

1.12327.0500

Microscopy

LEUCOGNOST® Fixing Mixture

for enzyme cytochemistry

IVD In Vitro Diagnostic Medical Device



This "LEUCOGNOST® Fixing Mixture - for enzyme cytochemistry" is used for human-medical cell diagnosis and serves the purpose of the hematological and cytological investigation of sample material of human origin. It is a fixative that when used together with other in vitro diagnostic products from our portfolio makes target structures (by fixing, staining, where necessary counterstaining, mounting) in hematological and clinico-cytological specimen materials, for example smears of whole blood and bone marrow, evaluable for diagnostic purposes.

Principle

This LEUCOGNOST® Fixing Mixture is especially developed for the fixation of blood and bone marrow smears using the various LEUCOGNOST® kits. LEUCOGNOST® Fixing Mixture optimally protects enzyme activities, and the reaction times of the different working solutions are specially matched to the LEUCOGNOST® Fixing Mixture.

Sample material

Cyocentrifuge material, and fresh, native blood or bone-marrow smears should be used as the starting material for all stains. The use of e.g. EDTA as anticoagulant significantly reduces the enzyme reaction. In any case it is not recommended to add any anticoagulant substances.

Reagents

Cat. No. 1.12327.0500
LEUCOGNOST® Fixing Mixture
for enzyme cytochemistry 500 ml

For use in conjunction with:

Cat. No. 116198	LEUCOGNOST® NASDCL Detection of naphthol AS-D chloroacetate esterase in granulocytes	12 units
Cat. No. 116301	LEUCOGNOST® EST Detection of the alpha naphthyl acetate esterase reaction in leucocytes	12 units
Cat. No. 116302	LEUCOGNOST® PAS Detection of the periodic acid-Schiff reaction in leukocytes	12 units
Cat. No. 116303	LEUCOGNOST® POX Detection of the peroxidase reaction in leukocytes	12 units
Cat. No. 116304	LEUCOGNOST® AP Detection of the acid phosphatase reaction in leukocytes	12 units

Sample preparation

The sampling must be performed by qualified personnel.

Please use thin, air-dried blood or bone-marrow smears that have been stored not longer than three days.

The smears must be dried in air for at least 30 minutes and be fixed with LEUCOGNOST® Fixing Mixture according to the relevant instructions prior to the actual cytochemical reaction (see "Procedure").

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

The LEUCOGNOST® Fixing Mixture - for enzyme cytochemistry used is ready-to-use, dilution of the solution is not necessary.

Procedure

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

Fix the air-dried blood or bone-marrow smears in LEUCOGNOST® Fixing Mixture	1 - 3 min
Rinse with running tap water	10 sec
Air-dry or process directly using one of the LEUCOGNOST® kits.	

After fixing the smears can be stored in the refrigerator for up to 3 days or directly processed using one of the LEUCOGNOST® kits.

Staining is performed as per the protocol of the corresponding LEUCOGNOST® kit.

Staining in the 60-ml Hellendahl cell

The slides must be immersed and moved briefly in the solutions, simple immersion alone yields inadequate staining results.

The slides should be allowed to drip off well after the individual staining steps as a measure to avoid any unnecessary cross-contamination of solutions.

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

Slide with fixed smear	
Place in freshly prepared staining solution (preparation acc. to instruction)	time acc. to instruction
Place in distilled water	time acc. to instruction
Air-dry (if necessary, acc. to instruction)	
Counter-stain with Mayer's hemalum solution	time acc. to instruction
Rinse with running tap water	time acc. to instruction
Air-dry (e.g. over night or at 50 °C in the drying cabinet)	
Mount, if necessary, with Aquatex® and cover glass.	

To enable hematology specimens to be stored over a period of several months, it is advisable to cover them with an aqueous mounting medium (e.g. Aquatex®) and a cover glass. When left unmounted, the stain remains stable for about 3 days, covered with immersion oil only for a few hours.

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

Technical notes

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

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 the LEUCOGNOST® Fixing Mixture - for enzyme cytochemistry at +15 °C to +25 °C.

Shelf-life

The LEUCOGNOST® Fixing Mixture - for enzyme cytochemistry 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 +15 °C to +25 °C.

The bottles must be kept tightly closed at all times.

Capacity

All LEUCOGNOST® kits are sufficient for 12 stainings with up to 16 slides.

It is possible to simultaneously fix up to 8 microscope slides or 16 standing back to back in 60-ml Hellendahl cells with extensions (corresponds to one staining preparation).

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.

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.	116300	LEUCOGNOST® ALPA Detection of the alkaline leukocyte phosphatase activity in leukocytes	12 units
Cat. No.	116301	LEUCOGNOST® EST Detection of the alpha naphthyl acetate esterase reaction in leukocytes	12 units
Cat. No.	116302	LEUCOGNOST® PAS Detection of the periodic acid-Schiff reaction in leukocytes	12 units
Cat. No.	116303	LEUCOGNOST® POX Detection of the peroxidase reaction in leukocytes	12 units
Cat. No.	116304	LEUCOGNOST® AP Detection of the acid phosphatase reaction in leukocytes	12 units
Cat. No.	117198	LEUCOGNOST® NASDCL new Detection of naphthol AS-D chloroacetate esterase in granulocytes	12 units

Safety classification

Cat. No. 1.12327.0500

Please observe the hazard classification 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 product components

Art. 1.12327.0500

$C_6H_8O_7 \times H_2O$	1.01 g/l
$C_6H_5Na_3O_7 \times 2 H_2O$	0.71 g/l
NaCl	0.19 g/l
C_3H_6O	548 g/l
$C_3H_6O_2$	34.56 g/l
1 l =	0.90 kg

Other IVD products

Cat. No.	100014	Acetone for analysis EMSURE® ACS,ISO,Reag. Ph Eur	1 l, 2.5 l, 5 l
Cat. No.	100974	Ethanol denatured with about 1 % methyl ethyl ketone for analysis EMSURE®	1 l, 2.5 l
Cat. No.	104699	Immersion oil for microscopy	100-ml dropping bottle, 100ml, 500 ml
Cat. No.	108562	Aquatex® (aqueous mounting agent) for microscopy	50-ml dropping bottle
Cat. No.	109033	Schiff's reagent for microscopy	500 ml, 2.5 l
Cat. No.	109249	Mayer's hemalum solution for microscopy	500 ml, 1 l, 2.5 l
Cat. No.	115355	CYTOCOLOR® Cytological standard stain acc. Szczepanik for microscopy	6x 500 ml

Literature

1. Löffler, H., Rastetter, J., Haferlach, T, Atlas der klinischen Hämatologie, 2004, Springer-Verlag Berlin Heidelberg
2. Routine Cytological Staining Techniques: Theoretical Background and Practice, Mathilde E. Boon, Johanna S. Drijver, 1986, Elsevier Science Publishing Company
3. 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

Status: 2017-10-05

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