



BD FACSLyric™ Flow Cytometry System

The power to transform



BD FACSLyric

Discover the difference of the BD FACSLyric™ flow cytometry system.

- Witness clinical **performance** results you have never seen before, through **high sensitivity** and **improved resolution**
- Streamline your lab workflow through **flexibility** and **automation**, enabling efficiency and productivity
- Achieve automated **standardization** through highly reproducible results and enable **collaboration** through assay portability

And see how the BD FACSLyric system can transform your lab.



The next generation of flow cytometry

The BD FACSLyric flow cytometry solution combines simplicity, speed and automation to ease workflow and improve productivity. This next-generation flow cytometer enables standardization and collaboration through consistent results and unique assay portability capabilities.

Built on a foundation of excellence, experience and expertise, the BD FACSLyric is a new diagnostic standard for clinical cell analysis, transforming the way your lab does flow cytometry. As with all BD instruments, the BD FACSLyric is backed by 40 years of BD expert training, service and support— so there's no limit to your potential.

Just the FACS

4-, 6-, 8-, 10- and 12-color configurations. Onsite **upgradeable** to adapt to your lab's changing needs

Up to **3 lasers**—blue, red and violet—**12 fluorescence channels** and **14 parameters**

35,000 events per second maximum acquisition rate; no limit on number of events acquired

Automated single-tube QC with BD™ CS&T beads

Fluorescence **compensation required only every 60 days**, improving efficiency and productivity

21 different loading options: plates or tubes^{*}; built-in flexibility with BD FACS™ Universal Loader

Compact and **quiet**; 63.2 x 57.9 x 57.9 cm (24.9 x 22.8 x 22.8 in.) and less than 55 dBA

^{*} Refer to the BD FACSLyric Technical Specifications Sheet for details

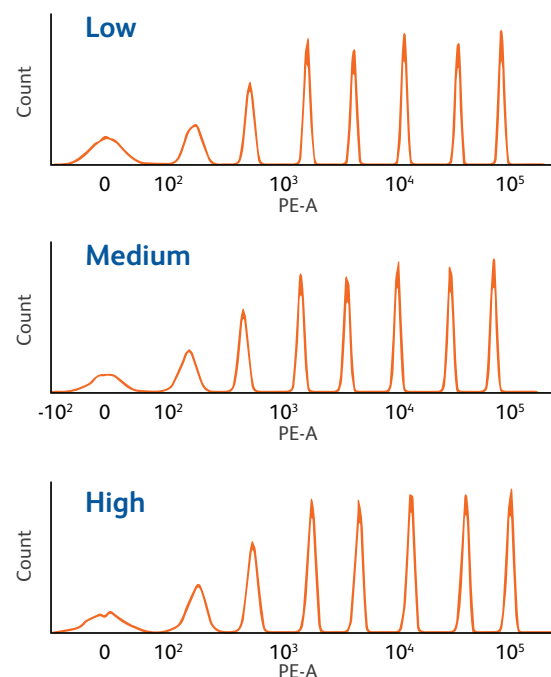




A new diagnostic standard delivering outstanding performance

The BD FACSLyric is a high-performance, highly sensitive flow cytometer that demonstrates exceptional resolution and improved separation to make dim and rare populations easier to resolve.

- Runs at rates of up to 35,000 events per second, allowing acquisition of a large number of events rapidly; useful for rare populations
- There is no limit on events acquired
- Sample carryover $\leq 0.1\%$ with the default sample injection tube (SIT) flush and as low as 0.05% up to 6 SIT flushes
- Outstanding resolution at all flow rates and enables faster detection without compromising quality (**Figure 1**)



Flow rate	$\mu\text{L}/\text{min}$
Low	12
Medium	60
High	120

Figure 1. Flow rate

Improvement in stain index of 8–190% across all parameters, ensures better separation and enables faster analysis and easier gating. **(Figure 2)**

