

BD FACSDuet™ Sample Preparation System

The BD FACSDuet[™] is an automated sample preparation system designed to prepare human biological specimens for acquisition on the BD FACSLyric[™] flow cytometer.

When the BD FACSDuet[™] is physically integrated with the BD FACSLyric[™] via the BD FACS[™] Universal Loader, the system provides ready-to-acquire samples to the flow cytometer, delivering a complete walkaway sample-to-answer solution.

BD FACSLyric[™] to BD FACSDuet[™] bidirectional data integration is provided by BD FACS[™] Workflow Manager software ensuring patient data integrity and security.

The BD FACSDuet[™] system provides preanalytical standardisation with complete traceability of specimens, reagents and samples throughout the entire workflow and across platforms through extensive use of barcodes.



At the same time, the system delivers high flexibility:

- Supporting a wide variety of blood collection tubes, both in size (8 different sizes) and from multiple manufacturers (BD Vacutainer[®], Sarstedt, Greiner and Streck) for a total of 20 different tube types.
- Allowing the use of multiple size reagent vials : up to 23 reagent vials/ rack for a total of 46 reagent vials in 2 racks and from a wide-range of non-BD manufacturers (Beckman Coulter, BioLegend, Cytognos, Invitrogen and Life Technologies).
- Supporting the use of BD IVD assays as well as user-defined protocols that can be designed and stored in the BD FACSDuet[™] software to guarantee standardization of processes across users and labs.

The system's modular design enables increasing functionality to cater to the evolving needs of the labs, including the possibility to prepare reagent cocktails.



BD FACDuet[™] Sample Preparation System **Technical Specifications**

Instrument

Dimensions

Height: 83.8 cm (33.0 in.)

Width: 106.2 cm (41.8 in.)

Width (with touchscreen extended): 153.19 cm (60.3 in.)

Depth: 74.4 cm (29.3 in.)

Weight (with rack loaded, monitor and ready to use): 174 kg (383.6 lb)

Power requirements 100–240 V / 6-2.5 A / 50–60 Hz

Power consumption mean 420W-peak consumption 600W

Fuses 2 A (150 V)

Environment

Storage temperature 5°C to 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 2000 meters)

Heat dissipation <500 BTU/hr

Noise level ≤57 dBA, under normal operating conditions

Facility requirements Please refer to the BD FACSDuet Site Preparation Guide for details

BD FACSDuet table

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

Preprogrammed settings (default for IVD multitest assays/panels/ absolute count)

Dispense volume Sample: 50 μL **Reagent:** 20 μL **Lyse:** 450 μL

Lyse. 190 µL

Preprogrammed incubation times (default for IVD multitest assays/panels/ absolute count)

Incubation time

Reagent: 15 - 30 minutes (min-max) Lyse: 15 - 30 minutes (min-max)

System performance (for IVD multitest assays/ panels/absolute count)

Specimen dispense volume: 50 μL 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% **Lyse** dispense volume: 450 μL A&P for lyse (in single- and multidispense mode) Accuracy: ±5.0% by volume Precision: CV = 5.0% **Carryover performance**

Specimen to specimen: ≤0.2% Reagent to reagent: ≤0.01%

Non-dispensed volume

Specimen: 250 μL(for 13 x 75 mm tubes)

 $\mbox{Reagents:}\ 130\ \mu\mbox{L}$ (in single- and multi-dispense mode)

Lyse: 170 mL

User-definable ranges

Dispense volumes Sample 5-400 µL (in increments of 1 µl)

Reagents 5-1000 μL (in increments of 1 $\mu l)$

BD Trucount[™] controls 5-50 μL (in increments of 1 μl)

BD FACS[™] lysing solution 5-1000 μL (in increments of 1 μL)

Incubation times Reagent 0-1000 minutes (in 1 minute increments) Lyse

0-1000 minutes (in1 minute increments)

Maximum volume per tube: 2 mL

Maintenance protocol

Instrument priming, rinsing, and cleaning procedures as well as probe alignment are pre-programed

System performance (for user-definable ranges)

Accuracy

Specimens: i. 5-10 µL ±1µL ii. >10-49 µL ±10.0% iii. >50-400 µL ±5.0% Reagents: iv. 5 µL ±20.0% v. >5-19 µL ±20.0% vi. >20-99 µL ±6.0% vii. >99-500 µL ±5.0% viii. 1000 µL (for lysing solution)±5.0%

Precision

Specimens: i. 5-10 μ L \leq 20.0% ii. > 10-49 μ L \leq 10.0% iii. > 50-400 μ L \leq 3.0% Reagents: iv. 5 μ L \leq 20.0% v. >5-19 μ L \leq 20.0% vi. >20-99 μ L \leq 10.0% vii. >99-500 μ L \leq 10.0% viii. 1000 μ L (for lysing solution) \leq 5.0%

Sample loading

Primary tube racks

Up to 4 primary 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

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[™] 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

2mL flat

Specimen tube adapter sizing chart

Compatible specimen tubes

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

Carrier compatibility

BD FACSLyric[™] 30 tube rack BD FACSLyric[™] 40 tube rack Use with 12x75mm BD Trucount[™] tubes and 5mL K-Resin or Polystyrene or Polypropylene tubes

Cocktailing functionality

Up to 45 unique reagents within each given 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). 2 Reports generated for each cocktail preparation: worklist and preparation reports.

Import and export of cocktail recipes.

Fluidic

Dimensions 10L tanks

Height: 25.4 cm (10 in.) Width: 24.1 cm (9.5 in.) Depth: 29.2 cm (11.5 in.)

Tank capacities

Saline tank: 10 L DI water tank: 10 L Waste tank: 10 L Lyse tank: 1 L

Barcode 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

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).

BD FACS™ Lysing Solution, as intended in this document, as well as BD Vacutainer® Tubes, BD™ Multi-Check products, BD Trucount™ Controls, BD FACS™ Universal Loader, BD FACSDuet™ Sample Preparation System, and BD FACSLyric™ Flow Cytometer with the BD FACSuite™ Clinical and BD FACSuite™ applications are CE marked in compliance with the European In Vitro Diagnostic Medical Device Directive 98/79/EC.

BD FACSDuet[™] Sample Preparation System and BD FACSLyric[™] Flow Cytometer are Class 1 Laser Products.

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