Boule Con-Diff Tri-Level

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

SUMMARY AND PRINCIPLES
Boule Con-Diff 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 Boule reagents. ASSIGNED VALUES are confirmed by multiple analysis of the control product.

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

STORAGE AND STABILITY
Boule Con-Diff Hematology Control is shipped in a thermally insulated container designed to keep it cool. When stored at 2-10° C, sealed vials are stable at least until the expiration date shown on the TABLE OF EXPECTED RESULTS.
Open vial stability 14 days after opening when returned to refrigerator after each use.
Storage of product with cap down (inverted) might require additional mixing for complete resuspension of cellular components.

INSTRUCTIONS FOR USE
1. Remove Boule Con-Diff 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.
4. **For instruments with cap-piercing** capability, analyze the control as directed in the analyzer's Product Manual.
   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 7a above may indicate instrument and/or control problems. To identify the source of the problem see investigational procedure section.
   c. "FD" Flags may be ignored on control results providing the flagged parameter recovers within the expected range.

INDICATIONS OF INSTABILITY OR DETERIORATION
Inability to obtain expected values may indicate product deterioration. Discoloration of the product may be caused by overheating or freezing during shipping or storage. Darkly colored supernatant may be indicative of product deterioration, however, moderately colored supernatant is normal and should not be confused with product deterioration. If the recovered values are not within the expected ranges:
1. Review the control product package insert and the operating procedure of the instrument
2. Check the expiration date of the Boule Con-Diff. Discard outdated products.
3. Assay an unopened vial of Boule Con-Diff.

Note: After the manufacturing process is complete, a portion of each lot is retained by Boule. Significant deterioration of the product is cause for prompt issuance of appropriate notification to all users.

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.

PRECAUTIONS
- For In-Vitro diagnostic use.
- All human source material used to manufacture this product was non-reactive for antigens to Hepatitis B and negative by tests for antibodies to HIV (HIV-1, HIV-2) and Hepatitis C using techniques specified by the U.S. Food and Drug Administration. Because no known test method can assure complete absence of human pathogens, this product should be handled with appropriate precautions.
- This product should not be disposed in general waste, but should be disposed with infectious medical waste. Disposal by incineration is recommended.
- This product is intended for use as supplied. Adulteration by dilution or addition of any materials to the product as supplied invalidates any diagnostic use of the product.
- Controls are not to be used as calibrators.

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.

ORDERING INFORMATION AND SERVICE
Contact your local distributor for orders and support. Please have the catalog number ready for orders. For other assistance contact Clinical Diagnostic Solutions at 800-453-3328, fax 954-791-7118.

Ordering no:	Description	Packaging
501-605	Boule Con-Diff Tri-Level	6 x 4.5 mL
501-607	Boule Con-Diff Tri-Level	9 x 4.5 mL
501-608	Boule Con-Diff Tri-Level	12 x 4.5 mL

Manufactured for Boule Medical (www.boule.se)
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