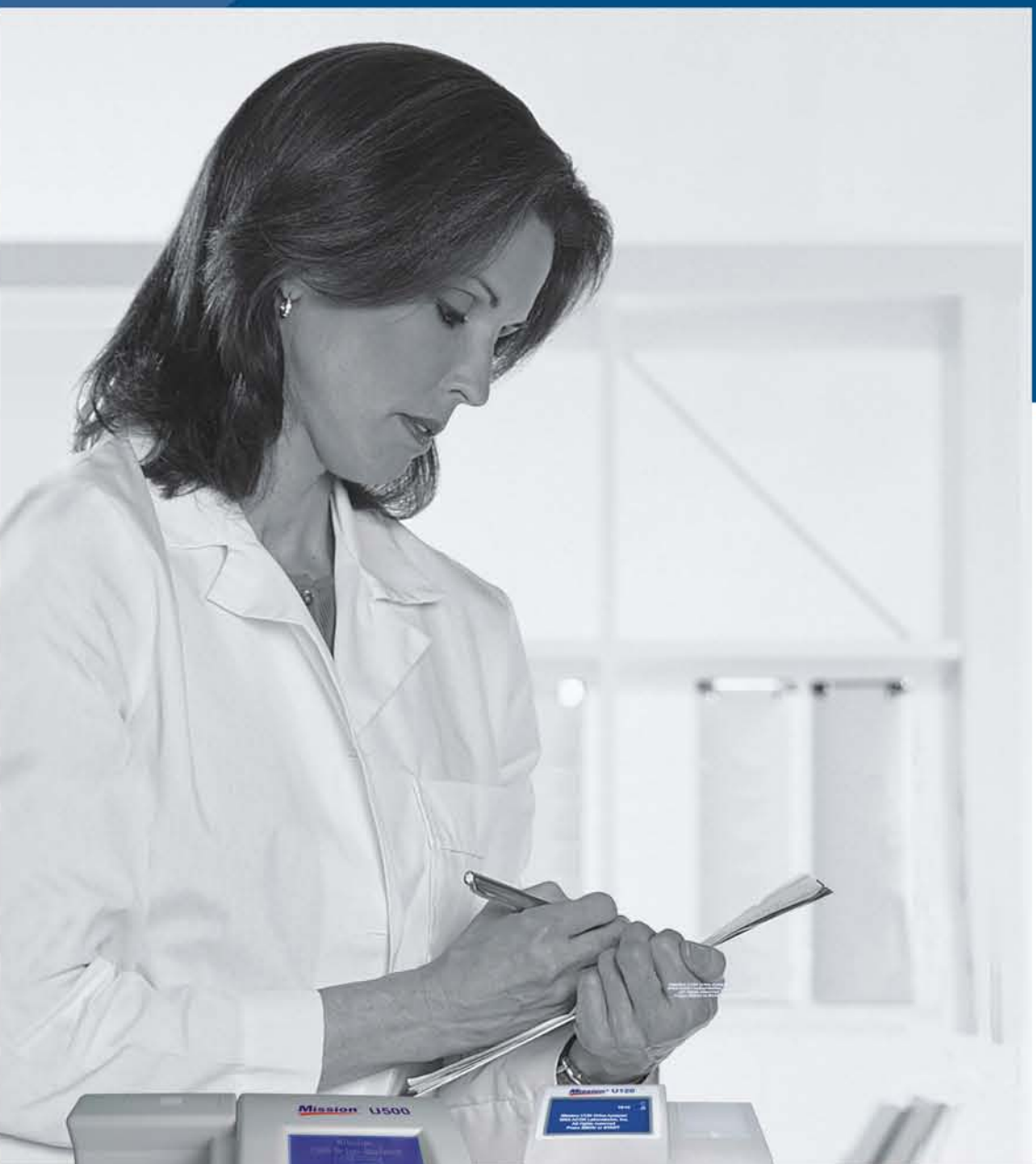
Mission® Urinalysis Reagent Strips and Urine Analyzers



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

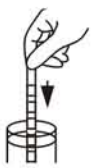
- Analytical sensitivity better than or comparable to market leaders
- High quality color chart ensures accurate visual reading

Flexible

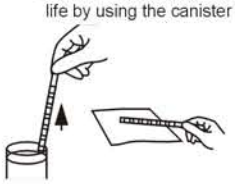
- Compatible for visual and analyzer reading
- More than 30 different combinations available

Multiple Packaging Options and Long Shelf Life

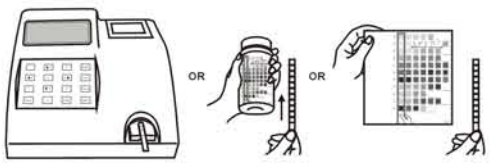
- Canister Packaging
  - Available in 25, 50, 100 and 150 strips per kit
  - 2 year shelf life for unopened canisters which offers cost savings and convenience for high volume testing
  - 3 month shelf life for strips in opened canisters
- Pouch Packaging ***New!***
  - Single-strip Pouch
    - Individually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

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† 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.

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Please visit our website for details: www.aconlabs.com

1150449703

Nutrient Agar

M001

Intended use

Nutrient Agar is used as a general purpose medium for the cultivation of less fastidious microorganisms, can be enriched with blood or other biological fluids.

Composition**

Ingredients	Gms / Litre
Peptone	5.000
Sodium chloride	5.000
HM peptone B#	1.500
Yeast extract	1.500
Agar	15.000
Final pH (at 25°C)	7.4±0.2

**Formula adjusted, standardized to suit performance parameters

- Equivalent to Beef extract

Directions

Suspend 28.0 grams in 1000 ml purified / distilled water. Heat to boiling to dissolve the medium completely. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes. Cool to 45-50°C. If desired ,the medium can be enriched with 5-10% blood or other biological fluids. Mix well and pour into sterile Petri plates.

Principle And Interpretation

Nutrient media are basic culture media used for maintaining microorganisms, cultivating fastidious organisms by enriching with serum or blood and are also used for purity checking prior to biochemical or serological testing (1,2). Nutrient Agar is ideal for demonstration and teaching purposes where a more prolonged survival of cultures at ambient temperature is often required without risk of overgrowth that can occur with more nutritious substrate. This relatively simple formula has been retained and is still widely used in the microbiological examination of variety of materials and is also recommended by standard methods. It is one of the several non-selective media useful in routine cultivation of microorganisms (3,4). It can be used for the cultivation and enumeration of bacteria which are not particularly fastidious. Addition of different biological fluids such as horse or sheep blood, serum, egg yolk etc. makes it suitable for the cultivation of related fastidious organisms. Peptone, HM peptone B and yeast extract provide the necessary nitrogen compounds, carbon, vitamins and also some trace ingredients necessary for the growth of bacteria. Sodium chloride maintains the osmotic equilibrium of the medium.

Type of specimen

Clinical samples - faeces, urine ; Food and dairy samples; Water samples

Specimen Collection and Handling:

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (5,6).
For food and dairy samples, follow appropriate techniques for sample collection and processing as per guidelines (3,4,7).
For water samples, follow appropriate techniques for sample collection, processing as per guidelines and local standards (8).
After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions :

In Vitro diagnostic use. For professional use only. Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations :

1. Individual organisms differ in their growth requirement and may show variable growth patterns on the medium.

2.Each lot of the medium has been tested for the organisms specified on the COA. It is recommended to users to validate the medium for any specific microorganism other than mentioned in the COA based on the user's unique requirement.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance
Cream to yellow homogeneous free flowing powder

Gelling
Firm, comparable with 1.5% Agar gel

Colour and Clarity of prepared medium
Light yellow coloured clear to slightly opalescent gel forms in Petri plates

Reaction
Reaction of 2.8% w/v aqueous solution at 25°C. pH : 7.4±0.2

pH
7.20-7.60

Cultural Response
Cultural characteristics observed after an incubation at 35-37°C for 18-48 hours.

Organism	Inoculum (CFU)	Growth	Recovery
Escherichia coli ATCC 25922 (00013*)	50-100	good-luxuriant	>=70%
Pseudomonas aeruginosa ATCC 27853 (00025*)	50-100	good-luxuriant	>=70%
Salmonella Typhi ATCC 6539	50-100	good-luxuriant	>=70%
Staphylococcus aureus subsp. aureus ATCC 25923 (00034*)	50-100	good-luxuriant	>=70%
Streptococcus pyogenes ATCC 19615	50-100	good-luxuriant	>=70%
Salmonella Enteritidis ATCC 13076 (00030*)	50-100	good-luxuriant	>=70%
Salmonella Typhimurium ATCC 14028 (00031*)	50-100	good-luxuriant	>=70%
Yersinia enterocolitica ATCC 9610 (00038*)	50-100	good-luxuriant	>=70%
Yersinia enterocolitica ATCC 23715 (00160*)	50-100	good-luxuriant	>=70%

Key : (*) Corresponding WDCM numbers.

Storage and Shelf Life

Store between 10-30°C in a tightly closed container and the prepared medium at 20-30°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition. Seal the container tightly after use. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (5,6).

Reference

1.Lapage S., Shelton J. and Mitchell T., 1970, Methods in Microbiology', Norris J. and Ribbons D., (Eds.), Vol. 3A, Academic Press, London.
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3.American Public Health Association, Standard Methods for the Examination of Dairy Products, 1978, 14th Ed., Washington D.C.
4.Salfinger Y., and Tortorello M.L., 2015, Compendium of Methods for the Microbiological Examination of Foods, 5th Ed., American Public Health Association, Washington, D.C.
5.Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
6.Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.
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8.Baird R.B., Eaton A.D., and Rice E.W., (Eds.), 2015, Standard Methods for the Examination of Water and Wastewater, 23rd ed., APHA, Washington, D.C.

