1.00579.0500
1.07960.0500
1.07961.0100
1.07961.0500
1.00869.0500
1.01691.0025
1.01691.0100
1.03973.0001
1.09016.0100
1.09016.0500

Microscopy

DPX new
non-aqueous mounting medium for microscopy

Entellan®
rapid mounting medium for microscopy

Entellan® new
rapid mounting medium for microscopy

Entellan® new for cover slipper
for microscopy

Canada balsam
for microscopy

M-GLAS®
liquid cover glass for microscopy

Neo-Mount®
anhydrous mounting medium for microscopy

For professional use only

IVD In Vitro Diagnostic Medical Device CE

Intended purpose
These ready-to-use anhydrous mounting media are suited for mounting dehydrated sample material of human origin after these have been fixed and embedded as necessary, and then histologically, bacteriologically, hematologically (enzyme-cytochemically), or cytologically stained and, where applicable, counterstained with other in vitro diagnostic products from our portfolio, thus making them evaluable for further diagnostic procedures. Samples are mounted on slides to enable the specimen material to be examined by light microscopy, at the same time preserving it and thus enabling it to be re-examined many years later.

The appropriate anhydrous mounting medium for the respective application is given in the corresponding instructions for use for our In Vitro Diagnostic staining solutions, solid dyes, and test kits.

Using the auxiliary reagents from our portfolio creates the conditions that enable authorized and qualified investigators to make a correct diagnosis at the end of the diagnostic process. In this regard, auxiliary IVD reagents serve inter alia to process human specimen material (e.g. fixing, decalcifying, dehydrating, clarifying, paraffin-embedding, mounting, microscoping, archiving). When used together with the corresponding staining solutions, this enables the visualization of cellular structures that are otherwise low in contrast, thus rendering them evaluable under the optical microscope. Further examinations may be necessary to reach a definitive diagnosis.

Principle
Mounting media are viscous, clear liquids with brilliant light-refraction properties. They are either won from natural materials or else are made e.g. of acryl-resin mixtures that are dissolved in aromatic solvents such as toluene, xylene, or a xylene substitute (e.g. Neo-Clear®, Cat. No. 109843).

In the last steps of the staining process prior to mounting, the still aqueous, stained specimen slides pass through a series of baths with ascending alcohol concentrations, ultimately ending up in an anhydrous solvent that is also referred to as an intermedium, e.g. toluene, xylene, or a xylene substitute (e.g. Neo-Clear®, Cat. No. 109843).
The anhydrous mounting media in their dissolved form are then dropped onto the stained and dehydrated specimen of human origin, and the slide is covered air-tight with a cover glass. The evaporation of the intermedium causes the mounting medium to harden, forming a solid, clear film under the cover glass, preserving the stained specimen material and thus enabling it to be kept for several years for re-analysis at a later date. As a result of the glass-similar refractive properties of the cover glass, the sample can now be observed under a microscope without any interference.

Thanks to the practical user-friendly dropping bottle, the mounting medium can be easily and safely dropped onto the slide without smearing. The closure of the nozzle ensures that the viscosity of the medium remains constant, meaning that the mounting medium is immediately ready for use.

Sample material
Starting materials are

- formalin-fixed, paraffin-embedded, histologically stained tissue specimens (3 - 5 µm thick paraffin sections)
- fixed and stained cytological smears, e.g. sputum, fine needle aspiration biopsies (FNAB), rinses, imprints, effusions
- air-dried, heat-fixed, and stained smears of bacteriological specimen material, e.g. liquid and solid enrichment cultures of bacteria from body fluids, exsudates, pus
- hematologically processed and stained blood or bone-marrow smears from all regions of the human body.

Reagents

Cat. No.	100579	DPX new non-aqueous mounting medium for microscopy	500 ml
Cat. No.	107960	Entellan® rapid mounting medium for microscopy	500 ml
Cat. No.	107961	Entellan® new rapid mounting medium for microscopy	100 ml, 500 ml, 1 l
Cat. No.	100869	Entellan® new for cover slipper for microscopy	500 ml
Cat. No.	101691	Canada balsam for microscopy	25 ml, 100 ml
Cat. No.	103973	M-GLAS® liquid cover glass for microscopy	500 ml
Cat. No.	109016	Neo-Mount® anhydrous mounting medium for microscopy	100-ml dropping bottle, 500 ml

Specifications
Cat. No. 100579 DPX new, non-aqueous mounting medium for microscopy

is a water-free mounting medium for microscopy, in which the teratogenic ingredient Dibutyl phthalate (DBP) has been avoided.

