



BD FACSLyric™ Flow Cytometry System



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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™ Flow Cytometry Solution 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™ Flow Cytometry Solution is backed by over 50 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**; 63.3 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

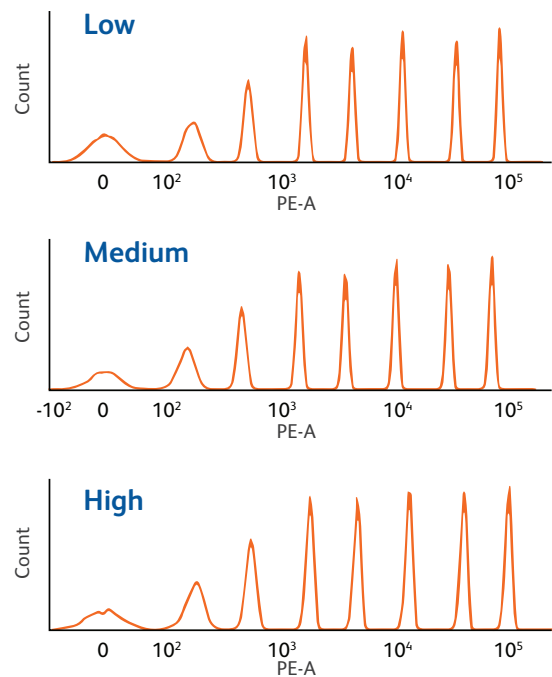




A new diagnostic standard delivering outstanding performance

The BD FACSLyric™ System 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 $<0.05\%^*$ with 500 μL of sample with 3 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

