Hematology Devices (for in vitro diagnostic use)

ABX Minotrol CRP

01/08/08
A01A00087CEN

2042005 -> Level 1
2042006 -> Level 2
2042007 -> Level 3
2042205-> Twin Pack: 2x Level 1
2042206-> Twin Pack: 2x Level 2
2042207-> Twin Pack: 2x Level 3

REF

CONTROL 2,5mL

IVD CE

Exclusive use:

ABX Minos STX
ABX Argos
ABX Micros 45
ABX Micros 60
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
ABX Slide Preparation System

HORIBA ABX
BP 7290 - 34184 Montpellier
cedex 4 - France

1. Intended use

ABX MINOTROL CRP is a tri-level control designed for use in monitoring the accuracy and precision of impedance blood cell counts on ABX MICROS 60/CRP instrument ranges and in the CRP concentration on ABX MICROS CRP instrument ranges.

2. Summary

The use of stabilized blood cell preparations and human serum – based and CRP control fluid,is an established method for documenting acceptable performance of ABX MICROS CRP and MICROS 60 instrument ranges.

ABX MINOTROL CRP 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 parameters and CRP concentration.

ABX MINOTROL CRP should be handled in the same manner and with the same precautions as a human blood sample.

3. Controls

ABX MINOTROL CRP contains human red blood cells, simulated white blood cells, mammalian platelets, and human serum – based and CRP control fluid 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. The above referenced products were only formed with these donors. 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 and disposed of as if potentially infectious.

Use safe laboratory procedures as outlined in biosafety in microbiological and biomedical laboratories.

5. Instructions for Use

1. Bring controls to room temperature by rolling a control tube between the palms of your hands until the red blood cell sediment is completely suspended. Do not shake.

2. Immediately before sampling, gently invert each control tube 8-10 times.

3. Aspirate ABX MINOTROL CRP using instrument sample probe as described in the instrument user manual for both counting and CRP modes.

4. After use, wipe threads of control tube and cap with lint-free gauze.

5. Recap control tubes and refrigerate promptly after use.

6. Storage and Stability

Do not freeze. ABX MINOTROL CRP control tubes should be tightly capped and stored at 2-8°C when not in use.

ABX MINOTROL CRP 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[a].

ABX MINOTROL CRP in unopened control tubes 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 CRP are not suitable for morphological differential analysis. Incomplete mixing of the control tube prior to use invalidates both the sample that is withdrawn and the remainder of the ABX MINOTROL CRP in the control tube.

8. Expected values

The assay values provided for each parameter of ABX MINOTROL CRP are specific for the lot indicated on the assay value sheet. Assay values are based on replicate analyses on whole blood and Crp calibrated HORIBA ABX instruments using HORIBA ABX 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.

9. References

Biosafety in microbiological and biomedical laboratories

a.Modification from index B to C : stability informations