Using Quality Management Methods to Compare Competing Mid-Volume Segment Immunoassay (IA) Systems that Perform Infectious Disease (ID) Testing

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Introduction

Diagnostic laboratories continue to face the challenge of providing timely and accurate testing results while hospitals shrink lab budgets, staff hours and floor space. In addition, new assays that positively impact patient and public health are being added in increasing numbers to the overall lab menu.

Lab management has responded to this challenge by employing appropriately sized analyzers which:

- Are operationally easy to use by staff
- Use fewer staff FTEs
- Will complete sample volumes and related tests within hospital turnaround time (TAT) protocols

Further, lab management is also using analyzers with special features (a form of automation) that will:

- Complete routine testing with minimal staff involvement including repeats, auto dilutions, and reflex testing
- Provide significant walkaway (minimum of 10 minutes) capabilities

Many mid-sized hospitals now perform both immunoassay (IA) and infectious disease (ID) testing but do not have the capital budget or floor space for a large integrated system. These labs require a single analyzer characterized by a small footprint, assay flexibility, and high productivity that meets lab testing protocols. This article examines five analyzers currently in use and evaluates their productivity, using the following characteristics:

- Operational ease of use
- Labor efficiency
- Testing throughput

Conducting this analysis is Nexus Global Solutions (Nexus), a third-party consulting firm that specializes in performance improvement for product developers (healthcare corporations) and end-users (laboratories). A study protocol was developed to objectively evaluate the productivity of the Siemens ADVIA Centaur® CP compared to four competitive IA/ID systems. The competitive systems[1] include:

- Abbott AxSYM®
- Beckman Coulter Access®2
- Ortho-Clinical Diagnostics VITROS® ECiQ
- Roche Diagnostics Elecsys® 2010

The protocol consisted of observing each competitive system in an operating lab for two days. Detailed time study data and operator comments/feedback were collected. Additionally, the daily worklist of patient samples and ordered tests was recorded. These "real-world" worklists were then run on the ADVIA Centaur CP and the same detailed time study data was recorded. The observed lab operations and worklist comparisons were the basis of the productivity evaluation within a working lab environment.

Study Methodology

Interviews with lab management and staff found a changing set of criteria for the ideal system. In general, a valid test result is treated as a commodity for systems manufactured by the product developers. Each of the previous systems mentioned may have differing detection sensitivity or normal ranges, but in general provide a quality

result that is accepted by most physicians. This study does not address the issue of qualitative results, but assumes that each system will provide a valid result with small variances on accuracy.

The more important question now deals with the shrinking labor pool for medical technologists and how to maximize the use of their lab knowledge balanced with their daily testing work. The three possible solutions are:

- The lab staff will be required to work longer hours
- More work will need to be performed (i.e., productivity increases) during the workday
- Services will need to be reduced to match staffing levels

Lab management preference is to improve productivity and not work more hours (which can lead to fatigue, errors, burnout and higher labor costs). Additionally, lab management and staff want systems that have throughput capacity and TATs to meet the physician's information needs (usually less than 1 hour for STATs and 4 hours for routine tests). Finally, while cost is an important variable, it is not the overriding factor in deciding which system to use. This study does not address the cost differences for each system other than to highlight ongoing operating consumables, system fluids, and labor required to produce a test result.

The criteria used to evaluate the competing systems include the following:

- Operator ease of use
  - Access analyzer for start-up & maintenance
  - Load/unload samples, reagents, consumables
  - Complete solid/liquid waste disposal
  - Control analyzer via User Interface

- Analyzer features assisting in labor efficiency
  - Enables visual observation of all key processes
  - Performs routine tasks automatically
  - Broad assay menu
  - Inventories onboard consumables to minimize restocking cycles
  - Has high level of reliability

- Productivity enhancements
  - Minimizes total manual labor time
  - Maximizes ease of use/ergonomics
    - Visual
    - Audio
    - Reach
    - Weight
  - Allows for operator to walk away from analyzer for more than 10 min. at a time
  - Communicates "problems" to operator
    - When near analyzer
    - When in walkaway status
  - Provides optimal testing throughput

Data Collection

Comparison data to evaluate the strengths and weaknesses of each system was collected though direct observation and targeted interviewing. For this study, three US labs and one ex-US lab were identified as representatives of mid-volume segment IA systems performing ID testing (50,000 – 100,000 tests/year). The participating sites represented the following demographics:

- Northeast US community hospital
- Southeast US community hospital
- Southeast US medium-sized university health center
- Ex-US community hospital

Based on the collected data, observations and interviews, each analyzer is ranked on a scale from 1 (lowest) to 10 (highest) for these fourteen criteria. For consistency, the same Nexus personnel conducted all data collection and interviews at each

site. The category rankings were used to create an overall scorecard for each analyzer. Run times are provided for the observed worklist at each site.

