

INTENDED PURPOSE

Boule Cal-5Diff G2 is intended for in vitro diagnostic use for calibration of RBC, MCV, PLT, MPV, WBC, HGB, RDW cv on the Quintus5-part analyzer.

IVD

SUMMARY AND PRINCIPLES

Multi-parameter hematology analyzers require regular calibration in order to produce accurate results on patient samples. Calibration can be accomplished by transferring information to the analyzer through fresh blood samples, which have been assayed by reference methods. A more direct and convenient approach is to use a calibrator material with System Specific Values (SSV) assigned such as Boule Cal-5Diff G2.

Boule Cal-5Diff G2 is a stable suspension of red blood cells, white blood cells and platelets. Assigned values are derived from replicate analyses on whole blood calibrated hematology analyzers (see reference procedures). A user analyzes Boule Cal-5Diff G2 on their instrument and computes calibration factors by comparing recovered values and assigned values. These factors provide the basis for making adjustments to the instrument.

REAGENTS

Boule Cal-5Diff G2 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 Cal-5Diff G2 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 is 5 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.

INDICATION 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 calibrator product package insert and the operating procedure of the instrument.
2. Check the expiration date of the Boule Cal-5Diff G2. Discard outdated products.
3. Test an additional unopened vial of Boule Cal-5Diff G2.

INSTRUCTIONS FOR USE

1. Remove Boule Cal-5Diff G2 Calibrator 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 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. Refer to the User's manual for calibration procedure.
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 use.
6. For further assistance, please contact your local distributor.

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.



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.

REFERENCE PROCEDURES

WBC- A series of 1:500 dilutions are made using class A glassware. The lytic reagent is placed in the initial dilution flask before diluting to volume. The diluting agent is an isotonic solution for Beckman Coulter® instruments. The samples are counted on a Beckman Coulter Counter Z instrument.

RBC- A series of 1:50,000 dilutions are made using class A glassware. The diluting agent is an isotonic solution for Beckman Coulter® series instruments. The samples are counted on a Beckman Coulter Counter Z instrument.

Hgb- Hemoglobin concentration is determined by converting hemoglobin to hemiglobincyanide (HiCN) and measuring absorbance at 540 nm according to CLSI H15-A3 and ICSH recommendations. Hemoglobin concentration is calculated using millimolar absorption coefficient of 11.0.

HCT- Microhematocrit values are done in replicate on each sample, with capillary tubes filled and centrifuged according to the CLSI H7-A3 document. K3EDTA is used as the anticoagulant for collection of fresh specimens. The packed cell volume, or hematocrit, is read directly using a precision metric scale. No correction is made for trapped plasma.

Pit- A series of 1:125 macrodilutions are prepared using class A glassware in 1% Ammonium Oxalate. Charged hemacytometers are allowed to stand 20-30 minutes. Cells are counted using phase-contrast microscopy technique.

MPV- Based on a method using latex particles.

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

For translation of this instruction and explanation to symbols visit www.boule.com.

Ordering no:	Description	Packaging
1504375	Boule Cal-5Diff G2	1 x 3 mL
1504376	Boule Con-5Diff G2Tri	6 x 3 mL
1504382	Boule Con-5Diff G2 Low	1 x 3 mL



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www.boule.com



1504397

Instruction for Use Boule Cal-5Diff G2



1504379	Boule Con-5Diff G2 Low	6 x 3 mL
1504381	Boule Con-5Diff G2 Norm	1 x 3 mL
1504378	Boule Con-5Diff G2 Norm	6 x 3 mL
1504380	Boule Con-5Diff G2 High	1 x 3 mL
1504377	Boule Con-5Diff G2 High	6 x 3 mL



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