

Boule Cal and Boule Con

One of the most important elements of a complete hematology system is the quality control (QC) material. Our Calibrator and Control products are provided as part of the Boule Total Quality Concept to ensure performance of our hematology analyzers.



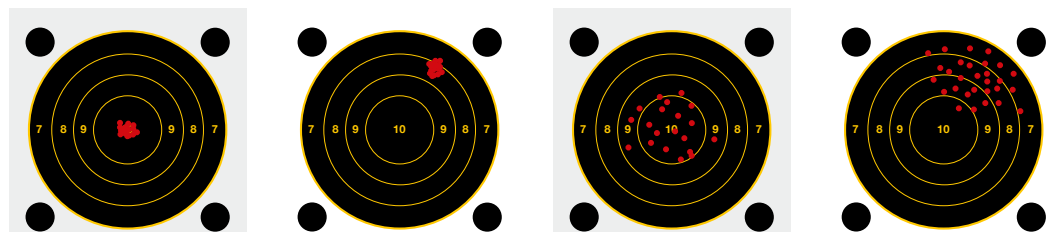
Barcode screening facilitates input of assay values, while preventing potential errors.

Use of Boule Cal:

- When a hematology analyzer is first installed in an end-user laboratory.
- After major preventive maintenance or replacement of critical parts.
- After yearly service.
- After major instrument repair.
- When results from control materials indicate an unusual trend or shift of analyzer performance (e.g., baseline drift).

Use of Boule Con:

- Every day as a routine QC procedure (frequency should reflect workload).
- At the start and end of a day's work.
- When the analyzer is restarted after a complete shut-down.
- When changing reagents between lots or within the same manufacturing lot.
- When an unexpected abnormal patient result is reported.

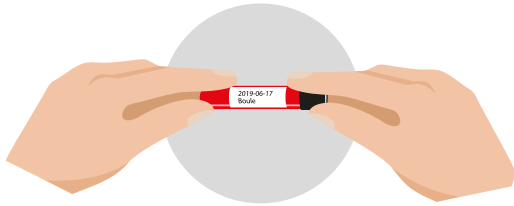


Accuracy	Yes	No	Yes	No
Precision	Yes	Yes	No	No

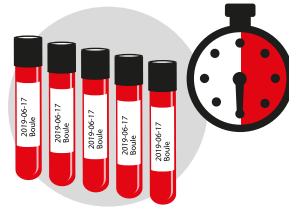
A calibrator is used to measure and adjust systematic error to ensure the instrument is working accurately, while a control is used to address random error and indicate whether the instrument works precisely.

Handling instructions for Boule calibrator and control products

- 1** Remove vial from refrigeration and check the expiration date of the vial. Discard outdated products.



- 2** Allow to warm to room temperature for 30 minutes before mixing.



- 3** Mix by hand as follows:
- Roll the tube or vial slowly between the palms of the hands 15–20 seconds in an upright position.
 - Invert the tube and slowly roll it back and forth for another 15–20 seconds.
 - Continue to mix in this manner until all cells are completely suspended. Tubes stored for a long time might require extra mixing.



- 4** Gently invert the tube 8 times immediately before sampling.



- 5** Analyze the control as directed in the User manual of the analyzer.

- 6** After analysis, carefully wipe the rim of the tube and inside of the cap with a lint-free tissue. Replace the cap and ensure it is tightly on.

- 7** Return the tubes to the refrigerator within 30 minutes of use.



- 8** Compare obtained values with expected results from the assay sheet.
- 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.

For more information, please see Boule Cal and Boule Con Instruction for use.