

# LEUKOGNOST PAS

CE IVD *In vitro* diagnostic medical device

Classified acc. to Regulation (EU) 2017/746 - Class A device

## Kit for detection of periodic acid-Schiff's reaction in leukocytes

### INSTRUCTIONS FOR USE

<b>BASIC UDI number</b>	385889212HPC30702CYTOS9		
<b>EMDN code</b>	W01030702		
<b>REF</b>	<b>Catalog number</b>	<b>Volume</b>	<b>UDI-DI number</b>
LKG-PAS	For at least 100 tests		03858892122471



#### Intended use and test principle

The LeukoGnost kit contains reagents for cytochemical diagnosis of leukemia in whole blood or bone marrow samples. The principle of this method is based on the oxidation reaction of intracellular glycogen and neutral mucopolysaccharides in the presence of periodic acid and Schiff's reagent. Molecules with glycolic groups under the influence of periodic acid create aldehydes that are affected by Schiff's reagent and paint them in an intense magenta color. The kit is designed for individual testing of horizontally placed slides and contains reagents for at least 100 tests for the detection of the reaction of periodic acid and Schiff's reagent in leukocytes. The reagents are applied by dripping until the entire preparation is covered (1-2 mL).

#### Product description

- **LeukoGnost PAS** – kit for detecting the reaction of periodic acid and Schiff's reagent in leukocytes

The kit contains:	LKG-PAS (100 tests)	Storage temperature:
Reagent 1 (Periodic acid, LeukoGnost)	PKL-OT-100 (2x100 mL)	15-25 °C
Reagent 2 (Sodium metabisulfite, LeukoGnost)	NMLKG-OT-10 (2x10 mL)	15-25 °C
Reagent 3 (HCL reagent, LeukoGnost)	HCLLP-OT-10 (2x10 mL)	15-25 °C
Reagent 4 (BioSchiff Forte reagent)	BSF-OT-100 (2x100 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

#### Additional reagents and materials that can be used in the 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 the sulphite solution:

- step 1: Mix Reagent 2 and Reagent 3 in a clean test tube
- step 2: add distilled/demineralized water to the mixture of Reagent 2 and Reagent 3

Note: make the sulfite solution directly before starting the test. Adjust the volume of the prepared sulphite solution to the number of slides.

#### Adjust the reagent volume as required:

STEP	REAGENT	FOR 1 PREPARATION	FOR 12 PREPARATIONS	FOR 24 PREPARATIONS
step 1	Reagent 2	200 µL (4 drops)	2.4 mL	4.8 mL
	Reagent 3	200 µL (4 drops)	2.4 mL	4.8 mL
step 2	distilled water	4 mL	48 mL	96 mL

#### Preparation of samples for staining

- Prepare the peripheral blood or bone marrow smear to be thin and dry (dry for min. 30 minutes). Smears 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 smear by applying LeukoGnost Fixative (1-2 mL)	1-3 min
2.	Rinse the slide under running tap water	10 sec
3.	Air dry the slide	

- Slides prepared and fixed in this way can be stored at a temperature of 2-8 °C and used for a maximum of three days.

#### NOTE

Apply the reagent so that it completely covers the slide.

**Be sure to close the bottle containing BioSchiff Forte well so that sulfur dioxide does not evaporate and so that the quality of the reagent is preserved. BioSchiff Forte is a colourless or slightly orange solution. If it changes color to pink, it is not suitable for use.**

