FORMALDEHYDE 37% FOR USE IN HISTOLOGY

IVD In vitro diagnostic medical device

37% stabilized formaldehyde solution

Synonym: Concentrated formalin

INSTRUCTIONS FOR USE

REF Product code: F37H-1L (1000 mL) F37H-5L (5000 mL)

F37H-10L (10000 mL)

F37H-20L (20000 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. Although there are hundreds of histological fixatives and at least tens of formaldehyde-based fixatives, neutral buffered formaldehyde solutions with a concentration range from 4% to 10% are the most commonly used fixatives, primarily because of their simple and universal application. 37% formaldehyde for use in histology is used in cellular diagnosis for fixating histological samples of human tissues. The solution is immediately ready to be used. It enables better visualization of structures (by fixation, fitting, staining, counterstaining and mounting) of histological samples, i. e. histological sections of organs and tissues.

Product description

• FORMALDEHYDE 37% FOR USE IN HISTOLOGY - 37% formaldehyde solution, stabilized using methanol Synonym: concentrated formalin

Fixating instructions

- Always wear protective gloves while handling formaldehyde and fixated tissue samples. The rooms in which the formaldehyde 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 formaldehyde 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 50 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, fixation temperature, tissue and fixative volume ratio, as well as the concentration of formaldehyde in the fixative.
- Selection of concentration of formaldehyde 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.

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 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 Formaldehyde 37% for use in histology in a tightly sealed original packaging at temperature of 15°C to 25°C. 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.

Instructions F37H-1L F37H-5L F37H-10L F37H-20L version 2 29 June 2018 Approved by: VR

Â	Refer to the supplied documentation	°0.4	Storage temperature range	Σ	Number of tests in package	REF	Product code	CE	European Conformity		BIOGNOST Ltd. Medjugorska 59 10040 Zagreb	C	E
[]i]	Refer to supplied instructions		Keep away from heat and sunlight	8	Valid until		Lot number	444	Manufacturer		CROATIA www.biognost.com		
IVD	For in vitro diagnostic use only	Ĵ	Keep in dry place	<u> </u>	Caution - fragile					_			