

# BIOFIX HD



IVD *In vitro* diagnostic medical device

Classified acc. to Regulation (EU) 2017/746 - **Class A** device

## Fixative that enables fast fixation and better visualization of lymph nodes

### INSTRUCTIONS FOR USE

<b>BASIC UDI number</b>	385889212HPC30705FIXAQX		
<b>EMDN code</b>	W01030705		
<b>REF</b>	<b>Catalog number</b>	<b>Volume</b>	<b>UDI-DI number</b>
	BFHD-500	500 mL	03858890003536
	BFHD-1L	1000 mL	03858890003543
	BFHD-5L	5000 mL	03858892121702



#### Intended use and test principle

BioFix HD fixative is formulated according to the Hartmann/Davidson formula. It contains acetic acid, alcohol and formalin, and is used for fixing and preserving tissue samples. When processing colon and breast tissue samples, and when lymph node detection is required, it is recommended to leave the sample to fix overnight. BioFix HD infiltrates the tissue rapidly while keeping the morphological details well preserved. It is also suitable for fixing samples to be used in immunohistochemistry. BioFix HD's fixation results are similar to those of the Bouin's solution. As opposed to Bouin's solution, BioFix HD does not contain the toxic picric acid, it is safer to use and causes less tissue shrinkage.

#### Product description

- **BIOFIX HD** – alcoholic fixative that contains formalin and acetic acid for fast fixation of samples and visualization of lymph nodes

#### Recommended fixation time:

- Small biopsies – up to 24 hours
- Mouse eyes - up to 12 hours
- Rat and rabbit eyes - up to 24 hours
- Large eyes (of humans or larger animals) - 48-72 hours
- Lymph nodes - up to 24 hours; lymph nodes of up to 5 mm or smaller need to be cut in half. Lymph nodes larger than 5 mm need to be cut to pieces of up to 2-3 mm.

#### Sample processing:

- Immerse fresh tissue sample into BioFix HD immediately after surgical excision. Fixative volume needs to be at least 15-20 times larger than sample volume  
Note: if sample was previously immersed in 4% neutral buffered formalin, it needs to be thoroughly rinsed under tap water before transferring it to BioFix HD
- Keep samples in BioFix HD until processing or up to 72 hours  
Note: it is not recommended to store tissue in BioFix HD; if long – term storage is required, after 72 hours transfer the sample from BioFix HD to 4% neutral buffered formalin or 70% alcohol
- Rinse the tissue fixed in BioFixom HD in distilled/demineralized water for 1-2 minutes.
- Store fixed tissue until processing in 4% neutral buffered formalin or in 70% alcohol (BioGnost's Histanol 70)
- Process the tissue according to standard laboratory procedure

#### Limitations

This product is intended for professional laboratory use for diagnostic purposes only. Deviations from the fixing 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, process of fixing, processing 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. Eltoun, Isam, Jerry Fredenburgh, Russell Myers and William Grizzle. "Introduction to the Theory and Practice of Fixation of Tissues." The Journal of Histotechnology 24.3 (2001): 173-190.
2. Cook, D. J. (2006): Cellular pathology, 2. izd. Banbury: Scion Publishing Ltd.

3. Kiernan, J. A. (2008) Histological and histochemical methods, 4th ed. Bloxham: Scion Publishing Ltd.
4. Latendresse, John R., Alan R. Warbritton, Henning Jonassen, and Dianne M. Creasy. "Fixation of Testes and Eyes Using a Modified Davidson's Fluid: Comparison with Bouin's Fluid and Conventional Davidson's Fluid." Toxicologic Pathology(2002): 524-33.

Warnings and precautions regarding the materials contained in the product:	
	<p>H225 Highly flammable liquid and vapor.            H302 Harmful if swallowed.            H312 Harmful in contact with skin.            H314 Causes severe burns and eye damage.            H317 May cause an allergic skin reaction.            H332 Harmful if inhaled.            H341 Suspected of causing genetic defects.            H350 May cause cancer.</p> <p>P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.            P301+P310 IF SWALLOWED: call immediately POISON CENTER/doctor.            P302+P352 IF ON SKIN: wash with plenty of water            P304+P340 IF INHALED: remove person to fresh air and keep comfortable for breathing.            P305+351+P338 IF IN EYES: rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.            P308+313 IF exposed or concerned: get medical advice/attention.</p>

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 Manufacturer	 Batch code	 Consult instructions for use	 <i>In vitro</i> diagnostic medical device
 Date of manufacture	 Catalogue number	 Caution	 European conformity
 Use-by date	 Temperature limit	 Contains hazardous substances	 Unique device Identifier

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Version	Description / reason for change	Date
5	Revised in acc to Regulation (EU) 2017/746 - IVDR	06.02.2026.