BD FACSCount CD4 Reagents

Features

Provides absolute CD4 counts and CD4 percentage results

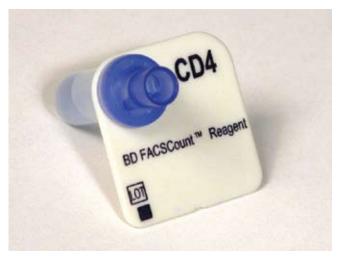
Uses unlysed whole blood

30-minute incubation time

Includes automated data analysis and built-in quality control

Runs on trusted BD FACSCount system

"This new BD FACSCount system is a simple and reliable system for enumeration of absolute and percentage CD4+ T lymphocytes. Having one system giving both results should reduce the cost and thus increase access to CD4 testing . . . " Kovit Pattanapanyasat, PhD.



The ready-to-use BD FACSCount CD4 reagent tube contains everything required for absolute CD4 counts and CD4 percentages.

New CD4 reagents on the proven BD FACSCount™ system provide absolute CD4 counts and percentage results in an easy-to-use, single-tube assay.

The results you need – simply, reliably, and economically The BD FACSCount system is a turnkey, automated instrument and reagent system designed for CD4 counting in a wide range of laboratory environments. Setup and operator training are minimal. The software identifies the lymphocyte populations of interest and calculates absolute CD4 counts (cells/µL) and CD4 percentages automatically, saving time, minimizing human errors, and reducing costs.

More efficient workflow

BD FACSCount CD4 reagents are provided in one ready-to-use reagent tube. The assay uses unlysed whole blood, simplifying sample preparation. Incubation time is 30 minutes, speeding time to results. Fluorescence reference beads, included in the reagent tube, ensure accurate enumeration of lymphocytes of interest with no operator intervention. The software includes built-in quality control and a retrievable results file containing data from the last 100 runs, allowing access to previously run samples and transfer to a third-party computer. These features provide laboratories with a more efficient workflow and greater confidence in results.

A familiar, proven system

The BD FACSCount system has been an integral part of CD4 monitoring in global HIV/AIDS treatment programs for over a decade. Around the world, its simplicity of operation and robust performance in a wide range of laboratory settings make it a system of choice. With this quality of results, clinicians can depend on it for patient management.

Global training and support from BD Biosciences

BD Biosciences offers comprehensive training and service programs, carried out by experienced, knowledgeable BD support and field service teams around the world.

Visit bdbiosciences.com for more information.



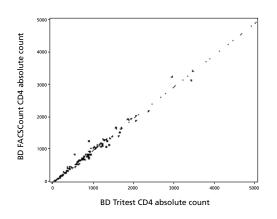
US Orders: **877.232.8995** bdbiosciences.com

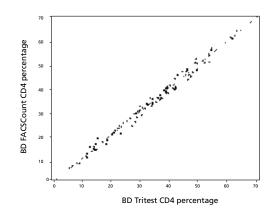
BD FACSCount CD4 Reagents

Accuracy

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 Multitest™ software.

Parameters	n	R ²	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





Regression plot of test versus predicate for CD4 absolute counts

Regression plot of test versus predicate for CD4 percentages

Precision

Precision was estimated using BD™ Multi-check low and normal controls. Two replicates of each control were analyzed in each run, and two runs were performed per day for a total of 21 days.

	CD4 Absol	ute Counts	CD4 Percentages	
	Low Control	Normal Control	Low Control	Normal Control
	% CV		SD	
ithin Device	4.82	4.28	0.38	1.28
ithin Run	4.04	3.46	0.35	1.15

User-Reportable Ranges

Absolute counts: 50 to 5,000 CD4 cells/µL

Percentages: 5% to 65%

Stability

Staining: Within 24 hours of draw Analysis: Within 48 hours of staining

Ordering Information

Class I (1) laser product.

Product description	Quantity	Reg Status	Cat No.
BD FACSCount CD4 Reagents	50 Tests	IVD	339010
BD FACSCount CD4 Software and User's Guide Assembly	4 Disks	_	339011

