



BD FACSCount System

Technical Specifications

The BD FACSCount™ system is a complete, dedicated system for measuring CD4 absolute counts and percentages or CD4, CD8, and CD3 T-cell counts. For persons infected with HIV, serial measurements of absolute CD4 counts or CD4 percentages are used as an indicator for initiation of antiretroviral therapy, determination of response to therapy, and disease progression. The compact, self-contained system incorporates the instrument, reagents, and controls. It eliminates the need for hematology results to obtain absolute count values, reduces variability, and simplifies sample preparation. The BD FACSCount system uses whole blood, eliminating lyse and wash steps. A unique software algorithm automatically identifies the lymphocyte populations of interest. Easy to use, cost effective, and reliable in the clinical laboratory, the BD FACSCount system is designed to use the power and advantages of flow cytometry.

System Performance

Sample stability

48 hours after preparation when stored at room temperature (20° to 25°C, 68° to 77°F)

Whole blood stability

BD FACSCount Reagents and BD FACSCount CD4/CD3 Reagents*
48 hours after draw when stored at room temperature (20° to 25°C, 68° to 77°F)

BD FACSCount CD4 Reagents
24 hours after draw when stored at room temperature (20° to 25°C, 68° to 77°F)

User reportable range

The following ranges meet BD performance characteristics.

BD FACSCount Reagents and BD FACSCount CD4/CD3 Reagents*

CD4⁺: 50 to 2,000 cells/μL

CD8⁺: 100 to 2,000 cells/μL

CD3⁺: 100 to 3,500 cells/μL

BD FACSCount CD4 Reagents

CD4⁺: 50 to 5,000 cells/μL
5% to 65%

Precision

<10% CV

BD FACSCount Instrument

Laser

Convection-cooled laser

Sample flow rate

60 μL/min ±10%

Power

120 VAC ±10% 60 Hz ±5%

100 VAC ±10% 60 Hz ±5%

220/240 VAC ±10% 50 Hz ±5%

160 W (maximum rated power)

Dimensions

Width: 43.2 cm (17 in.)

Height: 38.1 cm (15 in.)

Depth: 55.9 cm (22 in.)

Weight

25.9 kg (57.1 lb), fluid reservoirs empty

Heat dissipation

<146.5 (<500 BTU/h)

Fluid reservoir capacity

2 L

Fuses

2.5 A (T), 250 VAC (IEC127), SEMKO approved 5 x 20-mm fuse

Regulatory status

For In Vitro Diagnostic Use in the United States⁵

Instrument Accessories

Barcode reader

The optional barcode reader reads the following barcode standards:

- Code 39
- Code-a-bar
- Interleaved 2 of 5
- Universal Product Code (UPC)
- European Article Numbering (EAN)

Workstation

Provides a place to hold supplies while preparing and running samples

Dimensions:

Width: 48.3 cm (19 in.)

Height: 9.1 cm (3.6 in.)

Depth: 18.5 cm (7.3 in.)

Electronic pipette

Preprogrammed to accurately deliver 50 μL of fluid

Coring station

Used to open reagent and control tubes

BD FACSCount CD4 Reagents

Single tube contains everything required for absolute CD4 counts and CD4 percentages (1 reagent tube per test, 50 tests per kit)

Packaging

Premeasured in sealed tubes, ready for the operator to add whole blood

Fluorochromes

CD4 PE, CD14 PE-CyTM5, CD15 PE-Cy5

Contents

Reference beads and fluorochrome-conjugated monoclonal antibody reagents, and fluorescent nuclear dye in 0.4 mL buffered solution with stabilizer and 0.1% sodium azide

Fixative solution

5% formaldehyde in phosphate buffered saline (PBS), sufficient volume for 50 tests

Shelf life

Reagents are shipped to customers with an expiration date of 5 months or longer

Storage

2° to 8°C (36° to 46°F)

Regulatory status

For In Vitro Diagnostic Use in the United States and European Union[§]

BD FACSCount CD4/CD3 Reagents*

Single-tube CD4/CD3 reagent for enumeration of CD4 and CD3 T cells (1 reagent tube per test, 50 tests per kit)

Packaging

Premeasured in sealed tubes, ready for the operator to add whole blood

Fluorochromes

CD4 PE, CD3 PE-Cy5

Contents

Reference beads and fluorochrome-conjugated monoclonal antibody reagents in 0.4 mL buffered solution with stabilizer and 0.1% sodium azide

Fixative solution

5% formaldehyde in phosphate buffered saline (PBS), sufficient volume for 50 tests

Shelf life

Reagents are shipped to customers with an expiration date of 5 months or longer

Storage

2° to 8°C (36° to 46°F)

Regulatory status

For Export Only, not for sale or distribution in the United States^{§*}

BD FACSCount Reagents

Paired tubes of CD4/CD3 and CD8/CD3 reagents for enumeration of CD4, CD3, and CD8 T cells (2 reagent tubes per test, 50 tests per kit)

Packaging

Premeasured in sealed tubes, ready for the operator to add whole blood

Fluorochromes

CD4 PE, CD8 PE, CD3 PE-Cy5

Contents

Reference beads and fluorochrome-conjugated monoclonal antibody reagents in 0.4 mL buffered solution with stabilizer and 0.1% sodium azide

Fixative solution

5% formaldehyde in phosphate buffered saline (PBS), sufficient volume for 50 tests

Shelf life

Reagents are shipped to customers with an expiration date of 5 months or longer

Storage

2° to 8°C (36° to 46°F)

Regulatory status

For In Vitro Diagnostic Use in the United States and European Union[§]

BD FACSCount Controls

For performing system quality control to verify linearity and accuracy of the system, pipetting technique, and precision of cell counts between control tubes

Contents

Four bead controls (Zero, Low, Medium, High) provided at 25 control runs per kit. Beads are in 0.5 mL of buffered solution with stabilizer and 0.1% sodium azide.

Shelf life

Controls are shipped to customers with an expiration date of 6 months or longer

Storage

2° to 8°C (36° to 46°F)

Regulatory status

For In Vitro Diagnostic Use in the United States and European Union[§]

Class I (1) laser product.

For In Vitro Diagnostic Use.

§ For the product regulatory status in other countries, contact your local BD representative.

* BD FACSCount CD4/CD3 reagents are neither cleared for In Vitro Diagnostic Use in the US nor CE marked under the IVD directive and are for export only and not for sale or distribution in a number of jurisdictions, including the US, Canada, Japan, and European Union member states.

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