BIOGNOST®

FORMALDEHYDE 4%

CE IVD *In vitro* diagnostic medical device Classification according to Regulation (EU) 2017/746 - **Class A** device

Stabilized 10% formalin solution

INSTRUCTIONS FOR USE

Basic UDI-DI	385889212HPC30705FIXAQX				
EMDN code	W01030705				
REF **Catalog number**	**Volume**	**UDI-DI**	REF **Catalog number**	**Volume**	**UDI-DI**
F4-1L	1 L	03858888828943	F4-10L	10 L	03858890007725
F4-5L	5 L	03858892124178	F4-20L	20 L	03858890007732

Intended use and test principle

Quality fixation is a prerequisite for an accurate histological diagnosis of the sample. Tissue samples must be immersed in an appropriate fixative as soon as possible after sampling, as timely fixation prevents autolysis, putrefaction, and other undesirable cellular changes. Although there are a large number of histological fixative formulations, as well as several types of formaldehyde fixatives, formaldehyde solutions at concentrations of 4 to 10% are most commonly used worldwide due to their simple and universal application. Fixation in formaldehyde solution leads to the formation of cross-links (methylene bridges) between proteins, thereby preserving the tissue structure in a state similar to that of *in vivo*. Properly fixed tissue can withstand further histological processing and staining without difficulty. Formaldehyde 4% corresponds to 10% formalin, where the difference is purely terminological, while the composition of the solutions is identical. Formaldehyde 4% is suitable for fixation of biopsy material, smaller tissue samples, and long-term storage of fixed samples. It is a colorless solution with a characteristic odor, ready for use. The addition of methyl alcohol prevents polymerization of formaldehyde. It is a primary tissue fixative, and samples can be fixed and/or stored for extended periods without significant tissue hardening. It is suitable for use in all automatic tissue processing devices as well as for manual histological techniques, and is conveniently packaged in 1-liter bottles and 5, 10, and 20-liter canisters. It is suitable for use in automatic tissue processors as well as in manual histological procedures.

Product description

- **FORMALDEHYDE 4%** - stabilized 10% formalin solution

Limitations

This product is intended for professional laboratory use for diagnostic purposes only.
If tissue is not well or properly preserved and stabilized by the fixation procedure or if no suitable fixative is selected, all subsequent tissue processing procedures and diagnostics will be of mediocre or unusable quality. If the fixative is not appropriate or the ratio of tissue volume to the volume and concentration of the active substance in the fixative is not appropriate, inadequate fixation, tissue deterioration and consequently misdiagnosis may occur. Certain tissues and tissue structures cannot be adequately fixed in 10% Formaldehyde. If there is doubt about the correct selection of fixatives for a particular type of tissue, it is necessary to consult an experienced histotechnician or look for the necessary information in the professional literature listed at the end of this Instructions for Use. The user is responsible for selecting the appropriate fixative and fixation conditions according to the type of tissue.

Note:

The selection of fixatives prior to fixation must be consistent with planned histological, histochemical or immunohistochemical diagnostic methods.

Always wear protective gloves when handling formaldehyde solution and fixed tissue. Rooms where buffered formaldehyde is used should be well ventilated using an exhaust fan or fume hood to remove toxic fumes. Additional safety information can be read in the Safety Data Sheet of this product

Fixation procedure

- Immerse the tissue into the fixative as soon as possible after sampling
- If it is not possible to immediately place the tissue in a fixative, it should be kept moist and stored cool. Saline or isotonic PBS solution may be used for this purpose
- The tissue sample inside the container in which it is to be fixed must not be bent or folded. Samples should be 3 to 5 mm wide for adequate fixation. All samples must be clearly marked
- During fixation, the tissue must be immersed in a sufficient amount of fixative. The ideal ratio of fixative to tissue should be in the range of 20 to 50 parts of fixative to 1 part of tissue. This applies particularly to Formaldehyde 4%, while the ratio when using Formaldehyde 10% may be lower. The ratio of fixative to tissue should not be less than 10 to 20 parts of fixative to 1 part of tissue
- If an entire organ is fixed, the fixative should be injected into the organ itself or the organ can be cut into thin sections to allow the solution to penetrate the tissue as thoroughly as possible
- The fixative can be poured into hollow organs, and they can also be filled with gauze soaked in the fixative before immersion in the container with the fixative. Certain organs, such as the colon, may be opened and secured to a flat surface prior to immersion in the fixative. Encapsulated tissue must be processed by qualified personnel in order for the fixation to be effective
- The time required for fixation can vary from only a few hours to a few weeks. Fixation time depends on the tissue type, sample size and thickness, fixation temperature, the ratio of tissue volume to fixative, and the formaldehyde concentration in the fixative
- Selection of formaldehyde concentration and duration of fixation should be determined in accordance with histotechnological norms and experience. In case of fixation of a larger tissue sample or organ, fixation takes 24 hours, but a longer fixation period is also possible. The fixation time can be shortened by fixing the sample in an incubator or in a microwave oven

- After fixation is completed, the fixed tissue should be cut to a thickness of no more than 3 to 5 mm and placed in a tissue processing device for paraffin treatment

Sample preparation and diagnostics

Use only appropriate instruments for collecting and preparing the samples. Process the samples using modern technology and mark them clearly. It is necessary to follow the manufacturer's instructions for use. To avoid errors, the process of fixation, tissue processing, staining, and diagnosis can only be carried out by qualified personnel. Use a microscope that complies with medical diagnostic laboratory standards.
If a serious incident occurs during use or as a result of its use, please report it to the manufacturer and/or authorized representative and the 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 in accordance with national guidelines. Reagents used in this procedure can pose a danger to human health. The examined tissue samples are potentially infectious, therefore it is necessary to implement human health protection measures in accordance with good laboratory practice guidelines. It is mandatory to read and act according to the information and warning signs printed on the product label, instructions for use, 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 in 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 production date and expiration date are printed on the product label.

References

1. Carson, F. L., Hladik, C. (2009): *Histotechnology: A Self-Instructional Text*, 3rd ed., Chicago: ASCP Press
2. Cook, D. J. (2006): *Cellular Pathology*, 2nd ed., Banbury: Scion Publishing Ltd.
3. Kiernan, J.A. (2008): *Histological and Histochemical Methods, Theory and Practice*, 4th ed., Scion Publishing Ltd, Banbury.

Warnings and precautions regarding the materials contained in the product:		
	H315	Causes skin irritation.
	H317	May cause an allergic skin reaction.
	H319	Causes serious eye irritation.
	H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
	H341	Suspected of causing genetic defects.
	H350	May cause cancer.
	P201	Obtain special instructions before use.
	P202	Do not handle until all safety precautions have been read and understood.
	P261	Avoid breathing dust/fume/gas/mist/vapors/spray.
	P280	Wear protective gloves/protective clothing/eye protection/face protection.
	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+P351+P338	IF IN EYES: Rinse cautiously 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	IVD	*In vitro* diagnostic medical device
	Date of manufacture	REF	Catalogue number		Caution	CE	European conformity
	Use-by date	°C	Temperature limit		Contains hazardous substances	UDI	Unique device identifier

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Version	Description / reason for change	Date
4	Revised in accordance with Regulation (EU) 2017/746 – IVDR and Commission Delegated Regulation (EU) 2024/2564	16.07.2026.