BIOGNOST®

HAYEM'S SOLUTION

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

Solution for manual counting of erythrocytes

INSTRUCTIONS FOR USE

BASIC UDI-DI	385889212HPC3010302HMCA	
EMDN code	W0103010302	
REF **Catalog number**	**Volume**	**UDI-DI**
HY-OT-100	100 mL	03858888822125
HY-OT-500	500 mL	03858888822132
HY-OT-1L	1000 mL	03858890009194

Intended use and test principle

Hayem's solution is used in the routine method of erythrocyte counting. In every counting method, it is important to correctly prepare and dilute the blood sample in a defined volume. The main advantages of Hayem's solution over other erythrocyte counting solutions are its isotonicity (no hemolysis occurs), fixation (the shape of erythrocytes remains unchanged, no autolysis occurs, so counting can be performed several hours after blood dilution). Hayem's solution also prevents agglutination and has a long shelf life.

Product description

- **HAYEM'S SOLUTION** – isotonic solution for manual erythrocyte counting

Additional reagents and materials that can be used in the method

- VitroGnost slides and coverslips for use in histopathology and cytology
- Counting chamber (Neubauer or Bürker-Türk grid)
- Erythrocyte diluting pipette (Thoma pipette)

Test sample

- Non-coagulated venous blood or capillary blood

Preparation

Filling the diluting pipette

Draw blood into the erythrocyte diluting pipette up to the 0.5 mark, then draw Hayem's solution up to the 101 mark. The dilution is 200-fold. Carefully mix the blood with Hayem's solution; use the prepared sample within a few hours.

Filling the counting chamber

Discard the first two 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 erythrocytes in the central part of the grid. Typically, four diagonal fields (64 small squares) are counted, and for greater precision, one additional peripheral field can be counted (80 small squares in total).

Result

Counting

The side length of one small square is 1/20 mm, and the depth (after placing the coverslip) is 1/10 mm. Calculate the mean number of erythrocytes per one small cube and from that derive the number of erythrocytes per mm^3 of blood. Do not forget the dilution factor - multiply the obtained erythrocyte count by 200!

Results are expressed as the mean value of duplicate counts.

Normal erythrocyte values

Women: 3.86 - 5.08 x 10^{12}/L
Men: 4.34 - 5.72 x 10^{12}/L

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 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, the counting and staining procedures, as well as 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 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 in 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. Pal, G.K. et Parvati, Pal. (2006): Textbook Of Practical Physiology, 2nd ed., Orient Blackswan
3. Softić, N. (1988): *Hematological Laboratory Tests*, Tisak 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:		
	H302	Harmful if swallowed.
	P280	Wear protective gloves/protective clothing/eye protection/face protection.
	P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor.
	P308+P313	IF exposed or concerned: Get medical advice/attention.

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	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
5	Revised acc. to Regulation (EU) 2017/746 - IVDR	10.04.2026.