Clinical Chemistry & Immunoassay Solutions – An Operational Comparison Abbott Alinity ci-series & Siemens Healthineers Atellica Solution

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Introduction

The IVD industry is continually improving their product offerings within the high-volume clinical laboratory environment. Today's cutting-edge solutions are highly automated, robust, and accurate. Laboratory professionals expect and demand that all vendor's core lab solutions provide similar clinical outcomes and operational efficiencies. This is especially true within the high-volume clinical chemistry (CC) and immunoassay (IA) areas.

Because it is generally agreed upon that there are fewer clinical differences between most main-stream CC/IA systems, the operational characteristics and requirements of various product offerings have become more of a focus. These operational traits often play a significant role in determining what solution is ultimately integrated into the laboratory space.

This article outlines and compares the operational attributes of two CC/IA solutions: 1) The Abbott Alinity® ciseries (Alinity) and 2) the Siemens Healthineers Atellica® Solution. A study protocol, based upon quality management methodology, was utilized to objectively evaluate the operational characteristics of the two solutions. The performance of the CC/IA solutions under the study protocol may serve as a proxy for the overall operational effectiveness of the two systems.

Conducting this analysis was Nexus Global Solutions, Inc. (Nexus), an independent workflow consulting and marketing research firm providing operational solutions and market intelligence to both laboratory suppliers (diagnostic companies) and clinical end-users (laboratories).¹

Study Overview

Protocol

To conduct a direct operational comparison between the Alinity and Atellica CC/IA systems, a specific data collection protocol was developed. First, the Alinity ci-series was studied at a high volume, commercial lab environment running a routine CC/IA workload. When the Alinity site study was completed, LIS data was utilized to construct a precise "Load List" of samples and assays which were later replicated on the Atellica Solution. In this way the same number of samples and identical test requests were introduced to each CC/IA Solution at the same general time during the shift.

Load List #1: 730 samplesLoad List #2: 261 samples

System Configurations

The Alinity was observed at a commercial laboratory site and was configured as follows: 1) samples were introduced via an Abbott Accelerator® a3600 input/output module, 2) all testing modules were connected via an Abbott Accelerator track-based transport system, 3) samples were aspirated directly from track, and 4) there were a total of five chemistry and two immunoassay modules.

The Atellica Solution was observed at a non-commercial site and was configured as follows: 1) samples were loaded via the Atellica Sample Handler, 2) all testing modules were connected via the Atellica Magline®

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¹ www.thenexuscorp.com

Transport, 3) samples were aspirated direct from the Atellica Magline Transport, and 4) there were a total of two chemistry and one immunoassay modules.

Methodology

To compare the operational requirements of the two CC/IA Solutions, operational data was collected through direct workflow observations, time and motion studies, LIS data retrieval, and targeted interviews of system operators at two U.S. based laboratories. After completing data collection activities at the two study locations, the following operational attributes or metrics were developed for comparison purposes:

- 1. <u>Daily Start-up Time Requirements</u>: Operational process steps and time requirements (manual and automation) to prepare analytical systems for patient samples and routine testing. This time is required each day and is consistent regardless of the daily testing volume. The times exclude calibrators and controls.
- 2. <u>System Turn-Around-Time (TAT)</u>: Total time to run each CC/IA protocol or Load List (Sample Load thru final test result).
- 3. <u>Space Requirements</u>: The total CC/IA analytical footprint of all systems at the corresponding study locations.

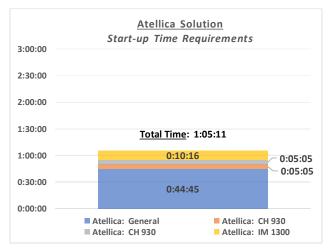
Results

<u>Daily Start-up Time Requirements</u> (Manual + Automation)

Graph 1 compares the total daily "Start-up Times" documented for Alinity and Atellica Solution for all modules and platforms as configured at the respective laboratory locations. Start-up time includes both manual and automation cycle times and may include daily maintenance, system initialization, consumable preparation/loading, and general system interactions. Daily maintenance time is independent of the number of samples run per day. Note that calibrator or quality control preparation or automated run times are *not* included for this comparison.



Graph 1: Daily Start-up & Maintenance



Time Format: h:mm:ss

As illustrated in Graph 1, the total daily start-up time for the Alinity ci was just over 2 ½ hours. The Atellica Solution required just over 1 hour to complete.

In addition, the Atellica Solution enabled the participating laboratory to pre-program the system to automatically start daily maintenance at off-peak hours. Therefore, no operator intervention was required to commence daily maintenance and no active participation was required throughout the automated maintenance procedures across all platforms and systems.

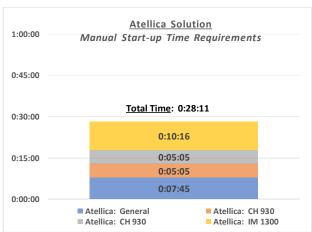
Manual Start-up Time Requirements (Manual Only)

Graph 2 compares the *manual* time requirements ("hands-on" time) for all start-up activities. This included all modules / platforms as they were configured at the respective laboratory locations. Manual cycle times include daily maintenance procedures, consumable preparation / loading, and general system interactions to prepare the systems for testing.

Calibrator and quality control preparation steps are *not* included for this comparison.



Graph 2: Manual Time Requirements



Time Format: h:mm:ss

The manual (or hands-on) time requirements to prepare and start-up the Alinity ci platforms was approximately 46 minutes while the Atellica Solution required 28 minutes of manual time by the operator. The Atellica Solution required 39% less hands-on time compared to the Alinity ci as configured at the sites.