*Determined for CD45 population using CD45 PerCP

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

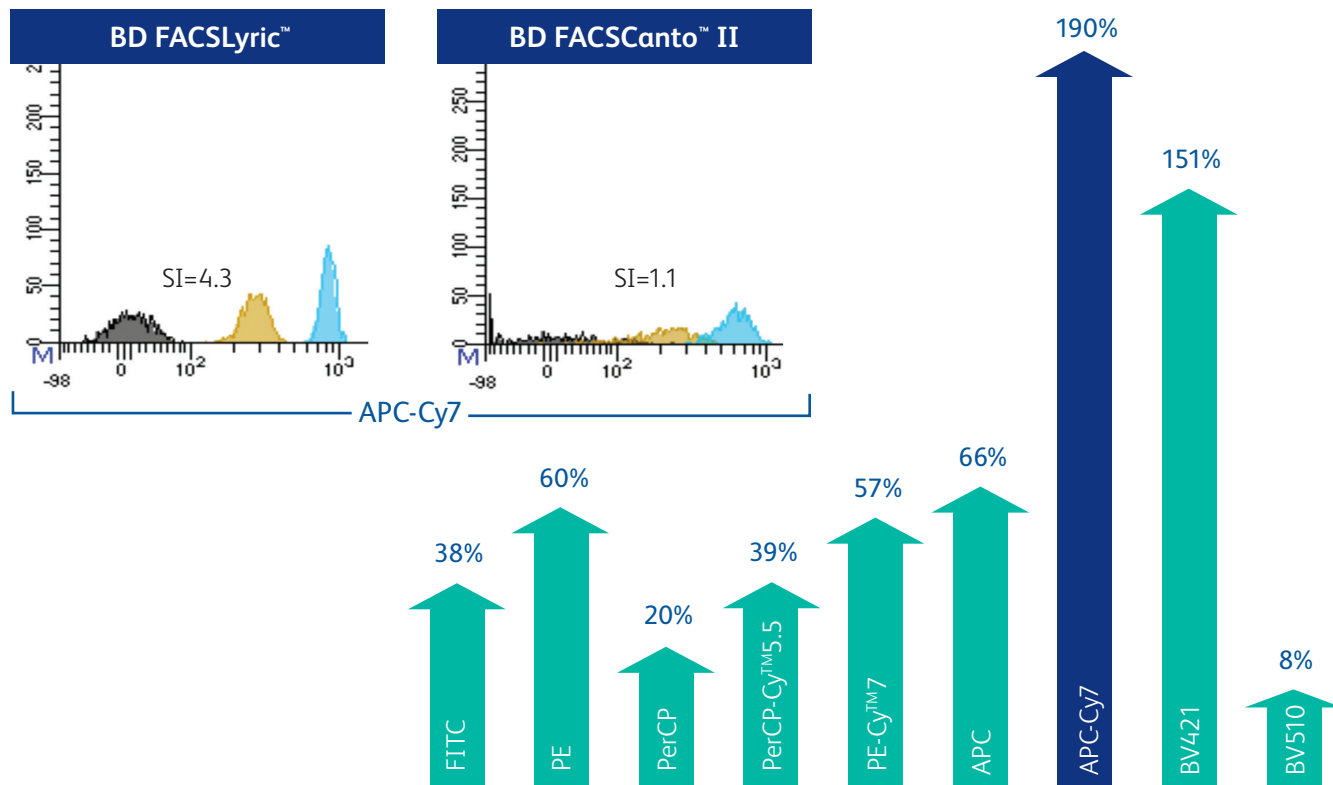
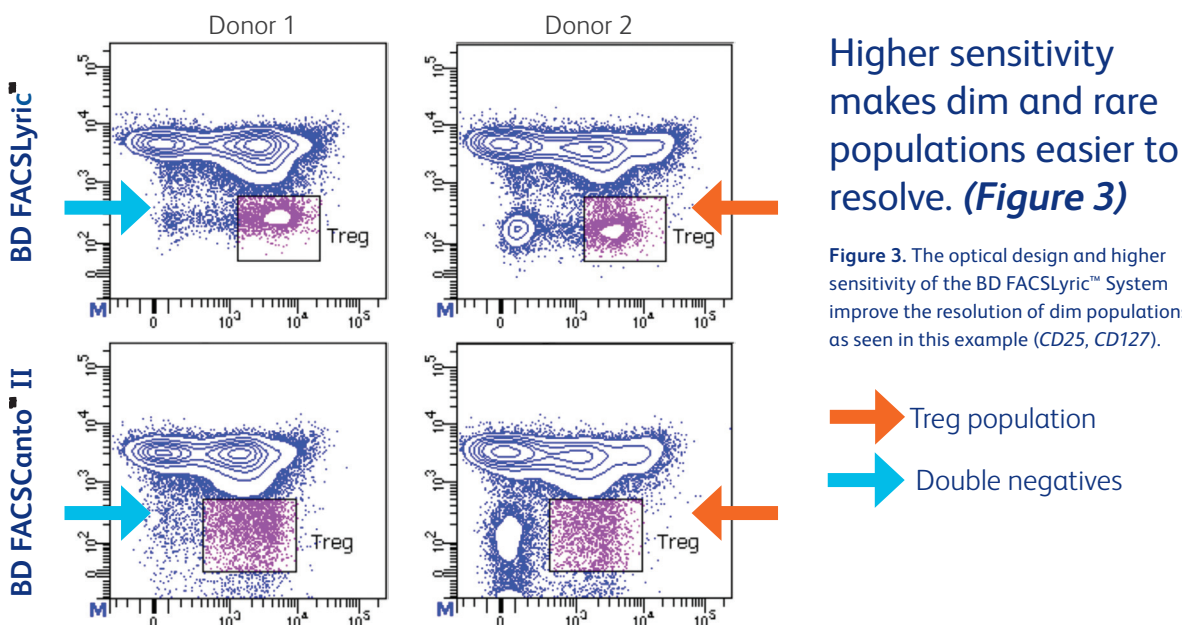




Figure 2. Improvement in stain index enhances peak resolution of the BD FACSLyric™ as compared to the BD FACSCanto™ II System

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™ System and the BD FACSCanto™ II System are also shown.



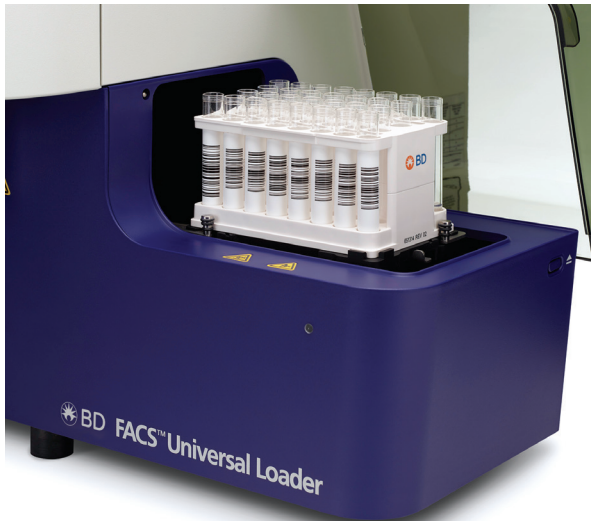
Higher sensitivity makes dim and rare populations easier to resolve. **(Figure 3)**

