEMENT SYSTEM CERTIFICATION BODY
«CONFORMITY ASSESSMENT BODY «PROMSTANDART», LLC
certifies that the enterprise

EKVITESTLAB
Limited Liability Company

registration code 38745936

legal address:
Ukraine, 03150, Kyiv, 114 Velyka Vasylkivska street,

manufacturer's address:
Ukraine, 04212, Kyiv, 60/2 Peremohy Avenue

has established and applies quality management system for
development, production, storage and sale of ELISA kits for in vitro diagnostic

Audit, № report 2020/015-20.2.1
confirmed that the requirements

ISO 13485:2016
«Medical devices — Quality management systems — Requirements for regulatory purposes»

are performed.

The control of conformity of the certified quality management system to the requirements of the specified standard is carried out by means of supervisory audit, the periodicity and procedures of which are regulated by the program.

Certificate registration number	№ UA.QMS.00014-21
Registered	06 April 2021
Valid until	05 April 2024

8O156
DSTU EN ISO/IEC 17021-1

Director of Certification Body
«CAB «PROMSTANDART», LLC

stamp (signature)

Sergiy Dubrovskyi

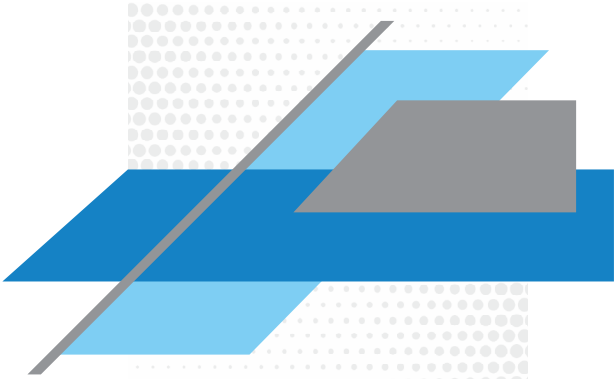
The validity of certificate can be verified by telephone: (056) 742-82-39
or on website of «CAB «PROMSTANDART», LLC: prom-standart.com.ua

210107

Toxocara canis IgG

ELISA kit for the qualitative detection of IgG antibodies to *Toxocara canis*

Instructions for use



IVD

REF EI-603

Σ 96 tests

CE

EQUI Toxocara canis IgG

ELISA kit for the qualitative detection of
IgG antibodies to *Toxocara canis*

1. INTENDED USE

The «EQUI Toxocara canis IgG» is ELISA kit intended to qualitatively detect anti-*Toxocara canis* IgG in human serum or plasma by enzyme-linked immunosorbent assay (ELISA) in order to diagnose toxocariasis. The testing procedure is designed for both manual arrangement with automatic pipettes and standard equipment, and for automated «open» immunoassay analysers.

Target group: children, pet owners, rural people, summer visitors, forest guards, veterinarians.

Usage: ELISA kit is used in clinical diagnostic laboratories and other institutions engaged in *in vitro* diagnostics.

2. CLINICAL SIGNIFICANCE

Toxocariasis is a common disease induced by *Toxocara* helminth which is transmitted from animals to human. Toxocariasis is spread throughout the world, however, it is more common in depressed areas with poor hygienic conditions. In some regions, up to 90 % of puppies and up to 10 % of adult domesticated dogs are infested with toxocara. The risk of infestation is higher for owners of cats and dogs and for children due to playing in the sandpits and on the playgrounds contaminated with animal faeces.

Toxocara are threadworms belonging to *Nematoda*. Human conditions are mostly caused by *Toxocara canis*, which infested canids, rare - *Toxocara cati*, which is more common in felids. Adult toxocara in the body of infested animals reaches 5–15 cm in length; their propagation takes place here. Female helminths lay about 200 thous eggs daily, which are excreted in the environment with faeces. If conditions are favourable, following several weeks of maturation in the soil they become invasive — a larva is developed in the eggs. In the paratenic host (mice, poultry, cows, pigs, etc.). larva develops without propagation. If the conditions are unfavourable, larvae are encapsulated and may maintain viability for a long time (up to 10 years). They may also be the source of invasion.

People are infested through faecal-oral route when ingesting *Toxocara canis* mature eggs with soil-contaminated vegetables, fruits, berries, via dirty hands or when consuming meat of paratenic hosts. In the small intestine, larvae leave their cover and penetrates blood circulation through the intestinal walls. The larvae migrate to other organs and tissues with blood, namely: liver, lungs, muscles, eyes, CNS, etc. In the most of the infested, toxocariasis is asymptomatic. Clinical manifestations of this disease are associated with the site of larvae migration and depend on the intensity of invasion and age of the host. Visceral syndrome larva migrans is typical after infestation of the internal organs with *Toxocara canis* and ocular

toxocariasis, when eye and optic nerve are involved. Symptoms of visceral toxocariasis: fever, fatigue, abdominal pain, anorexia, hepatomegaly, cough and others. Heart and respiratory failure may develop in severe cases. Due to a strong immune response to larvae antigens, immediate and delayed hypersensitivity reactions develop. Granulomatosis in occular toxocariasis may result in retinal detachment and loss of vision.

Diagnosis of toxocariasis is complicated due to the lack of specific manifestations of the disease, even upon intense invasion. Furthermore, a man is an intermediate host of *Toxocara canis* and does not excrete parasites in the environment, whereas it is difficult to localise larvae in certain organs via non-invasive methods. Eosinophilia may appear in blood tests, however, serological tests are more common to detect toxocariasis (immunofluorescence reaction, ELISA and immunoblotting). Detection of specific anti-*Toxocara canis* IgG to larvae antigens may suggest current or previous invasion. High titter of IgE antibodies is also typical for active invasion. However, the combination of clinical manifestations and laboratory findings are necessary for diagnosis.

3. ANALYSIS PRINCIPLE

The procedure of testing for anti-*Toxocara canis* IgG in «EQUI Toxocara canis IgG» ELISA kit is based on «indirect» solid-phase ELISA with a two-stage incubation. Antigens of *Toxocara canis* larvae are entrapped in the wells. During the first step of incubation of ELISA plate wells with test samples, specific anti-*Toxocara canis* antibodies (if present in the samples) bind to the solid-phase antigens. The wells are washed to remove unbound antibodies and have only specific antigen-antibody complexes left. Then, a conjugate of anti-species IgG monoclonal antibodies with horseradish peroxidase is added, which binds to solid-phase immune complexes. Unbound components are removed by washing. Antigen-antibody complexes are detected by adding a solution of chromogen 3,3',5,5'-tetramethylbenzidine (TMB) with hydrogen peroxide. After 30-minute incubation, the reaction is stopped by adding the stop solution. The optical density (OD) in the wells is determined using a spectrophotometer at 450/620-695 nm. The intensity of the yellow colour is proportional to the level of antibodies in the sample.

