VITROS® 5600 Integrated System External Validation Testing: Throughput/Turnaround Time Study*

Kathleen A. Madden, Yinghua Qiu, John Petersen, Amin Mohammad, Anthony O. Okorodudu, University of Texas Medical Branch, Galveston, TX 77555-0551

Abstract

Background: Sample through-put as indicated by turn around time (TAT) for patients that require both immunoassay and routine chemistry is often prolonged because of multiple sample handling requirements. Different laboratories have handled this problem by protocols that may include pre-analytical aliquotting requiring creation of daughter tubes to be run simultaneously on different analyzers. This approach may improve the TAT intermittently. The VITROS® 5600 Integrated System is designed to optimize TAT and enhance productivity by intelligently accounting for variable sample and test mixes, eliminating the need to split the sample on the analyzer or move sample trays between modules. The System also offers an increased menu capacity with 150 reagent positions that allow over 100 assays to be on-board at once.

Objective: The purpose of this study was to assess the efficiency of handling our laboratory's workload on the new VITROS 5600 Integrated system. This was evaluated by comparing a sample workflow between the VITROS 5,1 FS Chemistry System, VITROS ECi Immunodiagnostic System and VITROS 5600 Integrated System. The results from the VITROS 5600 system were analyzed and compared to the results from the VITROS 5,1 FS System and VITROS ECi System combined.

Methodology: A workflow test design was created and preprogrammed exactly the same on each of the three analyzers: VITROS ECi System, VITROS 5600 System, and VITROS 5,1 FS System. The test design consisted of 9 trays, each of which would be timed and recorded according to when the tray was placed on the specific analyzer, when the tray was first sampled from, when all tests were completed for that tray, when the tray was removed from that analyzer and when all results were completed for that tray. A side-by-side comparison of the 9 individual tray completion times, across the 3 analyzers, was used to determine the efficiency of the VITROS 5600 System, as well as the total tray completion time. The tray completion time was determined by measuring the time the analyzer first started sampling to completion of all results for that particular tray.

Results: The VITROS 5600 System proved to be much more efficient, with the average difference for each tray time (delta time), between the VITROS 5600 System and VITROS 5,1 FS/ VITROS ECi Systems, being 17.57_+ 4.31 minutes. When assessing the total time of completion for all 9 trays, based on the time the analyzer started the first tray to when the last tray was completed, the VITROS 5600 had a 56 minutes TAT advantage relative to the comparative analyzers, thus proving much more efficient than the comparative analyzers combined.

Conclusion: Based on these customized workflow studies, the VITROS 5600 Integrated System was found to be more efficient than the combination of the VITROS 5,1 FS and the VITROS ECi Systems running in parallel, thus making the VITROS 5600 System a valuable asset to laboratories that have substantial sample workloads. The VITROS 5600 System should make the laboratory TAT more reliable in terms of percentage of samples meeting defined TAT goals.

Introduction

Present methods for routine chemistry and immunoassay tests in clinical laboratories require the use of multiple instruments. The VITROS® 5600 Integrated System is an intricate system that incorporates chemistry and immunoassay processing in one instrument. It includes five technologies: MicroSlide, MicroTip, MicroWell, IntelliCheck®, and MicroSensor. The MicroSlide technology allows for tests to be processed on microslides and read by an electrometer and reflectometer in the MicroSlide subsystem center. The MicroTip technology utilizes cuvettes for tests to be processed in and read by the photometer in the MicroTip subsystem center. The MicroWell technology processes tests in wells that are incubated in the MicroWell incubator and read by a luminometer. IntelliCheck technology is used throughout the testing process to verify the integrity of the sample and assay processing as well as eliminating sample/reagent contamination. MicroSensor technology automatically screens the sample for hemolysis, icterus and turbidity.

