BD FACSDuet™ Sample Preparation System

The BD FACSDuet™ Sample Preparation System (BD FACSDuet™ System) is an in vitro diagnostic instrument designed to prepare specimens for acquisition on the BD FACSLyric™ Flow Cytometer. When the BD FACSDuet™ System is physically integrated with the BD FACSLyric™ Flow Cytometer via the BD FACSLyric™ universal loader, it provides automatic sample transfer to the flow cytometer, delivering a complete walkaway sample-to-answer solution.

Bidirectional data integration between BD FACSDuet™ Sample Preparation System, BD FACSLyric™ Flow Cytometer and the Laboratory Information System (LIS) is provided by the BD FACS™ Workflow Manager middleware software, ensuring patient data integrity and security.

The BD FACSDuet™ System, integrated with the BD FACSLyric™ Flow Cytometer, is designed to provide complete traceability of specimens, reagents and samples across the system through extensive use of barcodes. Additionally, an audit trail tracks activity on the system in order to help the laboratories to be compliant with 21 CFR Part 11.

The BD FACSDuet™ Sample Preparation System also provides flexibility:

- Support for a wide variety of blood collection tubes, both in size (eight different adapters) and from multiple manufacturers (BD Vacutainer® Tubes, SARSTEDT, Greiner and Streck) for a total of 20 different specimen tube types
- Compatibility with multiple reagent vial sizes and from a wide range of manufacturers (Beckman Coulter, BioLegend, BD-Cytognos, Dako, Invitrogen and Life Technologies)

The BD FACSDuet™ Sample Preparation System is available as either a BD FACSDuet™ Sample Preparation System (Base) or BD FACSDuet™ Premium Sample Preparation System. The system has been designed as modular and upgradable. The BD FACSDuet™ Sample Preparation System (Base) can be upgraded to the BD FACSDuet™ Premium Sample Preparation System configuration onsite by BD service engineers. The BD FACSDuet™ Premium Sample Preparation System configuration has additional hardware not available on the BD FACSDuet™ Sample Preparation System (Base) model, including centrifuge, wash carousel and a dedicated bulk fluid tanks drawer, to enable also user-defined preparation methods that include wash steps.

The BD FACSDuet™ Premium System comes with pre-defined standard workflow templates for prewash/stain/lyse/wash and fix/perm workflows. Users can either use or adapt these templates or design their own user-defined preparation methods. BD Multitest™ IMK, 4C, and 6C IVD Reagents and process controls for lymphocyte subset enumeration have been validated for both configurations.

Unless otherwise noted, specifications in this document apply to both the BD FACSDuet™ Sample Preparation System (Base) and the BD FACSDuet™ Premium Sample Preparation System. Where differences exist between the systems, both systems will be separately defined.

BD

Technical specifications

Instrument

Dimensions

Height: 83.8 cm (33.0 in.)
Width: 106.2 cm (41.8 in.)
Width with touchscreen extended:
153.7 cm (60.5 in.)
Depth: 74.4 cm (29.3 in.)

Weight

With racks loaded, attached workstation, and ready to use (does not include three 10-L tanks):
BD FACSDuet™ System (Base):
169 kg (372.6 lb.)
BD FACSDuet™ Premium System:
177 kg (390.2 lb.)

Power requirements

100–240 V / 6–2.5 A / 50–60 Hz

Power consumption

Mean: 420 W
Peak: 600 W

Environment

Storage temperature

5–45 °C

Operating temperature

15 °C (59 °F) to 30 °C (86 °F)

Operating relative humidity

20% to 80% (non-condensing)

Operating barometric pressure

≥0.8 atm (approximately 2,000 meters)

Heat dissipation

<500 BTU/hr

Noise level

≤ 64 dBA, under normal operating conditions

Facility requirements

Please refer to the BD FACSDuet™ System Site Preparation Guide for details

BD FACSDuet™ System table

Recommended when BD FACSLyric™ and BD FACSDuet™ Systems are physically integrated
Height: 86.35 cm (33.99 in.)
Length: 200.0 cm (78.74 in.)
Depth: 97.0 cm (38.19 in.)

