

GIEMSA HP KIT

CE IVD *In vitro* diagnostic medical device

Classified acc. to Regulation (EU) 2017/746 - Class A device

Four-reagent kit for staining *Helicobacter pylori* in histology sections according to Lennart

INSTRUCTIONS FOR USE

BASIC UDI number	385889212HPC30708STARVF		
EMDN code	W01030708		
REF Catalog number	Volume	UDI-DI number	
GMHP-100T	100 tests	03858890008333	



Intended use and test principle

Polychromatic Romanowsky stains are standardly used for staining blood smears and bone marrow in hematology. Giemsa is one of the Romanowsky dyes and beside hematology, it can be used in histology for visualization of *Helicobacter pylori* in gastroscopic samples of stomach. This staining method is also known as slow Giemsa staining according to Lennart. Giemsa solution may also be used to identify blood parasites, inclusion bodies and mastocytes in histology sections. Giemsa HP kit for 100 tests contains reagents for differentiation and rehydration in Ready-to-Use jars, enabling the sections to be directly immersed during the staining procedure. The jars are closed after the use, and reagents can be reused.

Product description

- **GIEMSA HP KIT**- Four – reagent kit for staining bacteria *Helicobacter pylori*

The kit contains:	100 tests (GMHP-100T)	Storage temperature
Giemsa solution	50 mL (GM-OT-50)	15-25 °C
Buffer solution, pH 7.2	100 mL (PUF72-OT-100)	15-25 °C
Differentiating reagent for Giemsa HP kit	2 x 100 mL (RGHP-OT-100)	15-25 °C
Dehydrating reagent	2 x 100 mL (RDH-OT-100)	15-25 °C
Plastic graduated Pasteur pipette	1 pc	15-25 °C

Additional reagents and materials that can be used in this method

- Fixatives such as BioGnost's neutral buffered formaldehyde solutions: Formaldehyde NB 4%, Formaldehyde NB 10%
- Dehydrating/rehydrating agent, such as BioGnost's alcohol solutions: Histanol 70, Histanol 80, Histanol 95 and Histanol 100
- Clearing agent, such as BioClear xylene or its aliphatic hydrocarbon substitutes, such as BioClear New
- Infiltration and embedding agent, such as BioGnost's granulated paraffin BioWax Plus 56/58, BioWax 56/68, BioWax Blue
- Covering agents for microscopic sections and mounting cover glass, such as BioGnost's BioMount, BioMount High, BioMount M, BioMount New, BioMount DPX, BioMount DPX High, BioMount DPX Low, BioMount C, BioMount Aqua
- VitroGnost slides and coverslips for use in histopathology and cytology
- BioGnost's immersion oils, such as Immersion oil, Cedarwood oil, Immersion oils types A and C, FF, 37 or Tropical Grade

Preparation of histological sections for staining

- Fix (Formaldehyde NB 4%, Formaldehyde NB 10%) and process the tissue sample
- Embed the tissue in a paraffin block (BioWax 52/54, BioWax 56/58, BioWax Plus 56/58, BioWax Blue)
- Cut the paraffin block into 4-6 µm thin slices and mount on a VitroGnost microscope slide

NOTE

Apply the reagent so it completely covers the section.

Sample staining procedure

1.	Deparaffinize in xylene (BioClear) or xylene substitute (BioClear New)	3 exchanges, 2 min each
2.	Rehydrate in 100% alcohol (Histanol 100)	2 exchanges, 5 and 3 min
3.	Rehydrate in 95% alcohol (Histanol 95)	2 min
4.	Rehydrate in distilled/demineralized water	2 min
5.	Preparation of working Giemsa solution : mix 43 ml of distilled/demineralized water and 5 ml of Buffer solution, pH 7.2. Add 2 ml of Giemsa solution and mix	
6.	Immerse into working Giemsa solution Note: discard Giemsa working solution after staining	30-60 min
7.	Rinse in distilled/demineralized water	
8.	Differentiate in Differentiating reagent for Giemsa HP kit Note: if the section is treated with Differentiating reagent for too long, it may result in excessive release of blue-purple dye off the section	several rapid dips
9.	Dehydrate in Dehydrating reagent Note: if the section is treated with Dehydrating reagent for too long, it may result in excessive release of blue-purple dye off the section	1-2 min
10.	Clear in xylene (BioClear) or xylene substitute (BioClear New)	2 exchanges, 2 min each

Immediately after clearing apply an appropriate BioMount medium for covering/mounting on the section. If BioClear xylene was used, use one of BioGnost's mounting xylene-based media (BioMount, BioMount High, BioMount M, BioMount DPX, BioMount C, or universal BioMount New). If BioClear New xylene substitute was used, the appropriate covering agent is BioMount New. Cover the section with VitroGnost cover glass.

Result

Helicobacter pylori – dark blue

Nuclei – blue

Cytoplasm – from pink to blue

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. Be sure to follow the manufacturer's handling instructions. To avoid errors, 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. Beck, R.C. (1938): *Laboratory Manual of Hematological Technique*, Philadelphia, W.B. Saunders & Co.
2. Dacie, J. et Lewis S. (1995): *Practical haematology*, 4th ed., London, Churchill Livingstone.
3. Giemsa, G. (1922): Das Wesen der Giemsa-Färbung, *Zentralbl f Bakt*; 89, str. 99-106.
4. International Committee for Standardization in Haematology (1984): ICSH reference method for staining of blood and bone marrow films by azure B and eosin Y (Romanowsky stain), *British Journal of Haematology*, 57, str. 707-710.
5. May, R. et Grünwald L. (1909): *Über die Färbung von Feuchtpreparaten mit meiner Azur-Eosine methode*, *Deutsche med Xschr*, 35, str. 1751-1752.

Warnings and precautions regarding the materials contained in the product:	
	<p>H225 Highly flammable liquid and vapor.</p> <p>H301 + H311 + H331 Toxic if swallowed, in contact with skin or if inhaled.</p> <p>H370 Causes damage to organs.</p> <p>P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.</p> <p>P233 Keep container tightly closed.</p> <p>P280 Wear protective gloves/protective clothing/eye protection/face protection.</p> <p>P301 + P310 IF SWALLOWED: immediately call a POISON CENTER/doctor</p> <p>P302 + P352 IF ON SKIN: wash with plenty of water</p> <p>P304 + P340 IF INHALED: remove person to fresh air and keep comfortable for breathing</p> <p>P308 + P311 IF exposed or concerned: call a POISON CENTER/doctor</p>

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 Manufacturer	 Batch code	 Consult instructions for use	 Contains sufficient for <n> tests
 Date of manufacture	 Catalogue number	 Caution	 European conformity
 Use-by date	 Temperature limit	 <i>In vitro</i> diagnostic medical device	 Unique device identifier

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Version	Description / reason for change	Date
4	Revised in acc. to Regulation (EU) 2017/746 - IVDR	19.02.2026.