

1.15355.0001

Microscopy

CYTOCOLOR®

Cytological standard stain

acc. Szczepanik

for microscopy

For professional use only

IVD

In Vitro Diagnostic Medical Device



Intended purpose

This „CYTOCOLOR® Cytological standard stain acc. Szczepanik - for microscopy“ kit is used for human-medical cell diagnosis and serves the purpose of the 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 cytological target structures evaluable for diagnostic purposes (by fixing, staining, counterstaining, mounting) in human gynecological and clinico-cytological specimen materials, e.g. cervical smears.

CYTOCOLOR® is a quick staining kit based on the standard staining method acc. to Szczepanik for use in the analysis of cytology specimens.

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 examinations may be necessary to reach a definitive diagnosis.

Principle

The cytological standard staining acc. to Szczepanik is intended for the staining of exfoliative cells in cytological specimens. This CYTOCOLOR® quick staining kit contains modified hematoxylin and polychromatic solutions. Consequently, a cytological sample can be stained in about 3 minutes.

First, the cell nuclei are stained with a hematoxylin solution. The polychromatic solution EA 31 contained in the kit is a so-called polychromatic mixture of eosin, light green SF, and vesuvine (Bismarck brown) and serves to enhance the staining reaction in the cytoplasm. Due to their different molecular weights, in relation to the different pore sizes of the cell membrane eosin and light green SF enable a differentiated staining of the structure in the various cycle stages of the cells.

Sample material

Gynecological smears
non-gynecological specimens as e.g. smears from fine needle aspiration biopsies (FNAB) (smear method), excision specimens (squash technique) and sediment or centrifugate obtained from body fluids

Reagents

Cat. No. 1.15355.0001

CYTOCOLOR® Cytological standard stain acc. Szczepanik for microscopy

Package components:

The staining kit contains

Reagent 1: CYTOCOLOR® modified hematoxylin solution	500 ml
Reagent 2: CYTOCOLOR® modified polychromatic solution	500 ml
Reagent 3: CYTOCOLOR® 2-Propanol for analysis ACS,ISO	3x 500 ml
Reagent 4: CYTOCOLOR® Xylene isomeric mixture	500 ml

Sample preparation

The sampling must be performed by qualified personnel.

Smears are obtained and prepared in the usual manner.

For intraoperative cytodiagnosis, the "squash and smear" technique is used: The excision specimen is cut open and finger pressure is applied to both sides of one half so that the surface of the cut bulges out. A microscope slide is then smeared across the cut surface in one direction.

The smears must be fixed **immediately** with M-FIX® spray fixative. Only if the smears are fixed while still moist any structural peculiarities of the cells will be retained.

Spray-fixing protects the cell material from the effects of drying out. Once fixed with M-FIX®, smears can be stained immediately without having to be processed via a descending alcohol series.

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 reagents 1, 2, and 4 of the CYTOCOLOR® Cytological standard stain acc. Szczepanik - for microscopy 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.

Precipitates of dye may form in **Reagent 1**. In this case the solution must be filtered over a paper filter.

Reagent 3a (80 % 2-propanol solution)

For preparation of approx. 100 ml solution mix:

Reagent 3 (2-Propanol)	80 ml
Distilled water	20 ml

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.

Slide with fixed smear	
Distilled water	10 sec
Reagent 1 (modified hematoxylin solution)	1 min
Running tap water	10 sec
Reagent 3 (2-propanol)	2 sec
Reagent 2 (modified polychromatic solution)	1 min
Reagent 3a (2-propanol 80 %)	5 sec
Reagent 3 (2-propanol)	10 sec
Reagent 4 (xylene)	5 sec
Reagent 4 (xylene)	5 sec
Mount immediately the xylene-wet slides with M-Glas® (without cover-glass) or with e.g. Entellan® new and cover glass.	

After dehydration (ascending alcohol series) and clarification with xylene, cytological samples can be mounted with water-free mounting agents (e.g. Entellan® new) 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

Cyanophilic (basophilic) cytoplasm	blue-green
Eosinophilic (acidophilic) cytoplasm	pink
Keratinised cytoplasm	pink to intensely pink
Nuclei	blue, dark violet, black
Microorganisms	blue-violet, grey-blue, grey-green
Erythrocytes	red

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 CYTOCOLOR® Cytological standard stain acc. Szczepanik - for microscopy kit at +15 °C to +25 °C.

Shelf-life

The CYTOCOLOR® Cytological standard stain acc. Szczepanik - for microscopy kit 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

The package is sufficient for approx. 1000 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. 103973	M-Glas® liquid cover glass for microscopy	100 ml, 500 ml
Cat. No. 103981	M-FIX® spray fixative for cytodiagnosis	100 ml, 1 l
Cat. No. 104699	Immersion oil for microscopy	100-ml dropping bottle, 100 ml, 500 ml
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

Hazard classification

Cat. No. 1.15355.0001

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. 1.15355.0001

Reagent 1

C.I. No. 75290	6.0 g/l
Al ₂ (SO ₄) ₃ 18 H ₂ O	42 g/l
C ₆ H ₈ O ₇ ·H ₂ O	1.3 g/l
1 l = 1.05 kg	

Reagent 2

C.I. No. 42095	1.4 g/l
C.I. No. 21010	0.04 g/l
C.I. No. 45380	2.9 g/l
H ₃ [P(W ₃ O ₁₀) ₄]	1.7 g/l
CH ₃ COOH	1.0 g/l
C ₂ H ₆ O ₂	22 g/l
1 l = 0.82 kg	

Reagent 3

C₃H₈OH

Reagent 4

C₈H₁₀

Other IVD products

Cat. No. 106887	Papanicolaou's solution 2b Orange II solution for cytology	500 ml, 2.5 l
Cat. No. 106888	Papanicolaou's solution 2a Orange G solution (OG6) for cytology	500 ml, 1 l, 2.5 l
Cat. No. 109253	Papanicolaou's solution 1a Harris hematoxylin solution for cytology	500 ml, 1 l, 2.5 l
Cat. No. 109254	Papanicolaou's solution 1b Hematoxylin solution S for cytology	500 ml, 2.5 l
Cat. No. 109269	Papanicolaou's solution 3d polychromatic solution EA 65 for cytology	100 ml, 2.5 l
Cat. No. 109270	Papanicolaou's solution 3c polychromatic solution EA 65 for cytology	100 ml
Cat. No. 109271	Papanicolaou's solution 3a polychromatic solution EA 31 for cytology	500 ml, 2.5 l
Cat. No. 109272	Papanicolaou's solution 3b polychromatic solution EA 50 for cytology	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. Routine Cytological Staining Techniques: Theoretical Background and Practice, Mathilde E. Boon, Johanna S. Drijver, 1986, Elsevier Science Publishing Company
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. Romeis - Mikroskopische Technik, Editors: Maria Mulisch, Ulrich Welsch, 2015, Springer Spektrum, 19. Auflage
4. Theory and Practice of Histological Techniques, John D Bancroft and Marilyn Gamble, 6th Edition
5. Gynäkologische Zytodiagnostik Lehrbuch und Atlas, Hans-Jürgen Soost, Siegfried Baur, Georg Thieme Verlag Stuttgart, Auflage, 1990



Consult instructions for use



Manufacturer



Catalog number



Batch code



Caution, consult accompanying documents



Use by YYYY-MM-DD



Temperature limitation

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