

REF	1300159584
REAGENT	5 L

 **HORIBA ABX SAS**
Parc Euromédecine
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BP 7290
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FRANCE

Yumivet FluoStain 5L

- Yumivet VH2500

Hematology Devices (for *in vitro* diagnostic use)

Intended Use

The **Yumivet FluoStain 5L** is a staining solution intended for *in vitro* diagnostic use and designed for reticulocytes and optical platelets counting on HORIBA blood cell counters.

Veterinary use only.

Warnings and Precautions

- **Yumivet FluoStain 5L** 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 FluoStain 5L**.
- 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.
This reagent contains less than 0.1% of sodium azide as a preservative.

Microbiological State

Not applicable.

Description and Composition

Description

Limpid and light orangy aqueous solution. Photosensitive.

Composition

Chromophore	< 1%
Alcohol	< 3%
Preservative	< 0.1%

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Storage and Stability

- **Storage condition (before opening):** 18-25°C (65-77°F).
Do not freeze.
- **Open stability:** 2 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

- Veterinary automated hematology analyzer.
- Calibrator: **Yumivet Cal** (1300159380).
- Controls:
Yumivet QC pack+ (1300159368)
Yumivet BFtol (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.

1. Refer to the user manual to identify **Yumivet FluoStain 5L** using the barcode reader or manually.
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 **Yumivet FluoStain 5L** container 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

The **Yumivet FluoStain 5L** contains a fluorescent stain which is specific to nucleic acids: thiazol orange (Thiazol orange is a patented product from Becton Dickinson San Jose, CA, USA).

For the reticulocytes measurement, the stain molecules enter through the cell membrane and fix the ribonucleic acid molecules.

The binding gives an increase of fluorescence.

The laser optical bench simultaneously measures the fluorescence of the cells passing through the measuring point into the flowcell, and volume by impedance.

For the Optical platelets, each cell is measured both in resistivity (volume) and absorbency (cytochemistry).

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.

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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 **Yumivet FluoStain 5L** 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 FluoStain 5L** should be replaced.

Temperature limits

Do not use the **Yumivet FluoStain 5L** if it has been stored at temperatures outside the recommended storage conditions.

Before using **Yumivet FluoStain 5L**, 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).

