Hematology

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CONTROL 3 mL

IVD CE 2797

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ESRtrol

- Yumizen H500E OT / CT / H550E

Hematology Devices (for *in vitro* diagnostic use)

Intended Use

ESRtrol 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 "ESR" 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

- **ESRtrol** 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 **ESRtrol**.
- Do not use the product if the recommended storage conditions, including temperature, are not followed.
- 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.
This reagent contains less than 0.1% of sodium azide as a preservative. Sodium azide may react with lead and copper to form explosive metal azides.

Microbiological State

Not applicable.

Description and Composition

Description

ESRtrol is similar in appearance to fresh whole blood. A light pink-tinted supernatant is normal.

Composition

ESRtrol contains leukocytes (WBCs), erythrocytes (RBCs) and thrombocytes (PLTs) of human or animal origin suspended in a plasma-like fluid

ESRtrol

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: ESRtrol** is stable for sampling events over a maximum of 30 days at 2-8°C (35-46°F) after opening and within the expiration limit.
  ESRtrol 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

ESRtrol 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 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. These must conform to the current accreditation requirements and pertinent regulations.

1. Bring **ESRtrol** 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 **ESRtrol** using the barcode reader or manuallly.
3. Gently invert the tube 8 to 10 times immediately before sampling.
   Tubes stored for more than 3 months require extra mixing.
4. Run **ESRtrol** 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 **ESRtrol** assay value data sheet for specific instrument models.
Refer to the instrument user manual for detailed analysis and control procedures.

Methodology

ESRtrol 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 instrument reference.
ESRtrol is run on the instrument in the same way as a patient blood sample (absorbance measurement).

Performance Characteristics and Limitations

The mean assay values indicated for each **ESRtrol** 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 **ESRtrol** should be analyzed in parallel with the lot of **ESRtrol** 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.

Calculation and Interpretation of Results

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

ESRtrol

Changes in the Procedure and in the Performance

Packaging spoiling

In case of protective packaging spoiling, do not use **ESRtrol** 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.) **ESRtrol** should be replaced.

Incorrect mixing

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

Temperature limits

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

Internal Quality Control

HORIBA Medical control bloods must be used to periodically assess the integrity of the reagents and the instrument in the specified ranges.
HORIBA Medical offers an Online Interlaboratory Comparison Program (QCP) which provides internet access to:

- Submit Internal Quality Control results online.
- Monitor analytical performances and compare directly with hundreds of laboratories worldwide.
- Obtain real time peer group statistical reports from QCP

More informations are available at:
http://qcp.horiba-abx.com

Traceability of Calibrators and Control Materials

The erythrocyte sedimentation relative to aggregation is specific to fresh blood.
ESRtrol assay value assignment is performed on reference instruments calibrated on fresh bloods : Hematology analyzers in the Quality Assurance Laboratory are whole blood calibrated to values obtained using the diluted Westergren reference method (5).
Whole blood samples drawn from normal, healthy donors are collected in EDTA anticoagulant and analyzed within six hours of collection.

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).
5. ICSH review of the measurement of the erythocyte sedimentation rate. International Journal of Laboratory Hematology: J.M. Jou, S. M. Lewis, C. Briggs, S.-H. Lee, B. De la Salle, S. McFadden for the International Council for Standardization in Haematology. Int. Jnl. Lab. Hem. 2011, **33**, 125-132.