BIOGNOST®

LEUKOGNOST ACP

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

Kit for detection of acid phosphatase activity in leukocytes

INSTRUCTIONS FOR USE

BASIC UDI-DI	385889212HPC30702CYTOS9	
EMDN code	W01030702	
REF **Catalog number**	**Volume**	**UDI-DI**
LKG-ACP	for at least 50 tests	03858892122440

Intended use and test principle

The LeukoGnost ACP kit contains reagents for cytochemical diagnosis of leukemias on whole blood or bone marrow smears. The method is based on the ability of cellular phosphatase to hydrolyze naphthol AS-BI phosphate in an acidic environment. This reaction produces naphthol AS-BI, 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 placed preparations and contains reagents for at least 50 tests for the detection of acid phosphatase activity in leukocytes. The reagents are applied by dripping until the entire preparation is covered (1-2 mL).

Product description

- **LeukoGnost ACP** – kit for detection of acid phosphatase activity in leukocytes

The kit contains:	LKG-ACP (for 50 tests)	Storage temperature
Reagent 1 (Sodium nitrite, solution)	NAN-OT-5 (5 mL)	2-8°C
Reagent 2 (Fast Garnet GBC, solution)	FGGBC-OT-2 (2 mL)	2-8°C
Reagent 3 (ACP buffer)	NAP-OT-100 (100 mL)	2-8°C
Reagent 4 (ACP substrate)	NASBI-OT-5 (5 mL)	2-8°C
Reagent 5 (ACP inhibitor)	NATA-OT-10 (2x10 mL)	2-8°C

Other reagents required in the staining method

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

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 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 a thin and dry smear of peripheral blood or bone marrow (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 slide	1-3 minutes
2.	Rinse the preparation 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 or without phosphatase inhibitor) (1-2 mL) to the slide	3 hours
2.	Rinse the slide vigorously in distilled/demineralized water	10 seconds
3.	Dry the slide	
4.	Stain the slide with LeukoGnost HEM reagent	15 minutes
5.	Rinse the slide under running tap water	3 minutes
6.	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

Most leukocytes – red granular staining of the cytoplasm; when using the staining solution with the acid phosphatase inhibitor, there is no staining.

When using the staining solution that includes the acid phosphatase inhibitor, no specific staining of most leukocytes occurs; instead, red granular staining of the cytoplasm appears only in hairy cell leukemia cells.

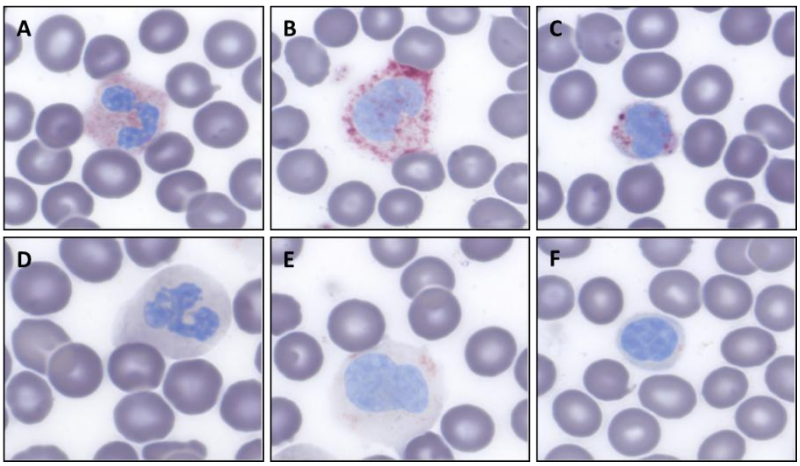

Figure 1. *Display of peripheral blood smears stained with the LeukoGnost ACP kit. Neutrophils (A,D), monocytes (B, E), and lymphocytes (C, F) are shown. Staining was performed without (A, B, C) or with (D, E, F) acid phosphatase inhibitor. Magnification 1000x.*

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 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. 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:

H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H317	May cause an allergic skin reaction.
H332	Harmful if inhaled.
H350	May cause cancer.
H319	Causes severe eye irritation.
H360D	May damage the unborn child.
P201	Obtain special instructions before use.
P261	Avoid breathing dust/fume/gas/mist/vapors/spray.
P234	Keep only in original packaging.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P312	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
P302+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse the skin with water [or shower].
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.
P332+P337+P313	If skin irritation occurs: If eye irritation persists: get medical advice/attention.

LKG-ACP-IFU, ENV3, 29.07.2026., IŠP

	Manufacturer	LOT	Batch code		Consult instructions for use	Σ	Contains sufficient for <n>tests		Contains hazardous substances
	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
3	Revised acc. to Regulation (EU) 2017/746 - IVDR	29.07.2026.