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CONTROL 2 x 3 mL

HORIBA ABX SAS
Parc Euromédecine
Rue du Caducée
BP 7290
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FRANCE

Yumivet BFtrol

- Yumivet VH2500

Hematology Devices (for *in vitro* diagnostic use)

Intended Use

The **Yumivet BFtrol** is a multiparameter control intended for *in vitro* diagnostic use and designed for use in monitoring the accuracy and precision of HORIBA blood cell counters for leucocytes (BFWBC, BFMN#, BFMN%, BFPN#, BFPN%) and erythrocytes (BFRBC) in body fluids.
Veterinary use only.

Warnings and Precautions

- **Yumivet BFtrol** is for professional *in vitro* diagnostic use only.
  For veterinary 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.
- **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).
- **Warning:** This reagent is obtained from substances of animal origin. Consequently, it should be treated as potentially infectious and handled with the appropriate cautions in accordance with good laboratory practices (2).
- Users are advised to wear approved protective clothing when handling **Yumivet BFtrol**: 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 BFtrol**.
- 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 BFtrol** is a two-level control: **Yumivet BFtrol N** and **Yumivet BFtrol H**.
After mixing, **Yumivet BFtrol** is similar to diluted whole blood. In unmixed tubes, the supernatant may appear cloudy and reddish.

Yumivet BFtrol

Composition

Contains human erythrocytes and animal leukocytes suspended in a fluid with preservatives.

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 BFtrol** is stable for 30 days (or until the "expiration date" whatever comes first) at 2-8°C (35-46°F) after opening.
  Yumivet BFtrol 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 BFtrol is ready to use.
An analysis of the control must be carried out on a daily basis at the same time as the patient samples, including each time a calibration or a maintenance is carried out. The frequency of the controls depends on the laboratory requirements. Each laboratory must establish the quality assurance procedures to be followed.

1. Bring **Yumivet BFtrol** to room temperature for 15 min before mixing.
2. Mix by rolling the tube between the palms of your hands until the red blood cell sediment is completely suspended. Do not shake.
3. Gently invert the tube 8 to 10 times immediately before sampling.
4. Run **Yumivet BFtrol** according to the procedure described in the user manual.
5. Refrigerate the tube promptly after use.

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

Methodology

The **Yumivet BFtrol** is a stable preparation used to monitor the accuracy and precision of blood cell counters. Assigned values have been obtained by replicate analyses on instruments calibrated to standard reference method. When assayed in the QC Analysis mode of a properly calibrated and functioning instrument, **Yumivet BFtrol** provides values within the expected ranges specified for the control.

Performance Characteristics and Limitations

The mean assay values provided for each **Yumivet BFtrol** parameter are derived from replicated analyses on calibrated instruments. The assays were performed using reagents recommended by HORIBA. The expected ranges are representative of estimates of the variation between different laboratories for each parameter.
Nevertheless, values stated on the assay sheets shall only be indicative for internal quality control purposes and shall not be used for calibration.
Assay values and limits have been established through exclusive use of HORIBA reagents and are valid only with laboratory use of HORIBA recommended reagents.
According to CLSI C24-A4 (4), the assay mean and standard deviation must be established by serial testing in the laboratory. For that, a new lot of **Yumivet BFtrol** should be analyzed in parallel with the lot of **Yumivet BFtrol** in current use.
Ideally, a minimum of 10 measurements should be made during at least 10 separate days and on a correctly calibrated analyser to establish the assay means. The control means established by the laboratory should fall within the expected range specified for the control. Standard Deviation must be defined over a longer period, to include long-term sources of variability.

Calculation and Interpretation of Results

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

Yumivet BFtrol

Changes in the Procedure and in the Performance

Packaging spoiling

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

Incorrect mixing

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

Temperature limits

Do not use the **Yumivet BFtrol** if it has been frozen or stored at temperatures outside the recommended storage conditions.
Before using **Yumivet BFtrol**, make sure it has reached the operating temperature conditions as described in the instrument user manual.

Traceability of Calibrators and Control Materials

HORIBA calibrator 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 (5).
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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. Statistical Quality Control for quantitative Measurement Procedures: Principles and Definitions; Approved Guideline - Fourth Edition. CLSI C24-A4 (2016).
5. 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.