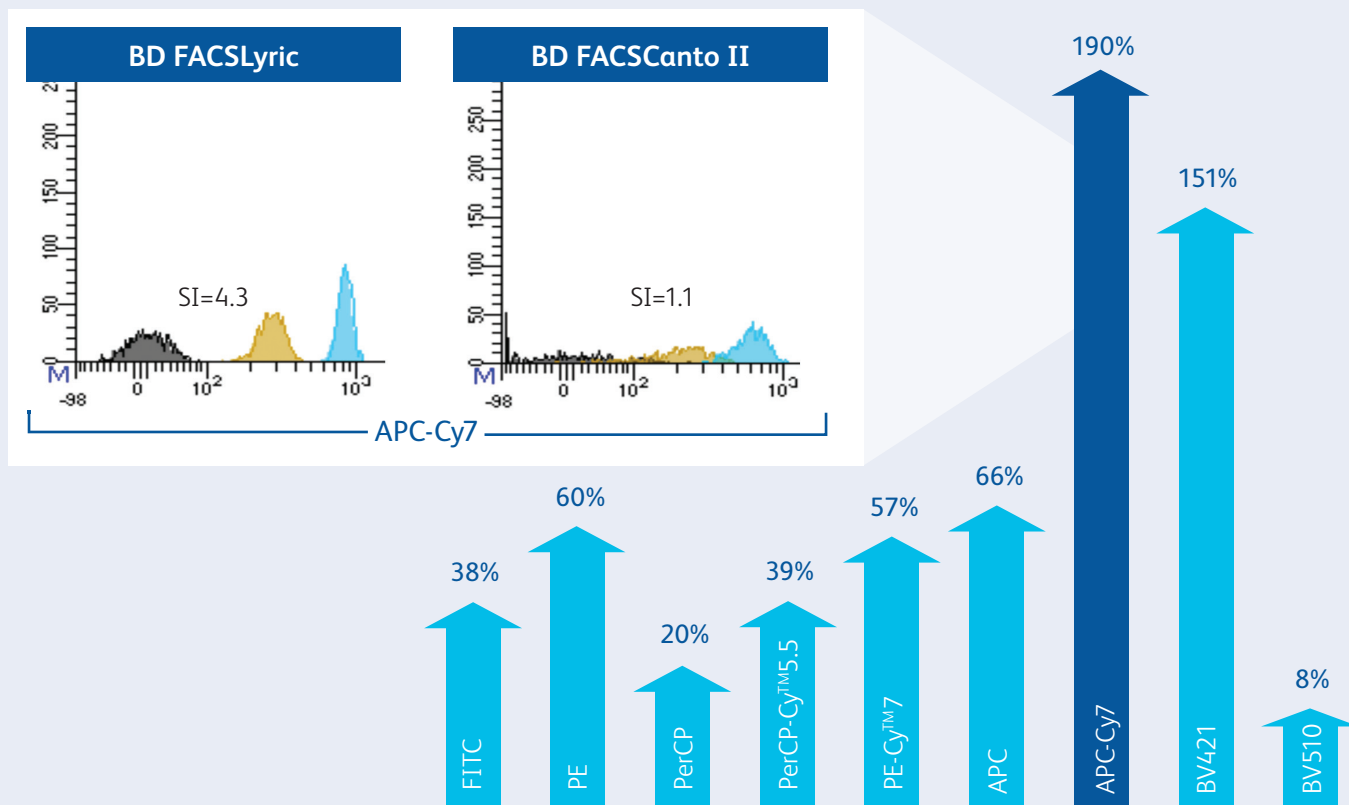
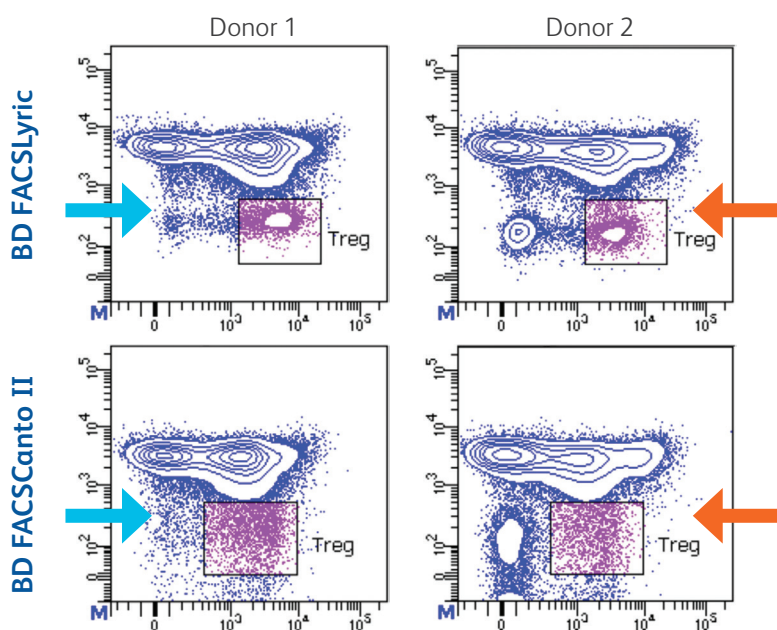




Figure 2. Improvement in stain index enhances peak resolution of the BD FACSLyric as compared to the BD FACSCanto™ II system

One set of single-color stains of peripheral blood samples was acquired on a BD FACSCanto II and a BD FACSLyric cytometer. Stain index was calculated for all parameters on both instruments. The % increase in stain index (*BD FACSLyric/BD FACSCanto II*) is shown. Histograms from the BD FACSLyric and the BD FACSCanto II are also shown.



Higher sensitivity makes dim and rare populations easier to resolve. **(Figure 3)**

Figure 3. The optical design and higher sensitivity of the BD FACSLyric improve the resolution of dim populations, as seen in this example (*CD25, CD127*).

 Treg population
 Double negatives

Improving efficiency and productivity through flexibility and automation

Intelligent system design simplifies your laboratory workflow through built-in flexibility and automation thus enabling your technicians to be more productive.



