Lean Data Findings

BD FACSDuet™ Premium Sample Preparation System

Executive Summary

Flow cytometry laboratories are increasingly integrating automation technologies into their routine workflows to meet the challenges of increasing workloads, assay complexity, limited human resources and regulatory requirements.

The BD FACSDuet™ Premium Sample Preparation System, physically integrated with the BD FACSLyric™ Flow Cytometer, is the CE-IVD BD sample-to-answer solution addressing these laboratories workflow challenges. The BD FACSDuet™ Premium Sample Preparation System provides full automated and walkaway end-to-end sample processing including: on-board sample washing and on-board centrifugation, process standardization and reproducibility, flexibility in protocols design, and creation of reagent cocktails.

This e-book gathers five (5) posters that were presented at the 2023 ESCCA (European Society of Clinical Cell Analysis) Conference. They cover representative flow cytometry data* and a collection of Lean Data defined as “Total Process Time” (TPT), “Hands-On Time” (HOT), “Error Prone Tasks” and “Critical Error Prone Tasks”. Lean data was generated at 3 different European laboratories** using well-defined protocols*** to assess:

- Workflow efficiency and throughput: different conditions and with various processing workflows of the BD FACSDuet™ Premium Sample Preparation system (semi-automated or fully automated).(posters #OTH-05, #OTH-06 and #OTH-07)
- Possible concurrent workflow combinations to explore the most efficient use of the system for users with different sample preparation requirements. (poster #OTH-08)
- Impact on human resources, consistency, and flexibility when using the BD FACSDuet™ System for antibody cocktail preparation as compared to manual preparation. (poster #OTH-05)
- Performance* characteristics of samples processed on the BD FACSDuet™ Premium Sample Preparation System compared to manual processing with a 12-color dried research panel. (poster #IMM-20)

* Data generated in BD Biosciences.

** The Institutions involved in Lean data generation were provided with reagents at no cost by BD and compensated by BD at fair market value for their time spent on the test studies.

*** Results presented are applicable to the different sites and specific to the type of protocols, prep methods, assay type, number of specimens and secondary tubes, number of people involved in manual tasks. Results may vary and may not be representative of those measured in other clinical laboratory settings and in different conditions.

Poster # IMM-20

Immunophenotyping of normal whole blood using a 12-color BD Horizon™ Chroma Dried Research Panel on the BD FACSDuet™ Premium Sample Preparation System integrated with the BD FACSLyric™ Flow Cytometer

Farzad Oreizy, Angela Chen, Bao Nguyen, Chih-Hung Lai, Punam Roka, Beverly Lu, Yang Zeng
BD Biosciences, San Jose, CA

Abstract

Traditional workflows in flow cytometry laboratories involve multiple manual processing steps including pipetting multicolor reagent cocktails, washing, staining and lysing. This involves significant hands-on time and is increasingly challenging as the number of parameters rises.

The BD FACSDuet™ Premium Sample Preparation System integrated with the BD FACSLyric™ Flow Cytometer has shown the capacity to reduce the number of error-prone steps while also reducing hands-on time spent acquiring datasets.

BD Horizon™ Chroma Reagents are pre-aliquoted, multicolor cocktails in a dried-down, ready-to-use format with increased shelf life that can be made to order based on user design.

In this study, we evaluated a fully automated workflow using the BD FACSDuet™ Premium Sample Preparation System integrated with the BD FACSLyric™ Flow Cytometer to prepare and acquire 20 normal whole blood samples stained with a 12-color BD Horizon™ Chroma Dried Panel (CD7 FITC/Anti-Lambda PE/CD34 PerCP-Cy5.5/CD19 PE-Cy7/Anti-Kappa APC/CD5 APC-R700/CD20 APC-H7/CD3 V450/CD45 V500-C/CD8 BV605/CD10 BV711/CD4 BV786) and compared it with manual processing. BD FACSLyric™ Flow Cytometer setup and compensation were completed using BD® CS&T Beads, BD® FC Beads and batch-matched BD dried single-color reagents. Sample preparation was fully automated onboard the BD FACSDuet™ Premium Sample Preparation System by rehydrating the dried cocktail, prewashing fresh whole blood, and transferring to the rehydrated reagent tube, followed by a stain/lyse/wash and automatic transfer to the BD FACSLyric™ Flow Cytometer.

Immunophenotyping and characterization was performed for T-cell and B-cell subsets. Overall comparison between automatic and manual sample processing was statistically analyzed and shown in Figure 2 and Table 2.

Method

Study design:

- Specimen and reagents:
  - 20 normal donor peripheral blood samples (EDTA as anticoagulant) processed and stained with a 12-color BD Horizon™ Chroma Dried Panel.
- Method comparison study:
  - Automated method on the BD FACSDuet™ Premium Sample Preparation System integrated with the BD FACSLyric™ Flow Cytometer for sample preparation and data acquisition.
  - Manual method for sample preparation and data acquisition on the same BD FACSLyric™ Flow Cytometer.

Table 1. 12-color BD Horizon™ Chroma Dried Panel

Format	Biomarker	Clone	Cell Population
FITC	CD7	M-T701	T-cell lymphocytes
PE	Lambda	1-155-2	B-cell lymphocytes
PerCP-Cy5.5	CD34	8G12	Early hematopoietic progenitors
PE-Cy7	CD19	SJ25C1	B-cell lymphocytes
APC	Kappa	TB28-2	B-cell lymphocytes
APC-R700	CD5	L17F12	T-cell lymphocytes
APC-H7	CD20	L27	B-cell lymphocytes
BV450	CD3	SK7	T-cell lymphocytes
V500-C	CD45	2D1	Leukocytes
BV605	CD8	SK1	T-cell lymphocytes
BV711	CD10	HI10a	Subset of B-cell lymphocytes and granulocytes
BV786	CD4	SK3	T-cell lymphocytes

Instrument setup:

- The BD FACSLyric™ Flow Cytometer was set up using BD® CS&T Beads. Reference settings were created using BD® FC Beads and batch-matched BD dried single-color reagents (CD19 PE-Cy7, CD5 APC-R700, CD20 APC-H7, CD8 BV605, CD10 BV711, CD4 BV786).
- PQC and Assay/tube settings setup were run and passed acceptance criteria before samples were processed and acquired.

Assay Setup:

- A user-defined assay was created in BD FACSuite™ Application v1.5 for the comparison study and published to the BD FACSDuet™ Premium System.
- A 2-tube assay was created on the BD FACSDuet™ Premium Sample Preparation System for sample preparation
  - The 1st tube is for the Pre-Wash preparation steps
  - The 2nd tube is for the Stain/Lyse/Wash preparation steps

Results

Figure 1. Workflow description

Automated process | Manual process

Sample Prewash

- Prewash donor whole blood sample (300 µL) using 3 mL of wash buffer (1X PBS + 0.5% BSA +0.1% NaN3) on the BD FACSDuet™ Premium Sample Preparation System with 4x automated wash steps
- Prewash whole blood sample from the same donor (1000 µL) using 10 mL of wash buffer with 3x wash step

Sample staining and processing

Note: all steps are automated onboard the FACSDuet™ Premium Sample Preparation System

- Re-hydrate the 12-color BD Horizon ™ Chroma Dried Panel tubes with 50 µL of BD Horizon™ Brilliant Stain Buffer (BSB).
- Transfer 100 µL of prewashed samples to the rehydrated reagent tube to stain cells for 30 min.
- Lyse for 10 min with 1X BD FACS™ Lysing Solution followed by centrifugation
- Wash cells with 2 mL of wash buffer 2 times.
- Resuspend cells by adding 450 µL of wash buffer.

