BIOGNOST®

OSTEOFAST 1

IVD *In vitro* diagnostic medical device CE

Light blue fixative and decalcifying solution for bone and hard tissue in histology
INSTRUCTIONS FOR USE

REF Catalogue number: OF1-OT-1L (1000 ml) OF1-OT-2.5L (2500 mL)

Introduction

It is necessary to conduct decalcification of bones and other hard tissue for the purpose of microscopic analysis of the sample during regular histological processing. 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. OsteoFast 1 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).
OsteoFast 1's light blue color distinguishes the product from other BioGnost's products for decalcification (light yellow OsteoFast 2 and colorless OsteoSens). Because of this, it can also be distinguished from other fixatives and solvents used in histological laboratories.

Product description

- **OSTEOFAST 1** - Light blue fixative and decalcifying solution for bone and hard tissue in histology. Contains formaldehyde and hydrochloric acid.

Other sections and reagents that may be used in staining:

- Fixatives such as BioGnost's neutral buffered formaldehyde solutions: Formaldehyde NB 4%, Formaldehyde NB 10%
- Dehydrating/rehydrating agent, such as BioGnost's alcohol solutions: Histanol 70, Histanol 80, Histanol 95 and Histanol 100
- Clearing agents, such as BioClear xylene or a substitute, such as BioClear New agent on the aliphatic hydrocarbons basis
- Infiltration and fitting agent, such as BioGnost's granulated paraffin BioWax Plus56/58, BioWax 52/54, BioWax 56/68, BioWax Blue, BioWax Micro.
- Covering agents for microscopic sections and mounting cover glass, such as BioGnost's BioMount, BioMount High, BioMount M, BioMount New, BioMount New Low, BioMount DPX, BioMount DPX High, BioMount DPX Low, BioMount DPX Low Eco, BioMount C, BioMount Aqua
- High-quality glass slides for use in histopathology and cytology, such as VitroGnost SUPER GRADE, VitroGnost COLOR or one of more than 30 models of BioGnost's VitroGnost glass slides
- VitroGnost cover glass, dimensions range from 18x18mm to 24x60mm
- BioGnost's immersion media, such as Immersion oil, Immersion oil, types A, C, FF, 37, or Immersion oil Tropical Grade
- BioGnost's 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 OsteoFast 1 and decalcify it completely.

Decalcification

Bone, teeth, hard tissue
The length of time needed for decalcification and amount of used OsteoFast 1 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 OsteoFast 1 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 OsteoFast 1 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.

Note

If the process of decalcification lasts for too long, it can lead to destruction of morphological structure of tissue and in turn negatively influence the consequent nucleus staining. Immunohistological methods cannot be applied after decalcification using OsteoFast 1 because blood antigens are no longer detectable. If immunohistological methods are necessary for the diagnosis, you should use OsteoSens (EDTA-based decalcifying solution that does not damage the blood antigens).

Usability

30 ml of OsteoFast 1 (enough to cover the entire section) is sufficient for 2 uses. The solution must be clear and uncontaminated.

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 BioGnost's material safety data sheet.

Storing, stability and expiry date

Keep OsteoFast 1 in a tightly sealed original packaging at temperature of +15°C 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.

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	Refer to the supplied documentation	°C	Storage temperature range	Σ	Number of tests in package	REF	Product code	CE	European Conformity		BIOGNOST Ltd. Medjugorska 59 10040 Zagreb CROATIA www.biognost.com
	Refer to supplied instructions		Keep away from heat and sunlight		Valid until	LOT	Lot number		Manufacturer		
IVD	For *in vitro* diagnostic use only		Keep in dry place		Caution - fragile					CE	