BIOGNOST®

FIELD KIT

IVD *In vitro* diagnostic medical device CE

Two-reagent kit for staining in hematology and parasitology

Contains blue and red component for fast and efficient hematology samples staining

INSTRUCTIONS FOR USE

REF Product code: FD-100T (for 100 tests) FD-K-500

Introduction

Field kit is primarily used for staining standard thin and thick blood smears, i.e. dense drops for purpose of diagnosing blood parasites (such as *Plasmodium* which causes malaria). Because the amount of parasites in blood samples tends to be low and almost unobservable in standard blood smear, the preparation of thick blood smear enables 15-20 times higher sensitivity of diagnostic method. Thick blood smears are not fixed; they are treated with hypotonic dye solution after drying on air. During that procedure white blood cells (leukocytes) are preserved and stained, while red blood cells (erythrocytes) are hemolyzed which in turn makes viewing of other present structures in blood under microscope easier. Thin blood smear staining should always be conducted at the same time as thick blood smear staining, because the control of such smear enables parasite differentiation. Beside this, Field kit can also be used as a Romanowsky dye for rapid routine staining in hematology; it can be used for staining standard blood smears and bone marrow, but also for staining *Helicobacter pylori* in stomach histology samples. Each part of Field kit is stabilized separately and prepared according to the highest standards.

Product description

FIELD KIT – Kit for rapid and efficient staining and detection of parasites in hematology samples.

The kit contains:	FD-100T (100 tests)	FD-K-500 (2x500 mL)
Field, solution A	100 mL (FDA-RTU)	500 mL (FDA-OT-500)
Field, solution B	100 mL (FDB-RTU)	500 mL (FDB-OT-500)

Other slides and reagents that may be used in staining:

- Methyl alcohol for fixing thin blood samples, such as Histanol M
- BioGnost's immersion oils, such as BioGnost's Immersion oil, Cedarwood oil, Immersion oils types 37, A, B, FF and NVH
- Glass slides used in hematology, such as VitroGnost STANDARD GRADE or high quality glass slides used in histopathology and cytology, such as VitroGnost SUPER GRADE or one of more than 30 models of VitroGnost glass slides

Preparation of blood smears

Prepare thin and thick blood smear from the same fresh sample of peripheral blood at the same time

Thin blood smear

- Add one drop to one end of completely clear glass slide and use another glass slide to smear the drop at the edge of the slide. After that, draw the slide to the other end under 45 degrees angle in order to create the smear. Let the smear dry.

Thick blood smear (dense drop)

- Place 2-3 drops on a completely clean glass slide and use glass stick to mix them into a round, transparent smear (1-2 cm diameter). Let the smear dry.

A) Thin blood smear staining procedure

1.	Fix the blood sample in methanol (Histanol M)	1 min
2.	Immerse the section into Field, solution B.	1 x 5 seconds
3.	Rinse the excessive dye in tap water and decant the section using filter paper	
4.	Immerse the section in Field, solution A	10-30 seconds
	Note: longer incubation period enhances blue/purple hues of the section	
5.	Rinse the excessive dye in tap water and decant the section using filter paper	
6.	Dry the preparation	

Result

Leukocytes - dark purple nucleus with pink-purple cytoplasm
Erythrocytes - blue-purple
Parasites - dark red chromatin with light blue cytoplasm

Note: in order to confirm the type of parasite present in the blood smear, we recommend repeating staining using May-Gruenwald Giemsa staining method that provides more precise results with parasite differentiation.

B) Thick blood sample staining procedure (dense drops)

1.	Immerse the dried sample in Field, solution A	1 x 5 seconds
2.	Rinse the excessive dye in tap water and decant the section using filter paper	
3.	Immerse the section into Field, solution B.	1 x 1 seconds

4.	Rinse the excessive dye in tap water and decant the section using filter paper	
5.	Dry the preparation	

Note: during viewing under microscope, view the peripheral parts of the section

Result

Leukocytes - dark purple nucleus with pale blue cytoplasm
Erythrocytes - hemolyzed, only residual pale stains can be seen
Parasites - dark red chromatin with pale blue cytoplasm

Note

Time periods of staining processes are not entirely standardized in clinical and laboratory practical experience. Time periods specified in the instruction approximately correspond to a longtime work practice with optimal results. Intensity of staining depends on the period of immersion in the dye. Real staining protocol depends on personal requests and priorities.

Preparing the sample and diagnostics

Use only appropriate instruments for collecting and preparing the samples. Process the samples with modern technology and mark them clearly. Follow the manufacturer's instructions for handling and application. In order to avoid mistakes, the staining procedure and diagnostics should only be conducted by authorized and qualified personnel. Use only microscope according to standards of the medical diagnostic laboratory.

Safety at work and environmental protection

Handle the product in accordance with safety at work and environmental protection guidelines. Used solutions and out of date solutions should be disposed of as special waste in accordance with national guidelines. Chemicals used in this procedure could pose danger to human health. Tested tissue specimens are potentially infectious. Necessary safety measures for protecting human health should be taken in accordance with good laboratory practice. Act in accordance with signs and warnings notices printed on the product's label, as well as in BioGnost's material safety data sheet.

Storing, stability and expiry date

Keep Field kit in a tightly closed original package at temperature between 15°C and 25°C. Do not keep in cold places, do not freeze and avoid exposing to direct sunlight. Date of manufacture and expiry date are printed on the product's label.

References

1. Beck, R.C. (1938): *Laboratory Manual of Heamtological Technique,* Philadelphia, W.B. Saunders & Co.
2. Dacie, J. et Lewis S. (1995): *Practical haematology*, 4th ed., London, Churchill Livingstone.
3. Giemsa, G. (1922): Das Wesen der Giemsa-Farbung, *Zentralb f Bakt*; 89, str. 99-106.
4. Kiernan, J.A. (2008): *Histological and histochemical methods: Theory and Practice,* 4th ed., Bloxham, Scion Publishing Ltd.
5. May, R. et Grünwald L. (1909): *Über die Farbung von Feutchpraparaten mit meiner Azur-Eosine methode,* Deutsche med Xschr, 35, str. 1751-1752.

FD-X, V3-EN1, 23 December 2016, AK/VR

	Refer to the supplied documentation	°C	Storage temperature range	Σ	Number of tests in package	REF	Product code	CE	European Conformity		BIOGNOST Ltd. Medjugorska 59 10040 Zagreb CROATIA www.biognost.com
	Refer to supplied instructions		Keep away from heat and sunlight		Valid until	LOT	Lot number		Manufacturer		
IVD	For *in vitro* diagnostic use only		Keep in dry place		Caution - fragile						