

Handling instructions for Boule Quality Control (QC) products (Boule CON-Diff)

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 Discard outdated products. 	2 Allow to warm to room temperature for 30 minutes before mixing. 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: a. Roll the tube or vial slowly between the palms of the hands 15–20 seconds in an upright position. b. Invert the tube and slowly roll it back and forth for another 15–20 seconds. c. 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. <i>* See footnote</i>	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.	

* Step 6 does not apply if only analyzing the control in the Cap Pierce Mode of operation (if applicable)

For more information, please see the Boule Con-Diff Instruction for Use (IFU) (p/n 201043)

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