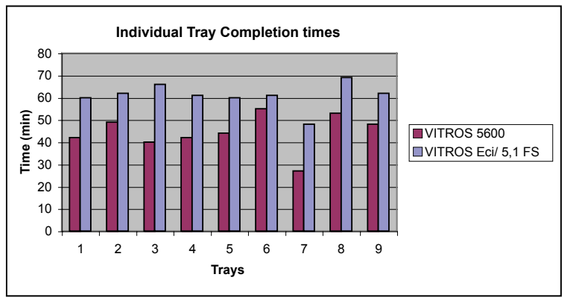
Methods

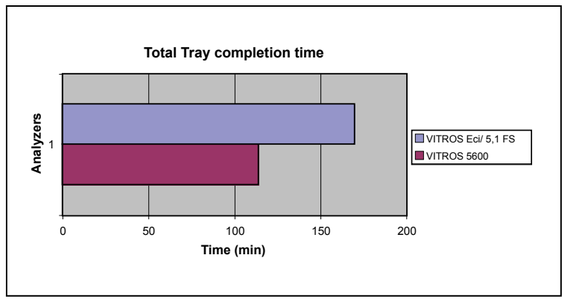
A workflow test design of 7 routine chemistry panels utilizing 36 assays** was created (to the right) and preprogrammed on each of the analyzers. The total number of tests performed was 518, with the majority being MicroSlide assays (79%). MicroWell and MicroTip assays comprised 15% and 7% respectively. The test design consisted of 9 trays, each of which was timed and recorded according to: time the tray was placed on the specific analyzer with sample metering "on", metering time of first sample, time of results reported for that tray, time of tray removal from that analyzer and time of all results completed for all 9 trays. A comparison of the 9 individual tray completion times for each of the analyzers was assessed. This was defined as the time the analyzer first started sampling from that tray to when all results were completed for that particular tray. The total tray completion time from start to finish for all of the 9 trays on each analyzer was also used to verify efficiency.

Tray 1	Tray 2	Tray 3	Tray 4	Tray 5	Tray 6	Tray 7	Tray 8	Tray 9
Comprehensive Metabolic	comprehensive Metabolic	CRBM	Thyroid/ALB	comprehensive Metabolic/ PSA, CEA	Cardiac	FE, dTIBC	comprehensive Metabolic/ Thyroid	comprehensive Metabolic/ TSH
Lipid	comprehensive Metabolic/Thyroid	Renal/ PSA, CEA	FE	NTBNP, dLDL	Renal	GENT	Thyroid/GLU	FE
RF	GENT, TSH	GLU	comprehensive Metabolic	GENT	GENT	Cardiac	CREA U	Lipid/TP
Cardiac	Hepatic	CREA U, mALB	comprehensive Metabolic	CREA U, mALB	CRBM	GENT	comprehensive Metabolic	Cardiac
GENT	Cardiac	PSA, CEA, TP, TSH	Cardiac	Renal	comprehensive Metabolic/ Lipid	Hepatic	Thyroid/GLU	Hepatic
Renal	Lipid/ GLU/TSH	GENT	mALB	Thyroid	RF	CREA U, mALB	Cardiac	Thyroid/ K
CREA U, mALB	PSA, CEA, TP, TSH	Cardiac	PSA, CEA, TP	TP	Lipid/ GLU	comprehensive Metabolic	dLDL, GENT	comprehensive Metabolic
Thyroid/ GLU	FE, dTIBC	comprehensive Metabolic/ TSH	comprehensive Metabolic/ Lipid	comprehensive Metabolic/ NTBNP	PSA, CEA, TSH, TP	CREA U	Lipid	comprehensive Metabolic/Thyroid
AMYL	GENT	RF	Renal	mALB	Renal	Lipid	GLU, AMYL	GENT
PSA, CEA, TP	comprehensive Metabolic	Lipid/ Renal	CRBM	CREA U	Thyroid/GLU	mALB	dLDL	Renal

Results

When analyzing each individual tray time, the VITROS 5600 Integrated System yielded results in significantly less time relative to the comparative analyzers. The average delta time for each tray was about 18 minutes. The VITROS 5,1 FS Chemistry System and VITROS ECi Immunodiagnostic System finished all nine trays in 170 minutes, while the VITROS 5600 Integrated System finished in 114 minutes.





Conclusions

❑ The incorporation of the VITROS 5600 Integrated System in clinical laboratories would dramatically improve TAT and a quicker reporting of patient results.

❑ This integrated concept will also help clinical laboratories in the efficient utilization of space and less demand for instrument versatility.

❑ The VITROS 5600 Integrated System is fully capable of competently processing a high sample volume.

* Part of External Trials and Partly Supported by Ortho Clinical Diagnostics

** Product Availability Subject to Local Regulatory Requirements