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Size Matters – A Consideration for Instrument Selection

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Introduction

A typical hospital laboratory has fixed walls that define the workspace. This space is often "land locked" which makes operational expansion nearly impossible. These barriers along with ever increasing test and sample volumes can create stress on lab operations. Besides the workspace challenges, physicians are demanding faster test results at a time when labs have fewer technologists to perform testing activities. These operational realities create a "How do I do this" dilemma for laboratory management.

IVD vendors continue to find ways to address these operational issues by providing solutions that offer expanded test menus, are highly efficient, and are compact in design. This article compares two chemistry-immunoassay systems and assesses them against the "How do I do this" question and the following metrics:

- Testing throughput
- Individual assay turnaround times (TAT)
- Required floorspace

In addition to the core metrics, general Workflow Observations were also captured and documented.

Conducting this analysis was Nexus Global Solutions, Inc. (Nexus), an independent, third-party consulting firm that specializes in diagnostic product research as well as providing consulting services to both laboratory suppliers and diagnostic laboratories[1].

[1] www.thenexuscorp.com

Study Methodology

A study protocol was developed to objectively evaluate the productivity of the following chemistry-immunoassay systems: The Siemens Healthcare Diagnostics VersaCell™ System (connected to an ADVIA® 1800 Chemistry System and an ADVIA Centaur® XP Immunoassay System) and the Beckman Coulter UniCel® DxC 880i Synchron® Access® Clinical System (configured with two analyzers, each utilizing one UniCel® DxC 800 chemistry module and one UniCel® DxI 800 IA module)[2].

The DxC 880i system was selected as the baseline target system for the purposes of this evaluation. The DxC 880i site was a European public hospital with an annual volume of 1.2 million tests. The lab operates two DxC 880i systems that have been in use for over two years. The facility was efficiently managed and followed Lean practices. Nexus obtained two workload lists through direct observation of the DxC 880i systems over two days of testing. The captured data included:

- Individual sample load time
- Ordered assays for each sample
- Result time for each ordered assay
- Operational space requirements

[2] The systems by manufacturer are as follows:
Siemens VersaCell™ System – Siemens Healthcare Diagnostics, Tarrytown, NY 10591
Beckman Coulter UniCel® DxC 880i Synchron® Access® Clinical System – Beckman Coulter, Inc., Brea, CA 92821

These workload lists are identified as Protocol #1 (P1) and Protocol #2 (P2) in the data summary shown below:

Table 1: Protocol Data Summary

Protocol Data Summary	**P1**	**P2**
Total # Samples Loaded	325	609
Total # Tests Ordered	1,981	3,816
Chemistry Tests	96.9%	94.4%
IA Tests	3.1%	5.6%
Avg. # Tests/Sample	6.1	6.3
Elapsed Time to Load All Samples	5h:25m	5h:45m
VersaCell system configuration	1	1
DxC 880i system configuration	1	2

During the two-day observation period, the DxC 880i instruments processed few urgent (STAT) samples, performed indices (HIL) testing on all samples, and did not utilize the auto-repeat testing capability. The second phase of the analysis was to 1) duplicate the same worklist on the VersaCell System, and 2) capture the same timestamp data. This approach allowed for a direct comparison of throughput and TATs.

The VersaCell system study was completed in a research and development laboratory in order to replicate the DxC 880i load times[3].

Protocol Results

Each observed protocol was different for 1) the number of samples and tests, and 2) the system configuration. P1 was for a single DxC 880i where 326 samples were tested and P2 was run on two DxC 880is' and 609 samples were tested The Chemistry to IA mix is nearly identical for each protocol and the average number of tests ordered for each sample is consistent.