- Re-hydrate the 12-color BD Horizon™ Chroma Dried Panel tubes with 50 µL of BSB
- Transfer 100 µL of pre-washed samples to the rehydrated reagent tube to stain cells for 30 min.
- Lyse for 10 min with 1X BD FACS™ Lysing Solution followed by centrifugation
- Wash cells with 2 mL of wash buffer 2 times
- Resuspend cells by adding 300 µL of wash buffer.

Flow cytometry acquisition

- Worklist was automatically published to the BD FACSLyric™ Flow Cytometer
- Prepared samples were automatically delivered to the physically integrated BD FACSLyric™ Flow Cytometer for acquisition.

- Manually create worklist on the BD FACSLyric™ Flow Cytometer
- Prepared samples were manually acquired on the same BD FACSLyric™ Flow Cytometer

Data Analysis

- Both automatically and manually collected data were analyzed using BD FACSuite™ Application V1.5.
- Doublets and debris were excluded during gating
- Lymphocyte subsets were further gated and analyzed based on T-cell and B- cell biomarkers.

Figure 3. Box plot of cell percentages

Compare automated vs manual processing using normal donor blood (N=20)

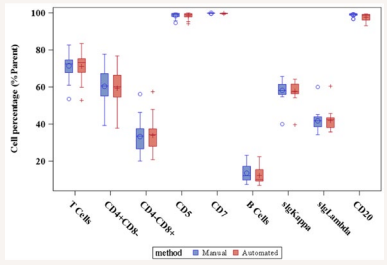


Figure 4. Gating Hierarchy

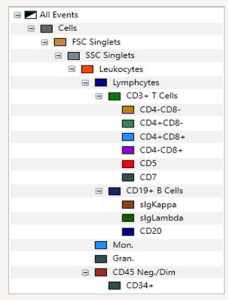
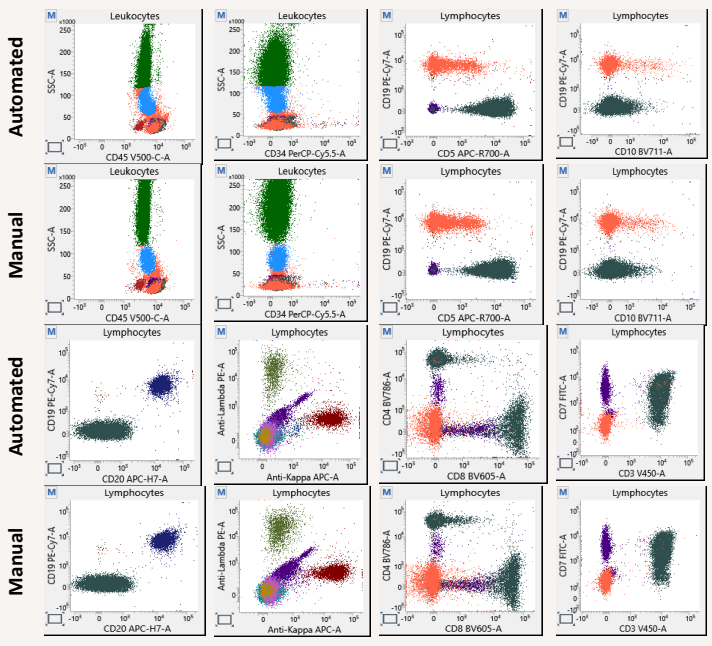


Table 2. Comparison of automated vs manual method on %Cell %Parent of normal peripheral blood (N = 20)

Parameter	Parent	Mean Automated	Mean Manual	Mean %Diff with 95% CI
CD19+ B cells	Lymphocytes	12.2	13.5	-9.5 (-11.8, -7.26)
CD20+ B cells	CD19+ B cells	97.6	99.0	-1.4 (-2.3, -0.5)
Anti-Lambda+ B cells	CD19+ B cells	41.9	41.7	0.5 (-0.5, 1.5)
Anti-Kappa+ B cells	CD19+ B cells	57.8	58.2	-0.7 (-1.5, 0)
CD3+ T cells	Lymphocytes	71.1	71.4	-0.4 (-1.4, 0.6)
CD8+ T cells	CD3+ T cells	33.9	33.3	1.9 (0.6, 3.2)
CD4+ T cells	CD3+ T cells	59.3	60.4	-1.8 (-2.5, -1.1)
CD7+ T cells	CD3+ T cells	99.7	99.8	-0.1 (-0.2, -0.1)
CD5+ T cells	CD3+ T cells	98.4	98.6	-0.2 (-0.2, -0.1)

Results

Figure 2. Dot plot comparison between automated and manual methods using 12-color BD Horizon™ Chroma Dried Panel



Conclusions

- We assessed performance of the 12-color BD Horizon™ Chroma Dried Panel using 20 normal donor whole blood samples to compare two methods: manual sample processing/acquisition and automated method onboard of the BD FACSDuet™ Premium Sample Preparation System integrated with the BD FACSLyric™ Flow Cytometer.
- We demonstrated a sample-to-results automated workflow for the dried reagents using a two-tube preparation method on the BD FACSDuet™ Premium Sample Preparation System physically integrated with the BD FACSLyric™ Flow Cytometer.
- The fully automated workflow resulted in comparable dot plot distribution and cell percentages relative to conventional manual method.

Disclaimers: This research is scientific in nature.
BD FACSDuet™ Premium Sample Preparation System and BD Flow Cytometers are Class 1 Laser Products.

CE The BD FACSDuet™ Premium Sample Preparation System, the BD FACSLyric™ Flow Cytometer with the BD FACSuite™ Clinical and BD FACSuite™ Applications, BD FACS™ Lysing Solution, BD® CS&T Beads (656504, 656505), BD® FC Beads 5-Color Kit (661564), BD® FC Beads 7-Color Kit (656867) are in vitro diagnostic medical device bearing a CE mark.

CE 2797 CE-IVD single color reagents 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).

BD Horizon™ Chroma Dried Panel, BD Horizon™ Brilliant Stain Buffer and RUO Single Color Reagents are for Research Use Only. Not for use in diagnostic or therapeutic procedures.
BD CS&T Beads (662414) and BD™ FC Beads 7-Color Kit (662961) are in vitro diagnostic medical devices available to US market and are not available for EMEA region.

BD, the BD Logo, BD FACSDuet, BD FACSLyric, BD FACSLyse, BD FACSuite and Horizon are trademarks of Becton, Dickinson and Company or its affiliates.
© 2023 BD. All rights reserved. BD-104313 (v1.0) 0923

Cy is a trademark of Global Life Sciences Solutions Germany GmbH or an affiliate doing business as Cytiva.

Poster OTH-05

The impact on human resource, flexibility and consistency with the BD FACSDuet™ Premium Sample Preparation System versus manual processing.

David Bloxham, Fiona Cullen: Cambridge University Hospitals NHS Foundation Trust , Addenbrooke's Hospital, Cambridge Biomedical Campus, Cambridge CB2 0QQ, UK
Lori Apoll, Lucia Testolin, Nicolas Bailly, and David Sowter: BD Biosciences, San Jose, CA, 95131, US.

NHS Cambridge University Hospitals NHS Foundation Trust

Introduction

- The growing capability of flow cytometry analysers allows users to increase the complexity of immunophenotyping investigations to facilitate more efficient and accurate diagnoses.
- The preparation of multi-colour antibody cocktails is an error prone process requiring high levels of competence, concentration and manual dexterity.
- The downstream impact of errors can be severe, including misdiagnosis, inappropriate clinical decision making, and significant financial losses.
- Manufacturer developed CE-IVD compliant dried reagents may reduce the risk of error but can be limited in scope.
- Laboratories may require the flexibility to use a combination of approaches.
- The BD FACSDuet™ and BD FACSDuet™ Premium Sample Preparation devices offer fully automated sample preparation with integration of the BD FACSLyric™ Flow Cytometer to provide end to end sample processing including bespoke cocktail production and sample processing protocols which allow flexible use of reagents.