Results

The Abbott AxSYM:

Table 1: AxSYM Ease of Operation

AxSYM - Ease of Operation			
Access Analyzer for Start-up and Maintainence	Load/Unload Samples, Reagents, and Consumables	Complete Solid/Liquid Waste Disposal	Control Analyzer via User-Interface
6.5	5	6.5	4.5

AxSYM Ease of Use Comments

- Access – Specimen racks, reagent cartridges and reaction vessels are easily accessed on the top of the analyzer. Solid and liquid waste containers are located in the lower bay. Aspiration probes are externally located for easy maintenance. However, any internal system issue would require a service call.
- Load/Unload Process – Ten position AxSYM curved racks are loaded as they become available into the sample loading carousel on the top of the analyzer. Loading new racks does cause a temporary stoppage of pipetting specimens already on the analyzer. Reagent cartridges are loaded into the reagent loading carousel but cannot be loaded/unloaded while the AxSYM is in testing mode. Reaction vessels are snapped into the reaction vessel carousel when the AxSYM is in stand-by mode. The lab at which the study was performed does not load specimen tubes on the AxSYM but utilizes a small sample cup for testing. The operator aliquots a sample from the primary tube to the sample cup. This is done to minimize sample volume required for testing (a larger sample volume is required for direct aspiration from a tube vs. cup).
- Waste Disposal – The AxSYM does not require a liquid waste drain but has an onboard container. The AxSYM's dry consumables, a reaction vessel and matrix cell, are collected in a waste container that has easy access for removal.
- Control via User Interface – All AxSYM operations are controlled via an attached keyboard and 15 in. touch-screen monitor. The screen is small and dim and has no color graphics to assist the operator in visually monitoring the testing process. The User Interface does not display real-time information (the data must be manually refreshed on a regular basis) on testing, assays and consumables. The AxSYM has a limited variety of menu and message screens.

Table 2: AxSYM Labor Efficiency

AxSYM - Labor Efficiency				
Visually Observe all Key Processes	Performs Routine Tasks Automatically	Has Broad Assay Menu	Inventory Sufficient Supplies to Minimize Restocking	Has High Level of Reliability
5.5	6.5	9.5	7	9.5

AxSYM Labor Efficiency Comments

- Visual Observations – The AxSYM provides a reasonably clear view for the operator to monitor key operating processes. The User Interface does not provide information that is readily viewable or accessible.
- Routine Tasks – The AxSYM completes the basic testing process, but does require the active participation of the operator. User Interface screens must be manually refreshed to monitor consumables usage. The operator must also monitor reagent onboard stability due to the lack of a refrigerated reagent bay. The AxSYM

can perform auto-repeat, auto-dilution and reflex testing.

- Menu – The AxSYM has 81 assays available worldwide.
- Onboard Inventory – The AxSYM holds 20 assay cartridges (100 tests ea.), 100 reaction vessels, and 200 matrix cells at the start of testing.
- Reliability – The AxSYM is operationally reliable but has a history of back-orders on certain assays.

Table 3: AxSYM Productivity

AxSYM - Productivity				
Minimize Total Labor Time	Maximize Ease of Use/Ergonomics	Operator Can Walk Away for More Than 10 mins	Communicates Problems to Operator	Throughput
7	5	8	6	9

AxSYM Productivity Comments

- Total Labor Time – The AxSYM required 33 min. of direct manual time for testing versus 17 min. for the ADVIA Centaur CP for the same worklist. Additionally, the AxSYM does not have onboard refrigeration for the Reagent Carousel. This requires the operator to continually remove/reload minimally used assays in order to maximize reagent onboard stability.
- Use/Ergonomics – The AxSYM is a floor standing unit and the largest and noisiest of the studied analyzers. During start-up and after 40 minutes of inactivity the AxSYM completes a 3 minute "agitation cycle" to mix onboard reagents. This procedure is loud and adds to the testing dB levels. Operators could reach the loading and reagent bays with no difficulty. However, the 10 liter Line Diluent Solution container weighs approximately 35 lbs., causing difficulty in removing or loading it into the lower bay.
- Walkaway – The AxSYM operator can walkaway from the analyzer once racks are loaded. However, the operator must remain nearby and vigilant during testing in order to remove/reload reagent cartridges. The reagent carousel holds 20 reagent packs which may need to be routinely rotated for labs operating with a broad test menu.
- Communication – The AxSYM provides adequate visual notification and an audible alarm that facilitates the ability of the operator to walk away from the analyzer.