Figure 3. The optical design and higher sensitivity of the BD FACSLyric™ System 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 63.3 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



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 difference of <0.4% (**Figure 4**)
- 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

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.



STARTUP

Automated startup at scheduled days and times

SETUP AND QC

Daily QC in 5 minutes

COMPENSATION

A single procedure sets SOVs that are valid for 2 months

ASSAY DEFINITION

Create user-defined panels using BD FACSuite™ Application

ACQUIRE AND ANALYZE DATA

Optical design and higher sensitivity improve resolution

SHUTDOWN

Automated shutdown



Chip-coded filter-mirror units allow automatic identification and documentation of the instrument configuration.



Elevating standardization and collaboration to a new level

Universal Setup ensures reproducible and accurate results day to day with stable instrument performance of <0.4%. **(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

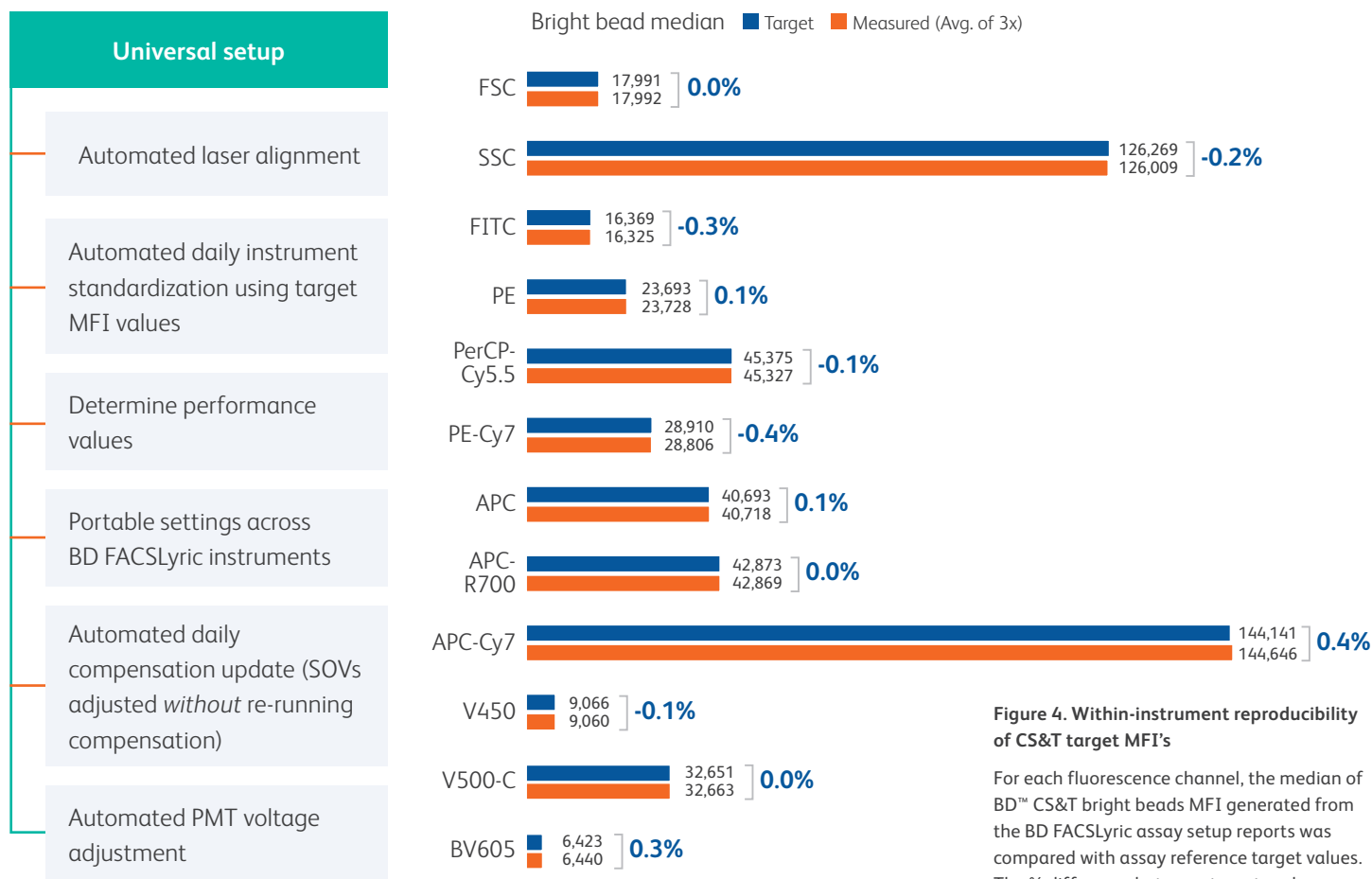


Figure 4. Within-instrument reproducibility of CS&T target MFI's

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™ System 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
- The time required to set up additional instruments is reduced
- Assay portability simplifies and standardizes instrument setup within your lab and between labs, making collaboration effective and efficient

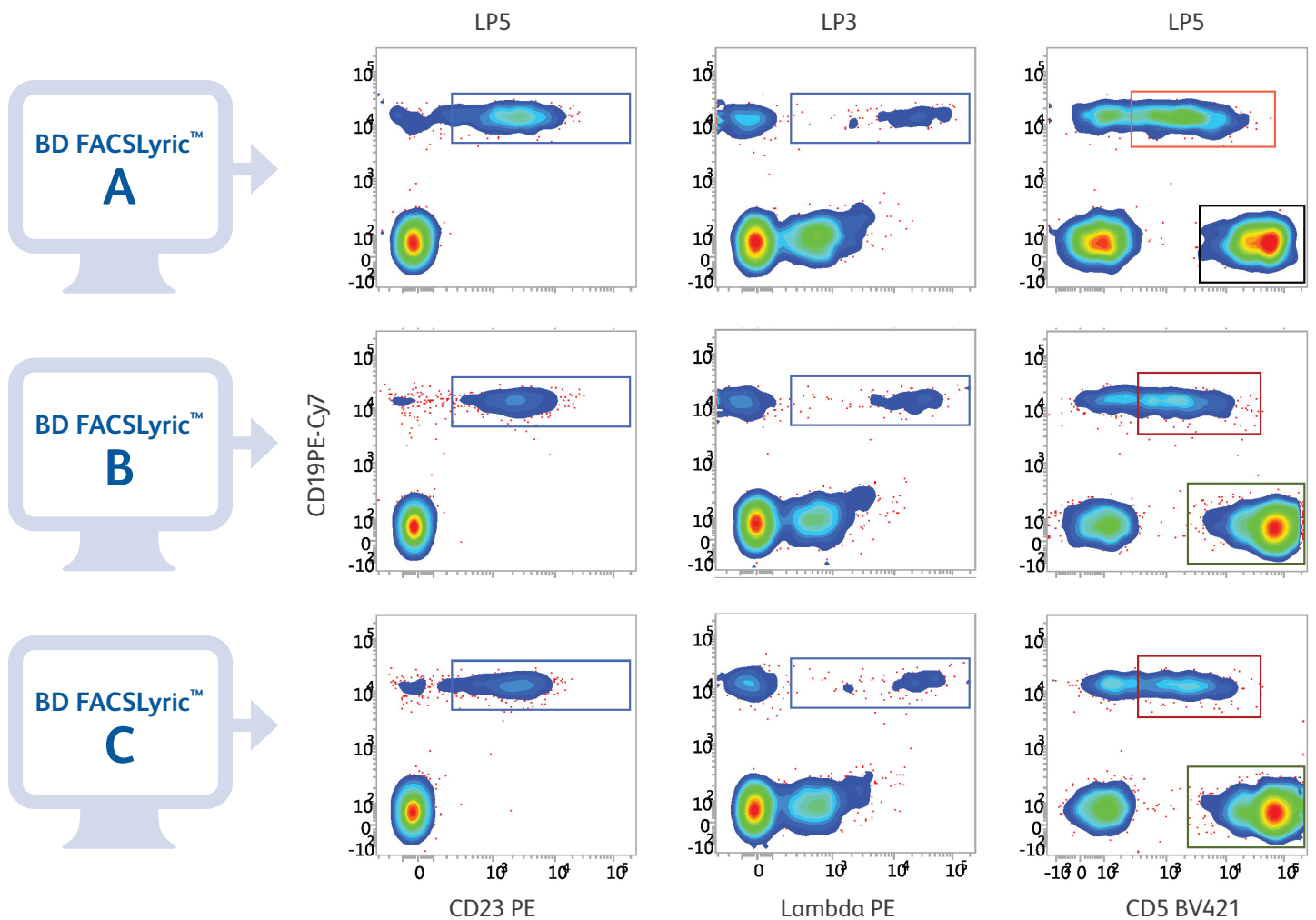
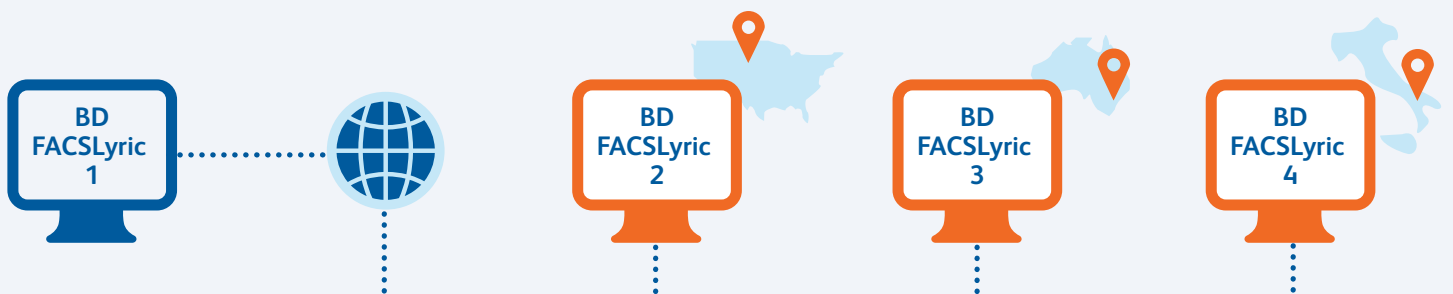


