

Hematology Devices (for in vitro diagnostic use)

ABX Leucodiff

18/05/2010
A95A00014GEN

REF 0206013 (1L)

REAGENT 1L

IVD 



HORIBA ABX SAS
Parc Euromédecine
Rue du Caducée
BP 7290
34184 Montpellier Cedex 4
FRANCE

Exclusive use:

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

1. Functions

Reagent for differentiation of leucocyte subpopulations on HORIBA Medical 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: maximum 3 months after a vial has been opened.

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

3. Measurements, principles & results

Directions for use: see «Section: Maintenance & Troubleshooting» in the instrument User Manual. This reagent is for professional *in-vitro* diagnostic use only.

Measuring Principles : see «Section: Description & technology» in the instrument User Manual.

Results: see «Section: Workflow» in the instrument User Manual

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

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

4. Composition & handling precautions^a

Composition:

Propanol-2..... <20%
Quaternary ammonium salt <20%
Detergent..... <20%
Preservative..... <1%

pH: 7,1 +/- 0,1 (T = 20°C)

Resistivity: 59 +/- 1 Ω (T = 20°C)

Description: Deep blue aqueous solution, smells of alcohol.

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.

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

5. Limitations & waste disposal

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

Safe Waste Disposal: see «Section: Specifications» in the instrument User Manual. Please refer to the MSDS associated with the reagent.

a.Modification from index F to G: Paragraph «Composition» modified, pH and resistivity modified