Revision : 06/2022

HiMedia Laboratories Pvt. Limited,
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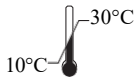
IVD ***In vitro* diagnostic medical device**



Storage temperature

EC REP CEpartner4U, Esdoornlaan 13,
3951DB Maarn, NL
www.cepartner4u.eu

CE Marking

Do not use if package is damaged

Disclaimer :

User must ensure suitability of the product(s) in their application prior to use. Products conform solely to the information contained in this and other related HiMedia™ publications. The information contained in this publication is based on our research and development work and is to the best of our knowledge true and accurate. HiMedia™ Laboratories Pvt Ltd reserves the right to make changes to specifications and information related to the products at any time. Products are not intended for human or animal or therapeutic use but for laboratory,diagnostic, research or further manufacturing use only, unless otherwise specified. Statements contained herein should not be considered as a warranty of any kind, expressed or implied, and no liability is accepted for infringement of any patents.

SELECTROL

Discurile cu tulpini de referință Selectrol® sunt destinate utilizării în laboratoarele de microbiologie în scop de control a metodelor de testare. Fiind **derivați de primă generație** trasabili la tulpinile de tip național renumite, discurile Selectrol sunt bine primite în laboratoare acreditate pentru producția culturilor de lucru.

Discurile Selectrol sunt un produs microbial congelat fabricat exclusiv din culturi ale NCTC (Colecția Națională a Tipurilor de Culturi) și NCPF (Colecția Națională a Fungilor Patogeni). Viabilitatea microorganismelor este stabilizată prin incorporarea cărbunelui activat în disc și a silica gelului din flacon.

PRECAUȚIUNI ȘI PĂSTRARE

- Discurile Selectrol conțin microorganisme patogene și trebuie folosite doar în laboratoarele special echipate pentru manipularea acestora de către microbiologi calificați.
- Păstrați la temperatura indicată pe flacon. Pierdere de viabilitate poate apărea la păstrarea necorespunzătoare pe timp îndelungat (temperaturi mai mari decât cea indicată pe flacon).
- Lăsați flaconul să ajungă la temperatura camerei și închideți flaconul imediat după îndepărtarea dusculuI/discurilor. Umiditatea din aer ar putea duce la reducerea numărului de microorganisme de pe disc.
- Nu folosiți produsul după expirarea termenului de valabilitate sau dacă culoarea silica gelului din flacon își schimbă culoarea. Aceștia sunt indicatori ai pierderii viabilității și modificărilor în antibiotice și reacții chimice.

Îndepărtarea unui disc din flacon: aceasta se efectuează ușor cu forceps steril sau ansă sterilă de 10 µl.

Utilizarea cu medii solide: Plasați discul pe mediul solid corespunzător.Lăsați discul să se înmoaie timp de 10-15 minute. Placa poate fi plasată în incubator pentru a grăbi procesul. Apoi împrăștiați discul pe suprafața mediului și incubați la condițiile optime/corespunzătoare.

Utilizarea cu medii lichide: Plasați discul în 1-10ml de bulion corespunzător. Amestecați ușor bulionul pentru a dilua discul, evitând formarea aerosolilor. Incubați la condițiile optime/corespunzătoare. Pentru uz rapid, folosiți metode alternative precum dizolvarea discului și incubarea bulionului la 35-37°C timp de o oră apoi să-l folosiți imediat. Puteți face careva experiențe proprii pentru a descoperi metoda de diluție corespunzătoare Dvs.

Limitări: Sub-cultura repetată poate cauza modificare a caracteristicilor tulpinii. Este recomandată folosirea discurilor prospete pentru fiecare set de testări.

În laboratoarele de acreditare, discurilor pot fi folosite doar pentru producerea stocurilor de lucru. Sub-cultura de apoi va invalida uzul lor.

RUPERE, SCURGERI ȘI ELIMINARE

1. Toate discurile expuse, pachetele contaminate și sticlele stricate trebuie plasate într-un container corespunzător și incinerate sau autoclavate la 121°C timp de 30 minute.
2. Flacoanele întregi pot fi îndepărtate cu forceps, spălate cu soluție bactericidă corespunzătoare, uscate și utilizate ulterior.
3. Toate suprafețele contaminate trebuie dezinfectate cu soluție bactericidă corespunzătoare.

accuracy and quality as a science

tcs biosciences

Selectrol® Technical Guide

Selectrol® : Manufactured under licence from Public Health England Culture Collections

SELECTROL® - FREEZE-DRIED ORGANISMS IN A DISC

Quality control of microbial characterisation tests, culture media and antimicrobial susceptibility determinations is best accomplished by the use of microorganisms with well-documented and stable phenotypic and genotypic characteristics.

Bacterial and fungal strains have been selected and recommended by expert bodies, such as EUCAST, CLSI and the European Pharmacopoeia, on the basis of their suitability for monitoring test performance and ensuring the validity of results for testing used in clinical, food, pharmaceutical, water and veterinary laboratories.

Products derived from the cultures in the collections should be manufactured using the minimum number of sub-cultures, to minimise the possibility of alterations to the phenotype due to mutations. See also page 14.

Selectrol strains are manufactured exclusively from Public Health England Culture Collections (NCTC® and NCPF®) and are first generation subcultures, unlike many products on the market which are 2nd, 3rd or 4th generation subcultures. They are preserved by long-term storage as freeze-dried cells in order to minimise any alterations to the phenotype caused by mutations.

Passages

A Selectrol® disc is a first generation subculture from a **master culture** sourced from Public Health England Culture Collections, and is designed to be used to obtain **working stock** cultures for use in testing. It is generally accepted that no more than a total of five passages should be made from the **master culture**, in order to avoid genetic drift and mutant selection. Therefore, no more than four passages (fresh cultures) from the **working stock** should be made.

Shelf life

For most strains, Selectrol® discs are guaranteed to contain at least 10^6 organisms at the time of purchase; this number is sufficient to ensure that when the discs are used and stored as directed there will be viable organisms cultivable up to the stated end of the shelf life, which is usually 9 months from the time the vial is first opened.

Quality Control

Selectrol® batches are tested in our UKAS accredited testing laboratory number 2496. A test report for each batch of Selectrol® can be accessed via our website. The reporting of Selectrol® test results via the website comes under our UKAS accreditation.

Selectrol® cultures are rigorously tested to confirm identity, to confirm the possession of essential phenotypic characteristics and to exclude contamination with other organisms. Photographic evidence of the test results is retained for each batch, along with retained appropriately stored samples.

Glossary

AMRHAI: Antimicrobial Resistance and Healthcare Associated Infections reference unit

ATCC®: American Type Culture Collection. ATCC® strains are listed for reference only. ATCC® is a registered trademark of the American Type Culture Collection.

BSAC: British Society for Antimicrobial Chemotherapy - Now superseded by EUCAST

CLSI: Clinical Laboratory Standards Institute. (USA)

CPE: Carbapenemase Producing Enterobacteriaceae

CRE: Carbapenem Resistant Enterobacteriaceae

Culture collection: Cultures of fully characterised organisms maintained in such a way as to minimise sub-culturing. See page 14.

ESBL: Extended Spectrum Beta-Lactamase-producing organism.

EUCAST: European Committee on Antimicrobial Susceptibility Testing.

First generation derivative: A single passage from a master culture, for example a Selectrol® disc.

Master culture: Culture derived from a reference culture vial.

NCPF®: National Collection of Pathogenic Fungi. NCPF® is a registered trademark of Public Health England.

NCTC®: National Collection of Type Cultures. NCTC® is a registered trademark of Public Health England.

Passage: An equivalent term for a subculture.

PHE: Public Health England.

Reference cultures: Quality control strains selected on the basis of their phenotypic biochemical and antimicrobial susceptibility characteristics to be used as controls in microbiological testing. These are obtained as freeze-dried vials from culture collections.

Stock culture: Cultures derived from a Selectrol® disc, which can be stored for up to a week, usually on agar slants.

Working cultures: Stock cultures further sub-cultured to provide 18-24 hour growth for use in testing.

WDCM: World Data Centre for Microorganisms

WFCC: World Federation for Culture Collections

SIGNIFICANT PROPERTIES AND USES OF SELECTROL® ORGANISMS

Aspergillus brasiliensis (formerly *Aspergillus niger*)**:**

MM94 – NCPF® 2275 / ATCC® 16404 / WDCM 00053 – used in pharmaceutical industry for testing media and preservatives. Colonies are initially white or yellowish and on the reverse greyish or greenish-yellow. Sporing heads on the colony surface are initially pale, becoming dark brown to black. Sporulation may be inhibited in sealed plates.

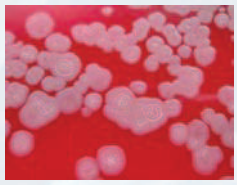
***Bacillus cereus*:**

MM21 – NCTC® 10320 / ATCC® 9634 / WDCM 00001 (recently renamed *Bacillus toyonensis*) – ISO 11133 recommended media and ID test control organism.

MM86 – NCTC® 7464 / ATCC® 10876 – PHE recommended media and ID test control organism.

Bacillus subtilis *(Bacillus subtilis* subsp. *spizizenii)***:**

MM29 – NCTC® 10400 / ATCC® 6633 / WDCM 00003 – used in antibiotic assays (fully sensitive), PHE recommended media and ID test control organism.



***Bacteroides fragilis*:**

MM44 – NCTC® 9343 / ATCC® 25285 – type strain, PHE recommended strain for media and sensitivity test control.

Campylobacter jejuni *(Campylobacter jejuni* subsp. *jejuni)***:**

MM82 – NCTC® 11322 / ATCC® 29428 / WDCM 00156 – PHE recommended strain for media control.

MM36 – NCTC® 11351 / ATCC® 33560 – EUCAST recommended strain for susceptibility testing.

***Candida albicans*:**

MM28 – NCPF® 3255 / ATCC® 2091 / WDCM 00055 – sensitivity control / industrial use.

MM42 – NCPF® 3179 / ATCC® 10231 / WDCM 00054 – pharmaceutical / media testing / PHE recommended strain for media control.

CRE ≡ 'Carbapenem Resistant Enterobacteriaceae' / CPE ≡ 'Carbapenemase Producing Enterobacteriaceae'

There are 5 carbapenemases which are currently a significant problem in the UK – KPC, OXA-48, IMP, NDM and VIM – and PHE recommend that all clinically-significant Gram-negative bacteria should be routinely screened for carbapenemase production, using a recommended carbapenem[2] such as ertapenem or meropenem. Resistant isolates may be investigated further to determine which resistance mechanism is involved using the Modified Hodge Test, MALDI-TOF, PCR or a reference laboratory.