Refractive index (20°C)	1.518 - 1.521
Viscosity (20°C)	600 - 700 mPa*s

Cat. No. 107960 Entellan®, rapid mounting medium for microscopy

is a water-free mounting medium for microscopy for the permanent mounting of specimen is an anhydrous mounting medium for microscopy that is used for the permanent mounting and storage of specimens, and consists of a polymer made of mixed acrylates dissolved in toluene. As it contains toluene, it should be used with water-free specimens that have been processed with xylene previous mounting.

Refractive index (20°C)	1.492 - 1.500
Density (20°C / 4°C)	0.925 - 0.935 g/cm³
Viscosity (20°C)	60 - 100 mPa*s
Fluorescence	≤ 100 ppb

Cat. No. 107961 Entellan® new, rapid mounting medium for microscopy

is a water-free mounting medium for microscopy that consists of a polymer of mixed acrylates which are solubilized in xylene. Therefore, it should be used with specimens that have been cleared with xylene previous mounting.

Refractive index (20°C)	1.490 - 1.500
Density (20°C / 4°C)	0.94 - 0.96 g/cm³
Viscosity (20°C)	250 - 600 mPa*s

Cat. No. 100869 Entellan® new for cover slipper for microscopy

is a mounting medium for microscopy that is especially suited for standard commercial automated-mounting instruments that operate with glas coverslips. It is used as described in the instruction manual for cover slippers and the ideal amount of mounting agent is determined in a pilot run. There, empty cover glasses and specimen holders, according to the size of the cover glass and the size and thickness of the specimen, are used and these conditions are re-checked when a new bottle of the mounting medium is used. As its viscosity range is adjusted to a narrow range, the effort for new the calibration of the instrument is minimized.

Refractive index (20°C)	1.490 - 1.500
Viscosity (20°C)	500 - 600 mPa*s

Cat. No. 101691 Canada balsam for microscopy

is a commonly used mounting medium for microscopy to prepare permanent slides. It is produced from the resin of the balsam fir tree and its use can be combined with xylene-containing specimens.

Refractive index (20°C)	1.515 - 1.530
Density (20°C / 4°C)	0.980 g/cm^3
Viscosity (20°C)	3000 mPa*s

Cat. No. 103973 M-GLAS®, liquid cover glass for microscopy

is used in cytology instead of a cover glass to ensure that the stained specimens are homogenously covered. A few drops are applied onto the specimen, taking care that the mounting medium is evenly distributed over the specimen material. After the solvent has evaporated, a solid, protective lacquer film remains that ensures that the specimen material is preserved. The M-GLAS® layer is not resilient to immersion oils. In exceptional cases, the time for which the specimen is exposed to the immersion oil should be kept to less than 10 minutes, since otherwise a residue-free removal of the oil can no longer be guaranteed. If the exposure time is longer, it is recommended to remove as much of the immersion oil from the specimen as possible, immerse it in xylene, and to mount it anew.

Refractive index (20°C)	1.490 - 1.500
Density (20°C / 4°C)	0.980 g/cm^3
Viscosity (20°C)	500 - 600 mPa*s
Fluorescence	≤ 250 ppb

Cat. No. 109016 Neo-Mount®, anhydrous mounting medium for microscopy

is an extremely color-stable mounting medium for microscopy, which is produced with solvents based on mixtures of aliphatic hydrocarbons. It contains an aromatic-free substitute for xylene, thus, Neo-Mount® needs to be combined with Neo-Clear® (Cat. No. 109843) exclusively. Xylene must be avoided in the mounting step, as it will cause the slides to become cloudy and streaked. The application of Neo-Mount® is not recommended in fluorescence microscopy for clinical diagnostics. In addition, by placing the dehydrated slides on filter paper for approx. 1 minute prior mounting, any excess of Neo-Clear® could be circumvented, as air bubbles might arise under the coverslip. The same precondition should also be met when mounting specimens using cover-slip machines; in this area, Neo-Clear® can be most efficiently eliminated by incubation of the slides for one minute in an empty slide rack.

Refractive index (20°C)	1.417 - 1.465
Viscosity (20°C)	250 - 350 mPa*s

Also required:

Cat. No.	100974	Ethanol denatured with about 1 % methyl ethyl ketone for analysis EMSURE®	1 l, 2.5 l
Cat. No.	108298	Xylene (isomeric mixture) for histology	4 l
Cat. No.	109843	Neo-Clear® (xylene substitute) for microscopy	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.