Reagent and fluid capacities

Reagents

On-board reagents are kept in an insulated and light protected reagent bay that only opens when reagents are being pipetted.
23 reagent vials per rack, two racks loaded at one time.
Reagent adapters are available to accommodate the use of different vials.
BD Horizon™ Brilliant Stain Buffer position.
Two 50-mL bulk reagent positions.

Tank capacities

Saline tank: 10 L
DI water tank: 10 L
Waste tank: 10 L

BD FACSDuet™ System (Base):
One (1) Lyse tank: 1 L

BD FACSDuet™ Premium System:
Five (5) bulk fluidic tanks for lyse, fix and other fluids:
2x250 mL
3x600 mL

10-L tank dimensions:
Height: 38.1 cm (15 in.)
Width: 16.1 cm (6.3 in.)
Depth: 35.6 cm (14 in.)

User-definable ranges

Dispense and fluid volumes

Specimen dispense
5–400 µL (in increments of 1 µL)

Reagents dispense
5–1,000 µL (in increments of 1 µL)

BD Trucount™ Tube Controls
5–50 µL (in increments of 1 µL)

BD FACSDuet™ System (Base):
BD FACS™ Lysing Solution
5–1,000 µL (in increments of 1 µL)

BD FACSDuet™ Premium System:
Bulk fluids tanks via injectors (e.g., wash solution)
2x250-mL tanks (Tanks A and B): 50–450 µL;
2x600-mL tanks (Tanks C, D): 100–4,000 µL;
1x600-mL tanks (Tank E): 50–4,000 µL.

NOTE: Tanks A–D can also be accessed by the reagent probe (5–1,000 µL range)

Reagent multidispense:
Enabled for sets of five dispenses in the following volume ranges:

Volume ranges:
5–6 µL
16–50 µL
301–450 µL

Specimen multidispense
Specimen multidispense can be done with the following volumes and number of repeats:

Sample distribution volume rage	Maximum number of repeats
20 µL	20
21–49 µL	8
50–74 µL	5
75–99 µL	4
100–133 µL	3
134–200 µL	2

Aspirate volume (BD FACSDuet™ Premium System only)
Minimum volume remaining:
150 µL (1 µL increments)

Maximum volume per tube:
4 mL during wash and centrifuge (BD FACSDuet™ Premium System)
2 mL for final transfer to BD FACSLyric™ System

Unreachable volumes
Specimen tubes: 250 µL
5-mL amber vials: 130 µL
BD plastic vials (0.5–4 mL): 50 µL
Lyse (BD FACSDuet™ System Base): 170 mL

Centrifuge:
(BD FACSDuet™ Premium System only)
Speed: 200g–900g
Holds 16 tubes
Automated centrifuge balancing

Incubation times:
0–1,000 minutes (1 minute increments)

Maintenance protocol
Instrument priming, rinsing and cleaning procedures as well as probe alignment are preprogrammed

Performance and settings for IVD assays with BD Multitest™ Assays with BD Trucount™ Tubes

Dispense volumes

Specimen: 50 µL
Reagent: 20 µL
Lyse: 450 µL

Incubation times

Reagent: 15–30 min
Lyse: 15–30 min

Performance

Accuracy and precision (A&P) for specimen

Accuracy: ±3.0% by volume
Precision: CV = 3.0%

Reagent dispense volume: 20 µL

A & P for reagents (in single- and multidispense mode)

Accuracy: ±20.0% by volume
Precision: CV = 10.0%

A&P for lyse (in single- and multidispense mode)

Accuracy: ±5.0% by volume
Precision: CV = 5.0%

System performance for user-definable ranges

NOTE: The reagent probe dispenses from the bulk lyse tank on the BD FACSDuet™ Sample Preparation System (Base). In the BD FACSDuet™ Premium Sample Preparation System, the reagent probe dispenses from bulk tanks A–D in the bulk fluids drawer. The BD FACSDuet™ Premium Sample Preparation System bulk tank accuracy and precision data below refer to the fluidic system that dispenses directly into the wash carousel.