MM55 *Klebsiella pneumoniae* – NCTC® 13440 – produces a Class B VIM-1 Carbapenemase.

MM56 *Klebsiella pneumoniae* – NCTC® 13443 – produces a Class B NDM-1 Carbapenemase.

MM58 *Klebsiella pneumoniae* – NCTC® 13438 – produces a Class A KPC-3 Carbapenemase.

MM59 *Klebsiella pneumoniae* – NCTC® 13442 – produces a Class D OXA-48 Carbapenemase.

MM57 *Escherichia coli* – NCTC® 13476 – produces a Class B IMP Carbapenemase.

MM33 *Escherichia coli* – NCTC® 10418 / ATCC® 10536 – recommended by PHE as a negative control for CRE testing.

***Citrobacter freundii*:**

MM27 – NCTC® 9750 / ATCC® 8090 – type strain.

***Clostridium perfringens*:**

MM45 – NCTC® 8237 / ATCC® 13124 / WDCM 00007 – type strain. PHE recommended strain for food testing (Tryptose Sulphite Cycloserine agar – lactose and gelatin positive) and sensitivity test control. *Clostridium perfringens* is listed in Schedule 5 of the Anti-terrorism, Crime and Security Act 2001, and should be securely stored in accordance with the guidelines of the Act. However, MM45 is a type A strain, which does not produce the lethal epsilon toxin of potential interest to bioterrorists.

***Clostridium sporogenes*:**

MM31 – NCTC® 532 / ATCC® 19404 / WDCM 00008 – used for media control. PHE recommended strain for media QC (lactose gelatin medium for ID of *C. perfringens* lactose negative and gelatin positive).

***Enterobacter aerogenes*:**

MM26 – NCTC® 10006 / ATCC® 13048 / WDCM 00175 – type strain; used in water, paint and adhesive testing.

***Enterobacter cloacae*:**

MM01 – NCTC® 13380 / ATCC® 23355 / WDCM 00082 – disinfectant control, media testing.

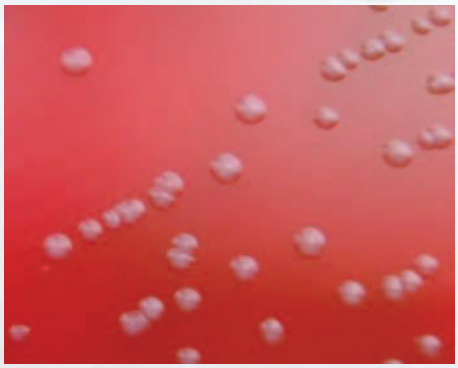
MM51– NCTC® 13406 – PHE recommended strain for QC of AmpC (de-repressed) detection.

***Enterococcus faecalis*:**

MM52 – NCTC® 13379 / ATCC® 51299 / WDCM 00085 – is vancomycin resistant (low-level VanB mediated) and also shows high-level resistance to aminoglycosides. It is used to confirm methodologies used to detect these resistances are working correctly. Lancefield group D.

MM17 – NCTC® 775 / ATCC® 19433 / WDCM 00009 – used in water industry and QC. PHE recommended strain for media control. Fully sensitive. Lancefield group D.

MM18 – NCTC® 12697 / ATCC® 29212 / WDCM 00087 – is fully sensitive to vancomycin and gentamicin. PHE recommended positive control strain for aesculin test. CLSI, EUCAST recommended media control for sulpha / trimethoprim testing and general susceptibility testing control. Lancefield group D.

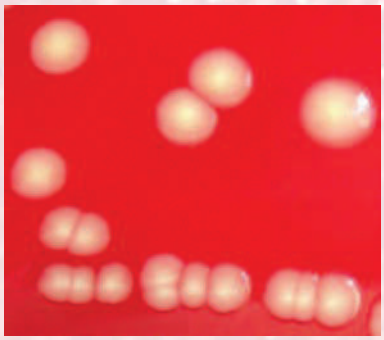


***Enterococcus hirae*:**

MM35 – NCTC® 13383 / ATCC® 10541 / WDCM 00011 – disinfectant control. Used in microbiological assays. Colonies are alpha-haemolytic on sheep blood agar.

***Escherichia coli* strains:**

MM02 – NCTC® 12241 / ATCC® 25922 / WDCM 00013 – EUCAST, CLSI, PHE recommended control strain for susceptibility testing (fully sensitive). Exhibits 2 colony types – the most prevalent type is slightly irregular, smooth and translucent. The secondary type appears more opaque. It is preferable to maintain cultures on agar as passage in broth can result in a change in MIC levels.



MM57 – NCTC® 13476 – CRE testing control; produces a Class B IMP Carbapenemase.

MM33 – NCTC® 10418 / ATCC® 10536 – (PHE recommended alternative to NCTC 12241) fully sensitive control strain. PHE recommended positive control for indole test, ONPG test, negative control for oxidase test, PHE recommended negative control for CRE and ESBL testing.

MM24 – NCTC® 11954 / ATCC® 35218 – beta-lactamase positive strain. CLSI recommended strain for susceptibility testing ONLY for penicillin / beta-lactamase inhibitor combinations. Sensitive to amoxicillin / clavulanic acid.

MM75 – NCTC® 9001 / ATCC® 11775 / WDCM 00090 – used in water / chemical industry. PHE recommended strain for media QC.

MM93 – NCTC® 12900 / ATCC® 700728 / WDCM 00014 – O157 strain (non-toxigenic). PHE recommended strain for media QC.

MM63 – NCTC® 11560 – beta-lactamase positive strain.

MM38 – NCTC® 12923 / ATCC® 8739 / WDCM 00012 – used in pharmaceutical / water industry. Three colony types: A) Entire, glistening, smooth and translucent. B) Entire, glistening smooth and opaque. C) Irregular, rough and translucent. The rough colonies appear after 48 hours incubation.

MM34 – NCTC® 13846 – Possesses the plasmid-mediated mcr-1 colistin resistance mechanism gene and is recommended by PHE and EUCAST as a control for tests to detect this increasingly prevalent resistance, in conjunction with NCTC® 12241 / ATCC® 25922 (Selectrol strain MM02) as a negative control.

***Haemophilus influenzae* strains:**

MM81 - NCTC® 12699 / ATCC® 49247 – is a 'BLNAR' strain – (beta-lactamase non-producing ampicillin / amoxycillin resistant). These strains are important clinically because the susceptibility results obtained using conventional testing procedures maybe misleading in the case cephalosporins. PHE, CLSI recommended QC strain for susceptibility testing media.

MM98 – NCTC® 11931 – a fully sensitive strain. PHE recommended strain for porphyrin synthesis test, chocolate agar control.

MM100 – NCTC® 8468 / ATCC® 9334 / CCUG 23946 – another fully sensitive strain, which reportedly gives results which are easier to interpret when Mueller-Hinton medium is used in preference to Iso-Sensitest medium. MIC for amoxycillin is 0.5 mg/l.

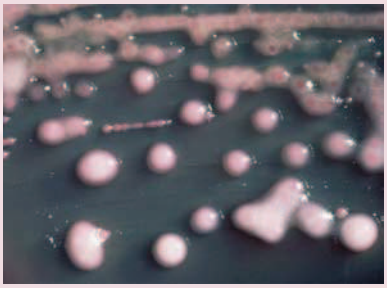
MM37 – NCTC® 12975 / ATCC® 49766 – recommended by EUCAST.

***Klebsiella* strains:**

MM04 *Klebsiella pneumoniae* – NCTC® 9633 / ATCC® 13883 / WDCM 00097 – type strain. Two colony types may be seen. The predominant type is entire and opaque. The secondary type is slightly smaller and translucent.

MM83 *Klebsiella pneumoniae* – NCTC® 13368 / ATCC® 700603 – ESBL-producing strain used as control for ESBL testing. There are two colony types.

MM55 *Klebsiella pneumoniae* – NCTC® 13440 – CRE testing control; produces a Class B VIM-1 Carbapenemase.



MM56 *Klebsiella pneumoniae* – NCTC® 13443 – CRE testing control; produces a Class B NDM-1 Carbapenemase.

MM58 *Klebsiella pneumoniae* – NCTC® 13438 – CRE testing control; produces a Class A KPC-3 Carbapenemase.

MM59 *Klebsiella pneumoniae* – NCTC® 13442 – CRE testing control; produces a Class D OXA-48 Carbapenemase.

MM88 *Klebsiella aerogenes (Raoultella planticola)* – NCTC® 9528 – used in water / pharmaceutical industry. PHE recommended negative control for Tryptone Bile X-Glucuronide agar and Yeast Extract agar.

***Lactobacillus brevis*:**

MM76 – NCTC® 13386 / ATCC® 8287 – used in food industry.

***Legionella pneumophila* serogroup 1:**

MM08 – NCTC® 11192 / ATCC® 33152 / WDCM 00107 – derived from strain isolated from first recognised outbreak of legionellosis in Philadelphia at the Legionnaires' Convention 1976

***Listeria innocua*:**

MM92 – NCTC® 11288 / ATCC® 33090 / WDCM 00017 – type strain. Non-pathogenic.

***Listeria monocytogenes*:**

MM87 – NCTC® 11994 / WDCM 00019 – type strain, PHE recommended positive control strain for Listeria detection in food. Serotype 4b, most common serovar isolated from human infections.

MM48 – NCTC® 7973 / ATCC® 35152 / WDCM 00109 – produces 2 phenotypes, one is beta-haemolytic and virulent, the other non-haemolytic and non-virulent. Serovar 1/2a.

MM77 – NCTC® 13372 / ATCC® 7644 – used in food microbiology Q.C. Colonies exhibit beta-haemolysis on sheep blood agar.