Throughput Analysis

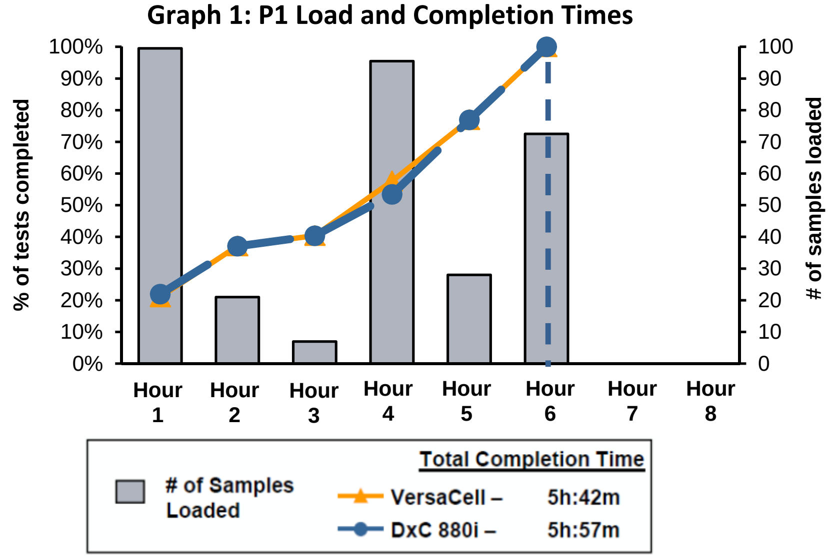
For P1, all samples were fully loaded on each system after 5 hours and 25 minutes. For P2, all samples were loaded on each system after 5 hours and 45 minutes. The following table details the total run-time (defined as starting with loading the first sample and ending with the last test result) for each protocol and analyzer. The VersaCell System completed P1 in 15 minutes less time than the DxC 880i system. Additionally, P2 was completed by the single VersaCell system in 30 minutes less time than the two DxC 880i analyzers.

Table 2: System Run-times

System	**P1 Run-time**	**P2 Run-time**
DxC 880i	5h:57m	7h:23m
Siemens VersaCell	5h:42m	6h:53m

A graphical representation of each protocol throughput is shown below:

Graph 1: P1 Load and Completion Times



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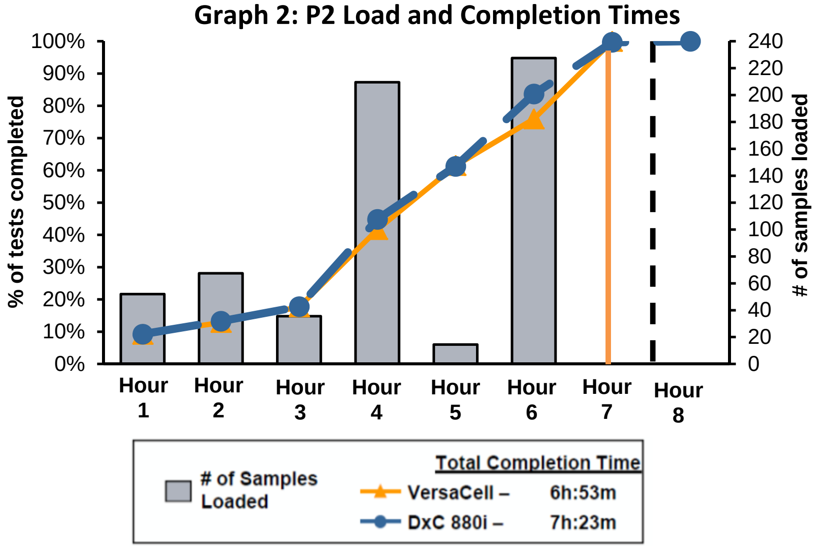
[3] P1 was loaded and run on a single VersaCell system and a single DxC 880i analyzer. P2 was loaded and run on a single VersaCell system and two DxC 880i systems.