A lab-friendly system, with a small footprint, quiet operation and BD FACS Universal Loader

- Automated loader can accommodate 30 or 40 tubes
- 21 different loading options to choose from between 96-well and 384-well plates
- Automated vortexing of tubes and plates for mixing and resuspending
- Automated sample tracking tubes and plates (*barcode enabled*)
- Compact instrument size 63.2 x 57.9 x 57.9 cm (24.9 x 22.8 x 22.8 in.) for smaller lab spaces
- Noise levels of ≤ 55 dBA for a quieter lab environment



BD™ FC Beads*

Patented BD bead technologies enable data reproducibility

- Daily setup and performance checks using BD CS&T beads automatically adjust more than 70 instrument parameters ensuring stable instrument performance with CV of $<0.4\%$ (**Figure 6**)
- PMT voltages are automatically updated to maintain target MFI values as a part of QC
- Spillover values (SOVs) are automatically updated as part of daily QC
- Compensation only needs to be performed every 2 months

*BD FC Beads are NIST certified, bringing flow cytometry one step closer to standardization.



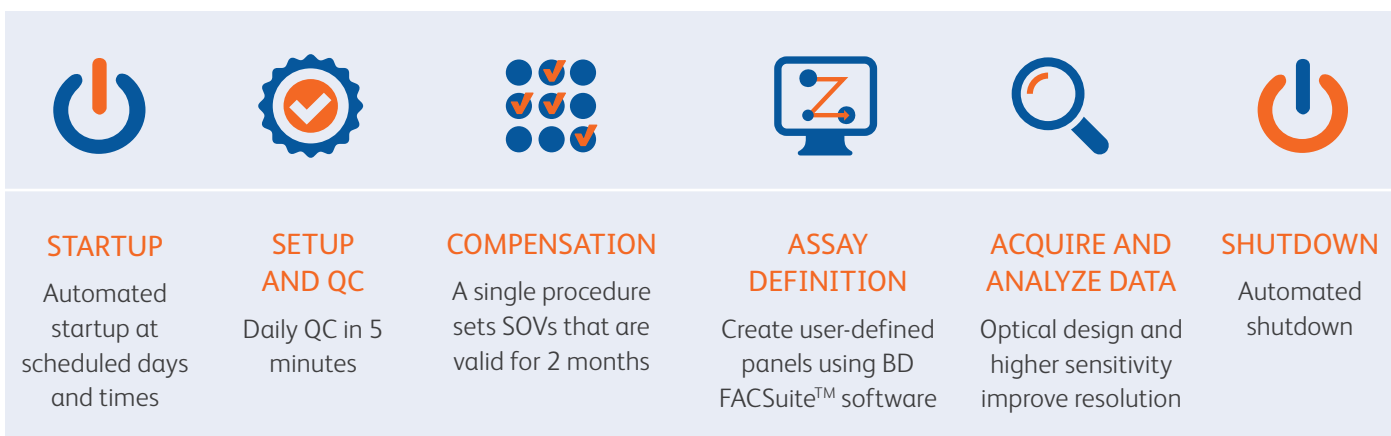
“BD is positioned with CS&T and FC bead technology to enable instrument standardization simply from day to day, instrument to instrument, and lab to lab. Reference control based instrument standardization is the most important “next step” for clinical flow cytometry.”

Lili Wang, NIST, Gaithersburg, MD

Spend zero minutes on startup and shutdown.

- Pre-programmable startup means instruments are ready to run the minute users walk in
- Automated shutdown and power off also contributes to maximizing instrument productivity

Automation streamlines your daily workflow, improving efficiency and productivity.



Elevating standardization and collaboration to a new level

Universal Setup ensures reproducible and accurate results day to day with stable instrument performance of <math><0.4\%</math>. **(Figure 4)**

- Universal Setup, a series of built-in daily performance checks
- Optimal instrument performance is achieved through one-tube daily CS&T as part of universal setup