***Neisseria gonorrhoeae*:**

MM96 – NCTC® 12700 / ATCC® 49226 – has low-level, but clinically relevant, resistance to penicillin – MIC of penicillin is 0.5 mg/l. PHE recommended control for susceptibility testing – methodology assesses the ability of testing to detect resistance rather than sensitivity; this strain has low-level, but clinically relevant, resistance to penicillin – MIC of penicillin is 0.5 mg/l. Some variation in size and texture of colonies may be observed. Increased CO_2 is helpful in growth.

MM05 – NCTC® 8375 / ATCC® 19424 – is fully sensitive – MIC of penicillin is 0.06 mg/l. PHE recommended strain for media QC.

***Proteus mirabilis*:**

MM43 – NCTC® 13376 / ATCC® 14153 – pharmaceutical / disinfectant / media control.

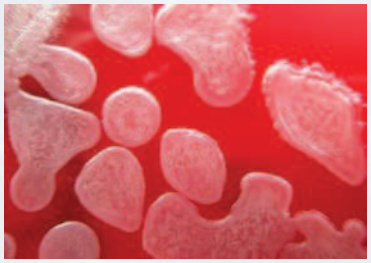
MM68 – NCTC® 10975 – media control. PHE recommended control for motility test.

***Proteus vulgaris*:**

MM09 – NCTC® 4175 / ATCC® 13315 – was the type strain, but is atypical and has been recognised as a separate species – *Proteus hauseri* – it is used for media control. Colonies are glistening with spreading edges.

***Pseudomonas aeruginosa* strains:**

MM10 – NCTC® 12903 / ATCC® 27853 / WDCM 00025 – is fully sensitive to anti-pseudomonal antibiotics (EUCAST susceptibility test control). 2 colony types may be observed: A) predominantly flat, spreading edges and rough surface; B) small and compact. Produces both fluorescein and pyocyanin pigments.



MM65 – NCTC® 10662 / ATCC® 25668 / WDCM 00114 – is fully sensitive. PHE recommended control strain for media control

MM40 – NCTC® 12924 / ATCC® 9027 / WDCM 00026 – used in water industry / disinfectant testing. Colonies on agar plates are entire, glistening and mucoid with a grainy surface. This strain also produces both fluorescein and pyocyanin pigments.

MM41 – NCTC® 13359 / ATCC® 15442 – used in water industry / disinfectant testing. May produce up to 3 different colony types. Pyocyanin is not produced.

***Rhodococcus equi*:**

MM97 – NCTC® 1621 / ATCC® 6939 / WDCM 00028 – type strain.

***Saccharomyces cerevisiae*:**

MM73 – NCPF® 3178 – PHE recommended strain for food testing and enumeration of yeasts and moulds.

MM50 — NCTC® 10716 / WDCM 00058 – used for QC of culture media and for antifungal susceptibility testing.

***Salmonella serotypes*:**

MM11 *Salmonella* Typhimurium – NCTC® 12023 / ATCC® 14028 / WDCM 00031 – (1,4,5,12: i: 1,2) Used for media/test QC. This is a common serotype from animals and from human infections.

The strains listed below are unusual serotypes, used to avoid any chance of confusion with strains commonly found in animals, food, etc, and are used to control media and detection methods in the food industry:

MM89 *Salmonella* Poona – NCTC® 4840 – (13,22: z: 1,6) PHE recommended control strain for food testing.

MM84 *Salmonella* Nottingham – NCTC® 7832 – (16: d: e,n,z15) PHE recommended control for water testing.

***Serratia marcescens*:**

MM12 – NCTC® 13382 / ATCC® 8100 – used for disinfectant testing. PHE recommended negative control for indole test. Colonies are entire, glistening, smooth and translucent. Non-pigmented.

***Staphylococcus aureus*:**

(A) Fully sensitive:

MM85 – NCTC® 6571 / ATCC® 9144 / WDCM 00035 – historically used for susceptibility testing ('Oxford staph'), but largely superseded by MM13 as it has unusually low MIC's and so is unrepresentative of normal range of Staph aureus strains. Sensitive to penicillin and cefoxitin / methicillin / oxacillin. PHE recommended coagulase, DNAse and catalase positive control.

MM13 – NCTC® 12981 / ATCC® 25923 / WDCM 00034 – used in susceptibility and media testing/QC. Fully sensitive to all anti-staphylococcal antibiotics (including penicillin and methicillin / oxacillin). It is preferable to maintain cultures on agar as passage in broth can result in a change in MIC levels. Colonies are circular white to cream, convex to flat in elevation. After 48 hours incubation a few grey/translucent variants may be noted. Beta-haemolytic on sheep blood agar.

B) Penicillin resistant:

MM14 – NCTC® 12973 / ATCC® 29213 / WDCM 00131 – used for susceptibility testing, especially for automated methodology. EUCAST, CLSI strain. Sensitive to cefoxitin / methicillin / oxacillin. Penicillin resistant – weak beta-lactamase producer. Colonies are beta-haemolytic, and a golden-orange colour.

MM30 – NCTC® 7447 / ATCC® 6538P / WDCM 00033 – used for susceptibility testing/antibiotic assay, disinfectant testing. Cefoxitin / methicillin / oxacillin sensitive. Penicillin resistant. Colonies are weakly beta-haemolytic, coagulase positive and beta-lactamase negative.

(C) MRSA (cefoxitin / methicillin / oxacillin resistant):

MM91 – NCTC® 13373 / ATCC® 43300 / WDCM 00211 (MRSA) – Possesses mecA gene but is hetero-resistant, (so as few as one per thousand cells demonstrate the resistance) and consequently has low-level cefoxitin /oxacillin/methicillin resistance (4.0 mg/l MIC of oxacillin, 8.0 mg/l MIC of cefoxitin – methicillin sensitive strains have MIC of 0.12-0.5 for oxacillin and 1-4 for cefoxitin.); it is used to confirm testing procedures for methicillin resistance are working and provides a more stringent test than testing with an MRSA which shows homogeneous resistance and has a much higher MIC. This organism will have a zone of inhibition reduced in size compared to a fully cefoxitin / oxacillin / methicillin sensitive strain (such as MM13). CLSI recommended strain for MRSA testing. There are two colony types: 1) Beta-haemolytic with a slight yellow tint. 2) Non-haemolytic and white.

MM64 – NCTC® 12493 / WDCM 00212 (MRSA) – possesses mecA gene and shows homogeneous resistance with MIC of >64 for methicillin, which produces high-level cefoxitin / methicillin / oxacillin resistance. EUCAST recommended strain. Instances have been reported where loss of the mecA gene has occurred during storage.

D) Other:

MM46 – NCTC® 10788 / ATCC® 6538 / WDCM 00032 – used in pharmaceutical industry for testing disinfectants etc. Usually yellow pigmented colonies, or can produce a white colonial variant. Beta-haemolytic.

***Staphylococcus epidermidis*:**

MM15 – NCTC® 13360 / ATCC® 12228 / WDCM 00036 – used for media control / antibiotic assay. Colonies are small and beta-haemolytic.

***Streptococcus agalactiae*:** (Beta-haemolytic Streptococcus group B)

MM16 – NCTC® 8181 / ATCC® 13813 – type strain, used for QC. PHE recommended negative control for aesculin test.

Streptococcus pneumoniae strains:

MM95 – NCTC® 12977 / ATCC® 49619 – has low-level, but clinically relevant, resistance to penicillin – this organism is used to assess detection of resistance rather than sensitivity. PHE recommended positive control for bile solubility test. CLSI, EUCAST recommended control strain for susceptibility testing. Serotype 19F.

MM19 – NCTC® 12695 / ATCC® 6303 – is fully sensitive. Colonies are mucoid and alpha-haemolytic. A few colonies may have an irregular edge. Serotype 3.

***Streptococcus pyogenes*:**

MM20 – NCTC® 12696 / ATCC® 19615 – used for QC and media testing. Lancefield group A, beta-haemolytic.
PHE recommended blood agar control.

***Vibrio parahaemolyticus*:**

MM06 – NCTC® 10885 / WDCM 00185 – used for QC of media and ID testing. PHE recommended strain used mainly in the food industry.

***Yersinia enterocolitica*:**

MM80 – NCTC® 12982 / ATCC® 9610 / WDCM 00038 – type strain, used for media control. Serotype O:8, which is a pathogenic serotype, commonest in USA.

References:

1 European Committee on Antimicrobial Susceptibility Testing (EUCAST). Routine and Extended Internal Quality Control for MIC Determination and Disc Diffusion. Version 7.0 - 01.01.2017.

2 UK Standards for Microbiology Investigations. Example Reference Strains for Microbiology Investigations Test Procedures: Bacteriology—Test Procedures | TP 1 | Issue No. 2 | 05.01.2015. Public Health England (PHE).

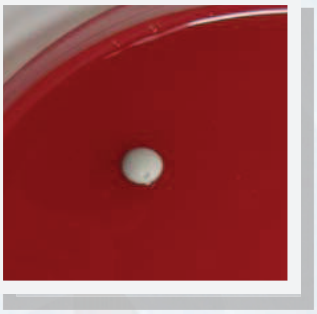
3 Performance Standards for Antimicrobial Disc Susceptibility Tests: Approved Standard—11th Edition. Clinical and Laboratory Standards Institute (CLSI).

How to use Selectrol®

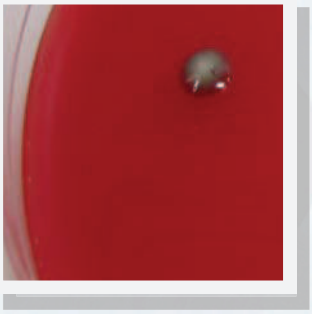
Always warm the vial to ambient temperature before opening.

Be sure to use non-selective culture media to revive the organisms.

For the more fastidious organisms, such as anaerobes, it is generally better to use agar rather than broth for revival.

