

FORMALDEHYDE 37% FOR USE IN HISTOLOGY



IVD In vitro diagnostic medical device

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

100% formalin solution stable at low temperatures

Synonym: Concentrated formalin

INSTRUCTIONS FOR USE

BASIC UDI number		385889212HPC30705FIXAQX					
EMDN code		W01030705					
REF	Catalog number	Volume	UDI-DI number	REF	Catalog number	Volume	UDI-DI number
	F37H-1L	1 L	03858890002409		F37H-10L	10 L	03858890002645
	F37H-2.5L	2.5 L	03858892123027		F37H-20L	20 L	03858890005677
	F37H-5L	5 L	03858890001198				



Introduction

High quality fixation is a prerequisite for an accurate histological diagnosis of the sample. Tissue samples should be immersed in the appropriate fixative as soon as possible after sampling, as timely fixation prevents autolysis, rotting and other undesirable cellular changes. Although there are a large number of histological fixative formulations, as well as several types of formaldehyde fixatives, neutrally buffered formaldehyde solutions at concentrations of 4 to 10% are most commonly used in the world due to their simple and universal application. 37% formaldehyde is used in cell diagnosis to fix histological samples of human origin, however the solution must be diluted to 4% formaldehyde and 10% formalin before use (1:10 dilution). BioGnost's 37% formaldehyde for histology contains methanol (up to 10%), which prevents the polymerization of formaldehyde into paraformaldehyde at low temperatures or during prolonged storage.

Product description

- **FORMALDEHYDE 37% FOR USE IN HISTOLOGY** - 100% formalin solution stable at low temperatures

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 digester to remove toxic fumes. Additional safety information can be read in the Safety Data Sheet of this product

Preparation of 4% formaldehyde solution (10% formalin solution) ready for use

- To prepare 1000 mL of 4% formaldehyde solution, mix 100 mL of 37% formaldehyde solution with 900 mL of phosphate buffer. Measure the pH and adjust it if it gets outside the neutral range (6.8 – 7.2)

Fixation procedure (using 4% formaldehyde)

- Immerse the tissue into the fixative as soon as possible after sampling
- If it is not possible to immediately place the tissue in the fixative, it should be kept moist and kept cool. Saline or isotonic PBS solution may be used.
- 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 ratio of fixative to tissue sample must be between 20:1 and 50:1. 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 parts to allow the solution to penetrate the tissue as best as possible
- The fixative can be poured into the hollow organs, and they can also be filled with gauze soaked in the fixative before immersion into 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, fixation temperature, the ratio of sample volume to fixative, and the formaldehyde concentration
- 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 sample of tissues or organs, fixation takes 24 hours, but a longer fixation period is also possible. The fixation time can be shortened by fixing the sample in the incubator or in the microwave oven
- After the 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. The first alcohol solution that comes into contact with the tissue should be 70%, to avoid precipitation of phosphate salts that are neutrally buffered with formaldehyde 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 well fixed in a formalin fixative. If there is doubt about the correct selection of fixatives for a specific 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 Instruction. The user is responsible for selecting the appropriate fixative and fixation conditions according to the type of tissue. Methanol, which is found in formaldehyde as a stabilizer, can adversely affect and impair the quality of the native structure of proteins and membranes/lipids and is not recommended for immunohistochemical staining methods, immunofluorescence and electron microscopy.

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 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, 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 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 production date and expiration date are printed on the product label.

References

- 1. Bancroft, J.D. and Gamble, M. (2013) *Theory and Practice of Histological Techniques*. 7th Edition, Churchill Livingstone of Elsevier, Philadelphia, 172-186.
- 2. Carson, FL, Hladik, C. (2009): *Histotechnology: A Self-Instructional Text*, 3rd ed., Chicago: ASCP Press
- 3. Cook, D.J. (2006): *Cellular Pathology*, 2nd ed., Banbury: Scion Publishing Ltd.
- 4. Kiernan, JA (2008): *Histological and Histochemical Methods, Theory and Practice*, 4th ed., Scion Publishing Ltd, Banbury.

Warnings and precautions regarding the materials contained in the product:		
	H301	Toxic if swallowed.
	H311	Toxic in contact with skin.
	H331	Toxic if inhaled.
	H314	Causes severe skin burns and eye damage.
	H317	May cause an allergic skin reaction.
	H341	Suspected of causing genetic damage.
	H350	May cause cancer.
	P280	Wear protective gloves/protective clothing/eye protection/face protection.
	P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor.
	P303+P361+P353	IF ON SKIN (or hair): immediately take off all contaminated clothing. Rinse the skin with water (shower).
	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		Batch code		Consult instructions for use		In vitro diagnostic medical device
	Date of manufacture		Catalogue number		Caution		European conformity
	Use-by date		Temperature limit		Contains hazardous substances		Unique device identifier

 **BioGnost Ltd.**
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Version	Description / reason for change	Date
4	Aligned with Commission Delegated Regulation (EU) 2024/2564	16.07.2026