VOLUME - 11, ISSUE - 04, APRIL - 2022 • PRINT ISSN No. 2277 - 8160 • DOI : 10.36106/gjra

Original Research Paper | Clinical Laboratory

POSITIVE IMPACT OF AN AUTOMATED PRE-ANALYTICAL & POST-ANALYTICAL WORKFLOW SYSTEM IN A TERTIARY HIGH-VOLUME REFERRAL CLINICAL LABORATORY

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ABSTRACT

Context: Handling of biological samples in a laboratory is labour intensive complex process and automation has become a necessity for optimizing health care costs, reduce medical errors and to aid in safety of healthcare workers. Biological Sample handling in the sample reception area involves sample tube de-capping for ready processing, sorting section-wise, scanning the sample to track its progress, distribution to various analysers and archival for storage. **Objective:** The aim of the present study is to evaluate the positive effects of an automatic pre analytical automation in our clinical laboratory workflow. **Design:** We recently installed Beckman Automate 2550 analyser for our workflow pre & post analytical automation.This preanalytical unit processes blood specimens through automated specimen sorting, centrifugation, de-capping, labelling, aliquoting, and placement of the processed specimen in the analytical rack. We analysed the system by processing samples to test the salient features of this system. Turnaround time with increase in volume of tests with no additional manpower was analysed pre & post automation. **Results:** The turnaround time (TAT) of various laboratory processes demonstrated a significant improvement. The number of errors experienced in tube sorting with manual processing, sorting mislabelled tubes, unlabelled tubes, specimen lost, wrong destination entered for tubes and tube mismatch was decreased post-implementation of the system. Also, increased workload was handled by the sorter efficiently. **Conclusions:** Reduction time in pre analytical processing and sorting of samples led to significant improvements in TAT and specimen processing after automation. The manual errors & manhours associated with sorting, labelling, aliquoting the blood samples also reduced. These results conclude that automated sample sorting improves specimen accessioning and processing workflow.

KEYWORDS : Turn Around time, Pre analytical automation, Specimen sorting, Specimen archival

INTRODUCTION:

Laboratory testing has been traditionally divided into three phases pre, intra and post analytical. The pre-analytical step involves the processes required to make a sample suitable for analysis: centrifugation, aliquoting and sorting the specimens into batches for their introduction into automated analysers. When performed by technologists unaided by automation, the pre-analytic tasks account for the most labour-intensive phase of testing in the medical laboratory. The specimen preparation step, which contributes to approximately 19% of the overall cost of analysing a single specimen, is also time-consuming (37% of time spent in producing a result). [1] The manual handling of potentially infectious samples exposes laboratory staff to biohazards. Increasing workload with limited manpower may increase risk of human error due to physical and mental fatigue in laboratory personnel.

We analysed Beckman Automate 2550 for preanalytical automation at Metropolis healthcare Ltd, Global Reference Laboratory (GRL), Mumbai. The laboratory is National Accreditation board for testing and calibration laboratories (NABL) and College of American Pathologists (CAP) Accredited, operates day and night processing approximately 40, 00,000 specimens annually.

MATERIALS & METHODS:

In January 2018 Metropolis Healthcare Ltd, Global reference laboratory (GRL) installed Beckman Automate 2550 as automated laboratory solution for pre analytic processes de-capping, sorting, distribution, receiving & post analytic archival of sample tubes. Registration of samples and barcoding was done in local hubs, collection centres and satellite labs. Logistics coordination with cold chain transport was ensured. Preregistered barcoded samples were received in the sample accession area. They were verified with the Test Requisition Form (TRF) and centrifuged.