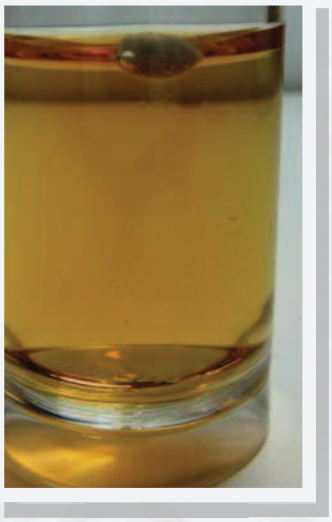


Place disc on suitable growth medium such as blood agar



Leave disc for a few minutes to liquefy, then spread plate and incubate to produce isolated colonies

Obtain a stock culture which can be used to prepare an inoculum for biochemical and antibiotic susceptibility tests



Place disc in a small volume of a suitable broth medium such as brain-heart infusion

Allow disc a few minutes to dissolve, then spread aliquot onto a plate of suitable growth medium

Out-of-specification results

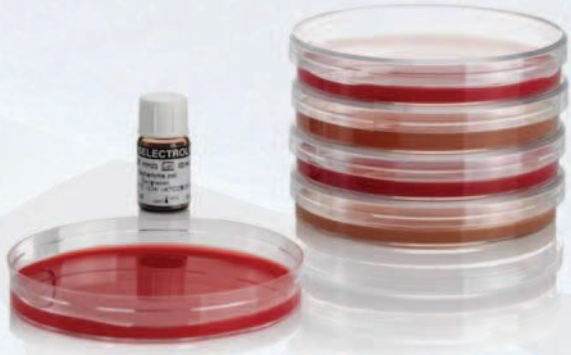
Laboratories use Selectrol® for Quality Control of culture media, biochemical identification tests and antimicrobial susceptibility testing. When a laboratory test result, an MIC or biochemical reaction, is unexpected or out-of-specification, the test should first be repeated to confirm it; an out-of-specification result is an indication that the testing procedure should be reviewed; it is not, in the first instance, a sign of a problem with the control organism.

If incorrect results are obtained on retesting, the explanation could be:

- The test procedure was not followed correctly – check standard operating procedures
- There is an instrumentation error – check calibration, mechanical functioning, etc
- There is a problem with the consumables – out of date, incorrect storage, etc
- The culture of the control organism has become contaminated

Technical Support

If no explanation for out-of-spec results can be found, but repeated tests still give unacceptable results, please contact TCS and / or your relevant reference laboratory or instrument manufacturer for advice. For example, contact AMRHAI at Colindale, London if MIC results are consistently outside the acceptable range. Please retain any remaining discs of organisms about which you have concerns so they can be returned to TCS and investigated alongside retained samples.



Preparing QC and Validation Spikes from Selectrol®

Preparing the spike

- Place a Selectrol® disc in Brain Heart Infusion (BHI) broth* or equivalent, and culture (typically for 18 hours) at the appropriate temperature for the organism (typically 37°C)
- Assume the count in the broth to be 10^8 organisms per ml ---------- (A)
- Mix and transfer 100 µl of (A) to 100 ml of saline or ¼ strength Ringer's solution -- (B)
- Mix and transfer 100 µl of (B) to 10 ml of saline or ¼ strength Ringer's solution --- (C)
- Mix and transfer 100 µl of (C) to your homogenised food sample.

Verifying the inoculum

- Pipette 5 x 10 µl drops from (C) onto each of two agar plates for Miles and Misra counts.

Using the assumptions and dilutions above:

- (A) contains 10^8 organisms per ml
- (B) contains 10^5 organisms per ml
- (C) contains 10^3 organisms per ml

If the Miles and Misra counts indicate that the required count was not achieved:

- If the count was too high by a factor of 10, reduce the volume transferred from (A) to (B) from 100 µl to 10 µl
- If the count was too low by a factor of 10, increase the volume transferred from (A) to (B) from 100 µl to 1 ml.

Keep a record of the correct dilutions for each organism type for future use. You will find that this method is very repeatable.

*Note: BHI broth will work for most of the Selectrol® organisms; however, for fastidious organisms an appropriate culture broth must be selected, e.g. Fastidious Anaerobe Broth for strictly anaerobic organisms.

Culture Collections

Cultures of microorganisms have been deposited and subsequently maintained in 589 collections in 68 countries, and many of the cultures are derived from the same original isolate; the history of each organism, its properties and names of the culture collections which hold it are detailed in the relevant catalogues and websites.

Some of the organisms have been selected and recommended by expert organisations to be supplied as controls for microbiological tests, and when the identical cultures are present in more than one collection they will have a specific designation for each, incorporating the abbreviation for the collection and a reference number.

For example:- *Staphylococcus aureus* NCTC 7447, widely recommended as a control for antimicrobial susceptibility testing, is held in 30 collections, and consequently the phenotypically and genotypically identical organism has 30 different references, such as ATCC 6538P, CIP 53.156, DSM 346 and so on.

In an effort to minimise potential confusion and help users find local sources of reference strains, the WFCC and the WDCM initiated a system that ascribes each recommended QC strain a reference number (WDCM 00001 onwards), cites all collections that contain it and provides contact details and each collection's unique reference. For example, the strain of *Staphylococcus aureus* NCTC 7447 (Selectrol® strain MM33) mentioned above is designated WDCM 00033.

Staphylococcus aureus WDCM 00033

AHU 1142; ATCC™ 6538P; BCRC 10451 ; BTCC 209P; BU 395; CCM 2022; CCTM 596; CCUG 1828; CECT 240; CIP 53.156; CN 3784; CNCTC Mau 28/58; DSM 346; FIRDI 451; IAM 1011; IAM 12082; IEM Mau 28/58; IFO 12732; IFO 3061; IID 671; IMET 10904; JCM 2151; LMG 8195; NCIMB 8625; NCTC 7447; NRRL B-313; OUT 8232; PCI 1209; PZH 8/54; RIMD 3109007; VNIIA 209P;

Products derived from the cultures in the collections should be manufactured using the minimum number of sub-cultures, to minimise the possibility of alterations to the phenotype due to mutations. Ideally, as in the case of **Selectrol®**, a single sub-culture only is used, so the **Selectrol®** product is a 'first generation derivative' of a culture supplied by NCTC, and will be identical with regard to its properties and suitability for use in QC applications to a culture of the particular organism obtained from any of the other WDCM listed culture collections.

Selectrol Strain Index

Strain Name	Designation	Code	WDCM
Aspergillus brasiliensis	NCPF® 2275 / ATCC® 16404	MM94	00053
Bacillus cereus	NCTC® 10320 / ATCC® 9634	MM21	00001
Bacillus cereus	NCTC® 7464 / ATCC® 10876	MM86	
Bacillus subtilis	NCTC® 10400 / ATCC® 6633	MM29	00003
Bacteroides fragilis	NCTC® 9343 / ATCC® 25285	MM44	
Campylobacter jejuni	NCTC® 11351 / ATCC® 33560	MM36	
Campylobacter jejuni	NCTC® 11322 / ATCC® 29428	MM82	00156
Candida albicans	NCPF® 3255 / ATCC® 2091	MM28	00055
Candida albicans	NCPF® 3179 / ATCC® 10231	MM42	00054
Citrobacter freundii	NCTC® 9750 / ATCC® 8090	MM27	
Clostridium perfringens	NCTC® 8237 / ATCC® 13124	MM45	00007
Clostridium sporogenes	NCTC® 532 / ATCC® 19404	MM31	00008
Enterobacter aerogenes	NCTC® 10006 / ATCC® 13048	MM26	00175
Enterobacter cloacae	NCTC® 13380 / ATCC® 23355	MM01	00082
Enterobacter cloacae	NCTC® 13406	MM51	
Enterococcus faecalis	NCTC® 775 / ATCC® 19433	MM17	00009
Enterococcus faecalis	NCTC® 12697 / ATCC® 29212	MM18	00087
Enterococcus faecalis	NCTC® 13379 / ATCC® 51299	MM52	00085
Enterococcus hirae	NCTC® 13383 /ATCC® 10541	MM35	00011
Escherichia coli	NCTC® 12241 / ATCC® 25922	MM02	00013
Escherichia coli	NCTC® 11954 / ATCC® 35218	MM24	
Escherichia coli	NCTC® 10418 / ATCC® 10536	MM33	
Escherichia coli	NCTC® 12923 / ATCC® 8739	MM38	00012
Escherichia coli	NCTC® 11560	MM63	
Escherichia coli	NCTC® 9001 / ATCC® 11775	MM75	00090
Escherichia coli CRE	NCTC® 13476	MM57	
Escherichia coli (mcr-1)	NCTC® 13846	MM34	
Escherichia coli O157 (non-toxigenic)	NCTC® 12900 / ATCC® 700728	MM93	00014
Haemophilus influenzae	NCTC® 8468 / ATCC® 9334	MM100	
Haemophilus influenzae	NCTC® 12975 / ATCC® 49766	MM37	
Haemophilus influenzae	NCTC® 12699 / ATCC® 49247	MM81	
Haemophilus influenzae	NCTC® 11931	MM98	
Klebsiella aerogenes	NCTC® 9528	MM88	
Klebsiella pneumoniae	NCTC® 9633 / ATCC® 13883	MM04	00097
Klebsiella pneumoniae	NCTC® 13368 / ATCC® 700603	MM83	
Klebsiella pneumoniae CRE	NCTC® 13440	MM55	
Klebsiella pneumoniae CRE	NCTC® 13443	MM56	
Klebsiella pneumoniae CRE	NCTC® 13438	MM58	

