

HEMOGNOST PERLS KIT

CE IVD In vitro diagnostic medical device

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

HemoGnost Perls (Prussian blue) kit for the detection of free ferric (Fe³⁺) ions in cells

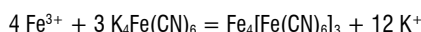
INSTRUCTION FOR USE

BASIC UDI number	385889212HPC30708STARVF		
EMDN code	W01030708		
REF	Catalog number	Volume	UDI-DI number
HP-100T	For 100 testiranja	303858890001020	03858890001020
HP-K-250	3x250 mL	0385888822156	0385888822156



Intended use and test principle

HemoGnost Perls kit is used for detection of free ferric ions (Fe³⁺) (not bound to hemoglobin) in cells. It is most often used in bone marrow and spleen cells. The method is based on Prussian/Berlin blue reaction and it is used for staining hemosiderin, a bluish pigment in macrophages (liver, spleen, bone marrow) and iron deposits in cells in case hemochromatosis, siderosis or hemorrhage. Prussian blue derives its name from the German pathologist Max Perls, who described the technique. The staining method is based on the reaction of ferric ion (Fe³⁺), not bound to hemoglobin with potassium hexacyanoferrate (II) in HCl – solution creating a blue non – soluble sediment (salt complex).



In order to achieve the best possible visual differentiation of ferric deposits in cytoplasm, Nuclear Fast Red reagent is used as counterstain - it stains the nuclei red.

Product description

- **HEMOGNOST PERLS KIT** – three-reagent kit for detection of free ferric ions in cells

The kit contains:	100 tests (HP-100T)	HP-K-250 (3 x 250 mL)	Storage temperature
Potassium hexacyanoferrate, solution	30 mL (KHC-OT-30)	250 mL (KHC-OT-250)	15-25°C
HCL reagent, HemoGnost Perls	30 mL (HCLH-OT-30)	250 mL (HCLH-OT-250)	15-25°C
Nuclear Fast Red (Kernechtrot) reagent	30 mL (KR-OT-30)	250 mL (KR-OT-250)	15-25°C

Additional reagents and materials that can be used in this method

- Fixatives such as BioGnost's neutral buffered formaldehyde solutions: Formaldehyde NB 4%, Formaldehyde NB 10%
- Dehydrating/rehydrating agent, such as BioGnost's alcohol solutions: Histanol 70, Histanol 80, Histanol 95 and Histanol 100
- Clearing agent, such as BioClear xylene or its aliphatic hydrocarbon substitutes, such as BioClear New
- Infiltration and embedding agent, such as BioGnost's granulated paraffin BioWax Plus 56/58, BioWax 56/68, BioWax Blue
- Covering agents for microscopic sections and mounting cover glass, such as BioGnost's BioMount, BioMount High, BioMount M, BioMount New, BioMount DPX, BioMount DPX High, BioMount DPX Low, BioMount C, BioMount Aqua
- VitroGnost slides and coverslips for use in histopathology and cytology
- BioGnost's immersion oils, such as Immersion oil, Cedarwood oil, Immersion oils types A and C, FF, 37 or Tropical Grade

Preparation of histological sections for staining

- Fix (Formaldehyde NB 4%, Formaldehyde NB 10%) and process the tissue sample
- Embed the tissue in a paraffin block (BioWax 52/54, BioWax 56/58, BioWax Plus 56/58, BioWax Blue)
- Cut the paraffin block into 4-6 μm thin slices and mount on a VitroGnost microscope slide

NOTE

Apply the reagent so it completely covers the section.

Histological sample staining procedure

a) using kit for 100 tests (HP-100T)

1.	Deparaffinize in xylene (BioClear) or xylene substitute (BioClear New)	3 exchanges, 2 min each
2.	Rehydrate in 100% alcohol (Histanol 100)	2 exchanges, 5 and 3 min
3.	Rehydrate in 95% alcohol (Histanol 95)	2 min
4.	Rehydrate in distilled/demineralized water	2 min
5.	Add ≥ 5 drops of Potassium hexacyanoferrate, solution and ≥ 5 drops of HCL reagent, HemoGnost Perls. Gently stir Make sure that the drops ratio of Potassium hexacyanoferrateheksacijanoferata, solution and HCL reagent, HemoGnost Perls is the same!	20 min
6.	Carefully rinse in distilled/demineralized water	
7.	Stain using Nuclear Fast Red (Kernechtrot) reagent(≥5 drops)	5 min
8.	Rinse in distilled/demineralized water	
9.	Dehydrate in 70% alcohol (Histanol 70)	2 exchanges, 1 min each
10.	Dehydrate in 95% alcohol (Histanol 95)	2 exchanges, 1 min each
11.	Dehydrate in 100% alcohol (Histanol 100)	2 exchanges, 1 min each
12.	Clear in xylene (BioClear) or xylene substitute (BioClear New)	2 exchanges, 2 min each

