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

Digitally signed by Monastîrschii Viorica
Date: 2023.05.30 11:41:59 EEST
Reason: MoldSign Signature
Location: Moldova

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

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

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Product Service

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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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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®

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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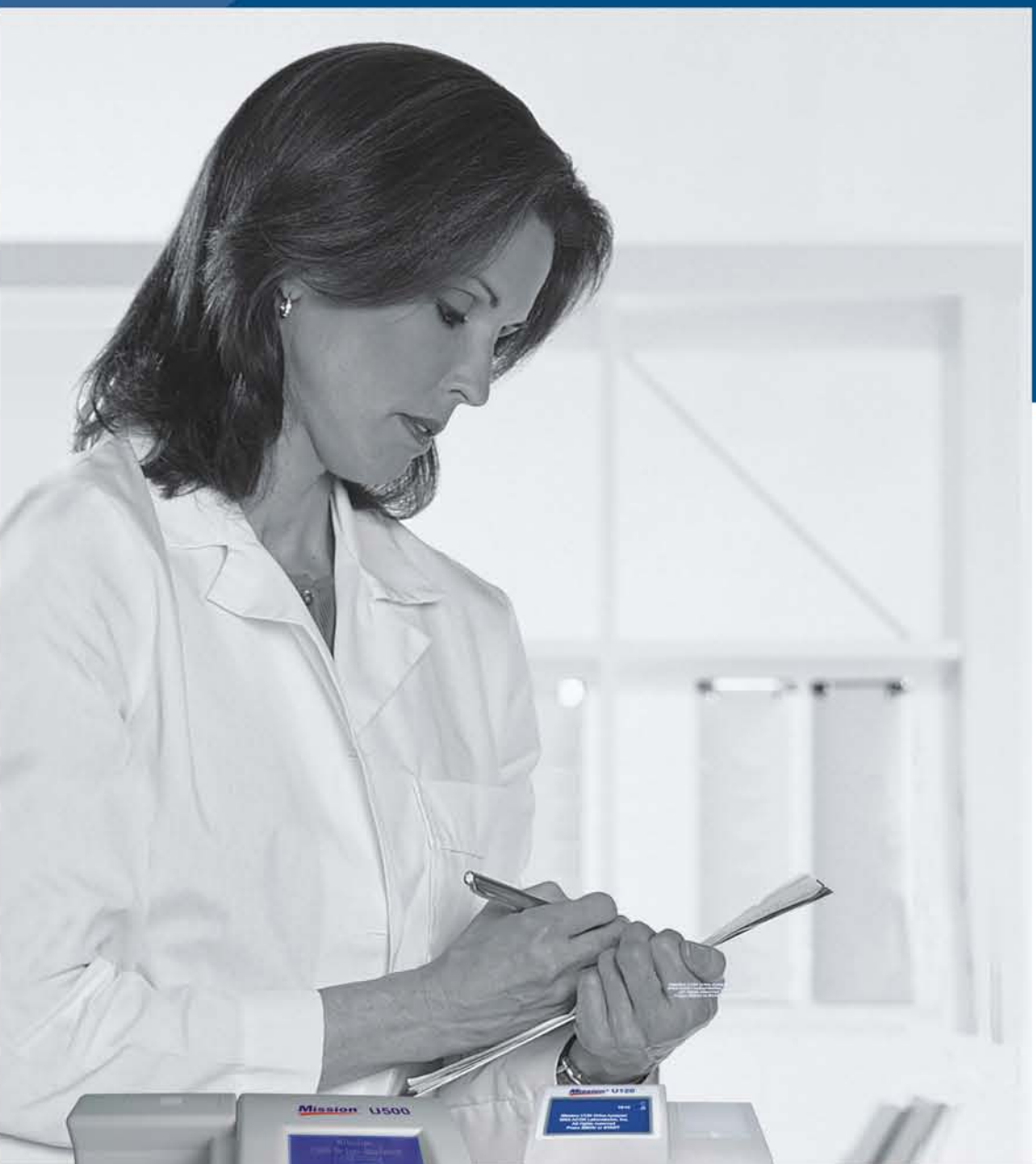
TÜV®

