

Hematology Devices (for in vitro diagnostic use)

ABX Lysebio

29/09/09
A95A00011FEN

Exclusive use:

Pentra 60 (0,4L)
Pentra 60 C+ (0,4L)
Pentra ES60 (0,4L)
Pentra 80 (0,4L)
Pentra XL 80 (0,4L)
Pentra 120 (1L)
Pentra 120 Retic (1L)
Pentra DF 120 (1L)
Pentra DX 120 (1L)
Slide Preparation System

REF 0906012 (1L)
0906013 (0,4L)

REAGENT 1L
0,4L

IVD 



HORIBA ABX SAS
BP 7290 - 34184 Montpellier
cedex 4 - France

1. Functions

This reagent is used on HORIBA Medical blood cell counters to lyse red blood cells and determine hemoglobin concentration ^a.

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: Stored at 15°C (59°F) to 30°C (86°F) away from light.

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.

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

Composition :

Quarternary ammonium salt < 20%

pH: 6,95 +/- 0,1 (T = 20°C)

Resistivity: 40 +/- 1 Ω (T = 20°C)

Description: Colorless, odorless.

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 E to F: Pentra ES60 added

