BIOGNOST®

# OSTEOSENS

CE IVD *In vitro* diagnostic medical device Classified acc. to Regulation (EU) 2017/746 - **Class A** device

## Decalcifying solution for sensitive calcified tissues in histology

## INSTRUCTIONS FOR USE

| **BASIC UDI number** | 385889212HPC30799PROCYU | |
|---|---|---|
| **EMDN code** | W01030799 | |
| REF **Catalog number** | **Volume** | **UDI-DI number** |
| OS-OT-1L | 1000 mL | 03858888821470 |
| OS-OT-2.5L | 2500 mL | 03858890007206 |

### Intended use and test principle

Hard tissue decalcification is necessary for microscopical analysis of the tested sample in standard histological methods. The length of time needed for demineralization (decalcification) depends on the size and density of the treated sample. During decalcification of sensitive calcified tissue, a reagent such as OsteoSens is used. Based on the chelating compound ethylenediaminetetraacetic acid (EDTA), it binds calcium ions, thereby softening the tissue and preparing it for further processing. The samples examined include sensitive hard tissues such as the iliac crest (lat. Crista iliaca) and keratinized tissue such as blood vessels. By using the OsteoSens decalcification agent, the antigenic structures of the tissue are preserved, making it possible to perform further immunohistological methods.

### Product description

- **OSTEOSENS** – Decalcification solution for sensitive calcified tissue in histology. It contains ethylenediaminetetraacetic acid (EDTA).

### Additional reagents and materials that can be used in decalcification method

- Fixatives such as BioGnost's neutral buffered formaldehyde solutions: Formaldehyde NB 4%, Formaldehyde NB 10%

### Decalcification procedure

### Preparing the tissue sample for decalcification

- It is **necessary** that the tissue sample first be fix (Formaldehyde NB 4%, Formaldehyde NB 10%**)**
- Immerse the tissue sample completely in OsteoSens so that its entire surface is covered

The crest of the ilium (Latin Crista iliaca) and other hard tissues

The length of time needed for decalcification and amount of used OsteoSens depends on the size, type and density of the treated sample. A bone with dimensions of 15 x 9 x 3 mm separated from the crest of the ilium should be immersed in approximately 50 mL of OsteoSens for 18-24 hours.

Compact, calcified tissue

A compact, calcified piece of tissue (1.5 x 1 x 0.3 cm) takes 48-72 hours to decalcify.
**Note:** If the further procedure does not require conducting immunohistological method of processing, decalcification can be sped up by using BioGnost's OsteoFast solution for fixation and decalcification of bones and hard tissues in histology.

The end of decalcification process

For example, during the crest of the ilium decalcification, the process is finished when the sample floats in the solution.

### Result

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

### Usability

Use a fresh amount of OsteoSens solution for each new tissue sample.

### Limitations

This product is intended for professional laboratory use for diagnostic purposes only. Deviations from the decalcification procedure described in this Instruction for use may cause differences in staining results.

### Sample preparation and diagnostics

Use only appropriate instruments for collecting and preparing the samples. Process the samples using modern technology and mark them clearly. Be sure to follow the manufacturer's handling instructions. To avoid errors, staining, mounting of the slides, and diagnosis can only be carried out by qualified personnel. Use a microscope equipped according to medical diagnostic laboratory standards. To avoid an incorrect staining result, it is advised to use a positive and negative control.
If a serious incident occurs during use of this product or as a result of its use, please report it to the manufacturer or authorized representative and competent authority.

### Safety at work and environmental protection

Handle the product in accordance with occupational health and environmental protection guidelines. Used and expired solutions must be disposed of as special waste following national guidelines. Reagents used in this procedure can pose a danger to human health. The examined tissue samples are potentially infectious, and it is necessary to take the measures needed to protect human health in accordance with the guidelines of good laboratory practice. It is mandatory to read and act according to the information and warning signs printed on the product label and in the Safety Data Sheet, which is available on request.

**Storage, stability, and shelf life**

Upon receipt, store the product in a dry place and well-closed original packaging at a temperature of +15 °C to +25 °C. Do not freeze or expose to direct sunlight. After first opening, the product can be used until the specified expiry date, if stored properly. The expiration date is printed on the product 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.


| **Warnings and precautions regarding the materials contained in the product:** | | |
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|  | H319 | Causes serious eye irritation. |
| | P280 | Wear protective gloves/protective clothing/eye protection/face protection. |
| | P305+P351+P338 | IF IN EYES: rinse carefully with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing. |
| | P308+P313 | IF exposed or concerned: get medical advice/attention. |

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| | Manufacturer | LOT | Batch code | | Consult instructions for use | CE | European conformity |
| | Date of manufacture | REF | Catalogue number | | Caution | UDI | Unique device identifier |
| | Use-by date | °C | Temperature limit | IVD | *In vitro* diagnostic medical device | | |


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| Version | Description / reason for change | Date |
|---|---|---|
| 8 | Revised acc. to Regulation (EU) 2017/746 - IVDR | 25.02.2026. |