

LEUKOGNOST NSE



IVD In vitro diagnostic medical device

Classification according to Regulation (EU) 2017/746 - **Class A** device

Kit for detection of non-specific esterase activity in leukocytes

INSTRUCTIONS FOR USE

Basic UDI-DI	385889212HPC30702CYTOS9		
EMDN code	W01030702		
REF	Catalog number	Volume	UDI-DI
LKG-NSE		for at least 100 tests	03858892122464



Intended use and test principle

The LeukoGnost NSE kit contains reagents for cytochemical diagnosis of leukemia on peripheral blood or bone marrow smears. The method is based on the ability of cellular esterase to hydrolyze 1-naphthyl acetate. In this reaction, free naphthol is produced, which reacts with diazonium salts to form an insoluble red-brown precipitate at the site of the reaction. The kit is designed for individual testing of horizontally positioned preparations and contains reagents for at least 100 tests for the detection of non-specific esterase activity in leukocytes. The reagents are applied by dripping until the entire preparation is covered (1-2 mL).

Product description

- LEUKOGNOST NSE** – kit for detection of non-specific esterase activity in leukocytes

The kit contains:	LKG-NSE (for 100 tests)	Storage temperature:
Reagent 1 (Sodium nitrite, solution)	NAN-OT-5 (5 mL)	2-8°C
Reagent 2 (Pararosanilin, solution)	PARA-OT-3 (3 mL)	2-8°C
Reagent 3 (NSE buffer)	NSEP-OT-100 (2x100 mL)	2-8°C
Reagent 4 (NSE substrate)	NAFA-OT-10 (10 mL)	2-8°C
Reagent 5 (NSE inhibitor)	NAFO-OT-15 (3x15 mL)	2-8°C

Other reagents required in the staining method

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

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 preparations 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)

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 (option with nonspecific esterase inhibition): add Reagent 5 to the mixture from step 3.

Adjust the reagent volume as needed:

STEP	REAGENT	FOR 1 PREPARATION	FOR 12 PREPARATIONS	FOR 24 PREPARATIONS
step 1	Reagent 1	50 µL (1 drop)	600 µL (12 drops)	1.2 mL (24 drops)
	Reagent 2	25 µL (1 drop)	300 µL (12 drops)	600 µL (24 drops)
step 2	Reagent 3	2 mL	24 mL	48 mL
step 3	Reagent 4	100 µL (4 drops)	1.2 mL	2.4 mL
step 4 (optional: with inhibition)	Reagent 5	400 µL (8 drops)	4.8 mL	9.6 mL

Preparation of samples for staining

- Prepare the peripheral blood or bone marrow smear to be thin and dry (dry for at least 30 minutes). 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 smear	1-3 minutes
2.	Rinse the sample 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 45 minutes.

Sample staining procedure

1.	Apply the staining solution (with and/or without esterase inhibitor) (1-2 mL) to the slide	1 hour and 30 minutes
2.	Rinse the slide vigorously in distilled/demineralized water	10 seconds
3.	Stain the slide with LeukoGnost HEM reagent	15 minutes
4.	Rinse the slide under running 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 preparation.

Result

Monocytes, plasma cells, erythroblasts, megakaryocytes, monocytic leukemia cells – brown-red granular staining of the cytoplasm.

When using the staining solution that includes the nonspecific esterase inhibitor, no specific staining of monocytes, plasma cells, erythroblasts, megakaryocytes, and monocytic leukemia cells occurs.

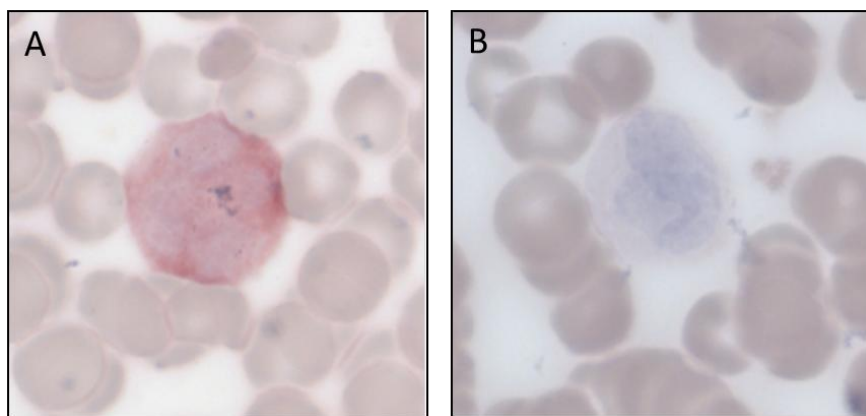


Figure 1. Peripheral blood smears stained with the LeukoGnost NSE kit. Preparations were stained without (A) or with (B) nonspecific esterase inhibitor. Monocytes are shown. Magnification 1000x.

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 and/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 BioGnost's 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. Lam KW, Li CY, Yam LT. Simultaneous demonstration of nonspecific esterase and chloroacetate esterase in human blood cells. Stain Technol. 1985;60:169-72.
3. Shibata A, Bennett JM, Castoldi GL, Catovsky D, Flandrin G, Jaffe ES, Katayama I, Nanba K, Schmalzl F, Yam LT, 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.
	H350	May cause cancer.
	H370	Causes damage to organs.
	P201	Obtain special instructions before use.
	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.
	P264	Wash affected parts thoroughly after handling.
	P270	Do not eat, drink or smoke when using this product.
	P280	Wear protective gloves/protective clothing/eye protection/face protection.
	P251	Do not pierce or burn, even after use.
	P301 + P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor/...
	P308 + P313	IF exposed or concerned: Get medical advice/attention.
	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.
	P302 + P352	IF ON SKIN: wash with plenty of water
	P305 + P351 + P338	IF IN EYES: rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.

LKG-NSE-IFU, ENV3, 29.07.2026., IŠP

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

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Version	Description / reason for change	Date
3	Revised in accordance with Regulation (EU) 2017/746 – IVD	29.07.2026.