4. MATERIALS AND EQUIPMENT

4.1. Contents of the ELISA kit

STRIPS	1 x 96 wells	**Microplate** Each plate well is coated with *Toxocara canis* larval antigens. The wells are detachable. After the first opening, store unused strips in the package at 2-8 °C for a maximum of 6 months

CONTROL +	1 x 0,25 ml	**Positive control** Conjugated specific monoclonal antibody solution with preservative (pink). Store at 2-8 °C
CONTROL -	1 x 0,6 ml	**Negative control** Negative human serum with a preservative (yellow). Store at 2-8 °C
DIL SAMPLE	1 x 13 ml	**Serum dilution solution** Buffer solution with a milk extract, a detergent and a preservative (brown). Store at 2-8 °C
SOLN CONJ	1 x 13 ml	**Conjugate solution (ready to use)** Buffer solution of monoclonal antibodies to human IgG, conjugated with horseradish peroxidase, with stabilizers and preservative (green). Store at 2-8 °C
SOLN TMB	1 x 13 ml	**TMB solution (ready to use)** TMB solution, H_2O_2, a stabilizer, a preservative (colourless). Store at 2-8 °C
TWEEN WASH 20x	1 x 50 ml	**Washing solution TWEEN (20x concentrated)** 20-fold phosphate buffer concentrate with Tween-20 (colourless). Dilute TWEEN detergent (20x) at 1:20 with distilled or deionized water (e. g., 5 mL of concentrate + 95 mL of water for 8 wells) before use. Store the diluted solution at 2-8 °C for a maximum of 7 days
SOLN STOP	1 x 13 ml	**Stop Solution (ready to use)** 0.5 mol H_2SO_4 solution (colourless). Store at 2-8 °C

The ELISA kit also includes adhesive films (2 items), sample application plan (1 item), checklist, and instruction for use.

4.2. Optional reagents, materials and equipment

Automatic single and multichannel pipettes 10–1000 µL, tips, volumetric laboratory glassware (10–1,000 mL), deionized or distilled water, thermostat at 37 °C, automatic or semi-automatic plate washer, spectrophotometer (reader) for microplates at 450/620-695 nm, appropriate containers for potentially contaminated waste, timer, filter paper, disposable powder-free gloves, disinfectants.

5. PRECAUTIONS AND SAFETY

5.1. Precautions

Be sure to read the instructions for use carefully before the test. The validity of the test results depends on strict following of the test procedure.

– do not use the ELISA kit components after the expiry date;
– do not use for analysis or mix components of different batches, components of kits for different nosologies, or reagents from other manufacturers with the «EQUI Toxocara canis IgG» ELISA kit;

– do not freeze the ELISA kit or its contents;
– after using a reagent, close each vial with its cap;
– when washing, control filling and complete aspiration of solution from the wells;
– use a new pipette tip each time you add samples or reagents;
– prevent direct sunlight from reaching the reagents from the ELISA kit;
– SOLN|TMB solution must be colourless before use. Do not use the solution if its colour is blue or yellow. Avoid contact of SOLN|TMB with metals or metal ions. Use only clean glassware thoroughly rinsed with distilled water;
– do not use reagents with colour not in line with para. 4.1;
– under no circumstances should the same glassware be used for SOLN|CONJ and SOLN|TMB;
– do not evaluate the test results visually (without a reader);
– any optional equipment that is in direct contact with biological material or kit components should be considered contaminated and requires cleaning and decontamination;
– the ELISA kit includes materials for 96 tests. Dispose of the used components as well as any remaining unused components.

5.2. Safety requirements

– all reagents in the ELISA kit are for laboratory professional use for *in vitro* diagnosis only and may only be used by qualified personnel;
– conduct the tests in disposable powder-free gloves and goggles only;
– do not eat, drink, smoke, or apply make-up in the test room;
– do not mouth-pipette the solutions;
– controls from the «EQUI Toxocara canis IgG» ELISA kit have been tested and found to be for anti-HIV1/2, anti-HCV and anti-*Treponema pallidum* antibodies and HBsAg negative; however, controls and test samples should be handled as potentially hazardous infectious materials;
– some of the kit components contain low concentrations of harmful substances and can damage skin or mucoga. In case of contact of SOLN|TMB, SOLN|STOP and SOLN|CONJ with mucous membranes or skin, immediately wash the affected area with plenty of water;
– in case of spillage of acid-free solutions, e. g. sera, treat the surface with a disinfectant solution and then wipe dry with filter paper. Otherwise first neutralize acid with sodium bicarbonate solution and then wipe the surface dry as described above.

5.3. Waste inactivation and disposal

– the liquid waste must be inactivated, for example, with hydrogen peroxide solution at the final concentration of 6% for 3 hours at room temperature, or with sodium hypochlorite at the final concentration of 5% for 30 minutes, or with other approved disinfectants;

– the solid waste must be inactivated by autoclaving at a temperature not less than 132°C;
– do not autoclave the solutions that contain sodium azide or sodium hypochlorite;
– disposal of inactivated waste must be conducted due to national laws and regulations.

6. STORAGE AND STABILITY

ELISA kit is stable up to the expiry date stated on the label when stored at 2-8°C. The kit should be transported at 2-8°C. Single transportation at a temperature up to 23°C for two days is possible.

7. SAMPLE COLLECTION, TRANSPORTATION AND STORAGE GUIDELINES

Collect blood from the vein into the sterile test tube. Test tube must be marked with patient ID and date of sample collecting. Blood before serum separation can be stored at 2-8 ºC for 24 hours, avoiding freezing.

Serum or plasma can be stored at 2-8 °C for maximum 3 days. Frozen serum can be stored for longer periods of time at -20 °C or -70 °C. Thaw frozen samples and keep them at room temperature for 30 minutes before use. After thawing, the stir samples to achieve homogeneity. Avoid repeated freezing-thawing cycles for test samples. If serum (or plasma) is turbid, remove insoluble inclusions by centrifugation at 3000 rpm for 10-15 minutes. Do not use serum samples with hyperlipidemia, hemolysis, and bacterial growth.

