BIOGNOST®

HISTANOL M

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

Methyl alcohol for use in histology and cytology

INSTRUCTIONS FOR USE

BASIC UDI-DI		
EMDN code		
REF **Catalog number**	**Volume**	**UDI-DI**
HM-1L	1000 mL	03858888822224
HM-5L	5000 mL	03858888827274
HM-10L	10000 mL	03858890008098

Intended use and test principle

BioGnost's Histanol M is an ideal dehydrating and fixing agent in many scientific fields such as histology, cytology, immunocytochemistry and many other related fields where quality microscopy is a priority. Methanol is the simplest of all alcohols and fixes proteins by denaturing and precipitating them. It is very often combined with ethanol or acetic acid, depending on the sample and the method used. The use of methanol as a fixative of blood smears before their staining with Romanowsky dyes in differential hematology is widely known.

Product description

- **HISTANOL M** - Alcoholic methanol solution for histological and cytological analysis.

Example of the use of Histanol M in staining hematological smears in combination with Giemsa solution:

Additional reagents and materials that can be used in the staining method

- Polychromatic Romanowsky reagents such as BioGnost's Giemsa solution
- VitroGnost slides and coverslips for use in histopathology and cytology
- Immersion oils such as BioGnost's Immersion Oil, Immersion Oils types A, C, FF, 37, or Immersion Oil Tropical Grade
- BioGnost Buffer Tablets pH 6.8 or 7.2

Preparation of solutions

Buffer solution pH 6.8

- Disolve 1 buffer tablet pH 6.8 in 1 liter of distilled/demineralized water while stirring.

Note: In the staining procedure, it is also possible to use a buffer solution with a pH value of 7.2 or a combination of buffer solutions with a pH value of 6.8 and 7.2. The results of the staining procedure may differ in a shift towards the red or blue color spectrum.

Giemsa working solution for standard staining method

- Add 10 mL of Giemsa solution to 190 mL of pH 6.8 buffer solution, mix well, and let it rest for 10 minutes. Filter if necessary.

Giemsa working solution for rapid staining method

- Add 33 mL of Giemsa solution to 66 mL of pH 6.8 buffer solution, mix well, and let it rest for 10 minutes. Filter if necessary.

A1) Procedure for staining blood smears with Giemsa solution

1.	Air dry the blood smear	
2.	Fix air-dried blood smears by exposure to methanol (Histanol M)	5 min
3.	Immerse the fixed smear in working Giemsa solution	15-20 min
4.	Rinse the smear in buffer solution pH 6.8 – two exchanges	2 exchanges, 1 min each
5.	Air dry the slide.	

A2) Procedure for staining blood smears with the rapid Giemsa method

1.	Air dry the blood smear	
2.	Fix air-dried blood smears by exposure to methanol (Histanol M)	1-3 min
3.	Immerse the fixed smear in working Giemsa solution	3 min
4.	Rinse the smear in buffer solution pH 6.8	2 exchanges, 1 min each
5.	Air dry the slide	

It is recommended to use immersion oil during microscopic analysis of the stained slide at magnifications greater than 40x.

Result (pH 6.8)

Nuclei – purple to violet
Lymphocyte plasma – blue
Monocyte plasma – grayish-blue
Neutrophil granule – light purple
Eosinophilic granule – light red
Basophilic granule – dark purple to black
Platelets – purple
Erythrocytes – reddish

Limitations

This product is intended for professional laboratory use for diagnostic purposes only. Deviations from the staining 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. It is necessary to follow the manufacturer's instructions for use. To avoid errors, histological processing of samples and diagnosis may only be performed by qualified personnel. Use a microscope that complies with medical diagnostic laboratory standards. To avoid a false result, it is recommended to use a positive and negative control.

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, transport, 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. Beesley, J. E. (1989): Colloidal gold: A new perspective for cytochemical marking. Royal Microscopy Handbook #17. Oxford Univ. Press. p. 48.
2. Haas, G.G. Jr. et al. (1988): The effect of fixatives and/or air-drying on the plasma and acrosomal membranes of human sperm. *Fertil Ster.* 50 (3); p. 487-492.
3. Hoetelmans, R. W. et al. (2001): Effects of acetone, methanol, or paraformaldehyde on cellular structure, visualized by reflection contrast microscopy and transmission and scanning electron microscopy. *Appl. Immunohistochem. Mol. Morphol.* 9 (4); p. 346-351.
4. Kumarasinghe, m.p. (1997): Methanol as an alternative fixative for cytological smears. *Malays. J. Pathol.* 19(2); p. 137-140.

Warnings and precautions regarding the materials contained in the product:

H225	Highly flammable liquid and vapour.
H301+H311+H331	Toxic if swallowed, in contact with skin, or if inhaled.
H370	Causes damage to organs (eyes).
P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233	Keep container tightly closed.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor.
P302+P352	IF ONSKIN: wash with plenty of water.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P308+P311	IF exposed or concerned: Call a POISON CENTER or doctor.

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

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Version	Description / reason for change	Date
7	Revised acc. to Regulation (EU) 2017/746 - IVDR	09.04.2026.