

# BD FACSCount™ System



Helping all people  
live healthy lives

An easy-to-use and complete system  
for cost-effective monitoring of HIV/AIDS



# A Robust and Trusted System for Determining Absolute Cell Counts and CD4 Percentages

The BD FACSCount™ system is a proven, turnkey system designed to provide absolute and percentage results of CD4 T lymphocytes to stage progression of HIV/AIDS, to guide treatment decisions for HIV-infected persons, and to evaluate effectiveness of therapy in a wide range of laboratory settings.

As the system of choice for CD4 monitoring in global HIV/AIDS treatment programs for over a decade, the BD FACSCount system is recognized for its simplicity of operation, robust performance, and reliable results. Today clinicians in programs throughout Africa, Asia, Eastern Europe, and Latin America continue to rely on the system for cost-effective, simple, and dependable CD4 testing.

Recent improvement in the accessibility of drug therapies for HIV/AIDS and the accompanying requirement for effective monitoring of these therapies have kept BD focused on making CD4 testing technology as affordable, appropriate, and accessible as possible.

Since the first BD FACSCount system was delivered in 1994, BD has continued to be committed to technology innovation and investments that help people with immunodeficiency diseases as part of our larger global health initiatives and ongoing mission to help all people live healthy lives.

## Proven Reliability and Ease-of-Use

# Easy to Install, Set Up, and Run with Confidence

To provide users with reliable results independent of user training and lab infrastructure availability, the BD FACSCount system is designed for simplicity of installation, setup, and operation.

The BD FACSCount system includes the BD FACSCount instrument, software, a workstation, reagents, and controls. The instrument is easy to install, operates from a standard electrical outlet, and requires no hardware adjustments or calibration. Only minimal training is needed to set up the instrument and to run samples.

Simple prompts on the display guide operators through testing, from input of patient information to final results. Results are objective, requiring no interpretation or subjective analysis by the operators.

**Simple Three-Step Sample Preparation**

Sample preparation follows an easy three-step process. First, blood is added to a tube that contains premeasured reagents. Then the sample is vortexed and incubated. In the second step, a fixative is added to the tube, which is then vortexed and incubated. In step three, the sample is vortexed and run on the instrument.

**Simplified Sample Handling**

Sample preparation is an easy three-step process:



**Step 1:** Add 50  $\mu$ L of blood to the reagent tube (containing pre-measured reagents), vortex, and incubate.

# WORKFLOW



**Step 2:** Add 50  $\mu\text{L}$  of fixative solution to the sample tube, vortex, and incubate.



**Step 3:** Vortex and run on the BD FACSCount system.

## Absolute Counts and Percentages

# BD FACSCount CD4 Reagents

The BD FACSCount system precisely measures absolute numbers and percentage results of CD4-positive T lymphocytes, the cellular parameter most closely associated with HIV/AIDS disease progression and therapy decisions. The system also measures absolute numbers of CD3 and CD8 T lymphocytes. The system provides reproducible and accurate results even with low CD4 counts.

BD FACSCount reagents are provided as complete kits that streamline CD4 counting. These kits contain ready-to-use tubes with premeasured antibodies and beads for absolute counting, and fixative solution.

Three reliable assay kits are available to meet specific needs for CD4 counting. All BD FACSCount kits can be used with unlysed whole blood, which simplifies sample preparation and allows streamlining of the workflow.

### BD FACSCount CD4 Reagent Kit

The BD FACSCount CD4 reagent kit enables the simultaneous enumeration of absolute counts and determination of CD4 percentages in unlysed whole blood. It is an essential tool in pediatric CD4 testing.\*

### BD FACSCount CD4/CD3 Reagent Kit

The BD FACSCount CD4/CD3 reagent kit allow the uncoupling of CD4 and CD3 enumerations from CD8. The single-tube format reduces cost and sample processing time, allowing limited resources to go further in the HIV/AIDS treatment program.

### BD FACSCount Reagent Kit

The BD FACSCount Reagent kit is provided in a 2-tube format—one tube containing CD4 and CD3 antibodies and a second tube containing CD8 and CD3 antibodies—this assay delivers absolute CD4, CD3, and CD8 counts, and a CD4/8 ratio.

\* Pattanapanyasat K, Sukapirom K, Kowawisatsut L, Thepthai C. New BD FACSCount™ CD4 reagent system for simultaneous enumeration of percent and absolute CD4 T-lymphocytes in HIV-1-infected pediatric patients. *Clin Cytom.* 2008;74 Suppl 1:S98-S106.

## BD FACSCount CD4 Reagents



BD FACSCount CD4 Reagent  
(Cat. No. 339010)

This reagent delivers absolute CD4 counts and CD4 percentages.



BD FACSCount CD4/CD3 Reagent Kit  
(Cat. No. 342512)

This reagent delivers absolute CD4 counts.



# CONSISTENT RESULTS



## **BD Good Laboratory Practices Workshops**

The BD commitment to help prevent, diagnose, and treat HIV/AIDS goes beyond the application of technology. BD actively collaborates across public and private sectors with national governments, non-governmental organizations, industry, faith-based organizations, public officials, and healthcare providers to create effective and sustainable programs to build healthcare capacity.

BD Good Laboratory Practices Workshops provide hands-on training to laboratory workers, focusing on the

implementation of Standard Operating Procedures (SOPs) for immune system monitoring of HIV/AIDS patients (CD4 testing). The workshops also include training of fundamental laboratory practices such as quality control and blood sampling.