Transport serum samples in insulated containers. To do that, put closed labelled tubes in a plastic bag, tightly seal it and place in the centre of an insulated container.Put the frozen cold packs on the bottom, along the side walls of the insulated container and on top of the serum samples.

8. REAGENT PREPARATION

NOTE! It is very important to keep all ELISA kit components for at least 30 min at room temperature 18-25 ºC before the assay!

8.1. Microplate preparation

To prevent water condensation in the wells, keep the STRIPS for 30 minutes at a room temperature before opening. Open the vacuum pack, detach the appropriate number of wells, and carefully pack the remaining wells with a desiccant and store tightly zip-locked at 2-8 °C. Storing the packed plate this way ensures its stability for 6 months.

8.2. Washing solution preparation

To prepare detergent, dilute TWEEN WASH 20x at 1:20 (1+19) with distilled or deionized water and stir. E. g., 5 mL of concentrate + 95 mL of water, which is enough for 8 wells. If there are crystals present in the detergent concentrate, heat the vial at 37 °C until the crystals dissolve completely (15–20 minutes). Store the diluted solution at 2-8 °C for a maximum of 7 days.

9. ASSAY PROCEDURE

9.1. Prepare the necessary number of wells (four wells for controls and a necessary number of wells for test samples) and insert them into the ELISA plate frame. Be sure to add control wells in every test run.

9.2. Fill in the sample application plan.

9.3. Prepare the detergent as per para. 8.2.

9.4. Add 90 µL of DIL SAMPLE into each plate well.

9.5. Add 10 µL of controls and test samples into the wells:
CONTROL + – into well A1,
CONTROL - – into wells B1, C1 and D1,
and test samples into the remaining wells.
At the time of adding, the solution changes its colour from brown to blue. Pipette the mix in the wells carefully to avoid foaming.

9.6. Cover the strips up with adhesive film and incubate for **30 minutes at 37 °C**.

9.7. Remove and discard the adhesive film and wash all wells 5 times with automatic washer or 8-channel pipette as follows:
– aspirate the content of all wells into a liquid waste container;
– add a minimum of 300 µl of diluted washing solution to each well, soak each well for 30 seconds;
– aspirate the content of all wells again. The residual volume after every aspiration should be less than 5 µl;
– repeat the washing step 4 more times;
– after the final aspiration, eliminate extra moisture by tapping the plate against a piece of filter paper.

9.8. Add 100 µL of SOLN CONJ into each well. Cover the strips with a new piece of adhesive film and incubate for **30 minutes at 37 °C**.

9.9. Following incubation, remove the film carefully and wash the wells five times as described in para. 9.7.

9.10. Add 100 µL of SOLN TMB into the wells; do not touch the bottom and the walls of the plate wells.

9.11. Incubate the strips for **30 minutes** in a dark place at a room temperature of 18-25 °C. Do not use adhesive film at this stage.

9.12. Add 100 µL of SOLN STOP into each strip well to stop the enzymatic reaction; adhere to the same sequence of actions as when adding SOLN TMB. At the time of adding, the solution colour changes from blue to yellow, and clear solution slightly changes its shade.

9.13. Measure the optical density (OD) of the wells at 450/620-695 nm wavelength using an ELISA microplate reader within 5 minutes after stopping the reaction. Pay attention to the cleanness of the plate bottom and the absence of bubbles in the wells before reading.

Measurement at the single wavelength of 450 nm is possible, in that case, it is needed to leave one well for blank (only SOLN TMB and SOLN STOP must be added

in blank well).

10. CALCULATION AND INTERPRETATION OF RESULTS

10.1. Calculation of results

Calculate the average OD for the negative control ($\overline{Nc}$), Cut off (CO) and a sample positivity index (IP_{sample}).

$$\overline{Nc} = (Nc1 + Nc2 + Nc3)/3; \quad CO = \overline{Nc} + 0,3$$

$IP_{sample} = OD_{sample}/CO$, where: OD_{sample} is the OD sample.

10.2. Quality control (assay validation)

The test results are considered valid if they meet the following requirements:

CONTROL + $OD \geq 1,0$

CONTROL - $OD \leq 0,150$

CONTROL - $\overline{Nc} \times 0,5 \leq Ncn \leq \overline{Nc} \times 2,0$ where Ncn is the OD for each Nc run

If any of the OD values for the negative control is beyond the above interval, it should be discarded, and $\overline{Nc}$ is calculated based on the remaining OD values for the negative control. If several OD values for the negative control fail to meet the above requirements, the test is considered invalid and requires a new run.

10.3. Interpretation of results

$IP_{sample} > 1,1$	POSITIVE
$0,9 \leq IP_{sample} \leq 1,1$	BORDERLINE*
$IP_{sample} < 0,9$	NEGATIVE

* Uncertain samples are recommended to be re-examined in two wells of the ELISA kit. If the results are again uncertain, a new sample should be selected and analyzed in 2-4 weeks. In case of repeated indeterminate results, such samples shall be considered negative.

11. PERFORMANCE CHARACTERISTICS

11.1. Analytical performance characteristics

Precision of measurement

Intra assay repeatability

The coefficient of variation (CV) for three sera with different levels of specific antibodies was evaluated in 24 replicates on one series of ELISA kits.

Sample No.	OD_{av}	IP_{av}	CV, %
669	0,927	2,81	4,8
544	1,503	4,56	1,4
666	1,694	5,14	4,5

Inter assay reproducibility

The coefficient of variation (CV) for three sera with different levels of specific antibodies was evaluated for 4 days in 4 sets of analysis, 8 replicates in each analysis.

Sample No.	OD_{av}	IP_{av}	CV, %
669	1,016	3,04	4,7
544	1,516	4,54	1,9
666	1,683	5,04	4,1

Analytical specificity

The test results are not affected by bilirubin at up to 0.21 mg/mL (361.8 μmol/L), haemoglobin at up to 10 mg/mL and triglycerides at up to 10 mg/mL (11.3 mmol/l) present in the sample.

11.2. Diagnostic characteristics

To evaluate diagnostic characteristics of «EQUI Toxocara canis IgG» ELISA kits, 78 serum samples from patients with clinical symptoms typical for toxocariasis and 60 serum samples from patients without clinical manifestations (seronegative in terms of *Toxocara canis*) were used. Clinical sensitivity of «EQUI Toxocara canis IgG» ELISA kits was 98.7 %, clinical specificity — 96.7 %.