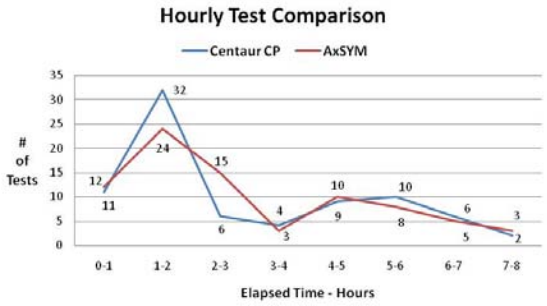
The AxSYM testing protocol was observed in a Southeast US community hospital. A total of 51 samples with 80 tests (21.2% ID and 78.8% IA) were loaded and resulted on both analyzers. The total run time to complete the 80 tests on each analyzer is shown in Table 4.

Table 4: AxSYM Run Time Comparison

Instrument	AxSYM	CP
Total Run Time (h:mm:ss)	7:22:27	6:59:21

The ADVIA Centaur CP completed this protocol in 23 fewer minutes. The AxSYM does not have a separate STAT loading process. However, the operator can designate a STAT specimen via the User Interface, causing that specimen to be moved to the head of the queue for the next possible aspiration.

Chart 1: AxSYM Hourly Test Comparison



The Beckman-Coulter Access2:

Table 5: Access2 Ease of Operation

Access2 - Ease of Operation			
Access Analyzer for Start-up and Maintainence	Load/Unload Samples, Reagents, and Consumables	Complete Solid/Liquid Waste Disposal	Control Analyzer via User-Interface
6.5	5.5	7.5	8.5

Access2 Ease of Use Comments

- Access – The Access2 upper bay door lifts up for maintenance and allows for the replacement of three separate probes (six total probes with three rotated for weekly cleaning). Probe access is limited due to the tight interior space and the positioning of the probes. Additionally, access to the lower bay requires two people to manually lift and remove the protective cover. Specimen racks, reagents and consumables are loaded through an easily accessible door on the top of the analyzer.
- Load/Unload Process – Ten position Access2 curved racks are loaded as they become available into the Specimen Bay on the top of the analyzer. Loading new racks does cause a temporary stoppage of pipetting specimens already on the analyzer. Reagent wedges are loaded via a Reagent Door but cannot be loaded/unloaded while the Access2 is in testing mode.
- Waste Disposal – The Access2 does not require a liquid waste drain but has an onboard container. The Access2 usage of system fluids (Wash Buffer) may require the liquid waste bottle to be emptied multiple times during testing. The Access2 dry consumable (reaction vessels) is collected in a disposable bag that has easy access for removal.
- Control via User Interface – All Access2 operations are controlled via an attached keyboard and 15 in. touch-screen monitor. The User Interface displays real-time information on testing, assays and consumables. The screens utilize data and graphics that are easy to see and interpret.

Table 6: Access2 Labor Efficiency

Access2 - Labor Efficiency				
Visually Observe all Key Processes	Performs Routine Tasks Automatically	Has Broad Assay Menu	Inventory Sufficient Supplies to Minimize Restocking	Has High Level of Reliability
6	8	8.5	7	7

Access2 Labor Efficiency Comments

- Visual Observations – The Access2 is a bench-top analyzer that provides a reasonably clear view for the operator to monitor key operating processes. The User Interface provides information that is readily viewable and easy to understand.
- Routine Tasks – The Access2 completes routine tasks and automatically monitors the analyzer. These tasks include auto-repeat, auto-dilution, and user-defined reflex testing. The User Interface provides real-time updates which highlight important parameters that allow reasonable walkaway time.
- Menu – The Access2 has 74 assays available worldwide.
- Onboard Inventory – The Access2 holds 24 assay cartridges (100 tests ea.) and 294 reaction vessels at the start of testing. Additional reaction vessels can only be added while in standby mode. The Access2 was observed to consume a large volume (1400 mL) of wash buffer (total volume of 1950 mL) solution for a batch of 25 specimens.
- Reliability – The Access2 is operationally reliable. A daily maintenance time of 88 min. (due to the B-12 assay) is the longest of the studied analyzers and reduces the availability of

the Access2 for testing. The resupply of necessary consumables was delayed for one hour while the Access2 completed the pending tests and then returned to standby mode.

Table 7: Access2 Productivity

Access2 - Productivity				
Minimize Total Labor Time	Maximize Ease of Use/Ergonomics	Operator Can Walk Away for More Than 10 mins	Communicates Problems to Operator	Throughput
7.5	7	8	6	4

Access2 Productivity Comments

- Total Labor Time – The Access2 required 33.5 min. of direct manual time for testing versus 3 min. for the ADVIA Centaur CP for the same worklist. Additionally, the daily maintenance for the Access2 when using the B-12 assay increases in number of steps, complexity (preparation of 10 cups containing cleaning solutions) and time (18 min. manual and 70 min. automation for a total of 88 min.).
- Use/Ergonomics – Operators can reach the loading and reagent bays with no difficulty. The reaction vessels must be inserted and snapped into an interior bay. The study site stated a reaction vessel will occasionally slip out of position and become lodged within the interior (once a month occurrence). When this occurs, the operator will retrieve the vessel or may seek a service technician to remedy the situation.
- Walkaway – The Access2 operator can walk away from the analyzer once racks are loaded. The reagent bay is refrigerated and holds 24 reagent packs, minimizing reagent change out requirements.
- Communication – The Access2 provides adequate visual notification and an audible alarm that facilitates the ability of the operator to walk-away from the analyzer.