The specimen material is processed, stained (and counterstained where applicable), and mounted according to the instructions for use of our In Vitro Diagnostic staining solutions, solid dyes, and test kits.
Histological and cytological specimens must be completely dehydrated before mounting. In the last stage, either xylene or a xylene substitute should be used to prevent the occurrence of turbidity due to aqueous solutions.

Reagent preparation

All listed anhydrous mounting media are ready-to-use, dilution of the mounting media is not necessary.

When exchanging one anhydrous mounting medium in a cover slipper for another, e. g. when switching from Entellan® to Entellan® new, it is absolutely imperative to rinse the entire injection system of the cover slipper with the solvent xylene before using the new mounting medium. Only then can the new mounting medium be used.
If this is not done, oil-drop-shaped artefacts will form on the slide.

Procedure

The mounting medium must contain the same solvent, used for the water-clearing procedure to obtain the optimal optical properties and transparency of the slides.

All mounting procedures should be carried out in a fume hood.

The mounting medium is applied to the horizontal slide, using a glass rod or else directly dropping approx. 0.2 ml of one of the listed mounting media from the dropping bottle. As soon as a homogeneous distribution of the solution is guaranteed, gently add a clean cover glass, so that the space between the slide and cover glass is filled without air bubbles with mounting medium. Allow this setup to dry and harden for about 20 - 30 min in a horizontal position.

When pre-treated in the correct manner, the color of the specimens remains stable.

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

Note

In the case of mounted specimens, the cover slips can be detached again by immersing them in xylene. Specimens that have been mounted with M-GLAS® (Cat. No. 103973) can also be treated in this manner.

Cat. No. 100579 DPX new, non-aqueous mounting medium for microscopy

Solvent	Xylene
Immersion time	approx. 65 hours

Cat. No. 107960 Entellan®, rapid mounting medium for microscopy

Solvent	Xylene
Immersion time	approx. 24 hours

Cat. No. 107961 Entellan® new, rapid mounting medium for microscopy

Solvent	Xylene
Immersion time	approx. 72 hours

Cat. No. 100869 Entellan® new for cover slipper for microscopy

Solvent	Xylene
Immersion time	approx. 72 hours

Cat. No. 101691 Canada balsam for microscopy

Solvent	Xylene
Immersion time	approx. 51 hours

Cat. No. 103973 M-GLAS®, liquid cover glass for microscopy

Solvent	Xylene
Immersion time	approx. 17 hours

Cat. No. 109016 Neo-Mount®, anhydrous mounting medium for microscopy

Solvent	Xylene
Immersion time	approx. 24 hours

Result

The use of these anhydrous, ready-to-use mounting media results in completely airtight specimen slides, the structure and stain pattern of which remains preserved over the long term, enabling them to be microscopically re-analyzed at a later date.

Trouble-shooting

Oil-drop-shaped artefacts on the slide

- When exchanging one anhydrous mounting medium in a cover slipper for another, e. g. when switching from Entellan® to Entellan® new, it is absolutely imperative to rinse the entire injection system of the cover slipper with the solvent xylene before using the new mounting medium. Only then can the new mounting medium be used.

Turbidity of the slides

- As a measure to ensure that the specimen slides retain optimal optical properties and their transparency, in all cases a mounting medium must be used that is based on the solvent / intermediate used for the clarification process. The Neo-Mount® mounting medium is, for example, not compatible with xylene and hence should be used only in combination with the intermediate Neo-Clear®.

No color stability over longer storage times

- A minimum quality of the solvents must be observed.
  Technical-grade solvents may have a relatively high water content, which may result in incomplete dehydration and hence in the stained specimen becoming turbid or decolorized.
- Care must be taken to maintain a minimum quality and dye concentration of the staining solutions as a measure to stabilize the stain of the specimen.

Air bubbles and inclusions

- In all cases a mounting medium must be used that is based on the solvent / intermediate used for the clarification process.
- The volume of the mounting medium applied to the specimen must be carefully monitored (to avoid too much or too little mounting medium).
- The drying times for the specimens must be observed.
  The specimens must be completely dehydrated before microscopy with immersion oil, i. e. always allow the specimens to dry completely and mount thoroughly.
- The evaporation of the solvent after mounting must be borne in mind, and specimen slides must be dried for at least 20 - 30 min.