Method characteristics in comparison with equal commercial ELISA kit was studied in target paediatric population (160 samples) and population of donors (298 samples). For paediatric population serum, relative specificity of «EQUI Toxocara canis IgG» ELISA kits was established at the level of 99.28 % and percent agreement was 97.45 %. For donor population serum, relative specificity of was 89.19 %, relative specificity — 93.55 % and percent agreement was 91.73 %.

12. LIMITATIONS OF ASSAY

Positive result in «EQUI Toxocara canis IgG» ELISA kit supports presence of anti-*Toxocara canis* specific IgG antibodies. Presence of this class antibodies in newborns is not an evidence of *Toxocara canis* invasion.

Inconclusive results may suggest a history of *Toxocara canis* invasion.

Negative result of «EQUI Toxocara canis IgG» ELISA kit supports the absence of anti-*Toxocara canis* specific IgG antibodies in the test sample or concentration of specific antibodies is below the sensitivity limit of the assay.

The results of serological test only are not the basis for final diagnosis. When establishing the diagnosis, the results of complex laboratory and instrumental tests, as well as clinical manifestations should be considered. Cross-reactions with antibodies to antigens of other helminths cannot be fully ruled out.

13. DIFFICULTIES THAT CAN OCCUR DURING THE ASSAY PROCEDURE

Possible reasons	Solution
High background in all wells	
Contaminated washer	Clean the washer head and rinse according to the instructions for use
Poor quality or contaminated water	Use purified water with specific resistance ≥ 10 MΩ · cm
Use of poorly washed glassware	Use chemically clean utensils
Use of chlorinated disinfectants	Do not use chlorine disinfectants
Use of contaminated tips	Use new tips
Increased incubation times or change in the temperature conditions	Adhere to the incubation regime according to the instructions for use
High background in a row of wells	
Repeat application of TMB solution	TMB solution should be applied once
Contamination of the automatic pipette nozzle with conjugate solution	Clean the pipette and dial carefully liquid
Contamination of one of the washer's channel	Clean the flush channel, rinse washer
Received OD of the positive control is below the border value	
One of the reagents (conjugate solution or TMB solution) was not prepared in a correct way or was not added	Re-conduct ELISA, pay attention to the correctness of the introduction of these reagents
Reduced incubation times at any stage	Incubate according to instructions for use
The colour density of the wells fails to meet the obtained optical density value	
This may suggest that the optical beam has been displaced	Check the correct operation of the reader

14. TECHNICAL ASSISTANCE AND CUSTOMER SERVICE

In case of technical problems, you can obtain assistance by contacting the manufacturer.

REFERENCES

1. Cobzaru R. G., Rîpă C. et al. Correlation between asthma and Toxocara canis infection // Rev Med Chir Soc Med Nat Iasi. - 2012. - Vol. 116(3). - P. 727–730.
2. Despommier D. Toxocariasis: Clinical Aspects, Epidemiology, Medical Ecology, and Molecular Aspects // Clinical Microbiology Reviews. - 2003. - Vol. 16, No. 2. - P. 265–272.
3. Havasiová-Reiterová K., Tomašovicová O. and Dubinský P. Effect of various doses of infective Toxocara canis and Toxocara cati eggs on the humoral response and distribution of larvae in mice // Parasitology Research. - 1995. - Vol. 81. - P. 13–17.
4. Iddawela D., Ehambaram K., and Bandara P. Prevalence of Toxocara antibodies among patients clinically suspected to have ocular toxocariasis: A retrospective descriptive study in Sri Lanka // BMC Ophthalmology. - 2017. - Vol. 17. - 6 p.
5. Maizels R. M. Toxocara canis: Molecular basis of immune recognition and evasion // Veterinary Parasitology. - 2013. - Vol. 193 (4). - P. 365–374.
6. Magnaval J.-F., Glickman L. T. et al. Highlights of human toxocariasis // Korean Journal of Parasitology. - 2001. - Vol. 39 (1). - P. 1–11.
7. McGuinness S. L., Leder K. Global Burden of Toxocariasis: A Common Neglected Infection of Poverty // Current Tropical Medicine Reports. - 2014. - Vol. 1 (1). - P. 52–61.
8. Núñez C. R., Mendoza Martínez G. D. et al. Prevalence and Risk Factors Associated with Toxocara canis Infection in Children // The Scientific World Journal. - Volume 2013. - Article ID 572089. - 4 p.
9. Okulewicz A., Perec-Matysiak A. et al. Toxocara canis, Toxocara cati and Toxascaris leonina in wild and domestic carnivores // Helminthologia. - 2012. - Vol. 49. - P. 3–10.
10. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.
11. Закон України «Про відходи» // Відомості Верховної Ради України. - 1998. - №36-37.
12. Наказ МОЗ України №325 від 08.06.2015 «Про затвердження Державних санітарно-протиепідемічних правил і норм щодо поводження з медичними відходами».
13. Постанова КМУ від 02 жовтня 2013р. №754 «Про затвердження технічного регламенту щодо медичних виробів для діагностики in vitro».
14. Hanna Tolonen, Kari Kuulasmaa, Tiina Laatikainen, Hermann Wolf and the European Health Risk Monitoring Project. Recommendation for indicators, international collaboration, protocol and manual of operations for chronic disease risk factor surveys Part 4.Storage and transfer of serum/plasma samples// Finnish National Public Health Institute 2002// https://thl.fi/publications/ehrm/product2/part_iii4.htm
15. Surveillance Guidelines for Measles, Rubella and Congenital Rubella Syndrome in the WHO European Region. Annex 3.Collection, storage and shipment of specimens for laboratory diagnosis and interpretation of results//Geneva: World Health Organization; 2012 Dec.

	Manufacturer
EC REP	Authorized Representative in the European Community
IVD	In vitro diagnostic medical device
REF	Catalogue number
	Date of manufacture
	Use by date
LOT	Batch code
	Temperature limit
Σ	Contains sufficient for <n> tests
	Caution
NON STERILE	Non-Sterile
	Consult instructions for use
	Keep away from sunlight
	Keep dry
CE	Compliance with EU safety requirements

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For questions and suggestions regarding the ELISA kit contact:

EC REP

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ASSAY PROCEDURE SCHEME

Keep all reagents for 30 min at temperature18-25°C before use
Dispense 90 µl DIL SAMPLE into the wells (brown)
Add to 10 µl of controls and samples into the wells: A1 – CONTROL +, B1, C1, D1 – CONTROL –, other wells – examined samples (change of colour from brown to blue)
Cover strips with an adhesive film, incubate for **30 min at 37°C**
Rinse the wells 5 times with prepared 1:20 (1+19) washing solution TWEEN (300 µl per well)
Add 100 µl of SOLN CONJ into all wells (green)
Cover strips with an adhesive film, incubate for **30 min at 37°C**
Rinse the wells 5 times with prepared 1:20 (1+19) washing solution TWEEN (300 µl per well)
Add 100 µl of SOLN TMB into all wells
Incubate for **30 min** in the dark at **18-25°C**
Add 100 µl of SOLN STOP into all wells (change of colour from blue to yellow)
Measure the optical density (OD) with an ELISA microplate reader at 450/620-695 nm

CALCULATION OF RESULTS

$\overline{Nc} = (Nc1 + Nc2 + Nc3)/3;$

$CO = \overline{Nc} + 0,3;$

$IP_{sample} = OD_{sample}/CO$

$\overline{Nc}$ - the average value of OD 3-x CONTROL –

CO - Cut off

IP_{sample} - sample positivity index

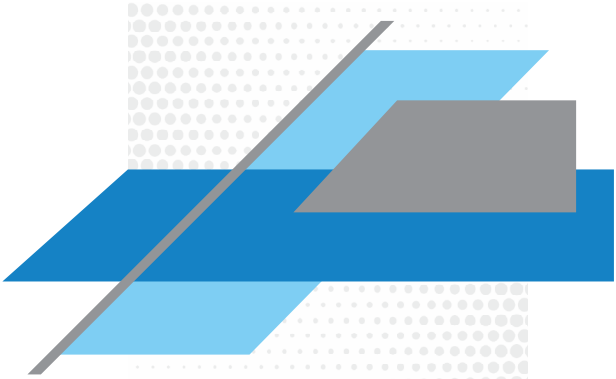
INTERPRETATION OF RESULTS

$IP_{sample} > 1,1$	POSITIVE
$0,9 \leq IP_{sample} \leq 1,1$	BORDERLINE
$IP_{sample} < 0,9$	NEGATIVE

anti-Lamblia

ELISA kit for the qualitative detection of antibodies to *Giardia lamblia (intestinalis)*

Instructions for use



IVD

REF EI-606

Σ 96 tests

CE

EQUI anti-Lamblia

ELISA kit for the qualitative detection of antibodies to
до *Giardia lamblia (intestinalis)*

1. INTENDED USE

The «EQUI anti-Lamblia» is ELISA kit intended to qualitatively detect antibodies to *Giardia lamblia (intestinalis)* in human serum or plasma by enzyme-linked immunosorbent assay (ELISA) to diagnose giardiasis. The testing procedure is designed for both manual arrangement with automatic pipettes and standard equipment, and for automated «open» immunoassay analysers.

Target group: children, pet owners, citizens of rural areas, summer house owners.

Usage: ELISA kit is used in clinical diagnostic laboratories and other institutions engaged in *in vitro* diagnostics.

2. CLINICAL SIGNIFICANCE

Giardiasis is considered one of the most common parasitic diseases of the small intestine in the world. This infection is a major cause of acute and chronic diarrhea, especially in children. The etiological agent of giardiasis is *Giardia lamblia*, which is also called *Giardia intestinalis* or *Giardia duodenalis*.

Giardia lamblia are unicellular flagellate protozoa that parasitize in the intestines of humans and some other mammals. During the life cycle of these parasites, two stages alternate: cysts, resistant to external conditions, and a vegetative form - trophozoites. Infection occurs when cysts enter the human gastrointestinal tract. After experiencing the effects of gastric acid, cysts in the duodenum turn into trophozoites, which parasitize in the upper parts of the small intestine. They absorb nutrients from the intestinal lumen, block parietal digestion and disrupt the motility of the intestine.

Humans get infected via fecal-oral routes through cyst-contaminated food, water, unwashed hands, and so on. Giardia can also be transmitted to humans from infected cats, dogs, and livestock. Giardiasis is especially common in regions with poor sanitation. In addition, human-to-human transmission is common in preschools.

In many cases, the invasion of Giardia occurs without clinical manifestations. In other cases, the first symptoms of giardiasis appear in 1-3 weeks after infection. They are most often manifested by spasms, bloating, nausea and diarrhea, which leads to dehydration and weight loss. The acute form of the disease can last up to two weeks and end in recovery without additional treatment or become chronic. Chronic giardiasis develops when the duration of the invasion is longer than 2 month and the exacerbation of clinical manifestations (diarrhea) is cyclical. *Giardia lamblia* parasitism can lead to malabsorption syndrome, which disrupts the absorption of carbohydrates and fats, as well as the metabolism of vitamins B12, A and C.

Immune response to invasion and non-immune factors are important to control the development of the disease and the severity of clinical manifestations. Both

humoral and cellular immunity play the part in the eradication of the pathogen, the role of which is still subjected to scientific research. In addition, partial resistance to re-infection is formed due to protective mechanisms of the body.

Typically, to diagnose giardiasis, the duodenal contents and feces are examined for trophozoites and cysts of giardiasis. In case of the chronic course of the disease, cysts get excreted periodically, and, considering this, the additional tests should be performed regularly for several weeks. Another method of diagnosing giardiasis is to detect *Giardia lamblia* antigens in the feces. However, serodiagnosis with the detection of specific antibodies to Giardia antigens is an important step in assessing the immune response of patients. Detection of specific IgM antibodies suggests an acute stage of giardiasis. However, the detection of specific IgG and IgA antibodies should be interpreted with caution: in some regions they persist for a long time after infection, while in others their level decreases after eradication of the pathogen.

3. ANALYSIS PRINCIPLE

The procedure of testing for *Giardia lamblia* specific antibodies in «EQUI anti-Lamblia» ELISA kit is based on «indirect» solid-phase ELISA with a two-stage incubation. Recombinant *Giardia lamblia* antigens are entrapped in the wells. During the first step of incubation of the test samples in the wells of the ELISA plate, *Giardia lamblia*-specific antibodies, if present in the samples, bind to the solid phase antigens. The wells are washed to remove unbound antibodies and have only specific antigen-antibody complexes left. Then, a conjugate of anti-species (anti-IgG and anti-IgA) monoclonal antibodies with horseradish peroxidase is added, which binds to solid-phase immune complexes. Unbound components are removed by washing. Antigen-antibody complexes are detected by adding a solution of chromogen 3,3',5,5'-tetramethylbenzidine (TMB) with hydrogen peroxide. After 30-minute incubation, the reaction is stopped by adding the stop solution. The optical density (OD) in the wells is determined using a spectrophotometer at 450/620-695 nm. The intensity of the yellow colour is proportional to the level of antibodies in the sample.

