Hematology

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CONTROL 3 mL

IVD CE 2797

HORIBA ABX SAS
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BFTROL

- Yumizen H1500 / H2500

Hematology Devices (for *in vitro* diagnostic use)

Intended Use [a] [b] [c]

BFTROL is a control intended for *in vitro* diagnostic use and designed for use in monitoring the accuracy and precision of HORIBA Medical hematology blood cell counters for leucocytes (BFWBC, BFMN#, BFMN%, BFPN#, BFPN%) and erythrocytes (BFRBC) in body fluids in clinical laboratories.
Parameters can be different according to the instrument, please refer to the assay value data sheet for specific instrument models.

Warnings and Precautions [d]

- **BFTROL** is for professional *in vitro* diagnostic use only. For 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.
- Human source material. Treat as potentially infectious. Each plasma donor unit used in the preparation of this product has been tested by an FDA approved method and found negative for the presence of HBsAg, HCV and antibody to HIV1/2. Because no known test method can offer complete assurance that hepatitis B virus, Human Immunodeficiency Virus (HIV) or other infectious agents are absent, the products 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).
- 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 **BFTROL**.
- User must be trained by a HORIBA Medical 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.
- 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.

[a]Modification: new leaflet form.
[b]Modification: modification of intended use.
[c]Modification: modification of CE mark.
[d]Modification: recommendation added.

BFTROL

Description and Composition [e]

Description:

After mixing, **BFTROL** is similar to diluted whole blood. In unmixed tubes, the supernatant may appear cloudy and reddish.

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: BFTROL** is stable for 30 days (or until the "expiration date" whatever comes first) at 2-8°C (35-46°F) after opening.
  BFTROL must be tightly capped after use.
- **Expiration date:** refer to "expiration date" reagent packaging label.

Materials Required but not Provided

- Automated hematology analyzer.
- Standard laboratory equipment.

Specimen

Not applicable.

Procedure

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 **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 **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

BFTROL is a stable preparation used to monitor the accuracy and precision of blood cell counters. Reference values have been obtained from replicate analyses on instruments which have been whole blood calibrated to values obtained from reference methodes. **BFTROL** is run on the instrument in the same way as a patient blood sample (resistivity, absorbance and spectrophotometry measurements).

Performance Characteristics and Limitations [f]

The mean assay values indicated for each **BFTROL** parameter are obtained from replicated assays performed on analysers that have been calibrated using whole blood. The assays were performed using reagents recommended by HORIBA Medical. The expected ranges are representative of estimates of the variation between different laboratories for each parameter.
Nevertheless, values stated on the assay sheets should only be indicative for control purposes and should not be used for calibration.
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 **BFTROL** should be analyzed in parallel with the lot of **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. Standard Deviation must be defined over a longer period, to include long-term sources of variability.
See paragraph Traceability of Calibrators and Control Materials.

[e]Modification: composition changed.
[f]Modification: batch to batch variability modification.

BFTROL

Calculation and Interpretation of Results

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

Changes in the Procedure and in the Performance

Packaging spoiling

In case of protective packaging spoiling, do not use **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.) **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 **BFTROL** in the tube.

Temperature limits

Do not use **BFTROL** if it has been frozen or kept at excessive heat.
Before using **BFTROL**, make sure it has reached the operating temperature conditions as described in the instrument user manual.

Traceability of Calibrators and Control Materials

HORIBA Medical controls and calibrators are 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.
** All brands and products are trademarks or registered trademarks of their respective companies.*

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. 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 - Third Edition. CLSI (NCCLS), document M29-A3 (2005) **25** (10).
4. Statistical Quality Control for quantitative Measurement Procedures: Principles and Definitions; Approved Guideline - Fourth Edition. CLSI C24-A4 (2016).