Selectrol Strain Index

Strain Name	Designation	Code	WDCM
Klebsiella pneumoniae CRE	NCTC® 13442	MM59	
Lactobacillus brevis	NCTC® 13386 / ATCC® 8287	MM76	
Legionella pneumophila serogroup 1	NCTC® 11192 / ATCC® 33152	MM08	00107
Listeria innocua	NCTC® 11288 / ATCC® 33090	MM92	00017
Listeria monocytogenes	NCTC® 7973 / ATCC® 35152	MM48	00109
Listeria monocytogenes	NCTC® 13372 ATCC® 7644	MM77	
Listeria monocytogenes	NCTC® 11994	MM87	00019
Neisseria gonorrhoeae	NCTC® 8375 / ATCC® 19424	MM05	
Neisseria gonorrhoeae	NCTC® 12700 / ATCC® 49226	MM96	
Proteus mirabilis	NCTC® 13376 / ATCC® 14153	MM43	
Proteus mirabilis	NCTC® 10975	MM68	
Proteus vulgaris	NCTC® 4175 / ATCC® 13315	MM09	
Pseudomonas aeruginosa	NCTC® 12903 / ATCC® 27853	MM10	00025
Pseudomonas aeruginosa	NCTC® 12924 / ATCC® 9027	MM40	00026
Pseudomonas aeruginosa	NCTC® 13359 / ATCC® 15442	MM41	
Pseudomonas aeruginosa	NCTC® 10662 / ATCC® 25668	MM65	00114
Rhodococcus equi	NCTC® 1621 / ATCC® 6939	MM97	00028
Saccharomyces cerevisiae	NCTC® 10716/ ATCC® 9763	MM50	00058
Saccharomyces cerevisiae	NCPF® 3178	MM73	
Salmonella Nottingham	NCTC® 7832	MM84	
Salmonella Poona	NCTC® 4840	MM89	
Salmonella Typhimurium	NCTC® 12023/ ATCC® 14028	MM11	00031
Serratia marcescens	NCTC® 13382 / ATCC® 8100	MM12	
Staphylococcus aureus	NCTC®12981 / ATCC® 25923	MM13	00034
Staphylococcus aureus	NCTC® 12973 / ATCC® 29213	MM14	00131
Staphylococcus aureus	NCTC® 7447 / ATCC® 6538P	MM30	00033
Staphylococcus aureus	NCTC® 10788 / ATCC® 6538	MM46	00032
Staphylococcus aureus	NCTC® 6571 / ATCC® 9144	MM85	00035
Staphylococcus aureus (MRSA)	NCTC® 12493	MM64	00212
Staphylococcus aureus (MRSA)	NCTC® 13373 / ATCC® 43300	MM91	00211
Staphylococcus epidermidis	NCTC® 13360 / ATCC® 12228	MM15	00036
Streptococcus agalactiae	NCTC® 8181 / ATCC® 13813	MM16	
Streptococcus pneumoniae	NCTC® 12695 /ATCC® 6303	MM19	
Streptococcus pneumoniae	NCTC® 12977 /ATCC® 49619	MM95	
Streptococcus pyogenes	NCTC® 12696 /ATCC® 19615	MM20	
Vibrio parahaemolyticus	NCTC® 10885	MM06	00185
Yersinia enterocolitica	NCTC® 12982 / ATCC® 9610	MM80	00038

Selectrol Strains Listed by WDCM Number

WDCM	Strain Name	Designation	Code
00001	*Bacillus cereus*	NCTC® 10320 / ATCC® 9634	MM21
00003	*Bacillus subtilis*	NCTC® 10400 / ATCC® 6633	MM29
00007	*Clostridium perfringens*	NCTC® 8237 / ATCC® 13124	MM45
00008	*Clostridium sporogenes*	NCTC® 532 / ATCC® 19404	MM31
00009	*Enterococcus faecalis*	NCTC® 775 / ATCC® 19433	MM17
00011	*Enterococcus hirae*	NCTC® 13383 /ATCC® 10541	MM35
00012	*Escherichia coli*	NCTC® 12923 / ATCC® 8739	MM38
00013	*Escherichia coli*	NCTC® 12241 / ATCC® 25922	MM02
00014	*Escherichia coli* O157 (non-toxigenic)	NCTC® 12900 / ATCC® 700728	MM93
00017	*Listeria innocua*	NCTC® 11288 / ATCC® 33090	MM92
00019	*Listeria monocytogenes*	NCTC® 11994	MM87
00025	*Pseudomonas aeruginosa*	NCTC® 12903 / ATCC® 27853	MM10
00026	*Pseudomonas aeruginosa*	NCTC® 12924 / ATCC® 9027	MM40
00028	*Rhodococcus equi*	NCTC® 1621 / ATCC® 6939	MM97
00031	*Salmonella* Typhimurium	NCTC® 12023/ ATCC® 14028	MM11
00032	*Staphylococcus aureus*	NCTC® 10788 / ATCC® 6538	MM46
00033	*Staphylococcus aureus*	NCTC® 7447 / ATCC® 6538P	MM30
00034	*Staphylococcus aureus*	NCTC® 12981 / ATCC® 25923	MM13
00035	*Staphylococcus aureus*	NCTC® 6571 / ATCC® 9144	MM85
00036	*Staphylococcus epidermidis*	NCTC® 13360 / ATCC® 12228	MM15
00038	*Yersinia enterocolitica*	NCTC® 12982 / ATCC® 9610	MM80
00053	*Aspergillus brasiliensis*	NCPF® 2275 / ATCC® 16404	MM94
00054	*Candida albicans*	NCPF® 3179 / ATCC® 10231	MM42
00055	*Candida albicans*	NCPF® 3255 / ATCC® 2091	MM28
00058	*Saccharomyces cerevisiae*	NCTC® 10716/ ATCC® 9763	MM50
00082	*Enterobacter cloacae*	NCTC® 13380 / ATCC® 23355	MM01
00085	*Enterococcus faecalis*	NCTC® 13379 / ATCC® 51299	MM52
00087	*Enterococcus faecalis*	NCTC® 12697 / ATCC® 29212	MM18
00090	*Escherichia coli*	NCTC® 9001 / ATCC® 11775	MM75
00097	*Klebsiella pneumoniae*	NCTC® 9633 / ATCC® 13883	MM04
00107	*Legionella pneumophila* serogroup 1	NCTC® 11192 / ATCC® 33152	MM08
00109	*Listeria monocytogenes*	NCTC® 7973 / ATCC® 35152	MM48
00114	*Pseudomonas aeruginosa*	NCTC® 10662 / ATCC® 25668	MM65
00131	*Staphylococcus aureus*	NCTC® 12973 / ATCC® 29213	MM14
00156	*Campylobacter jejuni*	NCTC® 11322 / ATCC® 29428	MM82
00175	*Enterobacter aerogenes*	NCTC® 10006 / ATCC® 13048	MM26
00185	*Vibrio parahaemolyticus*	NCTC® 10885	MM06
00211	*Staphylococcus aureus* (MRSA)	NCTC® 13373 / ATCC® 43300	MM91
00212	*Staphylococcus aureus* (MRSA)	NCTC® 12493	MM64

Notes

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экспертизы средств
медицинского применения

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ПАСПОРТ
ФАРМАКОПЕЙНЫЙ СТАНДАРТНЫЙ ОБРАЗЕЦ ГОСУДАРСТВЕННОЙ ФАРМАКОПЕИ РОССИЙСКОЙ ФЕДЕРАЦИИ
(отраслевой)

СТАНДАРТНЫЙ ОБРАЗЕЦ СОДЕРЖАНИЯ АНТИАЛЬФАСТАФИЛОЛИЗИНА

ФСО 3.1.00342 (ОСО 42–28–342)

СЕРИЯ: 041-110722

1. НАЗНАЧЕНИЕ: фармакопейный стандартный образец (ФСО) предназначен для определения антиальфастафилолизина в сывороточных препаратах крови человека и животных, а также для определения лимита гемолитического действия (Lh) стафилококкового токсина.

2. АТТЕСТОВАННАЯ ХАРАКТЕРИСТИКА: содержание антиальфастафилолизина 21 МЕ/мл, расширенная неопределенность: ±1 МЕ/мл (коэффициент охвата 2, уровень доверия 95%).

3. ОПИСАНИЕ, ДОПОЛНИТЕЛЬНЫЕ СВЕДЕНИЯ: ФСО представляет собой очищенную концентрированную лиофилизированную сыворотку лошади, иммунизированной стафилококковым анатоксином, содержащую антитела к альфастафилолизину. Содержание антиальфастафилолизина определено при сравнении с Международным стандартным образцом - International Standard for Staphylococcus Alpha Antitoxin Equine NIBSC в реакции нейтрализации гемолитических свойств стафилококкового альфатоксина специфическими антителами.

4. ПОРЯДОК ПРИМЕНЕНИЯ: в соответствии с ОФС.1.8.2.0008.15 ГФ РФ.

5. КОМПЛЕКТ ПОСТАВКИ: 1 флакон по 10 мл, паспорт на ФСО.

6. УСЛОВИЯ ХРАНЕНИЯ И ТРАНСПОРТИРОВАНИЯ: ФСО должен храниться при температуре от 2 до 8 °С в защищенном от света месте. Транспортирование всеми видами крытого транспорта при температуре не выше 8 °С в течение 5 суток.
Стабильность значений аттестованной характеристики в течение срока годности ФСО гарантируется при соблюдении условий транспортирования, хранения и порядка применения.

7. ТРЕБОВАНИЯ БЕЗОПАСНОСТИ: материал ФСО предназначен для лабораторных испытаний и не предназначен для введения людям.

8. ДАТА ВЫПУСКА: 11.07.2022 г.

9. СРОК ГОДНОСТИ: 11.01.2024 г.

Директор Центра экспертизы и контроля МИБП,
ФГБУ «НЦЭСМП» Минздрава России МП В.П. Бондарев

ФГБУ "НИЦЭМ им. Н.Ф. Гамалеи" Минздрава России
(Филиал "Медгамал" ФГБУ "НИЦЭМ им. Н.Ф. Гамалеи" Минздрава России)
123098 Москва, ул.Гамалеи, 18 тел. (499) 193-30-50, (499) 190-44-59, факс: (499) 190-66

ПАСПОРТ 1692

Набор реагентов для определения уровня антиальфастафилолизин сывороточных препаратах крови человека «Токсин стафилококков диагностическ

Серия № *76* Срок годности *до 06.2024*

Дата изготовления *06.2022*

Объем серии *88 ампул*

Анализ выполнен по ТУ 21.20.23-001-01894956-2018.