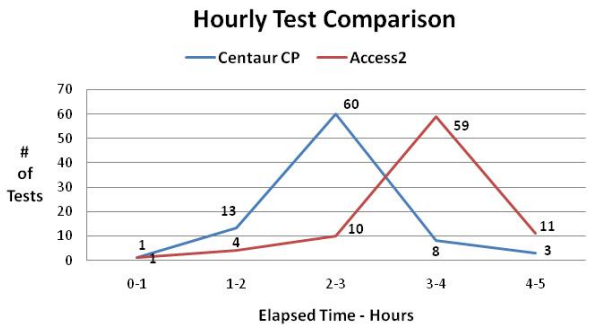
The Access2 testing protocol was observed in a Northeast US community hospital. A total of 45 samples with 85 tests (1.2% ID and 98.8% IA) were loaded and resulted on both analyzers. The total run time to complete the 85 tests on each analyzer is shown in Table 8.

Table 8: Access2 Run Time Comparison

Instrument	Access2	CP
Total Run Time (h:mm:ss)	4:59:30	4:36:38

The ADVIA Centaur CP completed this protocol in 23 fewer minutes. The Access2 does not have a separate STAT loading process. However, the operator can designate a STAT specimen via the User Interface. This will cause that specimen to be moved to the head of the queue for the next possible aspiration.

Chart 2: Access2 Hourly Test Comparison



The Ortho ECiQ:

Table 9: ECiQ Ease of Operation

ECiQ - Ease of Operation			
Access Analyzer for Start-up and Maintainence	Load/Unload Samples, Reagents, and Consumables	Complete Solid/Liquid Waste Disposal	Control Analyzer via User-Interface
8.5	5.5	7.5	7.5

ECiQ Ease of Use Comments

- Access – The analyzer employs safety covers and access doors that elevate to positions allowing for unimpeded reach to the interior for maintenance and troubleshooting. The resupply of an ECiQ pipette tip is manually completed via a small opening on the top of the analyzer requiring a high level of manual dexterity by the operator.
- Load/Unload Process – Ten position ECiQ carousel racks are loaded as they become available into the specimen bay on the top of the analyzer. Reagent wedges are loaded via a reagent door and can be loaded/unloaded while the ECiQ is in testing mode. Each test requires a pipette tip. The carousel rack holds 10 tips and a separate tip carousel holds an additional 20 tips. The ECiQ will skip tests if no tips are available, requiring the operator to continually monitor the supply of tips. The operator at this site presorts specimens by test prior to loading. The operator placed all long duration TAT tests in the front of the queue and all short duration TAT tests at the back of the queue. This manual presort was done in an effort to improve ECiQ throughput. The operator carefully aligned all barcode labels within the carousel rack to minimize a misread once onboard.
- Waste Disposal – The ECiQ does not require a liquid waste drain but has onboard containers. The ECiQ usage of system fluids may require the liquid waste bottle to be emptied multiple times during testing. ECiQ dry consumables are collected in a disposable container that has easy access for removal.
- Control via User Interface – All ECiQ operations are controlled via an attached keyboard and 15 in. touch-screen monitor. The User Interface displays real-time information on testing, assays and consumables. The screens utilize data and graphics that are easy to see and interpret.

Table 10: ECiQ Labor Efficiency

ECiQ - Labor Efficiency				
Visually Observe all Key Processes	Performs Routine Tasks Automatically	Has Broad Assay Menu	Inventory Sufficient Supplies to Minimize Restocking	Has High Level of Reliability
6	7	5.5	5.5	8.5

ECiQ Labor Efficiency Comments

- Visual Observations – The ECiQ provides a clear view for the operator to monitor key operating processes. The User Interface provides information that is readily viewable and comprehensive.
- Routine Tasks – The ECiQ completes routine tasks and automatically monitors the analyzer. These tasks include auto-repeat, auto-dilution and reflex testing. However, the operator must manually monitor and resupply pipette tips critical to the testing process during periods of high volume testing.
- Menu – The ECiQ has 40 assays available worldwide.
- Onboard Inventory – The ECiQ holds 20 assay cartridges (100 tests ea.), 60 pipette tips in loaded six specimen racks, and 20 pipette tips at the start of testing. A minimum of one tip per test is necessary. The operator must monitor and load additional tips every 5 – 10 minutes

when multiple tests are routinely ordered for a large batch of specimens.

