

REF 0401005

REAGENT 0.5 L

IVD **CE**

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

ABX Minocclair 0.5L

- ABX Micros 60
- ABX Micros ES60 / ESV60
- ABX Pentra 60 / 60C+
- ABX Pentra XL80
- Pentra XLR
- Pentra DX Nexus / DF Nexus
- Pentra ES60 / MS60 / MS CRP
- Micros Care ST
- Microsemi CRP
- Yumizen H500 OT / CT / H550
- Yumizen H1500 / H2500

Hematology Devices (for *in vitro* diagnostic use)

Intended Use ^{a b c}

ABX Minocclair 0.5L is a chemical solution intended for *in vitro* diagnostic use and designed for the cleaning of HORIBA Medical blood cell counters. Clinical laboratories use.

Warnings and Precautions ^d

- **ABX Minocclair 0.5L** 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**
H290: May be corrosive to metals.
H412: Harmful to aquatic life with long lasting effects.
P234: Keep only in original packaging.
P273: Avoid release to the environment.
P390: Absorb spillage to prevent material damage.
P406: Store in corrosive resistant container with a resistant inner liner.
- 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 Minocclair 0.5L**.
- 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.

Microbiological State

Not applicable.

Description and Composition

Description:

Basic, limpid and yellowish aqueous solution. Smells of bleach.

^aModification: new reagent leaflet form.

^bModification: instrument removed.

^cModification: modification of intended use.

^dModification: recommendation added.

ABX Minocclair 0.5L

Composition:

Chemical cleaning agent	< 5%
Stabilizer	< 1%

Storage and Stability

- **Storage condition (before opening):** 18-25°C (65-77°F).
Do not freeze.
- **Open stability:** 6 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 ^e

- Automated hematology analyzer.
- Standard laboratory equipment.

Specimen ^e

Not applicable.

Procedure

This reagent is ready to use.
ABX Minocclair 0.5L is used during auto-concentrated cleaning procedure. Refer to the instrument user manual for running auto-concentrated cleaning.

Methodology

ABX Minocclair 0.5L has an oxydizing action to clean up the hydraulic parts of the instrument.

Performance Characteristics and Limitations ^e

Not applicable.

Calculation and Interpretation of Analytical Results ^e

Not applicable.

Changes in the Procedure and in the Performance

Packaging spoiling

In case of protective packaging spoiling, do not use **ABX Minocclair 0.5L** 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 Minocclair 0.5L** should be replaced.

Temperature limits

Do not use **ABX Minocclair 0.5L** if it has been frozen or kept at excessive heat.
Before using **ABX Minocclair 0.5L**, make sure it has reached the operating temperature conditions as described in the instrument user manual.

Internal Quality Control ^e

Not applicable.

Traceability of Calibrators and Control Materials

Not applicable.

Reference Intervals

Not applicable.

^eModification: correction.