BD case study

Improving workflow efficiency and standardisation of CD4 Flow Cytometric counting in an HIV laboratory

Ampath Laboratories, Pretoria, South Africa

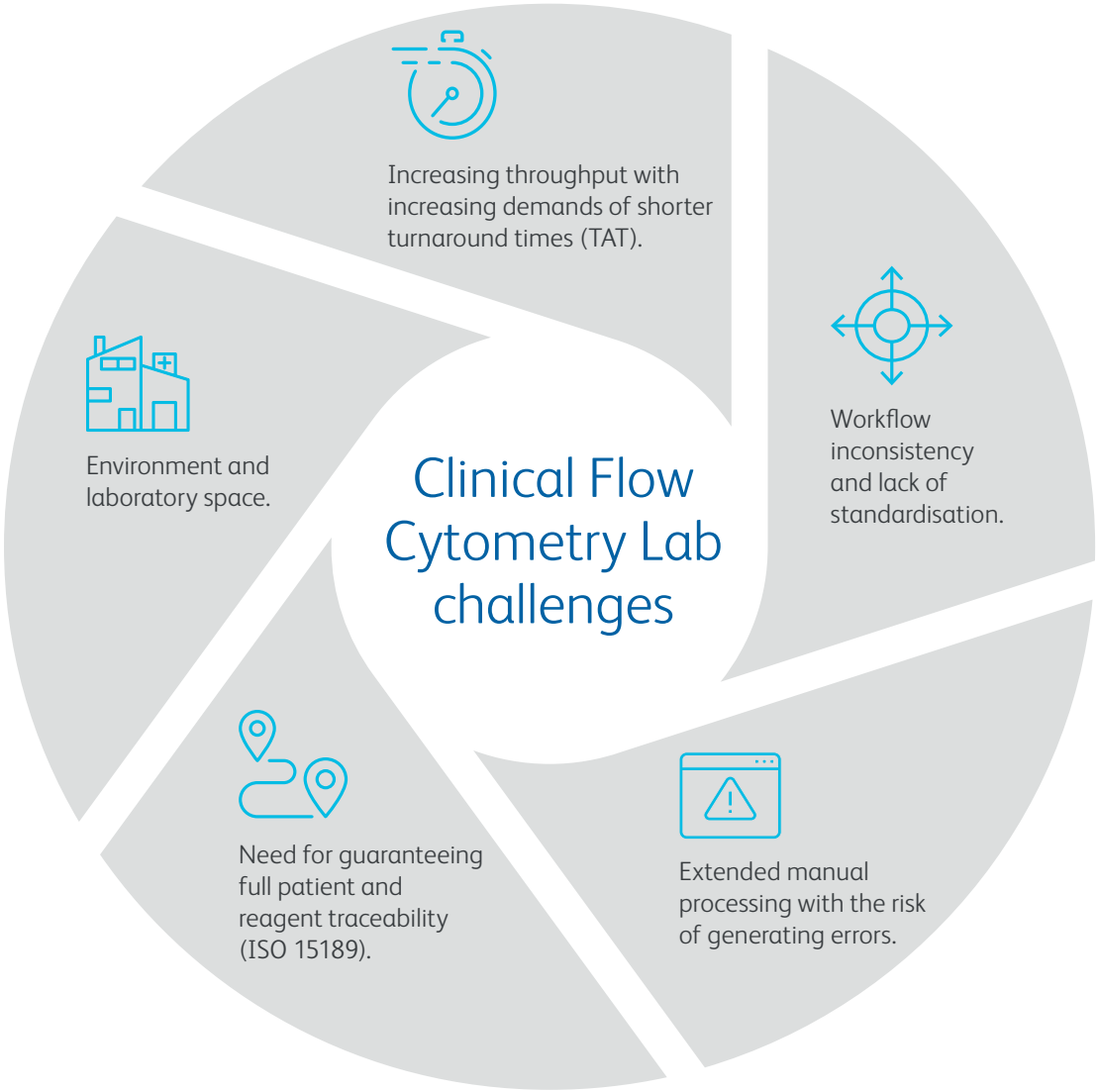
BD

Evidence statement

98%

98% of the in-patients will undergo a diagnostic lab test during a hospital stay[1]

Accurate diagnostics and subsequent treatment decisions are dependent upon standardised testing to produce consistent, timely and quality results[2].



Why automation?

