Hematology Control

CE
IVD

EN

INTENDED USE
For *in vitro* diagnostic use as a control to monitor the performance of multi-parameter hematology instruments.

SUMMARY AND PRINCIPLES
Erba Hematology Control is prepared from stabilized human blood so that repeated measurements can be made daily to monitor the performance of hematology analyzer systems. ASSIGNED VALUES and EXPECTED RANGES are determined on systems using specific ERBA LACHEMA® reagents. ASSIGNED VALUES are confirmed by multiple analysis of the control product and should be considered a **suggested average** until you establish your own running mean.

REAGENTS
Erba Hematology Control contains treated, stabilized human erythrocytes and a stabilized platelet-sized component in an isotonic, bacteriostatic medium. Fixed erythrocytes are added to stimulate leukocytes.

WARNING
POTENTIAL BIOHAZARDOUS MATERIAL
Each donor unit used in the preparation of this material was tested by an FDA approved method for the presence of the antibody to Human Immunodeficiency Virus (HIV) as well as for Hepatitis B virus surface antigen and found to be negative (were not repeatedly reactive). Because no test method can offer complete assurance that Hepatitis B virus, HIV, or other infectious agents are absent, this specimen/reagent should be handled at biosafety level 2, as recommended for any potentially infectious human serum or blood specimen in the Centers for Disease Control / National Institutes of Health manual "Biosafety in Microbiological and Biomedical Laboratories", 1988.

FOR IN VITRO DIAGNOSTIC USE WITH AUTOMATED AND SEMI-AUTOMATED HEMATOLOGY ANALYZERS AND ERBA LACHEMA REAGENT SYSTEMS.

STORAGE AND STABILITY
Erba Hematology Control is shipped in a thermally insulated container designed to keep it cool. When stored at 2° to 10° C, sealed vials are stable at least until the expiration date shown on the TABLE OF EXPECTED RESULTS.

Storage of product with cap down (inverted) might require additional mixing for complete resuspension of cellular components.

INDICATIONS OF INSTABILITY OR DETERIORATION
Inability to obtain expected values or gross hemolysis (darkly-colored supernatant) is indicative of deterioration of the product.
Note: After the manufacturing process is complete; a portion of each lot is retained by ERBA LACHEMA. Significant deterioration of the product is cause for prompt issuance of appropriate notification to all users.

INSTRUCTIONS

1) Remove ERBA LACHEMA Erba Hematology Control from refrigeration and allow to warm to room temperature for 30 minutes before mixing.

2) Mix by hand as follows:
a) Roll the tube or vial slowly between the palms of the hands 15-20 seconds in an upright position.
b) Invert the tube and slowly roll it back and forth for another 15-20 seconds.
c) DO NOT MIX MECHANICALLY.
d) Continue to mix in this manner until all cells are completely suspended. Tubes stored for a long time may require extra mixing.
e) Gently invert the tube 8 times immediately before sampling.

3) Note: If your analyzer includes an autosampler/mixer, first mix as directed above then place control on instrument. Do not use any other type of mechanical blood mixer.

4) a) For instruments with cap-piercing capability, analyze the control as directed in the analyzer's Product Manual.
b) For instruments without cap-piercing capability, remove the cap to analyze the control as directed in the Product Manual.

5) After open sampling, carefully wipe the rim of the tube and inside of the cap with a lint-free tissue. Replace the cap ensuring it is on tight.

6) Return the tubes to the refrigerator within 30 minutes of use.

7) Compare instrument values to those given in the TABLE OF EXPECTED RESULTS.
a) The instrument is considered well maintained and operating correctly if: 95% of the recovered values fall within expected range. No more than three consecutive values exceed the expected range. Recovered values do not trend outside the expected range.
b) Failure to achieve the conditions listed in **7)** a) above may indicate instrument and/or control problems. To identify the source of the problem see investigational procedure section.

8) For consistency and best precision data, use the three levels of the cell control in the following order: abnormal low, normal, and abnormal high.

9) Before expiration of the current lot, good laboratory practice requires that a new lot of cell control be analyzed in parallel with the existing lot until a laboratory mean is established on the new lot.

PERFORMANCE LIMITS
Individual laboratories should expect better precision than that shown in the expected range column. Refer to your Product Manual for performance characteristics of precision for your instrument.

INVESTIGATIONAL PROCEDURE

If you need help in resolving control recovery problems, call our customer service department. To provide faster handling of your inquiry, please have the following information available when you call:

- Expiration dates and lot numbers of all reagents, the control(s) in question and other levels of cell control that you use.
- Data supporting the problem for the lot number in question.
- Previous cell control lot numbers and the data you have for these previous lots.
- Data from a current reproducibility study (N=10) using a fresh whole blood specimen and performed according to your product manual.
- Data from the last Peer survey as well as data from your last instrument calibration.

MANUFACTURER
Erba Lachema s.r.o.
Karásek 1d, 621 33 Brno, Czech Republic
Tel: +420 517 077 111 Fax: +420 517 077 077
www.lachema.com

Date of last revision: 31.8.2011