

1.00496.0700

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1.00496.8350

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1.00496.9011

Microscopy

Formaldehyde solution 4%, buffered, pH 6.9

(approx. 10% Formalin solution) for histology

For professional use only



In Vitro Diagnostic Medical Device



Intended purpose

This "Formaldehyde solution 4%, buffered, pH 6.9 - (approx. 10% Formalin solution) for histology" is used for human-medical cell diagnosis and serves the purpose of the histological fixation of sample material of human origin.

An optimal fixation in the pre-analytical phase of the histological process is one of the most important preconditions for ensuring the good preservation status of the tissue in question and of the structures and macromolecules it contains and thus for enabling a precise histopathological analysis of specimen material. When used properly, this fixing solution is optimally suited for this purpose.

The product is a ready-to-use 4 % formaldehyde solution, buffered, pH 6.9, corresponding to a so-called "formalin solution 10 %". The term "10 % formalin solution" is a well-established term used in histological circles for solutions of 4 % formaldehyde in water. This has historical reasons.

Used in conjunction with other in vitro diagnostic products from our portfolio, in the pre-analytical phase of the histological process it serves the purpose of preserving tissue structures and macromolecules, which are of decisive relevance in histopathological analyses.

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

The fixation of the specimen tissue using 4 % formaldehyde solution results in the cross-linking of protein structures, thus stabilizing the tissue and preventing its autolysis.

The permeation of the tissue with the aqueous formalin solution takes place passively by diffusion. Depending on the size of the specimen, this process can last several hours. The specimen material must be fixed swiftly to preserve the structure and macromolecules. This is why care must be taken to keep the time before the tissue specimen is immersed in the fixing solution, as well as the diffusion time as short as possible. The diffusion time can be shortened by reducing the size of the tissue specimens to a maximum thickness of 0.5 cm. The diffusion time can be shortened further still by physical measures (e.g. by heating to 37 °C).

This Formaldehyde solution 4 %, buffered, can directly be used as working solution.

Sample material

Specimen from tissue or organs (histological specimens)

Reagents

Cat. No. 100496

Formaldehyde solution 4%, buffered, pH 6.9 (approx. 10% Formalin solution) for histology

350 ml (in 500-ml bottle with wide neck),
700 ml (in 1-l bottle with wide neck),
5 l, 10 l, 10 l Titripac®

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.

Procedure

Wherever possible, the tissue specimen should be immersed in the fixing solution immediately after it has been taken. The ratio of specimen to fixing solution should be 1:10 to 1:50, in any case the tissue specimen must be completely immersed in the fixing solution. Entire organs should be incised or dissected. The sections should have a maximum thickness of 1 cm.

The fixing process for small biopsy specimens in the millimeter range is surely completed after approx. 1 hour. In the case of larger (thicker) specimens, the fixing process can last up to 24 hours.

After the fixation, is first washed in running tap water.

After that the dehydration takes place in ascending alcohol series.

Trouble-shooting

Incomplete fixation of the tissue

- The thickness of the material in ratio to the volume of the fixative should be reconsidered. Optimal fixation result with a ratio of 1:10 - 1:50 of tissue to fixative.
- The evaporation of the fixative should be considered. As Formaldehyde solutions commonly contain solvents (methanol, ethanol), the concentration of the fixative may vary due to evaporation effects. This may influence the quality of fixation.

Precipitation of salts in histoprocessing

- When phosphate-buffered formaldehyde is used, in the first histoprocessing step the fixed tissue specimen should come into contact only with 70 % ethanol, contact with alcohol of higher concentrations (>70 %) may result in the precipitation of the salts.

Technical notes

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

When using histoprocessors, please follow the instructions for use supplied by the supplier of the system and software.

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

Store the Formaldehyde solution 4%, buffered, pH 6.9 - (approx. 10% Formalin solution) for histology at +15 °C to +25 °C.

Shelf-life

The Formaldehyde solution 4%, buffered, pH 6.9 - (approx. 10% Formalin solution) for histology can be used up to the stated expiry date.

After first opening, 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.

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.

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. 103999	Formaldehyde solution min. 37% free from acid stabilized with about 10% methanol and calcium carbonate for histology	1 l, 2.5 l, 25 l
Cat. No. 107164	Paraffin pastilles solidification point about 56-58°C for histology	10 kg (4x 2.5 kg)
Cat. No. 108298	Xylene (isomeric mixture) for histology	4 l
Cat. No. 109843	Neo-Clear® (xylene substitute) for microscopy	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. 115161	Histosec® pastilles (without DMSO) solidification point 56-58°C embedding agent for histology	10 kg (4x 2.5 kg), 25 kg

Hazard classification

Cat. No. 100496

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! Contains CMR substances. Please observe the corresponding safety instructions given in the safety data sheet.

Main components of the product

Cat. No. 100496

CH₂O 40 g/l

M = 30.03 g/mol

Other IVD products

Cat. No. 102439	Eosin Y-solution 0.5%, alcoholic for microscopy	500 ml, 2.5 l
Cat. No. 105174	Hematoxylin solution modified acc. to Gill III for microscopy	500 ml, 1 l, 2.5 l
Cat. No. 105175	Hematoxylin solution modified acc. to Gill II for microscopy	500 ml, 2.5 l
Cat. No. 109844	Eosin Y-solution 0.5% aqueous for microscopy	1 l, 2.5 l
Cat. No. 117081	Eosin Y solution 1%, alcoholic for microscopy	1 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. Romeis - Mikroskopische Technik, Editors: Maria Mulisch, Ulrich Welsch, 2015, Springer Spektrum, 19. Auflage
2. Basiswissen Histologie und Zytologie, Karl Heinz Stein, Hellmut Flenker, 2004, 3. Auflage
3. Theory and Practice of Histological Techniques, John D Bancroft, Marilyn Gamble, 2008, Churchill Livingstone ELSEVIER, sixth Edition
4. Histological and Histochemical Methods, Theory and practice, J.A. Kiernan, 2015, Scion Publishing Ltd, 5th Edition
5. Histotechnik, Gudrun Lang, 2013 Springer Verlag, 2. Auflage
6. Laboratory Manual of Histochemistry, Linda L. Vacca, 1985, Raven Press
7. Staining Procedures, George Clark, 1981, Williams&Wilkins, fourth Edition



Consult instructions for use



Manufacturer



Catalog number



Batch code



Caution, consult accompanying documents



Use by YYYY-MM-DD



Temperature limitation

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