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

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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 Systems 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

	TPT/Ab	Range	HOT/Ab	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

TABLE 1: Cocktail Preparation: TPT and HOT per Antibody (Ab)

- **Processing times are predictable and consistent using automated cocktail preparation**
  - Manual cocktail preparation shows high variability in process times (TABLE 1)
  - 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
- **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

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

TABLE 2: Cocktail Preparation: Error Prone Tasks

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

Total Workflow Assessment

	TPT	HOT	Tasks	Error prone	% Error Prone	% HOT	% reduction of HOT Duet 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 AVE (average of runs 1-3)	01:32:08	00:11:47	44	4	9.10%	12.80%	

TABLE 3: Time for tasks

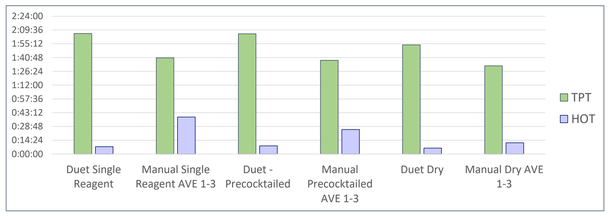


FIGURE 1: TPT and HOT for tasks

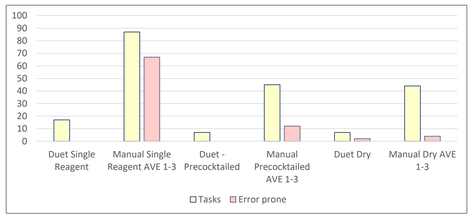


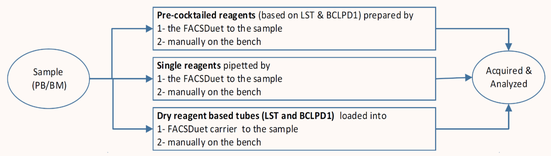
FIGURE 2: Tasks and Error Prone tasks

- **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 offer 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

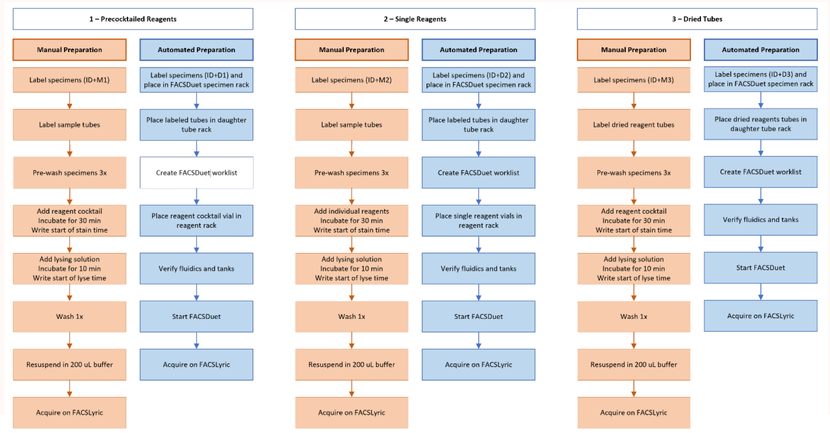
- Samples were set up using both traditional manual and automated BD FACSDuet™ Premium Sample Preparation System physically integrated with the BD FACSLyric™ Flow Cytometer.
- Antibodies in the two-tube testing method consisted of a screening tube containing a 12 antibody panel and a second tube with 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 SOPs 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.



FACSDuet, BD FACSDuet™ System
FACSLyric, BD FACSLyric™ System

This research is scientific in nature.

BD Biosciences provided materials and instruments for this study.