Aims

- Compare fully automated sample processing using the BD FACSDuet™ Premium Sample Preparation System with manual sample processing using:
  - Dried antibody reagents
  - Liquid reagents pipetted individually
  - Cocktailed reagents prepared using automation
- Assess the two workstreams in relation to:
  - Total Process Times
  - Hands-On Time
  - Error/risk Prone Steps

Conclusions

When compared to manual processing, automation with the BD FACSDuet™ Premium Sample Preparation System provides:

- rapid preparation of complex, multi-colour antibody cocktails from any manufacturer
- significant saving of hands-on time
- reduction of error prone tasks
- consistent, reproducible preparation processes
- a complete and fully searchable audit trail
- user defined flexibility

Analysis & Results

Antibody Cocktail Preparation

Table 1: Cocktail Preparation: TPT and HOT

	TPT/ Ab	TPT Range	HOT/ Ab	HOT Range
BD FACSDuet™ System cocktail preparation	0:00:44		0:00:24	
Manual cocktail Preparation	0:00:45	00:00:18 - 00:01:40	0:03:01	00:00:37 - 00:03:21

Processing times are predictable and consistent using automated cocktail preparation

- Manual cocktail preparation shows high variability in process times (Table 1, TPT Range)
- This may be due to operator experience, requirement for additional reagents, interruptions/distractions

Automated cocktail preparation significantly reduces Hands-On Time (HOT)

- Manual record keeping increases HOT during cocktail preparation
- Automated cocktail preparation using the BD FACSDuet™ Sample Preparation System* provides fully searchable records

* Both BD FACSDuet™ Sample Preparation System and BD FACSDuet™ Premium Sample Preparation System provide cocktailing functionality

Automated cocktail preparation using the BD FACSDuet™ Sample Preparation System eliminates error prone tasks

- Manual cocktail preparation has a high risk of error (Table 2)
- Tasks within the process may have several potential sources of error (identification, volume pipetted, documentation)
- Barcoded reagents remove the risk of adding incorrect reagents
- All tasks are fully documented on the BD FACSDuet™ Sample Preparation System providing searchable records for audit and regulatory requirements

Table 2: Cocktail Preparation: Error Prone Tasks

	Tasks	Error Prone Tasks	%EPT
BD FACSDuet™ System cocktail preparation	19	0	0.0%
Manual cocktail Preparation	48	70	145.8%

Total Workflow Assessment

Table 3: Time for tasks

	TPT	HOT	Tasks	Error prone	% Error Prone	% HOT	% reduction of HOT BD FACSDuet™ System time compared to Manual
BD FACSDuet™ System - Single Reagent	02:05:57	00:07:39	17	0	0.00%	6.10%	80.20%
Manual Single Reagent (average of runs 1-3)	01:40:28	00:38:39	87	67	77.00%	38.50%	
BD FACSDuet™ System - Precocktailed	02:05:34	00:08:32	7	0	0.00%	6.80%	66.70%
Manual Precocktailed (average of runs 1-3)	01:37:56	00:25:36	45	12	26.70%	26.10%	
BD FACSDuet™ System - Dry	01:54:03	00:06:10	7	2	28.60%	5.40%	47.60%
Manual Dry (average of runs 1-3)	01:32:08	00:11:47	44	4	9.10%	12.80%	

Figure 1: TPT and HOT for tasks

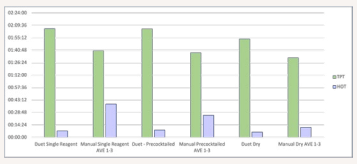
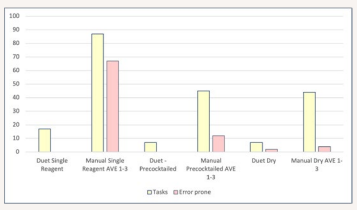


Figure 2: Tasks and Error Prone tasks



Automated sample processing significantly reduces Hands-On Time, irrespective of reagent choice

- During manual processing the total HOT requirement was similar across all three reagent conditions (5.4-6.8% of total processing time)
- Automation offers significant reductions in HOT (Table 3 & Figure 1)
- The most significant reduction in HOT is seen for single reagent pipetting requiring less than 20% of the human resource needed for manual processing

Error Prone Tasks can be eliminated when using automated sample processing (Table 3 & Figure 2)

- Barcoded reagents prevent the use of erroneous or out of date reagents during single reagent dispensing and cocktail production.
- Reagent library configuration standardizes the volume of reagent used
- Integration with LIMS prevents the requisition of incorrect assays

Choice of reagent format has no significant impact on Total Process Times (TPT)

- TPTs are increased when using fully automated sample processing by an average of 25% (range 23-28%)
- Laboratories can flexibly combine different reagent options using bespoke protocols

The use of automated sample processing allows for the redistribution of human resources

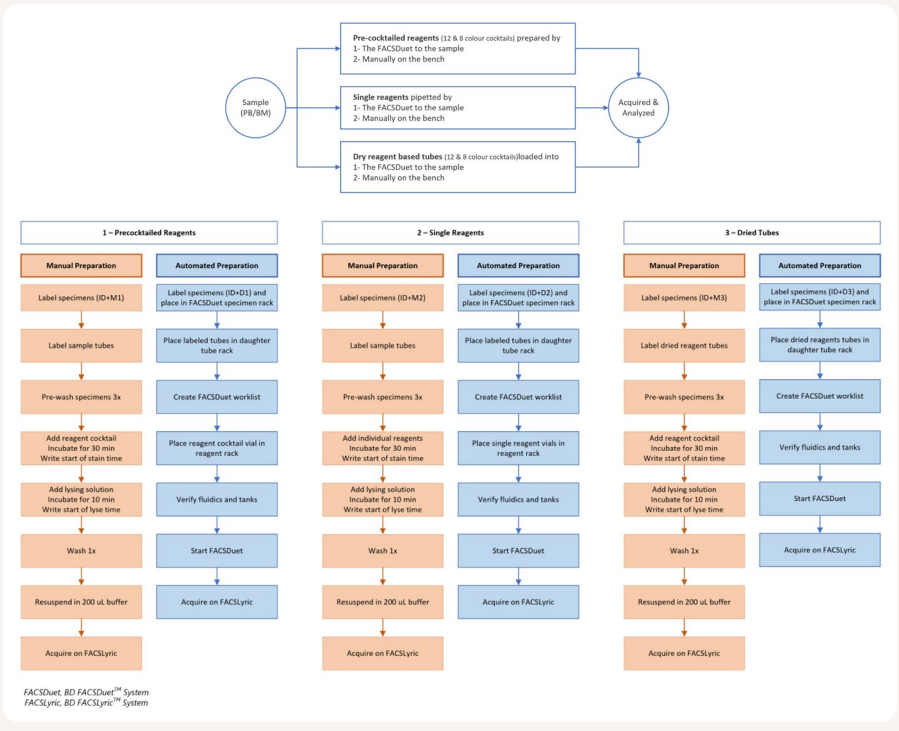
- Flow cytometry represents only one aspect of the overall sample pathway
- Predictable processing times allows the reallocation of resources to other aspects of the process
- Scientific staff time can be utilised for interpretative tasks

Method

Three different antibody formats were tested during this study:

a. single dispensed reagents
b. pre-cocktailed reagents
c. dry reagent tubes

- Samples were set up using both traditional manual and automated BD FACSDuet™ Premium Sample Preparation System physically integrated with the BD FACSLyric™ Flow Cytometer.
- Antibodies in the two-tube testing method consisted of a screening tube containing a 12 antibody panel and a second tube with an 8 antibody panel.
- Additional data was collected for manual cocktail creation to reflect variation in processing times associated with cocktails of differing levels of complexity and staff with differing levels of experience.



