

REF 0903010

REAGENT 1 L

IVD **CE**

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

ABX Cleaner 1L

- ABX Pentra 60 / 60C+
- Pentra ES60 / MS60 / MS CRP
- Pentra DX Nexus / DF Nexus
- ABX Pentra XL80
- Pentra XLR
- Yumizen H500 OT / CT / H550
- Yumizen H500E OT / CT / H550E
- Yumizen H1500 / H2500

Hematology Devices (for *in vitro* diagnostic use)

Intended Use ^a

ABX Cleaner 1L is an enzymatic solution intended for *in vitro* diagnostic use with proteolytic action for the cleaning of HORIBA Medical blood cell counters. Clinical laboratories use.

Warnings and Precautions ^b

- **ABX Cleaner 1L** is for professional *in vitro* diagnostic use only.
For laboratory use.
- It is the user's responsibility to verify that this document is applicable to the product use.
- This reagent is classified as hazardous in compliance with regulation (EC) N°.1272/2008.
- **Warning**
H317: May cause an allergic skin reaction.
H412: Harmful to aquatic life with long lasting effects.
P261: Avoid breathing dust/fume/gas/mist/vapours/spray.
P280: Wear protective gloves or clothing and eye or face protection.
P302 + P352: IF ON SKIN: Wash with plenty of soap and water.
P333 + P313: If skin irritation or rash occurs: Get medical advice/attention.
P501: Dispose of contents and container in accordance with all local, regional, national and international regulations.
- Users are advised to wear approved protective clothing when handling chemical products: lab coat, gloves, and eye protection.
- Observe the standard laboratory precautions for use and follow national or local health and safety guidelines.

- User must be trained by a HORIBA Medical representative before attempting to operate the device.
- In the event of a malaise following skin contact, ingestion, or inhalation, consult a doctor.
- Please refer to the Safety Data Sheet (SDS) associated with **ABX Cleaner 1L**.
- Do not use the product if the recommended storage conditions, including temperature, are not followed.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the country in which the user and/or the patient is established.
- The reagent containers are disposable and should be disposed of in accordance with the local legal requirements.
- For technical assistance, you can call +33 (0)4 67 14 15 16.
- This reagent is destined for use with HORIBA Medical blood cell counters specified above. HORIBA Medical cannot guarantee the correct functioning of this reagent with instruments other than those specified above, or with instruments not manufactured by HORIBA Medical.

Waste Management

Please refer to local legal requirements. This reagent contains less than 0.1% of sodium azide as a preservative. Sodium azide may react with lead and copper to form explosive metal azides.

Microbiological State

Not applicable.

^aModification: new reagent leaflet form.

^bModification: classification changed.

ABX Cleaner 1L

Description and Composition

Description:

Lipid and colourless to light yellowish aqueous solution.

Composition:

Organic buffer	< 5%
Proteolytic enzyme	< 1%
Preservative	< 1%

Storage and Stability

- **Storage condition (before opening):** 18-25°C (65-77°F).
Do not freeze.
- **Open stability:** 3 months maximum at 18-25°C (65-77°F) after opening and within the expiration limit.
- **Expiration date:** refer to "expiration date" reagent packaging label.

Materials Required but not Provided

- Automated hematology analyzer.
- Standard laboratory equipment.

Specimen

Not applicable.

Procedure

This reagent is ready to use.

Procedure for reagent with stopper and straw

Reagent with stopper and straw is used on:

- ABX Pentra 60
- ABX Pentra 60 C+
- Pentra ES 60
- Pentra MS 60
- Pentra MS CRP
- ABX Pentra XL 80
- Pentra XLR
- Yumizen H500 OT / CT / H550
- Yumizen H500E OT / CT / H550E

1. Refer to the user manual to identify **ABX Cleaner 1L** using the barcode reader or manually.

2. Open the door of the reagent compartment.
3. If necessary, remove the empty **ABX Cleaner 1L** from the reagent compartment.
4. Uncap the new reagent bottle.
5. Insert the stopper assembly straw into the bottle.
6. Tighten the stopper assembly to ensure an adequate seal.
7. Install **ABX Cleaner 1L** into the reagent compartment of the instrument.
8. Close the door of the reagent compartment.

Follow instructions displayed on your instrument software.

Refer to the instrument user manual for detailed analysis and control procedures.

Methodology

ABX Cleaner 1L: the combined action of a proteolytic enzyme with a detergent eliminates protein residues and prevents the hydraulic tubes from clogging and / or blocking. It is used also to break down the protein build-ups in the counting chambers and apertures.

Performance Characteristics and Limitations

Not applicable.

Calculation and Interpretation of Analytical Results

Not applicable.

Changes in the Procedure and in the Performance

Packaging spoiling

In case of protective packaging spoiling, do not use **ABX Cleaner 1L** if the damages might have an effect on the product performance.

Signs of deterioration

In the event of any signs of physical or chemical deterioration (turbidity, change in colour etc.) **ABX Cleaner 1L** should be replaced.

ABX Cleaner 1L

Temperature limits

Do not use **ABX Cleaner 1L** if it has been frozen or kept at excessive heat.

Before using **ABX Cleaner 1L**, make sure it has reached the operating temperature conditions as described in the instrument user manual.

Internal Quality Control

Not applicable.

Traceability of Calibrators and Control Materials

Not applicable.

Reference Intervals

Not applicable.