Workflow before Automate 2550:

Accessioning department received samples from various locations across Mumbai, pan India and international. The samples were arranged & checked for sample type & number of vacutainer tubes. (Figure 1 A) Registration of each sample was done in Laboratory Information Management system (LIMS). Barcoding of samples & cross checking against TRF was carried out. After centrifugation of samples, "out time stamp" scan was logged when the sample was sent from accession department to processing department. Manual sorting of samples in the lab was done according to the department barcode and dispatched to individual departments for further analysis. Various departments in the referral lab, such as Chemistry, haematology would scan the samples manually in Microsoft excel software when the samples reached the department for 'in time stamp'. Technologists did manual sorting of samples according to test on barcode & segregated in various machine racks. A person would then manually de cap the samples & load into the respective machine. (Figure 1 B, C) After the tests were processed, the technologist would send the samples for archival. Archival was done manually using a Microsoft excel sheet. In the meantime, he would generate pending tests worksheets for each analyser to check for pending tests from archived samples.



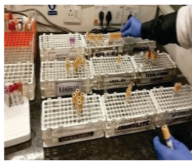

Figure 1A: Manual scanning of samples in software
Figure 1 B: Manual de-capping of sample
Figure 1C: Manual sorting of samples

Need for Automation:

The entire manual process of collection, registration and distribution of tests was time consuming & accompanied with unpredicted errors. Samples in different vacutainers from peripheral laboratories & hospitals were submitted to the central laboratory, hence busy traffic.

The main concerns being complex sample workflow steps, from collection of samples, registration to distribution in the department (Figure 2).

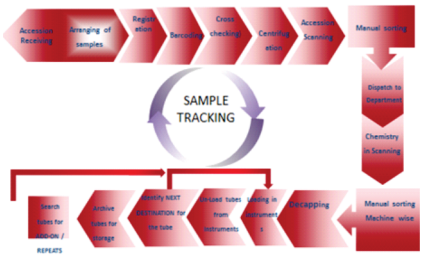

Figure 2: Complexity of Pre-Analytical Workflow

Entire process being manual increased waiting period of the blood sample in accession impacting the overall turnaround time (TAT). Increased risk of sample loss during inter department sample interchange was increased. Retrieval of pending tests was done after manual archival of samples which would further add to the TAT.

Laboratory testing, a highly complex process and most errors occur in the pre-analytical phase, with a reported error rate of 46-68.2 per cent. [2] The pre analytical specimen processing area of the clinical laboratory operation is prone to multiple errors associated with specimen handling and overall represents a tedious and manual section of the clinical laboratory operation.[3] Pre-analytical robotic workstations automate many steps in sample receiving to sorting and reduce the number of manual steps, involving less people.

An important incentive for implementation of laboratory automation was to reduce human errors which occur during sorting of specimen, aliquoting, order entry and so on. [4]

Considering these factors and address increase in workload, pre-analytical automation was considered to assist with specimen sorting and to aid in other steps of accessioning.

Automation pre-plan:

Workflow study was performed to demonstrate the strengths and weaknesses of the existing process so that an informed decision can be made as to whether automation will lead to a real improvement. As a supplement to internal reviews conducted by our laboratory subject experts, competing vendors brought specialists into the laboratory to study and report their findings. In addition to identifying and enabling the correction of some process flaws, these findings further reinforced the potential benefits of automation. [5] Some of their findings included streamlining sorting and manual checking of samples, error free aliquoting using an automated system to feed multiple instruments with aliquots at same time to reduce TAT.

In January 2018, Beckman Automate 2550 was installed in Metropolis healthcare Ltd GRL, Mumbai for automated laboratory solution for pre analytic processes (de-capping, sorting, distribution, receiving and if necessary aliquoting samples) and post analytic processes like archival of sample tubes. This was followed by samples distribution to designated workstations. The aim of the present study was to evaluate the effects of an automatic tube sorting system on specimen processing performance in a high-volume laboratory. [6]

Automation workflow and design

The Beckmann Coulter Automate 2550 is designed for clinical laboratories for pre analytic processes (de-capping, sorting, distribution, aliquoting) & post analytic processes (archival of sample tubes) of closed primary sample tubes in accordance with barcode information and through queries in the Laboratory Information System (LIS). (Table 1)