Data collection

The Lean component of this study used timers, paper logging, and video to capture the Total Process Time (TPT), Hands-On Time (HOT), and Error Prone Tasks (EPT) for time and motion. The time captured is from "Start of sample prep" to "ready for acquisition".

- Using calibrated timers, video equipment was aligned with the instrumentation to ensure accuracy of record times (hh:mm:ss) for each step in the process to capture Total Process Time and Hands-On Time. Steps were also evaluated as to whether they were considered error prone.
- No patient identification was captured in documentation or by video equipment.
- Along with video equipment for tracking processes, paper records were made during the process in conjunction with the sites SOP.
- Lean specialists with a background in flow cytometry are crucial in identifying all steps and in the determination of error prone steps or deviations from SOP's that may lead to bias in the results.
- Laboratory staff performed tasks uninterrupted by the lean specialist to ensure there were no disruptions in the times observed or distractions from the SOPs.

This research is scientific in nature.

BD Biosciences provided materials and instruments for this study.

BD FACSDuet™ Sample Preparation System, the BD FACSDuet™ Premium Sample Preparation System and BD Flow Cytometers are Class I Laser Products.

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

BD, the BD Logo, BD FACSDuet™ , BD FACSLyric™, BD FACSuite™ are trademarks of Becton, Dickinson and Company or its affiliates. © 2023 BD. All rights reserved. BD-104314 (v1.0) 0923

Workflow assessment case study in batching samples for high throughput or running consecutively in single runs in multiple sites on the BD FACSDuet™ Premium Sample Preparation System

David Bloxham, Fiona Cullen, Cambridge University Hospitals NHS Foundation Trust , Addenbrooke's Hospital, Cambridge Biomedical Campus, Cambridge CB2 0QQ, UK.
Marco Chiarini, Anna Galvagni, Viviana Giustini, Daniele Moratto, Duilio Brugnoni: Flow Cytometry Unit, Clinical Chemistry Laboratory, ASST Spedali Civili of Brescia, 25123 Brescia, Italy.
Lori Apoll, Lucia Testolin, Nicolas Bailly, Manuele Ongari, David Sowter, and Ira Racoma: BD Biosciences, San Jose, CA 95131, U.S.

Introduction

- Flow cytometry laboratories are increasingly integrating (semi) automated technologies into their routine workflows to meet the challenges of increasing workloads, assay complexity, limited human resources and regulatory requirements.
- The key areas in which automation can have the greatest impact are:
  - Reduction of Hands-On Time (HOT).
  - Reduction in Error Prone Tasks (EPT).
  - Process standardization and reproducibility.
- The BD FACSDuet™ Premium Sample Preparation System is a fully automated sample preparation device which integrates with the BD FACSLyric™ Flow Cytometer providing end to end sample processing including on-board sample washing and centrifugation.

Aims

- Compare fully automated sample processing with manually prewashed specimens completed on automation using:
  - Total sample processing time for both batched specimens and single specimens run consecutively.
  - Total hands-on time required during sample processing.
  - Number of error prone tasks.

Conclusions

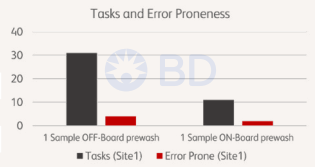
- BD FACSDuet™ Premium Sample Preparation System provides reproducible and predictable sample processing times.
- Hands-on time and error prone tasks are reduced when processes are fully (physically and digitally) automated.
- Sample throughput can be increased by batched sample processing.
- Maintaining some manual components, such as off-board pre-wash, may further increase throughput but could also increase variability, impact quality and increase error prone tasks.

Analysis & Results

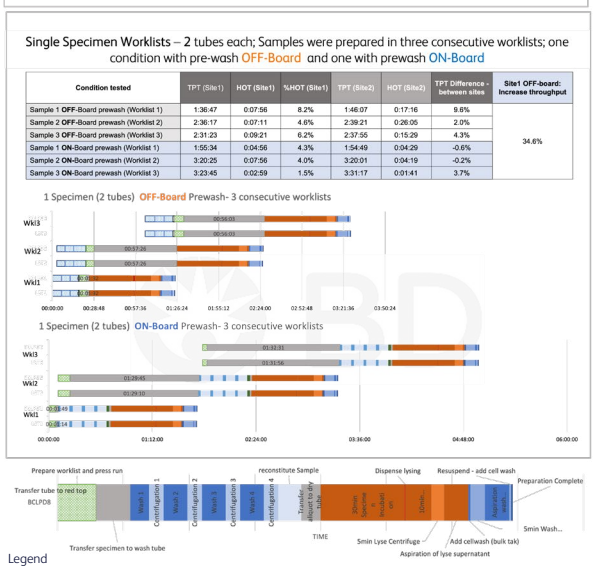
Hands-On Time (HOT) and Error Prone Tasks are significantly reduced by use of BD FACSDuet™ Premium Sample Preparation System for fully automated sample processing

- HOT was significantly lower (1.5% to 5.6% of TPT) compared to samples prewashed prior to completion on automation (4.6% to 12.7% of TPT).
- Assuming the use of an integrated laboratory information system, fully automated sample processing reduces the number of tasks by 64.5%, and reduces the Error Prone Tasks by 50%
- Error Prone Tasks could be further reduced with the use of barcoded reagents on the BD FACSDuet™ Premium Sample Preparation System.

Condition tested	Tasks (Site1)	Error Prone (Site1)	%ERR
1 Sample OFF-Board prewash	31	4	12.9%
1 Sample ON-Board prewash	11	2	18.2%
Reduction with ON-Board prewash	64.5%	50.0%	



The total number of tasks and error prone tasks was determined for both sample handling procedures.



Fully automated processing provides more predictable Total Process Times (TPT)

- Lower variation in TPT was observed across both sites (0.2% to 3.7% variation) when compared to specimens prewashed prior to completion on automation (2.0% to 23.5% variation).
- Fewer manual interventions removes delays associated with human resource availability
- TPTs may be further impacted by variability of sample quality/cellularity impacting on acquisition time affecting throughput (data not included).

Batched sample processing increases sample throughput

- When using fully automated processes, TPT observed for batched 8 specimens (16 tubes) was 37.8% faster than TPT for 3 consecutive worklists with 3 single specimens (6 tubes). While the number of tubes differ between the two scenarios, this comparison is helpful in assessing the value of batching specimens to increase throughput and could be used in tandem with consecutive worklists depending on sample arrival into the laboratory.

Fully Automated Runs	TPT (Site1)	Batching time gain
8 Samples (1 worklist)	3:15:03	37.8%
Sample 1-3 (3 worklists)	5:13:34	

- Samples run in consecutive worklists may be inaccessible during the time between loading and start of stain in some run scenarios (those that include washing steps), precluding their use in other laboratory processes.
- Prewashing specimens prior completion on automation may increase throughput by 34.6% to 42.2%. The impact of delayed time to processing on specimen quality requires further assessment.