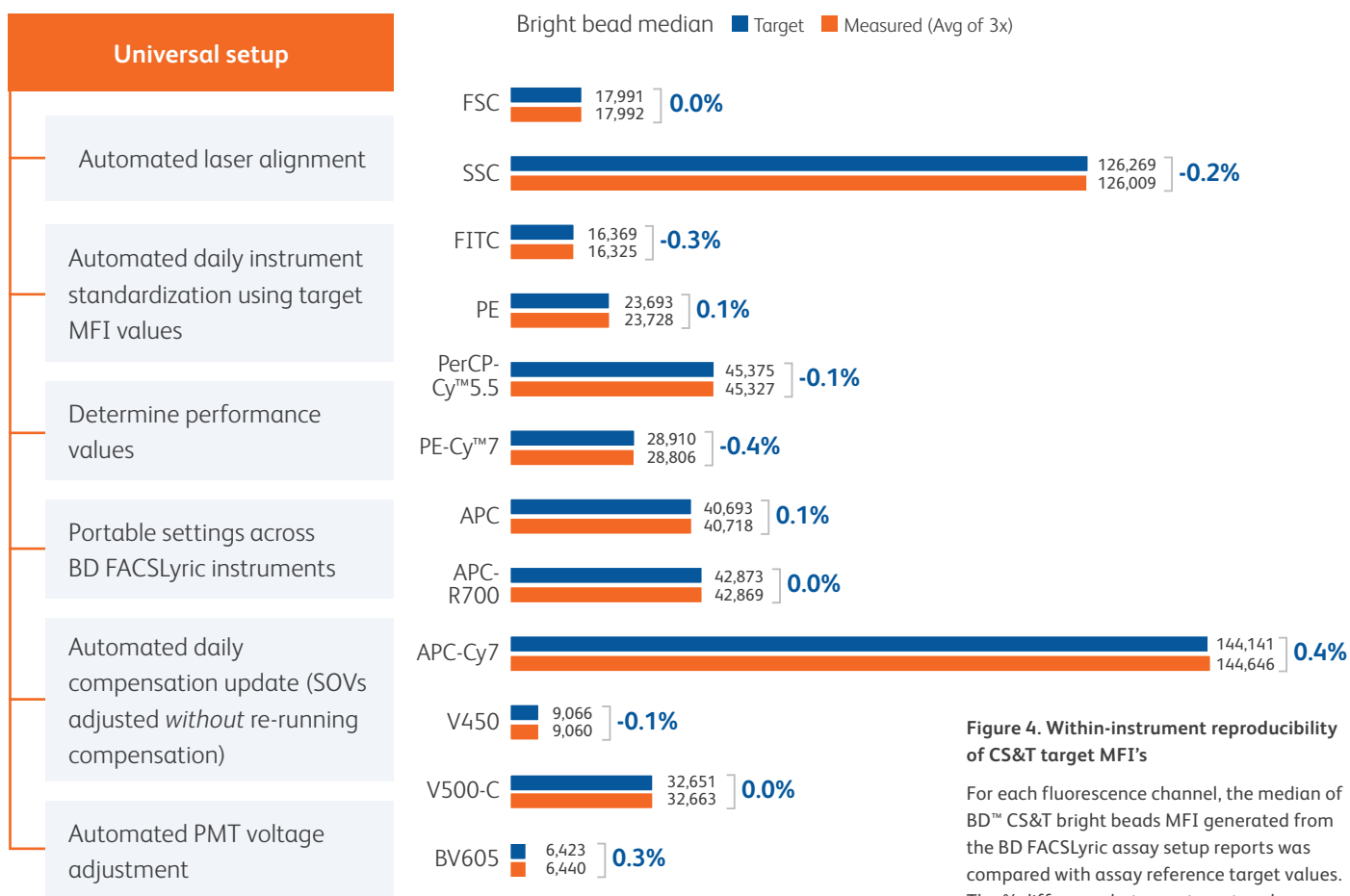


Figure 4. Within-instrument reproducibility of CS&T target MFI's

For each fluorescence channel, the median of BD™ CS&T bright beads MFI generated from the BD FACSLyric assay setup reports was compared with assay reference target values. The % difference between target and measured was calculated and is shown.

Assay portability and sharing in 4 easy steps



The BD FACSLyric was designed with collaboration in mind. The unique assay portability feature enables the sharing and exchange of data, ideas and user-defined protocols within and between institutions.

- User-defined assays are saved and electronically transferred via USB or email to another BD FACSLyric system
- Assay portability simplifies and standardizes instrument setup within your lab and between labs, making collaboration effective and efficient
- The time required to set up additional instruments is reduced