Figure 5. User-defined assay across three instruments shows the reproducible and accurate performance of the BD FACSLyric™ Universal Setup.

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



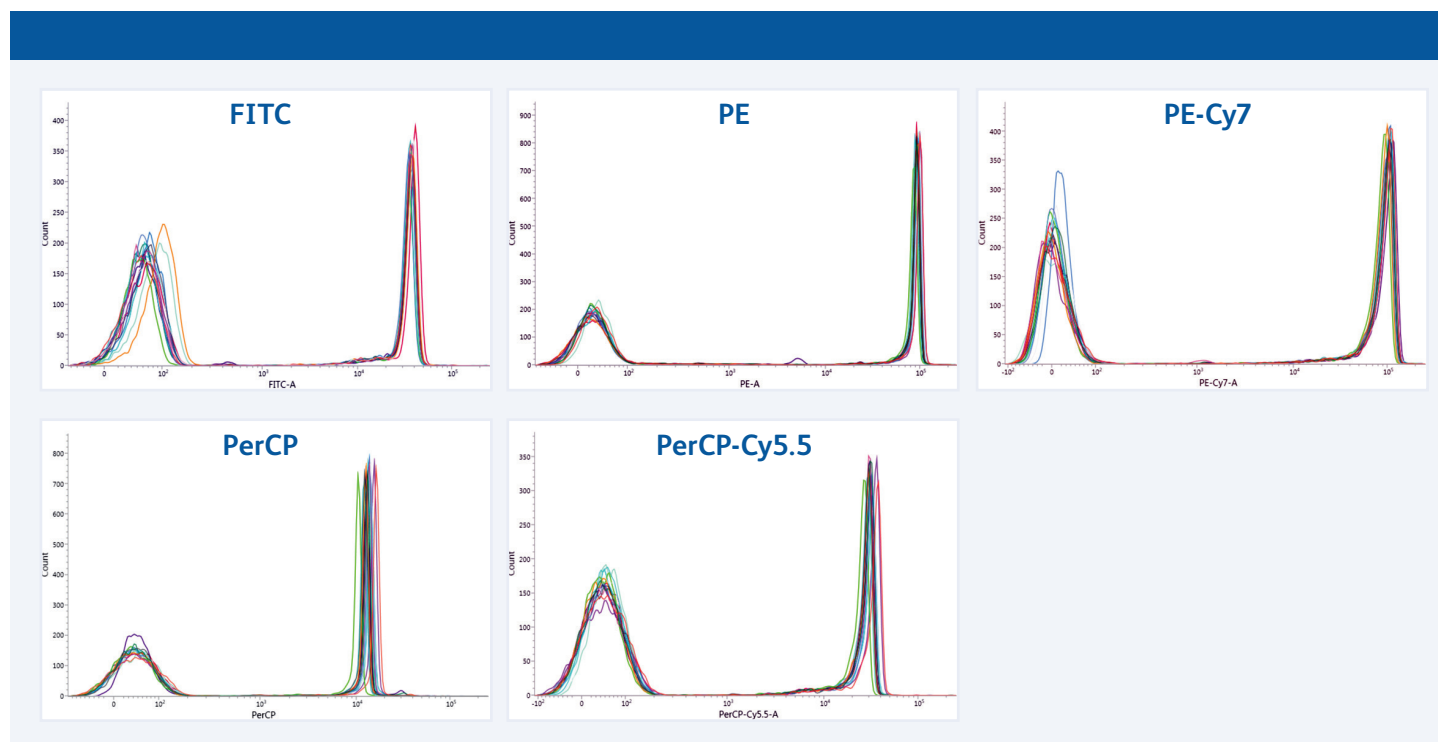
Highly reproducible results between instruments drive standardization.

BD FACSLyric™ Variance (CVs)					
15 BD FACSLyric™ 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-C	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 FACSLyric™ System

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 FACSLyric™ Cytometers. For each instrument, the PMTV gains were automatically adjusted to meet the target values. BD FC beads acquired on each BD FACSLyric™ 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.