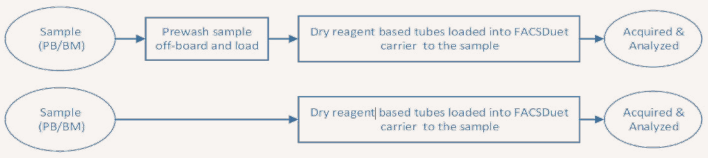
Variability between sites reflects the 'real world' challenges faced by flow cytometry laboratories

- Less predictable TPTs and increased HOT when processing manually prewashed samples were observed on both sites which may be impacted by:
  - Availability of staff due to conflicting pressures (assisting others, answering telephone calls/queries etc.)
  - Laboratory layout and access to shared equipment (centrifuges, pipettes)
  - Variations in sample processing (choice of method of supernatant removal for example)

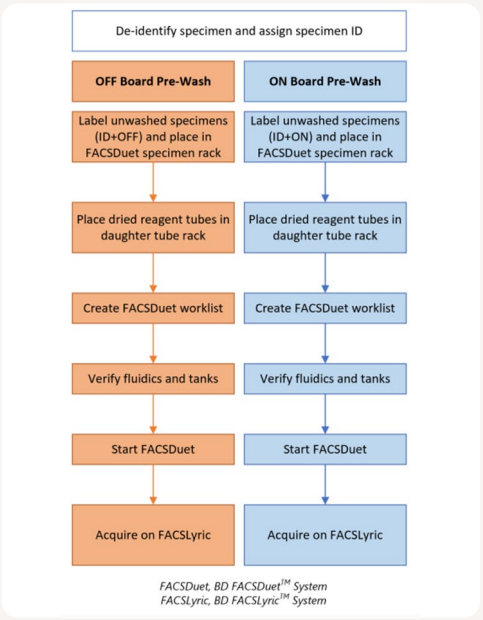
Please note: TPT, HOT and Error Prone Tasks are highly dependent on the method used for preparation, etc. , meaning that this data may not be representative of what other labs may achieve . However, if the exportable preparation protocol option on the BD FACSDuet™ Premium Sample Preparation System is used, the automated portion of the preparation can be standardized within labs and across collaborating labs.

Study Design and Method

Study Design



Specimen processing was completed at two sites using (a) full automation (BD FACSDuet™ Premium Sample Preparation System), inclusive of sample pre-washes, compared to (b) manual prewashing with process completed on automation (BD FACSDuet™ Premium Sample Preparation System). All manual prewash steps were matched on the automation. Total Processing Times (TPT), Hands-On Time (HOT), and number of Error Prone Tasks (EPT) were assessed on the following: (1) single specimen with two secondary tubes; (2) three consecutive worklists with a single specimen of two secondary tubes; and (3) batch of 8 specimens with 16 secondary tubes.



Data collection

The Lean component of this study used timers, paper logging, and video to capture the Total Process Time (TPT), Hands-On Time (HOT), and Error Prone Tasks (EPT) for time and motion. The time captured is from "Start of sample prep" to "ready for acquisition".

- Using calibrated timers, video equipment was aligned with the instrumentation to ensure accuracy of record times (hh:mm:ss) for each step in the process to capture Total Process Time and Hands-On Time. Steps were also evaluated as to whether they were considered error prone.
- No patient identification was captured in documentation or by video equipment.
- Along with video equipment for tracking processes, paper records were made during the process in conjunction with the sites SOP.
- Lean specialists with a background in flow cytometry are crucial in identifying all steps and in the determination of error prone steps or deviations from SOP's that may lead to bias in the results.
- Laboratory staff performed tasks uninterrupted by the lean specialist to ensure there were no disruptions in the times observed or distractions from the SOPs.

This research is scientific in nature

BD Biosciences provided materials and instruments for this study.

Disclaimers:
BD FACSDuet™ Premium Sample Preparation System and BD Flow Cytometers are Class I Laser Products.

CE The BD FACSDuet™ Premium Sample Preparation System and BD FACSLyric™ Flow Cytometer with the BD FACSuite™ Clinical and BD FACSuite™ Applications are in vitro diagnostic medical devices bearing a CE mark.

BD, the BD Logo, BD FACSDuet™, BD FACSLyric™, BD FACSuite™ are trademarks of Becton, Dickinson and Company or its affiliates. © 2023 BD. All rights reserved. BD-104315 (v1.0) 0923

Poster # OTH-07

Flexibility in sample preparation for laboratories running on a Single Sample Preparation device with alternatives in post-stain washing.

Marco Chiarini, Anna Galvagni, Viviana Giustini, Daniele Moratto, Duilio Brugnoni: Flow Cytometry Unit, Clinical Chemistry Laboratory, ASST Spedali Civili of Brescia, 25123 Brescia, Italy.
Jana De Wolf, Annick Willems, Mattias Hofmans: Department of Laboratory Medicine, Ghent University Hospital, 9000 Ghent, Belgium.
Ira Racoma, Lori Apoll, Lucia Testolin; Maureen Martin, Nicolas Bailly, Anne-Catherine Dolens, Manuele Ongari: BD Biosciences, San Jose, CA 95131, U.S.

Introduction

Advanced sample preparation automation in flow cytometry laboratories utilizes on-board centrifugation to process samples, similar to bench processing. For laboratories running both Lyse-No-Wash and Lyse-Wash assays and without a system with on-board washing capabilities and/or using methods requiring system off-board procedure, a post-stain off-board wash processing might be advantageous for workflow purposes.

The BD FACSDuet™ Premium Sample Preparation System is a fully automated sample preparation device with on-board sample washing and on-board centrifugation and was used to assess a post-stain on-board wash method compared with two semi-automated / manual workflows with post-stain off-board wash.

Metrics measured were a) Total Process Time (TPT) for both fully automated workflows and workflows with post-stain off-board washes; and b) Hands-On Time (HOT) required during sample processing.

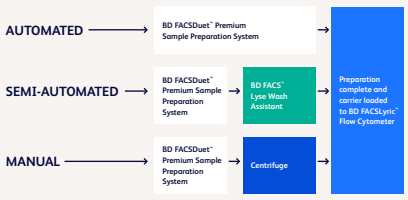
Method

Two sites participated in this study. They compared two post-stain off-board wash methods with a fully automated post-stain on-board wash one. (Figure 1)

In the specific, for all three (3) conditions, a BD FACSDuet™ Premium Sample Preparation System physically integrated with a BD FACSLyric™ Flow Cytometer for automated transfer and acquisition of stained and washed samples were used. Pre-washed off-board specimens (excluded from time measurements) and secondary tubes containing dried reagents were loaded on the BD FACSDuet™ Premium System. All scenarios were run with 16 secondary tubes.

1. The entire AUTOMATED process - comprising of specimen dispensing to secondary tube, reagent incubation, lysing addition and incubation, 3x post-stain washes - was performed on board of the BD FACSDuet™ Premium Sample Preparation System; stained samples were automatically transferred for acquisition on to the physically integrated BD FACSLyric™ Flow Cytometer.
2. The process from specimen dispensing to lysing was performed on board of the BD FACSDuet™ Premium Sample Preparation System, followed by off-board removal of stained and lysed samples for SEMI-AUTOMATED off-board washes on a BD FACS™ Lyse Wash Assistant (LWA), and loading of the off-board washed samples to the BD FACSLyric™ Flow Cytometer for acquisition. (further details in Table 1)
3. The process from specimen dispensing to lysing was performed on board of the BD FACSDuet™ Premium Sample Preparation System, followed by off-board removal of stained and lysed samples for MANUAL off-board washes on a laboratory centrifuge, and loading of the off-board washed samples to the BD FACSLyric™ Flow Cytometer for acquisition. (further details in Table 2)

Figure 1: Workflows



Please note: TPT, HOT and Error prone tasks are highly dependent on the method used for preparation, etc. Meaning that this data may not be representative of what other labs may achieve . However, if the exportable preparation protocol option on the BD FACSDuet™ Premium Sample Preparation System is used, the automated portion of the preparation can be standardized within labs and across collaborating labs.

Analysis & Results

Samples were tested using the methods described in Tables 1 & 2 in comparison to complete processing on the BD FACSDuet™ Premium Sample Preparation System.

- Process times started with "Run Worklist" to remove any variability attributed to the manual technique used by the laboratory in loading the BD FACSDuet™ Premium Sample Preparation System with specimen, secondary tubes, reagents.
- The fully automated process had neither post-stain manual intervention nor Hands-On time in the measured process being assessed (Table 3)

Comparisons at both sites demonstrated no difference between preparation with full BD FACSDuet™ Premium sample processing with 0.0% HOT (Figure 2 and Table 3) and TPT (Figure 3 and Table 4).