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

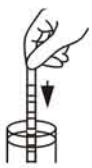
- Analytical sensitivity better than or comparable to market leaders
- High quality color chart ensures accurate visual reading

Flexible

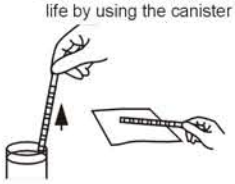
- Compatible for visual and analyzer reading
- More than 30 different combinations available

Multiple Packaging Options and Long Shelf Life

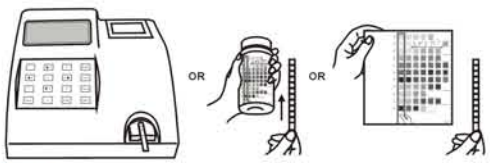
- Canister Packaging
  - Available in 25, 50, 100 and 150 strips per kit
  - 2 year shelf life for unopened canisters which offers cost savings and convenience for high volume testing
  - 3 month shelf life for strips in opened canisters
- Pouch Packaging ***New!***
  - Single-strip Pouch
    - Individually 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

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.

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

Declaration Ref No: DC21-0035

CE Declaration of Conformity

According to Annex III of the IVD Directive 98/79/EC

We,

Atlas Medical

Head office: Ludwig-Erhard-Ring 3
Blankenfelde-Mahlow, Germany.
Tel: +49 - 33708 – 3550 30
Email: info@atlas-medical.com

Middle East Site: Sahab Free Zone Area, P. O. Box 212555, Amman, Jordan.
Tel.: +962 6 4026468
Fax: +962 6 4022588
Email: info@atlas-medical.com

Declare our responsibility that the following product:

See Attached list

- Comply with all essential requirements (AnnexI) of the IVD Directive 98/79/EC. This compliance has been properly documented and covers the items listed in Annex I of the IVD Directive.
- This product is produced under Atlas quality system (ISO13485:2016) issued by GMED:
  Certificate N^0.: 36655 rev 1
  Expiry Date: October 8 th.2023
- Comply with the essential requirements of following standards (EN 18113-1, -2,-4:2011, EN ISO 15223:2016 , EN ISO 23640:2015, EN ISO 14971:2019, ISO 2859/1:1999, EN ISO 13612:2002, EN ISO 13641:2002.

And
Intended for In-Vitro Professional use only.

Manufacturer
Atlas Medical
Ludwig-Erhard-Ring 3
Blankenfelde-Mahlow , Germany.

Atlas Medical
Quality Diagnostic Products

Atlas Medical	Issue date	Date of review	Management approval	MRXDO10F.10 08.02.2011
	March.2021	09.03.2021		

Atlas Medical

CE Declaration of Conformity

According to Annex III of the IVD Directive 98/79/EC

Product Description
8.00.02.0.0100 : ASO Latex Kit, 100 Tests (4ml Latex, 2x1.0ml controls).
8.00.00.0.0100: CRP Latex Kit, 100 Tests (4 ml Latex, 2x1.0 ml Controls)
8.00.04.0.0100: RF Latex Kit, 100 Tests (4ml Latex, 2x1.0ml controls)
8.00.17.0.0100: D-Dimer Latex Kit, 100 Tests
8.00.13.0.0300 : Streptococcus Latex Kit, 6 Groups, 6x50 Tests (5x1.5ml Latex (A,B,C,G,F), 1x3ml Latex(D), 1x1.0ml Positive Control, 1x2ml Extraction Reagent E, 1x1.5ml Extraction Reagent 1, 1x1.5ml Extraction Reagent 2, 2x2.5ml Extraction Reagent 3, Stirring Sticks, Glass Slide).
8.00.18.3.0500 : RPR Syphilis (Coarse Grain) Kit, 500 Tests (10 ml latex, 2x1ml control) Without card,stirring sticks.
8.00.18.3.1000 RPR Carbon Antigen (Coarse Grain) Kit, 1000 Tests (Reagent only).

