1.11955.2500

Microscopy

Hemacolor® Rapid staining of blood smear

Solution 1: fixing solution

For professional use only

IVD In Vitro Diagnostic Medical Device CE

Intended purpose

This "Hemacolor® Rapid staining of blood smear - Solution 1: fixing solution" is used for human-medical cell diagnosis and serves the fixing of native blood and bone-marrow smears of human origin. It is a ready-to-use solution that when used together with other in vitro diagnostic products from our portfolio makes target structures evaluable for diagnostic purposes (by fixing, staining, counterstaining, mounting) in hematological and clinico-cytological specimen materials, for example smears of whole blood and bone marrow.

The fixatives that are appropriate for use from case to case are described in the corresponding instructions for use for in vitro diagnostic staining solutions and test kits.

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

The staining with Hemacolor® yields a staining result that corresponds to the Pappenheim stain, with predominantly magenta stained nuclei. This is based on the molecular interaction of the Eosin Y dye and a complex of Azur B with DNA. Both dyes assemble to an Eosin Y - Azur B-DNA complex and the intensity of the resulting stain depends on the content of Azur B and the ratio of Azur B : Eosin Y.
Furthermore, the resulting stain can vary depending on the influence of fixation, staining times, pH-value of the solutions or buffer substances. By using pH 7.2 buffered solutions in the Hemacolor® staining kit, a high stability of the stain and clean, precipitation-free staining results can be guaranteed.

Sample material

Fresh, native whole blood or bone-marrow smears as well as clinico-cytological material like urine sediment, sputum, smears from fine needle aspiration biopsies (FNAB), rinses, imprints are used as starting material.

Reagents

Cat. No. 1.11955.2500
Hemacolor® Rapid staining of blood smear 2.5 l
Solution 1: fixing solution

Also required:

Cat. No. 111956	Hemacolor® Rapid staining of blood smear Solution 2: colour reagent red	2.5 l
Cat. No. 111957	Hemacolor® Rapid staining of blood smear Solution 3: colour reagent blue	2.5 l
Cat. No. 109468	Buffer tablets pH 7.2 for preparing buffer solution acc. to WEISE for staining of blood smears	100 tabs

Alternatively:

Instead of the combination of single reagents, the staining kits 1.11661.0001 and 1.11674.0001 can be used:

Cat. No. 1.11674.0001
Hemacolor® Rapid staining of blood smear 1 set

Cat. No. 1.11661.0001
Hemacolor® Rapid staining of blood smear 1 set

Sample preparation

The sampling must be performed by qualified personnel.

Please use thin, air-dried blood or bone-marrow smears, as well as clinico-cytological materials, that have been stored not longer than three days. The smears must be dried in air for at least 30 minutes and be fixed according to the relevant instructions prior to the actual reaction.

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

The Hemacolor® Rapid staining of blood smear - Solution 1: fixing solution is ready-to-use, dilution of the solution is not necessary and merely produces a deterioration of the staining result and its stability.

Buffer solution pH 7.2

Dissolve 1 buffer tablet pH 7.2 in 1 l distilled water while stirring.
It is recommended to prepare the Buffer solution one day before use.

Procedure

Staining in the staining cell

The slides must be immersed and moved 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 in order to guarantee an optimal staining result.

Slide with air-dried smear	
Hemacolor® Solution 1: fixing solution	5 x 1 sec
Hemacolor® Solution 2: colour reagent red	3 x 1 sec
Hemacolor® Solution 3: colour reagent blue	6 x 1 sec
Buffer solution pH 7.2	2 x 10 sec
Air-dry	
Mount, if necessary, with Neo-Mount®, DPX new or Entellan® new and cover glass.	