Post-stain off-board wash using semi-automated BD FACS™ LWA showed 0.6% faster TPT between sites (TABLE 4), with average 1.5% HOT (Table 3).

Post-stain off-board wash using traditional (manual) centrifugation had TPT 21.9% longer at Site 2 (Table 4) with average HOT across both sites of 30.3%. (Table 3).

Full automation with BD FACSDuet™ Premium Sample Preparation System might not decrease total process time but reduces hands-on-time and hands-on tasks, reducing the risk for errors.

Table 1: SEMI-AUTOMATED Post Stain method

BD FACSDuet™ Premium Sample Preparation System to BD FACS™ Lyse Wash Assistant	
Process on BD FACSDuet™ Premium Sample Preparation Syste	Process from specimen dispensing to lyse incubation Carrier was unloaded for post-stain off-board wash
Process for washing on BD FACS™ LWA (IVD protocol WASH Only)	Wash procedure on each sample tube uses 6,4ml BD® CellWASH
	Cells are pelleted in 10 sec at a precipitation G force of 461g, the buffer is added while the tube is spinning at a Wash G force of 350g at a flow rate of 800ul/sec.
	Approximately 350uL of residual cell suspension remains in each tube after the wash procedure
	At the end of the WASH Only procedure, the instrument takes 2 extra minutes to wash the spindle and the tubing; during this time, the cell suspensions cannot be unloaded.

Table 2: MANUAL Post Stain method

BD FACSDuet™ Premium Sample Preparation System to Centrifuge	
Process on BD FACSDuet™ Premium Sample Preparation System	Process from specimen dispensing to lyse incubation Carrier was unloaded for post-stain off-board wash
Process for washing on BD FACS™ LWA (IVD protocol WASH Only)	5min Lyse Centrifuge
	Aspiration of lyse supernatant
	Add BD® CellWASH (bulk tank)
	5min Wash Centrifugation (incl. wash disp)
	Aspiration wash supernatant
	Resuspend - add BD® CellWASH
	Preparation Complete - ready to run on BD FACSLyric™ Flow Cytometer

Figure 2: Hands-On Time and Total process Time

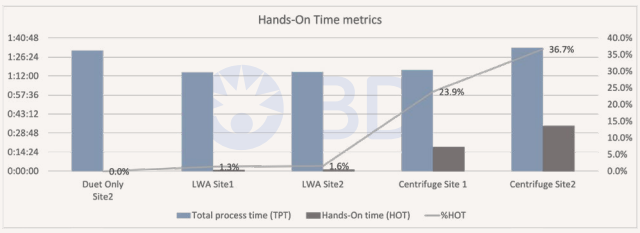


Table 3: Hands-On Time

Description	BD FACSDuet™ Premium System Only Site2	BD FACS™ LWA Site 1	BD FACS™ LWA Site 2	Lab Centrifuge Site 1	Lab Centrifuge Site 2
Total process time (TPT)	1:31:21	1:14:53	1:15:21	1:16:46	1:33:33
Hands-On time (HOT)	0:00:00	0:01:00		0:18:21	0:34:19
%HOT	0.0%	1.3%	0:01:12	23.9%	36.7%
%Difference HOT Site1 to Site2			-0.6%		-21.9%
Average HOT	0.0%		1.5%		30.3%

Site 1: University Hospital Ghent – Belgium
Site 2: ASST degli Spedali Civili Brescia - Italy

Advantages in having flexibility to do off-board tasks were, but not limited to:

- Use for Lyse-Wash assays on a BD FACSDuet™ Sample Preparation System without washing and centrifugation capabilities.
- Increase throughput with multiple worklists/carriers prepped by one BD FACSDuet™ Sample Preparation System and/or BD FACSDuet™ Premium Sample Preparation System serving multiple BD FACSLyric™ Flow Cytometers.
- Optimize automation of samples requiring off-board steps like stimulation steps and/or incubation at 37 degrees.

Advantages identified for full automation are, but possibly not limited to:

- Standardization, consistency and reproducibility of processing and times.
- Reduction of variability due to manual techniques and staff proficiency levels.
- Risk reduction of manual errors (such as sample exchange or transcription errors).
- Automated traceability of steps, time and users with on-board audit trails.

Figure 3: Total Process Timev

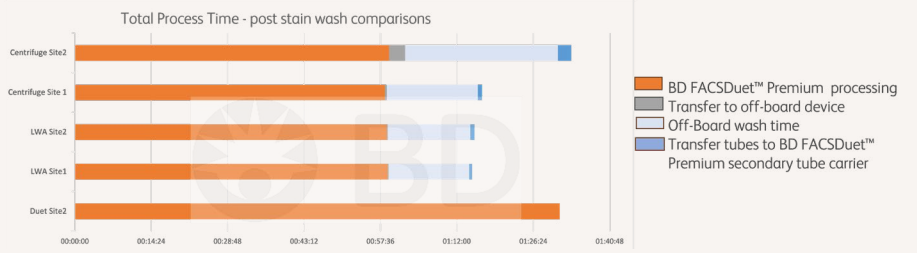


Table 4: Total Process Time

Description	BD FACSDuet™ Premium System OnlySite2	BD FACS™ LWA Site 1	BD FACS™ LWA Site 2	Lab Centrifuge Site 1	Lab Centrifuge Site 2
BD FACSDuet™ Premium System processing		0:58:57	0:58:49	0:58:25	0:59:14
Transfer to off-board device		0:00:10	0:00:11	0:00:23	0:03:01
Off-Board wash time	1:31:21	0:15:11	0:15:32	0:17:09	0:28:46
Transfer tubes to BD FACSDuet™ Premium System secondary tube carrier		0:00:35	0:00:49	0:00:49	0:02:32
Total Time	**1:31:21**	**1:14:53**	**1:15:21**	**1:16:46**	**1:33:33**
%Difference TPT Site1 to Site2			-0.6%		-21.9%
Average TPT	1:31:21		1:15:07		1:25:10

Site 1: University Hospital Ghent – Belgium
Site 2: ASST degli Spedali Civili Brescia - Italy

Conclusions

- Predictable workflows were achieved with automation in processing on the BD FACSDuet™ Premium Sample Preparation System or with off-boarding for a post-stain wash using BD FACS™ Lyse Wash Assistant. Processing with traditional centrifugation for post-stain off-board washing showed higher variability between the sites, used more hands-on time, and could introduce errors in processing.
- While full process automation did not decrease the total process time compared to the semi-automated processing, it reduced hands-on time and hands-on tasks and the risk for manual errors. Automation provides process standardization across sites, eliminating the variability between users independently of the proficiency level, thus providing process consistency and reproducibility.
- Semi-automated processing with off-board post-stain washing with the BD FACS™ LWA, used with the BD FACSDuet™ Sample Preparation System and/or BD FACSDuet™ Premium Sample Preparation System, can provide an automated system with flexibility in protocols that incorporate special requirements, while minimizing the risk of errors and the number of manual interaction.

The Lean component of this study used timers, paper logging, and video to capture
Total Process Tme (TPT), Hands-On Time (HOT), and Error Prone Tasks (EPT) for time and motion.

- Time capture will be from "Press RUN" to "samples ready for acquisition".
- Using calibrated timers, video equipment with the instrumentation to align times across platforms and record time as hh:mm:ss for each step in the process for TPT and HOT. Steps are also assessed whether they are Error Prone.
- Ensure no patient identification is captured in documentation or video equipment.
- Along with video equipment for tracking process, paper documentation is taken immediately during the process that is prepared in advance with the sites SOP's to streamline note taking.
- Lean specialist with background in flow cytometry is crucial in identifying all steps and assessment of error prone steps and deviations from SOP's that may lead to bias in the results.
- The presence of the lean specialist did not interfere with sample preparations and laboratories' Standard Operating Procedures

This research is scientific in nature

BD Biosciences provided materials and instruments for this study.

