

Instructions for use

Boule Vet-Con-5Diff



Revision history

Latest revision: 2024-04. Previous revision: None.

Changes: None. New document.

Intended purpose and user requirements

- Boule Vet-Con-5Diff is an assayed whole blood control intended to monitor multi-parameter values on veterinary hematology analyzers.
- The control is intended for professional use. Operator must have basic laboratory skills, be aware of good laboratory practice, and read the user manual before use.

Summary and principles

Boule Vet-Con-5Diff is prepared from stabilized blood so that repeated measurements can be made daily to monitor the performance of hematology analyzer systems. Mean values and 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 each laboratory has established its own running mean. The control material is sampled in the same manner as a patient specimen.

Reagents

Boule Vet-Con-5Diff contains stabilized human erythrocytes, mammalian leukocytes, and mammalian platelets suspended in a plasma-like fluid with preservatives.

Storage and stability

Store Boule Vet-Con-5Diff upright at 2°C to 8°C when not in use. Protect tubes from overheating and freezing. Unopened tubes are stable until the expiration date. Opened tubes are stable for 13 days, provided they are handled properly.

Indication of deterioration

After mixing, the product should be similar in appearance to fresh whole blood. In unmixed tubes, the supernatant may appear cloudy and reddish; this is normal and does not indicate deterioration. Other discoloration, very dark red supernatant or unacceptable results may indicate deterioration. **Do not use the product if deterioration is suspected.**

Precautions



RISK OF INFECTION

As there are no assurances of the absence of HIV, Hepatitis B or C viruses or other infectious agents in blood samples, controls, and calibrators these products should be handled as potentially biohazardous. Refer to local regulations and established laboratory protocol for handling biohazardous materials.



CAUTION

Never use an opened vial longer than recommended by the manufacturer, past the expiration date, or subject any vial to excessive heat or agitation.

- Please read the relevant Safety Data Sheet (SDS) before use. SDSs are available at www.boule.com.
- 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 materials to the product as supplied invalidates diagnostic use of the product.

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Prerequisite: Remove tubes from the refrigerator and allow to warm to room temperature (15°C to 30°C) for 15 minutes before mixing.

Do not use a vibrating mechanical mixer to mix Boule Vet-Con-5Diff.

1. Do the following:
 - a. Hold the sample tube in a horizontal position between the palms of your hands and roll the tube slowly 8 times.
 - b. Invert the tube and slowly roll it between the palms of your hands 8 times.
 - c. Continue to mix in this manner until all cells are completely suspended. Tubes stored for a long time might require extra mixing.
 - d. Gently invert the tube 8 times immediately before analysis.

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- Analyze the sample as instructed in the Quality control section of the user manual for your analyzer.
- After open sampling, carefully wipe the rim of the tube and the inside of the cap with a lint-free tissue. Replace the cap ensuring it is on tight.
- Return the tubes to the refrigerator within 30 minutes of use.
- Compare analyzer values to those given in the assay sheet available at www.boule.com. The analyzer is considered well maintained and operating correctly if:
 - Recovered values fall within expected range.
 - Recovered values do not trend outside the expected range.
- 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

Verify that the lot number on the tube matches the lot number on the assay sheet. Assay values are determined on well maintained, properly calibrated analyzers using the analyzer manufacturer's recommended reagents.

Assigned values are presented as a mean and range. The mean is derived from replicate testing on analyzers operated and maintained according to the manufacturer's instructions. The range is an estimate of variation between laboratories and also takes into account the inherent imprecision of the method and expected biological variability of the control material.

Reagent differences, maintenance, operating technique, and calibration may contribute to inter-laboratory variation.

Limitations










The performance of this product is assured only if it is properly stored and used as described in this instruction for use. Incomplete mixing of a tube prior to use invalidates both the sample withdrawn and any remaining material in the tube.

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 user manual.
- Data from your last analyzer calibration.

Meaning of symbols on product labels

		
Article number	Content	Lot number
		
Manufacturer	Use-by date	Temperature limitation
 <small>www.boule.com</small>		
Consult electronic instructions for use available on website	Biohazard	Control

Ordering information and service

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

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Article number	Description	Packaging
1440181	Boule Vet-Con-5Diff N	1 × 3 mL
1440182	Boule Vet-Con-5Diff N	6 × 3 mL

Contact information



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SE-163 53 Spånga, Sweden
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Regulatory information

Boule Vet-Con-5Diff are under the Regulation (EC 1907/2006) on the registration, evaluation, authorization and restriction of chemicals (REACH) and Regulation (EC 1272/2008) on the classification, labelling and packaging of substances and mixtures (CLP).