

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 Cytometry System. When the BD FACSDuet" System is physically integrated with the BD FACSLyric" Flow Cytometry System via the BD FACSLyric" System universal loader, it provides automatic sample transfer to the flow cytometer, delivering a complete walkaway sample-to-answer solution.

Bidirectional data integration from the BD FACSLyric[®] Flow Cytometry System to BD FACSDuet[®] System is provided by BD FACSLink[®] Software, which also enables Laboratory Information System (LIS) integration.

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 support 21 CFR Part 11 compliance.

The BD FACSDuet[®] Sample Preparation System also provides:

• Support for a wide variety of blood collection tubes, both in size (eight different sizes) 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 from a wide range of manufacturers (Beckman Coulter, BioLegend, 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 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 additional bulk fluid tanks, to enable user-defined preparation methods that include wash steps.

The BD FACSDuet" Premium System comes with predefined standard workflow templates for prewash/stain/ lyse/wash and fix/perm workflows. Users can 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. The BD FACSDuet" Sample Preparation System (Base) can be upgraded to the BD FACSDuet" Premium Sample Preparation System configuration onsite by BD service engineers.

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



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 rack 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 ℃

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 Automated reagent cocktailing for up to 45 unique reagents per cocktail 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):

Lyse tank: 1 L

BD FACSDuet[™] Premium System: 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 μ L (in increments of 1 μ L)

Reagents dispense

5–1,000 μL (in increments of 1 $\mu L)$

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 $\mu L)$

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). The BD FACSDuet[™] Premium Sample Preparation System, 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 μ L: \leq 3.0%

Reagent Probe

- 5 μL: ≤ 20%
- >5−19 μL: ≤ 20.0%
- >20−99 μL: ≤ 10.0%
- >99−500 μL: ≤ 10.0%
- 1,000 μ L (for lysing solution): \leq 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 userdefined 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.*

Sample loading

Primary specimen tube rack

Up to four primary specimen tube racks with tube adaptors

Up to 10 tubes/rack for a total of 40 primary tubes at any given time from multiple providers

Reagent vial compatibility

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

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

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

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

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

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

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	D13 x L75	
mL and 4.0 mL		
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	

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

Barcoder reader

The following barcodes are supported for primary specimen tubes: ISBT 128 Code 128 Code 39 Codabar interleave 2 of 5 standard barcode 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 FACSLink" Hardware and Software for LIS connectivity



The BD FACSDuet" Sample Preparation System and BD FACSDuet" Premium Sample Preparation System are Class 1 Laser Products. The BD FACSDuet" Sample Preparation System and BD FACSDuet" Premium Sample Preparation System are for In Vitro Diagnostic Use. Sample preparation for user-defined protocols and cocktailing functions are for Research Use Only, not for use in diagnostic or therapeutic procedures.

EU

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