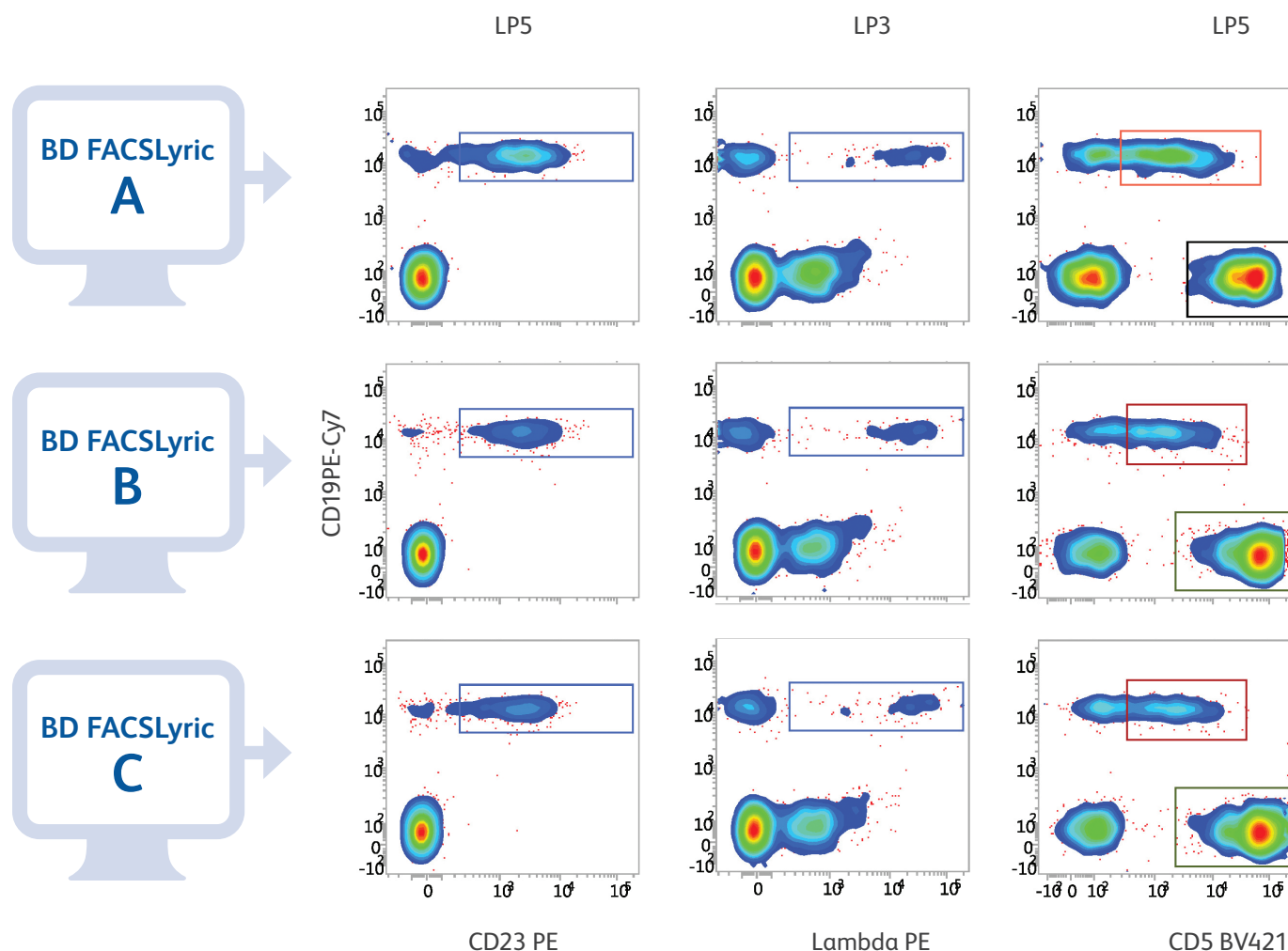
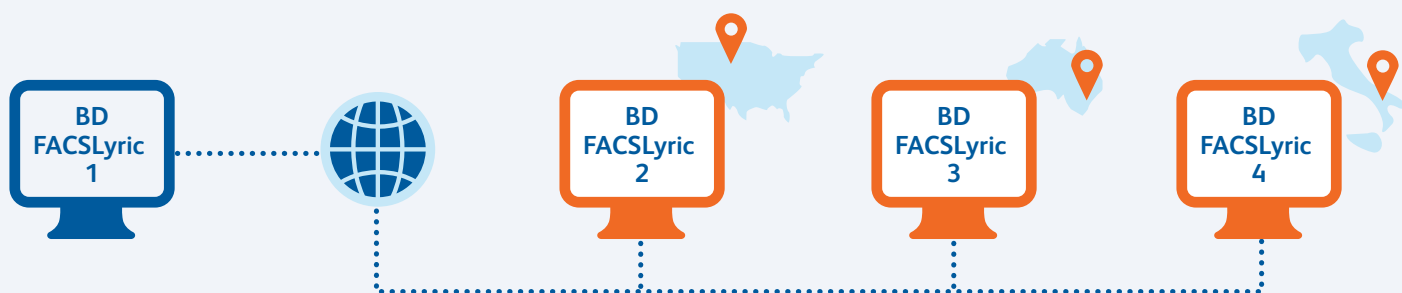


Figure 5. User-defined assay across three instruments shows the reproducible and accurate performance of the BD FACSLyric Universal Setup.

Strengthening partnerships and expanding global collaborations through assay portability and sharing.



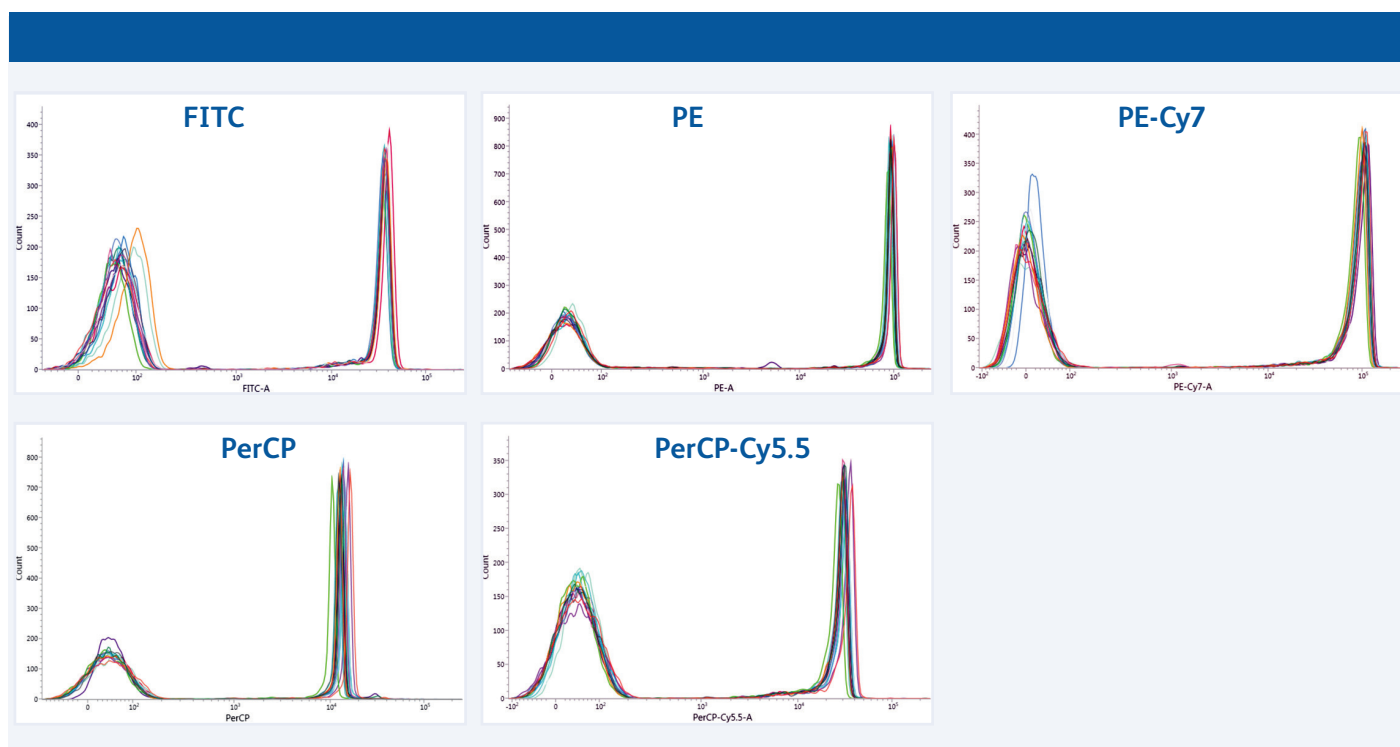
Highly reproducible results between instruments drive standardization.

