

### INTENDED PURPOSE

Boule Con-5Diff A1 is intended for monitoring the performance of WBC, NEU#, LYM#, MON#, EO#, BAS#, NEU, LYM, MON, EO, BAS, RBC, Hgb, Hct, MCV, MCH, MCHC, RDWcv, Plt, MPV on the Medonic M51 and Swelab Lumi hematology analyzer.

IVD

### SUMMARY AND PRINCIPLE

It is an established laboratory practice to use a stable control to monitor the performance of diagnostic tests. This control is composed of stable materials that provide a means of monitoring the performance of hematology blood cell counters. It is sampled in the same manner as a patient specimen.

### REAGENTS

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



### PRECAUTION

Boule Con-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](http://www.boule.com).

Hazard Code	Explanation
EUH 210	Safety Data Sheet available on request.



### STABILITY AND STORAGE

Store Boule Con-5Diff A1 upright at 2° - 8° C (35° - 46° F) when not in use. **Protect tubes from overheating and freezing.** Unopened tubes are stable through the expiration date. Opened tubes are stable for 14 days, provided they are handled properly.

### INDICATIONS OF DETERIORATION

After mixing, 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.**



### INSTRUCTIONS FOR USE

1. Remove tubes from the refrigerator and allow to warm to room temperature (15 to 30°C or 59 - 86°F) for 15 minutes before mixing.

2. To mix, hold a tube horizontally between the palms of the hands. **Do not pre-mix on a mechanical mixer.**
  - a) Roll the tube back and forth for 20 - 30 seconds; occasionally invert the tube. Mix vigorously, but do not shake.
  - b) Continue to mix in this manner until the red cells are completely suspended. Tubes stored for a long time may require extra mixing.
  - c) Gently invert the tube 8 - 10 times immediately before sampling.
3. Analyze the sample as instructed in the Quality Control section of the User Manual for your instrument.  
After sampling:
  - a) If tube has been opened for sampling, clean residual material from the cap and tube rim with a lint-free tissue. Replace the cap tightly.
  - b) Return tubes to refrigerator within 30 minutes of use.

### 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 instruments using the instrument manufacturer's recommended reagents. Reagent differences, maintenance, operating technique, and calibration may contribute to inter-laboratory variation.

### PERFORMANCE CHARACTERISTICS

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

Assay values on a new lot of control should be confirmed before the new lot is put into routine use. Test the new lot when the instrument is in good working order and quality control results on the old lot are acceptable. The laboratory's recovered mean should be within the assay range.

For greater control sensitivity each laboratory should establish its own mean and acceptable range and periodically reevaluate the mean. The laboratory range may include values outside of the assay range. The user may establish assay values not listed on the Assay Sheet, if the control is suitable for the method.

### 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 prior to use invalidates both the sample withdrawn and any remaining material in the tube.

### 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](http://www.boule.com)

Swelab and Medonic are trademarks of Boule Medical AB.



	Description	Packaging
1504518	Boule Con-5Diff A1Tri	3 x 2 x 3 mL
1504521	Boule Con-5Diff A1 Low	1 x 3 mL
1504520	Boule Con-5Diff A1 Norm	1 x 3 mL
1504519	Boule Con-5Diff A1 Norm	6 x 3 mL
1504522	Boule Con-5Diff A1 High	1 x 3 mL