Table 1: System Specification

Features	
Name	Beckman Coulter AutoMate 2500
Pre Analytical Processor	Yes
Decapper	Yes
Recapping	Yes.
Centrifuge	No. Separate module
Archive	Yes
Aliquoting	Yes
Total Lab Automation	No
Way of loading	Rack wise,
Sorting Throughput	1200 tubes/hour
	75 tubes per 3.75 mins
Specimen Integrity Monitor Available	No
Sample volume detection	Yes
Sample image capture	Yes
Reading through bar-coded tubes	Yes
Up-front sorting rules	Yes
Input	300
Functions	Sample scanning and receiving, Sample sorting, Sample archiving, Sample decapping, Sample recapping, Sample Lower Level Detection/volume detection
Target Bins/Racks	Standard company analyzer racks,
Output	Base frames (1200 tubes per racks)

It is a sorting system used after centrifugation, can process various sizes (5ml & 10 ml), types of cylindrical tubes without adjustment and that too together in a single load.

All tubes, including Serum separator Gel tubes, EDTA Vacutainers, Heparin Vacutainers, Citrate Vacutainers, Fluoride Vacutainers, Plain serum vials, are easily processed.

It is capable of sorting up to 1200 tubes per hour.
Each tube is identified from the others, its unique identification barcode is scanned, and it is sorted into the output racks or designated workplace or department according to the barcode information. Sorting rules can be defined by the scanned barcodes or querying the LIS. It can aliquot primary tube into 7 daughter tubes, each of them labelled with tube identification, barcode and designated test name.

Different sorting modes can be applied in the Automate, making it flexible and adaptable for different sorting routines required by laboratories. Moreover, if there is a deformation of

the sample barcode and/or if the barcode is pressed into a different code, or if there are cases that the LIS cannot approve, these tubes are then sorted into the error rack.

Customisation of masters programming was done according to analysers. The tests list of each analyser was fed in sorting drive. Sorting Sequence of analysers was mapped according to priority of tests. If there was sharing of tests for one patient between 2-3 analysers the sequence of the 1st, 2nd and 3rd machine was mapped. Workplace assigned and mapped for Clinical Chemistry, Special Chemistry, Haematology, Microbiology, Serology, Genetics, and Molecular Biology. Implementation of customised false bottom tubes was done. Trainings pertaining to remote registrations in Laboratory information management system (LIMS) software, handling of samples, operation and maintenance was given to all staff. Installation of Automate I-paw computers was done in Accession, Chemistry and Haematology Sections. Resorting of pending tests for multiple analysers was done by scanning on i-PAW PC. If no test found pending, then the samples was archived. Optimization of sample flow was done including the distribution workstations. Automate ensured traceability of the individual samples from receipt to archiving. It compiles statistics during operation, number of tubes, aliquots, tests, archival tubes, and primary tubes per hour. Receiving of samples in LIMS is done after scanning and sorting of tubes on Automate and it is used for all samples of Chemistry, Haematology, Serology, Microbiology, Genetics and Molecular Biology received in the laboratory. Twenty-five workplaces and 7000 test codes configured in output racks. Reduction in workflow time 6 months prior and after installation of automate was evaluated.

Data of TAT was collected from the laboratory information system (LIS). Steps and time taken for each step involved in accession area before and after automation were compared. Manpower requirement before and after automate installation was evaluated.

Verification and Pilot testing of the system:

Verification protocol was planned, reviewed and approved by 5th Jan 18. Interfacing connectivity of LIMS with Automate was completed by 11th Jan. Validation of pre analytical steps/activity Automate 2550 completed from 4th Jan to 2nd Feb 18.