BD FACSLytic Variance (CVs)					
15 BD FACSLytic Systems: Lyse/Wash settings and BD FC beads					
Blue laser	%CV	Red laser	%CV	Violet laser	%CV
FITC	4.2	APC	5.3	BD Horizon™ V450	11.1
PE	4.4	APC-Cy7	4.1	BD Horizon V500	11
PE-Cy7	4.8	APC-H7	3.9	BD Horizon BV605	13.6
PerCP	10.2	APC-R700	4.2	BD Horizon BV711	7.5
PerCP-Cy5.5	7.9			BD Horizon BV786	15.3

Table 1. Between-instrument reproducibility of target MFI values on the BD FACSLytic

Lyse/wash assay settings were imported across 15 instruments to show effects of standardization on beads. The CVs of the fluorescence intensity across all channels varies by less than 15.3%. (Figure 5) Daily QC with one lot of BD CS&T beads was run on fifteen BD FACSLytic cytometers. For each instrument, the PMTV gains were automatically adjusted to meet the target values. BD FC beads acquired on each BD FACSLytic instrument. The MFI of positive populations was measured for all parameters across all instruments. The %CV is shown.

The data for this internal study was acquired using BD FC beads across 15 instruments. Greater between-instrument variability could be observed when running biological samples, when using non-BD reagents or when comparing fewer instruments.



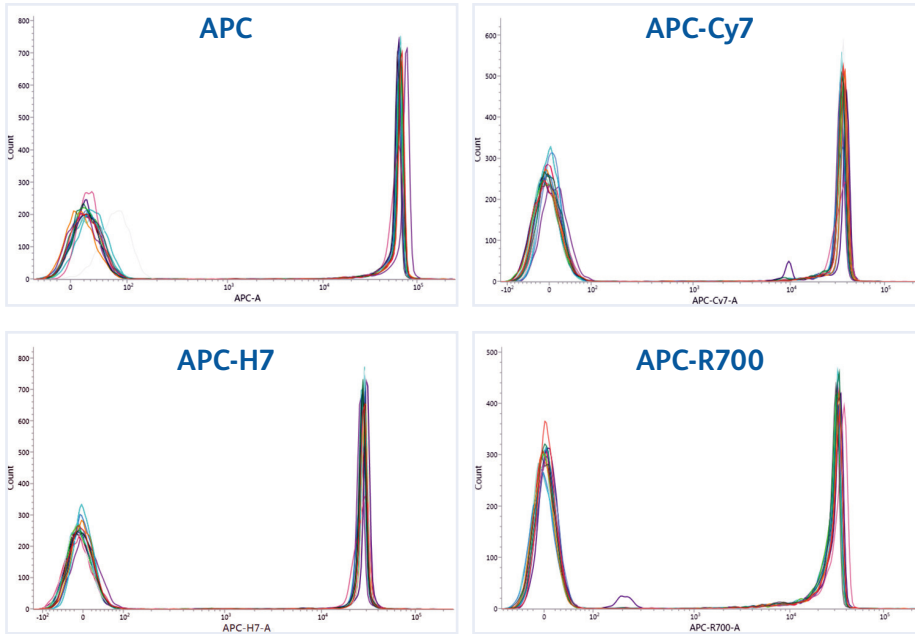
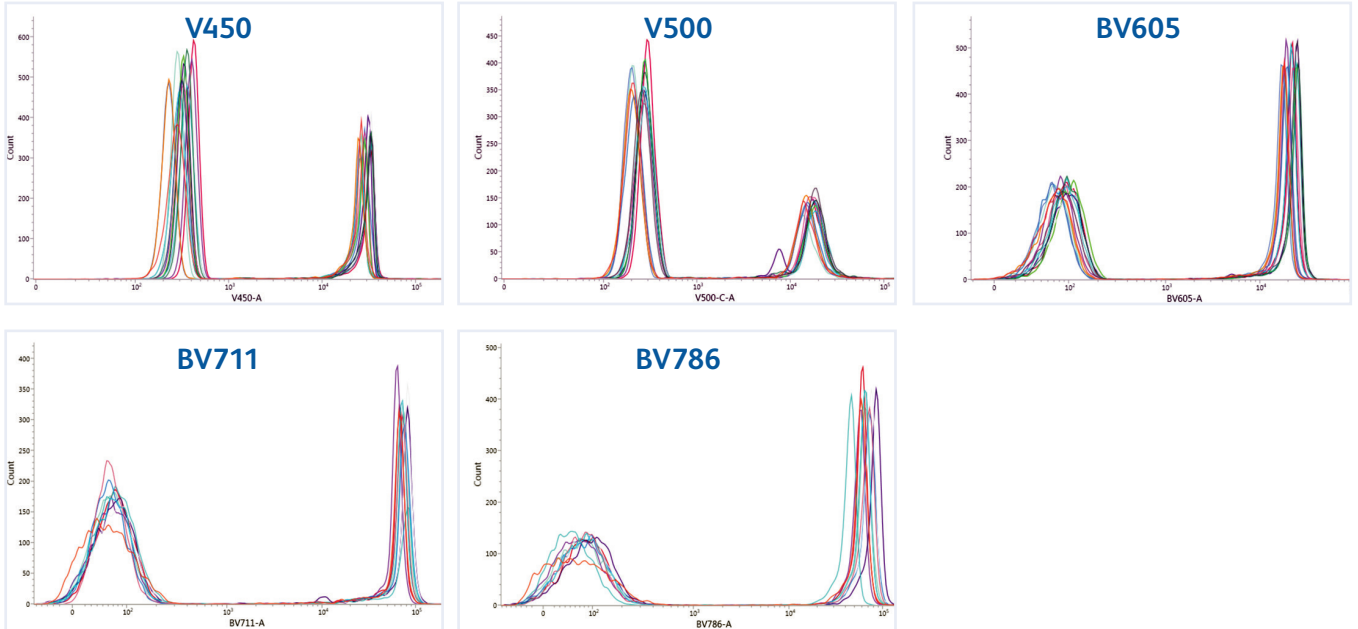


