

# Hematology Devices (for in vitro diagnostic use)

## ABX Minocal

15/04/2010  
A01A00049GEN

### Exclusive use:

ABX Micros 45/60  
ABX Micros ABC Vet  
ABX Micros ES60/ESV60  
SCIL Vet ABC Plus  
ABX Micros CRP/CRP 200  
ABX Pentra 60/60 C+  
ABX Pentra 80/XL 80  
ABX Pentra 120  
ABX Pentra 120 Retic  
ABX Pentra DX 120/DF 120  
Pentra ES60  
Pentra MS60  
Advia 60

**REF** 2032002

**CAL** 2mL

**IVD** 



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

## 1. Intended use

ABX Minocal is a multiparameter blood calibrator designed for use in the calibration of blood cell counters<sup>a</sup>.

## 2. Summary

The WBC, RBC, HGB, HCT, and PLT parameters on instruments require calibration on a periodic basis. ABX Minocal is a stable preparation which can be used to calibrate the instruments. Calibrator values for ABX Minocal have been obtained from replicate analyses on instruments which have been whole blood calibrated to values obtained from reference methods.

## 3. Calibrator

ABX Minocal contains human red blood cells, mammalian white blood cells, and platelets in a plasma-like fluid.

## 4. Warnings and Precautions

Potentially biohazardous material. For in vitro diagnostic use.

Each donor unit used in the preparation of this material was tested using FDA approved methods and was found to be non-reactive for antibody to HIV-1/HIV-2, antibody to hepatitis C, and for the presence of hepatitis B surface antigen and HIV-1 antigen. Because no known test method can provide total assurance that products derived from human blood will not transmit infectious diseases, products containing materials from human sources should be handled as if potentially infectious. Use safe laboratory procedures as

outlined in Biosafety in Microbiological and Biomedical Laboratories (HHS Publication Number [CDC] 84-8395).

## 5. Instructions for use

Refer to the instrument user manual, section «Calibration».

## 6. Storage and stability

Do not freeze. ABX Minocal vials should be tightly capped and stored at 2 - 8°C when not in use. ABX Minocal is stable for 1 day after the vial has been opened if it is properly handled and promptly refrigerated after use. When stored at 2 - 8°C, unopened vials of ABX Minocal are stable until the date listed on the label.

## 7. Procedural limitations

1. The components used to simulate white blood cells in ABX Minocal are not suitable for morphological differential analysis.
2. Incomplete mixing of the vial prior to use invalidates both the sample that is withdrawn and the remainder of the ABX Minocal in the vial.

## 8. Expected values

The calibrator values provided for each parameter of ABX Minocal are specific for the lot indicated on the assay value sheet. Assay values are based on replicate analyses on whole blood calibrated instruments using HORIBA Medical hematology reagents.

a.Modification from index F to G: Pentra MS60 added

After completing the calibration procedure, good laboratory practices recommend that a series of controls be analyzed as a quality control check. Failure to obtain the proper range of values in the assay of control materials may indicate calibrator, control or reagent deterioration, instrument malfunction, or procedural errors.

1. Review package insert to verify the lot number and expiration date of the calibrator and control products. Examine reagents for indications of contamination and to assure that none have expired.
2. Review the user manual for proper operation and maintenance of the instrument.

## 9. Reference methods

1. WBC and RBC: A large-volume, single-step dilution is made with calibrated glassware. Counts are performed on a single-aperture impedance cell counter and corrected for coincidence at all count levels.
2. HGB: Hemoglobin value is determined by spectrophotometric procedure according to CLSI Standard H15-A3 and is traceable to ICSH/WHO International Haemoglobinocyanide Standard.
3. HCT: Packed cell volume (PCV) is measured by the micro-hematocrit procedure according to CLSI Standard H7-A3. No correction is made for trapped plasma.
4. MCV: MCV is calculated:  $PCV/RBC \times 10$ .
5. PLT: Samples are diluted in 1 percent ammonium oxalate. Platelets are counted using a hemocytometer and phase contrast microscopy.
6. MPV: The MPV is calibrated according to the instrument manufacturer's instructions.

## 10. References

1. National Committee for Clinical Laboratory Standards now Clinical Laboratory Standards Institute. Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood, third edition; Approved Standard . NCCLS document H15-A3. Wayne, PA : NCCLS, 2000.
2. International Committee for Standardization in Hematology. World Health Organization International Standard held by Rijksinstituut Voor Volksgezondheiden Milieuhygiene-Bilthoven-The Netherlands. Haemiglobincyanide Solution.
3. National Committee for Clinical Laboratory Standards now Clinical Laboratory Standards Institute. Procedure for determining packed cell volume by the microhematocrit method, Approved Standard. NCCLS document H7-A3. Wayne, PA : NCCLS, 2001.
4. Henry, JB. Clinical Diagnosis and Management by Laboratory Methods. 18th Ed. Philadelphia, WB Saunders Co., 1991.
5. Van Assendelft, OW and England, MB, Advances in Hematological Methods: The Blood Count. CRC Press, Inc. Boca Raton, FL, 1982.