- **Automation enables laboratory scaling capacity, helping to ensure surges in patient specimen volumes do not impact quality and turn-around-time (TAT)[3] and subsequently, the ability for clinicians to manage patient care effectively and safely[4,5].**
- **Through automation, processes are also standardised, driving quality and consistency**

Evaluation of the BD automated flow cytometry workflow

The workflow of the automated BD solution, consisting an integrated BD FACSDuet™ Sample Preparation System and BD FACSLyric™ Flow Cytometer, was evaluated following a Lean Six-Sigma approach that compared the existing laboratory workflow (using another semi-automated solution) to the automated BD solution at Ampath laboratories, Pretoria, South Africa.

Parameters measured

- Total process time (time taken for a specimen arriving on the bench to being reported)
- Total hands-on time (time staff are working directly in the process)
- Error-prone and critical error-prone steps (affecting the audit trail and the patient outcome respectively).

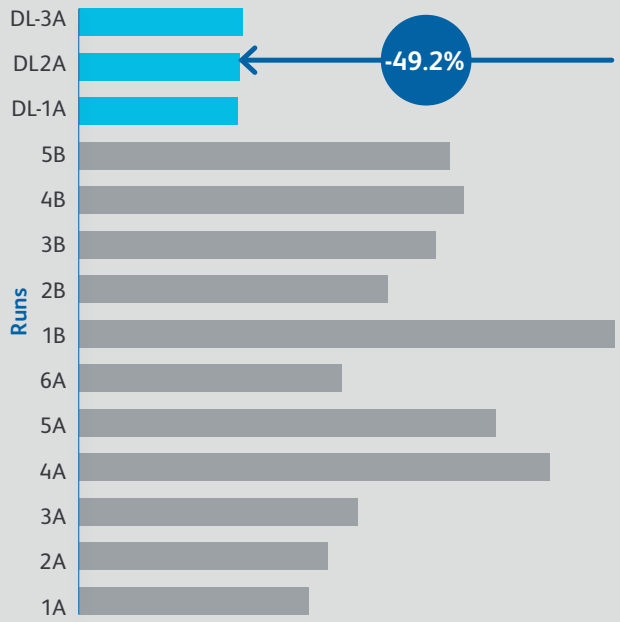
Results

At Ampath Laboratories, the CD4 lab, which is a part of the Immunology department, runs anywhere between 9000 and 14000 samples each month. 11 batches of 30 CD4 T cell subset counts using BD Multitest™ CD3 FITC/CD8 PE/CD45 PerCP/CD4 APC with BD Trucount™ Tubes were mapped on the legacy semi-automated solution and found to be highly variable.

With the new automated solution, using the fully integrated BD FACSDuet™ Sample Preparation System and BD FACSLyric™ Flow Cytometer, only 3 sample batches needed to be run as they showed high consistency and predictability that we expect from full automation.

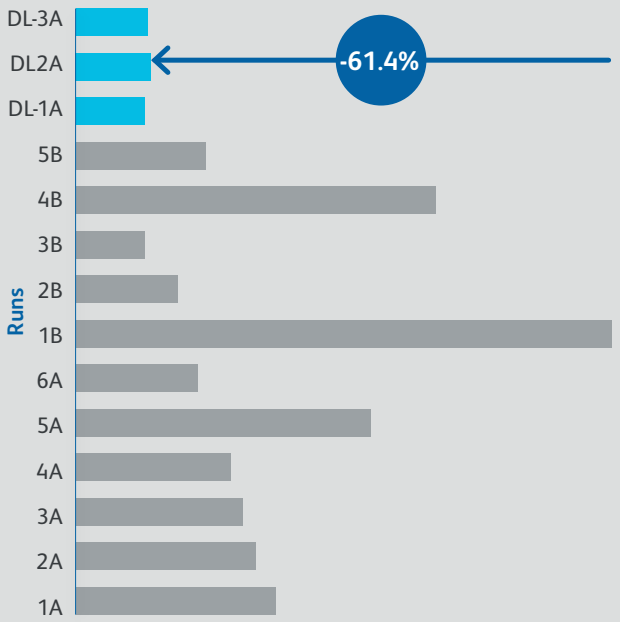
Reduction in total process time

Automation of the entire workflow resulted in consistency across runs, leading to a reduction in total process time by 49.2%.