Immediately after clearing apply an appropriate BioMount medium for covering/mounting on the section. If BioClear xylene was used, use one of BioGnost's mounting xylene-based media (BioMount, BioMount High, BioMount M, BioMount DPX, BioMount C, or universal BioMount New). If BioClear New xylene substitute was used, the appropriate covering agent is BioMount New. Cover the section with VitroGnost cover glass.

b) using three-reagent kit (HP-K-250)

1.	Deparaffinize in xylene (BioClear) or xylene substitute (BioClear New)	3 exchanges, 2 min each
2.	Rehydrate in 100% alcohol (Histanol 100)	2 exchanges, 5 and 3 min
3.	Rehydrate in 95% alcohol (Histanol 95)	2 min

4.	Rehydrate in distilled/demineralized water	2 min
5.	Mix 30 mL of Potassium hexacyanoferrate, solution and 30 mL of HCL reagent, HemoGnost Perls. Treat the slides with the prepared solution Note: Use fresh solution, discard after use.	20 min
6.	Carefully rinse in distilled/demineralized water	
7.	Stain using Nuclear Fast Red (Kernechtrot) reagent	5 min
8.	Rinse in distilled/demineralized water	
9.	Dehydrate in 70% alcohol (Histanol 70)	2 exchanges, 1 min each
10.	Dehydrate in 95% alcohol (Histanol 95)	2 exchanges, 1 min each
11.	Dehydrate in 100% alcohol (Histanol 100)	2 exchanges, 1 min each
12.	Clear in xylene (BioClear) or xylene substitute (BioClear New)	2 exchanges, 2 min each

Immediately after clearing apply an appropriate BioMount medium for covering/mounting on the section. If BioClear xylene was used, use one of BioGnost's mounting xylene-based media (BioMount, BioMount High, BioMount M, BioMount DPX, BioMount C, or universal BioMount New). If BioClear New xylene substitute was used, the appropriate covering agent is BioMount New. Cover the section with VitroGnost cover glass.

Result

Reactive ferric ions (Fe³⁺) – blue granules

Nuclei – red

Cytoplasm – pink

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. Be sure to follow the manufacturer's handling instructions. To avoid errors, staining and diagnosis can only be carried out by qualified personnel. Use a microscope equipped according to medical diagnostic laboratory standards. To avoid an incorrect staining result, it is advised to use a positive and negative control.

If a serious incident occurs during use of this product 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. Reagents used in this procedure can pose a danger to human health. The examined tissue samples are potentially infectious, and it is necessary to take the measures needed to protect human health in accordance with the guidelines of good laboratory practice. 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 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 expiration date is printed on the product label.


References

- Culling, C.F.A. (1974): Handbook of histopathological and histochemical techniques, 2 ed ed., Butterworth, London, UK.
- Sheehan D.C. et Hrapchak, B.B. (1980): Theory and Practice Histotechnology, 2nd ed., CV Mosby, St. Louis, (MO), pp 52, str. 14-167.

Warnings and precautions regarding the materials contained in the product:	
 	H226 Flammable liquid and vapor. H315 Causes skin irritation, H319 Causes serious eye irritation.
	P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P260 Do not breathe /fumes/gas/mist/vapors/spray.
	P280 Wear protective gloves/protective clothing/eye protection/face protection. 305 + P351 + P338 IF IN EYES: rinse carefully with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.
	P303 + P361 + P353 IF ON SKIN (or hair): remove immediately all contaminated clothing. Rinse with water (shower).
	P308 + P313 IF exposed or concerned: get medical advice/attention.

HP-IFU_ENV8, 25.02.2026., IŠP

 Manufacturer	 Batch code	 Temperature limit	 <i>In vitro</i> diagnostic medical device	 Unique device identifier
 Date of manufacture	 Catalogue number	 Consult instructions for use	 Contains sufficient for <n> tests	
 Use-by date	 Fragile, handle with care	 Caution	 European conformity	

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Version	Description / reason for change	Date
8	Revised acc. to Regulation (EU) 2017/746 - IVDR	25.02.2026.