Boule Cal

INTENDED USE
Boule Cal is manufactured for calibration multi-parameter hematology analyzers.

SUMMARY AND PRINCIPLES
Multi-parameter hematology analyzers require regular calibration in order to produce accurate results on patient samples. Calibration can be accomplished by transferring information to the analyzer through fresh blood samples, which have been assayed by reference methods. A more direct and convenient approach is to use a calibrator material with System Specific Values (SSV) assigned. Boule Cal is such a material.
Boule Cal is a stable suspension of red blood cells, white blood cells and platelets. Assigned values are derived from replicate analyses on whole blood calibrated hematology analyzers (see reference procedures). A user analyzes Boule Cal on their instrument and computes calibration factors by comparing recovered values and assigned values. These factors provide the basis for making adjustments to the instrument.

REAGENTS
Boule Cal contains human red blood cells, mammalian and simulated white blood cells, and a platelet component in a preservative medium.

STORAGE AND STABILITY
Boule Cal is stable through the expiration date when stored at 2° to 10° C. After opening, Boule Cal is stable throughout the open-vial dating, as indicated on the assay sheet when stored at 2° to 10° C.

INSTRUCTIONS FOR USE
1. Perform instrument start-up and routine cleaning procedures as defined in the instrument manufacturer's operator manual (i.e., blood sampling valve, counting apertures).
2. Remove Boule Cal from refrigeration and allow to warm to room temperature for 30 minutes before mixing.
3. 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.
4. Prime the instrument by aspirating two fresh blood samples. Disregard results.
5. Verify instrument precision. Refer to operator's manual for instructions and specifications.
6. Analyze Boule Cal a minimum of 6 times, disregard the first sample. (For auto-calibration, refer to procedure in the user's manual). Record the values recovered on the remaining 5 samples.
7. Calculate the mean for each parameter.
8. Compare the results of your calculations to the values listed for your instrument type.
   a. If the difference between your recovered mean values and the system values are less than the listed tolerance limits, the instrument does not require calibration.
   b. If the difference is greater, calibrate using the system specific values.
9. Calibration of the specific parameter(s) should be done in accordance with the procedure in your instrument manual. Calibration may not be required for all parameters.
10. Verify calibration by analyzing Boule Cal three times and repeat steps 7 and 8.
11. 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.
12. Return the tubes to the refrigerator within 30 minutes of use.
13. For further assistance, please contact your local distributor.

INDICATION OF PRODUCT DETERIORATION
Gross hemolysis (darkly colored supernatant) may be indicative of product deterioration or damage. If this is apparent, contact your local distributor.

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.

REFERENCE PROCEDURES
WBC- A series of 1:500 dilutions are made using class A glassware. The lytic reagent is placed in the initial dilution flask before diluting to volume. The diluting agent is an isotonic solution for Beckman Coulter® instruments. The samples are counted on a Beckman Coulter Counter Z instrument.

RBC- A series of 1:50,000 dilutions are made using class A glassware. The diluting agent is an isotonic solution for Beckman Coulter® series instruments. The samples are counted on a Beckman Coulter Counter Z instrument.

Hgb- Hemoglobin concentration is determined by converting hemoglobin to hemiglobincyanide (HiCN) and measuring absorbance at 540 nm according to CLSI H15-A3 and ICSH recommendations. Hemoglobin concentration is calculated using millimolar absorption coefficient of 11.0.

HCT- Microhematocrit values are done in replicate on each sample, with capillary tubes filled and centrifuged according to the CLSI H7-A3 document. K3EDTA is used as the anticoagulant for collection of fresh specimens. The packed cell volume, or hematocrit, is read directly using a precision metric scale. No correction is made for trapped plasma.

Plt- A series of 1:125 macrodilutions are prepared using class A glassware in 1% Ammonium Oxalate. Charged hemacytometers are allowed to stand 20-30 minutes. Cells are counted using phase-contrast microscopy technique.

MPV- Based on a method using latex particles.

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 or at info@cdsolinc.com

Ordering no:	Description	Packaging
502-018	Boule Cal	1 x 3.0 ml

Manufactured for Boule Medical AB
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