

1.15213.0001

Microscopy

Auto-Hemacolor®

Staining set for automatic blood smear staining with the HEMA-TEK* Slide Stainer

IVD In Vitro Diagnostic Medical Device



This "Auto-Hemacolor® - Staining set for automatic blood smear staining with the HEMA-TEK* Slide Stainer" 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 ready-to-use staining kit 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.

Auto-Hemacolor® is used for the rapid staining of hematological and cytological specimen material to produce a staining that corresponds to the Giemsa stain.

Principle

The staining with Auto-Hemacolor® yields a staining result that corresponds to the Giemsa 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 7.0 buffered solutions in the Auto-Hemacolor® staining kit, a high stability of the stain and clean, precipitation-free staining results can be guaranteed.

Sample material

Only 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 peroxidase reaction. In any case it is not recommended to add any anticoagulant substances.

Further, also clinical cytological material can be used: urine sediment, sputum, fine needle aspiration biopsies (FNAB), imprints, rinses.

Reagents

Cat. No. 1.15213.0001

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Package components:

The staining kit contains

Reagent 1: Auto-Hemacolor® Staining solution	200 ml
Reagent 2: Auto-Hemacolor® Buffer solution, pH 7.0	480 ml
Reagent 3: Auto-Hemacolor® Rinse solution, pH 7.0	950 ml

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

The reagents of the Auto-Hemacolor® Staining set for automatic blood smear staining with the HEMA-TEK* Slide Stainer used for staining are ready-to-use, dilution of the solutions is not necessary and merely produces a deterioration of the staining result and their stability.

The slides should be allowed to drip off well after the individual staining steps, as the staining is prepared by placing the Auto-Hemacolor® staining kit (including folding carton) into the automatic staining system.

Insert the Auto-Hemacolor® staining kit into the opening provided in the equipment. The pack must fit squarely.

Remove the pre-punched cardboard sections of the carton.

Insert the suction cannulas into the closures and push them firmly through as far as the protective ring seals on the suction cannulas.

Allow the instrument to run in order to remove air bubbles.

Procedure

Place the glass slides with the material downwards to the staining strip.

Air-dried blood smears are transported in a fully automatic flow system (no immersion system) over the staining strip.

Pass a carefully measured, fresh quantity of dye, buffer and rinse solutions, in this order, into the capillary space between the slides and the staining strip.

The solutions are transferred to the staining strip by adjustable peristaltic pumps.

Air-dry the slides (e.g. over night or at 50 °C in the drying cabinet).

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

Auto-Hemacolor® gives a comparable staining result to Giemsa's staining.

Cell nuclei	red-violet
Lymphocytes	plasma blue, azurophilic granules magenta
Monocytes	plasma blue-grey
Neutrophilic granulocytes	granules light violet
Eosinophilic granulocytes	granules reddish to red-brown
Basophilic granulocytes	granules dark violet
Thrombocytes	violet
Erythrocytes	reddish

Technical notes

If opened packs are not used for longer than 24 h, the puncture openings of the three reagent vessels must be tightly closed to avoid evaporation, which may result in changes in concentration and formation of precipitates.

Remove the cannulas, and clean the cannulas and tubes by placing the cannulas in methanol or ethanol and allowing the equipment to run.

Insert the clean and dry cannulas as far as the protective ring seals again, and leave them until the next staining; they usually close tightly.

An automatic sign on the equipment is given when the amount of solution left in the equipment is only sufficient for approx. 20 stainings. The sign "stain" is extinguished.

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 Auto-Hemacolor® Staining set for automatic blood smear staining with the HEMA-TEK* Slide Stainer at +15 °C to +25 °C.

Shelf-life

The Auto-Hemacolor® Staining set for automatic blood smear staining with the HEMA-TEK* Slide Stainer 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.

* Hematek slide stainer of SIEMENS Healthcare must be used. Follow the manufacturer's instructions for installation and service.

Capacity

Auto-Hemacolor® staining kit is sufficient for approx. 1000 stainings when in continuous use.

In non-continuous use, Auto-Hemacolor® staining set is sufficient for approx. 500 - 700 stainings.

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.	100579	DPX new non-aqueous mounting medium for microscopy	500 ml
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, 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.	109843	Neo-Clear® (xylene substitute) for microscopy	5 l

Hazard classification

Cat. No. 1.15213.0001

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 products

Cat. No. 1.15213.0001

Reagent 1 (staining solution)

C.I. 52015	0.9 g/l
C.I. 45380	1 g/l
C.I. 52000	0.1 g/l

contains CH₃OH

Reagent 2 (buffer solution, pH 7.0)

KH ₂ PO ₄	0.46 g/l
Na ₂ HPO ₄	0.47 g/l
pH	7.0

Reagent 3 (rinse solution, pH 7.0)

KH ₂ PO ₄	0.37 g/l
Na ₂ HPO ₄	0.38 g/l

contains CH₃OH

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.	109204	Giemsa's azur eosin methylene blue solution for microscopy	100 ml, 500 ml, 1 l, 2.5 l
Cat. No.	116302	LEUCOGNOST® PAS Detection of the periodic acid-Schiff reaction in leukocytes	12 units



Consult instructions for use



Manufacturer



Catalog number



Batch code



Caution, consult accompanying documents



Use by YYYY-MM-DD



Temperature limitation

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