

INTENDED USE

ABX Minotrol 16 is a tri-level control intended for in vitro diagnostic use in monitoring the accuracy and precision on **HORIBA ABX SAS** hematology blood cell counters using **HORIBA ABX SAS** reagents.

SUMMARY

It is an established laboratory procedure to use stable controls to monitor analytical methods. ABX Minotrol 16 is a stable material that provides a means of determining the accuracy and precision of hematology blood cell counters. It is handled in the same manner as a patient specimen. The assay tables are determined on validated instruments using the appropriate reagents.

REAGENTS

This whole blood reagent may contain any or all of the following: stabilized human red blood cells, a white blood cell component consisting of human and/or non-human analogs and a platelet component consisting of a human or non-human analog in a preservative medium.

WARNING AND PRECAUTIONS

Biological risk



1. **ABX Minotrol 16 is intended solely for in vitro diagnostic use by trained personnel.**
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

ABX Minotrol 16 is stable through the expiration date when stored at 2 °C - 8 °C (35 °F to 46 °F). After opening, ABX Minotrol 16 is stable throughout the open-vial dating, as indicated on the assay sheet, when stored at 2 °C - 8 °C (35 °F to 46 °F).

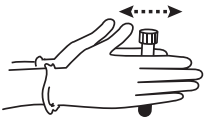
INDICATIONS OF PRODUCT DETERIORATION

Inability to obtain expected values may indicate product deterioration. Discoloration of the product may be caused by overheating or freezing during shipping or storage. Darkly colored supernatant may be indicative of product deterioration, however, moderately colored supernatant is normal and should not be confused with product deterioration. If the recovered values are not within the expected ranges:

1. Review control product package insert and the operating procedure of the instrument.
2. Check expiration date of ABX Minotrol 16. Discard outdated products.
3. Assay an unopened vial of ABX Minotrol 16. If the values are still outside the Expected Range, contact Customer Support Center at 1-888-903-5001.

INSTRUCTIONS FOR USE

1. Remove vials of control from the refrigerator and warm to room temperature (18 °C to 30 °C) for 15 minutes before use.
2. 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).
3. Refer to the instrument manual for the system in use for analyzing control materials.
 4. 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.

EXPECTED RESULTS

The mean assay values provided for each parameter are derived from replicate analyses on calibrated instruments as well as by manual reference methods. MCV and hematocrit values are not corrected for trapped plasma. The assay values are obtained using reagents recommended by the instrument manufacturer and are to be used for instrument control; they are not absolute assays for calibration. Upon receipt of a new control lot, it is good laboratory practice that an individual laboratory establish its own mean and limits for each parameter. However, the control means established by the laboratory should fall within the expected range specified for the control. The expected ranges listed represent estimates of variation due to different laboratories, instrument calibration, maintenance, and operator technique.

Assay values and expected ranges for instruments not listed on the assay sheet must be established by the user. Per CLSI H26-A2¹ it is recommended that each level of control be run twice a day for 3-5 days to establish individual lab means for each measurand.

Trending in the MCV parameter over the product shelf life is inherent to hematology control products. This characteristic does not indicate product instability. Ranges and limits for these parameters may need to be adjusted.

Verify that the lot number on the tube matches the lot number on the Assay Sheet. Refer to the assay table specified for your instrument.

LIMITATIONS

1. The components used to simulate white blood cells in the ABX Minotrol 16 are not suitable for microscopic differential analysis.
2. Incomplete mixing of the tube prior to sampling invalidates both the sample withdrawn and the remaining product in the tube.
3. ABX Minotrol 16 is a 3 part differential control and should not be used to calibrate instruments. Fresh whole blood or a calibrator (ABX Minocal) should be used to calibrate the instrument if necessary. The performance of this product is insured only if properly stored and used as described in this insert.

REFERENCES

1. Clinical and Laboratory Standards Institute, H26-A2, Validation, verification, and quality assurance of automated hematology analyzers; Approved Standard – Second Edition.

Rx Only

CONTROL

REF

Order Information:

5300100303 ABX Minotrol 16 Tri-Level Control 3x2.5mL
5300100306 ABX Minotrol 16 Tri-Level Control 6x2.5mL
5300100312 ABX Minotrol 16 Tri-Level Control 12x2.5mL

HORIBA Customer Support Center

Tel: (888) 903-5001

www.horiba.com/us/en/

HORIBA ABX SAS

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

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