Figure 6. Corresponding overlays of 15 BD FACSLytic systems show between-instrument variability of less than 8% for the red and blue channels

Variability is slightly higher off the violet channels and is between 7% and 16%. Violet channels show slightly increased variability due to characteristics of the violet optical configuration.



“The flow crossmatch market may be one of the smallest, but standardization has the potential to have one of the greatest clinical impacts. It’s the little things that make a big difference in healthcare.”

Dr. Robert Bray, Emory University, Atlanta, GA

Data management software

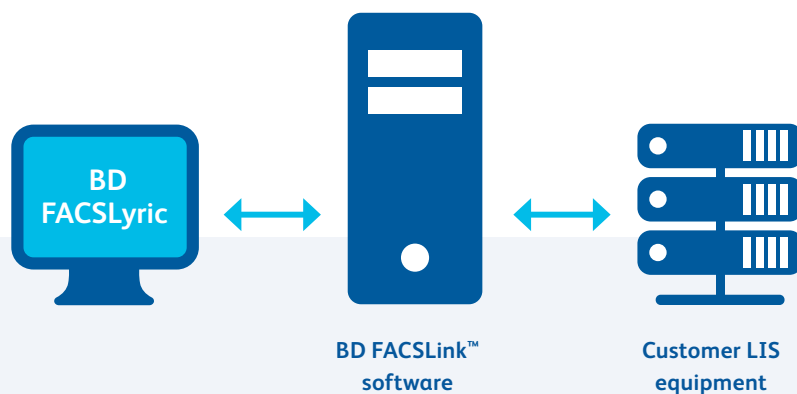
BD FACSuite™ acquisition and analysis software is robust and reliable, and has many functions and options relevant to 21 CFR Part 11.

- Password protection, audit trail, electronic signatures and IQ/OQ procedures assist in supporting 21 CFR Part 11 compliance and electronic record integrity.
- BD FACSuite software consists of two modules*. Both modules have a common user interface and identical menu navigation.
- Reports are customizable with tables, headers and footers.
- Built-in flexibility for creating customized calculations and expressions.
- With Microsoft® Windows® 10 improved security, BD FACSuite software is available for offline analysis.



WHAT IS 21 CFR PART 11?

21 CFR Part 11 applies to FDA-regulated industries. It requires that controls are put in place to ensure electronic records and signatures are accurate, authentic, trustworthy, reliable, confidential and equivalent to paper records and handwritten signatures on paper. These controls include elements such as access control, data protection, system validations, audit trails and where applicable, electronic signatures control.



Integrated solutions to optimize lab productivity and secure data from request to reporting

- Seamless laboratory information system (LIS) integration enabled by the BD FACSLink™ software interface solution reduces transcription errors and improves laboratory efficiency.
- Bidirectional transfer of information between your LIS and the BD FACSlyric using the BD FACSLink interface solution reduces transcription errors.
- Remote diagnostics and support with BD Assurity Linc™ enables identification of maintenance needs and off-site technical support.