- Reliability – The ECiQ has a high degree of operational reliability as the site staff stated a need for routine maintenance every 6 months.

Table 11: ECiQ Productivity

ECiQ - Productivity				
Minimize Total Labor Time	Maximize Ease of Use/Ergonomics	Operator Can Walk Away for More Than 10 mins	Communicates Problems to Operator	Throughput
4	5	5	6	8

ECiQ Productivity Comments

- Total Labor Time – The ECiQ required 18 min. of direct manual time for testing versus 2 min. for the ADVIA Centaur CP for the same worklist.
- Use/Ergonomics – Operators for each analyzer can reach the loading and reagent bays with no difficulty. Interior access is good for maintenance. The operator stated loading ECiQ pipette tips into the tip carousel was difficult and could result in a misaligned tip that would stop testing.
- Walkaway – The ECiQ operator cannot walkaway from the analyzer when completing a large batch of samples with multiple tests per sample. The operator at the study site continually monitored and resupplied the tip carousel. The ADVIA Centaur CP did not require this continual monitoring by the operator.
- Communication – The ECiQ provides adequate visual notification and an audible alarm that facilitates the ability of the operator to walk away from the analyzer.

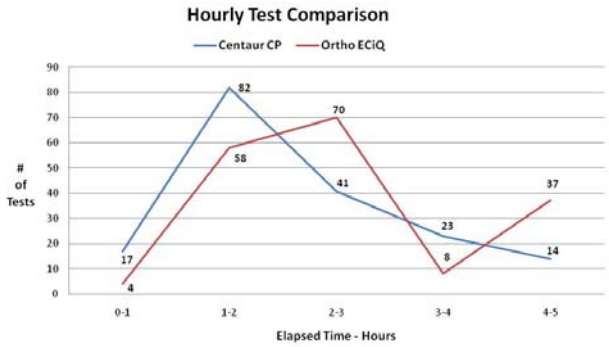
The ECiQ testing protocol was observed in a Southeast US community hospital. A total of 89 samples with 177 tests (100% ID) were loaded and resulted on both analyzers. The total run time to complete the 177 tests on each analyzer is shown in Table 12.

Table 12: ECiQ Run Time Comparison

Instrument	ECiQ	CP
Total Run Time (h:mm:ss)	4:55:45	4:10:55

The ADVIA Centaur CP completed this protocol in 45 fewer minutes. The ECiQ does not have a separate STAT loading process. The operator must manually remove a routine specimen from the next carousel rack and load the STAT specimen into that position.

Chart 3: ECiQ Hourly Test Comparison



The Roche Elecsys 2010:

Table 13: Elecsys 2010 Ease of Operation

2010 - Ease of Operation			
Access Analyzer for Start-up and Maintainence	Load/Unload Samples, Reagents, and Consumables	Complete Solid/Liquid Waste Disposal	Control Analyzer via User-Interface
9	7	7	3

2010 Ease of Use Comments

- Access – The analyzer employs safety covers and access doors that elevate to positions allowing for unimpeded access to the interior for maintenance and troubleshooting.
- Load/Unload Process – No reagents or consumables can be loaded/unloaded on the 2010 while in testing mode.
- Waste Disposal – No drain is required as the 2010 has liquid waste onboard containers. Dry consumables are collected in a tray that has easy access for removal.
- Control via User Interface – All 2010 operations are controlled via an attached numeric keyboard and 6 in. by 9 in. touch-screen monitor. The monitor's size and small graphics are difficult for the operator to see. The operator must stand directly in front of the screen for accurate viewing. Error alarms and visual notification are easily overlooked.

Table 14: Elecsys 2010 Labor Efficiency

2010 - Labor Efficiency				
Visually Observe all Key Processes	Performs Routine Tasks Automatically	Has Broad Assay Menu	Inventory Sufficient Supplies to Minimize Restocking	Has High Level of Reliability
8	7	8.5	7	9

2010 Labor Efficiency Comments

- Visual Observations – The 2010 provides a clear view for the operator to monitor key operating processes. The User Interface does not provide information that is readily viewable or accessible.
- Routine Tasks – The 2010 completes routine tasks, but cannot repeat a test due to the linear flow of specimen racks. The 2010 does perform auto-dilutions.
- Menu – The 2010 has 73 assays available worldwide.
- Onboard Inventory – The 2010 holds 18 assay cartridges (100 tests ea.), 180 Assay Cups, and 360 Assay Tips at the start of testing. However, some assays require additional diluents so that the effective number of assay cartridges is 15 – 16.
- Reliability – The 2010 is operationally reliable and requires only the replacement of a light cell every six months. The operator states that a fatal error occurs on average every two weeks, which stops testing.