Accuracy

Specimens

- 5–10 µL: +/- 1 µL
- >10–49 µL: +/- 10.0%
- >50–400 µL: +/- 5.0%

Reagent probe

- 5 µL: +/- 20%
- >5–19 µL: +/- 20.0%
- >20–99 µL: +/- 6.0%
- >99–500 µL: +/- 5.0%
- 1,000 µL (for lysing solution) +/- 5.0%

Wash carousel (BD FACSDuet™ Premium System only)

Injector dispense for Tank A and B

- 50–99 µL: +/- 10%
- 100–450 µL: +/- 6%

Injector dispense for Tank C and D

- 100–499 µL: +/- 10%
- 500–999 µL: +/- 6%

Injector dispense for Tank E

- 50–99 µL: +/- 10%
- 100–450 µL: +/- 6%
- 450–499 µL: +/- 10%
- 500–999 µL: +/- 6%
- 1,000–4,000 µL: +/- 3%

Aspiration probe (BD FACSDuet™ Premium System only)

- 150–299 µL: +/- 35%
- ≥300 µL: +/- 20%

Precision

Specimens

- 5–10 µL: ≤20.0%
- >10–49 µL: ≤10.0%
- >50–400 µL: ≤3.0%

Reagent Probe

- 5 µL: ≤20%
- >5–19 µL: ≤20.0%
- >20–99 µL: ≤10.0%
- >99–500 µL: ≤10.0%
- 1,000 µL (for lysing solution): ≤5.0%

Wash carousel (BD FACSDuet™ Premium System only)

<5% for all volumes

Aspiration probe (BD FACSDuet™ Premium System only)

- 150–299 µL: <15%
- ≥300 µL: <10%

Carryover

Specimen carryover

NOTE: Carryover was tested using fresh whole blood. This protocol was designed to only measure carryover from the BD FACSDuet™ Sample Preparation Systems. Cell analyzers, specimen types and protocol details can impact carryover and carryover must be validated for user-defined preparation methods.

- BD FACSDuet™ Sample Preparation System (Base)
  <0.02% with specimen dispense
- BD FACSDuet™ Premium Sample Preparation System
  <0.02% (200 ppm) with both the standard and high-stringency wash settings

Reagent carryover

<0.00002% (0.2 ppm)

Cell recovery

>80% recovery after 4x wash cycles as compared to manual preparation tested with specimen volumes from 100–300 µL

NOTE: Cell recovery was tested using fresh whole blood and may vary based on the specific preparation methods and manual techniques used. Recovery must be validated for user-defined preparation methods.

Throughput

16 tubes were run through a full 4x prewash, stain, lyse, wash protocol in <185 minutes.*

Cocktailing

Automated reagent cocktailing for up to 45 unique reagents per cocktail.
Indefinite number of cocktail recipes archivable in the software.
Up to a maximum of 4.5 mL of cocktail reagent in one 5mL Amber Vial (also available as Barcoded Amber Vials).
Two (2) reports generated for each cocktail preparation: worklist and preparation reports.
Audit trail for validation of cocktail preparation
Import and export of cocktail recipes.

Specimen loading

Primary specimen tube rack

Up to four primary specimen tube racks with tube adapters
Up to 10 tubes/rack for a total of 40 primary tubes at any given time from multiple providers

Primary specimen tube compatibility

BD Vacutainer®

13 x 75 mm: 2.0, 3.0 and 4.0 mL
13 x 100 mm: 6.0 and 7.0 mL
16 x 100 mm: 9.5 and 10.0 mL
Use BD Hemogard™ Closure or conventional cap (standard rubber stoppers)

Greiner

13 x 75 mm: 2.0 and 3.0 mL*
13 x 100 mm: 6.0 and 7.0 mL*
16 x 100 mm: 9.0 and 10.0 mL
*Use Premium or Non-Ridged Pull Cap

SARSTEDT S-Monovette™

8 x 66 mm: 1.2 mL
13 x 65 mm: 2.6 mL
11 x 66 mm: 2.7 mL
13 x 65 mm: 2.6 and 3.4 mL
15 x 75 mm: 4.0 mL
13 x 90 mm: 4.9 mL

Streck Cyto-Chex™ BCT

13 x 75 mm: 5.0 mL
2-mL flat

* Throughput can vary by protocol. Please consult your BD Application Specialist.

