Hennepin Healthcare

Improvement in Workflow and Efficiency for Measurement of Special Proteins Using the Optilite Standalone Automated Analyzer

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ABSTRACT

Background: Special protein assays (free light chains, IgA, IgG, IgM, rheumatoid factor, C3c, C4, haptoglobin and prealbumin) were analyzed on an automation/chemistry line (Roche cobas 8100/cobas c501) at our institution. However, during instrument upgrades to the c502 modules, poor analytical performance was observed for these assays. Testing was subsequently validated on the Binding Site Optilite®, a standalone automated turbidimetric platform optimized for measurement of special proteins. The objective of this study was to compare the process workflow and resources required between the Optilite® and the cobas systems, as well as determine the impact on efficiency and any financial implications between an automated versus standalone platform.

Methods: A side-by-side time and motion study was performed by an independent consulting company (Argent Global Services), who observed routine maintenance and testing activities for both systems over a period of 5 days. Historical data was collected to verify the observation data related to maintenance (daily, weekly, and monthly), quality control, calibration, and troubleshooting events. Testing volumes and dilution rates were assessed. Specific timing studies were also assessed for the Freelite assay, due to the higher volume of clinical testing and is representative of a special protein assay requiring a greater number of either automatic or manual dilutions. Routine specimens were analyzed daily across two shifts on both the Optilite and the cobas c502. The data are presented as weighted averages.

Results: The Optilite Freelite reagent setup and calibration required 30.5 minutes, while the cobas required 62.4 minutes. In addition, with the Optilite there was a 50% reduction in routine monthly instrument maintenance and consumables due to avoidance of QC and calibration failures on the cobas for special protein assays. The difference in the average analytical times per sample was not statistically significant between the Optilite and the cobas when dilutions were not required. However, the Optilite results were 12% faster than cobas results when specimens needed an auto-dilution, and 29% faster when manual dilutions were required on the cobas. Due to the extended reportable range(s) on the Optilite there was a 100% decrease in manual dilutions and a 34% overall decrease in auto-dilutions, with significant decreased Optilite dilutions compared to the cobas for Freelite Kappa (13.1% versus 31.2%) and IgA assays (5% versus 19.5%), respectively. The average same day turnaround time from receipt to verify for the Optilite was less than one hour. Average total reagent, QC, and calibration costs were 9.0% less for the Optilite special protein assays.

Conclusions: The Optilite required significantly less maintenance and labor to perform special protein testing, while providing faster overall analytical turnaround times and increased efficiency compared to assays analyzed on a high-throughput automation line. Fully automated special protein testing on a dedicated platform resulted in minimal or no manual intervention from technologists once specimens are loaded. Further reagent and QC cost savings were realized by utilizing integrated QC materials, compared to use of external QC.

BACKGROUND

- Quantitative determination of serum proteins serves as an important tool in diagnosing diseases, monitoring the course of a disease, and the effect of treatment.
- Historically these special protein assays (free light chains, IgG, IgA, IgM, rheumatoid factor, C3c, C4, haptoglobin, prealbumin) were analyzed on an automation/chemistry line (Roche cobas 8100/cobas c501) at our institution.
- During instrument upgrades to the cobas c502 modules, poor analytical performance, including precision, accuracy, and linearity, was observed for these assays.
- Significant average bias was observed between the cobas c501 and cobas c502 assay, specifically for Kappa Freelite (-16.9%), Freelite Chain Ratio (+38.3%) and IgM (-17.3%).
- Testing was subsequently validated on the Binding Site Optilite®, a standalone automated turbidimetric platform optimized for measurement of special proteins.
- All special protein assays met and exceeded the pre-specified performance/validation criteria on the Optilite.
- The objective of this study was to compare the process workflow and resources required between the Optilite® and the cobas systems, as well as determine the impact on efficiency and any financial implications between an automated versus standalone platform.

METHODS

- A side-by-side direct observation and time and motion study was conducted by an independent consulting company (Argent Global Services).
- Routine maintenance and clinical testing activities for both instruments was observed and monitored over a period of 5 days.
- Historical data was collected to verify observation data related to maintenance (daily, weekly, and monthly), quality control, calibration, and troubleshooting events.
- Special protein testing volumes and dilution rates were assessed.
- Interviews were conducted with laboratory staff and management to capture additional qualitative information.
- Specific timing studies were conducted for the Freelite assay, due to the higher volume of clinical testing. This assay is representative of a special protein assay requiring a greater number of either automatic or manual dilutions.
- Routine specimens were analyzed daily on both the Optilite and the cobas c502.
- Data are presented as weighted averages.

