



BD FACSPresto™ Near-Patient CD4 Counter

Complete CD4 testing solution for advanced HIV disease



Accurate and easy to use with results in 22 minutes



The BD FACSPresto™ Near-Patient CD4 Counter is a small portable multicolor fluorescent imaging cytometer and absorbance spectrometer that is used for direct quantification and enumeration of CD4 absolute count, CD4 percentage of lymphocytes, and determination of hemoglobin (Hb) concentration in normal and HIV-positive patients.

BD FACSPresto™ Near-Patient CD4 Counter

- Increase your workflow efficiency through ease of use, built in QC controls and higher throughput
- Achieve accurate and precise CD4 results in 22 minutes for advanced HIV patients
- See how the BD FACSPresto™ Near-Patient CD4 Counter can transform your advanced HIV disease patient management
- Meets In Vitro Diagnostic EU Regulations

Easy to use for resource limited settings



Easy to use, small and portable



Onboard videos and timers, language independent



No cold chain required with long shelf life



Built-in battery to ensure operation during power interruptions



Built-in quality controls, no need for additional costly external controls

Affordable



Accessible pricing
Compared to systems currently on the market



No added cost
Instrument placement with reagent rental agreement (minimum 3 years, 1,500 tests per year)



Inclusive of

- In-country training and on-site support
- Swap and repair offerings
- <72 hours guaranteed response

Simple workflow with high precision and accuracy



Choice of finger stick or venipuncture draw



18 minute incubation. Occurs outside device at room temperature



4 minute read

Quick results in 22 min. total time

- Absolute CD4, %CD4, and Hb in a single test
- Detects wide range of CD4 counts (50–4,000 cells/μL)
- Results on screen, in print or exported using USB

- For use on children, adolescents and adults
- Expanded menu: CD4, %CD4, and Hb concentration in whole blood samples
- Includes the instrument, integrated software, sample incubation workstation and single-use disposable cartridges
- Based on fluorescence imaging and absorbance-reading technology, with embedded software that reads patient samples from a single-use disposable cartridge
- The cartridges use dried-down fluorescently labeled antibodies to eliminate cold chain requirements, simplifying storage and reducing cost
- Intuitive, language-independent graphical touchscreen interface
- Onboard videos of key operations that provide a quick guide on start up, testing workflow and management
- Simple, one-time setup
- Incubation outside the device for high throughput
- Built-in quality controls to check system accuracy
- Onboard reagent QC to check performance
- Automatic display of results that are stored in the onboard database. The instrument can store up to 12,000 results in its internal memory
- Results can be printed or exported to a USB flash drive
- 2-hour training provided upon request

Initial setup



Instrument setup

Power-on self-test

- System verifies parameters and attributes
- Displays and prints message to indicate the system has passed all checks, including accuracy results for normal and low counts

Touch screen settings tab

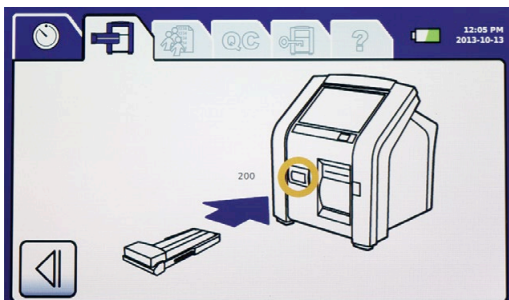
Simplify setup and workflow

- Enter laboratory/operator information and time format
- Set reporting units for hemoglobin (grams per liter or grams per deciliter)
- System uses graphics for ease of use and to minimize language barriers
- On-demand videos are available from the Help tab

Integrated quality checks

Reduce cost

- Quality control feature automatically checks counting accuracy at the beginning of the day after the self-test and on demand
- Eliminates the need for an external instrument quality control cartridge, simplifying and speeding up workflow
- System is technically compatible with commercially available process control and external quality assurance products for independent system performance assessment



Touchscreen interface for ease of use

The touchscreen interface is operated using graphics to allow for easy task execution and to minimize language barriers. On-demand videos for key operations are available from the Help tab to assist with user training.

Blood collection



Ready-to-use cartridges for all tests

- The BD FACSPresto[®] Near-Patient CD4 Counter includes ready-to-use, single-use disposable cartridges that contain dried-down reagents to simultaneously identify and enumerate CD4 T lymphocytes for absolute and percentage results from whole blood samples.
- In addition to performing absolute and percent CD4 tests, the BD FACSPresto[®] Cartridge also measures total hemoglobin concentration on the same sample and delivers all results concurrently.

Flexible workflow, choice of draw

- The system's unique BD FACSPresto[®] Cartridges are designed for use with both finger stick samples and venous whole blood collected in EDTA tubes.



- For finger stick blood collection, the BD FACSPresto[®] Finger Stick Sample Collection Kit comes with a lancet, bandage, alcohol pad and nonwoven sponge.
- The fingertip is punctured with the lancet and the first drop of blood is wiped. The second drop of blood is added into the inlet port of the cartridge.
- The finger is cleaned, the cartridge is capped and a bandage is applied to the finger.



- For blood collected by venipuncture draw, a pipet is provided to collect blood from the tube and to add into the inlet port on the cartridge.
- No manual sample preparation is required for either collection method, saving time.



Blood and reagent mix

- Once the blood is added and the cartridge is capped, the blood picks up the dried reagent and flows along a channel inside the cartridge.
- At the end of the channel, a fill indicator ensures that the blood has properly flowed along the entire channel to its endpoint.

