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1.15942.1000

Microscopy

Malachite green oxalate (C.I. 42000)

for microscopy Certistain®

For professional use only

IVD In Vitro Diagnostic Medical Device

CE

Intended purpose

This staining dye "Malachite green oxalate (C.I. 42000) - for microscopy Certistain®" is used for human-medical cell diagnosis and serves the purpose of the bacteriological investigation of sample material of human origin. It is a dry staining dye that is used to prepare a staining solution, that when used together with other in vitro diagnostic products from our portfolio makes bacteriological target structures evaluable for diagnostic purposes (by fixing, embedding where necessary, staining with the above malachite green oxalate solution, counterstaining, mounting) in bacteriological specimen materials.

Unstained structures are relatively low in contrast and are extremely difficult to distinguish under the light microscope. The images created using the staining solutions help the authorized and qualified investigator to better define the form and structure in such cases. Further tests must be carried out according to recognized, valid methods to reach a definitive diagnosis.

Principle

Malachite green is used for routine staining methods in bacteriology, e.g. the spore-staining method acc. to Rakette (differential spore staining with malachite green in bacteriological samples).
The dye is used in a hot staining method to stain specifically target structures. Counterstaining is done with a red dye, e.g. eosin Y.

Sample material

Smears of bacteriological material of human origin that have been air-dried and heat-fixed like sputum, smears from fine needle aspiration biopsies (FNAB), rinses, imprints, effusions, pus, exsudates, liquid and solid cultures

Reagents

Cat. No. 115942
Malachite green oxalate (C.I. 42000) for microscopy Certistain® — 100 g, 1 kg
Color Index No.: 42000
Color Index Name: Basic green 4

Also required:

Cat. No. 115935 Eosin Y (yellowish) (C.I.45380) for microscopy Certistain® — 25 g, 100 g

Sample preparation

The sampling must be performed by qualified personnel.

All samples must be treated using state-of-the-art technology.
All samples must be clearly labeled.
Suitable instruments must be used for taking samples and their preparation. Follow the manufacturer's instructions for application / use.

When using the corresponding auxiliary reagents, the corresponding instructions for use must be observed.

Reagent preparation

Malachite green solution

For preparation of approx. 100 ml solution mix:

Malachite green oxalate (C.I. 42000) Certistain®	5.0 g
dissolve in distilled water and make up with it to 100 ml	

Eosin Y solution

For preparation of approx. 100 ml solution mix:

Eosin Y (yellowish) (C.I.45380) Certistain®	2.5 g
dissolve in distilled water and make up with it to 100 ml	

The freshly prepared staining solutions should be filtered before use.

Procedure

Staining on the staining rack

The stated times should be adhered to in order to guarantee an optimal staining result.

Slide with fixed smear		
Malachite green solution	cover completely and heat until steam is generated and leave to react	3x 30 sec
DI water	rinse off	30 sec
Eosin Y solution	cover completely and leave to react (counterstaining)	1 min
DI water	rinse off	30 sec
Air-dry (e.g. over night or at 50 °C in the drying cabinet)		

After dehydration (ascending alcohol series) and clarification with xylene or Neo-Clear®, bacteriological slides can be covered with non-aqueous mounting agents (e.g. Neo-Mount®, Entellan® new, or DPX new) and a cover glass and can then be stored. When left unmounted, the stain remains stable for approx. 3 days, covered with immersion oil for just a few hours.

The use of immersion oil is recommended for the analysis of stained slides with a microscopic magnification >40x.

Result

Spores	emerald green
vegetative material	red

Technical notes

The microscope used should meet the requirements of a medical diagnostic laboratory.
The freshly prepared staining solutions should be filtered before use.

Remove surplus immersion oil before filing.

Diagnostics

Diagnoses are to be made only by authorized and qualified personnel.
Valid nomenclatures must be used.
This method can be supplementarily used in human diagnostics.
Further tests must be selected and implemented according to recognized methods.
Suitable controls should be conducted with each application in order to avoid an incorrect result.

