2018/01/04
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ABX Minotrol 16

REF
2042001 (L)*
2042002 (N)*
2042003 (H)*
2042202 (2N)*
2042208 (2L)*
2042209 (2H)*

CONTROL 2.5 mL

- ABX Micros / Advia 60
- ABX Micros 60 / ABC Vet
- ABX Micros ES60 / ESV60
- ABX Micros CRP / CRP200
- ABX Pentra 60 / 60C+
- ABX Pentra 80 / XL80
- Pentra XLR
- ABX Pentra 120 / 120 Retic
- ABX Pentra DX120 / DF120
- scil Vet abc Plus+
- Pentra ES60
- Micros Care ST
- Microsemi CRP
- Pentra DX Nexus / DF Nexus

IVD CE 0120

HORIBA ABX SAS
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B.P. 7290
34184 MONTPELLIER Cedex 4
FRANCE

Hematology Devices (for *in vitro* diagnostic use)

Intended Use *

ABX Minotrol 16 is a tri-level multiparameter control intended for *in vitro* diagnostic use and designed for use in monitoring the accuracy and precision of hematology blood cell counters.
Refer to the **ABX Minotrol 16** assay value data sheet for specific instrument models.
ABX Minotrol 16 can be used for self-testing on Micros Care ST only.

Warnings and Precautions

- 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 Material Safety Data Sheet (MSDS) associated with **ABX Minotrol 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:

ABX Minotrol 16 is similar in appearance to fresh whole blood. A light pink-tinted supernatant is normal.

Composition:

ABX Minotrol 16 contains mammalian leucocytes (WBC), erythrocytes (RBC) and thrombocytes (PLT) suspended in a plasma-like fluid.

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 16** 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 16 must be tightly capped after use.
- **Expiration date:** refer to "expiration date" reagent packaging label.

*Modification: designation modification.

ABX Minotrol 16

Materials Required but not Provided

- Automated hematology analyzer.
- Standard laboratory equipment.

Specimen

Not applicable.

Procedure

ABX Minotrol 16 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 16** 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 16** using the barcode reader or manuallly.
3. Gently invert the tube 8 to 10 times immediately before sampling.
4. Run **ABX Minotrol 16** 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 16** assay value data sheet for specific instrument models.
Refer to the instrument user manual for detailed analysis and control procedures.

Methodology

ABX Minotrol 16 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. **ABX Minotrol 16** is run on the instrument in the same way as a patient blood sample (resistivity, absorbance and spectrophotometry measurements).

Performance Characteristics and Limitations

The mean assay values of each **ABX Minotrol 16** 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. Values obtained with **ABX Minotrol 16** (if used before its expiry date) should fall within the expected range. The expected ranges are representative of estimates of the variation between different laboratories for each parameter. Inter-laboratory variations are the consequence of instrument calibration, maintenance, and operating technique. The reference results are therefore only indicative for control purposes and should not be used for calibration. At least five consecutive analyses, on a correctly calibrated analyser, are needed to establish the assay means and standard deviations for each **ABX Minotrol 16** parameter.
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.

Changes in the Procedure and in the Performance

Packaging spoiling

In case of protective packaging spoiling, do not use **ABX Minotrol 16** 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 16** 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 16** in the tube.

Temperature limits

Do not use **ABX Minotrol 16** if it has been frozen or kept at excessive heat.

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Before using **ABX Minotrol 16**, 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 (4). Readings are made at 540 nm in a colorimeter/ spectrophotometer calibrated according to CLSI H15-A3 and ICSH recommendations (4).
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 (5). 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. Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard - Third Edition. CLSI (NCCLS), document H15-A3 (2000) **20** (28).
5. Procedure for Determining Packed Cell Volume by Microhematocrit Method; Approved Standard - Third Edition. CLSI (NCCLS), document H7-A3 (2001) **20** (18).