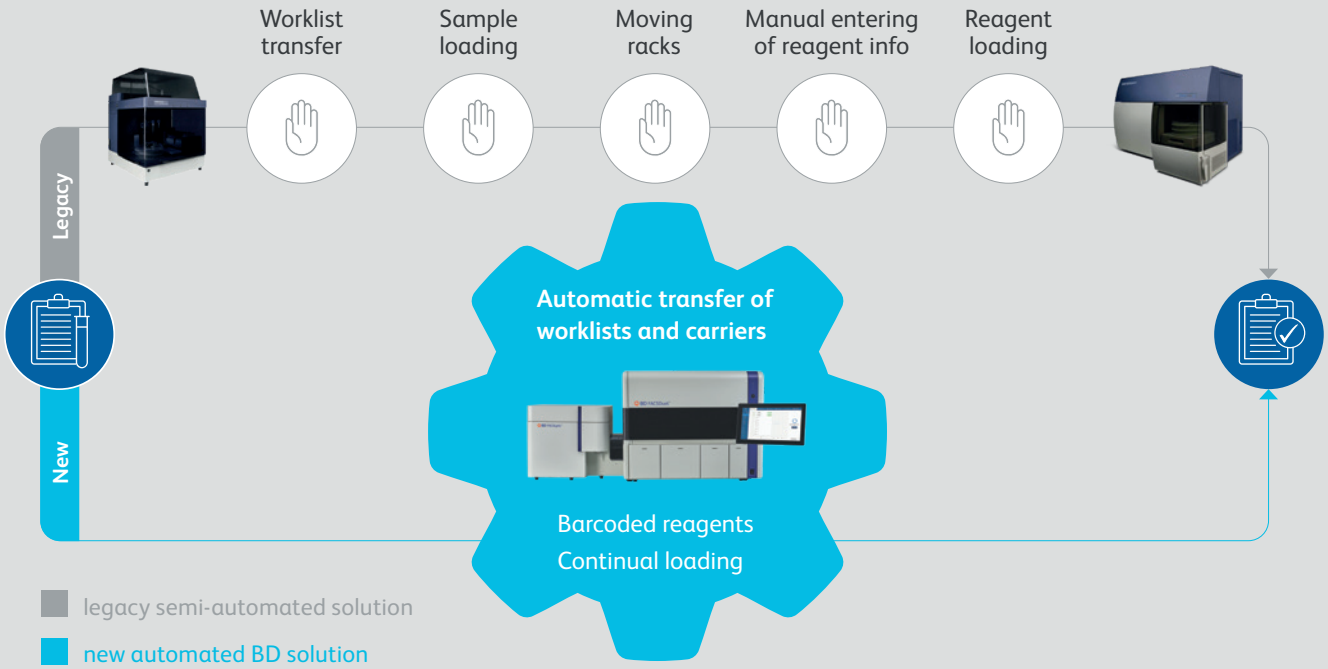
Reduction in hands-on time

By removing manual intervention steps and using a QC controlled automated-results export option, the average process hands-on time was reduced by 61.4%