Storage

Store Malachite green oxalate (C.I. 42000) - for microscopy Certistain® at +5 °C to +30 °C.

Shelf-life

Malachite green oxalate (C.I. 42000) - for microscopy Certistain® can be used until the stated expiry date.

After first opening of the bottle, the contents can be used up to the stated expiry date when stored at +5 °C to +30 °C.

The bottles must be kept tightly closed at all times.

Additional instructions

For professional use only.
In order to avoid errors, the application must be carried out by qualified personnel only.
National guidelines for work safety and quality assurance must be followed.
Microscopes equipped according to the standard must be used.
If necessary use a standard centrifuge suitable for medical diagnostic laboratory.

Protection against infection

Effective measures must be taken to protect against infection in line with laboratory guidelines.

Instructions for disposal

The package must be disposed of in accordance with the current disposal guidelines.
Used solutions and solutions that are past their shelf-life must be disposed of as special waste in accordance with local guidelines. Information on disposal can be obtained under the Quick Link "Hints for Disposal of Microscopy Products" at www.microscopy-products.com. Within the EU the currently applicable REGULATION (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 applies.

Auxiliary reagents

Cat. No.	100579	DPX new non-aqueous mounting medium for microscopy	500 ml
Cat. No.	103699	Immersion oil Type N acc. to ISO 8036 for microscopy	100-ml dropping bottle
Cat. No.	104699	Immersion oil for microscopy	100-ml dropping bottle, 100 ml, 500 ml
Cat. No.	107960	Entellan® rapid mounting medium for microscopy	500 ml
Cat. No.	107961	Entellan® new rapid mounting medium for microscopy	100 ml, 500 ml, 1 l
Cat. No.	109016	Neo-Mount® anhydrous mounting medium for microscopy	100-ml dropping bottle, 500 ml
Cat. No.	115935	Eosin Y (yellowish) (C.I.45380) for microscopy Certistain®	25 g, 100 g

Hazard classification

Cat. No. 115942

Please observe the hazard classification printed on the label and the information given in the safety data sheet.
The safety data sheet is available on the website and on request.
CAUTION! Contains CMR substances. Please observe the corresponding safety instructions given in the safety data sheet.

Main components of the product

Cat. No. 115942

C.I. 42000 > 90 %
$C_{48}H_{50}N_4O_4 \times 2\ C_2HO_4 \times C_2H_2O_4$
M = 927.02 g/mol

Other IVD products

Cat. No.	100496	Formaldehyde solution 4%, buffered, pH 6.9 (approx. 10% Formalin solution) for histology	350 ml and 700 ml (in bottle with wide neck), 5 l, 10 l, 10 l Titripac®
Cat. No.	100497	AFB-Color modified Staining kit for the detection of acid-fast bacteria (AFB) by hot staining method	1 set
Cat. No.	109217	Gram's safranine solution for the Gram staining method	500 ml, 2.5 l
Cat. No.	115161	Histosec® pastilles (without DMSO) solidification point 56-58°C embedding agent for histology	10 kg (4x 2.5 kg), 25 kg
Cat. No.	116450	AFB-Color staining kit for the microscopic investigation of acid-fast bacteria (AFB) (cold staining)	1 set

General remark

If during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorised representative and to your national authority.

Literature

1. Romeis - Mikroskopische Technik, Editors: Maria Mulisch, Ulrich Welsch, 2015, Springer Spektrum, 19. Auflage
2. Conn's Biological Stains: A Handbook of Dyes, Stains and Fluorochromes for Use in Biology and Medicine, 10th Edition, (ed. Horobin, R.W. and Kiernan, J.A). Bios, 2002
3. Staining Procedures, George Clark, 1981, Williams & Wilkins, fourth Edition


Consult instructions for use


Manufacturer

Catalog number

Batch code


Caution, consult accompanying documents


Use by YYYY-MM-DD


Temperature limitation

Status: 2021-Jul-16

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