BOUIN'S SOLUTION

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

Aqueous solution of picric acid, formaldehyde and acetic acid for tissue fixation

INSTRUCTIONS FOR USE

BASIC UDI number	385889212HPC30705FIXAQX	
EMDN code	W01030705	
REF **Catalog number**	**Volume**	**UDI-DI number**
BOU-OT-100	100 mL	03858890000665
BOU-OT-1L	1000 mL	03858888821487
BOU-OT-5L	5000 mL	03858890007787
BOU-OT-10L	10000 mL	03858888821500

Intended use and test principle

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 alterations. The fixative alters the tissue by stabilizing proteins and making them resistant to further alterations. It also has to alter soluble cell components into insoluble cells in order for those components to be preserved in further processing. That alteration is called denaturation and it can be conducted chemically (fixative solutions) or physically (heat, drying). If fixated properly, the tissue sample can withstand additional histological tissue processing and staining. BioGnost's Bouin's solution is an excellent choice for tissue samples to be stained using trichrome methods and for preservation of soft and delicate structures. It is especially useful as a fixative for tissues with chromosomes in stages of mitosis and meiosis being observed because it preserves nuclei and chromosomes exceptionally well.
Bouin's solution is a compound fixative; each compound has a specific characteristic. Acetic acid causes swelling that is reversed by shrinking caused by picric acid. Hardening effect of formalin is alleviated by picric acid's mild fixative effect. The formalin-induced basophilic character of cytoplasm is neutralized with picric acid. In turn, that results in exceptionally clear staining of nucleus and cytoplasm using the HE staining methods

Product description

- **BOUIN'S SOLUTION** – Fixative with picric adic, formaldehyde and acetic acid for use in histopathology.

Sample processing:

- Additional dilution of Bouin's solution is not necessary.
- Treat small tissue samples (for instance, gastrointestinal tract tissue samples) for 3 hours before further processing. Larger tissue samples (lymph nodes, spleen, breast or colon) should be treated for 10-12 hours, although 4-6 hours of fixation will suffice.
- Excessive fixation can have adverse effect, so tissues should not be immersed in the fixative for longer than 24 hours.
- Bouin's solution is a component of BioGnost's trichrome special kits, such as Masson Trichrome kit, Masson Goldner Trichrome kit, Gomori Trichrome kit and A.F.O.G. kit. Information about staining procedures and Bouin's solution use within the aforementioned special kits can be found in their respective Instructions for use, which are available on BioGnost's website (https://www.biognost.com/).

Limitations

This product is intended for professional laboratory use for diagnostic purposes only. Deviations from the fixation procedure described in this Instruction for use may cause differences in staining results.

Sample preparation and diagnostics

Use only appropriate instruments for collecting and preparing the samples. Process the samples using modern technology and mark them clearly. Be sure to follow the manufacturer's handling instructions. To avoid errors, process of fixation, staining and diagnosis can only be carried out by qualified personnel. Use a microscope equipped according to medical diagnostic laboratory standards.
If a serious incident occurs during use of this product 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, and it is necessary to take the measures needed to protect human health in accordance with the guidelines of good laboratory practice. It is mandatory to read and act according to the information and warning signs printed on the product label 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 expiration date is printed on the product label.

References

1. Carson, F. L., Hladik, C. (2009): *Histotechnology: A Self-Instructional Text*, 3rd ed., Chicago: ASCP Press
2. Sheehan, D.C. i Hrapchak, B.B. (1980): *Theory and Practice of Histotechnology*, 2nd ed., St. Louise: CV Mosby Co.

Warnings and precautions regarding the materials contained in the product:		
	H302 + H312 + H332	Štetno ako se proguta, u dodiru s kožom i ako se udiše.
	H315	Causes skin irritation.
	H317	May cause an allergic skin reaction.
	H319	Causes serious eye irritation.
	H335	May cause respiratory irritation.
	H341	Suspected of causing genetic defects.
	H350	May cause cancer.
	P280	Wear protective gloves/protective clothing/eye protection/face protection.
	P301+P330+P331	IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
	P302+P352	IF ON SKIN: wash with plenty of water and soap.
	P304+P340	IF INHALED: remove person to fresh air and keep comfortable for breathing.
	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.

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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
8	Revised acc. to Regulation (EU) 2017/746 - IVDR	16.02.2026.