Specimen tube adapter sizing chart

Compatible specimen tubes	
SARSTEDT 1.2 mL	D8 x L66
SARSTEDT 2.6 mL and 3.4 mL	D13 x L65
SARSTEDT 2.7 mL	D11 x L66
BD Vacutainer® 2.0 mL, 3.0 mL and 4.0 mL	D13 x L75
Streck 5 mL	D13 x L75
Greiner 2.0 mL and 3.0 mL	D13 x L75
SARSTEDT 4.0 mL	D15 x L75
SARSTEDT 4.9 mL	D13 x L90
BD Vacutainer® 6.0 mL and 7.0 mL	D13 x L100
Greiner 6.0 mL and 7.0 mL	D13 x L100
BD Vacutainer® 9.5 mL and 10 mL	D16 x L100
Greiner 9.0 mL and 10.0 mL	D16 x L100

Reagent vial compatibility

The following reagent vial types are natively supported by BD FACSDuet™ System reagent racks and adapters and do not require any manual transfer of reagents.

BD

Glass Amber Vial: 36.8 x 21.8 mm: 5.0 mL
Glass Amber Vial: 38.1 x 22.0 mm: 5.0 mL
Plastic Vial: 47.3 x 10.2 mm: 0.5 mL
Plastic Vial: 47.3 x 10.2 mm: 2.0 mL
Plastic Vial: 38.8 x 16.0 mm: 4.0 mL

Beckman Coulter

Glass Amber Vial: 37.6 x 20.4 mm: 5.0 mL
Glass Amber Vial: 42.5 x 13.5 mm: 1.0 mL

BioLegend

Plastic Vial: 47.3 x 10.2 mm: 0.5 mL

BD-Cytognos

Glass Amber Vial: 38.9 x 18.2 mm: 4.0 mL
Plastic Vial: 46.6 x 10.16 mm: 0.5 mL

Dako

Glass Amber Vial: 47.0 x 17.7 mm - 6.0 mL

Invitrogen

Plastic Vial: 47.3 x 10.2 mm - 0.5 mL

Life Technologies

Glass Amber Vials: 43.8 x 21.8 mm - 6.0 mL
Plastic Vial: 47.3 x 10.2 mm: 0.5 mL

Carrier compatibility

BD FACSLyric™ System 30 tube rack
BD FACSLyric™ System 40 tube rack
Use with 12x75-mm BD Trucount™ Tubes and 5-mL
K-Resin or Polystyrene or Polypropylene tubes

96-well plate compatibility

Name
96 Well Plate Corning Standard flat bottom PS
96 Well Plate Corning Standard round bottom PS
96 Well Plate Corning Standard round bottom PP
96 Well Plate Corning Standard conical bottom PP
96 Well Plate Corning Deep 1-mL round bottom PP
96 Well Plate Corning Deep 2-mL conical bottom PP
96 Well Plate Eppendorf Deep 1-mL conical bottom PP
96 Well Plate Eppendorf Deep 2-mL conical bottom PP

Barcoder reader

The following barcodes are supported
for primary specimen tubes:
ISBT 128
Code 128
Code 39
Codabar
interleave 2 of 5 standard barcode
for reagent vials:
DataMatrix (reagent scanning only)

Computer

Operating System: Microsoft™ Win 10
Processor: Intel™ BayTrail J1900
64-Bit EMB English
Touch screen

Data management options

BD FACS™ Workflow Manager hardware and software for LIS connectivity (for more details refer to the BD FACS™ Workflow Manager technical specification document).

The BD FACSDuet™ Sample Preparation System, the BD FACSDuet™ Premium Sample Preparation System and BD Flow Cytometers for reagent vials: are Class 1 Laser Products.

CE BD FACSDuet™ Sample Preparation System, BD FACSDuet™ Premium Sample Preparation System, BD FACSLyric™ Flow Cytometer with the BD FACSuite™ Clinical and BD FACSuite™ Application and BD FACS™ Lysing solution are in vitro diagnostic medical devices bearing a CE mark.

CE 2797 BD Multitest™ CD3FITC/ CD8PE/ CD45PerCP/ CD4APC, BD Multitest™ CD3FITC/ CD16+56PE/ CD45PerCP/ CD19APC, with and without BD Trucount™ tubes, BD Multitest™ IMK kit, with and without BD Trucount™ tubes, BD Multitest™ 6-Color TBNK, with and without BD Trucount™ tubes, are in vitro diagnostic medical devices bearing a CE mark and are CE certified by BSI Group The Netherlands B.V. (Notified Body Number = 2797).

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