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CAL 2 mL

IVD CE

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

ABX Minocal

- ABX Micros 60
- ABX Micros ES60 / ESV60
- ABX Pentra 60 / 60C+
- ABX Pentra XL80
- Pentra XLR
- Micros Care ST / Microsemi CRP
- scil Vet abc Plus+
- Pentra ES60 / MS60 / MS CRP
- Pentra DX Nexus / DF Nexus
- Yumizen H500 OT / CT / H550
- Yumizen H500E OT / CT / H550E
- Yumizen H1500 / H2500

Hematology Devices (for *in vitro* diagnostic use)

Intended Use [a]

ABX Minocal is a multiparameter blood calibrator intended for *in vitro* diagnostic use and designed for use in calibration of hematology blood cell counters.
Refer to the **ABX Minocal** assay value data sheet for specific instrument models.

Warnings and Precautions

- **ABX Minocal** 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 Minocal**.
- 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:

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

Composition:

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

[a]Modification: new reagent leaflet form.

ABX Minocal

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 Minocal** is stable for 1 day after the tube has been opened if it is properly handled and promptly refrigerated at 2-8°C (35-46°F) after use.
  ABX Minocal 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

ABX Minocal is ready to use.
The calibration on HORIBA Medical instruments is an important procedure, which may need to be performed during certain technical situations such as installation, maintenance and service interventions. Calibration should not be performed to compensate for a drift in results due to a blockage on the instrument.
Frequent re-calibration needs to be reported to HORIBA Medical Technical Support to determine the actual cause and appropriate remedy. After calibration, ensure the values for MCV, MCH and MCHC on patient samples agree with usual population means for these parameters.

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

Methodology

ABX Minocal is a stable preparation used to calibrate blood cell counters. Calibration values have been obtained from replicate analyses on instruments which have been whole blood calibrated to values obtained from reference methodes. **ABX Minocal** is run on the instrument in the same way as a patient blood sample (resistivity, absorbance and spectrophotometry measurements) and is used to calibrate leucocytes (WBC), erythrocytes (RBC), hemoglobin, hematocrit and thrombocytes (PLT) values.

Performance Characteristics and Limitations

Refer to the assay value data sheet for the target values and their tolerances regarding the instrument used.
See paragraph Traceability of Calibrators and Control Materials.

Calculation and Interpretation of Results

Refer to the instrument user manual for calibration 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 Minocal** 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 Minocal** should be replaced.

ABX Minocal

Incorrect mixing

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

Temperature limits

Do not use **ABX Minocal** if it has been frozen or kept at excessive heat.
Before using **ABX Minocal**, 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 [b]

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 (4).
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 (5).
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 (6). No correction is made for trapped plasma.
Platelets are assayed using a hemocytometer and phase contrast optics (7).
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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 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.
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).
6. Procedure for Determining Packed Cell Volume by Microhematocrit Method; Approved Standard - Third Edition. CLSI (NCCLS), document H7-A3 (2001) **20** (18).
7. Platelet counting by the RBC/platelet ratio method: A reference method. International Council for Standardization in Haematology Expert Panel on Cytometry; International Society of Laboratory Hematology Task Force on Platelet Counting. American Journal of Clinical Pathology. (2001) **115** (3): 460-464.

[b]Modification: bibliography evolution.