Atlas Medical
Quality Diagnostic Products

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

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,
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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

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

SGS Belgium NV
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

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

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.

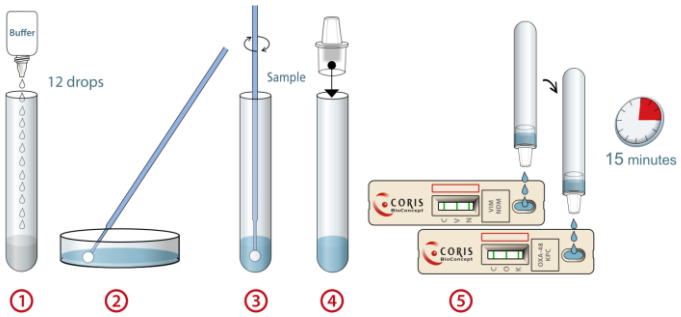
VII. SPECIMEN HANDLING AND COLLECTION

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.

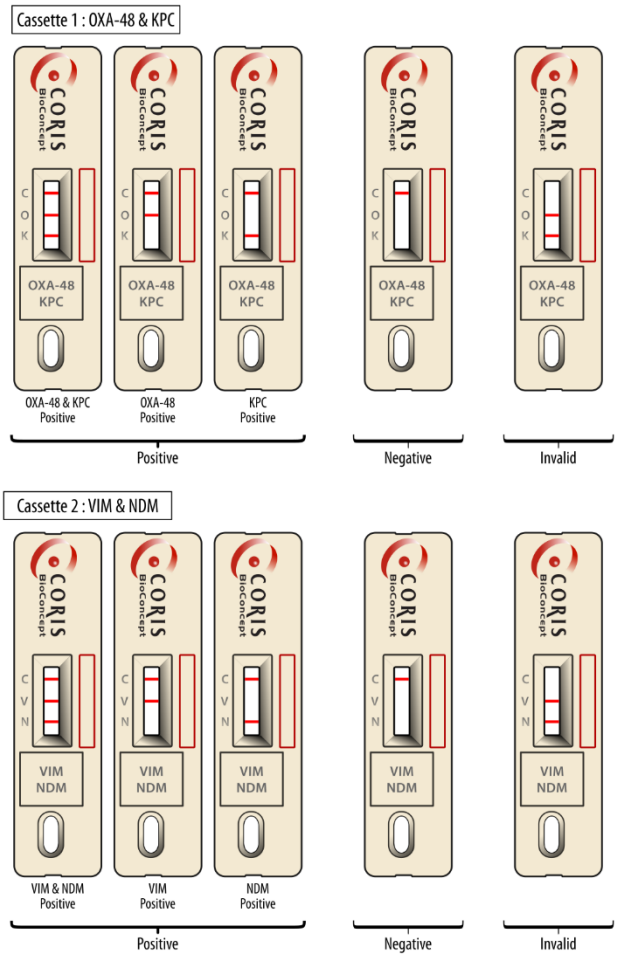
1. Prepare one semi-rigid tube and add **12** drops of LY-A buffer in the tube.
2. Harvest bacteria by taking one colony with a disposable bacteriological loop and dip the loop in the bottom of the semi-rigid tube containing the buffer.
3. Stir thoroughly before removing the loop
4. Insert tightly the 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

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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

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

Science Park CREALYS
Rue Jean Sonet 4A
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TEL : + 32(0)81.719.917
FAX : +32(0)81.719.919
e-mail : info@corisbio.com
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

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

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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.

CE IVD REF **52.01** STERILE Σ 100

ЗАО «ЭКОлаб
ул. Буденного, д.1
г. Электрогорск,
Московская обл.,
Россия
142530

EC REP

CEpartner4U B.V.,
ESDOORNLAAN 13,
3951 DB MAARN,
THE NETHERLANDS

Кат № 52.01

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.

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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

CE	CE marking of conformity
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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*
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«ПРОМТЕХСТАНДАРТ»
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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)

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