Hematology Devices (for in vitro diagnostic use)

ABX Difftrol

08/09/08
A01A00053DEN

REF
2062011 -> 1L
2062012 -> 1N
2062013 -> 1H
2062203 -> Twin Pack: 2N
2062204-> Twin Pack: 1L 1H
2062207 -> Twin Pack: 2L
2062208 -> Twin Pack: 2H

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/DF 120
ABX Slide Preparation System

HORIBA ABX
BP 7290 - 34184 Montpellier
cedex 4 - France

1. Intended Use

ABX DIFFTROL is a tri-level control intended for in vitro diagnostic use and designed for use in monitoring the accuracy and precision of the ABX hematology blood cell counters with the HORIBA ABX reagents. Refer to the assay tables for specific instrument models.

2. Summary

It is an established laboratory procedure to use stable controls to monitor analytical methods. ABX DIFFTROL is a stable material that provides a mean 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.

3. Control

ABX DIFFTROL is an in vitro diagnostic reagent composed of cells simulating human erythrocytes, mammalian leukocytes, and mammalian platelets in a plasma-like fluid with preservatives.

4. Warning and precautions

Potentially biohazardous material. For in vitro diagnostic use only.

Each human donor unit used in preparation of this product has been tested by an FDA approved method 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 product follow precautions recommended by current biosafety regulations for any potentially infectious human blood specimen.

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. 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. Stability and storage

Store the tubes vertically in their original package at 2 to 8°C (35 to 46°F) when not in use. DO NOT FREEZE. Unopened tubes are stable until the expiration date listed on the label. ABX Difftrol 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].

7. Indications of deterioration

ABX DIFFTROL should be similar in appearance to fresh whole blood. In unmixed tubes the supernatant may appear pink or cloudy. This is normal and does not indicate deterioration. A dark red supernatant fluid or discoloration of the product may indicate

a.Modification from index c to d : stability informations

deterioration. Overheating, freezing, and contamination are frequent causes of product damage. Unacceptable results may be due to instrument malfunction, procedural error, incomplete mixing, or product deterioration. Do not use the product if deterioration is suspected.

8. Expected results

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.

9. Performance and characteristics

Assigned values are presented as a Mean Value together with maximum and minimum Ranges. The Mean Value is derived from replicate testing on instruments operated and maintained according to the manufacturer instructions. The Range is an estimate of variation between laboratories and also takes into account expected biological variability of the control material.

Assay values on a new lot of control should be confirmed before it is put into routine use. Test the new lot when instrument is in good working order and quality control results on the previous lot are acceptable. The laboratory recovered mean should be within the assay range.

10. Limitations

The components used to simulate white blood cells in the ABX DIFFTROL are not suitable for microscopic differential analysis.

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

ABX DIFFTROL is a 5 part differential control and should not be used to calibrate instruments. Fresh whole blood or a calibrator (ABX MINOCAL Réf. 2032002) 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.

11. Kit Contents

2062203: Twin-pack 2N

2 x ABX DIFFTROL Normal blood control vials
2062016 ABX Lysebio floppy disk
2062015 ABX Alphalyse floppy disk
9930033 Sheet value ABX DIFFTROL

2062204: Twin-pack 1L+1H

1 x ABX DIFFTROL low control blood vial
1 x ABX DIFFTROL high control blood vial
2062016 ABX Lysebio floppy disk
2062015 ABX Alphalyse floppy disk
9930033 Sheet value ABX DIFFTROL

2062207: Twin-pack 2L

2 x ABX DIFFTROL low control blood vial
2062016 ABX Lysebio floppy disk
2062015 ABX Alphalyse floppy disk
9930033 Sheet value ABX DIFFTROL

2062208: Twin-pack 2H

2 x ABX DIFFTROL high control blood vial
2062016 ABX Lysebio floppy disk
2062015 ABX Alphalyse floppy disk
9930033 Sheet value ABX DIFFTROL

2062011: ABX DIFFTROL Low 3mL

1 x ABX DIFFTROL low control blood vial

2062012: ABX DIFFTROL Normal 3mL

1 x ABX DIFFTROL normal control blood vial

2062013: ABX DIFFTROL High 3mL

1 x ABX DIFFTROL high control blood vial