Verification of de-capping, sorting and resorting of samples was carried out by testing 100 samples. Samples from all departments were loaded into the input racks. All samples were de-capped properly, sorted according to tests and analyser & placed into the designated workplace racks. Testing for resorting of Chemistry pending tests was done reloading these samples again into input racks. All samples were resorted for pending tests according to the priority given in the designated workplaces. (Table No 2)

Table 2: Priority wise Automate workplace ID

Workplace priority	AutoMate workplace ID	Workplace
10	415	Critical Chemistry
20	510	Special Chemistry (Critical)
25	332	Glucose
30	220	Cobas 8000
40	218	Cobas 502
50	219	Architect 1
70	222	SARS-COV-2
80	229	IMMULITE
90	228	Perkin
100	335	Phadia
180	227	BN/RxL
220	336	UniCel DxI
230	334	Liason-XL
235	414	Special Chemistry (with ELISA)
240	413	Microbiology / Serology
260	410	Genetics
280	409	Molecular Biology
285	411	HLA
290	408	Molecular Pathology
300	300	Hematology STAT
310	330	Hematology Automated
320	331	Transfusion / Manual Hematology
330	333	Flow Cytometry
340	337	Coagulation
350	412	Referred

Laboratory Information System Verification for Attune receiving of samples on Beckman Automate were done on 17th April, 18th April, and 24th April and for iPAW was done on 28th June 2018. (Table No 3)

Table 3: Verification and pilot testing of system

Date	Step
4th Jan 2018	Hardware set up by Beckman and base frame set up Tube programming
8th Jan 2018	Installation of software in sorting drive and electrical connection
9th Jan to 11th Jan	Basic rules defined on sorting drive. All instruments configured. I Paw installed.
12th to 13th Jan 2018	Demonstration and training by vendor to all department teams.
15th Jan to 19th Jan 2018	Laboratory Information System Connectivity Established.
17th ,18th, 24th Jan 2018	Laboratory Information System Verification for Attune receiving of samples
20th Jan onwards	Verification of de capping, sorting and resorting of samples was carried out by testing 100 samples.
	Trouble shooting of errors, tube type, cap and color programming done.
29th Jan 2018	Go Live for Immunoassay/Biochemistry
30TH Jan 2018.	Laboratory Information System Modifications as per test level configuration.
31st Jan 2018	Sorting done for all orgs of the Laboratory information management system
9th Feb Onwards	Go Live for all departments
20th March	Ordered ipaw dongles
25th March	False Bottom tubes concluded & order placed.
4th May	Automate receiving in Laboratory information management system activated
8th June	ipaw dongle installed in Immunochemistry, hematology and accession.
	Started Archival of samples with resorting in Immunochemistry
4th June	Implemented new false bottom tubes
14th June	Sample receiving started in Sorter and Ipaw
	Batch sheet receiving stopped in accession
28th June	Verification done in live environment for iPAW
29th June	Sample receiving started in iPAW in accession.

Samples were tested in Transferred, received, recollect, Cancel, Reject and rerun status. All samples passed the verification. (Table No 4)

Table 4: Automate verification results:

Parameters	% Result
Recapping	100%

Verification for Beckman Automate and Ipaw	100%
Laboratory Information system Verification	100%
Verification for Beckman Automate Resorting	100%

Statistical analysis

Data was analysed using R software version 4.0.3. Qualitative variables are expressed as frequency and percentage and Quantitative Variables are expressed as mean (±SD), median [IQR], range. Shapiro-Wilks Test is used to determine whether data sets differed from a normal distribution. For continuous variables, between two groups means is compared using unpaired t test or Mann Whitney U test based on normality testing and results is considered significant at P <.05

Results:

Workflow post Automation

Pre-registered barcoded samples received in accession were loaded in the input racks of Automate 2550. Samples were scanned, de capped and sorted into respective workstations through LIS request configured department wise and analyser wise. As the sample was sorted, the LIMS sent the LIS request to the sorting drive and it was received in the LIMS software. (Table No 5)

