

1.15924.0025

Microscopy**Nigrosine (C.I. 50420) water-soluble**

for microscopy Certistain®



In Vitro Diagnostic Medical Device



for negative visualization of capsule in bacteriological material

This staining dye "Nigrosine (C.I. 50420) water-soluble - for microscopy Certistain®" is used for human-medical cell diagnosis and serves 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 target structures evaluable for diagnostic purposes (by fixing, embedding, staining with the above nigrosine solution, counterstaining, mounting) in bacteriological specimen materials.

Principle

Nigrosine stain is used as a negative, acidic stain that permits the visualization of capsules and spores of many organisms such as protozoa, fungi and spirochaetes.

It has also been described as a staining agent for viable cells in e.g. stem cell biology.

The Nigrosine negative stain is a quick and simple staining technic to determine the cellular morphology of an organism.

It provides a dark background against light shapes of the cell which are clearly visible with a good contrast.

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. 1.15924.0025

Nigrosine (C.I. 50420) water-soluble for microscopy Certistain® 25 g

Color Index No.: 50420

Color Index Name: Acid black 2

Also required:

Cat. No. 103999 Formaldehyde solution min. 37% free from acid stabilized with about 10% methanol and calcium carbonate for histology 1 l, 2.5 l, 25 l

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.

Reagent preparation**Nigrosin working solution**

For preparation of approx. 100 ml solution mix:

Nigrosine (C.I. 50420) water-soluble Certistain®	10 g
Distilled water	100 ml
stir in, boil for 10 min, allow to cool	
Formaldehyde solution min. 37%	0.5 ml
add, mix, and filter	

The freshly prepared staining solution should be filtered before use.

Procedure

Bring some bacteria material to a glass slide, rub together with 1 loop of Nigrosin working solution. Place a cover glass and press, seal the rims optionally.

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

Result

Bacteria unstained
Background dark grey to dark violet

Technical notes

The microscope used should meet the requirements of a medical diagnostic laboratory.

The freshly prepared staining solution should be filtered before use.

Remove surplus immersion oil before filing.

Diagnostics

Diagnoses are to be made only by authorized and trained personnel. Valid nomenclatures must be used.

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 Nigrosine (C.I. 50420) water-soluble - for microscopy Certistain® at +5 °C to +30 °C.

Shelf-life

Nigrosine (C.I. 50420) water-soluble - 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. 103699	Immersion oil acc. to ISO 8036 for microscopy	100-ml dropping bottle
Cat. No. 103999	Formaldehyde solution min. 37% free from acid stabilized with about 10% methanol and calcium carbonate for histology	1 l, 2.5 l, 25 l
Cat. No. 104699	Immersion oil for microscopy	100-ml dropping bottle, 100 ml, 500 ml

Hazard classification

Cat. No. 1.15924.0025

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.

Main components of the product

Cat. No. 1.15924.0025

Loss on drying $\leq 15\%$

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	Tb-color modified Staining kit for the detection of mycobacteria (AFB) by hot staining method	1 unit
Cat. No. 108512	Tb-color carbol fuchsin solution for the microscopic cold staining of mycobacteria	500 ml, 2.5 l

Literature

1. Theory and application of Microbiological Assay, Hewitt, W. and Vincent, S., 1989, Academic Press
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



Consult instructions for use



Manufacturer



Catalog number



Batch code



Caution, consult accompanying documents



Use by YYYY-MM-DD



Temperature limitation

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