4. MATERIALS AND EQUIPMENT

4.1. Contents of the ELISA kit

		Microplate
STRIPS	1 x 96 wells	Each plate well is coated with *Giardia lamblia* purified antigens. The wells are detachable. After the first opening, store unused strips in the package at 2-8 °C for a maximum of 6 months
		Positive control
CONTROL +	1 x 0,35 ml	Conjugated specific monoclonal antibody solution with preservative (pink). Store at 2-8 °C
		Negative control
CONTROL -	1 x 1,2 ml	Negative human serum with a preservative (yellow). Store at 2-8 °C

DIL SAMPLE	1 x 11 ml	**Serum dilution solution** Buffer solution with a milk extract, a detergent and a preservative (purple). Store at 2-8 °C
SOLN CONJ	1 x 13 ml	**Conjugate solution (ready to use)** Buffer solution of monoclonal antibodies to human IgG and IgA, conjugated with horseradish peroxidase, with stabilizers and preservative (green). Store at 2-8 °C
SOLN TMB	1 x 13 ml	**TMB solution (ready to use)** TMB solution, H_2O_2, a stabilizer, a preservative (colourless). Store at 2-8 °C
TWEEN WASH 20x	1 x 50 ml	**Washing solution TWEEN (20x concentrated)** 20-fold phosphate buffer concentrate with Tween-20 (colourless). Dilute TWEEN detergent (20x) at 1:20 with distilled or deionized water (e. g., 5 mL of concentrate + 95 mL of water for 8 wells) before use. Store the diluted solution at 2-8 °C for a maximum of 7 days
SOLN STOP	1 x 13 ml	**Stop Solution (ready to use)** 0.5 mol H_2SO_4 solution (colourless). Store at 2-8 °C

The ELISA kit also includes adhesive films (2 items), sample application plan (1 item), checklist, and instruction for use.

4.2. Optional reagents, materials and equipment

Automatic single and multichannel pipettes 10–1000 µL, tips, volumetric laboratory glassware (10–1,000 mL), deionized or distilled water, thermostat at 37 °C, automatic or semi-automatic plate washer, spectrophotometer (reader) for microplates at 450/620-695 nm, appropriate containers for potentially contaminated waste, timer, filter paper, disposable powder-free gloves, disinfectants.

5. PRECAUTIONS AND SAFETY

5.1. Precautions

Be sure to read the instructions for use carefully before the test. The validity of the test results depends on strict following of the test procedure.

- do not use the ELISA kit components after the expiry date;
- do not use for analysis or mix components of different batches, components of kits for different nosologies, or reagents from other manufacturers with the «EQUI anti-Lamblia» ELISA kit;
- do not freeze the ELISA kit or its contents;
- after using a reagent, close each vial with its cap;
- when washing, control filling and complete aspiration of solution from the wells;
- use a new pipette tip each time you add samples or reagents;
- prevent direct sunlight from reaching the reagents from the ELISA kit;
- SOLN TMB solution must be colourless before use. Do not use the solution if its colour is blue or yellow. Avoid contact of SOLN TMB with metals or metal ions. Use only clean glassware thoroughly rinsed with distilled water;

– do not use reagents with colour not in line with para. 4.1;
– under no circumstances should the same glassware be used for SOLN|CONJ and SOLN|TMB;
– do not evaluate the test results visually (without a reader);
– any optional equipment that is in direct contact with biological material or kit components should be considered contaminated and requires cleaning and decontamination;
– the ELISA kit includes materials for 96 tests. Dispose of the used components as well as any remaining unused components.

5.2. Safety requirements

– all reagents in the ELISA kit are for laboratory professional use for *in vitro* diagnosis only and may only be used by qualified personnel;
– conduct the tests in disposable powder-free gloves and goggles only;
– do not eat, drink, smoke, or apply make-up in the test room;
– do not mouth-pipette the solutions;
– controls from the «EQUI anti-Lamblia» ELISA kit have been tested and found to be for anti-HIV1/2, anti-HCV and anti-*Treponema pallidum* antibodies and HBsAg negative; however, controls and test samples should be handled as potentially hazardous infectious materials;
– some of the kit components contain low concentrations of harmful substances and can damage skin or mucoga. In case of contact of SOLN|TMB, SOLN|STOP and SOLN|CONJ with mucous membranes or skin, immediately wash the affected area with plenty of water;
– in case of spillage of acid-free solutions, e. g. sera, treat the surface with a disinfectant solution and then wipe dry with filter paper. Otherwise first neutralize acid with sodium bicarbonate solution and then wipe the surface dry as described above.

5.3. Waste inactivation and disposal

– the liquid waste must be inactivated, for example, with hydrogen peroxide solution at the final concentration of 6% for 3 hours at room temperature, or with sodium hypochlorite at the final concentration of 5% for 30 minutes, or with other approved disinfectants;
– the solid waste must be inactivated by autoclaving at a temperature not less than 132°C;
– do not autoclave the solutions that contain sodium azide or sodium hypochlorite;
– disposal of inactivated waste must be conducted due to national laws and regulations.

6. STORAGE AND STABILITY

ELISA kit is stable up to the expiry date stated on the label when stored at 2-8°C. The kit should be transported at 2-8°C. Single transportation at a

temperature up to 23°C for two days is possible.

7. SAMPLE COLLECTION, TRANSPORTATION AND STORAGE GUIDELINES

Collect blood from the vein into the sterile test tube. Test tube must be marked with patient ID and date of sample collecting. Blood before serum separation can be stored at 2-8 ºC for 24 hours, avoiding freezing.

Serum or plasma can be stored at 2-8 °C for maximum 3 days. Frozen serum can be stored for longer periods of time at -20 °C or -70 °C. Thaw frozen samples and keep them at room temperature for 30 minutes before use. After thawing, the stir samples to achieve homogeneity. Avoid repeated freezing-thawing cycles for test samples. If serum (or plasma) is turbid, remove insoluble inclusions by centrifugation at 3000 rpm for 10-15 minutes. Do not use serum samples with hyperlipidemia, hemolysis, and bacterial growth.

Transport serum samples in insulated containers. To do that, put closed labelled tubes in a plastic bag, tightly seal it and place in the centre of an insulated container.Put the frozen cold packs on the bottom, along the side walls of the insulated container and on top of the serum samples.

8. REAGENT PREPARATION

NOTE! It is very important to keep all ELISA kit components for at least 30 min at room temperature 18-25 ºC before the assay!