Table 5: Comparison of workflow before and after installation of sorter

Pre Automate 2550	Post Automate 2550
Samples received manually checked & received in Laboratory information management system	Samples received, loaded on Automate, received through Laboratory information system and sorted into racks.
Manual sorting of tubes for chemistry, hematology, Serology & other departments	Sample tubes sorted basis Laboratory information management system test mapping. (EDTA for Hematology/HbA1c; Serum tube for Chemistry & Citrate tube for Coagulation respectively)
Manual loading into different analyzer racks and manual checking of pending worksheet.	De-capping & sorting into instrument specific racks. Resorting automatically done for pending tests once test on the first analyzer completed.
Manual checking for Sample Volume.	Volume checked as per test requirement. Alarm and sample diverted to error rack.
Manual planning and alignment of tests in different machines.	Test request identified basis rules in sorting drive & tubes sorted for same/multiple tests on different machines in priority sequence.
Manual identification of STAT samples.	Identification & processing of STAT samples on priority
Manual searching of samples from archived racks for add on tests.	Automated archiving of samples. samples checked for 'completion' of test requests using iPAW and archived accordingly.
Single tube travelling to multiple analyzers/departments.	Aliquots the primary tube into pre-barcoded daughter tubes using volume sensing disposable tubes. Eases inter department flow.

The samples were removed from the output racks and loaded into the respective analysers. After the samples were processed on 1 analyser, they are reloaded in the input racks of Automate again for resorting. The Automate 2550 resorts the samples again according to pending tests for the 2nd analyser.

The technologist loads the re-sorted samples into the analyser. This has reduced the need for searching of samples and printing of pending worksheets.

Critical tests are given 1st priority while sorting. Low Volume samples, no requests, bad barcodes on samples are detected by the system and sorted into the ERROR Rack. This prevents aspiration errors; LIS request errors before loading of samples in Analysers.

Lean workflow:

Introduction of sorter led to reduction in time taken for manual labour-intensive steps in accession viz sample arranging, receiving, accession and department in scanning, de-capping and sorting. It significantly reduced sample wait time and time required for archival. (Table No. 6) This time of 85 minutes was cut down to 34 mins after automation.

Table 6- Reduction of workflow time periods

Result	Pre sorter (Human dependent) Time in min	Post sorter (Done by Machine) Time in min
Accession team arranging samples	15	0
Sample Receiving	5	0
Centrifuging	10	10
Accession Scanning	10	0
Sample wait time	15	5
Department In time scan	5	5
De-capping	10	
Sorting	5	
Resorting	0	10
Archival	10	10
Total	85	40

There was reduction in number of steps involved in the sample reception area, from 7 steps before introduction of sorter to 3 steps after the sorter was introduced. (Table no 7) (Figure 4)

Table 7: Number of steps in sample receiving

Parameters	Accession Steps Before Decentralization & Sorter	Accession Steps After Decentralization & Sorter
Steps	Sample Acceptance	Sample Acceptance, Cross checking
	Arranging	Centrifuge Sample
	Registration	Sorting
	Bar-coding & Cross checking	
	Centrifuge Sample	
	Scanning	
	Sorting	
Total	7	3

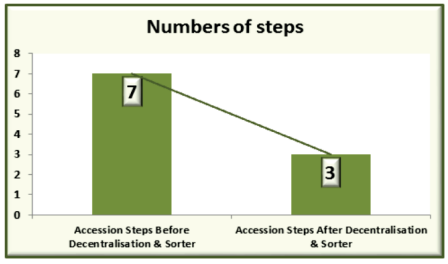

Figure 4: Number of steps

Turn Around Time:

By reducing delay in pre analytical process & sorting, significant improvement in TAT noted.

Significant reduction P <.0001 in time taken from sample receipt to validation of results for 2 consecutive years after installation of sorter. (Table No.8)

Table 8: Turnaround time

Year	TAT* Mean + SD (minutes)	P VALUE

Manual-2017	126+416	
Automate-2018	110+195	<.0001
Automate-2019	243+203	<.0001

*TAT- turnaround time

Despite increase in workload, 47% reduction in TAT was observed after introduction of sorter.

