Instruction for Use
Boule Vet-Con

INTENDED USE

For Veterinary use as a control to monitor the performance of multi-parameter hematology instruments.

SUMMARY AND PRINCIPLES

Boule Veterinary 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 Veterinary 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 Veterinary 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 16 days after opening when returned to refrigerator after each use.
Storage of product with cap down (inverted) might require additional mixing for complete re-suspension of cellular components.

INSTRUCTIONS FOR USE

1. Warm Boule Veterinary Hematology Control at ambient temperature, 18-32°C, (30 min.)
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. Gently invert the tube eight times.
3. Inspect tube or vial contents; determine that all the cells have been uniformly distributed.
4. Repeat steps 2a to 2c if vial contents have not been totally distributed. **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.
5. **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/stopper to analyze the control as directed in the Product Manual.
   Warning: For your protection, use an absorbent material such as gauze or paper wipes when removing the rubber stopper from the vial. After use, immediately wipe the cap and mouth of the vial with gauze. Replace the cap.
6. Return the vial to the refrigerator within 1 hour.
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.
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.

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 Veterinary Hematology Control. Discard outdated products.
3. Assay an unopened vial of Boule Veterinary Hematology Control.

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 Veterinary 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.

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 the last peer survey as well as data from your last instrument calibration.

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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

This instruction is also available at www.boule.com

Ordering no:	Description	Packaging
1504027	Boule Vet-Con	6 x 4.5 ml
1504026	Boule Vet-Con	1 x 4.5 ml

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