Hematology Devices (for in vitro diagnostic use)

ABX Minipack LMG

01/02/08
A95A00032CEN

Exclusive use:

Micros
Micros CRP
Pentra 60
Pentra 60 C+
Pentra 80
Pentra XL 80
Pentra 120
Pentra 120 Retic
Pentra DX 120
Slide Preparation System

REF 0602050

REAGENT 1 0,5L

REAGENT 2 0,3L

REAGENT 3 3,4L

IVD CE

HORIBA ABX
BP 7290 - 34184
Montpellier
cedex 4 - France

1. Functions

R1: Enzymatic solution with proteolytic action for the cleaning of HORIBA ABX blood cell counters.

R2: Erythrocyte lysing agent for white blood cell counting, and differentiation and hemoglobin determination on HORIBA ABX blood cell counters.

R3: Buffered isotonic solution for the determination and the differentiation of blood cells, and the measurement of hematocrit on HORIBA ABX blood cell counters.

Measurement procedure to be followed in using the device:

Principle of the method, specific analytical performance characteristics, analytical sensitivity, diagnostic sensitivity, analytical specificity, diagnostic specificity, accuracy, repeatability, reproducibility (including control of known relevant interference), limits of detection, limitations of the method and information about the use of available reference measurement procedures and materials by the user: see «Section: Specifications» in the instrument User Manual.

2. Conservation & expiration

Storage conditions: Room temperature between 18°C (65°F) to 25°C (77°F).

Open stability[a]**:**

Maximum 1 month after the pack has been opened.

Expiration date: refer to «expiration date» reagent packaging label.

3. Measurements, principles & results

Directions for use[b]: see «Section: Maintenance & Troubleshooting» in the instrument User Manual.

Measuring Principles : see «Section: Technology» in the instrument User Manual.

Results: Refer to the instrument User Manual

Performance data: see «Section: Specifications» in the instrument User Manual.

Note: if performance changes, call your HORIBA ABX representative.

4. Composition & Handling precautions[c]

R1:	Organic Buffer .....< 20% Proteolytic enzyme.....< 1%	
	pH:	9,6 +/- 0,4 (T = 20°C)
	Resistivity:	72 +/- 2 Ω (T = 20°C)
	Description:	Colorless liquid.
R2:	Potassium cyanide.....< 0,03% Quaternary Ammonium salt < 20%	
	pH:	10 +/- 0,5 (T = 20°C)
	Resistivity:	213 +/- 10 Ω (T = 20°C)
	Description:	Colorless liquid.
R3:	Sodium fluoride .....< 3% Sodium Azide. .....< 0,1% Sodium Hydroxyde.....< 1% Dimethylolurea 0,1%	
	pH:	7 +/- 0,1 (T = 20°C)

a.Modifications from index B to C: Open stability

b.Modifications from index B to C: Directions for use
c.Modifications from index B to C: ~~Dimethylourea~~ Dimethylolurea

Resistivity:	60 +/- 6 Ω (T = 20°C)
Description:	Limpid and odourless aqueous solution.

Handling Precautions: Avoid contact with eyes, skin and clothing. Wear laboratory gloves when handling the product. The product may be harmful if ingested or inhaled. Keep the bottle closed when not in use. Please refer to the MSDS associated with the reagent.

Once the waste seal has been broken, the Minipack must be considered as potentially infectious! Use established, good laboratory working practices when handling the Pack.

Specimen Collection and Mixing: see «Section: Specimen collection and Mixing» in the instrument User Manual.

5. Limitations & waste disposal

Limitations: see «Section: Specifications» in the instrument User Manual.

Safe Waste Disposal: Follow your laboratory's protocol when neutralizing and disposing of waste. Please refer to the MSDS associated with the reagent.