BIOGNOST®

LEUKOGNOST MPO

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

Kit for detection of myeloperoxidase activity in leukocytes

INSTRUCTIONS FOR USE

BASIC UDI-DI	385889212HPC30702CYTOS9	
EMDN code	W01030702	
REF **Catalog number**	**Volume**	**UDI-DI**
LKG-MPO	For at least 100 tests	03858892122426

Intended use and test principle

The LeukoGnost MPO kit contains reagents for the cytochemical diagnosis of leukemias on whole blood or bone marrow smears. The staining method is based on the ability of cellular myeloperoxidase to catalyze the reduction of hydrogen peroxide, producing water and oxygen that oxidizes 4-chloro-1-naphthol, leading to the formation of dark blue to black precipitates at the site of active peroxidase. The kit is designed for individual testing of horizontally placed preparations and contains reagents for at least 100 tests for the detection of myeloperoxidase activity in leukocytes. The reagents are applied by dripping until the entire preparation is covered (1-2 mL).

Product description

- **LeukoGnost MPO** – kit for detection of myeloperoxidase activity in leukocytes

The kit contains:	LKG-MPO (for 100 tests)	Storage temperature:
Reagent 1 (MPO buffer)	PBSL-OT-100 (2x100 mL)	2-8°C
Reagent 2 (MPO substrate)	4K1N-OT-10 (10 mL)	2-8°C
Reagent 3 (Hydrogen peroxide, solution)	VPO-OT-10 (10 mL)	2-8°C

Other reagents required in the staining method

- **LeukoGnost Fixative (LKF-500)** – Fixative for use in the cytochemical diagnosis of leukemias
- **LeukoGnost HEM (LKH-OT-500)** – Hematoxylin for use in the cytochemical diagnosis of leukemias

or

- **LeukoGnost PLUS (LKG-PLUS)** – Set of additional reagents for LeukoGnost kits

Other preparations and reagents that may be used in the staining method

- Water-based agent for covering microscopic samples and mounting cover glasses such as BioGnost's BioMount Aqua (BMA-30)
- BioGnost's immersion media such as Immersion Oil (IU-30) or Immersion Oil Type A (IUA-30)

Preparation of staining solution

Prepare the staining solution as follows:

- step 1: mix Reagent 1 and Reagent 2 in a clean test tube. Allow to stand for 2 min.
- step 2: add Reagent 3 to the mixture of Reagent 1 and 2.
- step 3: add Reagent 4 to the prepared mixture from step 2.
- step 4 (acid phosphatase inhibition option): add Reagent 5 to the mixture from step 3.

Adjust the reagent volume as needed:

STEP	REAGENT	FOR 1 SLIDE	FOR 12 SLIDES	FOR 24 SLIDES
step 1	Reagent 1	2 mL	24 mL	48 mL
	Reagent 2	100 µL (4 drops)	1.2 mL	2.4 mL
step 2	Reagent 3	100 µL (2 drops)	1.2 mL	2.4 mL

Preparation of samples for staining

- Prepare the peripheral blood or bone marrow smear to be thin and dry (dry for at least 30 min). Samples must not be older than three days.
- It is not recommended to use anticoagulants as inhibition of the reaction may occur.
- Fix the sample as follows:

1.	Fix the sample by applying LeukoGnost Fixative (1-2 mL) to the slide	1-3 minutes
2.	Rinse the slide under running tap water	10 seconds
3.	Air dry the slide	

- Slides prepared and fixed in this way can be stored at 2-8 °C and used for up to three days.

NOTE

Apply the reagent so that it completely covers the slide.

Prepare the staining solution fresh before each staining. The prepared solution can be used within 3 hours.

Sample staining procedure

1.	Apply the staining solution (1-2 mL) to the slide	10 minutes
2.	Rinse vigorously in distilled/demineralized water	10 seconds
3.	Stain the slide with LeukoGnost HEM reagent	2 minutes
4.	Rinse under tap water	2 minutes
5.	Air dry the slide	

After drying the slide, it is recommended to mount a cover glass using BioMount Aqua to preserve the stain and quality of the slide.

Result

Neutrophils – intense black granular staining of the cytoplasm
Monocytes – weak black granular staining of the cytoplasm
Eosinophils – very intense black granular staining of the cytoplasm
Lymphocytes, basophils – no specific staining

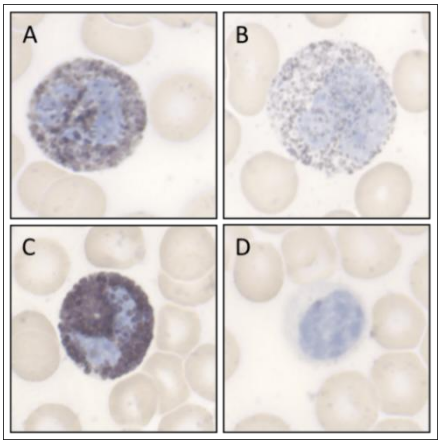

Figure 1. *View of a peripheral blood smear stained with the LeukoGnost MPO kit: neutrophil (A), monocyte (B), eosinophil (C), and lymphocyte (D). Magnification 1000x*

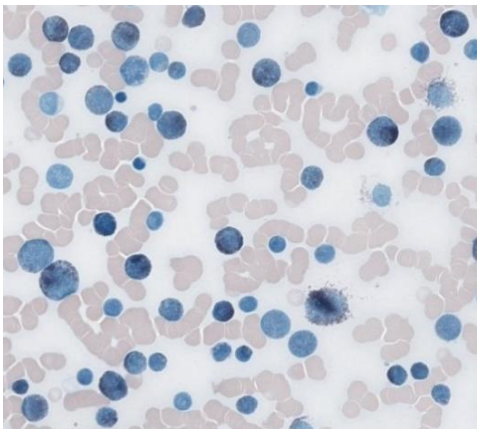

Figure 2. *Display of a bone marrow smear stained with the LeukoGnost MPO kit. Positive reaction of myeloid lineage cells in acute myeloid leukemia (AML) is shown. Magnification 200x.*

Limitations

This product is intended for professional laboratory use for diagnostic purposes only. Deviations from the staining procedure described in this Instructions 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, staining of samples and making a 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. Chemicals 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 and in the Safety Data Sheet, which is available on request.

Storage, stability, and shelf life

Upon receipt, store and keep the product in a dry place, in the original tightly closed packaging at a temperature of +2 to +8°C. The product is transported at a temperature of +2 to +8°C. Do not freeze and do not 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. et Hladik, C. (2009): Histology, 3 ed., American Society for Clinical Pathology Press, Hong Kong.
2. Shibata, A., Bennett, J.M., Castoldi, G.L., Catovsky, D., Flandrin, G., Jaffe, E.S., Katayama, I., Nanba, K., Schmalzl, F., Yam, L.T., et al. Recommended methods for cytological procedures in haematology. International Committee for Standardization in Haematology (ICSH). Clin Lab Haematol. 1985;7:55-74.

Warnings and precautions regarding the materials contained in the product:

H225	Highly flammable liquid and vapour.
H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H332	Harmful if inhaled.
H412	Harmful to aquatic life with long lasting effects.
H370	Causes damage to organs.
P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/doctor.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.

LKG-MPO-IFU, ENV4, 29.07.2026., IŠP

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

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Version	Description / reason for change	Date
4	Revised acc. to Regulation (EU) 2017/746 - IVDR	29.07.2026.