BIOGNOST®

NB FORMALDEHYDE CONCENTRATED 5X

CE IVD *In vitro* diagnostic medical device Classification according to Regulation (EU) 2017/746 - **Class A** device

Concentrated neutral buffered formalin for the preparation of a 10% buffered formalin solution (synonym: 4% buffered formaldehyde), pH 7.0

INSTRUCTIONS FOR USE

Basic UDI-DI	385889212HPC30705FIXAQX	
EMDN code	W01030705	
REF **Catalog number**	**Volume**	**UDI-DI**
FK5X-1L	1 L	03858890007824
FK5X-5L	5 L	03858890007817
FK5X-10L	10 L	03858890007800

Intended use and test principle

Quality fixation is a prerequisite for an accurate histological diagnosis of the sample. Tissue samples should be immersed in an appropriate fixative as soon as possible after sampling because timely fixation prevents autolysis, putrefaction 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. Fixation of tissue using a neutral buffered formaldehyde solution results in the formation of cross-links, i.e. methylene bridges between proteins, meaning the constituent parts of the tissue are preserved in their *in vivo* relationship. If properly fixed, the tissue can withstand subsequent histological processing and staining. NB Formaldehyde Concentrated 5X allows for the fast and economical preparation of a 4% formaldehyde solution (10% formalin). The abbreviation NB comes from the English term *neutral buffered*, which is the standard term used for this type of fixative. Formaldehyde NB 4% is the most commonly used fixative in the world. It is suitable for the fixation of biopsy material, smaller tissue samples and for the long-term storage of fixed samples. The phosphate buffer of optimal molality maintains a stable pH in the range of 6.8 to 7.2 at 25 °C, while the addition of methanol prevents the polymerization of formaldehyde. As a primary tissue fixative, it enables long-term fixation and/or storage of samples without significant tissue hardening or formation of formalin pigment (acid hematin).

Product description

- **NB FORMALDEHYDE CONCENTRATED 5X** – Concentrated neutral buffered formaldehyde solution intended for the preparation of a **4%** neutral buffered formaldehyde solution (pH 7.0)

Preparation of a 4% neutral buffered formaldehyde solution (pH 7.0)

- Mix 1 part concentrated formaldehyde with 4 parts distilled/demineralized water (1+4 dilution).
- One liter of Formaldehyde NB Concentrated 5X is sufficient to prepare 5 liters of Formaldehyde NB 4%.
- Five liters of Formaldehyde NB Concentrated 5X is sufficient to prepare 25 liters of Formaldehyde NB 4%.
- Ten liters of Formaldehyde NB Concentrated 5X is sufficient to prepare 50 liters of Formaldehyde NB 4%.

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 Formaldehyde NB 4%.If there is doubt about the correct selection of fixatives for a particular 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.

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

Fixation procedure

- Immerse the tissue in the prepared 4% neutral buffered formaldehyde fixative solution as soon as possible after specimen collection
- If it is not possible to immediately place the tissue in a fixative, it should be kept moist and stored 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 50:1This is particularly true for Formaldehyde NB 4%, while the ratio may be lower when using Formaldehyde NB 10%. 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 hollow organs, and they can also be filled with gauze soaked in the fixative before immersion in 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 to come into contact with the tissue should be 70%, to avoid precipitation of phosphate salts which serve as a neutral buffer of the formaldehyde solution

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. 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:

H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H335	May cause respiratory irritation.
H341	Suspected of causing genetic defects.
H350	May cause cancer.
H371	May cause damage to organs.
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P303+P361+P353	IF ON SKIN (or hair): Immediately take off all contaminated clothing. Rinse skin with water (shower).
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P301+P330+P331	IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
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.
EUH071	Corrosive to the respiratory tract.

FK5X-IFU_ENV4, 16.07.2026., IŠP

	Manufacturer	LOT	Batch code		Consult instructions for use	IVD	*In vitro* diagnostic medical device
	Date of manufacture	REF	Catalogue number		Caution	CE	European conformity
	Use-by date	°C	Temperature limit		Contains hazardous substances	UDI	Unique device identifier

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Version	Description / reason for change	Date
4	Revised acc. to Regulation (EU) 2017/746 – IVDR and Alignment with Commission Delegated Regulation (EU) 2024/2564	16.07.2026.