

IVD In vitro diagnostic medical device

CE

Decalcification solution for bones and hard tissues in histology INSTRUCTIONS FOR USE AND TECHNICAL INFORMATIONS

REF Catalogue number: R0060

Introduction

Hard tissue decalcification is necessary for microscopical analysis of the tested sample in standard histological methods. The sample is completely immersed in the decalcifying solution. The length of time needed for demineralization (decalcification) depends on the size and density of the treated sample. Bone and hard tissue decalcification requires inorganic or organic acids, or chelating reagents. Histo-Decal consists of inorganic hydrochloric acid. It rapidly removes calcium, that way softens the tissue and makes it ready for further processing. Test samples are bone and hard tissue (teeth) and keratinized tissue (filiform warts, nails). The light blue color distinguishes the product from other Histo-Line's products for decalcification.

Product description

· HISTO-DECAL - Decalcification solution for bones and hard tissues in histology. Contains formaldehyde and hydrochloric acid.

Other sections and reagents that may be used in staining:

- Fixatives such as neutral buffered formaldehyde solutions: Formaldehyde NB 4%, Formaldehyde NB 10%
- Dehydrating/rehydrating agent, such as alcohol solutions: Histoalcol 70, Histoalcol 80, Histoalcol 95 and Histoalcol 100
- Clearing agents, such as xylene or a substitute, such as HistoClear New agent on the aliphatic hydrocarbons basis
- Infiltration and fitting agent, such as granulated paraffin Lab-O-Wax Plus, Lab-O-Wax 52/54, Lab-O-Wax 56/58.
- Covering agents for microscopic sections and mounting cover glass.
- High-quality glass slides for use in histopathology and cytology.
- Cover glass, dimensions range from 18x18mm to 24x60mm
- Immersion media, such as Immersion oil, Immersion oil, types A, C, FF, 37, or Immersion oil Tropical Grade
- Staining reagents for use in histology

Preparing the sample for decalcification

- · It is **necessary** that the tissue sample first be fixated.
- · Immerse the tissue sample into Histo-Decal and decalcify it completely.

Decalcification

Bone, teeth, hard tissue

The length of time needed for decalcification and amount of used Histo-Decal depends on the size, type and density of the treated sample. 1 x 1 x 0.3 cm dimensions bone (such as the femur) should be calcified for 6-8 hours.

Note: Decalcification of teeth and other hard tissues must be controlled in order to appropriately define the end of the process.

Mildly calcified tissue

Mildly calcified tissue, such as blood vessels, should be calcified for 30-60 min.

Keratinized tissue

Keratinized tissue, such as nails and filiform warts, require mild decalcification by immersing the fitted section into Histo-Decal for 15-60 min. Cross section must be oriented down. The block then must be rinsed with tap water and cut in a usual manner. The cross section is 5 µm thick.

The end of decalcification process

The end of the process is determined by using the needle to puncture the part that is not important for further diagnostic procedure.

Incomplete decalcification

Incomplete decalcification of the fitted sample can be supplemented by immersing the surface of the section into the container filled with Histo-Decal for 15-20 min. Rinse with tap water afterward.

Result

Decalcified tissue is cartilaginous, similar to rubber. Further treatment is conducted with further histological procedures.

Using Histo-Decal leaves antigens of the tissue structures intact and it is possible to conduct further immunohistological methods.

Usability

Use a fresh amount of Histo-Decal solution for each new tissue sample.



Preparing the sample and diagnostics

Use only appropriate instruments for collecting and preparing the samples. Process the samples with modern technology and mark them clearly. Follow the manufacturer's instructions for handling. In order to avoid mistakes, the staining procedure and diagnostics should only be conducted by authorized and qualified personnel. Use only microscope according to standards of the medical diagnostic laboratory.

Safety at work and environmental protection

Handle the product in accordance with safety at work and environmental protection guidelines. Used solutions and out of date solutions should be disposed of as special waste in accordance with national guidelines. Chemicals used in this procedure could pose danger to human health. Tested tissue specimens are potentially infectious. Necessary safety measures for protecting human health should be taken in accordance with good laboratory practice. Act in accordance with signs and warnings notices printed on the product's label, as well as in material safety data sheet.

Storing, stability and expiry date

Keep Histo-Decal in a tightly sealed original packaging at temperature of 15 to 25 °C. Do not keep in cold places, do not freeze and avoid exposing to direct sunlight. Date of manufacture and expiry date are printed on the product's label.

References

- 1. Carson, F. L., Hladik, C. (2009): Histotechnology: A Self-Instructional Text, 3rd ed., Chicago: ASCP Press.
- 2. Kiernan, J.A. (2008): Histological and histochemical methods: Theory and Practice, 4th ed., Bloxham, Scion Publishing Ltd.
- 3. Callis, G., Sterchi, D. (1998): Decalcification of bone: literature review and practical study of various decalcifying agents, methods and their effects on bone histology. J. Histotechnol. 21:49-58.

À	Refer to the supplied documentation	°C A	Storage temperature range	\sum	Number of tests in package	REF	Product code	CE	European Conformity
[]i	Refer to supplied instructions	类	Keep away from heat and sunlight	26	Valid until	LOT	Lot number	***	Manufacturer
IVD	For in vitro diagnostic use only		Keep in dry place	4	Caution - fragile				





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