Instruction for Use
Boule Cal-5Diff A1

CAL

Boule

INTENDED PURPOSE

IVD

Boule Cal-5Diff A1 is intended for in vitro diagnostic use for calibration of RBC, MCV, HGB, PLT, WBC on the Medonic M51 and Swelab Lumi hematology analyzer.

SUMMARY AND PRINCIPLE

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 select hematology instruments. Calibrator values for Boule Cal-5Diff A1 are derived from replicate testing on instruments operated and maintained according to the manufacturer's instructions. Instruments are calibrated with whole blood using values determined by reference methods.

REAGENTS

Cal-5Diff A1 is an *in vitro* diagnostic reagent composed of human erythrocytes, mammalian leukocytes, and mammalian platelets suspended in a plasma-like fluid with preservatives.

PRECAUTION

Cal-5Diff A1 is intended for ***in vitro* diagnostic use** only by trained personnel.

WARNING:

POTENTIAL BIOHAZARDOUS MATERIAL For *in vitro* diagnostic use. Each human donor/unit used in the preparation of this product has been tested and yielded non-reactive / negative results for all conditions referenced in 21 CFR 610.40 (a) (b), as required by the FDA. Testing was conducted using FDA-licensed tests. No test method can offer complete assurance that infectious agents are absent; therefore, this material should be handled as potentially infectious. When handling or disposing of vials follow precautions for patient specimens as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.

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 210	Safety Data Sheet available on request.

STABILITY AND STORAGE

Store Cal-5Diff A1 upright at 2 - 8° C (35 - 46° F) when not in use. **Protect tubes/vials from overheating and freezing**. Unopened tubes/vials are stable through the expiration date. Opened tubes/vials are stable for 7 days, provided they are handled properly.

INDICATIONS OF DETERIORATION

After mixing, product should be similar in appearance to fresh whole blood. In unmixed tubes/vials, 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.**

INSTRUCTIONS FOR USE

A. Mixing and handling directions:

1. Remove tubes/vials from the refrigerator and allow to warm at room temperature (15 - 30°C or 59 - 86°F) for 15 minutes before mixing.
2. To mix, hold a tube/vial horizontally between the palms of the hands. **Do not pre-mix on a mechanical mixer.**
   a) Roll the tube/vial back and forth for 20 - 30 seconds; occasionally invert the tube/vial. Mix vigorously but do not shake.
   b) Continue to mix in this manner until the red cells are completely suspended. Tubes/vials stored for a long time may require extra mixing.
   c) Gently invert the tube/vial 8 - 10 times immediately before running each sample.
3. After sampling:
   a) Automatic Sample Handling: Remove the tube/vial from the sample handler immediately after sampling.
   b) Manual Sample Handling: Carefully wipe the tube/vial rim and cap with a lint-free tissue and replace the cap.
4. Return tubes/vials to refrigerator within 30 minutes of use.

B. Analyze Calibrator:

1. Prime the instrument once by aspirating calibrator sample. Discard the result.
2. Analyze calibrator according to the calibration procedure in the Operator's Manual for your instrument.
3. Compare the mean value for each parameter to the assigned value.
   a) If the difference is within the Range, calibration is optional.
   b) If the difference is not within the Range, calibration may be needed.
4. Ranges given on the assay sheet are intended as guidelines for evaluating instrument calibration. Acceptable ranges should be established by each laboratory. If the calibrator recovered data is outside the range found on the assay sheet with stable control results, interlaboratory QC and/or Proficiency Testing reports that have excellent peer group agreement, this may indicate possible product damage. **Do not use the product if deterioration is suspected.**

C. Adjust instrument calibration and verify results:

1. Calibrate the instrument by using the calibration adjustment procedures described in the User Manual for your instrument.
2. Verify calibration by analyzing calibrator and repeat step 3 under “Analyze Calibrator”.
3. Confirm calibration by running quality control material.

EXPECTED RESULTS

Verify that the lot number on the tube/vial matches the lot number on the table of assay values. Assay values are determined on well-maintained, properly calibrated instruments using the instrument manufacturer’s recommended reagents.

REFERENCE METHODS

1. **WBC:** A series of 1:500 dilutions are made with calibrated glassware. Counting is performed on a Coulter Counter Z series instrument. All counts are corrected for coincidence.
2. **RBC:** A series of 1:50,000 dilutions are made with calibrated glassware. Counting is performed on a Coulter Counter Z series instrument. All counts are corrected for coincidence.
3. **HGB:** Hemoglobin value is determined by spectrophotometric procedure according to CLSI Standard H15-A3 and is traceable to ICSH/WHO International Haemiglobincyanide Standard.
4. **HCT:** Packed cell volume (PCV) is measured by the microhematocrit procedure according to CLSI Standard H7-A3. No correction is made for trapped plasma.
5. **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.

LIMITATIONS

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

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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

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REF	Description	Packaging
1504517	Boule Cal-5Diff A1	1 x 3 mL

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