

BIOFIX C

IVD *In vitro* diagnostic medical device



Modified Carnoy fixative based on ethyl alcohol, chloroform and acetic acid INSTRUCTIONS FOR USE

REF Product code: BFC-500 (500 mL)

BFC-1L (1000 mL)

BFC-5L (5000 mL)

Introduction

BioFix C is BioGnost's modification of Carnoy's fixative that provides the same results like traditional Carnoy's fixative. BioFix C is a fixative that penetrates the tissues rapidly and is excellent for fixation of glycogens, Nissl's granules, and nuclear materials. Since it is an anhydrous fixative based on alcohol, BioFix C simultaneously fixates and dehydrates. It is recommended for use with samples stained according to AZAN or Congo Red Highman method.

CAUTION: Do not use with samples that contain acid-fast bacteria, because the bacteria will not be stained like acid-fast bacteria after being exposed to BioFix C. BioFix C also hemolyzes erythrocytes and dissolves granules and pigments soluble in acid media. If the samples are immersed in BioFix C for a prolonged period of time, excessive compression and hardening of samples may occur. Not recommended for use in immunohistochemistry.

Product description

- **BIOFIX C** – anhydrous fixative based on ethyl alcohol, chloroform, and acetic acid.

Other sections and reagents that may be used in fixing method:

- Dehydrating/rehydrating agent, such as BioGnost's alcohol solutions: Histanol 95 and Histanol 100
- Clearing agents, such as BioClear xylene or BioClear New agent on the aliphatic hydrocarbons basis
- Infiltration and fitting agent, such as BioGnost's granulated paraffin with polymers: BioWax Plus 56/58, BioWax 56/68, BioWax Blue, BioWax Micro

Histology sample processing procedure

Note: BioFix C to tissue sample ratio must not be lower than 20:1!

- Immerse the section in BioFix C fixative for 30 minutes to 4 hours.
Note: do not keep the sections in BioFix C for longer than 12 hours; it may cause compression of samples.
- After treating the sample in BioFix C, immerse the sample in absolute ethyl alcohol (Histanol 100) for 1 hour. Repeat this step once more.
Note: if the samples radius exceeds 5 mm, prolong exposure period.
- Move the sample into xylene (BioClear) for 1 hour. Repeat this step once more.
- Immerse the sample in paraffin (BioWax 56/58, BioWax Blue, BioWax Micro, BioWax Plus 56/58) for 1 hour and repeat this step twice.

Cytology sample processing procedure

- Fix in 95% ethyl alcohol (Histanol 95) for 15-20 minutes.
- Immerse in BioFix C for 10 minutes or less.
- Immerse in 95% alcohol (Histanol 95).

Note

Time periods of processes are not entirely standardized and they approximately correspond to clinical and laboratory practical experience. Real sample processing and staining protocol depends on personal requests and priorities.

Preparing the sample and diagnostics

Use only appropriate instruments for collecting and preparing the samples. All the samples must be processed with the most modern technology and be visibly marked. Follow the manufacturer's instructions for handling. In order to avoid mistakes, staining must be conducted by a trained professional. Only trained medical personnel may make a diagnosis. 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 solutions and out of date solutions should be disposed of as 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 which is available on demand.

Storing, stability and expiry date

Keep BioFix C 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. Bibbo, M. et Wilbur, D. (2008): Comprehensive Cytopathology, 3rd ed., Saunders Elsevier
2. Kiernan, J. A. (2008) Histological and histochemical methods, 4th ed. Bloxham: Scion Publishing Ltd.
3. American MasterTech: Carnoy's Fixative & Carnoy's 2000 Solution (http://www.americanmastertech.com/carnoy's_solution.htm)
4. Puchtler, H. et al. (1968): Carnoy fixation: Practical and Theoretical Considerations, *Histochemie* 16, str. 361-371

BFC-X, V3-EN3, 27 May 2019, VR/IŠP

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

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