Table 15: Elecsys 2010 Productivity

2010 - Productivity				
Minimize Total Labor Time	Maximize Ease of Use/Ergonomics	Operator Can Walk Away for More Than 10 mins	Communicates Problems to Operator	Throughput
8	7	9	5	8

2010 Productivity Comments

- Total Labor Time – The 2010 required 32 min. of direct manual time for testing versus 3 min. for the ADVIA Centaur CP for the same worklist.
- Use/Ergonomics – Operators for each analyzer can reach the loading and reagent bays with no difficulty. Interior access is good for maintenance. The 2010 experienced a "fatal error" (defined as error which stops testing)

during observed testing when a reaction assay cup was stuck in the incubation plate. The operator was clearly able to see and correct this error.

- Walkaway – The observed 2010 protocol had long periods of walkaway time (five separate loading times over 2:10 hours). However, the 2010 required 29 min. more direct labor time to complete the protocol than the ADVIA Centaur CP.
- Communication – The 2010 User Interface is small and error messages are difficult to view. The audible alarm operates at a dB level that is difficult to hear over ambient lab noise. The operator must be standing directly in front of the 2010 to detect any error notifications.

The 2010 testing protocol was observed in an ex-US community hospital. A total of 54 samples with 118 tests (83.1% ID and 16.9% IA) were loaded and resulted on both analyzers. The total run time to complete the 118 tests on each analyzer is shown in Table 16.

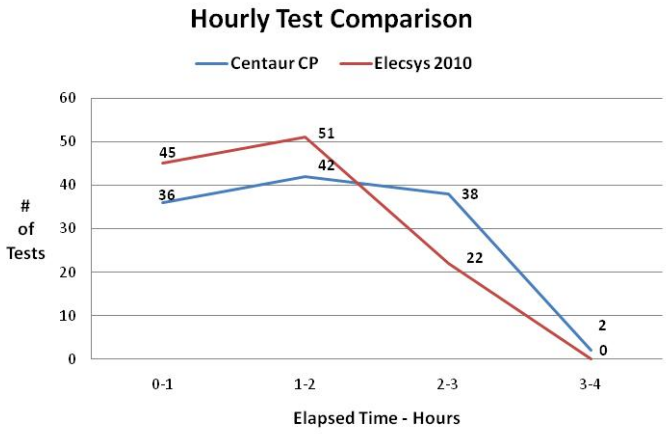
Table 16: Elecsys 2010 Run Time Comparison

Instrument	2010	CP
Total Run Time (h:mm:ss)	2:50:39	3:03:39

The 2010 completed this protocol in 13 fewer minutes than the ADVIA Centaur CP. However, the required manual labor time for the 2010 was 29 min. longer. This was caused by 12 tests that could not be initially completed due to either 1) the assay was not onboard, or 2) the onboard reagent had been fully consumed. The operator restocked the assay and reloaded these specimens during this time (Note: the User Interface does not notify the operator of insufficient reagent volumes resulting in skipped tests).

The 2010 has a dedicated STAT loading lane for a single 5-position rack. However, a newly loaded STAT specimen may have to wait until the current routine rack being aspirated (up to 5 specimen tubes and at least one aspiration per test) is completed before the STAT rack and specimen are aspirated. The time to complete a single rack of 5 tubes with one aspiration/tube took 3.5 minutes.

Chart 4: Elecsys 2010 Hourly Test Comparison



Siemens ADVIA Centaur CP:

Table 17: ADVIA Centaur CP Ease of Operation

CP - Ease of Operation			
Access Analyzer for Start-up and Maintainence	Load/Unload Samples, Reagents, and Consumables	Complete Solid/Liquid Waste Disposal	Control Analyzer via User-Interface
9	9	7	9

ADVIA Centaur CP Ease of Use Comments

- Access – The analyzer employs safety covers and access doors that elevate up allowing for unimpeded access to the interior for maintenance and troubleshooting. These covers are Plexiglas that allow for a direct view of all operations.
- Load/Unload Process – Both consumables and reagents can be loaded/unloaded while the ADVIA Centaur CP is in testing mode. A single access door is opened, the reagent rack is removed and replaced with the new reagent cartridge. The ADVIA Centaur CP's ability to load or change out reagent cartridges during testing provides flexibility in adding assays required for newly loaded specimens.
- Waste Disposal – No drain is required as the ADVIA Centaur CP has liquid waste onboard containers. Dry consumables are collected in a tray that has easy access for removal.
- Control via User Interface – All ADVIA Centaur CP operations are controlled via a free-standing full keyboard and 15 in. touch-screen monitor. The monitor can be rotated to provide for maximum viewing by operator. The graphics have a high resolution and are easy to see and interpret.

