2023/11/23
A01A00052MAEN

ABX Minotrol Retic

REF 2072001 ("1")
2072002 ("2")
2072003 ("3")
2072201 (2x"2")
2072202 ("1" & "3")

CONTROL 3 mL

IVD CE

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

- Pentra DX Nexus
- Pentra XLR
- Yumizen H2500

Hematology Devices (for *in vitro* diagnostic use)

Intended Use [a] [b]

ABX Minotrol Retic is a tri-level 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 reticulocyte (RET) parameter.
Refer to the **ABX Minotrol Retic** assay value data sheet for specific instrument models.

Warnings and Precautions [c]

- **ABX Minotrol Retic** 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).
- 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 **ABX Minotrol Retic**.
- 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.

Description and Composition

Description:

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

Composition:

ABX Minotrol Retic contains human erythrocytes and mammalian erythrocytes suspended in a plasma-like fluid.

[a]Modification: new reagent leaflet form.
[b]Modification: instrument removed.
[c]Modification: recommendation added.

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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: ABX Minotrol Retic** is stable for 16 sampling events over a maximum of 16 days at 2-8°C (35-46°F) after opening and within the expiration limit.
  ABX Minotrol Retic must be tightly capped after use.
- **Expiration date:** refer to "expiration date" reagent packaging label.
- If sample preparation is a separate step before counting, count the prepared sample within 15 minutes after the minimum incubation time.

Materials Required but not Provided

- Automated hematology analyzer.
- Standard laboratory equipment.

Specimen

Not applicable.

Procedure

ABX Minotrol Retic 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. These must conform to the current accreditation requirements and pertinent regulations.

1. Bring **ABX Minotrol Retic** 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 **ABX Minotrol Retic** using the barcode reader or manuallly.
3. Gently invert the tube 8 to 10 times immediately before sampling.
4. Run **ABX Minotrol Retic** 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 **ABX Minotrol Retic** assay value data sheet for specific instrument models.
Refer to the instrument user manual for detailed analysis and control procedures.

Methodology

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

Performance Characteristics and Limitations [d]

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

[d]Modification: batch to batch variability modification.

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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 **ABX Minotrol Retic** 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.) **ABX Minotrol Retic** should be replaced.

Incorrect mixing

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

Temperature limits

Do not use **ABX Minotrol Retic** if it has been frozen or kept at excessive heat.
Before using **ABX Minotrol Retic**, 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

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.
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 and ICSH recommendations (5, 6).
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 (7). No correction is made for trapped plasma.
Platelets are assayed using a hemocytometer and phase contrast optics.
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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. Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard - Third Edition. CLSI (NCCLS), document H15-A3 (2000) **20** (28).

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6. ICSH guidelines for the evaluation of blood cell analysers including those used for differential leucocyte and reticulocyte counting. International Council for Standardization in Haematology, writing group: C. Briggs, N. Culp, B. Davis, G. D'Onofrio, G. Zini, S. J. Machin, on behalf of the International Council for Standardization of Haematology. Int. Jnl. Lab.Hem. 2014 **36**, 613-627.
7. Procedure for Determining Packed Cell Volume by Microhematocrit Method; Approved Standard - Third Edition. CLSI (NCCLS), document H7-A3 (2001) **20** (18).