BD FACSPresto™ System

An accurate, fast and easy-to-use CD4 testing solution

BD

A solution as unique as you

The BD FACSPresto™ System includes the instrument, integrated software, sample incubation workstation and single-use disposable cartridges. The system is designed to provide absolute and percentage results of CD4 T lymphocytes and total hemoglobin (Hb) concentration in whole blood samples.

The system's unique BD FACSPresto™ cartridges are designed for use with both fingerstick samples and venous whole blood collected in EDTA tubes. The cartridges use dried-down fluorescently labeled antibodies to eliminate cold chain requirements, simplifying storage and reducing cost. Integrated software provides automated analysis and calculates results for CD4 absolute counting, %CD4, and total hemoglobin concentration. The software also checks the counting accuracy of the instrument at POST *(power-on self-test)* and reagent performance with each result.

A number of features make the system easy to learn and use. The large touchscreen interface is operated using graphics, making it language-independent. Technicians simply touch the interface tabs and buttons to navigate the menus and execute desired functions. On-board videos demonstrate system operations to assist in training and use.

The BD FACSPresto™ system is small, weighing just under 7 kilograms. It can be operated by a rechargeable battery and is designed to handle extreme environmental conditions, including both temperature and humidity.

The BD FACSPresto™ system is one of the most innovative testing solutions available. Its sophisticated technologies incorporate many checks to ensure quality and consistency of testing, and its user interface and workflow make the instrument very easy to learn, use and maintain. The BD FACSPresto™ system is delivered with BD quality and backed by your BD regional team.

The BD FACSPresto™ system is based on fluorescence imaging and absorbance-reading technology, with embedded software that reads patient samples from a single-use disposable cartridge.

Initial setup

Self-test on power-on

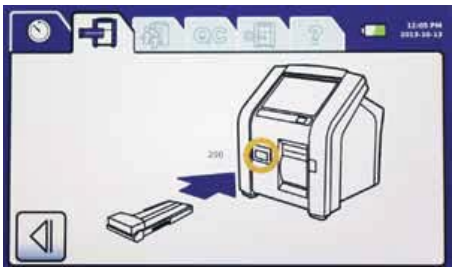
When the BD FACSPresto™ system is first started, the system automatically performs a power-on self-test to verify system parameters and attributes. Once the test is complete, the system displays a message and prints it to indicate that the BD FACSPresto™ has passed all checks, including accuracy results for normal and low counts.

Settings tab for lab and operator information

The system's integrated software and an intuitive touchscreen interface simplify setup and workflow. To set customized laboratory parameters, technicians use the touchscreen interface to select the Settings tab and enter laboratory and operator information, as well as a time format. Technicians can also set reporting units for hemoglobin *(grams per liter or grams per deciliter)* from the Settings tab.

Integrated quality checks reduce cost

After initial setup, the instrument quality control feature automatically checks counting accuracy at the beginning of the day after the self-test, and on demand. This eliminates the need for an external instrument quality control cartridge, simplifying and speeding workflow. In addition, the BD FACSPresto™ 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.

Setup procedure

From the Settings tab, the touchscreen interface guides the operator during setup. Customized lab parameters are entered, such as lab and operator information, time format, and reporting units for hemoglobin.

Blood collection

Ready-to-use cartridges for all tests

The BD FACSPresto™ system 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

Blood is added into the BD FACSPresto™ cartridge by fingerstick or venipuncture draw. For fingerstick blood collection, the BD FACSPresto™ fingerstick 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 add it 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.

Single-use disposable cartridge

Dried-down reagent technology eliminates the need for a cold chain, to simplify storage and reduce costs. The reagents are designed to meet the requirements of resource-limited settings and extreme environmental conditions.

