Value of Clinical IVD Systems

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Summary

Having the flexibility to adapt as the healthcare landscape continues to change is critical to your success. Abbott ARCHITECT *ci*16200 outperforms the Roche cobas 8000 in key areas that impact your laboratory's business operations enabling you to do more with less.

- 70% less hands-on time with ARCHITECT's maintenance protocol. This difference frees your staff for more strategic patient centered projects.
- 49% less downtime during ARCHITECT instrument maintenance providing more time for patient testing.
- 34% less critical area consumed with ARCHITECT's footprint.
- 50% less consumable waste produced with ARCHITECT's immunoassay testing design potentially reducing costs associated with consumables.
- 29% less specimen volume is required (36 µl less) for common panels reducing patient redraws.

Introduction

The healthcare industry is changing rapidly. Healthcare organizations are pressured by changes in funding, aging populations and increases in chronic diseases. Clinical laboratories that operate and use their resources efficiently in this environment have greater options for responding to change, whether it's the ability to shift staff to a new area of focus or commit space to new revenue producing technologies.

In this study, Enterprise Analysis Corporation (EAC), www.eacorp.com, visited two laboratories to observe and record some of the critical measures related to owning and operating clinical laboratory systems. The results provide a view of the day in the life of a clinical lab and the costs associated with operations based on analyzer choice.

This white paper reviews a summary of the study results, which are available upon request from Abbott.

Systems in the Study

- Abbott ARCHITECT *ci*16200
- Roche cobas 8000 (Configuration observed was ISE + c702 + c502 + one of two e602s)*

*Tracks connected analytical modules.

Methodology

EAC observed and measured the amount of human intervention and analyzer time required to perform common tasks such as maintenance. EAC also observed the amount of consumable waste generated and common parts replacement, and product inserts for sample volume requirements.

EAC went on-site to observe daily activities, a minimum of 8 hours per site. For analyzer tasks that could not be observed directly, EAC used times noted in the operations manuals. EAC recruited labs with comparable analyzer configurations and annual volumes. The institutions were of similar type and size and had comparable menu offerings. See Table 1 for summary information.[1] Technologists were very familiar with analyzers because both sites had recently replaced lower volume analyzers with higher volume analyzers from the same manufacturer. The Abbott site changed to the ARCHITECT *ci*16200 from the ARCHITECT *ci*8200 and the Roche site changed to the cobas 8000 from the cobas 6000.

Table 1 Site Summary

	Abbott Site	Roche Site
Site Location	Canada	Netherlands
Annual Clinical Chemistry/ Immunoassay tests	4.0 million	3.3 million
Configuration	2 integrated *ci*16200	2 cobas 8000 2 lines with ISE, c702, c502, 2 e602 modules

Table 2 Studied System Dimensions and Weight

	Abbott ARCHITECT *ci*16200	Roche cobas 8000
Height	4 feet/1.2 meters	4.4 feet/1.3 meters
Length	11.7 feet/3.6 meters	19.2 feet/5.9 meters
Depth (deepest component)	4.1 feet/1.2 meters	3.8 feet/1.2 meters
Area	48 ft^2/4.5 m^2	73 ft^2/6.8 m^2
Weight	2,626 pounds/1,191 kilograms	4,785 pounds/2,170 kilograms

Note: To create an equivalent system for comparison, one of the cobas site's e602 modules was not used for the study. Both of the cobas site's chemistry modules were required as the c702 performs general chemistries and the c502 performs urine chemistry testing, Drugs of Abuse (DOA), Therapeutic Drug Monitoring (TDM) tests, specific proteins and HbA1c testing. The ARCHITECT *c*16000 performs urine testing, DOAs, TDMs, specific proteins and HbA1c along with all routine clinical chemistry testing on a single system.

At each site, EAC worked with the senior technologists responsible for the analyzers. Observations were compared with manufacturer's operations manuals. Completion of tasks was tracked by two EAC consultants. They noted time spent by the technologist in prepping and interacting with the system and analyzer time for task completion.

Labs normally perform tasks together for efficiency. The assumption that tasks are grouped together means the analyzer is brought down and back up only once for the grouped activity.[2] Total daily time in the report is calculated based on this assumption.

Results

Maintenance

The Abbott ARCHITECT *ci*16200 outperformed the Roche cobas 8000 in both human time and analyzer downtime, in daily and weekly maintenance. For overall analyzer downtime, the ARCHITECT *ci*16200 was out of analytical service for daily maintenance 31 minutes less, and for weekly maintenance 93 minutes less than the cobas 8000.

