Hematology

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REAGENT 1 L

IVD CE

HORIBA ABX SAS
Parc Euromédecine - Rue du Caducée
B.P. 7290
34184 MONTPELLIER Cedex 4
FRANCE

ABX Minilyse LMG (1L)

- ABX Micros
- ABX Micros 60
- ABX Micros ES60

Hematology Devices (for *in vitro* diagnostic use)

Intended Use [a]

ABX Minilyse LMG 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 Medical blood cell counters.

Warnings and Precautions

- **ABX Minilyse LMG** is for professional *in vitro* diagnostic use only.
- It is the user's responsability to verify that this document is applicable to the product use.
- This reagent is classified as hazardous in compliance with regulations 67/548/EEC - 1999/45/EC.
- **Warning:** due to dodecyltrimethylammonium chloride presence,
  N: dangerous for the environment.
  R50/53: Very toxic to aquatic organism, may cause long term adverse effects in the aquatic environment.
- **Warning:** due to potassium cyanide presence, avoid contact with acid and aqueous acid environment: extremely toxic cyanide acid vapour can be formed.
- 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.
- Please refer to the Material Safety Data Sheet (MSDS) associated with **ABX Minilyse LMG**.
- 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.

Waste Management

Please refer to local legal requirements.

Microbiological State

Not applicable.

Description and Composition

Description:

Limpid and colourless aqueous solution.

Composition:

Lysing agent	< 0.1%
Detergent	< 5%

Storage and Shelf Life after First Opening

- **Storage condition:** 18-25°C (65-77°F).
  Do not freeze.
- **Open stability:** 1 month maximum at 18-25°C (65-77°F) after opening.
- **Expiration date:** refer to "expiration date" reagent packaging label.

Materials Required but not Provided

- Automated hematology analyzer.
- Calibrator: **ABX Minocal**.

[a] Modification from index D to E: new reagent leaflet form (Rev.3).

Form-0866 Rev.3

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- 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 consecutive tests) conclude with a relative sample stability claim of 48 hours for the CBC parameters and 24 hours for the DIF 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 consecutive tests) conclude with a relative sample stability claim of 48 hours for the CBC parameters and 24 hours for the DIF 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 Minilyse LMG** using the barcode reader or manuallly.
2. Open the door of the reagent compartment.
3. If necessary, remove the empty **ABX Minilyse LMG** 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 Minilyse LMG** 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.

Methodology

ABX Minilyse LMG 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 wavelenght of 550nm.
Detergent present in the solution differentiates also morphological populations of leucocytes (WBC).

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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 Minilyse LMG** 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 Minilyse LMG** should be replaced.

Temperature limits

Do not use **ABX Minilyse LMG** if it has been frozen or kept at excessive heat.
Before using **ABX Minilyse LMG**, 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 Comparaison 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).