

Instructions for use

Boule Vet-Cal-5Diff



Revision history

Latest revision: 2024-09. Previous revision: None.

Changes: None. New document.

Intended purpose and user requirements

- Boule Vet-Cal-5Diff is intended for use for calibration of red blood cells (RBC), hemoglobin (HGB), mean cell volume of red cells (MCV), white blood cells (WBC) and platelets (PLT) on veterinary hematology analyzers.
- The calibrator 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

Hematology analyzers require periodic calibration in order to generate accurate patient results. This calibrator is a stable, whole blood preparation that can be used to verify and adjust calibration of the H50V hematology analyzer.

Calibrator values for Boule Vet-Cal-5Diff are derived from replicate testing on analyzers operated and maintained according to the manufacturer's instructions. Analyzers are calibrated with whole blood using values determined by reference methods.

Reagents

Boule Vet-Cal-5Diff is a reagent composed of human erythrocytes, mammalian leukocytes and mammalian platelets suspended in a plasma-like fluid with preservatives.

Storage and stability

Store Boule Vet-Cal-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 4 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.

Instructions for use

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-Cal-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.

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- 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.
2. Prime the analyzer once by aspirating the calibrator sample. Discard the result.
3. Analyze the calibrator according to the calibration procedure in the user manual for your analyzer.
4. 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.
5. Return the tubes to the refrigerator within 30 minutes of use.
6. Compare the mean value for each parameter to the assigned value given in the assay sheet available at www.boule.com.
 - If the difference is within the acceptable range, calibration is optional.
 - If the difference is not within the acceptable range, calibration might be needed.
7. Ranges given on the assay sheet are intended as guidelines for evaluating analyzer calibration. Acceptable calibration should be established by each laboratory. If the calibrator recovered data is outside the range found on the assay sheet with stable control results and inter-laboratory QC and/or proficiency testing reports that have excellent peer group agreement, this might indicate product damage. **Do not use the product if deterioration is suspected.**
8. To adjust analyzer calibration and verify results, do the following:
 - a. Calibrate the analyzer by using the calibration adjustment procedures described in the user manual for your analyzer.
 - b. Verify calibration by analyzing calibrator and repeat Step 6.
 - c. Confirm calibration by running quality control.

Expected results

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

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.

Reference procedures

| | |
|------------|--|
| WBC | A series of 1:500 dilutions are made with calibrated glassware. Counting is performed on a Coulter Counter Z series analyzer. All counts are corrected for coincidence. |
| RBC | A series of 1:50,000 dilutions are made with calibrated glassware. Counting is performed on a Coulter Counter Z series analyzer. All counts are corrected for coincidence. |
| HGB | Hemoglobin value is determined by spectrophotometric procedure according to CLSI Standard H15-A3 and is traceable to ICSH/WHO International Haemoglobinocyanide Standard. |
| HCT | Packed cell volume (PCV) is measured by the microhematocrit procedure according to CLSI Standard H7-A3. No correction is made for trapped plasma. |
| PLT | A series of 1:126 dilutions are made using calibrated glassware in 1% ammonium oxalate. Platelets are counted using a hemocytometer and phase contrast microscopy. |

Meaning of symbols on product labels

| | | |
|----------------|-------------|------------------------|
| | | |
| Article number | Content | Lot number |
| | | |
| Manufacturer | Use-by date | Temperature limitation |

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www.boule.com

Consult electronic instructions for use available on website



Biohazard

CAL

Calibrator

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.

| Article number | Description | Packaging |
|----------------|---------------------|-----------|
| 1440184 | Boule Vet-Cal-5Diff | 1 × 3 mL |

Contact information



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Regulatory information

Boule Vet-Cal-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).