Hematology Devices (for in vitro diagnostic use)

ABX Minotrol Retic

08/09/08
A01A00052FEN

REF
2072001 -> Level 1
2072002 -> Level 2
2072003 -> Level 3
2072201-> Twin Pack: 2x Level 2
2072202-> Twin Pack: Level 1 + 3

CONTROL 3mL

IVD CE

Exclusive use:

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

HORIBA ABX
BP 7290 - 34184 Montpellier
cedex 4 - France

1. Intended use

ABX Minotrol Retic is a tri-level, assayed hematology control designed to document and monitor values obtained from manual and automated reticulocyte counting methods.

2. Summary and principle

It is an established laboratory procedure to use stable controls to monitor the performance of diagnostic tests. ABX Minotrol Retic is composed of stable materials that provide a means of verifying accuracy and precision of reticulocyte counting methods. Refer to the assay tables for specific methods.

ABX Minotrol Retic is available in three levels representing normal, moderately high, and very high levels of reticulocytes. ABX Minotrol Retic is handled in the same manner as patient specimens.

3. Controls

ABX Minotrol Retic is an in vitro diagnostic reagent composed of human erythrocytes and mammalian erythrocytes suspended in a plasma-like fluid with preservatives.

4. Precautions

Potentially biohazardous material. For in vitro diagnostic use only.

ABX Minotrol Retic is intended solely for in vitro diagnostic use by trained, qualified personnel. Each human donor unit used in preparation of this product has been tested using FDA approved methods and found nonreactive for HBsAg and HIV-1 Ag, and nonreactive for antibodies to HCV and HIV-1/HIV-2.

Because no known test method can offer complete assurance that infectious agents are absent, consider this product potentially infectious. When handling or disposing of products, follow precautions recommended by current biosafety regulations for any potentially infectious human blood specimen.

5. Instructions for use

1- Remove vials from the refrigerator and allow to warm at ambient room temperature (18° to 29.5°C) for 15 minutes before mixing.
2- Do not shake the vial or use a mechanical mixer.
3- To mix ABX Minotrol Retic:
◆ Hold a vial horizontally between the palms of your hands.
◆ Roll the vial back and forth 10 times.
◆ Gently invert the vial 10 times.
4- Examine the bottom of the vial. If the cells are not completely and uniformly suspended, repeat the mixing steps.
5- Prepare ABX Minotrol Retic for analysis exactly as a patient sample.
6- After sampling, carefully wipe the vial rim and cap with lint-free tissue. Replace the cap tightly and immediately return vials to the refrigerator.
7- For automated methods, analyze the control as instructed in the Operator's Manual of your instrument.
8- For manual methods, prepare smears of ABX Minotrol Retic and count exactly as a patient sample.

6. Stability and storage

Store ABX Minotrol Retic upright at 2° to 8°C when not in use. Protect vials from overheating and freezing.

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Unopened vials are stable until the expiration date. ABX Minotrol Retic 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]. If sample preparation is a separate step before counting, count the prepared sample within 15 minutes after the minimum incubation time.

7. Indications of deterioration

ABX Minotrol Retic should be similar in appearance to fresh whole blood. A light pink-tinted supernatant is normal. Discoloration of the supernatant fluid or visible hemolysis may indicate product deterioration. Overheating, freezing, rough handling and contamination are frequent causes of product damage. Inability to recover expected values may also indicate product deterioration. Incomplete mixing, instrument malfunction, or defective stains are other causes of unacceptable results. Do not use the product if deterioration is suspected.

8. Expected results

Verify that the lot number on the vial matches the lot number on the table of assay values. Refer to the assay values specified for your method.

9. Performance characteristics

Assay values are presented as a Mean and a Range. The Mean is derived from replicate testing by the specific method. The manual method is a direct microscopic count using the conventional reticulocyte counting procedure with New Methylene Blue stain.

The Range is an estimate of variation between laboratories and takes into account inherent imprecision of the method, differences in maintenance, operating technique, and equipment. It is recommended that each laboratory establish its own laboratory-specific ranges for greater control sensitivity.

Assay values on a new lot of control should be confirmed before it is put into routine use. Test the new lot when the instrument is in good working order and quality control results on the old lot are acceptable. The laboratory recovered mean should be within the assay range. Occasional individual results may fall outside the Range. Laboratories may consider results acceptable when at least 95 percent of results are within 2 SD of the laboratory mean.

10. Limitations

Incomplete mixing of the vial prior to use invalidates both the sample that is withdrawn and the remainder of the material in the vial. Values for methods not listed on the Table of Assay Values must be established by the user.

11. Bibliography

National Committee for Clinical Laboratory Standards.

Reticulocytes Counting by Flow Cytometry; Proposed Guideline. NCCSL document H44-P (ISBN 1-56238-207-1).

NCCSL, 771 East Lancaster Avenue, Villanova, Pennsylvania 19085, 1993.

a.Modification from index e to f : stability informations