BIOGNOST®

TUERK'S SOLUTION

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

Solution for manual counting of leukocytes

INSTRUCTIONS FOR USE

BASIC UDI-DI	385889212HPC3010302HMCA	
EMDN code	W0103010302	
REF **Catalog number**	**Volume**	**UDI-DI**
TU-OT-100	100 mL	03858888822392
TU-OT-500	500 mL	03858888822408
TU-OT-1L	1000 mL	03858890009200

Intended use and test principle

BioGnost's Tuerk's solution is used in the routine method of leukocyte counting. In every counting method, it is important to correctly prepare and dilute the blood sample in a defined volume. The acetic acid in Tuerk's solution hemolyzes erythrocytes, while the violet dye stains leukocytes. The stained leukocyte cells are counted in a precisely defined volume, and the number of cells per microliter of blood is then calculated.

Product description

- **TUERK'S SOLUTION** - an aqueous solution of Gentian violet powder dye with the addition of acetic acid

Additional reagents and materials that can be used in the method

- VitroGnost slides and coverslips for use in histopathology and cytology
- Neubauer counting chamber
- Leukocyte diluting pipette (Thoma pipette)

Test sample

- Non-coagulated venous blood or capillary blood

Sample preparation

Filling the diluting pipette

Draw blood into the leukocyte diluting pipette to the 1.0 mark, then draw Tuerk's solution to the 11 mark. The dilution is 1:10.
A 1:20 dilution can also be made (draw blood to the 0.5 mark and Tuerk's solution to the 11 mark).
Carefully mix the blood with Tuerk's solution; use the prepared sample within 1 hour.

Filling the counting chamber

Discard the first three drops and then fill the counting chamber.

Counting procedure

Counting under the microscope

Counting is performed under a microscope with a x10 objective; for older microscopes, it is necessary to lower the condenser and move the front lens outward.
Count the leukocytes in 4 large corner squares with sides of 1 mm in length.

It is recommended to repeat the count: the results must not differ by more than 15%.

Result

Counting

Leukocyte count = (x·10·10)/4 (dilution 1:10)

Leukocyte count = x·25 (no. of cells/µl)

X = total number of cells counted in 4 corner squares

Results are expressed as the mean of two independent cell counts.

Normal leukocyte count range

	Leukocyte count/µl
Adults	4,000 – 9,000
School-age children	5,000 – 12,000
Young children	6,000 – 15,000
Infants	7,000 – 17,000
Newborns	10,000 – 30,000

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 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 and/or authorized representative and the 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. Reagents 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, instructions for use and in the safety data sheet, which is available on request.

Storage, stability, and shelf life

Upon receipt, store the product in a dry place and well-closed original packaging at a temperature of +15 °C to +25 °C. Do not freeze or 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. Nagahashi, H. et al. (2000): Improved Sensitivity in the Measurement of Residual Leukocytes in Platelet Products Using an Automated Leukocyte Counter, *Labile Blood Components and Blood Donation,* 79; pp. 34-39.
2. Perretti, M. & Getting, S. J. (2003): Migration of Specific Leukocytes Subsets in Response to Cytokine or Chemokine Application In Vivo, in Inflammation Protocols; Methods in Molecular Biology, 225(2); pp. 139-146.
3. Softić, N. (1988): *Hematological Laboratory Tests*, Printed by Sveučilišna naklada Liber, Zagreb.
4. Teijlingen van, M. E. et al. (2000): In vivo visualization of hemodialysis-induced alterations in leukocyte-endothelial interactions. *Kidney International,* 57; pp. 2608-2617.

Warnings and precautions regarding the materials contained in the product:
Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

TU-IFU_ENV4, 10.04.2026. IŠP

	Manufacturer	LOT	Batch code		Consult instructions for use	CE	European conformity
	Date of manufacture	REF	Catalogue number		Caution	UDI	Unique device identifier
	Use-by date	°C	Temperature limit	IVD	*In vitro* diagnostic medical device		

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Version	Description / reason for change	Date
4	Revised acc. to Regulation (EU) 2017/746 - IVDR	10.04.2026.