BIOGNOST®

FORMALDEHYDE NB 10%

CE IVD *In vitro* diagnostic medical device Classified acc. to Regulation (EU) 2017/746 - **Class A** device

25% neutral buffered and stabilized formalin solution, pH 7.0

INSTRUCTIONS FOR USE

BASIC UDI number	385889212HPC30705FIXAQX				
EMDN code	W01030705				
REF **Catalog number**	**Volume**	**UDI-DI number**	REF **Catalogue number**	**Volume**	**UDI-DI number**
FNB10-1L	1 L	03858888820169	FNB10-10L	10 L	03858888820190
FNB10-5L	5 L	03858888820183	FNB10-20L	20 L	03858888820206

Intended use and test principle

Quality fixation is a prerequisite for an accurate histological diagnosis of the sample. Tissue samples should be immersed in the appropriate fixative as soon as possible after sampling, as timely fixation prevents autolysis, rotting 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 in a neutrally buffered formaldehyde solution leads to the formation of cross-links (methylene bridges) between proteins, thus preserving tissue structure in a relationship similar to that of *in vivo*. Properly fixed tissue can withstand further histological processing and staining without difficulty. Formaldehyde NB 10% corresponds to 25% buffered formalin (NBF 10%), where the difference is exclusively in terminology, while the composition of the solutions is the same. The abbreviation NB comes from the neutral buffered, which is standardly used for this type of fixative. When using Formaldehyde NB 10%, histological samples can be fixed for a shorter period and with a lower volume-to-fixed-tissue ratio than with a 4% formaldehyde solution. Due to the neutral pH, there is no formation of pigmentation in the tissues and the need for a procedure to remove the so-called acid hematin. It is suitable for use in all automated tissue processing devices as well as for manual histological techniques, and is available in 1-liter bottles and 5, 10, and 20-liter canisters.

Product description

- **FORMALDEHYDE NB 10% -** 25% neutral buffered and stabilized formalin solution, pH 7.0. Suitable for fixation of larger tissue samples.

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 10%. 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 references 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 into the fixative as soon as possible after sampling
- If it is not possible to immediately place the tissue in a fixative, it should be kept moist and kept 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 should be between 20:1 and 50:1. This is especially true for Formaldehyde NB 4%, while the ratio when using Formaldehyde NB 10% may be lower. The ratio of fixative to sample must be at least 10:1 to 20:1
- For whole organ fixation, the fixative must be injected into the organ or the organ must be sectioned into thin slices to ensure optimal penetration.
- 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 tissue sample or organ, 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 fixation is completed, the fixed tissue should be cut to sections of no more than 3 to 5 mm and placed in a tissue processing device for paraffin treatment. The initial alcohol solution used for specimen dehydration must be 70% to prevent the precipitation of phosphate salts from the neutral buffered 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. Bancroft, J.D. and Gamble, M. (2013) *Theory and Practice of Histological Techniques*. 7th Edition, Churchill Livingstone of Elsevier, Philadelphia, 172-186.
2. Carson, FL, Hladik, C. (2009): Histotechnology*: A Self-Instructional Text*, 3rd ed., Chicago: ASCP Press
3. Cook, D.J. (2006): *Cellular Pathology*, 2n.d ed., Banbury: Scion Publishing Ltd.
4. Kiernan, JA (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. H312 Harmful in contact with skin. H317 May cause an allergic skin reaction. H332 Harmful if inhaled. H341 Suspected of causing genetic damage. H350 May cause cancer. P280 Wear protective gloves/protective clothing/eye protection/face protection. P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor. P302+P352 IF ON SKIN: wash with plenty of water. P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P308+P313 IF exposed or concerned: Get medical advice/attention.

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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			Temperature limit		Contains hazardous substances	UDI	Unique device identifier

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Version	Description / reason for change	Date
06	Compliance with Commission Delegated Regulation (EU) 2024/2564	16.07.2026