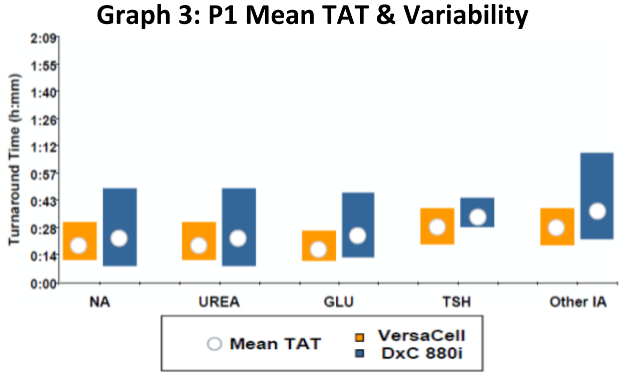
Graph 2: P2 Load and Completion Times



Turnaround Time Analysis

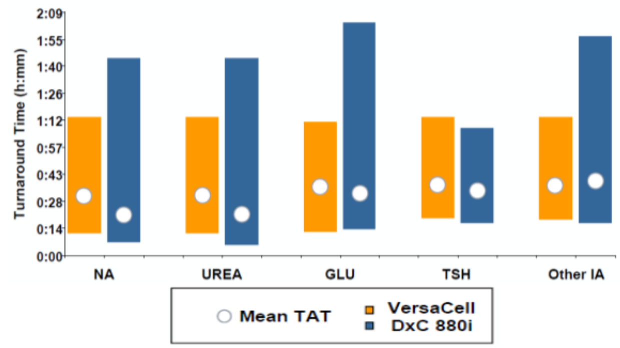
Individual test TAT times were captured for the approximately 6,000 tests completed for both protocols. The average TAT was calculated for each protocol. Graphs 3 and 4 show the shortest, longest and Mean[4] TATs for three common chemistry tests, one common IA test, and a summary of all other IA tests performed in each protocol.

Graph 3: P1 Mean TAT & Variability



[4] The Mean TAT is defined as the arithmetic average of a range of values (individual TATs), computed by dividing the total of all values by the number of values.

Graph 4: P2 Mean TAT & Variability



These data illustrate that for P1 the VersaCell system had slightly faster Mean TATs for the selected assays. For P2, the two DxC 880i instruments had slightly faster Mean TATs on all assays with the exception of Other IA tests. In addition, the VersaCell System TATs, in general, had a smaller TAT range and less variability relative to that of the DxC 880i instruments.

System Floorspace

A single DxC 880i system requires a functional area of 176.5 ft^2 of laboratory space, including all of the necessary instrument clearances. The DxC 880i is configured in a linear layout with no other design options. Nexus observed two DxC 880i systems within the lab occupying 353 ft^2 of floorspace (not including space for sample preparation, reagents, and consumables). The two systems observed were placed in parallel facing one another. This would be the optimal configuration for two systems.

The VersaCell system configuration used in this study had an ADVIA 1800 chemistry system connected on the right side of the VersaCell system and an ADVIA Centaur XP system connected on the left side. The floor space required for this configuration is 123 ft^2.

The following observations and comments were collected during each protocol.

Sample Loading – On the DxC 880i system, all samples are placed into 4-position racks. De-capping samples prior to loading is not required as the DxC 880i system has cap piercing capabilities. Up to a total of 180 samples can be loaded at one time. Should the central bay be unavailable, racks can be directly loaded onto the DxC 800 Chemistry side or the DxI 800 IA side. However, operators must remember to decap the samples when manually loading them on the DxI 880 system.

On the VersaCell system, samples must be decapped before loading them directly into the sample input area. The VersaCell system has 4 drawers with each drawer holding up to 50 samples for a total of 200 samples. The operator opens the appropriate drawer and places the sample into any open location. Completed tubes are removed in the same manner. Samples can also be directly loaded on either the ADVIA 1800 or Centaur XP as needed.

The observed sample loading times were similar for each system with the exception that there is one location to load on VersaCell system compared to two DxC 880i system input bays for loading (one input bay per analyzer). This design creates additional sorting and travel time for the operator to load each of the DxC 880i systems. In addition, this feature may require the operator to transfer samples between both DxC 880i systems if they do not operate with the same assay menu.

STAT Loading – STAT samples on the DxC 880i systems are placed in a 4-position rack and loaded into the central loading bay. The DxC 880i system includes a 10-position carousel module for transferring racks to the appropriate analyzer. Two positions (holding up to eight STAT tubes) are reserved for STAT samples.