Table 18: ADVIA Centaur CP Labor Efficiency

CP - Labor Efficiency				
Visually Observe all Key Processes	Performs Routine Tasks Automatically	Has Broad Assay Menu	Inventory Sufficient Supplies to Minimize Restocking	Has High Level of Reliability
8	9	8.5	9.5	8

ADVIA Centaur CP Labor Efficiency Comments

- Visual Observations – The ADVIA Centaur CP Plexiglas cover provides a clear view for the operator to monitor key operating processes. The User Interface provides information that is readily viewable or accessible.
- Routine Tasks – The ADVIA Centaur CP completes routine tasks and can repeat a test automatically without the manual transfer of specimen racks. Other tasks include auto-dilution and reflex testing. Specimens are designated as STATs by virtue of being loaded in the STAT lane or via the User Interface. STAT specimens are immediately moved to the head of the testing queue and aspirated.
- Menu – The ADVIA Centaur CP has 76 assays available worldwide.
- Onboard Inventory – The ADVIA Centaur CP holds 15 assay cartridges (100 tests ea.) plus 10 additional slots for ancillary assays, 400 cuvettes and 480 tips at the start of testing. Reagent cartridge change-out (any one of the 76 available assays) takes 12 sec. and can be completed while in test mode.
- Reliability – No long term reliability data is available for the ADVIA Centaur CP since it is a recently introduced analyzer. However, no mechanical failures occurred during any protocol worklist. The ADVIA Centaur CP is considered operationally reliable.

Table 19: ADVIA Centaur CP Productivity

CP - Productivity				
Minimize Total Labor Time	Maximize Ease of Use/Ergonomics	Operator Can Walk Away for More Than 10 mins	Communicates Problems to Operator	Throughput
8	9	9	6.5	7.5

ADVIA Centaur CP Productivity Comments

- Total Labor Time – The ADVIA Centaur CP labor times ranged from a low of 2 min. to a maximum of 17 min. for all worklists.
- Use/Ergonomics – The ADVIA Centaur CP operators can reach the loading and reagent bays with no difficulty. Interior access and visibility is good for maintenance.
- Walkaway – The operator can leave the ADVIA Centaur CP for extended periods of time by restocking any needed onboard consumables. The ADVIA Centaur CP will automatically reflex, rerun or perform a dilution, all of which allow for extending the operator walkaway time.
- Communication – The ADVIA Centaur CP User Interface provides adequate visual alerts of any operational issues. The operator can see the alert from multiple locations in front of the analyzer. The audible alarm is loud enough to allow the operator to walk away from the analyzer.

The ADVIA Centaur CP testing protocols for all site specific worklists were observed in an R & D laboratory. Specimens were loaded and tests ordered in the same manner and times as recorded at each site. A time comparison for each analyzer and the ADVIA Centaur CP is previously listed within Tables 4, 8, 12, and 16.

Summary

Evaluating diagnostic analyzers manufactured by different product developers is a difficult task. Each analyzer has a unique set of strengths and weaknesses, but they will all provide a valid test result. This study used the ADVIA Centaur CP as a common element for comparing four mid-volume analyzers, each operating in a unique testing environment.

The mid-volume ID and IA testing market is characterized by labs processing 50 to 125 specimens per day (this equates to approximately 75 to 200 tests per day). In addition to operating the ID/IA analyzer, the operator will also run other analyzers, most typically a chemistry analyzer. The workload varies from a constant to a rapid pace. The operators observed in these sites expressed a desire for "quality over quantity." By this, they wanted an analyzer that required less of their time to operate and allowed them to walk-away and complete their other daily work. Throughput and testing speed were less important than reducing the hands-on time or vigilant time for an analyzer.

All five analyzers studied possess characteristics which are normally found within today's rapidly advancing and automated laboratories. From test ordering until results are reported to the physician, all have the ability to produce effective outcomes. What differentiates the analyzers are the "value added" features that allow workflow and overall operator interaction to be as smooth as possible. Such features include a broad test menu, high quality user interface, and minimal interaction/touches with the instrument.

Table 20 is a compilation of the numeric rank assigned to each analyzer based on the feedback, observations and time studies recorded in the previous sections. Each analyzer was given a numeric rank ranging from 1 on the low end to 10 on the high end. A high score indicates more strengths and a higher satisfaction with the multiple characteristics of that analyzer. A low score indicates more problematic issues and less satisfaction with the analyzer. A total score for the three major categories and an overall score is provided for each analyzer (see Chart 5).

No single analyzer received a perfect score (140). The ADVIA Centaur CP did accumulate the highest score for each major category and the highest overall score. A summary of the total scores is listed below:

- 117.0 ADVIA Centaur CP
- 102.5 Roche Elecsys 2010
- 97.0 Beckman Coulter Access2
- 95.5 Abbott AxSYM
- 87.5 Ortho ECiQ

Based upon these site specific evaluations, the ADVIA Centaur CP has many of the "value added" features that mid-volume laboratories state they want. These features include 1) ease of loading/unloading reagents and specimens, 2) an ergonomic design providing access, visibility and information, 3) automation including auto-repeat, auto-dilution and reflex testing that allow the operator to walk away and complete other tasks, and 4) a throughput that meets STAT and routine TATs. Nexus expresses thanks to the participating laboratory[2] sites for sharing their experiences and opinions for each specific analyzer.