Over the course of a year, the time saved in performing daily and weekly maintenance will result in a total of 11.9 days more uptime for the Abbott ARCHITECT *ci*16200. Additionally, the Abbott ARCHITECT *ci*16200 requires 21 less minutes of hands on human time for daily maintenance and 50 less minutes when performing weekly maintenance, when compared to the Roche cobas 8000. Over the course of one year, this equates to 169 hours or four weeks of one full time equivalent. This labor savings can free up a technologist to work on other tasks.

Maintenance activities observed were those outlined in the operations manual and include cleaning probes, mixers and filters. In the labs observed, set times were established to perform maintenance tasks and manage reagents and consumables in order to optimize efficiency. The most common maintenance activities performed by a technologist include inspection and wiping down of analytic components such as probes and tubing, which are reported as human time. Human time often overlaps with analyzer downtime since certain tasks, such as wiping down probes, cannot be performed while the analyzer is in analytical service. Cleaning probes and mixers is required on both systems but the frequency differs. In order to follow good lab practices, EAC applied timed observations to the frequencies recommended by the operation's manual for each analyzer. For example, Roche recommends all probes be cleaned during daily maintenance and although the site observed does this during weekly maintenance the time to clean all probes was accounted for daily. Abbott's recommendation for cleaning probes varies by probe type. Some are cleaned daily and others weekly.

Figure 1: Daily Maintenance Times

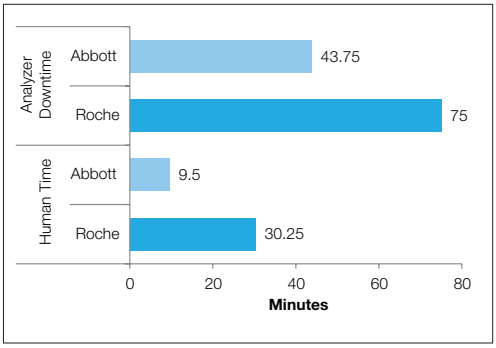


Figure 2: Weekly Maintenance Times

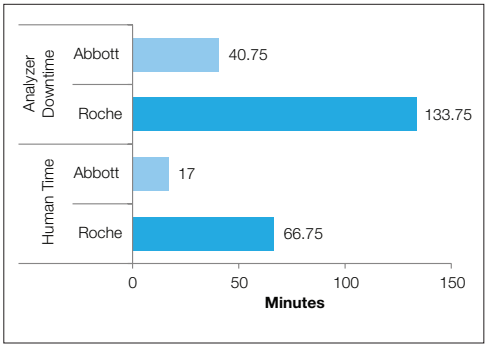
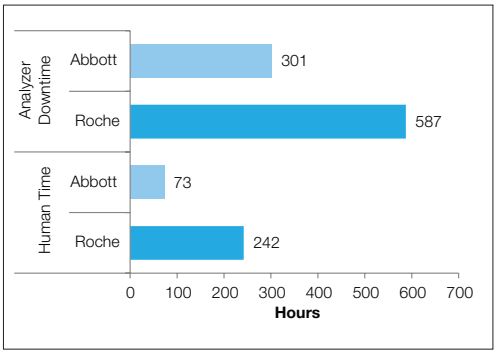


Figure 3: Annualized Maintenance Times



Note: Human time reflects the time spent by a technologist interacting with the analyzer, which is included in the analyzer downtime.

Both analyzers perform automated maintenance cycles that require the analyzer be out of analytical service. Once the analyzer is down for self-cleaning tasks there is a restart element that takes place. To restart the cobas 8000 the system must first be placed into a standby mode and then taken off standby mode. It takes 1.5 minutes for the c502/c702 modules and 2.5 minutes for the e602 to be put in standby. It takes 2.5 minutes for the c502/c702 and 6.5 minutes for the e602 to take them out of standby. This is not sequential time; different modules can be put in standby at the same time.

The Abbott ARCHITECT *ci*16200 does not need to be put in a standby mode, it only needs to be clear of any tubes in process. A ready to run cycle must then be performed. This cycle takes 3.25 minutes for both the chemistry and immunoassay units.

Note: The Roche cobas 8000 has an additional 30 minute task to clean the liquid flow path, to be performed every other week during maintenance. There is no comparable activity on the ARCHITECT *ci*16200.

Consumable Waste

The ARCHITECT *ci*16200 produces 50% less solid waste than the cobas 8000. EAC conducted a separate study protocol in whhich 644 chemistry and 61 immunoassay tests were performed and the solid waste generated was measured.