№ пп	Наименование показателей	Требования по НД	Результаты контроля ОКК
1	Описание	Прозрачная жидкость желтого цвета без посторонних видимых.	Прозрачная жидкость желтого цв без посторонних видимых.
2	Объем содержимого первичной упаковки	Не менее номинального.	Соответствует
3	Стерильность	Должен быть стерильным.	Стерилен
4	Аналитическая специфичность	Нейтрализация гемолитических свойств токсина только специфическими антителами (антиальфастафилолизином)	Соответствует
6	Аналитическая чувствительность	Предел обнаружения (Lh лимит гемолитического действия) стафилококкового токсина от 0,1 до 0,2 мл.	0.16
7	Производственный штамм	Для изготовления реагента «Токсин стафилококковый диагностический» используют штамм Staphylococcus aureus 015 из Государственной коллекции патогенных микроорганизмов, Россия (№ депозита 201064). Штамм хранится в ФГБУ «НЦЭСМП» Минздрава России и представляет собой грамположительные кокки правильной шаровидной формы диаметром 0,5 - 1,0 μкм, является коагулазоположительным и гемолизирует эритроциты кролика, при культивировании на жидких питательных средах образуется экзотоксин стафилококковый (син.: альфа-токсин, токсин стафилококковый, альфастафилолизин).	Соответствует
8	Упаковка	Упаковка - по 20 или 25 или 30 или 35 мл в ампулы ШП по ОСТ 64-2-485-85 или АШН с кольцом или точкой излома по ТУ 9462-001-83426370-2012 или аналогичные по свойствам объемом 20 или 25 или 30 или 35 мл из стекла марки НС-1, АБ-1, НС-3 по ГОСТ 19808-86 и HGB 1 гидролитического класса по ГОСТ 33202-2014. 1 ампулу упаковывают в металлический контейнер высотой 18,0 см/диаметром 4,0 см или высотой 18,0 см/ диаметром 6,0 см. В контейнер вкладывают инструкцию по применению и паспорт. Групповая упаковка и транспортная тара должны соответствовать ГОСТ 17768-90. Металлические контейнеры укладывают в ящик по ГОСТ 9142-2014 из гофрокартона по ГОСТ Р 52901-2007.	Соответствует.
9	Маркировка	На ампулу наклеивают этикетку из бумаги писчей ГОСТ 18510-87 или из бумаги этикеточной по ГОСТ 7625-86 с четко выполненной, несмываемой маркировкой с указанием: товарного знака изготовителя; сокращенного наименования Реагента («Токсин стафилококковый диагностический»); номера серии («Серия № XX»); даты изготовления («Дата изготовления XX.XXXX»); срока годности («Годен до XX.XXXX»); условий хранения; активности (Lh) токсина («Lh токсина X.XX»); объема Реагента («Объем XX мл»); знака «Биологический риск»; знака стерильности. Правый нижний угол этикетки дополнительно маркирован красным цветом. На контейнер наклеивают этикетку из бумаги писчей ГОСТ 18510-87 или из бумаги этикеточной по ГОСТ 7625-86 с указанием: наименования изготовителя и товарного знака изготовителя; - юридического адреса	Соответствует.

		сокращенного наименования Реагента; номера технических условий; номера серии («№ серии XX»); активности (Lh) токсина («Активность (Lh) X.XX мл»); даты изготовления («Дата изготовления XX.XXXX»); срока годности («Годен до XX.XXXX»); объема Реагента («Объем XX мл»); условий хранения и транспортирования; знаков «Биологический риск», «Осторожно! Обратитесь к инструкции по применению» штрихового кода; предупредительных надписей «Хранить в недоступном для детей месте», «Замораживание не допускается», «Для многократного использования»; Правый нижний угол этикетки дополнительно маркирован красным цветом. Контейнер опечатывают печатью ОБТК, используя пластилин разного цвета (ОСТ 6-15-1525-86).	
10	Срок годности	2 года	2 года
11	Транспортирование	Реагент транспортируют в соответствии с СП 3.3.2.3332-16 при темпера-туре от 2 °С до 8 °С. Замораживание не допускается.	Соответствует.
12	Хранение	Реагент хранят в соответствии с СП 3.3.2.3332-16 при температуре от 2 °С до 8 °С в сухом, защищенном от света месте. Реагент хранят в недоступном для детей месте. Замораживание не допускается.	Соответствует.

Заключение: препарат соответствует требованиям ТУ 21.20.23-001-01894956-2018.

"05" 07 2022 г. Зам. начальника ОКК _____ М. Ю. Черну

ФГБУ "НИЦЭМ им. Н.Ф. Гамалеи" Минздрава России
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ПАСПОРТ 849

Анатоксин стафилококковый очищенный адсорбированный

Регистрационное удостоверение Р N000649/01 от 28.07.2008 (Дата изменения 19.03.18)

Серия № *275*

Срок годности *до 11.21*

Дата изготовления *10.19*

Объем серии *600 упаковок*

Анализ выполнен по PN000649/01-280708, изм. № 1, 2, 3, 4, 5, 6.

№ п/п	Наименование показателей	Требования по НД	Результаты контроля ОБТК
1	Описание	Равномерная суспензия белого цвета с желтоватым оттенком, разделяющаяся при стоянии на прозрачную надосадочную жидкость и нежный рыхлый осадок, разбивается при встряхивании.	Равномерная суспензия белого цвета с желтоватым оттенком, осадок, образующийся при стоянии, полностью разбивается при встряхивании.
2	Подлинность	Должен вызывать образование антител к токсину стафилококковому.	Вызывает образование антител к токсину стафилококковому.
3	Номинальный объем	Не менее номинального.	1 мл
4	Герметизация	Ампулы должны быть герметичны	Ампулы герметичны.
5	pH	От 6,2 до 7,4	6.67
6	Дисперсность	От 0.6 до 1.4	1.37
7	Размер частиц	Должен свободно проходить в шприц через иглу № 0840.	Свободно проходит в шприц через иглу № 0840.
8	Время седиментационной устойчивости	После встряхивания не должен расслаиваться в течение 2 минут.	После встряхивания не расслаивается в течение 2 минут.
9	Стерильность	Должен быть стерильным	Стерилен
10	Токсичность	Должен быть нетоксичным	Нетоксичен
11	Специфическая безвредность	Должен быть безвредным	Безвреден
12	Специфическая активность	Не менее 3 МЕ/мл антиальфастафилолизина	13,3 МЕ/мл
13	Полнота сорбции	Сорбция стафилококкового анатоксина должна быть полной.	Сорбция полная.
14	Формальдегид	Не более 0,003 %	0.0005 %
16	Производственный штамм	Staphylococcus aureus 015, № депозита 201064 в коллекции ФГУН ГИСК им. Л.А.Тарасевича).	Staphylococcus aureus 015, № депозита 201064 в коллекции ФГУН ГИСК им. Л.А.Тарасевича).
17	Гель алюминия гидроксида	Алюминий от 0,9 до 1,3 мг/мл.	0.96 мг/мл
18	Мертиолят	От 80 до 120 мкг/мл.	89 мкг/мл
19	Упаковка	По 1.0 мл в ампулы ШП-2 из стекла НС-2 или НС-3 с кольцом или точкой излома по ОСТ 64-2-485-85; 10 ампул в пачке (тип 1-1, позиция 4 по РД 42-28-36-90) из картона коробочного по ГОСТ 7933-89. В пачку вкладывают инструкцию по применению. Транспортная тара по ГОСТ 17768-90.	По 1.0 мл в ампулы типа ШП-2 с кольцом и точкой излома по ОСТ 64-2-485-85; по 10 ампул в пачке из картона коробочного с инструкцией по применению.Транспортная тара по ГОСТ 17768-90.
20	Маркировка	На ампуле указывают сокращенное наименование предприятия-изготовителя (МЕДГАМАЛ), сокращенное название препарата - (Анат. стафил. очищ. адсорб.), номер серии и дату изготовления, объем в мл, количество доз, количество мл в дозе, срок годности, предупредительную надпись "Встряхивать". На пачке указывают наименование предприятия-изготовителя, почтовый адрес, телефон, факс, название препарата, лекарственную форму, номер серии и дату изготовления, срок годности,	На ампуле указаны сокращенное наименование предприятия-изготовителя (МЕДГАМАЛ), сокращенное название препарата - (Анат. стафил. очищ. адсорб.), номер серии и дата изготовления, объем в мл, количество доз, количество мл в дозе, срок годности,

		количество ампул, объем в мл в ампуле, активность (ЕС) в ампуле, количество доз в ампуле, доза и количество доз в упаковке, вещества, вносимые в препарат, условия хранения, регистрационный номер, дату регистрации, номер лицензии и срок её действия, штрих-код. Предупредительные надписи: "Стерильно", "Хранить в недоступном для детей месте", "Перед введением встряхивать", "Для лечебно-профилактических учреждений". Маркировки групповой и транспортной тары по РД 42-1100/1440-99-113 и ГОСТ 14192-96. На транспортную тару наносят предупредительные надписи: "СТЕКЛО", "БИОПРЕПАРАТЫ", "ЗАМОРАЖИВАНИЕ НЕ ДОПУСКАЕТСЯ".	предупредительная надпись "Встряхивать". На пачке указаны наименование предприятия-изготовителя, почтовый адрес, телефон, факс, название препарата, лекарственная форма, номер серии и дата изготовления, срок годности, количество ампул, объем в мл в ампуле, активность (ЕС) в ампуле, количество доз в ампуле, доза и количество доз в упаковке, вещества, вносимые в препарат, условия хранения, регистрационный номер, дата регистрации, номер лицензии и срок её действия, штрих-код. Предупредительные надписи: "Стерильно", "Хранить в недоступном для детей месте", "Перед введением встряхивать", "Для лечебно-профилактических учреждений". Маркировки групповой и транспортной тары по РД 42-1100/1440-99-113 и ГОСТ 14192-96. На транспортную тару наносят предупредительные надписи: "СТЕКЛО", "БИОПРЕПАРАТЫ", "ЗАМОРАЖИВАНИЕ НЕ ДОПУСКАЕТСЯ".
21	Срок годности	2 года	2 года

Заключение: препарат соответствует требованиям PN000649/01-280708, изм. № 1, 2, 3, 4, 5, 6.

"08" 10 2019 г.

