

REF 0906012

REAGENT 1 L

IVD CE

HORIBA ABX SAS
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FRANCE

ABX Lysebio (1L)

- ABX Pentra 80 / XL80
- ABX Pentra 120 / 120 Retic
- ABX Pentra DX120 / DF120
- Microsemi CRP
- Pentra DX Nexus / DF Nexus

Hematology Devices (for *in vitro* diagnostic use)

Intended Use

ABX Lysebio is a lysing solution intended for *in vitro* diagnostic use and designed for lysing erythrocytes (RBC) and for hemoglobin determination on HORIBA Medical blood cell counters.

Warnings and Precautions ^a

- **ABX Lysebio** is for professional *in vitro* diagnostic use only.
- It is the user's responsibility to verify that this document is applicable to the product use.
- This reagent is classified as non-hazardous in compliance with regulation (EC) N°.1272/2008.
- 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.
- In the event of a malaise following skin contact, ingestion, or inhalation, consult a doctor.
- Please refer to the Material Safety Data Sheet (MSDS) associated with **ABX Lysebio**.
- 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.

^aModification: classification changed.

^bModification: modification of Storage and Stability.

Microbiological State

Not applicable.

Description and Composition

Description:

Limpid and colourless aqueous solution.

Composition:

Organic buffer	< 5%
Detergent	< 2.5%

Storage and Stability ^b

- **Storage condition (before opening):** 15-30°C (59-86°F).
Keep protected from light.
Do not freeze.
- **Open stability:** 3 months maximum at 15-30°C (59-86°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.

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Specimen

Sample collection:

All blood samples should be collected using proper technique! Consider all specimens, reagents, calibrators, controls, etc. that contain human specimen extracts as potentially infectious and follow biosafety practices (1, 2). When collecting blood specimens, venous blood is recommended, but arterial blood may also be used in extreme cases. Blood collection must be placed in vacuum or atmospheric collection tubes (3, 4). The sample collection tube has to be filled to the exact quantity of blood indicated on the tube itself to avoid variations in the results.

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:

Sample stability at low temperature: Ten "normal" and ten "pathological" specimens were collected from the routine laboratory workload and stored at 4°C. Sample stability was assessed over a period of 72 hours. The results (mean of ten tests) conclude with a relative sample stability claim of:

- 48 hours for the CBC parameters
- 24 hours for the DIFF parameters
- 8 hours for the LMG parameters

Sample stability at room temperature: Ten "normal" and ten "pathological" specimens were collected from the routine laboratory workload and stored at room temperature (25°C). Sample stability was assessed over a period of 72 hours. The results (mean of ten tests) conclude with a relative sample stability claim of:

- 48 hours for the CBC parameters
- 24 hours for the DIFF parameters
- 8 hours for the LMG parameters

Three blood specimen containing measurable erythroblasts were sampled during the routine activity of a laboratory. Sample stability was assessed over a period of 48 hour period with a discontinuous analysis, in duplicate, of two aliquot fractions of the samples. The results conclude with a relative sample stability claim of 12 hours for the erythroblasts parameters (5).

Blood specimen were sampled during the routine activity of a laboratory. Sample stability was assessed over a period of 72 hours. The results conclude with a relative sample stability claim of 48 hours for the reticulocytes parameters (5).

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.

Procedure for reagent with stopper and straw outside instrument

Reagent with stopper and straw outside instrument is used on Microsemi CRP.

1. Refer to the user manual to identify **ABX Lysebio** using the barcode reader or manually.
2. Uncap the new reagent bottle.
3. Insert the stopper assembly straw into the bottle.
4. Tighten the stopper assembly to ensure an adequate seal.

Follow instructions displayed on your instrument software.

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

Procedure for reagent with stopper and straw

Reagent with stopper and straw is used on:

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- ABX Pentra 80
- ABX Pentra XL 80

1. Refer to the user manual to identify **ABX Lysebio** using the barcode reader or manually.
2. Open the door of the reagent compartment.
3. If necessary, remove the empty **ABX Lysebio** 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 Lysebio** 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.

Procedure for plugged-in reagent

Plugged-in reagent is used on:

- ABX Pentra 120
- ABX Pentra 120 Retic
- ABX Pentra DF 120
- ABX Pentra DX 120
- Pentra DX Nexus
- Pentra DF Nexus

1. If necessary, remove the empty **ABX Lysebio** from the reagent compartment.
2. Refer to the user manual to identify **ABX Lysebio** using the barcode reader or manually.
3. Install **ABX Lysebio** into the reagent compartment of the instrument.
4. Gently push it down in order to plug it correctly into the male connectors.

Follow instructions displayed on your instrument software.

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

Methodology

ABX Lysebio breaks down the erythrocyte (RBC) cell membrane. By addition of surfactive agent, hemoglobin is

released. All the heme iron is oxidized and resulting complexes are quantified by spectrophotometry at a wavelength of 550nm (6).

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 Lysebio** 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 Lysebio** should be replaced.

Temperature limits

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

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

Internal Quality Control

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

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HORIBA Medical 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. Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR 1910. 1030). Federal Register July 1, 1998; **6**: 267-280.
2. Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline - Third Edition. CLSI (NCCLS), document M29-A3 (2005) **25** (10).
3. Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard - Sixth Edition. CLSI (NCCLS), document H3-A6 (2007) **27** (26).
4. Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard - Sixth Edition. CLSI (NCCLS), document H4-A6 (2008) **28** (25).
5. Internal study used for 510K submission #K050719, in accordance with the ICSH directives: Guidelines for the Evaluation of blood cell analyzers including those used for differential leukocyte and reticulocyte counting and cell marker applications. International Council for Standardization in Hematology; Clin. Lab. Haemat. 1994 **16** 157-174.
6. Clinical Laboratory Standards Institute (CLSI/NCCLS) publication: H15-A3 Encyclopedia of Analytical Science, 2005, Pages 223-229 -R. A. Sherwood Adv Clin Chem. 1984; **23** (200). van Kampen EJ. "Spectrophotometry of hemoglobin and hemoglobin derivatives".