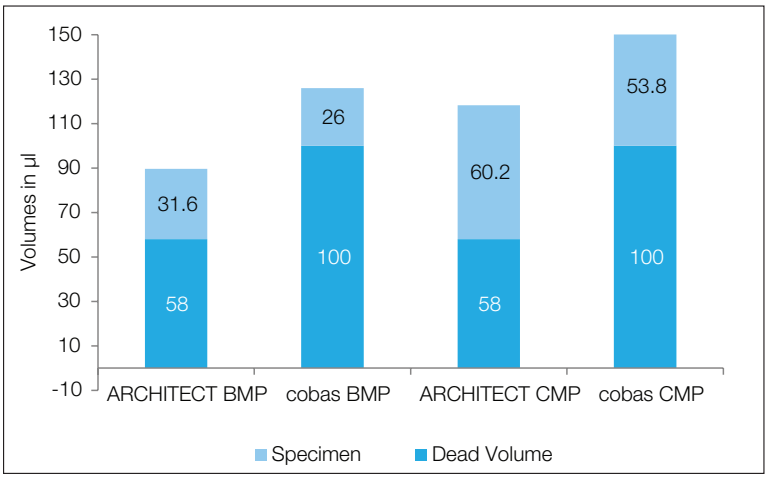
Solid waste on the ARCHITECT *ci*16200 represents the reaction vessels (RVs) and the plastic garbage bag while on the cobas 8000 it is the AssayCups, AssayTips, empty cup and tip trays and trash receptacle.

The Roche system produced double the amount of solid waste during this run, 0.1 kilogram for Abbott compared to 0.2 kilogram for Roche. In a lab the size of those observed, we assume that 15% to 20% of their annual volumes are comprised of immunoassay tests. Taking a midrange point of 17.5% of volumes being immunoassay tests, a lab running 3,300,000 tests annually generates 4,166 pounds (1,893 kilos) of solid waste with the cobas 8000. This same lab would generate 2,083 pounds (947 kilos) of solid waste with the ARCHITECT *ci*16200.

Specimen Volume Requirements

In an insert to insert comparison[3] that EAC conducted in addition to the site visit, we found that the specimen volume required varied by assay. EAC calculated the total specimen required to run an 8 test basic metabolic (BMP) and a 14 test comprehensive metabolic panel (CMP), including the dead volume requirement. See *Figure 4*.

Figure 4 Specimen Volumes



When the required dead volume is taken into account, the ARCHITECT *ci*16200 requires 29% less specimen than the cobas 8000 to run a basic metabolic panel and 23% less specimen to run a comprehensive metabolic panel from a sample cup.

Additionally, we did not find any short sample errors in our review of the ARCHITECT *ci*16200 message logs whereas the cobas 8000 had 5 short sample errors in a one week period.

Findings

The major advantage of the Abbott ARCHITECT *ci*16200 over the Roche cobas 8000 was in maintenance requirements, both daily and weekly. Maintenance procedures require the Roche cobas 8000 to be "off line", unable to analyze specimens, for 31 minutes longer for daily maintenance and 93 minutes longer for weekly maintenance, than the Abbott ARCHITECT *ci*16200. Over the course of one year, for a laboratory operating 24 hours a day, seven days a week, this equals 11.9 days of additional uptime.

Additionally, the Abbott ARCHITECT *ci*16200 produces 50% less waste in a typical two hour run. In a lab running 3.3 million annual chemistry and immunoassay tests, assuming 17.5% of those tests represent immunoassay tests, this translates to a difference of approximately 2,083 pounds (947 kilos) per year in solid waste.

The ARCHITECT *ci*16200 is also 34% smaller; occupying 48 square feet (4.5 square meters) compared to the Roche cobas 8000 at 73 square feet (6.8 square meters).

Lastly, the Abbott ARCHITECT *ci*16200 requires 29% less specimen volume than the Roche cobas 8000 for a common panel run from a sample cup. The Abbott ARCHITECT *ci*16200 requires more specimen to run both a basic and a comprehensive metabolic panel, but when the required dead volume is taken into account the ARCHITECT *ci*16200 requires less specimen than that of the Roche cobas 8000.

1. Compiled using information published on the Abbott and Roche websites.
2. EAC studied a single institution for each of the analyzer configurations and, therefore, could not address variability that may exist when observing and measuring similar configurations used by different institutions.
3. Volume requirements were taken from the "configure assay parameters" section in the Abbott package insert and the "test definition" section for Roche.