ABX Minocal

IVD

HORIBA

INTENDED USE
ABX Minocal is a multiparameter blood calibrator designed for use in the calibration of **HORIBA ABX SAS** hematology blood cell counters using **HORIBA ABX SAS** reagents.

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.

REAGENTS
This whole blood reagent may contain any or all of the following: stabilized human or animal red blood cells, human, animal or simulated white blood cells and a platelet component in a preservative medium.

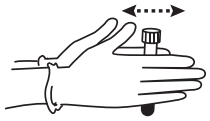
No additional materials are provided or required.

WARNING AND PRECAUTIONS
Potentially biohazardous material.

1. **For in vitro diagnostic use.**
2. **CAUTION: All blood products should be treated as potentially infectious. Source material from which this product was derived was found negative when tested in accordance with current FDA required tests. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents. When handling or disposing of product, follow precautions recommended by current biosafety regulations for any potentially infectious human blood specimens.**

STORAGE AND STABILITY
Do not freeze. ABX Minocal tubes should be tightly capped and stored at 2 °C - 8 °C (35 °F to 46 °F) when not in use. ABX Minocal is stable for five (5) days after the tube has been opened if it is properly handled and promptly refrigerated after use. When stored at 2 °C - 8 °C (35 °F to 46 °F), unopened tubes of ABX Minocal are stable until the date listed on the label.

INSTRUCTIONS FOR USE
1. ABX Minocal should only be used with the instruments listed on the assay.
2. Perform instrument start-up and routine cleaning procedures as defined in instrument manual (i.e., blood sampling valve, counting apertures).
3. Remove vials of calibrator from refrigeration and warm to room temperature (18 °C to 30 °C) for 15 minutes before use.
4. To mix: **(Do NOT mix mechanically or vortex.)**
   a. Hold the vial vertically and roll each vial between the palms of the hands for 15-20 seconds.



   b. Continue to mix by holding the vial by the ends between the thumb and finger, rapidly inverting the vial 20 times end-over-end using a very quick turning motion of the wrist.

   c. Analyze immediately after mixing. Subsequent analyses during this test period may be performed by inverting the vial 5 times prior to instrument analysis.
   d. Steps a-c must be repeated upon removing the sample from the refrigerator for the entire open-vial time period regardless of the method of analysis (open tube, cap piercing, auto sample or manual sample).
5. Refer to the instrument manual for detailed instructions on priming the instrument with normal patient samples (if applicable), verifying instrument repeatability according to specifications, executing the instrument auto-calibration process, and performance of calibration runs.
6. Calculate the mean value for each parameter.
7. Compare the results of your calculations to the values listed on the assay for your instrument.
   a. If the difference between your recovered mean values and the system specific values are less than the listed tolerance limits, the instrument does not require calibration.
   b. If the difference is greater, calibrate using the system specific values.
8. Calibration of the specific parameter(s) should be done in accordance with the procedure in your instrument manual. Calibration may not be required for all parameters.
9. Refer to instrument manual to determine if additional testing is required to verify calibration changes (if applicable) and/or verify calibration
10. After sampling, return to refrigeration for maximum open-vial stability. If run in the open mode, wipe the threads of both the vial and cap before replacing cap and returning to refrigeration.
11. For further assistance, contact Customer Support Center at 1-888-903-5001.

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 tube prior to sampling invalidates both the sample withdrawn and the remaining product in the tube.

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 ABX SAS** hematology reagents.

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 the assay sheet 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.

REFERENCE METHODS
Refer to the table of values on the enclosed assay sheet for target results. Assay values are derived from replicate testing on instruments operated and maintained according to manufacturer's instructions.

The following reference methods are used to whole blood calibrate instruments prior to system specific value assignment as indicated in CLSI H26-A2.[1]

WBC - A series of 1:500 dilutions are made using class A glassware. The lytic agent is placed in the initial dilution flask before diluting to volume. The diluting agent is an isotonic non-interfering solution. The samples are counted on a single aperture volume displacing particle counter.

RBC - A series of 1:50,000 dilutions are made using class A glassware. The diluting agent is an isotonic non-interfering solution. The samples are counted on a single aperture volume displacing particle counter.

Hb - Hemoglobin concentration is determined by converting hemoglobin to hemiglobincyanide (HiCN) and measuring absorbance at 540nm according to CLSI H15-A3[2] and ICSH recommendations. Hemoglobin concentration is calculated using millimolar absorption of 11.0.

Hct - Microhematocrit values are done in replicate on each sample, with capillary tubes filled and centrifuged according to the CLSI H07-A3[3] document. K_2EDTA is used as the anticoagulant for the collection of fresh specimens. The packed cell volume (hematocrit) is read directly using a precision metric scale. No correction is made for trapped plasma.

Plt - Platelet counting by the RBC/platelet ratio method (ICSH) is utilized as the reference method.

REFERENCES

1. Clinical Laboratory Standards Institute, H26-A2. Validation, verification and quality assurance of automated hematology analyzers. Approved Standard - Second Edition.
2. Clinical Laboratory Standards Institute, H15-A3, Reference and selected procedures for the quantitative determination of hemoglobin in blood. Approved Standard - Third Edition.
3. Clinical Laboratory Standards Institute, H07-A3, Procedure for determining packed cell volume by the microhematocrit method. Approved Standard - Third Edition.

Rx Only

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REF

Order Information:
5300100300 ABX Minocal 1 x 2.5mL

HORIBA Customer Support Center
Tel: (888) 903-5001
www.horiba.com/us/en/

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

Manufactured in the U.S. under contract for HORIBA ABX SAS

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