System Turn-Around-Time (TAT) for Protocol 1 (730 samples)

Table 1: Protocol 1 (730 samples) Comparison

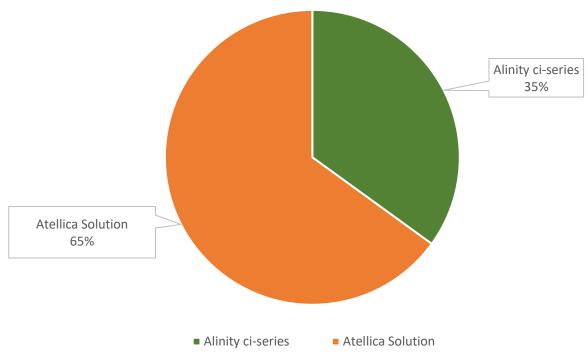
TAT Metric	Alinity ci-series	Atellica Solution
Time to first patient result	0:15:53	0:11:00
Total run time	5:59:28	5:16:00
Time between results	0:00:30	0:00:26

Time Format: h:mm:ss

Table 1 summarizes the outcome of Protocol 1 (730 samples). As stated in the study overview, the samples were loaded as they arrived into the laboratory, in a way they would normally be tested. Running this direct comparison demonstrates that the systems are roughly equivalent, although the Atellica Solution does have slightly faster times in total run time and the time to first result.

Of the 730 samples tested in Protocol 1, Atellica Solution provided quicker TAT's 475 times while Alinity was faster 255 times. Graph 3 illustrates the percentage of samples that were completed quicker by each of the CC/IA Solutions.

Graph 3: Percentage of Samples with Quicker TAT's



System Turn-Around-Time (TAT) for Protocol 2 (261 samples)

Table 2: Protocol 2 (261 samples) Comparison

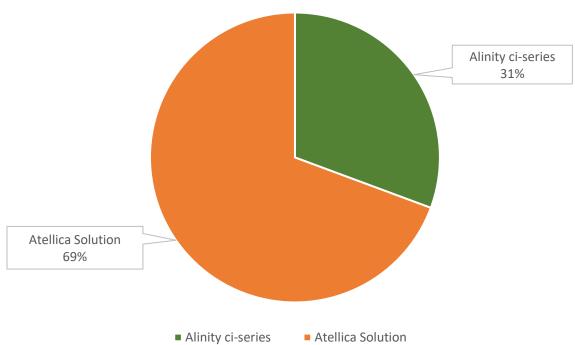
TAT Metric	Alinity ci-series	Atellica Solution
Time to first patient result	0:14:50	0:11:00
Total run time	3:35:14	2:37:00
Time between results	0:00:49	0:00:36

Time Format: h:mm:ss

Table 2 summarizes the outcome of Protocol 2 (261 samples). Like Protocol 1, the samples in this study were loaded as they arrived into the laboratory in a normal testing pattern. Atellica Solution was then replicated in the same loading pattern.

This protocol demonstrates that the Atellica Solution has a better turnaround time, and the metrics seem to improve at lower testing volumes. Of the 261 samples tested in Protocol 2, Atellica Solution provided quicker TAT's 181 times while Alinity was faster 80 times. Graph 4 illustrates the percentage of samples that were completed quicker by each of the CC/IA Solutions.

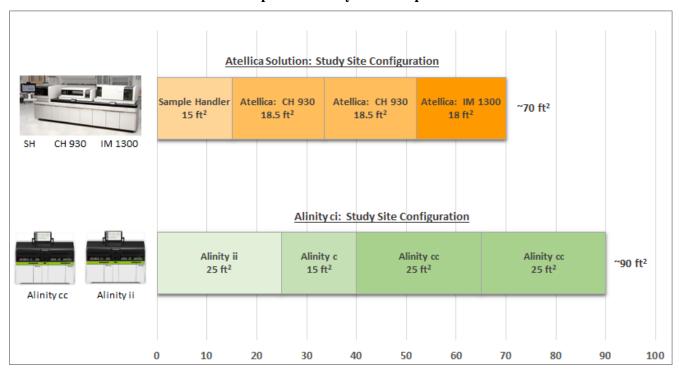
Graph 4: Percentage of Samples with Quicker TAT's



Space Requirements (System Footprint)

Graph 5 illustrates the total system footprint of the two CC/IA solutions at the participating laboratory sites. System footprint herein refers *only* to the physical dimension (width multiplied by depth) of each analytical or required automation module. System clearances, transportation systems (e.g., track) technical bench space, and inventory space is not included.

The Atellica Solution was comprised of four separate systems with a total footprint for all systems of 70 ft². The Alinity ci-series was comprised of four stand-alone systems. One system integrated two immunoassay (ii) modules, two integrated two chemistry (cc) modules and the fourth a single chemistry (c) module for a total of seven diagnostic modules. The total footprint for all Alinity systems and modules was 90 ft².



Graph 5: Total System Footprint

Summary

The Quality Management metrics used in this study provide an objective evaluation of these two CC/IA Solutions from an operational perspective. Table 3 summarizes and compares the operational metrics of the Alinity ci and Atellica Solution.

Table 3: Operational Metrics Comparison

Metric	Atellica Solution	Alinity ci
Daily Start-up & Maintenance (Total Time)	1.1 hours	2.5 hours
Manual Time Requirements - Daily Start-up	0.5 hours	0.75 hours
TAT - Total Run Time (Protocol 1)	5.3 hours	6.0 hours
Percentage of Samples with Quicker TAT's (Protocol 1)	65%	35%
TAT - Total Run Time (Protocol 2)	2.6 hours	3.6 hours
Percentage of Samples with Quicker TAT's (Protocol 2)	69%	31%
System Footprint (ft ²)	70 ft ²	90 ft ²

While both systems offer certain operational efficiencies, based on this study, the Atellica Solution provided greater operational benefits and efficiencies compared to the Alinity ci systems.

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