Staining in the automatic stainer

Reagent	Time	Station	DIP
Slide with air-dried smear			
Hemacolor® Solution 1: fixing solution	30 sec	1	on
Hemacolor® Solution 2: colour reagent red	3 sec	2	on
Hemacolor® Solution 3: colour reagent blue	6 sec	3	on
Buffer solution pH 7.2	10 sec	4	on
Buffer solution pH 7.2	10 sec	5	on
Air-dry	3 min	6	-
Mount, if necessary, with Neo-Mount®, DPX new or Entellan® new and cover glass.			

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

After dehydration (ascending alcohol series) and clarification with xylene or Neo-Clear®, cytological samples can be mounted with water-free mounting agents (e. g. Entellan® new, Neo-Mount®) and a cover glass and can then be stored.

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

Result

Nuclei	red-violet
Cytoplasm of lymphocytes	blue-grey
Cytoplasm of monocytes	mainly dove-blue
Neutrophilic granula	light violet
Eosinophilic granula	red to red-brown
Basophilic granula	dark violet to black
Thrombocytes	violet
Erythrocytes	reddish

Technical notes

The microscope used should meet the requirements of a medical diagnostic laboratory.
When using automatic staining systems, please follow the instructions for use supplied by the supplier of the system and software.

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 the Hemacolor® Rapid staining of blood smear - Solution 1: fixing solution at +15 °C to +25 °C.

Shelf-life

The Hemacolor® Rapid staining of blood smear - Solution 1: fixing solution 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.

If stored at +15 °C to +25 °C, the freshly prepared Buffer solution pH 7.2 can be used for minimum one working week. However, the solutions should be discarded when contaminations (e. g. fungi, bacteria), that occur at times, are observed.

Capacity

The package is sufficient for 1250 - 5000 applications.

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.	106009	Methanol for analysis EMSURE® ACS,ISO,Reag. Ph Eur	1 l, 2.5 l, 5 l
Cat. No.	107961	Entellan® new rapid mounting medium for microscopy	100 ml, 500 ml, 1 l
Cat. No.	108298	Xylene (isomeric mixture) for histology	4 l
Cat. No.	109016	Neo-Mount® anhydrous mounting medium for microscopy	100-ml dropping bottle, 500 ml
Cat. No.	109468	Buffer tablets pH 7.2 for preparing buffer solution acc. to WEISE for staining of blood smears	100 tabs
Cat. No.	109843	Neo-Clear® (xylene substitute) for microscopy	5 l
Cat. No.	111674	Hemacolor® Rapid staining of blood smear staining set for microscopy	1 set
Cat. No.	111956	Hemacolor® Rapid staining of blood smear Solution 2 colour reagent red	2.5 l
Cat. No.	111957	Hemacolor® Rapid staining of blood smear Solution 3 colour reagent blue	2.5 l

Hazard classification

Cat. No. 1.11955.2500

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. 1.11955.2500

contains CH_3OH

Other IVD products

Cat. No.	101383	Wright's eosin methylene blue solution for microscopy	100 ml, 500 ml, 2.5 l
Cat. No.	101424	May-Grünwald's eosine-methylene blue solution modified for microscopy	100 ml, 500 ml, 1 l, 2.5 l
Cat. No.	105387	Leishman's eosin methylene blue solution modified for microscopy	500 ml
Cat. No.	109204	Giemsa's azur eosin methylene blue solution for microscopy	100 ml, 500 ml, 1 l, 2.5 l

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. Atlas der klinischen Hämatologie, Löffler, Rastetter, Haferlach, 2004, Springer Verlag 6. Auflage
2. Histological & Histochemical Methods, J. A. Kiernan,1990, Pergamon Press, Second Edition
3. Romeis - Mikroskopische Technik, Editors: Maria Mulisch, Ulrich Welsch, 2015, Springer Spektrum, 19. Auflage
4. Sobotta, Lehrbuch Histologie, Welsch, 2006, Urban&Fischer, 2. Auflage


Consult instructions for use


Manufacturer

Catalog number

Batch code


Caution, consult accompanying documents


Use by YYYY-MM-DD


Temperature limitation

Status: 2020-Aug-24

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