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Assay and ISE Precision Analysis Comparing ADVIA Chemistry XPT System with ADVIA 1800 Clinical Chemistry System

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Introduction

Our central laboratory of the Hospital Maggiore della Carità di Novara, Italy, provides fast, reliable diagnostic testing for hospital inpatient and outpatient services supporting regional physician offices. The growing workload is currently at 3.2 million clinical chemistry and immunoassay tests per year.

The laboratory performed clinical chemistry testing using three ADVIA® 1800 Clinical Chemistry Systems and two ADVIA Centaur® XP Immunoassay Systems connected to an ADVIA® LabCell® Automation Solution in combination with preanalytical sample management, syngo® Lab Connectivity Manager, and CentraLink™ Data Management Systems. One stand-alone IMMULITE® 1000 Immunoassay System performs esoteric immunoassays.

Continuous growth and the need to deliver faster results demanded further consolidation of routine clinical chemistry and immunoassay testing. This, in turn, required a thorough investigation of new systems and innovative technologies available in the diagnostic market. In 2014, as Siemens prepared for the 2015 launch of the new ADVIA® Chemistry XPT System and the ADVIA Centaur® XPT Immunoassay System, Maggiore and Siemens partnered to evaluate the performance and usability of the new ADVIA Chemistry XPT System, integrating this system into our laboratory automation.

Figure 1 shows the ADVIA LabCell configuration with connected Siemens analyzers in use in our laboratory at the time of the study in November 2014. In 2015 we replaced two ADVIA Centaur XP Immunoassay Systems with two ADVIA Centaur XPT Immunoassay Systems, which is also shown in this figure.

Laboratory's objectives:

Our laboratory designed a study to validate the usability and performance of a new clinical chemistry system within the central laboratory's automation configuration. The study objectives centered around three specific areas:

- To evaluate analytical assay performance
- To evaluate ion-selective electrode (ISE) test performance
- To assess improvements in reliability and hands-on time for the ADVIA Chemistry XPT System

Methods and Results

Analytical ISE precision performance

Common to most ISE technologies is sensitivity to intermittent temperature fluctuation, which can result in a drift in sample recovery.

The ADVIA Chemistry XPT System uses a new ISE module technology developed to eliminate this drift. We designed a protocol that would demonstrate the effectiveness of the combination of new buffer, new baseline solution, new mixer motor, new mixer sensor, and new calculation algorithms utilized by the ADVIA Chemistry XPT System.

For this study the laboratory processed 640 samples on the ADVIA Chemistry XPT System and in parallel on all three ADVIA 1800 Clinical Chemistry Systems.

Our observation was that the ISE module has been improved significantly in terms of analytical performance. The CV for Chloride (Cl) was reduced by 73%, for Sodium (Na) by 39%, and for Potassium (K) by 43% (Figure 2).

Additionally, the ISE module showed higher reliability as well as less user intervention (manual hands-on time) and maintenance over our ADVIA 1800 Chemistry System.

Analytical assay precision performance

Similarly, all clinical chemistry assays run on the ADVIA Chemistry XPT System showed significant improved analytical performance. Figure 3 displays within-run precision.

Improvement in analytic performance of ISEs on the ADVIA Chemistry XPT System

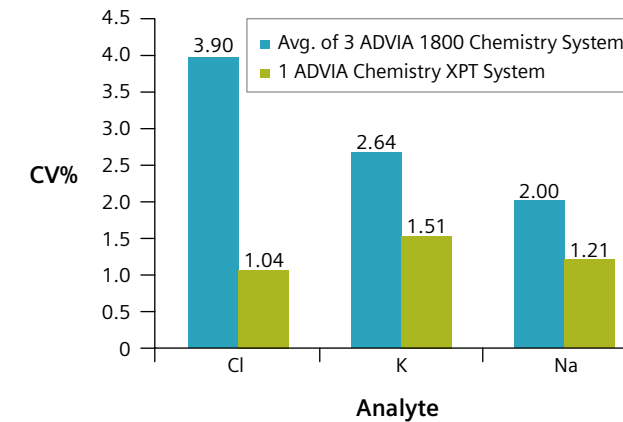


Figure 2: ISE precision performance analysis: CV for one ADVIA Chemistry XPT System compared with the CV for three ADVIA 1800 Chemistry Systems. The CV was compiled across the three ADVIA 1800 Chemistry Systems.

We also experienced minimized user intervention (manual hands-on time) and reduced maintenance. The ADVIA Chemistry XPT System sustained greater accuracy, precision and reliability.

The study has proven that the ADVIA Chemistry XPT System meets and exceeds our expectations in terms of analytical performance of ISE tests and chemistry assays, which we found to be a significant improvement compared to the legacy ADVIA Chemistry systems.

Conclusion

The ADVIA Chemistry XPT System will support our laboratory management to optimize efficiency and patient care. The ADVIA Chemistry XPT System has significantly demonstrated the delivery of high-quality patient results through improved analytical performance.

Additionally, our technicians mentioned the following, which has contributed to the overall satisfaction with the new ADVIA Chemistry XPT System in our laboratory:

- System reliability has improved and supports continuous throughput in peak workload times.
- Reduced daily and weekly system maintenance, easier ISE maintenance, and fewer manual interventions allow operators to focus on more important tasks.
- An increased number of reagent placements onboard increases walk-away capability.
- New software is easy to use with new intuitive driven icons; the same software across the immunoassay and clinical chemistry systems reduces training time for new technicians.
- The technicians very much appreciate the software's new management functions.