Начальник ОБТК _____ М. Ю. Чернуха

МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ РОССИЙСКОЙ ФЕДЕРАЦИИ ФЕДЕРАЛЬНОЕ ГОСУДАРСТВЕННОЕ БЮДЖЕТНОЕ УЧРЕЖДЕНИЕ «НАЦИОНАЛЬНЫЙ ИССЛЕДОВАТЕЛЬСКИЙ ЦЕНТР ЭПИДЕМИОЛОГИИ И МИКРОБИОЛОГИИ ИМЕНИ ПОЧЕТНОГО АКАДЕМИКА Н.Ф. ГАМАЛЕИ» ИНН 7734013214 ОГРН 1027739443555 ФИЛИАЛ «МЕДГАМАЛ» ОБТК МОСКВА

МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ РОССИЙСКОЙ ФЕДЕРАЦИИ ФЕДЕРАЛЬНОЕ ГОСУДАРСТВЕННОЕ БЮДЖЕТНОЕ УЧРЕЖДЕНИЕ «НАЦИОНАЛЬНЫЙ ИССЛЕДОВАТЕЛЬСКИЙ ЦЕНТР ЭПИДЕМИОЛОГИИ И МИКРОБИОЛОГИИ ИМЕНИ ПОЧЕТНОГО АКАДЕМИКА Н.Ф. ГАМАЛЕИ» ИНН 7734013214 ОГРН 1027739443555 ФИЛИАЛ «МЕДГАМАЛ» ОБТК МОСКВА

РОССИЙСКАЯ ФЕДЕРАЦИЯ

СЕРТИФИКАТ СООТВЕТСТВИЯ

на продукцию, включенную в единый перечень продукции, подлежащей обязательной сертификации

№ РОСС RU C-RU.ФМ13.А.00360/19

Срок действия с 25.11.2019 **по** -

ОРГАН ПО СЕРТИФИКАЦИИ № 0076048

рег. № RA.RU.11ФМ13 федерального государственного бюджетного учреждения "Научный центр экспертизы средств медицинского применения" Министерства здравоохранения Российской Федерации. 127051, РОССИЯ, город Москва, б-р. Петровский, д. 8, стр. 2, 3; 119002, РОССИЯ, город Москва, пер. Сивцев Вражек, д. 41, стр. 1; 121002, РОССИЯ, город Москва, пер. Плотников, д. 17/39, стр. 3. Телефон +74991901818, +74992419463, факс +74956254350.

ЗАЯВИТЕЛЬ

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Телефон (499) 193-30-50, факс (499) 190-66-71.

ИЗГОТОВИТЕЛЬ

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Адрес: 123098, г. Москва, ул. Гамалеи, д. 18.
ИНН 7734013214.

ПРОДУКЦИЯ

Анатоксин стафилококковый очищенный адсорбированный, суспензия для подкожного введения (ампула) 1.0 мл х 10 (пачка картонная).
Регистрационное удостоверение № Р N000649/01 от 28.07.2008 г., дата замены 19.03.2018 г., выданное Минздравом России.
Серия 275. Срок годности: до 11.2021 г.
Партия 600 упак.

код ОК
ОК 034-2014
(КПЕС 2008) (ОКПД 2)
21.20.21.126

код ТН ВЭД
-

СООТВЕТСТВУЕТ ТРЕБОВАНИЯМ НОРМАТИВНЫХ ДОКУМЕНТОВ

Р N000649/01-280708, Изменения № 1, 2, 3, 4, 5, 6.

СЕРТИФИКАТ ВЫДАН НА ОСНОВАНИИ

протокола испытаний № С1500/ИПК/19 от 22.11.2019 г. Испытательного центра экспертизы качества медицинских иммунобиологических препаратов федерального государственного бюджетного учреждения "Научный центр экспертизы средств медицинского применения" Министерства здравоохранения Российской Федерации, аттестат аккредитации рег. № RA.RU.21ФЛ32 от 29.02.2016 г., адрес: 119002, РОССИЯ, город Москва, пер. Сивцев Вражек, д. 41, стр. 1, 3.

ДОПОЛНИТЕЛЬНАЯ ИНФОРМАЦИЯ

Руководитель (заместитель руководителя) органа по сертификации — Е.А.Соловьев

М.П.

Эксперт (эксперты) — В.Б.Поступайло

подпись — инициалы, фамилия

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УТВЕРЖДАЮ
Главный государственный санитарный врач
Российской Федерации
_____Г.Г. Онищенко
«20» декабря 2007 г.
№ 01-11/229-07

ИНСТРУКЦИЯ ПО ПРИМЕНЕНИЮ
Анатоксина стафилококкового очищенного адсорбированного

Лекарственная форма. Суспензия для подкожного введения.

Анатоксин стафилококковый очищенный адсорбированный представляет собой токсин стафилококковый обезвреженный формалином и теплом, очищенный от балластных белков, адсорбированный на геле алюминия гидроксида.

Препарат представляет собой равномерную суспензию белого цвета с желтоватым оттенком, разделяющуюся при стоянии на прозрачную надосадочную жидкость и нежный рыхлый осадок, полностью разбивающийся при встряхивании.

В 1,0 мл препарата содержится 10 ЕС (2 дозы) стафилококкового анатоксина, алюминий (сорбент) – от 0,9 до 1,3 мг, мертиолят (консервант) – от 80 до 120 мкг.

Фармакотерапевтическая группа: МИБП

Иммунологические свойства. При введении препарат вызывает образование специфических антител к экзотоксину стафилококковому

Показания к применению.

- Профилактика стафилококковых инфекций у лиц с повышенным риском заболевания - промышленные и сельскохозяйственные рабочие, подвергающиеся по роду своей деятельности частому травматизму, а также у больных, которым предстоят плановые операции.
- Иммунизация доноров с целью получения антистафилококковой плазмы и антистафилококового иммуноглобулина.

Противопоказания. Противопоказаниями для применения анатоксина стафилококкового очищенного адсорбированного являются: острые инфекционные и неинфекционные заболевания, обострение хронических заболеваний (применение препарата возможно не ранее, чем через месяц после выздоровления или ремиссии); хронические заболевания в стадии декомпенсации; сильные аллергические реакции на пищевые, лекарственные и другие вещества; тимомегалия; болезни крови; злокачественные новообразования. С целью выявления противопоказаний при профилактическом применении препарата врач (фельдшер) должен провести опрос и в день прививки - осмотр прививаемого с обязательной термометрией.

Способ применения и дозы. Препарат вводят глубоко подкожно в область нижнего угла лопатки. Ампулу перед вскрытием тщательно встряхивают до получения гомогенной суспензии.

Непригоден к применению препарат, содержащийся в ампулах с нарушенной целостностью, маркировкой, при изменении физических свойств (наличие неразбивающихся хлопьев), с истекшим сроком годности, с нарушением условий хранения.

Вскрытие ампул и процедуру иммунизации осуществляют при строгом соблюдении правил асептики и антисептики.

Взамен инструкции, утвержденной 26 декабря 2003 г.

Разовая доза препарата составляет 0,5 мл.

Препарат во вскрытой ампуле хранению не подлежит.

Курс иммунизации промышленных и сельскохозяйственных рабочих состоит из двух инъекций (по 1 дозе каждая) с интервалом от 30 до 45 сут.

Первая ревакцинация проводится спустя три месяца после окончания курса иммунизации. Последующие ревакцинации проводят с интервалом 12 мес.

Курс иммунизации плановых хирургических больных (детей старше 1 года и взрослых) состоит из двух инъекций (по 1 дозе каждая) препарата с интервалом от 20 до 30 сут; вторую инъекцию проводят не позднее, чем за 4-5 сут до операции.

Курс иммунизации доноров состоит из трех инъекций препарата с интервалом 7 дней. При первой инъекции донорам вводят - 1,0 мл (2 дозы) препарата, при второй - 1,0 мл (2 дозы), при третьей - 2,0 мл (4 дозы).

Суммарное количество препарата, вводимое донору за полный курс иммунизации, составляет 4,0 мл (8 доз).

Иммунизация доноров проводится согласно действующей «Инструкции по иммунизации доноров стафилококковым анатоксином и проведению плазмофереза для получения антистафилококковой плазмы», утвержденной МЗ СССР 02.08.77г.

При подборе доноров для иммунизации и проведения плазмофереза необходимо руководствоваться общими положениями, предусмотренными «Инструкцией по медицинскому освидетельствованию доноров», утвержденной МЗ РФ 16.11.1998 г.

Побочное действие. Введение препарата у отдельных привитых может сопровождаться общей и местной реакцией. Общие реакции характеризуются легким недомоганием и субфебрильной температурой (до 37,5 °С) продолжительностью от 24 до 48 часов. Для местных реакций характерно развитие гиперемии и образование в месте инъекции инфильтрата диаметром до 5мм.

Гиперемия исчезает в течение 3-4 сут, инфильтрат сохраняется до 10 сут, а у части привитых - до 30 и более сут, в виде безболезненного уплотнения. При наличии инфильтрата очередную прививку производят на противоположной стороне.

Взаимодействие с другими лекарственными средствами.

Анатоксин стафилококковый очищенный адсорбированный следует вводить не ранее, чем через 3 недели после предшествующей инъекции иммуноглобулина человека или антистафилококковой плазмы.

Форма выпуска. В ампулах по 1,0 мл (2 дозы). Упаковка содержит 10 ампул и инструкцию по применению.

Транспортирование. В соответствии с СП 3.3.2.1248-03 при температуре от 2 до 8 °С. Замораживание не допускается.

Условия хранения. В соответствии с СП 3.3.2. 1248-03 при температуре от 2 до 8 °С в сухом, защищенном от света месте. Замораживание не допускается.

Условия отпуска. Для лечебно-профилактических учреждений.

Срок годности. Срок годности - 2 года.

Препарат с истекшим сроком годности применению не подлежит.

Производитель/претензии потребителей направлять по адресу: ФГБУ "НИЦЭМ им. Н.Ф. Гамалеи" Минздрава России (филиал "Медгамал" ФГБУ "НИЦЭМ им. Н.Ф. Гамалеи" Минздрава России); Россия, 123098, г. Москва, ул. Гамалеи, д.18; тел. (499)193-30-50, (499)190-44-59; факс (499)190-66-71.