Disclaimers:
BD FACSDuet™ Sample Preparation System, the BD FACSDuet™ Premium Sample Preparation System and BD Flow Cytometers are Class I Laser Products.

CE The BD FACSDuet™ Sample Preparation System, the BD FACSDuet™ Premium Sample Preparation System, the BD FACSLyric™ Flow Cytometer with the BD FACSuite™ Clinical and BD FACSuite™ Applications, the BD FACS™ Lyse Wash Assistant are in vitro diagnostic medical device bearing a CE mark.

BD® CellWASH is for Laboratory Use Only
BD, the BD Logo, BD FACSDuet™ , BD FACSLyric™, BD FACSuite™ are trademarks of Becton, Dickinson and Company or its affiliates. © 2023 BD. All rights reserved. BD-104378 (v1.0) 0923

Automated Sample Preparation for laboratories streamlining Lyse-No-Wash and Lyse-Wash methods on a single system using carriers or plates

Jana De Wolf, Annick Willems, Mattias Hofmans : Department of Laboratory Medicine, Ghent University Hospital, Ghent, Belgium.
Marco Chiarini, Anna Galvagni, Viviana Giustini, Daniele Moratto, Duilio Brugnoni: Flow Cytometry Unit, Clinical Chemistry Laboratory, ASST Spedali Civili of Brescia, Brescia, Italy.
Lucia Testolin, Lori Apoll, Maureen Martin, Nicolas Bailly, Anne-Catherine Dolens, Manuele Ongari, and Ira Racoma: BD Biosciences, San Jose, CA 95131, U.S

Introduction

In flow cytometry laboratories, Total Process Time (TPT) using automated sample preparation system physically integrated with a flow cytometer could be different depending on the order of various worklist workflows. Order optimization can increase efficiency and throughput, with the added flexibility of using tube carriers and/or plates.

As these laboratories may perform multiple different test assays, Lyse-Wash (LW) and Lyse-No-Wash (LNW), the ability to provide assay flexibility and to automate as many tests as possible on a single system is important for laboratory efficiency. In addition, advanced automation with the BD FACSDuet™ Premium Sample Preparation System physically integrated with the BD FACSLyric™ Flow Cytometer can reduce error prone steps, increase traceability, and increases walk-away efficiency.

Quantifying TPT for various workflow combinations can aid in identifying the most efficient use of the system to streamline workflow. With human resource strained environments, this can increase throughput for a given instrument and assist in identifying the appropriate compliment of instruments for an institution.

Method

Two sites with a BD FACSDuet™ Premium Sample Preparation System physically and data integrated with a BD FACSLyric™ Flow Cytometer explored different workflows. Five (5) different worklists were run in combinations of three (3) and evaluated across four (4) different conditions to assess the overall workflow behavior across various assay types (LW & LNW), carrier types (40 secondary tubes rack & 96-well plate), and centrifuge methods. Time was measured from specimen loading onto the BD FACSDuet™ Premium Sample Preparation System to the completion of acquisition in the BD FACSLyric™ Flow Cytometer. These conditions were compared to each other for workflow efficiency, Total Process Time and Hands-On Time measurements.

Part A (Figure 1): Three different workflow conditions were assessed using two (2) specimens in three (3) defined worklists with various run orders:

- Worklist A: LNW assay (BD Multitest™ 6-Color TBNK reagent) prepared in a tube carrier and acquired in BD FACSuite™ Clinical Application (BD CE-IVD Assay).
- Worklist B: LNW assay (user-defined 6-Color TBNK reagent) prepared in a 96-well plate and acquired in BD FACSuite™ Application.
- Worklist C: LW assay (dried reagent) specimen with off-board pre-wash, to mimic pre-loading cell concentration optimization, with assay prepared in tube carrier and acquired in BD FACSuite™ Application.

Part B (Figure 2): Two (2) different conditions were assessed for processing of 96 samples in different carrier types:

1. three (3) carriers with 32 secondary tubes each were processed concurrently (totaling 96 tubes). Each secondary tube was prepared from one specimen stained with BD Multitest™ 6-Color TBNK reagent (LNW assay) and acquired with BD FACSuite™ Clinical Application.
2. one (1) 96-well plate was processed from 12 specimens (8 replicates each) stained with user-defined 6-Color TBNK reagent and acquired in BD FACSuite™ Application.

Figure 1: Part A – Run Order

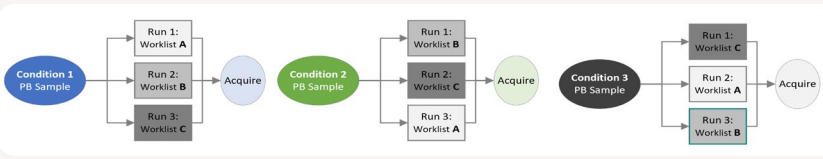
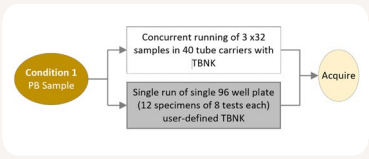


Figure 2: Part B - Scenarios



Analysis & Results

Part A: Various workflow conditions run concurrently

Of the three (3) workflow conditions run, the most efficient workflow resulted in Condition 3: Worklist C (LW assay with dried reagent) followed by Worklist A (BD CE-IVD LNW assay with BD Multitest™ 6-Color TBNK reagent), followed by Worklist B (LNW assay with user-defined 6-Color TBNK reagent) (Figure 3).

- Condition 3 completed 32.6% faster than Condition 1 where the LW assay was loaded last (Table1).
- When running the LW worklist at the end of the three (Condition 1) or as second in the sequence (Condition 2), a time difference of only 5.9% was measured (Table 1).
- BD FACSLyric™ Flow Cytometer runs worklists in the order of sample preparation completion.

Table 1: Total Process Time - complete condition run

Condition	Total Process Time (TPT)	Condition Total Process Time (TPT)
1	1:58:39	
2	1:51:40	5.9%
3	1:19:55	32.6%

Table 2: Total Process Time – Individual run

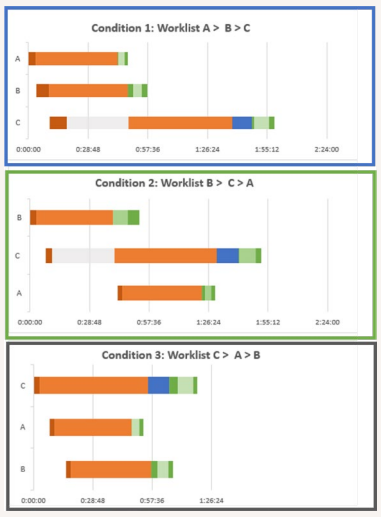
Condition	Individual BD FACSDuet™ Premium to BD FACSLyric™ run time		
1	0:44:39	0:47:33	1:10:16
2	0:49:48	1:10:57	0:44:48
3	1:16:24	0:43:06	0:49:49

Observations on Plate vs Carriers

- Plates and carriers can be run interchangeably on the system – Figure 3 and Table 2
- Regardless where Worklist A (LNW BD CE-IVD assay) and Worklist B (LNW in 96 well plate) are run in the consecutive worklists, their BD FACSDuet™ Premium System - BD FACSLyric™ run time is similar

Worklist A (Carrier LNW assay)
Worklist B (Plate LNW assay)
Worklist C (Carrier LW assay)

Figure 3: Concurrent Runs



Observations on assay type:

- The BD FACSDuet™ Premium Sample Preparation System can run up to three (3) worklists and these can be a mixed of both Lyse-Wash and Lyse-No-Wash assays.
- Condition 3 had the LW assay prepared first, allowing for both LNW assays to be prepared simultaneously during the incubation times of the LW one, resulting in the most optimized loading sequence (Figure 3).
  - Run time of the LW worklist is slightly longer in Condition 3 in comparison to the other conditions (Table 2). Here the LW worklist is prepared first on the BD FACSDuet™ Premium System yet acquired last. The BD FACSDuet™ Premium Sample Preparation System optimizes the time of all planned worklists, prioritizing some tasks of the LNW worklists (e.g. pipetting of worklists 2 or 3) prior to transferring the LW carrier to the BD FACSLyric™ flow cytometer for acquisition.
  - Operator should be aware of BD FACSuite™ Software requirements for worklist, needing either BD FACSuite™ Clinical or BD FACSuite™ Applications. Condition 3 minimized software Applications changes resulting in increased walkaway time.
- When LW assay was loaded last, as in Condition 1, the worklist did not begin sample preparation until the two previous LNW worklist preparations were completed. LW assays may have a higher number of steps associated with increased movements back and forth to the wash carousel and the on-board centrifuge, ensuring the time indicated for the prep-method is respected, e.g. min. and max. times for reagent and lyse incubations.
- The ability of the BD FACSDuet™ Sample Preparation System and/or the BD FACSDuet™ Premium Sample Preparation System to continually load LNW assays increases throughput and reduces TPT, whether using plates or carriers leading to predictable and reproducible processing times.

Part B: Cross site comparisons: 96 specimens using single 96-well plate or 3 carriers with 32 tubes each

Carriers:

- Three consecutive carriers (96 specimen) throughput at Site 1 had 25.1% lower TPT compared to Site 2. (Table 3) When assessing TPT of the process related to the BD FACSDuet™ Premium Sample Preparation System time alone, the carrier inter-site difference was only 1.7%
  - Sample preparation was consistent (hands-on-time [HOT] at 5.9% and 9.5% (Site 1 and 2 respectively as in Table 4) with manual intervention at the beginning of the process when loading the BD FACSDuet™ Premium Sample Preparation System
  - TPT difference observed was attributed to sample acquisition (Figure 4)
    - variation in sample types (some samples "timed out" in acquisition due to low cellularity)
    - Sample integrity (age and quality) can contribute to acquisition time differences

Plates:

- Inter-site plate HOT was 2.8% with HOT of 2.3% and 3.4% from Site 1 and 2 respectively. (Table 4)
- Samples run were different with fewer samples "timing out" on acquisition resulting in runs which were more consistent

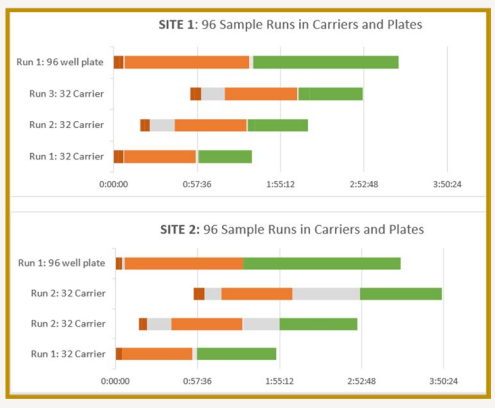
Table 3

96 specimen processing		TPT	TPT %Diff	TPT Duet Only	TPT %Diff Duet Only
Carrier	Site 1	2:52:00	25.1%	2:07:23	1.3%
	Site 2	3:49:46		2:04:23	
Plate	Site 1	3:16:48	-1.7%	1:25:44	4.4%
	Site 2	3:20:15		1:29:29	

Table 4

96 specimen processing		HOT	HOT%	Average HOT	xdiff
Carrier	Site 1	0:16:25	9.5%	7.7%	2.7
	Site 2	0:13:29	5.9%		
Plate	Site 1	0:06:37	3.4%	2.8%	
	Site 2	0:04:33	2.3%		

Figure 4: Site 1 and Site 2 Throughput for 96 specimens



Automated preparation considerations.

- Many variables need to be taken into consideration when optimizing workflow. To name a few, the minimum and maximum time of sample lysing, whether to batch samples based on arrival time into the lab, and creating preparation methods that use the system in the most efficient manner. Having an optimized workflow can help determine the correct number of instruments a lab will need for their workload.
- Understanding how the BD FACSDuet™ Premium Sample Preparation System prioritizes sample preparation will allow for the most efficient use of the system. Starting a LW worklist first and then batch LNW runs during that prep time increases throughput.
- Limiting the amount of times the flow cytometry software needs to be changed from BD FACSuite™ Clinical to BD FACSuite™ Application allows for increased walkaway efficiency.
- The specimens used for this study were peripheral blood. Other specimen types should be validated for use on the system.

The Lean component of this study used timers, paper logging, and video to capture total process time (TPT), hands-on time (HOT), and error prone tasks (EPT) for time and motion. Time capture will be from "Start of sample prep" to "completion of acquisition"

- Using calibrated timers, video equipment with the instrumentation to align times across platforms and record time as hh:mm:ss for each step in the process for Total Process Time and Hands-On Time. Steps are also assessed whether they are error prone
- Ensure no patient identification is captures in documentation or video equipment
- Along with video equipment for tracking process, paper documentation is taken immediately during the process that is prepared in advance with the sites SOP's to streamline note taking
- Lean specialist with background in flow cytometry is crucial in identifying all steps and assessment of error prone steps and deviations from SOP's that may lead to bias in the results
- Laboratory staff is to perform tasks uninterrupted by the lean specialist to ensure there is no disruption in the times observed or distractions from the SOPs

Conclusions

- The BD FACSDuet™ Premium Sample Preparation System allows flexibility of processing and loading configurations of assays, prep methods and workflows, with both carriers and plates.
- Due to removal of manual interventions, full automation (physical and digital) can be optimized and customized to achieve predictable process times for each combination of runs and workflows in any given flow cytometry laboratory.
- Sample preparation system physical integration is advantageous as it increases throughput, as it standardizes preparation time by removing manual sample transfers to a flow cytometry device.

This research is scientific in nature

BD Biosciences provided materials and instruments for this study.

Disclaimers:
The BD FACSDuet™ Premium Sample Preparation System and BD Flow Cytometers are Class I Laser Products.

CE The BD FACSDuet™ Premium Sample Preparation System, the BD FACSLyric™ Flow Cytometer with the BD FACSuite™ Clinical and BD FACSuite™ Applications are in vitro diagnostic medical device bearing a CE mark.

CE 2797 The BD Multitest™ 6-Color TBNK Reagent with and without BD Trucount™ tubes is an in vitro diagnostic medical device bearing a CE mark and are CE certified by BSI Group The Netherlands B.V. (Notified Body Number = 2797).

BD, the BD Logo, BD Multitest™ , BD Trucount™, BD FACSLyric™, BD FACSuite™ are trademarks of Becton, Dickinson and Company or its affiliates. © 2023 BD. All rights reserved. BD-104380 (v1.0) 0923

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

BD FACSDuet™ Sample Preparation System, BD FACSDuet™ Premium Sample Preparation System and BD Flow Cytometers are Class 1 Laser Products.

BD Switzerland Sàrl, Terre Bonne Park – A4 Route de Crassier 17, 1262 Eysins, Switzerland

bdbiosciences.com

BD, the BD Logo, BD FACSDuet™, BD FACSLyric™, BD FACSuite™, BD Multitest™, BD Trucount™, and BD FACSLyse are trademarks of Becton, Dickinson and Company or its affiliates. © 2024 BD. All rights reserved. BD-114213