Incubation



- Place the BD FACSPresto[®] Cartridge on the workstation outside the instrument for incubation
- Select the timer on the screen that corresponds to the incubation slot on the workstation
- Onboard timer automatically counts down
- a preset incubation time of 18 minutes

Gain greater flexibility since incubation occurs outside the device at room temperature



- When the incubation is complete, the timer graphic turns green and, if desired, an alarm sounds to indicate that the cartridge is ready to be processed

Convenient onboard incubation timer



Deliver accurate results in 22 minutes



Sample run and results

Tear-strip protects viewing channel to maximize accuracy

- After incubation, the operator removes the tear-strip that protects the viewing channel from dust and dirt, selects the Run Test tab, and enters the patient number that corresponds with the BD FACSPresto Cartridge.
- After a second patient ID verification step, the door opens for the cartridge to be placed into the instrument.

Automated quality control and testing

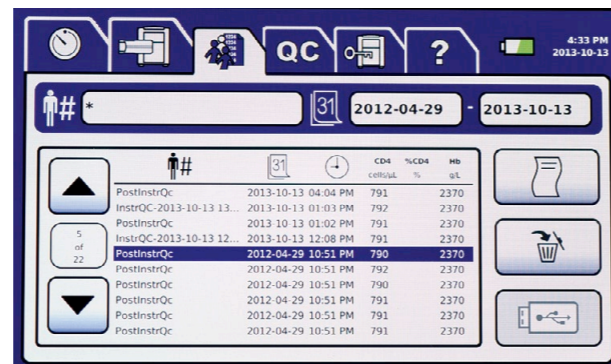
- A sensor inside the instrument detects the cartridge and draws it in and the door closes.
- This automatically starts the reading process.
- The onboard reagent quality control feature verifies that reagent and a sufficient amount of blood are present in the cartridge.

Status bar and notifications track status

- A status bar on the screen communicates testing progress.
- When testing is complete, about 4 minutes later, an audible tone sounds and the door opens to eject the cartridge.
- Since cartridges with samples are incubated outside the instrument, an operator can run up to 60 tests in an 8-hour day.

Results on screen, printed, or exported

- Results are automatically displayed on the screen, printed and stored in the onboard database.
- Test results can later be printed or exported to a USB flash drive located next to the printer.



Accuracy and precision: CD4, %CD4, and Hb

- In field studies, for both finger stick and venipuncture samples, the accuracy of CD4 cell count and %CD4 results with the BD FACSPresto Near-Patient CD4 Counter was consistent with the standard BD FACSCalibur Flow Cytometer/BD Tritest Reagent method.
- A 21-day field study (N = 168) was conducted to assess system precision.
- The study was conducted using commercially available CD4 and Hb controls, and the CLSI EP5 A2 protocol was followed.
- The results showed that %CVs for CD4 counts were below 8%. The %CVs for %CD4 were below 6%, and for Hb were below 4%

Accuracy
The following table shows size, correlation coefficients (R²) and Deming regression slopes.

Sample	BD FACSPresto vs Reference, San Francisco N = 92 (FS), 112 (VP)						BD FACSPresto vs Reference, Kisumu N = 123 (FS), 127 (VP)					
	CD4		%CD4		Hb		CD4		%CD4		Hb	
	R ²	Slope	R ²	Slope	R ²	Slope	R ²	Slope	R ²	Slope	R ²	Slope
VP	0.99	0.97	0.99	1.00	0.95	0.96	0.97	0.97	0.98	1.00	0.94	0.96
FS	0.97	1.04	0.98	0.97			0.94	1.05	0.95	0.97		

Training and services



Onboard videos guide use

- To help technicians come up to speed quickly, or to refresh technicians on proper procedures, the system has onboard videos that illustrate all workflow steps.

Workshops train laboratory personnel

- BD Good Start workshops feature instructor-led training followed by practical hands-on use of BD instruments and products.
- In addition, BD Good Start workshops are recommended to train laboratory personnel to reliably use diagnostic and monitoring tools following standard operating guidelines.
- Workshops seek to improve healthcare capacity and laboratory procedures in the countries they serve.
- In addition to on-site training, train-the-trainer workshops aim to promote sustainability of healthcare capacity by teaching training skills alongside technical content.

Empowering sustainable improvements in healthcare systems

- Through training and lab-strengthening programs, BD associates are able to transfer their knowledge and expertise to strengthen the healthcare systems of the developing world.



Visit our website for more information on the
BD FACSPresto™ Near-Patient CD4 Counter

Ordering information

Product Description	Catalog Number
BD FACSPresto™ Near-Patient CD4 Counter	651000
BD FACSPresto™ Cartridge Kit (100 tests): includes 100 cartridges (Cat. No. 657681) and the BD FACSPresto™ Finger Stick Sample Collection Kit (Cat. No. 657682) (100 lancets, alcohol pads, nonwoven sponges and plastic bandages)	655495
D FACSPresto™ Cartridges (100 test): includes 100 cartridges and 100 BD® Disposable 100-µL Pipets	657681

Accessories

BD FACSPresto™ Near-Patient CD4 Counter is shipped with the following accessories:

Workstation used for placement of BD FACSPresto™ Cartridges during
sample incubation

Instrument cover to protect the instrument from dust when not in use

Power supply for the instrument

Adapter cords for different regional needs

USB flash drive

Thermal printer paper

For In Vitro Diagnostic Use.

For E.U. under IVDD and IVDR, the BD FACSPresto™ Near-Patient CD4 Counter
and BD FACSPresto™ Cartridges are for In Vitro Diagnostic Use.

The BD FACSPresto™ Cartridge is an in vitro diagnostic device bearing a CE marking
and is CE certified by BSI Group the Netherlands B.V. (Notified Body Number : 2797).

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