BIOGNOST®

LEUKOGNOST FIXATIVE

IVD *In vitro* diagnostic medical device CE

Fixative for use in cytochemical diagnosis of leukemias

INSTRUCTIONS FOR USE

REF Product code: LKF-500 (500 mL)

Introduction

It is necessary to first adequately fix the samples in order to achieve an adequate assessment of enzymatic activities in samples of blood, bone marrow and other cytology material. LeukoGnost Fixative for use in cytochemistry is used for fixing biological material later used in different methods, preserving an optimal enzymatic activity level relevant for setting an adequate clinical diagnosis.

Product description

- **LEUKOGNOST FIXATIVE** – acetone and formalin-based fixative, suitable for fixing blood and blood marrow smears, recommended for cytochemical methods

Other sections and reagents that may be used with LeukoGnost Fixative:

- BioGnost's kits from LeukoGnost range used for detecting and classifying leukemias: **LeukoGnost MPO** (kit for detecting myeloperoxidase activity in leukocytes), **LeukoGnost ALP** (kit for detecting alkaline phosphatase activity in leukocytes), **LeukoGnost ACP** (kit for acid phosphatase activity detection in leukocytes), **LeukoGnost NSE** (kit for detecting non-specific esterase activity in leukocytes), **LeukoGnost SPE** (kit for detecting specific esterase activity in leukocytes), **LeukoGnost PAS** (kit for detecting periodic acid and Schiff's reagent reaction in leukocytes) and **LeukoGnost SPENSE** (kit for simultaneous detection of specific and non-specific esterase activity in leukocytes)
- Mounting medium for covering microscopy sections, such as **BioMount Aqua**
- High-quality glass slides for use in histopathology and cytology, such as VitroGnost SUPER GRADE, VitroGnost COLOR or one of more than 30 models of BioGnost's VitroGnost glass slides
- VitroGnost cover glass, dimensions range from 18x18mm to 24x60mm
- BioGnost's immersion media, such as Immersion oil, Immersion oil, types A, C, FF, 37, or Immersion oil Tropical Grade

Preparing the section for fixing

Fresh and dried whole blood or bone marrow samples or a centrifuged precipitate sample should be used as base material for fixing. It is not recommended to use EDTA as anticoagulant due to its interaction with enzymes.

Fixing procedure

1.	Fix the sample using LeukoGnost Fixative (1-2 mL)	1-3 minutes
2.	Rinse with distilled water	10 seconds
3.	Let the sample dry on air or further process the section	

Fixing guidelines

For that reason, the fixative must be manufactured in accordance with *in vitro* diagnostic medical devices norms and must bear the CE marking of conformity, and the processes of fixing, processing and staining must be carried out by a qualified person. Always wear protective gloves while handling the fixative and fixed tissue samples. The rooms in which LeukoGnost Fixative is being used should be well aerated by using an exhaust fan or a digester in order to remove toxic evaporation. Additional security information can be found in the Material Safety Data Sheet of this product.

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 use. In order to avoid mistakes, the covering or mounting and staining procedure as well as diagnostics should only be conducted by authorized and qualified personnel. Use only microscope according to standards of the medical diagnostic laboratory. In order to avoid an erroneous result, a positive and negative check is advised before application.

Safety at work and environmental protection

Handle the product in accordance with safety at work and environmental protection guidelines. Used medical products and out of date products should be taken care of as a 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

Keep LeukoGnost Fixative in a tightly sealed original packaging at temperature of +15°C to +25°C. Do not keep in cold places, do not freeze and avoid exposing to direct sunlight. Date of manufacture and expiry date are printed on the product's label.

References

1. Boon M.E., Drijver J.S. (1986): Routine cytological staining techniques: theoretical background and practice, Macmillan Education LTD
2. Cook, D. J. (2006): *Cellular Pathology*, 2nd ed., Banbury: Scion Publishing Ltd.
3. Kiernan, J.A. (2008): *Histological and Histochemical Methods, Theory and Practice*, 4th ed., Scion Publishing Ltd, Banbury.

LKF-500, V2-EN1, 15 December 2020, MŠ/IŠP

	Refer to the supplied documentation	°C	Storage temperature range		Number of tests in package	REF	Product code	CE	European Conformity		BIOGNOST Ltd. Medjugorska 59 10040 Zagreb CROATIA www.biognost.com
	Refer to supplied instructions		Keep away from heat and sunlight		Valid until	LOT	Lot number		Manufacturer		
IVD	For in vitro *diagnostic use only*		Keep in dry place		Caution - fragile						

CE