Instruction for Use
Hematology Control

INTENDED PURPOSE

IVD

Boule Con-Diff is intended for monitoring the performance of white blood cells (WBC); the absolute number and percentage for granulocytes (GRA), lymphocytes (LYM), mid-sized white cells (MID); red blood cells (RBC); hemoglobin (HGB); mean cell volume of red cells (MCV); hematocrit (HCT); mean cell hemoglobin (MCH); mean cell hemoglobin concentration (MCHC); red cell distribution relative width (RDW%); platelets (PLT); mean platelet volume (MPV).of on Medonic M-series and Swelab Alfa hematology analyzer.

SUMMARY AND PRINCIPLES

Boule Con 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 and should be considered a **suggested average** until you establish your own running mean.

REAGENTS

Boule Con 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 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.

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. Discard outdated products.
3. Test an additional unopened vial of Boule Con.

INSTRUCTIONS FOR USE

1. Remove Boule Con Hematology Control from refrigeration and allow to warm at ambient temperature (18-32°C) for 30 minutes before mixing.
2. After warming, mix by hand as follows:
   a. Roll the tube or vial slowly between the palms of the hands eight times in an upright position.
   b. Invert the tube and slowly roll it between the palms eight times.
   c. Continue to mix in this manner until all cells are completely suspended. Tubes stored for a long time may require extra mixing.
   d. Gently invert the tube 8 times immediately before sampling.
   e. Note: Use of a Mechanical Mixer is not recommended.
3. Follow instruction in User's Manual for each sampling mode.
4. 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.
5. Return the tubes to the refrigerator within 30 minutes of testing.
6. 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 6a above may indicate instrument and/or control problems. To identify the source of the problem, see investigational procedure section.
7. For consistency and best precision data, use the three levels of the cell control in the following order: abnormal low, normal, and abnormal high.
8. 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.

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.

SERIOUS INCIDENT

If a serious incident occurs in relation with Boule Medical´s product, a notice shall be reported to the distributor, the manufacturer Boule and the competent authority of the Member State in which the user and /or the patient is established.

HAZARD INFORMATION

Any hazard related to the content of a consumable is indicated by a hazard code on the product label. See table below. For more information refer to the relevant Safety Data Sheet (SDS) at www.boule.com.

Hazard Code	Explanation
EUH 208	Contains a reaction mass of 5-CHLORO-2-METHYL-2H-ISOTHIAZOL-3-ON and 2-METHYL-2H-ISOTHIAZOL-3-ON. May produce an allergic reaction.
EUH 210	Safety Data Sheet available on request.

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 your last instrument calibration.

ORDERING INFORMATION AND SERVICE

Contact your local Boule representative for orders and support. Please have the catalog number ready for orders. For other assistance contact Boule Medical AB at phone +46 8 7447700 or visit www.boule.com

Ordering no:	Description		Packaging
1504025	Boule Cal		1 x 3.0 ml
1504045	Boule Cal		2 x 3.0 ml
1504289	Boule Con-Diff Low	16 parameter	25 x 3.0 ml
1504288	Boule Con-Diff Normal	16 parameter	25 x 3.0 ml
1504290	Boule Con-Diff High	16 parameter	25 x 3.0 ml

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