Hematology Devices (for in vitro diagnostic use)

ABX Minotrol 16

18/08/09
A01A00051FEN

REF
2042001 -> 1L
2042002 -> 1N
2042003 -> 1H
2042202 -> Twin Pack: 2N
2042204 -> Twin Pack: 1L 1H
2042208 -> Twin Pack: 2L
2042209 -> Twin Pack: 2H

CONTROL 2,5mL

IVD CE

Exclusive use:

ABX Micros 45/60
ABX Micros ABC Vet
SCIL Vet ABC Plus
ABX Micros ES60/ESV60
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
Advia 60

HORIBA ABX SAS
BP 7290 - 34184 Montpellier
cedex 4 - France

1. Intended use

ABX Minotrol 16 is a tri-level control designed for use in monitoring the accuracy and precision of impedance blood cell counters[a].

2. Summary

The use of stabilized blood cell preparations is an established method for documenting acceptable performance of hematology instrumentation. ABX Minotrol 16 is a stable preparation which, when analyzed in the same manner as a human blood sample, provides a useful means of monitoring the accuracy and precision of hematology instrumentation and reagent systems. ABX Minotrol 16 should be handled in the same manner as a human blood sample

3. Controls

ABX Minotrol 16 contains human red blood cells, simulated white blood cells and mammalian platelets in a plasma-like fluid.

4. Warnings and Precautions

Potentially biohazardous material. For in vitro diagnostic use only. Each donor unit used in the preparation of this lot was tested using FDA approved methods and was found to be nonreactive for the presence of the antibody to HIV-1/HIV-2, antibody to hepatitis C, and for the surface antigen to hepatitis B. 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.

5. Instructions for Use

1- Remove the control blood from the refrigerator and allow to warm at room temperature (18 to 30°C or 65 to 86°F) for 15 minutes before mixing.
2- To mix hold the tube horizontally between the palms of the hands and roll the tube back and forth for 20-30 seconds. Invert the tube 8-10 times until the red cell sediment is completely resuspended.
3- Place the tube on the tray / rack of the automatic sample handler, if available on your instrument. Handle the control in the same manner as a patient sample. Refer to the Operator's manual of your instrument.
4- Immediately after sampling remove the tube from the sample handler and return it to the refrigerator.

6. Storage and Stability

Do not freeze. ABX Minotrol 16 vials should be tightly capped and stored at 2-8°C when not in use. ABX Minotrol 16 is stable for 16 sampling events over a maximum of 16 days after a vial has been opened, provided it is properly handled and promptly refrigerated after each use. ABX Minotrol 16 in unopened vials that have been stored at 2-8 C is stable until the expiration date listed on the label. Do not use grossly contaminated or hemolyzed control material.

7. Procedural limitations

The components used to simulate white blood cells in ABX Minotrol 16 are not suitable for morphological differential analysis. Incomplete mixing of the vial prior to use invalidates both the sample

a.Modification from index E to F : Pentra ES60, Advia 60 added

that is withdrawn and the remainder of the ABX Minotrol 16 in the vial.

8. Expected values

The assay values provided for each parameter of ABX Minotrol 16 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. Upon receipt of a new lot of hematology control, each laboratory should establish its own mean value and range. An individual laboratory mean should fall within the limits listed on the value sheet, while the range may include values above or below the limits. Failure to obtain proper values in the assay of control materials may indicate calibrator, control or reagent deterioration; instrument malfunction or procedural errors.

1. Review Value 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.