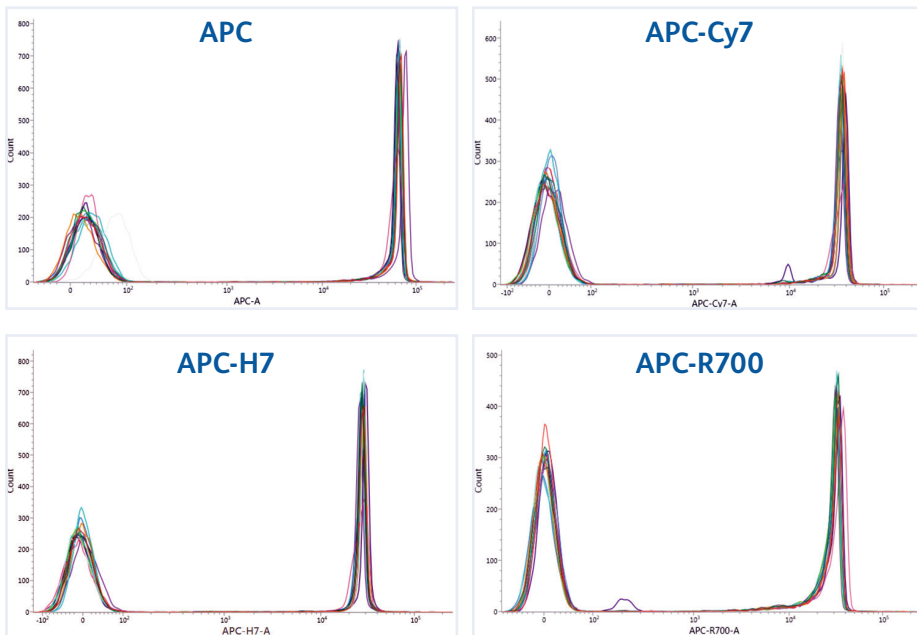
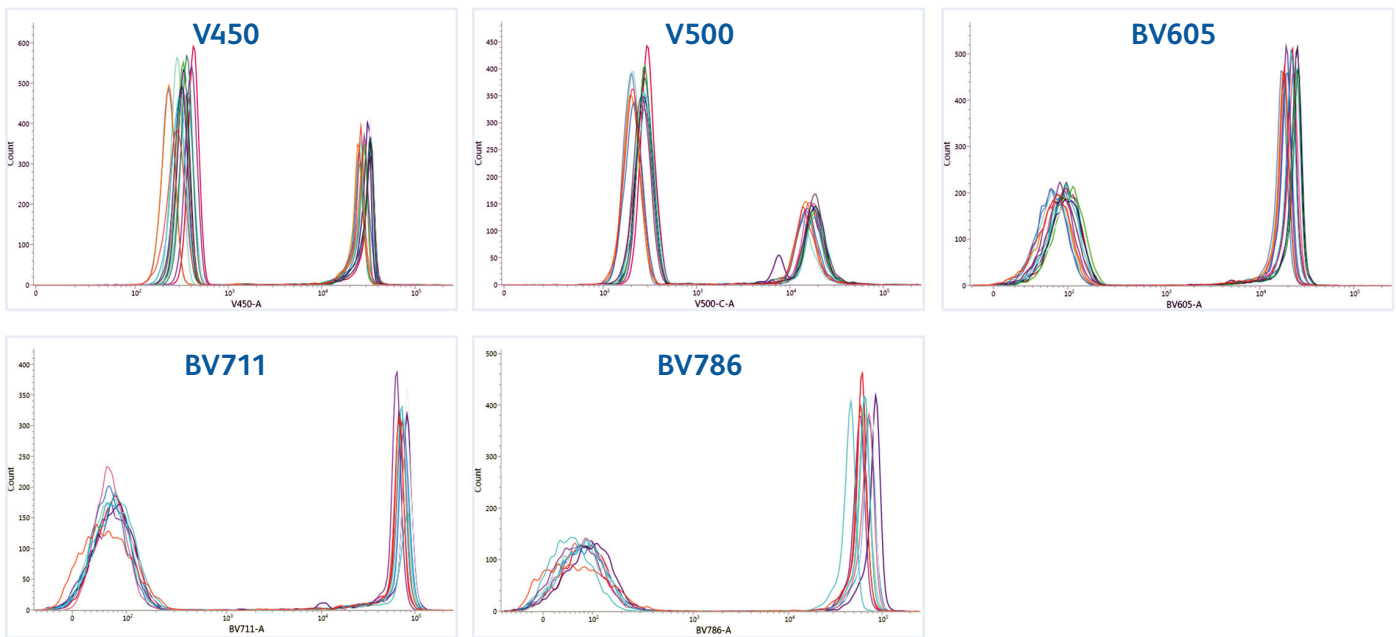


Figure 6. Corresponding overlays of 15 BD FACSLyric™ Systems show between-instrument variability of less than 8% for the red and blue channels

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

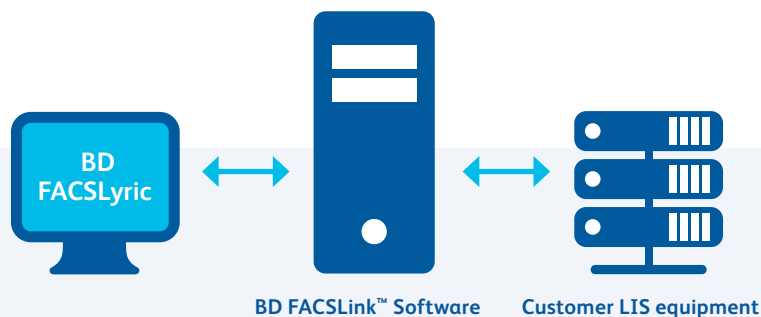
BD FACSuite™ and BD FACSuite™ Clinical Applications

BD FACSuite™ and BD FACSuite™ Clinical Applications are robust and reliable with 21 CFR Part 11 relevant features.

- Next-generation laboratory informatics applications designed to support user-defined and BD IVD assays with predefined assay templates to foster collaboration through the unique assay transfer features.
- Password protection, audit trail, electronic signatures and IQ/OQ procedures relevant to 21 CFR Part 11 and electronic record integrity.
- BD FACSuite™ Application and BD FACSuite™ Clinical Application are two separate applications. Both applications have a similar user interface and application navigation.
- BD ElastiGate™ Technology – machine learning enabled auto-gating algorithm, designed to reduce error-prone manual gating, boost standardization and enhance gating of populations – available on the BD FACSuite™ Application.
- 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™ Application is available for offline analysis
- Simple, reproducible and transferrable assay setup facilitating instrument-to-instrument and site-to-site standardization.