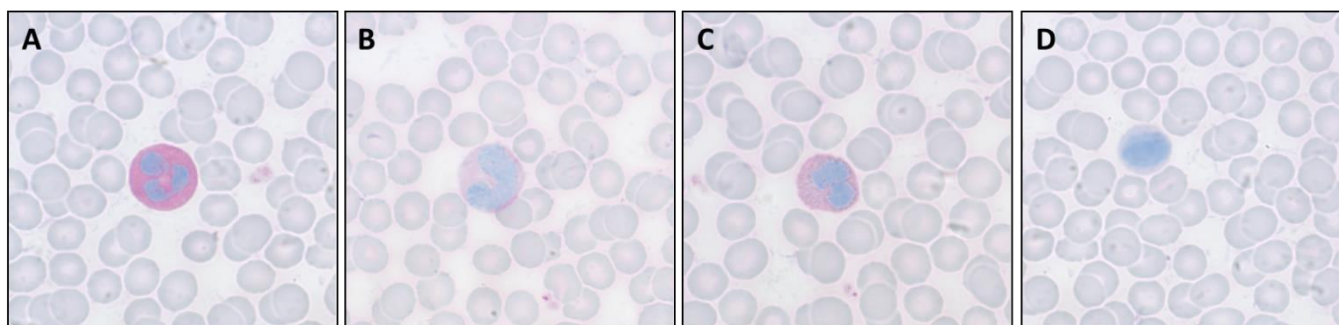
#### Sample staining procedure

1.	Apply Reagent 1 (1-2 mL) to the slide	10 min
2.	Rinse the slide in running tap water	10 sec
3.	Apply sulphite solution (1-2 mL) to the slide	1 min
4.	Apply Reagent 4 (1-2 mL) to the slide	15 min
5.	Rinse the slide in running tap water	10 sec
6.	Apply sulphite solution (1-2 mL) to the slide	3 min
7.	Rinse the slide in running tap water	3 min
8.	Stain the slide with LeukoGnost HEM reagent	3 min
9.	Rinse the slide under running tap water	3 min
10.	Air dry the slide	

After drying the slide, it is recommended to mount cover glasses with BioMount Aqua and store in the dark in order to permanently preserve the color and quality of the slide.

**Result**

Promyelocytes, monocytes, basophils, neutrophils, megakaryocytes, platelets, 10-40% lymphocytes – diffused to fine-grained magenta staining of the cytoplasm  
 Lymphoblasts, erythroblasts - magenta staining of the cytoplasm in the form of large granules  
 Normal myeloblasts, eosinophils and erythrocytes – no specific staining



**Image 1.** Display of peripheral blood smears stained with the LeukoGnost PAS kit. Specifically stained neutrophils (A), monocytes (B) and basophils (C), and unstained lymphocytes (D) 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 Instruction 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 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**

LeukoGnost PAS kit reagents have different temperature storage regimes, marked on their labels. The product can be transported at room or ambient temperature. Reagents should be stored at the prescribed temperatures, kept dry, not frozen and not exposed 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. Culling, GFA(1974): Handbook of histopathological and histochemical techniques, 2nd ed., Butterworth, London, UK.
2. Davey, FR et Nelson, DA(1977): Periodic Acid Schiff (PAS) Stain. IN Hematology, 2<sup>nd</sup> ed., WJ Williams, E. Buetler, AJ Erslev, RW Rundles, McGraw-Hill, New York, p. 1630-1632.
3. Hotchkiss, RD(1948): A microchemical reaction resulting in the staining of polysaccharide structures in fixed tissue preparations, *Arch. Biochem.* 16, p. 131.
4. Sheehan DC et Hrapchak, BB (1980): Theory and Practice Histotechnology, 2<sup>nd</sup> ed., CV Mosby, St. Louis, (MO), pp 52, p. 14-167.

**Warnings and precautions regarding the materials contained in the product:**

	EUH031	Releases toxic gas in contact with acids.
	H314	Causes severe skin burns and eye damage.
	H318	Causes serious eye damage.
	H335	May cause respiratory irritation.
	H350	May cause cancer.
	P201	Obtain special instructions before use.
	P405	Store locked up.
	P501	Dispose of contents/container in accordance with local guidelines.
	P308+P313	IF exposed or concerned: Get medical advice/attention.
	P304+P340+P310	IF INHALED: Remove person to fresh air and keep comfortable for breathing Immediately call a POISON CONTROL CENTER/physician/...
	P280	Wear protective gloves/protective clothing/eye protection/face protection.
	P303+P361+P353	IF ON SKIN (or hair): immediately take off all contaminated clothing. Rinse the skin with water or shower.
	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-PAS-IFU, ENV4 13.04.2026, 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
4	Revised in accordance with Regulation (EU) 2017/746 – IVDR; change in storage temperatures of BioSchiff Forte reagent to 2-8 °C	13/04/2026