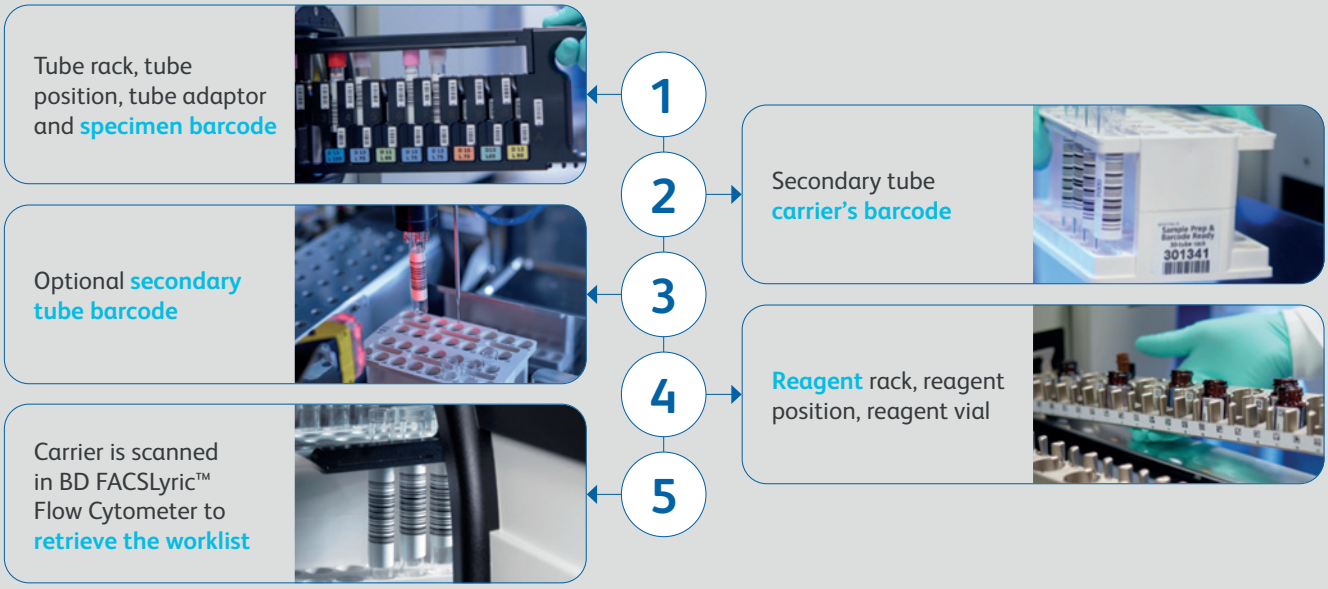
Reduction in manual steps

The integrated BD FACSDuet™ Sample Preparation System and BD FACSLyric™ Flow Cytometer system has only one manual step, which is loading the samples and reagents and pressing the 'on' button. The automation eliminates all problems related to manual operator intervention, resulting in a significant decrease in analytical total processing time and hands-on time.



Complete traceability

Using barcodes, all information about each sample and patient is saved by the software providing a traceable, auditable solution



"Working with the BD FACSDuet™ Sample Preparation System and BD FACSLyric™ Flow Cytometer system has been an incredibly amazing experience"

Debbie Bruno, CD4 Lab Manager of Ampath Labs, South Africa

The integrated BD FACSDuet™ Sample Preparation System and BD FACSLyric™ Flow Cytometer system has proven itself in Ampath Labs, an HIV testing lab with a very high workload. It has brought about a decrease in average hands-on time and total process time. It has also reduced error-prone manual steps and has provided complete sample and consumable traceability for each patient.

This solution from BD delivers process standardisation by minimising workflow error-prone steps whilst increasing workflow consistency and laboratory efficiency. Through delivering timely and accurate results to inform clinical decisions, the BD solution supports patient safety and good health outcomes[2].

Results presented are applicable to Ampath Labs, results will vary and may not be representative of those measured in other clinical laboratory settings.

Thank you to Debbie Bruno, CD4 Lab Manager of Ampath Labs, Cathy du Plessis, Lab Director and Cathy van Rooyen, Head Pathologist for their collaboration.

The Institutions providing testimonials in this presentation 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 to which the testimonials refer. However, the views, information, or opinions expressed during the testimonials are solely those of the individuals involved.

CE The BD FACSLyric™ Flow Cytometer with the BD FACSuite™ Clinical and BD FACSuite™ applications, BD FACSDuet™ Sample Preparation System, BD FACSCanto™ II Flow Cytometer BD FACS™ and Sample Prep Assistant III are *in vitro* diagnostic medical devices bearing a CE mark.

CE 2797 BD Multitest™ CD3 FITC/CD8 PE/CD45 PerCP/CD4 APC with BD Trucount™ Tubes is an *in vitro* diagnostic medical device bearing a CE mark and is CE certified by BSI Group the Netherlands B.V. (Notified Body Number = 2797).

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

1. Ngo A, Gandhi P, Miller WG. Frequency that laboratory tests influence medical decisions. J Applied Lab Med. 2017;1:410-414
2. WHO. Laboratory Quality Management System Handbook. 2011
3. Angeletti S, De Cesaris M, Hart JG, et al. Laboratory Automation and Intra-Laboratory Turnaround Time: Experience at the University Hospital Campus Bio-Medico of Rome. J Lab Autom. 2015;20(6):652-658
4. Howanitz J.H. and Howanitz P.J. Laboratory results. Timeliness as a quality attribute and strategy. Am J Clin Pathol. 2001;116(3):311-5
5. Carraro P. and Plebani M. Errors in a Stat Laboratory: Types and Frequencies 10 Years Later. Clinical Chemistry 2007;53: 1338-1342

BD FACSCanto™ II and BD FACS™ Sample Prep Assistant III are no longer available for sale.

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

bdbiosciences.com/eu