

BIOFIX GL

IVD *In vitro* diagnostic medical device



Glyoxal-based fixative for use in histology

INSTRUCTIONS FOR USE

REF Product code: BFGL-500 (500 mL) BFGL-1L (1000 mL) BFGL-5L (5000 mL) BFGL-10L (10000 mL)

Introduction

An impeccable sample fixation is a prerequisite for a correct histological diagnosis. Tissue samples must be immersed in an optimally chosen fixative immediately after sampling, because a timely fixation will prevent autolysis, putrefaction and other unwanted cellular changes. Glyoxal-based fixatives are an innovation in the field of histopathology, and they're characterized by non-toxicity and lesser environment impact compared to formalin fixatives. Tissue fixing with buffered glyoxal solution results in preserved tissue and cell morphology as well as better compatibility for further use of immunohistochemistry methods and methods requiring nucleic acids preservation. If fixated properly, the tissue sample can withstand additional histological tissue processing and staining. The solution is suitable for fixing bioptic specimens and smaller tissue samples. It is a light yellow solution with a characteristic odor, ready for use. Optimal molarity buffer is used for securing permanent pH range for optimal fixation, and by adding ethyl alcohol reactions get accelerated; this is why glyoxal-based fixatives require shorter fixing periods. Suitable for use in all automated tissue sampling devices as well as for manual histology techniques.

Product description

- **BIOFIX GL** - buffered and stabilized glyoxal solution. Suitable for fixing smaller tissue samples and biopsy materials.

Fixating guidelines

If the tissue was not properly stored or stabilized during the fixation process, or if an unsuitable fixative was used, all the subsequent procedures in tissue processing and diagnostics will be of mediocre quality or useless. If the fixative is of inferior quality, pH value over its physiological bounds, or if the volume ratios between tissue and active substance in the fixative are not suitable, improper fixation can occur as well as tissue degradation and misdiagnosis. For that reason the fixative must be produced in accordance with the *in vitro* diagnostic devices norms and must bear the CE marking of conformity, and the processes of fixating, processing and staining must be carried out by a qualified person (histotechnician). To avoid mistakes during work, a suitable fixative should be applied in accordance with standard histotechnology norms. If there is doubt regarding fixative choice and possibility that the tissue sample will not be satisfactorily preserved, it is necessary to consult an experienced histotechnician.

Fixing instructions

- Always wear protective gloves while handling glyoxal solution and fixed tissue samples. The rooms in which the fixative is being used should be well ventilated by using an exhaust fan or a digester in order to remove toxic evaporation. Additional security information can be found in the Material Safety Data Sheet of this product.
- Before the process a fixative should be chosen in accordance with the subsequent histological, histochemical or immunohistochemical diagnostic methods. If BioFix GL was chosen as an optimal fixative, the tissue sample should be immediately immersed in the solution container.
- The sample should be fixated as soon as possible in order to prevent autolysis, putrefaction, and other changes. If it is not possible to put the sample in the fixative immediately, it is advised to maintain it moist and keep it in a cold place. The sample should not be bent or folded in the fixation container. Samples should be 3 to 6 mm in width for a proper fixation. All the samples should be clearly marked.
- During the fixation the sample should be immersed in an adequate amount of fixative. An optimal ratio should be 10 to 30 parts of fixative to 1 part of tissue. The fixative to tissue sample ratio should never be lower than 10 parts of fixative to 1 part of tissue.
- If an entire organ is being fixated, the fixative should be injected into the organ or it can be cut into thin slices so that the solution can permeate the tissue thoroughly.
- The fixative can also be poured into hollow organs, and before immersing into the fixative container they can be filled with gauze soaked with the fixative. Certain organs, such as the colon, can be opened and pinned on a board before immersing in the fixative. Encapsulated tissue should be processed by an expert in order for the fixation to be successful.
- Fixation time can vary from a few hours to a few weeks. That depends on the type of tissue and sample thickness, fixing temperature, tissue and fixative volume ratio.
- Selection of fixative and fixation time must be determined in accordance with the norms of histotechnology and professional experience. In case of fixation of a larger tissue sample or an organ, fixation can last up to 24 hours or even more. The process can be shortened by fixating the sample in an incubator or a microwave oven.

If the tissue has not been dimensioned for processing prior to fixation, after the fixation it should be processed down to thickness of 3-5 mm. Processing and further fixed tissue treatment are conducted in the same manner as tissue samples fixed in formalin.

Preparing the sample and diagnostics

Use only appropriate instruments for collecting and preparing the samples. Process the samples with modern technology and mark them clearly. Follow the manufacturer's instructions for use. In order to avoid mistakes, the covering or mounting and staining procedure as well as diagnostics should only be conducted by authorized and qualified personnel. Use only microscope according to standards of the medical diagnostic laboratory. In order to avoid an erroneous result, a positive and negative check is advised before application.

Safety at work and environmental protection

Handle the product in accordance with safety at work and environmental protection guidelines. Used medical products and out of date products should be taken care of as a special waste in accordance with national guidelines. Chemicals used in this procedure could pose danger to human health. Tested tissue specimens are potentially infectious. Necessary safety measures for protecting human health should be taken in accordance with good laboratory practice. Act in accordance with signs and warnings notices printed on the product's label, as well as in BioGnost's material safety data sheet.














Storing, stability and expiry date

Keep BioFix GL fixative in a tightly sealed original packaging at temperature of +15°C to +25°C. Do not keep in cold places, do not freeze and avoid exposing to direct sunlight. Date of manufacture and expiry date are printed on the product's 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.

BFGL-X, V1-EN1, 26 September 2019, TG/IŠP

	Refer to the supplied documentation		Storage temperature range		Number of tests in package		Product code		European Conformity
	Refer to supplied instructions		Keep away from heat and sunlight		Valid until		Lot number		Manufacturer
	For in vitro diagnostic use only		Keep in dry place		Caution - fragile				

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