

REF 0906014

REAGENT 360 mL

IVD **CE**

HORIBA ABX SAS
Parc Euromédecine
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BP 7290
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FRANCE

ABX Alphalyse 360 mL

- ABX Micros 60
- ABX Micros ES60

Hematology Devices (for *in vitro* diagnostic use)

Intended Use ^a

ABX Alphalyse 360 mL is a lysing solution intended for *in vitro* diagnostic use and designed for lysing erythrocytes (RBC) for leucocytes (WBC) counting and differentiation and for hemoglobin determination on HORIBA blood cell counters.

Clinical laboratories use.

Warnings and Precautions ^{b c}

- **ABX Alphalyse 360 mL** 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**
H302: Harmful if swallowed.
H410: Very toxic to aquatic life with long lasting effects.
P264: Wash hands thoroughly after handling.
P270: Do not eat, drink or smoke when using this product.
P273: Avoid release to the environment.
P301 + P312: IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell.
P330: Rinse mouth.
P391: Collect spillage.
P501: Dispose of contents and container in accordance with all local, regional, national and international regulations.
- Contains: Potassium cyanide

- 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 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 Alphalyse 360 mL**.
- 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.
- Very toxic to the environment.
It is strongly recommended not to release the product into the environment.
- 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 blood cell counters specified above. HORIBA cannot guarantee the correct functioning of this reagent with instruments other than those specified above, or with instruments not manufactured by HORIBA.

Waste Management

Please refer to local legal requirements.

^aModification: new reagent leaflet form.

^bModification: classification changed.

^cModification: recommendation added.

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Microbiological State

Not applicable.

Description and Composition

Description:

Limpid and colourless aqueous solution.

Composition:

| | |
|--------------|--------|
| Lysing agent | < 0.1% |
| Detergent | < 5% |

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.
- Calibrator: **ABX Minocal**.
- Control: refer to the user manual for the specific control used with your instrument.
- Standard laboratory equipment.

Specimen^{d e}

Sample collection:

All specimen samples should be collected using proper technique. Consider all specimens, reagents, calibrators, controls, etc. that contain biological specimen extracts as potentially infectious and follow biosafety practices (1, 2, 3).

Specimen collection must be placed in vacuum or atmospheric collection tubes (4).

Please refer to the user manual for sample collection.

Recommended anti-coagulant:

The recommended anticoagulant is K₃-EDTA with the proper proportion of blood to anticoagulant as specified

by the tube manufacturer. K₂-EDTA is an acceptable alternative, as long as the sample collection is made in normal conditions. Otherwise, blood clots may be possible.

Blood sample stability:

Please refer to the user manual.

Microsampling:

Instrument sampling mode enables the user to work with microsamples for pediatrics and geriatrics (refer to the instrument user manual for the minimum blood sample volume). These microsamples can only be used in the following conditions:

- The tube must always be held in vertical position.
- Blood mixing must be obtained by slight tapping on the tube. Do not rotate the tube for mixing, otherwise the blood will be spread on the tube side, and the minimum required level will be lost.

Mixing:

Blood samples must be gently and thoroughly mixed just before sampling. This ensures a homogeneous mixture for measurement.

Procedure

This reagent is ready to use.

1. Refer to the user manual to identify **ABX Alphalyse 360 mL** using the barcode reader or manually.
2. Open the door of the reagent compartment.
3. If necessary, remove the empty **ABX Alphalyse 360 mL** 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 Alphalyse 360 mL** into the reagent compartment of the instrument.
8. Close the door of the reagent compartment.

Follow instructions displayed on your instrument software.

^dModification: bibliographic reference updated.

^eModification: correction.

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

Methodology

ABX Alphalyse 360 mL breaks down the erythrocyte (RBC) cell membrane and releases the hemoglobin within the cell. The hemoglobin, released by the lysing reagent, combines with the potassium cyanide from the lysing reagent to form a chromogenous cyanmethemoglobin compound. This compound is measured through the optical part of the flowcell by spectrophotometry at a wavelength of 550 nm.

Detergent present in the solution differentiates also morphological populations of leucocytes (WBC).

Performance Characteristics and Limitations of the Method

Refer to the user manual for the performance characteristics of the instrument and the limitations of the analyses on instrument parameters.

Calculation and Interpretation of Analytical Results

Refer to the instrument user manual for calculation and interpretation of analytical results.

Changes in the Procedure and in the Performance

Packaging spoiling

In case of protective packaging spoiling, do not use **ABX Alphalyse 360 mL** 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 Alphalyse 360 mL** should be replaced.

Temperature limits

Do not use **ABX Alphalyse 360 mL** if it has been frozen or kept at excessive heat.

Before using **ABX Alphalyse 360 mL**, make sure it has reached the operating temperature conditions as described in the instrument user manual.

Internal Quality Control

HORIBA control bloods must be used to periodically assess the integrity of the reagents and the instrument in the specified ranges.

HORIBA offers an Online Interlaboratory Comparison Program (QCP) which provides internet access to:

- Submit Internal Quality Control results online.
- Monitor analytical performances and compare directly with hundreds of laboratories worldwide.
- Obtain real time peer group statistical reports from QCP

More informations are available at:

<http://qcp.horiba-abx.com>

Traceability of Calibrators and Control Materials

Not applicable.

Reference Intervals

Not applicable.

Reference

1. US Department of labor, Occupational Safety and Health Administration. 29 CFR 1910. 1030: Occupational Safety and Health Standards: Bloodborne pathogens.
2. Council Directive (2000/54/EC). Official Journal of the European Communities. No. L262 from October 17, 2000: 21-45.
3. Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline - Fourth Edition. CLSI (NCCLS), document M29-A4 (2014) **34** (18).
4. Collection of Diagnostic Venous Blood Specimens - Seventh Edition. CLSI (NCCLS), document GP41 (2017).

