

REF 1300159586

REAGENT 1 L

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

Yumivet RedLyse 1L

- Yumivet VH2500

Hematology Devices (for *in vitro* diagnostic use)

Intended Use

The **Yumivet RedLyse 1L** is a lysing solution intended for *in vitro* diagnostic use and designed for leucocytes counting and for hemoglobin determination on HORIBA blood cell counters.
Veterinary use only.

Warnings and Precautions

- **Yumivet RedLyse 1L** is for professional *in vitro* diagnostic use only.
For veterinary laboratory use.
- 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.
- User must be trained by a HORIBA representative before attempting to operate the device.
- Please refer to the Safety Data Sheet (SDS) associated with **Yumivet RedLyse 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 functioning 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

Description

Limpid and colourless aqueous solution.

Composition

Buffer	< 5%
Detergent	< 2.5%

Storage and Stability

- **Storage condition (before opening):** 15-30°C (59-86°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.

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Materials Required but not Provided

- Veterinary automated hematology analyzer.
- Calibrator: **Yumivet Cal** (1300159380).
- Controls:
 - Yumivet QC pack+** (1300159368)
 - Yumivet BFtrol** (1300159369)
- Standard laboratory equipment.

Specimen

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).

Sample collection is species dependent.

Specimen collection must be placed in vacuum or atmospheric collection tubes.

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 (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 plugged-in reagent

Plugged-in reagent is used on:

- Yumivet VH2500

1. If necessary, remove the empty **Yumivet RedLyse 1L** from the reagent compartment.
2. Refer to the user manual to identify **Yumivet RedLyse 1L** using the barcode reader or manually.
3. Install **Yumivet RedLyse 1L** 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

Yumivet RedLyse 1L 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 550 nm (4).

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.

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Changes in the Procedure and in the Performance

Packaging spoiling

In case of protective packaging spoiling, do not use **Yumivet RedLyse 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.) **Yumivet RedLyse 1L** should be replaced.

Temperature limits

Do not use the **Yumivet RedLyse 1L** if it has been stored at temperatures outside the recommended storage conditions.

Before using **Yumivet RedLyse 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.

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. 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".

