LEUKOGNOST MPO

IVD In vitro diagnostic medical device

Kit for detection of myeloperoxidase activity in leukocytes

INSTRUCTIONS FOR USE

REF Product code: LKG-MPO (for at least 100 tests)

Introduction

LeukoGnost MPO kit contains reagents for cytochemical diagnosis of leukemia using bone marrow or whole blood smears.

The staining method is based on ability of cellular myeloperoxidase to catalyze hydrogen peroxide reduction, creating water and oxygen that oxidizes 4-chloro-1-naphthol, what in turn forms dark blue to black precipitates at the spot of active peroxidase.

The kit is intended for individual testing of horizontally placed slides and it contains reagents for at least 100 tests for detecting myeloperoxidase activity in leukocytes. The reagents are applied by dripping until the entire slide 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-0T-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 necessary for the staining method

- LeukoGnost Fixative (LKF-500) fixative for use in cytochemical diagnosis of leukemia
- LeukoGnost HEM (LKF-0T-500) hematoxylin for use in cytochemical diagnosis of leukemia or
- LeukoGnost PLUS (LKG-PLUS) set of additional reagents for LeukoGnost kits

Other sections and reagents that may be used with the staining procedure

- Water-based covering medium for microscope slides and mounting medium for cover glasses, such as BioGnost's **BioMount Aqua medium** (BMA-30)
- · BioGnost's immersion oils, such as Immersion oil (IU-30) or Immersion oil type A (IUA-30)

Preparing the solution for staining

Prepare the staining solution in the following way:

- step 1: mix Reagent 1 and Reagent 2 in a clean tube
- step 2: add Reagent 3 to mixture of Reagents 1 and 2

Modify the reagents' volume as necessary:

STEP	REAGENT	FOR 1 SECTION	FOR 12 SECTIONS	FOR 24 SECTIONS
ctop 1	reagent 1	2 mL	24 mL	48 mL
step 1 -	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

Preparing the section for staining

- Prepare the blood marrow or whole blood smear to be thin and dry (dry the smears for at least 30 mins). These sections must not be older than 3 days.
- Using anticoagulants is not recommended because it can inhibit the enzyme reaction.
- Fix the section the following way:

1.	Fix the sample by applying LeukoGnost Fixative (1-2 mL) onto the slide	1-3 minutes
2.	Rinse the slide in distilled water	10 seconds
3.	Dry the slide	

• Samples prepared and fixed in this manner can be stored at 2 to 8 °C and used for 3 days at most.

NOTE

Apply the reagent so it completely covers the slide.

Prepare fresh staining solution priori to each staining. The prepared solution must be used within 3 hours.

Sample staining procedure

1.	Apply staining solution (1-2 mL) on the sample	10 min
2.	Rinse the section in distilled water thoroughly	10 seconds
3.	Stain the sample using LeukoGnost HEM reagent	2 min
4.	Rinse the section under tap water.	2 min
5.	Drv the preparation	

After drying the sample, it is recommended to mount cover glass using BioMount Agua medium to preserve the color and guality of the sample.

Result

Neutrophils - intensive black granular cytoplasmic staining Monocytes - faint red granular cytoplasmic staining Eosinophils - very intensive black granular cytoplasmic staining Lymphocytes, basophils - no specific staining

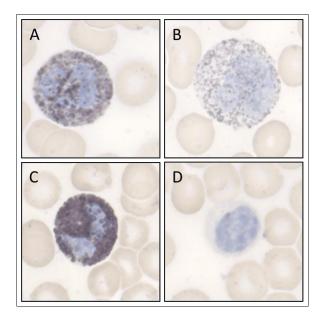


Figure 1. Smears of normal blood stained with LeukoGnost MPO kit. Neutrophil (A), monocyte (B), eosinophil (C) and lymphocyte (D) are shown.

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Preparing the sample and diagnostics

Use only appropriate instruments for collecting and preparing the samples. Process the samples with modern technology and mark them clearly. Follow the manufacturer's instructions for handling. In order to avoid mistakes, the staining procedure and diagnostics should only be conducted by authorized and qualified personnel. Use only microscope according to standards of the medical diagnostic laboratory.

Safety at work and environmental protection

Handle the product in accordance with safety at work and environmental protection guidelines. Used solutions and out of date solutions should be disposed of as special waste in accordance with national guidelines. Chemicals used in this procedure could pose danger to human health. Tested tissue specimens are potentially infectious. Necessary safety measures for protecting human health should be taken in accordance with good laboratory practice. Act in accordance with signs and warnings notices printed on the product's label, as well as in BioGnost's material safety data sheet.

Storing, stability and expiry date

Store LeukoGnost MPO kit's reagents in a tightly closed original packaging at temperature between +2 °C and +8 °C. Do not freeze and avoid exposing to direct sunlight. Date of manufacture and expiry date are printed on the product's label.

References

- 1. Carson, F.L. et Hladik, C. (2009): Histology, 3rd 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.

LKG-MPO, V5-EN1, 14 June 2021, MŠ/IŠP

CE	European Conformity	°C-	Storage temperature range	Σ	Number of tests in package	REF	Product code		BioGnost Ltd. Medjugorska 59 10040 Zagreb
[]i]	Refer to supplied instructions	歉	Keep away from heat and sunlight		Valid until	LOT	Lot number		Croatia, EŬ www.biognost.com
IVD	For <i>in vitro</i> diagnostic use only	Ť	Keep in dry place	4	Caution - fragile		Manufacturer	B	IOGNO