The ADVIA Chemistry XPT System will support our laboratory management to optimize efficiency and patient care and will support us to further strengthen the good reputation of the laboratory in the region.

“The CV for Chloride (Cl) was reduced by 73%, for Sodium (Na) by 39%, and for Potassium (K) by 43%.”

ADVIA LabCell configuration

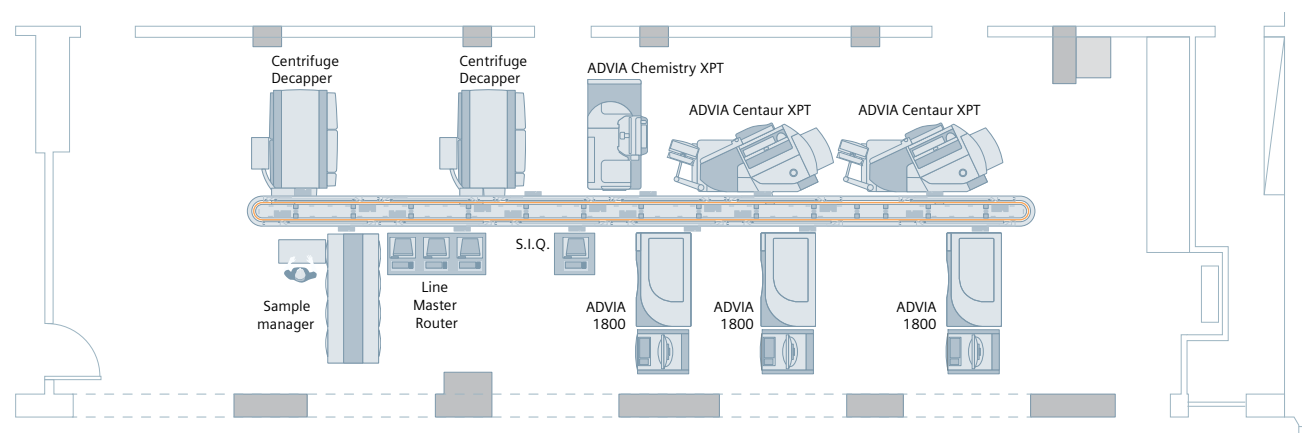


Figure 1. ADVIA LabCell configuration with connected Siemens analyzers in use in our laboratory at the time of the study in November 2014, reflecting replacement of two ADVIA Centaur XP Immunoassay Systems with two ADVIA Centaur XPT Immunoassay Systems in 2015.

Improvement in analytical assay precision on the ADVIA Chemistry XPT System

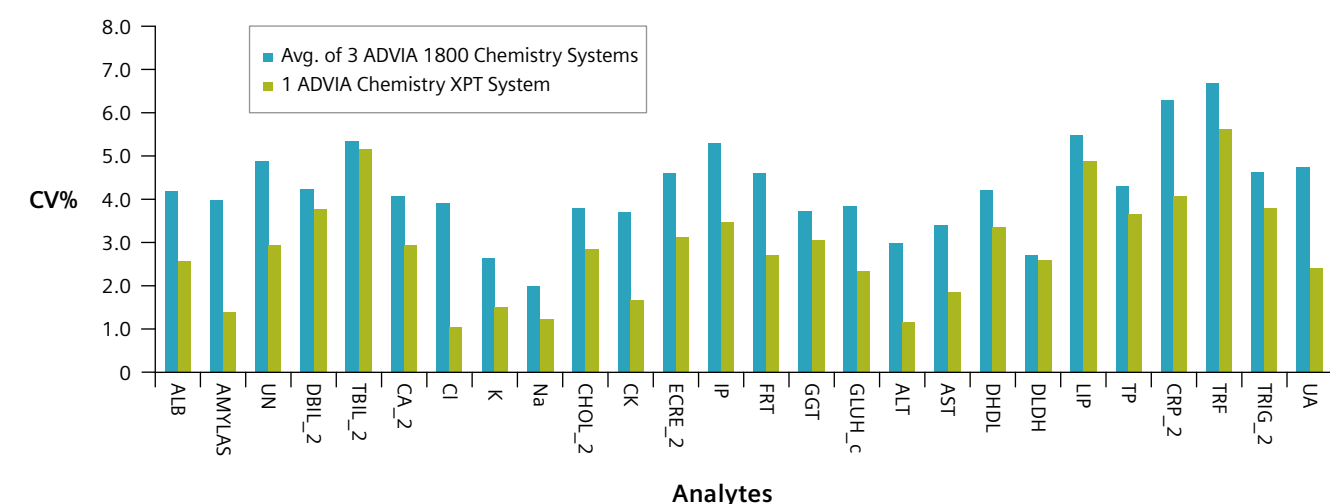


Figure 3: Assay precision analysis: CV for one ADVIA Chemistry XPT System (green) compared with the CV for three ADVIA 1800 Chemistry Systems (blue). The CV was compiled across the three ADVIA 1800 Chemistry Systems.