Technical notes

The microscope used should meet the requirements of a medical diagnostic laboratory.
When using automated-mounting instruments, 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 product is an auxiliary reagent that, when used together with other IVD products such as staining solutions, renders human specimen material evaluable for diagnostic purposes.
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

Cat. Nos. 100579, 107960, 107961, 100869, 103973, 109016:
Store the listed mounting media at +15 °C to +25 °C.

Cat. No. 101691:
Store the Canada balsam for microscopy at +5 °C to +30 °C.

Shelf-life

Cat. Nos. 100579, 107960, 107961, 100869, 103973, 109016:
The listed mounting media 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.

Cat. No. 101691:
The Canada balsam for microscopy can be used until the stated expiry date. After opening the bottle the first time and subsequent storage of the tightly reclosed bottle at +5°C to +30 °C, the medium can be used up to the printed expiry date.

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.	100974	Ethanol denatured with about 1 % methyl ethyl ketone for analysis EMSURE®	1 l, 2.5 l
Cat. No.	100983	Ethanol absolute for analysis EMSURE® ACS, ISO, Reag. Ph Eur	1 l, 2.5 l, 5 l
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.	108298	Xylene (isomeric mixture) for histology	4 l
Cat. No.	109843	Neo-Clear® (xylene substitute) for microscopy	5 l, 25 l

Hazard classification

Cat. Nos. 100579, 107960, 107961, 100869, 101691, 103973, 109016

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.
CAUTION! Cat. Nos. 100579, 107960, and 103973 contain CMR substances. Please observe the corresponding safety instructions given in the safety data sheet.

Main components of the products

Cat. No. 100579

Copolymer in 70 % (w/w) xylene

Cat. No. 107960

Mixed acrylate in 75 % (w/w) toluene
1 l = 0.93 kg

Cat. No. 107961

Polymer of mixed acrylates in 60 % (w/w) xylene
1 l = 0.95 kg

Cat. No. 100869

Polymer of mixed acrylates in 60 % (w/w) xylene
1 l = 0.95 kg

Cat. No. 101691

CAS-No 8007-47-4
1 l = 0.98 kg

Cat. No. 103973

Polymer of mixed acrylates in 73.3 % (w/w) toluene
1 l = 0.91 kg

Cat. No. 109016

Polymer of mixed acrylates in 64 % (w/w) Shellsol 140/165

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.	101646	PAS staining kit for detection of aldehyde and mucosubstances	2x 500 ml
Cat. No.	105174	Hematoxylin solution modified acc. to Gill III for microscopy	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.	111609	Histosec® pastilles solidification point 56-58°C embedding agent for histology	1 kg, 10 kg (4x 2.5 kg), 25 kg
Cat. No.	111885	Gram-color stain set for the Gram staining method	1 set
Cat. No.	115161	Histosec® pastilles (without DMSO) solidification point 56-58°C embedding agent for histology	10 kg (4x 2.5 kg), 25 kg

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. Romeis - Mikroskopische Technik, Editors: Maria Mulisch, Ulrich Welsch, 2015, Springer Spektrum, 19. Auflage
2. Theory and Practice of Histological Techniques, John D Bancroft, Marilyn Gamble, 2008, Churchill Livingstone ELSEVIER, sixth Edition
3. Histological and Histochemical Methods, Theory and practice, J.A. Kiernan, 2015, Scion Publishing Ltd, 5th Edition
4. Gynäkologische Zytodiagnostik, Lehrbuch und Atlas, Hans-Jürgen Soost und Sigfried Baur, Georg Thieme Verlag, 5. überarbeitete Auflage
5. Urinzytologie, Praxis und Atlas, Peter Rathert und Stephan Roth, Springer Verlag, 3. Auflage
6. Gynäkologische Zytodiagnostik, Lehrbuch und Atlas, Hans Friedrich Nauth, Georg Thieme Verlag, 2. aktualisierte Auflage


Consult instructions for use


Manufacturer

Catalog number

Batch code


Caution, consult accompanying documents


Use by YYYY-MM-DD


Temperature limitation

Status: 2021-Apr-07

Merck KGaA, 64271 Darmstadt, Germany,
Tel. +49(0)6151 72-2440
www.microscopy-products.com

EMD Millipore Corporation, 400 Summit Drive
Burlington MA 01803, USA, Tel. +1-978-715-4321

Sigma-Aldrich Canada Co. or Millipore (Canada) Ltd.
2149 Winston Park, Dr. Oakville, Ontario, L6H 6J8
Phone: +1 800-565-1400