

BIOFIX GL



IVD In vitro diagnostic medical device

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

Formalin substitute for histology

INSTRUCTIONS FOR USE

BASIC UDI-DI	385889212HPC30705FIXAQX				
EMDN code	W01030705				
[REF] Catalogue number	Volume	UDI-DI number	[REF] Catalogue number	Volume	UDI-DI number
BFGL-40-20	25 x 20 mL	03858890008043	BFGL-1L	1000 mL	03858892122495
BFGL-60-35	25 x 35 mL	03858890008050	BFGL-2.5L	2500 mL	03858892122235
BFGL-500	500 mL	03858892122488	BFGL-5L	5000 mL	03858892122501

Intended use and test principle

A prerequisite for accurate histological diagnosis is good fixation of tissue specimen. After sampling, tissue samples must be fixed as soon as possible with an optimally selected fixative. Good fixation will prevent autolysis, putrefaction and other undesirable cellular changes. BioFix GL is an optimized glyoxal-based formalin substitute for histology. Thus, BioFix GL meets the need to replace formalin fixatives with less toxic/carcinogenic alternatives to protect healthcare workers and the environment. At the same time, the quality of the histopathological diagnosis is not compromised. BioFix GL provides preservation of tissue and cell morphology, as well as better compatibility for immunohistochemistry and methods that require nucleic acid preservation. BioFix GL is suitable for fixation of all tissue types and sizes (from biopsy material and smaller tissue samples to larger samples). Fixation with BioFix GL solution is compatible with all protocols for tissue processing and staining.

Description of the product

- **BIOFIX GL** – an optimized glyoxal-based formalin substitute for histology

Tissue fixation instructions

- Always wear protective gloves when handling BioFix GL fixative or fixed tissue. Laboratory where the fixative is used should be well ventilated using an exhaust fan or fume hood. Additional safety information can be read in the Safety Data Sheet of this product.
- Immerse the tissue in a container with BioFix GL fixative immediately after sampling or as soon as possible. If the tissue cannot be immediately placed in the fixative, it should be kept moist and cool. The tissue sample inside the container in which it will be fixed must not be bent or folded. Samples should be a maximum of 6 mm thick for adequate fixation.
- All samples must be clearly marked.
- During fixation, the tissue must be immersed in sufficient volume 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. The ratio of fixative to tissue should never be less than 20 parts of fixative to 1 part of tissue.
- If whole organs are fixed, the fixative should be injected into the organ itself or the organ can be cut into thin sections so that the solution penetrates the tissue.
- The fixative can be poured into the hollow organs, and they can also be filled with gauze soaked in the fixative before being immersed in the container with the fixative. Some organs, such as the colon, can be opened and fixed on a flat plate before immersion in fixative. The encapsulated tissue needs to be professionally processed in order for the fixation to be effective.
- The time required for fixation can vary from just a few hours to several weeks depending on the type of tissue and the size and thickness of the sample, temperature fixation, tissue volume ratio and fixation.

Note

If the tissue is not well or properly preserved by the fixation or if the appropriate fixative is not used, all subsequent tissue processing and diagnostics will be of poor quality. If the ratio of tissue volume to volume of fixative or fixation time is not adequate, insufficient fixation and tissue deterioration may occur leading to false diagnosis. In order to avoid errors, the appropriate fixative must be applied in accordance with the histopathology standards.

Limitations

This product is intended for professional laboratory use for diagnostic purposes only. Deviations from the fixation procedure described in this Instruction for use may impair the quality of histological sample fixation.

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 a false result, it is recommended 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, transport, 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. 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:	
	H317 May cause an allergic skin reaction. P280 Wear protective gloves/protective clothing/eye/protection/face protection. P302+P352 IF ON SKIN: Wash with plenty of water. P308+P313 IF exposed or concerned: Get medical advice/attention.

BFGL-X, V4-EN4, 11.09.2026. MŠ/IŠP

	Manufacturer		Batch code		Consult instructions for use		European conformity
	Date of manufacture		Catalogue number		Caution		Unique device identifier
	Use-by date		Temperature limit		In vitro diagnostic medical device		

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Version	Description / reason for change	Date
4.	Revision of warnings and precautions and catalogue numbers	11.09.2026.