After installation of sorter, Significant (P < .0001) reduction in Turnaround time of thyroid function tests and prothrombin time was observed. (Table 9)

Table 9: Turnaround time of thyroid function tests and prothrombin time

Test	Manual	Automate	P VALUE
	Mean+SD	Mean+SD	
Thyroid panel 1(T3, T4, TSH)	383+394	330+388	<.0001
Prothrombin time	251+ 404	196+ 322	<.0001

Reducing Errors:

The sorter collects all wrong samples, like low volume samples, no requests and samples with bad barcodes in error rack ensuring the accuracy of results and greater productivity.

Manpower requirement:

The manpower required in accession reduced after introduction of sorter. The number of staff in accession was 48 before, reduced to 27 after sorter was installed. This staff was transferred & utilised in other sections to manage increasing workload.

DISCUSSION:

In our experience, automating pre and post analytical steps using the automated sample sorter & archival system led to reduction in number of workflow steps & hence time taken for each of the steps & total TAT. It also reduced the manpower. It significantly reduced preanalytical TAT in spite of an increase in sample load. We observed benefits as listed in table 10.

Table 10: Benefits of Automate:

Pre Examination
• Direct receipt of patient tubes through LIS system.
• De capping of tubes.
Examination
• Sorting of tubes into specific analyser racks.
• Recursive workflow. Resorts tubes again according to pending tests for next analyser. No search for pending tests' samples.
• Aliquoting of tubes for EQAS samples, Clinical Trial samples, Validation samples for sister labs, ELISA batch samples, Vendor sample requirements, based on request from LIS.
• Search function available according to barcode.
• Traceability of the individual sample from the path of receipt to archiving.
• Dedicated stat input area enables priority processing for rapid test turnaround time; error area for sample errors like barcode issues, short samples, etc.
Post Examination
• Archival of samples after processing
• Compile statistics during operation for number of tubes, patients, aliquots, tests, archive tubes. Storage of statistics even after machine is switched off.
• Reduction of sample processing times in the laboratory through concurrent distribution, processing and archiving processes.
• Improvement of lab service by TAT reduction for tests processed on multiple analysers

LIS: Laboratory information system

EQAS: External Quality Assurance Scheme

TAT: Turn Around time

Similar findings were noted in evaluation of HCTS2000 MK2, m-u-t AG by Ucar Et al. [6] They observed that by reducing delays and errors in the preanalytical processing and sorting of samples, significant improvements in TAT were made after establishment of the automated system.

Holman et al, [3] in their evaluation of GENESIS FE500 preanalytical sample processor, demonstrated that there was a large increase in throughput when the batch size increased, there was a noticeable decrease in laboratory errors attributable to specimen routing, sorting, aliquoting, and labelling of secondary tubes. In the current study, similar to the findings of Holman et al, Automate reduced the work associated with specimen processing and improved the integrity of specimen handling.

Hawker et al. [7] evaluated the implementation of an automated sorting system (MDS AutoLab Systems) on performance results over three years in a large reference laboratory. They showed that the median TAT decreased by an estimated 7 hours. In present study, 47% reduction in TAT was observed after introduction of sorter.

CONCLUSION:

Automation ensured traceability of the individual samples; enhanced lab-personnel safety due to automation of pre analytical processes. It improved lab services by TAT reduction by reducing delays and errors. Decreased sample processing time in the laboratory was possible through concurrent distribution, processing and archiving processes. Automation increased laboratory productivity by effective utilization of staff to focused work areas due to reduction in man-hours and assured accurate sample receipt for processing.

This suggests that an automated sorting & archival system is indicated for improvement of specimen processing, further studies should be performed to evaluate the impact of pre analytic automation on staff satisfaction and pre analytical errors minimization.

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