Boule Con-5Diff G2

CONTROL

INTENDED USE

For *in vitro* diagnostic use as a control to monitor the performance of multi-parameter hematology instruments.

IVD

SUMMARY AND PRINCIPLES

Boule Con-5Diff G2 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 Con-5Diff G2 contains treated, stabilized human erythro- cytes and a stabilized platelet-sized component in an isotonic, bacteriostatic medium. Fixed erythrocytes are added to simulate leukocytes.

STORAGE AND STABILITY

Boule Con-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 14 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.

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 Con-5Diff G2. Discard outdated products.
3. Test an additional unopened vial of Boule Con-5Diff G2.

INSTRUCTIONS FOR USE

1. Remove Boule Con-5Diff G2 from refrigeration and allow to warm at ambient temperature (18-32°C) for 10-15 minutes before mixing.
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. 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. Follow instruction in User's Manual for each sampling mode.
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 testing.
6. 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 6a above may indicate instrument and/or control problems. To identify the source of the problem see investigational procedure section.
7. For consistency and best precision data, use the three levels of the cell control in the following order: abnormal low, normal, and abnormal high.
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.

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 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.

Controls are not to be used as calibrators.

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 your last instrument calibration.

ORDERING INFORMATION AND SERVICE

Contact your local distributor for orders and support. The US customer service telephone number is: 800.453.3328 Fax: 954.791-7118, www.cdsolinc.com.

For translation of this instruction and explanation to symbols see www.quintus5part.com/ support/downloads

Ordering no:	Description	Packaging
502-115	Boule Con-5Diff G2, Trilevel	6 x 3.0 mL

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