NOTE: Site best practices dictated that when racks containing routine samples were waiting transfer to the 10-position carousel modules, any STAT rack was manually loaded at the front of the central loading bay queue. During periods where a large number of tubes were available for testing, the 10-position carousel module can be completely filled with racks. When this occurred, the STAT rack was observed to sit in the queue until a position in the 10-position carousel module became open.

STAT samples are loaded into the VersaCell system drawer designated for STATs. The operator opens the drawer and places the sample in the appropriate location within the drawer. The VersaCell system automatically prioritizes the sample processing of STAT samples ahead of routine samples.

Sample Handling – The DxC 880i system uses an internal aliquot vessel for samples requiring both chemistry and IA testing. The DxC 880i system creates a separate IA aliquot for testing on the DxI 800 module and releases the primary tube to the DxC 800 module for chemistry testing.

Because the DxC 880i system utilizes a 4-position rack for holding and transporting samples, TATs can be negatively affected in certain circumstances. For example, if a specific sample requires an add-on or repeat test, the other samples within the 4-position rack can be "held hostage" and prevented from moving to the required module for analysis.

Samples on the VersaCell system are individually moved via a robotic arm to the appropriate analyzer for testing. The sample tubes are returned to the VersaCell system after the liquid volume is aspirated from the tube. This capability allows the sample tube to be available for the other analyzer or operator as needed.

System Redundancy – The European hospital operates two DxC 880i systems. Should one system go down for any reason, the second acts as a backup allowing for continuous testing. The VersaCell system has one chemistry and one IA analyzer and therefore has no backup analyzer should one go offline. However, both analyzers can function independently of each other on the VersaCell system.

Operator – Nexus observed that one person was able to fully operate both systems. Both systems employed a user interface that was intuitive, easy to see, and provided adequate system information.

Because each DxC 880i system consists of one chemistry and one IA module, the European hospital with two DxC 880i systems had two chemistry and two IA analyzers to calibrate, run required controls, manage reagent usage, and resupply with consumables. Depending upon sample volumes, the DxC 880i system operator could spend more time per day performing these operations than a VersaCell system operator performing the same functions on the single chemistry and IA modules.

Conclusion

Both the Beckman Coulter DxC 880i and Siemens VersaCell systems provide a combination of chemistry and IA testing within a single automated platform. Nexus observed two different workloads captured in a hospital laboratory[5]. For these two workloads the following was determined:

- VersaCell system completed the high sample volume protocol of 609 samples and 3,816 tests using a single system versus two DxC 880i systems in 30 minutes less time (6h:53m vs. 7h:23m).
- VersaCell system completed the lower sample volume protocol of 325 samples and 1,981 tests in 15 minutes less time when using one VersaCell system versus one DxC 880i system.
- Completion times for each system from both protocols are similar considering a run time of ~6 hours for P1 and ~7 hours for P2. While the difference in completion times is not statistically significant, a single VersaCell system completed P2 in the same time as two DxC 880i.

In reviewing TATs for four of the larger volume tests:

- The Siemens VersaCell system provided slightly faster Mean TATs when compared directly to a single DxC 880i system.
- The system configuration of two DxC 880i analyzers provided slightly faster Mean TATs when compared directly to a single VersaCell system.
- TAT variability for both protocols was generally less for the VersaCell system than that of the DxC 880i system.

[5] Siemens Healthcare Diagnostics provided funding for this study. The study site was not informed of this funding in order to elicit unbiased feedback.

In comparing floorspace requirements, data revealed that:

- Two DxC 880i systems were used for daily testing and occupied 353 ft^2 of the laboratory.
- One VersaCell system completed the same daily testing volume while occupying 123 ft^2 of laboratory space.
- Although a VersaCell system backup was not utilized in this study, it is understood that many modern laboratories may have some form of redundant instrumentation, which would require additional instrument space.

In conclusion, Nexus found that a single VersaCell System and a single DxC 880i System had similar throughput and Mean TAT results for Protocol P1 (325 samples loaded over 5½ hours). Nexus also found that a single VersaCell System and two DxC880i Systems had similar throughput and Mean TAT results for Protocol P2 (609 samples loaded over 5¾ hours).