

SUDAN BLACK B KIT



IVD In vitro diagnostic medical device

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

Four-reagent kit for staining neutrophil granules in hematological smears

INSTRUCTIONS FOR USE

BASIC UDI number	385889212HPC30708STARVF		
EMDN code	W01030708		
REF	Catalog number	Volume	UDI-DI number
SBBH-K-100	For 350-400 tests		03858890001877



Intended use and test principle

BioGnost's Sudan Black B kit for staining in hematology is used for staining neutrophil granules in blood smears and bone marrow smears. Sudan Black B is a lipophilic dye, soluble in lipids and deposits in lipid-rich structures, such as specific neutrophil granules. The result of staining the leukocytes with Sudan Black B dye is similar to the result after staining with myeloperoxidase. Cells of lymphoid line will not be stained with Sudan Black B dye, while myeloid and monocytoid cells will demonstrate characteristic positive reaction, they will get stained dark blue to black. This is the reason why Sudan Black B is used in methods of determining myelocytic and myelomonocytic leukemia.

Product description

- **SUDAN BLACK B KIT** – Kit for staining neutrophil granules

The kit contains:	SBBH-K-100	Storage temperature
Sudan Black B reagent	2 x 100 mL (SBB-OT-100)	15-25°C
Hematoxylin G3	1 x 100 mL (HEMG3-OT-100)	15-25°C
Glutaraldehyde, 4% buffered solution	1 x 75 mL (G4-OT-75)	15-25°C
Acetone for histology	1 x 25 mL (AC-25)	15-25°C

Additional reagents and materials that can be used in this method

- 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
- Dehydrating/rehydrating agent, such as BioGnost's alcohol solution Histanol 70
- Bluing reagents such as BioGnost's Bluing reagent or Scott's solution

NOTE

Apply the reagent so it completely covers the section.

To achieve optimal results follow these rules:

- use only freshly sampled whole blood or anticoagulated blood, and bone marrow smear. Fix the samples in the shortest time period possible.
- if a precipitate appears in the reagent Glutaraldehyde, 4% buffered solution, it must be filtered (the precipitate does not affect the staining quality)
- cool down Glutaraldehyde, 4% buffered solution in a refrigerator at 2-8°C before use
- filter Sudan Black B reagent before use

Hematological smears staining procedure

1.	Cool Glutaraldehyde, 4% buffered solution in a refrigerator (2-8°C)	
2.	Fix the smear by immersing it into Glutaraldehyde, 4% buffered solution at 2-8°C with gentle agitation	1 min
3.	Thoroughly rinse in distilled/demineralized water	
4.	Immerse into Sudan Black B reagent with intermittent agitation	5 min
5.	Rinse 3 or more times in 70% alcohol (Histanol 70) until no more dye washes away	
6.	Thoroughly rinse in distilled/demineralized water	
7.	Immerse into Hematoxylin G3	5 min
	If sedimentation occurs or a metallic sheen forms in Hematoxylin G3, filter the reagent before use	
8.	Blue using Scott's solution or Bluing reagent, immerse into the reagent	1 min
	Note: If the mentioned reagents are not available, the section should be blued using indirect stream of water	3-5 min
9.	Air dry the sample.	

It is recommended to use an immersion oil for microscopic analysis of the stained sample with magnification of more than 40x.

Result

Neutrophil granules and neutrophil precursors – blue – black

Monocytes – blue – black (slightly stained)

Lymphocytes – not stained

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

1. Culling, C.F.A. (1974): Handbook of histopathological and histochemical techniques, 2nd ed., Butterworth, London, UK.
2. Davey, F.R. et Nelson, D.A. (1977): Sudan Black B staining. IN Hematology, 2nd ed., W. J. Williams, E. Beutler, A. J. Erslev, R. W. Rundles, Editors, McGraw-Hill, New York, str. 1629-1630
3. Sheehan H.L. et Storey G.W. (1947): An improved method of staining leukocyte granules with Sudan Black, J. Pathol Bacteriol, 59:336

Warnings and precautions regarding the materials contained in the product:	
	<p>H225 Highly flammable liquid and vapor. H302 Harmful if swallowed. H314 Causes severe skin burns and eye damage. . H315 Causes skin irritation. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H332 Harmful if inhaled. H336 May cause drowsiness or dizziness. H341 Suspected of causing genetic defects. EUH066 Repeated exposure may cause skin dryness and cracking.</p>
	<p>P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P233 Keep container tightly closed. P280 Wear protective gloves/protective clothing/eye protection/face protection. P331 Do NOT induce vomiting. P301 + P310 IF SWALLOWED: call immediately POISON CENTER/doctor. P301 + P312 IF SWALLOWED: if you feel unwell, call POISON CENTER/doctor. P302 + P352 IF ON SKIN: wash with plenty of water. P308 + P311 IF exposed or concerned: call POISON CENTER/doctor P303 + P361 + P353 IF ON SKIN (or hair): remove immediately all contaminated clothing. Rinse with water (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.</p>

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

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Version	Description / reason for change	Date
8	Revised acc. to Regulation (EU) 2017/746 - IVDR	27.02.2026.