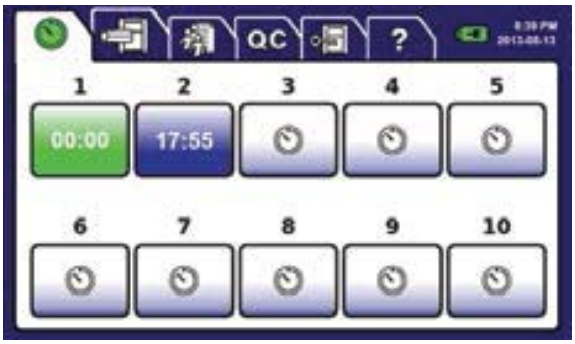
Incubation

Incubation outside the device increases throughput

The operator places the BD FACSPresto™ cartridge on the workstation outside the instrument for incubation. The operator selects the timer on the screen that corresponds to the incubation slot on the workstation. The on-board timer automatically counts down a preset incubation time of 18 minutes. Since incubation occurs outside the device, at room temperature, technicians gain greater flexibility.

Convenient on-board incubation timer

When the incubation is complete, the timer graphic turns green and if desired, an alarm sounds



Accuracy: CD4, %CD4 and Hb

In field studies, for both fingerstick and venipuncture samples, the accuracy of CD4 cell count and %CD4 results with the BD FACSPresto™ system was consistent with the standard BD FACSCalibur™/BD Tritest™ analyzer method.

Accuracy

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

Source: BD FACSPresto(TM) CD4/Hb Cartridge Instructions for Use

Table 1. Method comparison for venous blood

Parameter	N	R^2	Slope	Intercept	Range
CD4	717	0.99	0.97	0.02	5–5,204 cells/µL
%CD4	717	0.98	1.01	0.51	0.63–59.82%
Hb	721	0.91	1.03	–0.06	4.7–21.2 g/dL

Table 2. Method comparison for capillary blood

Parameter	N	R^2	Slope	Intercept	Range
CD4	682	0.97	1.03	0.72	8–5,216 cells/µL
%CD4	682	0.96	1.01	–0.31	0.57–58.5%
Hb	692	0.89	1.02	–0.37	4.7–18.7 g/dL

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 of the BD FACSPresto™ system 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 on-board 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 BD FACSPresto™ system screen, printed, and stored in the on-board database. Test results can later be printed or exported to a USB flash drive located next to the printer. Workflow is efficient.

BD FACSPresto™ System results can be exported to a USB flash drive to upload to a Laboratory Information System.

Precision: CD4, %CD4, and Hb

A whole-blood repeatability study was conducted at one site in the United States, BioCollections Worldwide, Inc., with 68 donors. Each donor was tested on three instruments and three lots in duplicate, resulting in a total of 18 replicates per donor. Three operators were involved in the study, one per instrument. The results of the repeatability study are shown in *Table 3*.

Table 3. Whole-blood repeatability study

	Instrument %CV	Lot %CV	With-in run %CV	Total %CV
CD4 *(cells/µL)*	1.02	0.68	3.49	3.70
%CD4 *(%)*	0.69	0.37	2.69	2.80
Hb *(g/dL)*	4.11	0.85	2.92	5.11

Training and services

Students in a BD Good Start workshop

On-board videos guide use

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

Workshops to train laboratory personnel

Workshops are recommended to train laboratory personnel to reliably use diagnostic and monitoring tools following standard operating guidelines.

Instructor-led, practical, hands-on training

BD customer education workshops feature instructor-led training followed by practical, hands-on use of BD instruments and products, including the BD FACSPresto™ System.

Designed for ease of use

The BD FACSPresto™ system is designed to fit the needs of operations at remote locations with resource-limited settings and smaller health facilities. Self-diagnosis at power-on and sophisticated reagent quality control systems ensure that the system is working within specified parameters. If a problem is encountered, the system reports a problem message number, and example solutions are provided in the Instructions for Use.

No routine maintenance

No preventive or routine maintenance is required for daily operation in the field. However, if a problem is encountered, a local resource can be contacted to arrange for the faulty instrument to be shipped back. A loaner instrument will be shipped out until the faulty instrument is fixed. Once the faulty instrument is fixed, it will be shipped back and the loaner instrument will be returned. If the instrument cannot be fixed, a new replacement instrument will be shipped if the faulty instrument is under warranty.

BD regional support

BD people are never far away to help support you. Our proven track record of dependability and supply chain excellence is one way we have demonstrated our commitment to your success and satisfaction.

For In Vitro Diagnostic Use.

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