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 includes 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 FACLink™ Software interface solution reduces transcription errors and improves laboratory efficiency.
- Bidirectional transfer of information between your LIS and the BD FACLyric™ System using the BD FACLink™ interface solution reduces transcription errors.
- Remote troubleshooting and support with BD Assurity Linc™ Software enables identification of maintenance needs and off-site technical support.

*Available on the BD FACSuite™ Application

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 +
Page 2 of 2

BD FACSuite™ Clinical Application report

BD 6 Color TBNK + Truc: Lab Report

Sample ID: MC low
Sample Name:
Case Number:

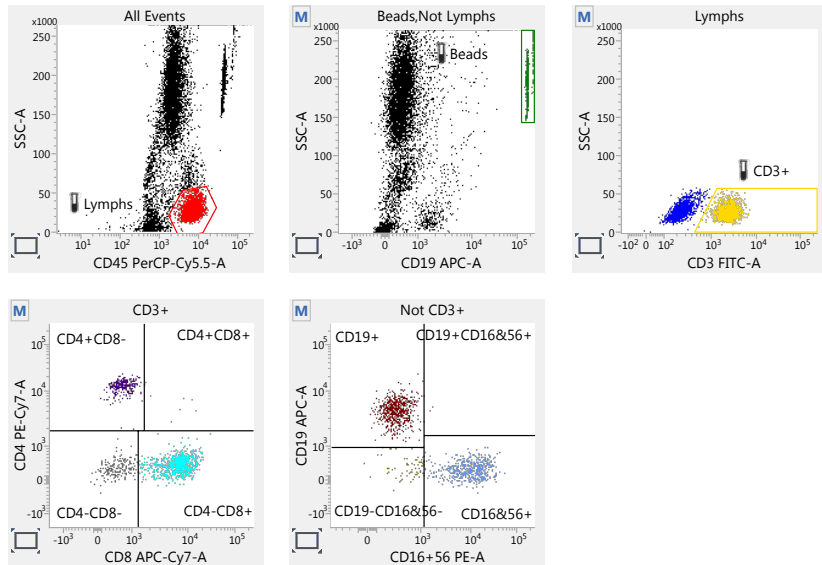
Acquired Using: TBNK Workflow_yz
 Trucount Lot ID: 17066
 Cytometer: BD FACSLyric
 Operator: Lyric Student

Approved: 11/30/2017 2:44:10 PM
 Beads Per Pellet: 49850
 Cytometer SN: R65918000085
 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 **50 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 troubleshooting, onsite preventative maintenance and field service. BD Assurity Linc™ System 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

BD Technical Services is your partner for performance

Maximum uptime

At BD, we understand the cost and consequences of unexpected downtime. Therefore, we are committed to maximizing your system uptime. Contract customers receive priority service compared to customers without a service contract. In addition, remote instrument diagnostics help maximize system uptime by properly troubleshooting issues.

- Responsive on-site repair
- Remote service capability
- Preventive maintenance

Peace of mind

No more wondering how and when your instrument will be repaired. Rest assured knowing you have access to BD service professionals whenever you need them. Having a dedicated project manager during installation helps with effective implementation, accelerates value realization and provides exceptional customer experience.

- Email and chat support
- Unlimited repairs
- Local field service expertise

Predictable expense

Protect your budget from unexpected costs. Our fee that covers both corrective and maintenance-related service needs. Customers also have the option to lock-in their contract price for multiple years.

- No hidden charges
- Extends your service warranty
- Multi-year pricing available

BD FACSLytic™ Flow Cytometers are Class 1 Laser Products.

The BD FACSLytic™ Flow Cytometer is for In Vitro Diagnostic Use with BD FACSuite™ Clinical Application for up to six colors.

The BD FACSLytic™ Flow Cytometer is for Research Use Only with BD FACSuite™ Application for up to 12 colors. Not for use in diagnostic or therapeutic procedures.

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