Hematology

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REF 0206010

REAGENT 1 L

IVD CE

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

ABX Eosinofix 1L

Applicable from Lot Number 260611G1

- ABX Pentra 60 / 60C+
- ABX Pentra XL80
- Pentra ES60 / MS60 / MS CRP
- Pentra XLR

Hematology Devices (for *in vitro* diagnostic use)

Intended Use [a]

ABX Eosinofix 1L is a lysing solution intended for *in vitro* diagnostic use and designed for lysing erythrocytes (RBC) for leucocytes (WBC) counting and differentiation on HORIBA blood cell counters.
Clinical laboratories use.

Warnings and Precautions [b]

- **ABX Eosinofix 1L** is for professional *in vitro* diagnostic use only.
  For laboratory use.
- It is the user's responsability 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.
- **EUH208:** May produce an allergic reaction.
  Contains: Glutaral
  Contains: reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)
- 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.
- User must be trained by a HORIBA representative before attempting to operate the device.
- Please refer to the Safety Data Sheet (SDS) associated with **ABX Eosinofix 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.
- This reagent is destined for use with HORIBA blood cell counters specified above. HORIBA cannot guarantee the correct functionning of this reagent with instruments other than those specified above, or with instruments not manufactured by HORIBA.
- Avoid release to 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.

Waste Management

Please refer to local legal requirements.

Microbiological State

Not applicable.

Description and Composition [c]

Description

Colourless liquid.
Light smell of alcohol.

[a]Modification: new reagent leaflet form.
[b]Modification: recommendation added.
[c]Modification: correction.

ABX Eosinofix 1L

Composition

Buffer	< 5%
Detergent	< 1%
Alcohol	< 10%
Preservative	< 0.1%

Storage and Stability [d]

- **Storage condition (before opening):** 18-25°C (65-77°F).
  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.

Specimen [c]

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

Please refer to the user manual.

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.

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

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

[d]Modification: modification of Storage and Stability.
[c]Modification: correction.

ABX Eosinofix 1L

Methodology [e]

The **ABX Eosinofix 1L** lyses the erythrocytes (RBC) and stabilizes the leucocytes (WBC).
The chemical reaction is stopped after a predefined time by the diluent. After the reaction/dilution step in the heating chamber, each cell is measured both in absorbance (cytochemistry) and resistivity (volume).

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 Eosinofix 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 Eosinofix 1L** should be replaced.

Temperature limits

Do not use the **ABX Eosinofix 1L** if it has been stored at temperatures outside the recommended storage conditions.
Before using **ABX Eosinofix 1L**, 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).

[e]Modification: methodology correction.