8.1. Microplate preparation

To prevent water condensation in the wells, keep the STRIPS for 30 minutes at a room temperature before opening. Open the vacuum pack, detach the appropriate number of wells, and carefully pack the remaining wells with a desiccant and store tightly zip-locked at 2-8 °C. Storing the packed plate this way ensures its stability for 6 months.

8.2. Washing solution preparation

To prepare detergent, dilute TWEEN WASH 20x at 1:20 (1+19) with distilled or deionized water and stir. E. g., 5 mL of concentrate + 95 mL of water, which is enough for 8 wells. If there are crystals present in the detergent concentrate, heat the vial at 37 °C until the crystals dissolve completely (15–20 minutes). Store the diluted solution at 2-8 °C for a maximum of 7 days.

9. ASSAY PROCEDURE

9.1. Prepare the necessary number of wells (four wells for controls and a necessary number of wells for test samples) and insert them into the ELISA plate frame. Be sure to add control wells in every test run.

9.2. Fill in the sample application plan.

9.3. Prepare the detergent as per para. 8.2.

9.4. Add 80 µL of DIL SAMPLE into each plate well.

9.5. Add 20 µL of controls and test samples into the wells:
CONTROL + – into well A1,
CONTROL - – into wells B1, C1 and D1,
and test samples into the remaining wells.

At the time of adding, the solution changes its colour from brown to blue. Pipette the mix in the wells carefully to avoid foaming.

9.6. Cover the strips up with adhesive film and incubate for **30 minutes at 37 °C**.

9.7. Remove and discard the adhesive film and wash all wells 5 times with automatic washer or 8-channel pipette as follows:
– aspirate the content of all wells into a liquid waste container;
– add a minimum of 300 µl of diluted washing solution to each well, soak each well for 30 seconds;
– aspirate the content of all wells again. The residual volume after every aspiration should be less than 5 µl;
– repeat the washing step 4 more times;
– after the final aspiration, eliminate extra moisture by tapping the plate against a piece of filter paper.

9.8. Add 100 µL of SOLN CONJ into each well. Cover the strips with a new piece of adhesive film and incubate for **30 minutes at 37 °C**.

9.9. Following incubation, remove the film carefully and wash the wells five times as described in para. 9.7.

9.10. Add 100 µL of SOLN TMB into the wells; do not touch the bottom and the walls of the plate wells.

9.11. Incubate the strips for **30 minutes** in a dark place at a room temperature of 18-25 °C. Do not use adhesive film at this stage.

9.12. Add 100 µL of SOLN STOP into each strip well to stop the enzymatic reaction; adhere to the same sequence of actions as when adding SOLN TMB. At the time of adding, the solution colour changes from blue to yellow, and clear solution slightly changes its shade.

9.13. Measure the optical density (OD) of the wells at 450/620-695 nm wavelength using an ELISA microplate reader within 5 minutes after stopping the reaction. Pay attention to the cleanness of the plate bottom and the absence of bubbles in the wells before reading.

Measurement at the single wavelength of 450 nm is possible, in that case, it is needed to leave one well for blank (only SOLN TMB and SOLN STOP must be added in blank well).

10. CALCULATION AND INTERPRETATION OF RESULTS

10.1. Calculation of results

Calculate the average OD for the negative control ($\overline{Nc}$), Cut off (CO) and a sample positivity index (IP_{sample}).

$$\overline{Nc} = (Nc1 + Nc2 + Nc3)/3; \quad CO = \overline{Nc} + 0{,}25$$

$$IP_{sample} = OD_{sample}/CO, \text{ where } OD_{sample} \text{ is the OD sample.}$$

10.2. Quality control (assay validation)

The test results are considered valid if they meet the following requirements:

CONTROL + OD ≥ 1,0

CONTROL - OD ≤ 0,150

CONTROL - $\overline{Nc} \times 0,5 \leq Ncn \leq \overline{Nc} \times 2,0$ where Ncn is the OD for each Nc run

If any of the OD values for the negative control is beyond the above interval, it should be discarded, and $\overline{Nc}$ is calculated based on the remaining OD values for the negative control. If several OD values for the negative control fail to meet the above requirements, the test is considered invalid and requires a new run.

10.3. Interpretation of results

$IP_{sample} > 1,1$	POSITIVE
$0,9 \leq IP_{sample} \leq 1,1$	BORDERLINE*
$IP_{sample} < 0,9$	NEGATIVE

* Uncertain samples are recommended to be re-examined in two wells of the ELISA kit. If the results are again uncertain, a new sample should be selected and analyzed in 2-4 weeks. In case of repeated indeterminate results, such samples shall be considered negative.

11. PERFORMANCE CHARACTERISTICS

11.1. Analytical performance characteristic

Precision of measurement

Intra assay repeatability

The coefficient of variation (CV) for two sera with different levels of specific antibodies was evaluated in 32 replicates on one series of ELISA kits.

Sample No.	OD_{av}	IP_{av}	CV, %
14L	0,679	2,47	6,5
16L	0,490	1,79	6,6

Inter assay reproducibility

The coefficient of variation (CV) for three sera with different levels of specific antibodies was evaluated for 3 days in 3 sets of analysis, 8 replicates in each analysis.

Sample No.	OD_{av}	IP_{av}	CV, %
14L	0,670	2,39	5,55
16L	0,463	1,65	7,06

Analytical specificity

The test results are not affected by bilirubin at up to 0.21 mg/mL (361.8 µmol/L), haemoglobin at up to 10 mg/mL and triglycerides at up to 10 mg/mL (11.3 mmol/l) present in the sample.

11.2. Diagnostic characteristics

Studies of the characteristics of the method in comparison with a similar commercial ELISA kit were performed on a sample of characterized sera, the target group of children and a group of donors. The relative sensitivity of «EQUI anti-Lamblia» ELISA kits was determined from a group of 23 serum samples that were tested for antibodies to *Giardia lamblia* and characterized as positive in a commercial ELISA kit. All sera were also determined to be positive in «EQUI anti-Lamblia» kits, so the relative sensitivity equals 100%. For 148 serum samples of children that were tested and characterized in commercial analogues, the relative specificity of «EQUI anti-Lamblia» ELISA kits was 92.86%, the percentage of coincidence - 93.24%. According to a similar principle, for 238 serum samples of donor blood, the relative specificity was 97% and the percentage of coincidence was 96.64%.

