2023/07/04
A95A00278AEN

REF 0901010

REAGENT 10 L

IVD CE

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

ABX Diluent 10L

- Yumizen H1500 / H2500

Hematology Devices (for *in vitro* diagnostic use)

Intended Use

ABX Diluent 10L is a buffered isotonic solution intended for *in vitro* diagnostic use and designed for sheathing and diluting leucocytes (WBC), and for the determination and differentiation of blood cells, and the measurement of hematocrit on HORIBA Medical blood cell counters.
Clinical laboratories use.

Warnings and Precautions

- **ABX Diluent 10L** 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.
- Risk of injury: when handling the ABX Diluent 10L, the reagent may fall due to handle breakage.
- 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 Medical representative before attempting to operate the device.
- Please refer to the Safety Data Sheet (SDS) associated with **ABX Diluent 10L**.
- 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 Medical blood cell counters specified above. HORIBA Medical cannot guarantee the correct functionning of this reagent with instruments other than those specified above, or with instruments not manufactured by HORIBA Medical.
- 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.
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.

Description and Composition

Description:

Limpid and colourless aqueous solution.

Composition:

Organic buffer	< 5%
Preservative	< 0.1%
Surfactant	< 0.1%

ABX Diluent 10L

Storage and Stability

- **Storage condition (before opening):** 18-25°C (65-77°F).
  Do not freeze.
- **Open stability:** 4 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

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 K_3-EDTA with the proper proportion of blood to anticoagulant as specified by the tube manufacturer. K_2-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

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

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 Diluent 10L** using the barcode reader or manuallly.
2. Uncap the new reagent container.
3. Insert the stopper assembly straw into the container.
4. Tighten the stopper assembly to ensure an adequate seal.
5. Install the **ABX Diluent 10L** container below the instrument as described in the user manual.

Follow instructions displayed on your instrument software.
Refer to the instrument user manual for detailed analysis and control procedures.

Methodology

ABX Diluent 10L is a saline and buffered electrolytic solution which allows the dilution and the preparation of blood sample for analysis. The presence of non-ionic

ABX Diluent 10L

surfactant ensures an optimal dynamic of flow in the whole hydraulic systems of the instrument. The electrolytic action supports the counting of the cells by impedance.
This reagent is also used to stop the chemical reactions of some other reagents. This reagent is also used in the rinsing and cleaning cycles of the hydraulic systems of the instrument.

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 Diluent 10L** 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 Diluent 10L** should be replaced.

Temperature limits

Do not use **ABX Diluent 10L** if it has been frozen or kept at excessive heat.
Before using **ABX Diluent 10L**, 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.

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 - Fourth Edition. CLSI (NCCLS), document M29-A4 (2014) **34** (18).
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).