



BD FACSCount™ Control Kit

For setting up the BD FACSCount instrument and for checking linearity

25 Runs—Catalog No. 340166

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1. INTENDED USE

The BD FACSCount™ control kit is intended for in vitro diagnostic use in setting up the BD FACSCount™ instrument and for checking linearity.

2. PRINCIPLES OF THE PROCEDURE

Four bead concentrations (Zero, Low, Medium, and High) are added to normal blood stained with BD FACSCount™ reagents and used daily when the instrument is first turned on, and whenever a new lot of reagent is opened. Data for the last control run is stored on the BD FACSCount instrument protocol diskette.

3. REAGENTS

Reagent Provided, Sufficient for 25 Runs

The BD FACSCount control kit includes four bead concentrations (Zero, Low, Medium, and High), contained in two tube pairs with color-coded tops.

- Pair one:
Zero (yellow top): 0 beads/μL
Low (red top): ~50 beads/μL
- Pair two:
Medium (blue top): ~250 beads/μL
High (purple top): ~1,000 beads/μL

Concentration values are listed in the following table:

BD FACSCount Control	Concentration (beads/mL)
Low bead	2.0×10^7 to 3.0×10^7
Medium bead	2.0×10^7 to 3.0×10^7
High bead	2.0×10^7 to 3.0×10^7

Reagents or Materials Required But Not Provided

- BD Vacutainer® EDTA blood collection tubes or equivalent
- Disposable pipet tips
- Vortex mixer
- BD FACSCount™ system

4. PROCEDURE

Use this procedure to prepare and run controls for the following kits:

Kit (assay)	Catalog No.
BD FACSCount™ Reagent Kit (CD4/CD8/CD3)	340167
BD FACSCount™ CD4 Reagents (CD4)	339010

Preparing Controls

WARNING All biological specimens and materials coming in contact with them are considered biohazards. Handle as if capable of transmitting infection^{1,2} and dispose of with proper precautions in accordance with federal, state, and local regulations. Never pipette by mouth. Wear suitable protective clothing, eyewear, and gloves.

WARNING Patient blood samples must be collected in BD Vacutainer EDTA blood collection tubes (or equivalent), and stored no longer than 48 hours at room temperature (20°C–25°C). Results obtained from samples that do not meet these criteria can be inaccurate.

1. Stain a whole blood sample from a normal donor following the instructions in the reagent instructions for use (IFU).

NOTE Stained samples can be stored for up to 24 hours before adding control beads.

2. Remove one pair of Zero/Low control beads and one pair of Medium/High control beads from the control kit and place them in the control area of the workstation.
 3. Uncap the stained sample tubes and discard the caps in an appropriate biohazard container.
 4. Set the vortex mixer to a midrange speed and vortex the Zero/Low control bead pair upside down for 5 seconds, then upright for 5 seconds.
 5. If you are running the CD4/CD8/CD3 assay, open the Zero control beads (yellow top) with the coring station and pipette 50 µL into the sample tube labeled *Zero*.
- NOTE** The Zero control is not necessary for the CD4 assay.
6. Open the Low control beads (red top) with the coring station and pipette 50 µL into the sample tube labeled *Low*.
 7. Vortex the Medium/High control bead pair upside down for 5 seconds, then upright for 5 seconds.
 8. Open the Medium control beads (blue top) with the coring station and pipette 50 µL into the sample tube labeled *Medium*.
 9. Open the High control beads (purple top) with the coring station and pipette 50 µL into the sample tube labeled *High*.
 10. Cap the sample tubes with new caps.
 11. Cap the two tube pairs of the BD FACSCount control beads and

store upright. For subsequent uses of the control beads, vortex upright for 5 seconds.

Verifying Control Tubes

- For the CD4/CD8/CD3 assay, you should have two sample tube pairs containing the control beads listed in the following table.

Pair	Reagent	Control
1	CD4 tube	Zero
	CD8 tube	Low
2	CD4 tube	Medium
	CD8 tube	High

- For the CD4 assay, you should have three sample tubes containing the control beads listed in the following table.

Tube	Control
1	Low
2	Medium
3	High

Run the tubes on the BD FACSCount instrument within 2 hours of adding control beads to the reagent tubes.

Store samples at room temperature in the workstation until they are run on the instrument. Vortex upright for 5 seconds immediately before running.

Running Controls

BD FACSCount reagents and control beads are each assigned specific lot codes and specific bead counts. Carefully enter the lot codes and bead counts before running controls or samples. This information is stored and does not need to be changed between runs unless a new lot of controls or a new lot of reagents is used. See the appropriate BD FACSCount

user's guide for instructions on entering lot codes and bead counts.

After you enter the normal control ID, the instrument prompts you for the first pair of controls.

WARNING Be sure you have added control beads to the reagent tubes (Preparing Controls on page 2).

- Vortex the *Zero/Low* tube pair upright for 5 seconds.
- If you are running the CD4/CD8/CD3 assay, uncap the *Zero* tube and set the cap aside.

If you are running the CD4 assay, skip to step 6.

- Place the *Zero* tube in the run position of the sample holder.
- Press RUN.
The software displays the event rate (events/second) and total events.
- When analysis is complete, remove the *Zero* tube and recap it.
- Uncap the *Low* tube and set the cap aside.
- Place the *Low* tube in the run position.
- Press RUN.
- When analysis is complete, remove the *Low* tube and recap it.
- Repeat steps 1 through 9 for the rest of the controls.

At the end of the control run, the results are displayed and printed. Discard the reagent pairs in an appropriate biohazard container.

WARRANTY

Unless otherwise indicated in any applicable BD general conditions of sale for non-US customers, the following warranty applies to the purchase of these products.

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TROUBLESHOOTING

See the appropriate BD FACSCount user's guide for troubleshooting information.

REFERENCES

1. *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline—Third Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2005. CLSI document M29-A3.
2. Centers for Disease Control. Perspectives in disease prevention and health promotion update: universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens in health-care settings. *MMWR*. 1988;37:377-388.