12. LIMITATIONS OF ASSAY

The final diagnosis cannot be made solely on the basis of serological test results, sunce clinical manifestations of the disease and laboratory data (such as the detection of cysts in faecal samples or trophozoites in duodenal contents; the results of detection of *Giardia lamblia* antigen in faeces) should be taken into account as well.

Addionally, cross-reactions with antibodies to antigens of other parasites cannot be completely ruled out.

Giardia lamblia-specific antibodies may not be detected in case of children with persistent and prolonged giardiasis.

It should be noted that IgG antibodies to *Giardia lamblia* can be detected via ELISA for a long time, even after successful treatment.

13. DIFFICULTIES THAT CAN OCCUR DURING THE ASSAY PROCEDURE

Possible reasons	Solution
High background in all wells	
Contaminated washer	Clean the washer head and rinse according to the instructions for use
Poor quality or contaminated water	Use purified water with specific resistance ≥ 10 MΩ · cm
Use of poorly washed glassware	Use chemically clean utensils
Use of chlorinated disinfectants	Do not use chlorine disinfectants
Use of contaminated tips	Use new tips
Increased incubation times or change in the temperature conditions	Adhere to the incubation regime according to the instructions for use
High background in a row of wells	

Repeat application of TMB solution	TMB solution should be applied once
Contamination of the automatic pipette nozzle with conjugate solution	Clean the pipette and dial carefully liquid
Contamination of one of the washer's channel	Clean the flush channel, rinse washer
Received OD of the positive control is below the border value	
One of the reagents (conjugate solution or TMB solution) was not prepared in a correct way or was not added	Re-conduct ELISA, pay attention to the correctness of the introduction of these reagents
Reduced incubation times at any stage	Incubate according to instructions for use
The colour density of the wells fails to meet the obtained optical density value	
This may suggest that the optical beam has been displaced	Check the correct operation of the reader

14. TECHNICAL ASSISTANCE AND CUSTOMER SERVICE

In case of technical problems, you can obtain assistance by contacting the manufacturer.

REFERENCES

1. Adam R. D. Biology of Giardia lamblia // Clinical Microbiology Reviews. - 2001. - Vol. 14(3). - P. 447–475.
2. CDC - Giardia // https://www.cdc.gov/parasites/giardia/index.html.
3. Choy S. H., Al-Mekhlafi H. M. et al. Prevalence and Associated Risk Factors of Giardia Infection among Indigenous Communities in Rural Malaysia // Scientific Reports. - 2014. - Vol. 4, Article number: 6909.
4. DuPont H. L. Giardia: both a harmless commensal and a devastating pathogen // Journal of Clinical Investigation. - 2013. - Vol. 123(6). - P. 2352–2354.
5. Faubert G. Immune Response to Giardia duodenalis // Clinical Microbiology Reviews. - 2000. - Vol. 13(1). - P. 35–54.
6. Lopez-Romero G., Quintero J. et al. Host defences against Giardia lamblia // Parasite Immunology. - 2015. -Vol. 37(8). - P. 394-406.
7. Saghaug C. S., Sørnes S. et al. Human Memory CD4+ T Cell Immune Responses against Giardia lamblia // Clinical and Vaccine Immunology. - 2016. - Vol. 23, No. 1. - P. 11-18.
8. Solaymani-Mohammadi S. and Singer S. M. Giardia duodenalis: The Double-edged Sword of Immune Responses in Giardiasis // Experimental Parasitology. - 2010. - Vol. 126 (3). - P. 292–297.
9. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.
10. Закон України «Про відходи» // Відомості Верховної Ради України. - 1998. - №36-37.
11. Наказ МОЗ України №325 від 08.06.2015 «Про затвердження Державних санітарно-протиепідемічних правил і норм щодо поводження з медичними відходами».
12. Постанова КМУ від 02 жовтня 2013р. №754 «Про затвердження технічного регламенту щодо медичних виробів для діагностики in vitro».
13. Hanna Tolonen, Kari Kuulasmaa, Tiina Laatikainen, Hermann Wolf and the European Health Risk Monitoring Project. Recommendation for indicators, international collaboration, protocol and manual of operations for chronic disease risk factor surveys Part 4.Storage and transfer of serum/plasma samples// Finnish National Public Health Institute 2002// https://thl.fi/publications/ehrm/product2/part_iii4.htm
14. Surveillance Guidelines for Measles, Rubella and Congenital Rubella Syndrome in the WHO European Region. Annex 3.Collection, storage and shipment of specimens for laboratory diagnosis and interpretation of results// Geneva: World Health Organization; 2012 Dec.

	Manufacturer
	Authorized Representative in the European Community
	In vitro diagnostic medical device
	Catalogue number
	Date of manufacture
	Use by date
	Batch code
	Temperature limit
	Contains sufficient for <n> tests
	Caution
	Non-Sterile
	Consult instructions for use
	Keep away from sunlight
	Keep dry
CE	Compliance with EU safety requirements

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For questions and suggestions regarding the ELISA kit contact:

EC REP

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ASSAY PROCEDURE SCHEME

Keep all reagents for 30 min at temperature18-25°C before use
Dispense 80 µl DIL SAMPLE into the wells (purple)
Add to 20 µl of controls and samples into the wells: A1 – CONTROL +, B1, C1, D1 – CONTROL –, other wells – examined samples (change of colour from purple to blue)
Cover strips with an adhesive film, incubate for **30 min at 37°C**
Rinse the wells 5 times with prepared 1:20 (1+19) washing solution TWEEN (300 µl per well)
Add 100 µl of SOLN CONJ into all wells (green)
Cover strips with an adhesive film, incubate for **30 min at 37°C**
Rinse the wells 5 times with prepared 1:20 (1+19) washing solution TWEEN (300 µl per well)
Add 100 µl of SOLN TMB into all wells
Incubate for **30 min** in the dark at **18-25°C**
Add 100 µl of SOLN STOP into all wells (change of colour from blue to yellow)
Measure the optical density (OD) with an ELISA microplate reader at 450/620-695 nm

CALCULATION OF RESULTS

$\overline{Nc} = (Nc1 + Nc2 + Nc3)/3;$

$CO = \overline{Nc} + 0,25;$

$IP_{sample} = OD_{sample}/CO$

$\overline{Nc}$ - the average value of OD 3-x CONTROL –

CO - Cut off

IP_{sample} - sample positivity index

INTERPRETATION OF RESULTS

$IP_{sample} > 1,1$	POSITIVE
$0,9 \leq IP_{sample} \leq 1,1$	BORDERLINE
$IP_{sample} < 0,9$	NEGATIVE