Figure 1: Average Analytical Time per Sample for All Special Protein Assays, With and Without Dilutions

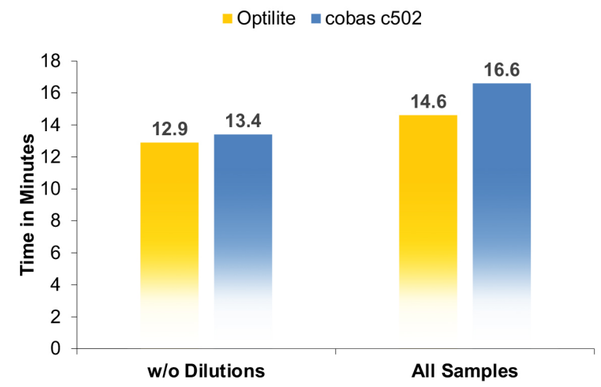


Figure 2: Comparison of FLC Results Requiring Optilite Auto-Dilution vs. cobas Auto/Manual Dilution

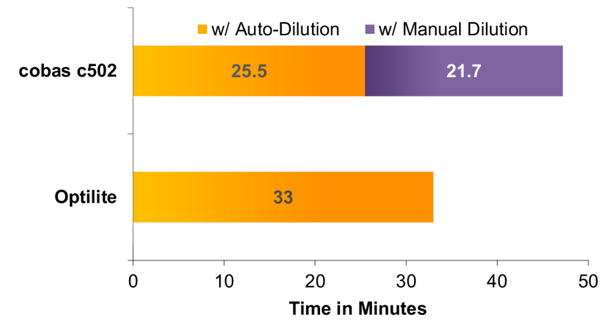
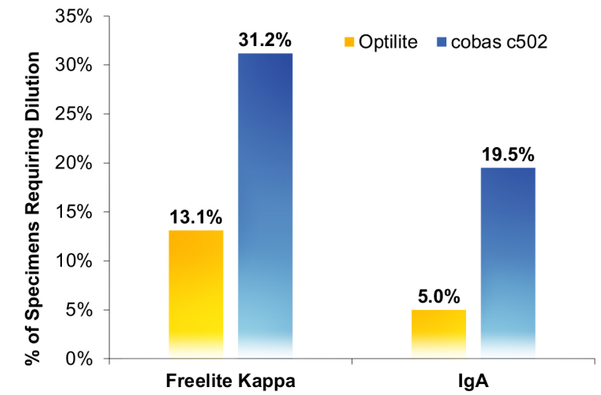


Figure 3: Average Overall Dilution Rates for Freelite Kappa and Immunoglobulin A



RESULTS

- Average analytical time per sample for special protein testing faster on the Optilite without dilutions and 12% faster with automatic dilutions **(Figure 1)**.
- For Freelite results requiring dilutions to report a result, Optilite results were 29% faster compared to automatic plus manual dilution on the cobas due to extended Optilite dilutional capabilities **(Figure 2)**.
- There was a 100% decrease in manual dilutions and a 34% overall decrease in automatic dilutions post-implementation.
- A significant decrease in the number of Optilite automatic dilutions compared to the cobas automatic and manual dilutions for Freelite Kappa (13.1% versus 31.2%) and IgA assays (5% versus 19.5%), respectively, was observed **(Figure 3)**.
- Optilite Freelite reagent setup and calibration required 30.5 minutes; cobas required 62.4 minutes **(Table 1)**.
- Average same day turnaround time from receipt to verify for the Optilite was less than one hour; turnaround time requirements were not affected.
- 50% reduction in routine monthly instrument maintenance and consumables switching to the Optilite.
- Average total reagent, QC, and calibration costs were 9.0% less for Optilite special protein assays.

Table 1: Freelite Assay Reagent Setup and Calibration Time (Minutes)

Instrument	Manual Hands-On Time	Wait/Cycle Time	Total Time
Optilite	5.4	25.1	**30.5**
cobas c502	22.0	40.4	**62.4**

CONCLUSIONS

- Optilite required significantly less maintenance and labor to perform special protein testing.
- Optilite provided faster overall analytical turnaround times and increased efficiency.
- There is minimal or no manual intervention required by medical technologists once specimens are loaded onto the Optilite.
- There are reagent and QC cost savings with Optilite due to integrated QC materials.

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