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Microscopy

OSTEOMOLL®

Solution for rapid decalcification (with fixation)
for histology

For professional use only

IVD In Vitro Diagnostic Medical Device



Intended purpose

This product, "OSTEOMOLL® - Solution for rapid decalcification (with fixation) for histology" is used for human cell diagnostics and serves to decalcify (deminate) bone tissue (e.g. punched bone-marrow specimens) and other hard materials and to soften keratinized tissue of human origin, fixing the specimens in the same process.

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

Decalcification methods are necessary for optical microscopic examinations of hard tissue in routine histological procedures.

The material to be decalcified is placed in an excess of OSTEOMOLL® decalcifying solution to deminate (decalcify) and fix it in the same process. The decalcification time is dependent on the size and structural density of the respective tissue, while the composition of the decalcifying solutions also exerts a decisive influence on the process.

Dense bones and hard material are decalcified using inorganic acids, as is the case with OSTEOMOLL®, which dissolve the calcium from the osseous substance, making the tissue soft and cuttable.

The decalcifying solution OSTEOMOLL® is stained blue to make it easier to identify. The dye used is inert in terms of any effect on the material to be decalcified.

Sample material

Unfixed or pre-fixed bone material and hard tissue (e.g. teeth) and keratinized tissue (acuminate warts, nails) for the preparation of paraffin sections in histology

OSTEOMOLL® should not be used for sensitive tissue, e.g. punched iliac crest specimens. OSTEOSOFT®, Cat. No. 101728, should be used for this purpose.

Reagents

Cat. No. 101736
OSTEOMOLL® 1 l, 2.5 l
Solution for rapid decalcification (with fixation) for histology

Alternatively:

Cat. No. 101728 OSTEOSOFT® 1 l, 10 l Titripac®
mild decalcifier-solution for histology

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 OSTEOMOLL® - Solution for rapid decalcification (with fixation) for histology used is ready-to-use, dilution of the solution is not necessary.

Procedure

Place the specimen material to be fixed and decalcified into a vessel (glass or plastic) containing an excess of the ready-to-use OSTEOMOLL® decalcifier-solution. OSTEOMOLL® can still be used for the decalcification step even if the material has already been pre-fixed.

The decalcification time and the quantity of OSTEOMOLL® required are dependent on the size, type, and density of the respective material:

Decalcification of bones, teeth, and other hard tissue

The time required for decalcification can vary considerably depending on the size and state of the specimen tissue; for this reason it is advisable to monitor the condition of the specimen material at regular intervals, see "Determining the end-point of the decalcification process" below. The process can correspondingly take from 6 to 72 hours.

Decalcification of slightly calcified material

Slightly calcified material, e.g. blood vessels, is decalcified after 30 - 60 minutes.

Softening keratinized material

Keratinized tissue, e.g. fingernails and plantar warts, can be made gently cuttable by immersing the cut paraffin-embedded material in OSTEOMOLL® with the cut surface facing downwards for at least 15 - 60 minutes and subsequently rinsing the specimen with tapwater, after which it can be cut in the usual manner.

The new section should be kept to a minimum (loss of material). Section thickness is 5 µm.

Determining the end-point of the decalcification process

The end-point of the decalcification process (the softness of the tissue) is determined by pricking a needle into the material.

The decalcified material is then taken for histoprocessing by the usual methods.

Incomplete decalcification

An incomplete decalcification of the embedded material can be rectified by immersing the cut surface of the block in a vessel containing OSTEOMOLL® for 15 - 20 minutes, subsequently rinsing the material with tap water, and repeating the section procedure.

Result

Decalcified material is cartilaginous or rubber-like in its consistency and exhibits only a weak resistance.

Determining the end-point of the decalcification process

The end-point of the decalcification process is determined by puncturing the material with a needle at a representative site not of decisive relevance for the diagnostic procedure.

Notes on use

Too long a decalcification of the material can result in the destruction of the morphological structure of the specimen and thus negatively affect the subsequent nucleus staining.

Immunohistological methods **cannot** be employed after decalcification with OSTEOMOLL®, since the antigen structures of the material can no longer be detected.

If immunohistological, molecular-biological, or enzymatic tests are required for the diagnosis, then OSTEOSOFT®, Cat. No. 101728, a mild, antigen-preserving decalcifying solution based on EDTA, must be used.

Technical notes

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

When using cryostats or 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 OSTEOMOLL® - Solution for rapid decalcification (with fixation) for histology at +15 °C to +25 °C.

Shelf-life

The OSTEOMOLL® - Solution for rapid decalcification (with fixation) for histology 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.

Any diminution in the color intensity of OSTEOMOLL® has no effect on the decalcification capacity.

Capacity

The quantity of OSTEOMOLL® required is dependent on the size, type, and density of the respective material.

An amount of 30 ml of OSTEOMOLL® that is necessary to completely cover the material can be used twice, for example, provided that the solution is still clear and is not contaminated.

The specimen must previously be cut to a maximum thickness of 5 mm and a surface of 6 cm² (= max. embedding cassette size).

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. 101728	OSTEOSOFT® mild decalcifier-solution for histology	1 l, 10 l Titripac®
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. 101736

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 product components

Cat. No. 101736

CH ₂ O	4 %
HCl	10 %

Other IVD products

Cat. No. 100485	Masson-Goldner staining kit for the visualization of connective tissue with trichromic staining	1 unit
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. 108298	Xylene (isomeric mixture) for histology	4 l
Cat. No. 109016	Neo-Mount® anhydrous mounting medium for microscopy	100-ml drop- ping bottle, 500 ml
Cat. No. 109204	Giemsa's azur eosin methylene blue solution for microscopy	100 ml, 500 ml, 1 l, 2.5 l
Cat. No. 109843	Neo-Clear® (xylene substitute) for microscopy	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. 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. Laboratory Manual of Histochemistry, Linda L. Vacca, 1985, Raven Press



Consult instructions
for use



Manufacturer



Catalog number



Batch code



Caution, consult
accompanying documents



Use by
YYYY-MM-DD



Temperature
limitation

Status: 2021-Apr-16

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