* BD FACSuite™ Clinical is used for BD IVD assays

Sample ID: MC low
Sample Name:
Case Number:
 Acquired Using: TBNK Workflow_yz
 Assay: 6 Color TBNK + Truc

Results Summary (Abs Cnt is in cells/ μ L)

Label	%Lymphs	Value or Abs Cnt
Bead Events		1,791
Lymphs Events		2,504
Lymphs		1,394
CD3+	52.76	735
CD3+CD4+	12.14	169
CD3+CD4+ (excl. dual pos.)	11.82	165
CD3+CD8+	33.39	465
CD3+CD8+ (excl. dual pos.)	33.07	461
CD3+CD4+CD8+	0.32	4
CD3+CD4-CD8-	7.55	105
CD19+	24.32	339
CD3-CD16+CD56+	19.89	277

QC Results

Label	Results
4/8 Ratio	0.36
%T-Sum (<10%)	7.55
Lymphosum (95-105%)	96.96

QC Messages

Showing 0 of 0 QC Messages

Signature: Lyric Student
Comments: good

For In Vitro Diagnostic Use.

6 Color TBNK +
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BD FACSuite Clinical software report

BD 6 Color TBNK + Truc: Lab Report

Sample ID: MC low
Sample Name:
Case Number:

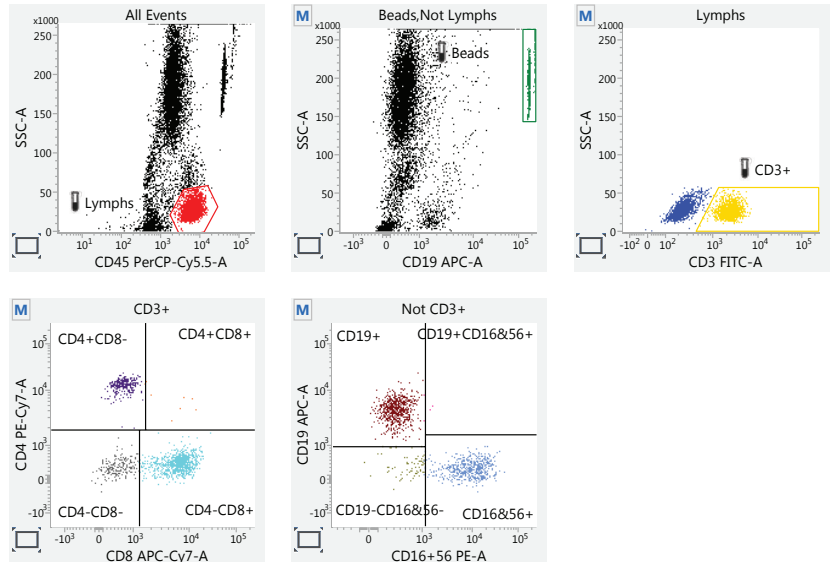
Acquired Using: TBNK Workflow_yz
 Trucount Lot ID: 17066
 Cytometer: BD FACSLyric
 Operator: Lyric Student

Approved: 11/30/2017 2:44:10 PM
 Beads Per Pellet: 49850
 Cytometer SN: R659180000085
 Director:
 Department: None

Entry Status: Approved
 Software: BD FACSuite Clinical v1.1.1
 Institution: None
 Address:

Tube Name: CD3/16+56/45/4/19/8 + Truc

Events Acquired	11,244	Acquisition Date	11/30/2017
Reagent Lot ID	Multitest 6-color TBNK Lot ID: 654321	Acquisition Time	2:27:23 PM
Keyword 1	<no value>	Keyword 2	<no value>



For In Vitro Diagnostic Use.

6 Color TBNK + Truc v1.0
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Flow cytometry solutions, built on a foundation of excellence, experience and expertise

Clinical laboratories expect high-quality solutions when they come to BD, a collaborative partner with more than **40 years of experience** in flow cytometry. BD is committed to providing excellence and expertise in the clinical environment with an innovative portfolio of solutions, products and tools.

Training

Course offerings led by BD instructors and application support specialists include training on instruments, software and applications. This training is delivered in a wide range of formats including instructor-led at the BD training center, virtually online, self-paced or at your location.

Qualification protocols

BD offers qualification assistance to help customers meet current Good Manufacturing Practice (cGMP) and Good Laboratory Practice (cGLP) standards. Factory-trained Field Service Engineers can provide installation qualification (IQ) and operational qualification (OQ).

Instrument support and service

Experienced BD cytometry experts help evaluate and resolve issues. These in-country services include telephone support, remote diagnostics and troubleshooting, onsite preventative maintenance and field service. BD Assurity Linc provides secure remote systems management that connects with a variety of BD cytometers.

Application support

Experienced BD clinical and research application specialists can provide additional telephone scientific support and on-site training in the areas of instruments, software and reagents.





BD FACSLyric™

BD FACS™ Universal Loader

Class 1 Laser Product.

The BD FACSLytic™ flow cytometer is for In Vitro Diagnostic Use. CE marked in compliance with the European In Vitro Medical Device Directive 98/79/EC.

The BD FACSCanto™ II is for In Vitro Diagnostic Use. CE marked in compliance with the European In Vitro Medical Device Directive 98/79/EC.

Unless otherwise noted for In Vitro Diagnostic Use. CE marked in compliance with the European In Vitro Medical Device Directive 98/79/EC.

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