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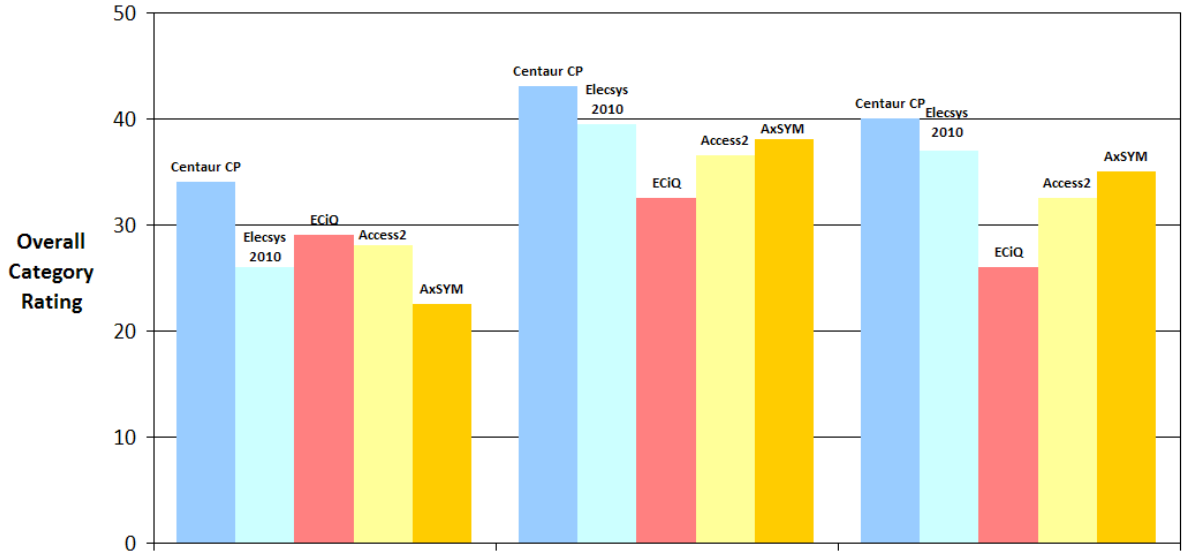
[1] Competitive systems by manufacturer are as follow:
Abbott AxSYM® – Abbott Laboratories, Abbott Park, IL 60064
Beckman Coulter Access®2 – Beckman Coulter, Inc., Fullerton, CA 92834
Ortho-Clinical Diagnostics VITROS® ECiQ – Ortho-Clinical Diagnostics, Inc., Rochester, NY 14626
Siemens ADVIA Centaur® CP – Siemens Healthcare Diagnostics, Tarrytown, NY 10591
Roche Diagnostics Elecsys® 2010 – Roche Diagnostics, Indianapolis, IN 46250

[2] Siemens Healthcare Diagnostics provided funding for this study. Study sites were not informed of this funding in order to elicit unbiased feedback.

Chart 5: Instrument Rating Comparison



	Ease of Operation	Labor Efficiency	Productivity	Total
Centaur CP	34	43	40	117
Elecsys 2010	26	39.5	37	102.5
ECiQ	29	32.5	26	87.5
Access2	28	36.5	32.5	97
AxSYM	22.5	38	35	95.5

Table 20: Instrument Rating Summary

		ADVIA Centaur CP	Roche Elecsys 2010	Ortho ECiQ	Beckman Access2	Abbott AxSYM
EASE OF OPERATION	Access Analyzer for Start-up and Maintainence	9	9	8.5	6.5	6.5
	Load/Unload Samples, Reagents, and Consumables	9	7	5.5	5.5	5
	Complete Solid/Liquid Waste Disposal	7	7	7.5	7.5	6.5
	Control Analyzer via User-Interface	9	3	7.5	8.5	4.5
LABOR EFFICIENT	Visually Observe all Key Processes	8	8	6	6	5.5
	Performs Routine Tasks Automatically	9	7	7	8	6.5
	Has Broad Assay menu	8.5	8.5	5.5	8.5	9.5
	Inventory Sufficient Supplies to Minimize Restocking Cycles	9.5	7	5.5	7	7
	Has High Level of Reliability	8	9	8.5	7	9.5
PRODUCTIVITY	Minimize Total Labor Time	8	8	4	7.5	7
	Maximize Ease of Use/Ergonomics	9	7	5	7	5
	Operator Can Walk Away for More Than 10 mins	9	9	5	8	8
	Communicates Problems to Operator	6.5	5	6	6	6
	Throughput	7.5	8	8	4	9