Thousands of healthcare workers in more than 50 developing countries have participated in the BD workshops, resulting in a significant improvement of clinical and laboratory services.



**BD FACSCount Reagent Kit**  
(Cat. No. 340167)

This reagent delivers absolute CD4, CD3, and CD8 counts, and a CD4/8 ratio.

Easy-to-Use, Turnkey

# A System of Choice for Quality

The BD FACSCount system has been an integral part of CD4 monitoring in global HIV/AIDS treatment programs for over a decade. On a worldwide level, the system's proven accuracy and quality have made it the preferred system for patient management.

## System Performance, Linearity, and Accuracy

BD FACSCount control kits consist of paired control bead sets, containing beads at four levels: zero, low, medium, and high. BD FACSCount control beads can be added to samples prepared with normal blood to validate laboratory practices and methodology and system linearity. The control run generates a printed report summarizing system performance. The result of the last control run is reported on each subsequent sample printout, to provide confidence in the result.

## BD FACSCount Software

BD FACSCount software enables automated analysis without any operator intervention. The automatic identification of the beads and of the lymphocyte populations of interest, and calculation of the absolute counts (cells/ $\mu$ L) and percentages, allow a time- and cost-effective workflow and minimizes potential errors.

Patients' results are summarized on a printed sample report that does not require interpretation or subjective analysis. Quality controls in the software ensure that reported results are accurate by detecting and flagging error conditions and suppressing results when control limits are exceeded.

## BD FACSCount %CD4 Run Report

BD Biosciences, Immunocytometry Systems  
BD FACSCount CD4 Software Version 1.0 01/08

### Sample Run Results

Lab ID : 50012121  
Operator: JH

Reagent Lot ID: 00002121  
Reference Bead Count: 1006 beads/ $\mu$ L

Date: 04/27/07 15:06

Last Control Run: Passed  
Control Run Date: 01/15/08 10:13  
Control Run Reagent Lot ID: 50012121  
Control Run Control Lot ID: 59041721

Accession #: 180407

CD4 Count: 2288 (cells/ $\mu$ L)  
CD4%: 46.71 (%)

Signature: \_\_\_\_\_

Comments: \_\_\_\_\_

## BD FACSCount Control Kit (Cat. No. 340166)



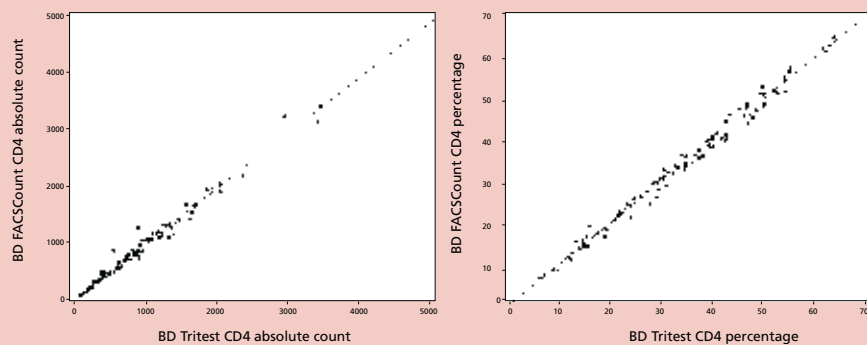




## Accuracy and Precision of BD FACSCount CD4 Reagents

CD4 absolute count and percentage results were compared with results from BD Tritest™ CD3 FITC/CD4 PE/CD45 PerCP with BD Trucount™ tubes on the BD FACSCalibur flow cytometer using BD Multiset™ software.

Parameters	n	R <sup>2</sup>	Slope	Intercept	Range
Absolute CD4 (cells/μL)	101	0.981	0.971	12.695	59 – 3,404
CD4 Percentage	99	0.99	0.999	-0.391	5.51 – 64.69



## Committed to Customer Success

BD Biosciences is fully committed to the success and satisfaction of its customers. The BD FACSCount system is backed by a world-class service and support organization with unmatched flow cytometry experience. Since 1974, BD has been an innovation leader in cell analysis for optimal performance, ease of use, and improved workflow. This expertise is made available to BD customers through comprehensive training, applications and technical support, and expert field service.

BD people are never far away to help support you and your lab. You'll get answers from a single, local point of contact who is never more than two days away. BD has a proven track record of dependability and supply chain excellence that customers have come to rely on for consistent, timely delivery of reagents and supplies.

### **Training**

Hands-on training provides participants with the skills and competency to perform reliable CD4 T lymphocyte enumeration using the BD FACSCount system. In addition, BD is working in developing countries to improve the fundamental capacity to deliver healthcare, including trained healthcare workers and access to clinical and laboratory products and services. With many years of experience both in clinical and in research studies, BD Biosciences scientific experts provide training on the use of BD flow cytometers and related BD applications. Trainings are offered at customer sites or in completely equipped BD Biosciences training centers.

### **Field service and support**

When instrument installation or service is required, BD Biosciences provides a full range of support options from telephone troubleshooting to on-site visits. On-site service and maintenance agreements are available for long-term support.



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### Discovery Labware

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### Immunocytometry Systems

Fax 800.325.9637

### Pharmingen

Fax 800.325.9637

Class I (1) laser product.

For In Vitro Diagnostic Use.

BD FACSCount CD4/CD3 reagents and BD FACSCount CD4/CD3 software are neither cleared for In Vitro Diagnostic Use nor CE marked under the IVD directive and are For Export Only. Not for sale or distribution in a number of jurisdictions, including US, Canada, Japan, and European Union Member States.

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