

REF	1300159380
CAL	2 mL

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

Yumivet Cal

- Yumivet VH2500

Hematology Devices (for *in vitro* diagnostic use)

Intended Use

The **Yumivet Cal** is a multiparameter calibrator intended for *in vitro* diagnostic use and designed for use in calibration of HORIBA blood cell counters for the following CBC parameters (WBC, RBC, HGB, PLT, MCV). Veterinary use only.

Warnings and Precautions

- **Yumivet Cal** 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.
- **Warning:** Human source material. Treat as potentially infectious. All products derived from blood are prepared exclusively from blood of donors tested individually and shown by approved methods to be free from HBsAg and antibodies to HCV and HIV. Because no known test method can offer complete assurance that hepatitis B virus, Human Immunodeficiency Virus (HIV) or other infectious agents are absent, the controls should be treated like patient specimens as potentially infectious and handled with appropriate cautions in accordance with good laboratory practices (1, 2, 3).
- Users are advised to wear approved protective clothing when handling **Yumivet Cal**: 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 Safety Data Sheet (SDS) associated with **Yumivet Cal**.
- Do not use the product if the recommended storage conditions, including temperature, are not followed.

- User must be trained by a HORIBA representative before attempting to operate the device.
- 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.
- 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

The **Yumivet Cal** is one-level calibrator. **Yumivet Cal** is similar in appearance to fresh whole blood. A light pink-tinted supernatant is normal.

Composition

Yumivet Cal contains mammalian leucocytes (WBC), erythrocytes (RBC) and thrombocytes (PLT) suspended in a plasma-like fluid.

Yumivet Cal

Storage and Stability

- **Storage condition (before opening):** 2-8°C (35-46°F). Do not freeze.
Store the tubes vertically in their original packages when not in use.
Storage in the door compartments of the refrigerator is not recommended.
- **Open stability:** **Yumivet Cal** is stable for 1 day after the tube has been opened if it is properly handled and promptly refrigerated at 2-8°C (35-46°F) after use. **Yumivet Cal** must be tightly capped after use.
- **Expiration date:** refer to "expiration date" reagent packaging label.

Materials Required but not Provided

- Veterinary automated hematology analyzer.
- Standard laboratory equipment.

Specimen

Not applicable.

Procedure

Yumivet Cal is ready to use.

The calibration on HORIBA instruments is an important procedure, which may need to be performed during certain technical situations such as installation, maintenance and service interventions. Calibration should not be performed to compensate for a drift in results due to a blockage on the instrument.

Frequent re-calibration needs to be reported to HORIBA Technical Support to determine the actual cause and appropriate remedy. After calibration, ensure the values for MCV, MCH and MCHC on patient samples agree with usual population means for these parameters.

1. Bring **Yumivet Cal** to room temperature by rolling the tube between the palms of your hands until the red blood cell sediment is completely suspended. Do not shake.
2. Refer to the user manual to identify **Yumivet Cal** using the barcode reader or manually.
3. Gently invert the tube 8 to 10 times immediately before sampling.
4. Run **Yumivet Cal** according to the procedure described in the user manual.
5. Wipe threads and cap of the tube after use with lint-free gauze.

6. Recap and refrigerate the tube promptly after use.

Refer to the **Yumivet Cal** assay value data sheet for specific instrument models.

Refer to the instrument user manual for detailed analysis and control procedures.

Methodology

The **Yumivet Cal** is a stable preparation used to calibrate or verify calibration of HORIBA blood cell counters. Assigned values have been obtained by replicate analyses on instruments calibrated to standard reference methods.

The **Yumivet Cal** is analyzed by the instrument the same way as blood samples (impedance and optical measurements) and is used to calibrate leucocytes (WBC), erythrocytes (RBC), hemoglobin (HGB), mean corpuscular volume (MCV) and thrombocytes (PLT) values.

Performance Characteristics and Limitations

Refer to the assay value data sheet for the target values and their tolerances regarding the instrument used. See paragraph Traceability of Calibrators and Control Materials.

Calculation and Interpretation of Results

Refer to the instrument user manual for calibration procedure and interpretation of results.

Changes in the Procedure and in the Performance

Packaging spoiling

In case of protective packaging spoiling, do not use **Yumivet Cal** 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 Cal** should be replaced.

Yumivet Cal

Incorrect mixing

Incomplete mixing of the tube prior to use invalidates both the sample that is withdrawn and the remainder of **Yumivet Cal** in the tube.

Temperature limits

Do not use the **Yumivet Cal** if it has been frozen or stored at temperatures outside the recommended storage conditions.

Before using **Yumivet Cal**, 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

Yumivet Cal is traceable to standard reference methods. Hematology analyzers in the Quality Assurance Laboratory are whole blood calibrated to values obtained using the following standard reference methods. Whole blood samples drawn from normal, healthy donors are collected in EDTA anticoagulant and analyzed within six hours of collection.

The **White Blood Cells (WBC)** and **Red Blood Cells (RBC)** are analyzed on a Coulter Counter Z series instrument*. All counts are corrected for coincidence (4).

Hemoglobin is measured using the Clinical Standards Institute (CLSI) recommended reagent for the hemoglobincyanide (cyanmethemoglobin) method (5). Readings are made at 540 nm in a colorimeter/spectrophotometer calibrated according to CLSI H15-A3 (5).

The **hematocrit** (packed cell volume) is measured using plain glass microhematocrit tubes (not coated with anticoagulant) centrifuged for 5 minutes in a microhematocrit centrifuge according to the CLSI H7-A3 document (6). No correction is made for trapped plasma.

Platelets are assayed using a hemocytometer and phase contrast optics (7).

** All brands and products are trademarks or registered trademarks of their respective companies.*

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. Reference method for the enumeration of erythrocytes and leucocytes. International Council for Standardization in Haematology; prepared by the Expert Panel on Cytometry. Clin. Lab. Haemat. (1994) **16** (2): 131-138.
5. Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard - Third Edition. CLSI (NCCLS), document H15-A3 (2000) **20** (28).
6. Procedure for Determining Packed Cell Volume by Microhematocrit Method; Approved Standard - Third Edition. CLSI (NCCLS), document H7-A3 (2001) **20** (18).
7. Platelet counting by the RBC/platelet ratio method: A reference method. International Council for Standardization in Haematology Expert Panel on Cytometry; International Society of Laboratory Hematology Task Force on Platelet Counting. American Journal of Clinical Pathology. (2001) **115** (3): 460-464.

Reference Intervals

Not applicable.

