

Comparative studies demonstrate that Lean management principles can be applied to routine ISD testing.

Siemens Dimension RxL system enables routine ISD testing with less complexity and a reduced risk of error.

Eliminating manual steps, reducing opportunities for errors, and improving quality are among today's labs most pressing challenges that are being addressed by Lean quality management. One area where Lean principles have not been broadly addressed is immunosuppressant drug (ISD) testing, which often requires specialized analyzers, dedicated personnel, and complex sample handling techniques.

Because organ rejection in transplant patients can occur at any time, lifelong administration and monitoring of ISDs is required to prevent graft rejection and minimize serious adverse drug reactions. Consequently, transplant physicians and coordinators require rapid and accurate ISD test results to appropriately manage their patients. Unfortunately, not all laboratories perform ISD testing as part of their routine workload. In those that do, ISD results are not always available 24 hours a day, 7 days a week. Hence, the information clinicians need to make critical decisions may not always be available.

In many labs, ISD tests are performed in batch mode by dedicated laboratory personnel because the testing requires complex, specialized handling procedures including manual pretreatment and extraction steps that extend the turnaround time (TAT) for reporting results. Slow TAT due to less efficient processes could impact transplant patient management.

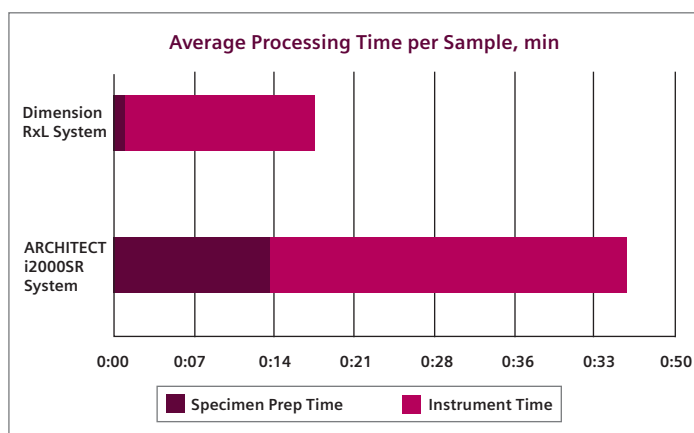
Study designed to compare TAT differences for ISD testing

A recent study was conducted to determine if Lean workflow initiatives could be applied to ISD testing in the routine laboratory setting. In this study, conducted by a third-party consultant, Nexus Global Solutions, process steps for ISD tests were compared for two systems: the Abbott ARCHITECT i2000SR System and the Siemens Dimension® RxL Integrated Chemistry System.¹ The number of steps and time required to perform ISD testing were recorded. ISD samples were tracked at a community hospital lab processing a mix of up to 30 cyclosporine, sirolimus, and tacrolimus tests per day on the ARCHITECT system. In this hospital, ISD testing is performed in batches once per day, and specimens received after the once daily ISD test run, are held over for testing the next day.

Results: fewer steps, faster processing time, and reduced risk of error

Recorded observations showed that the required manual preparation—pretreatment and extraction—of ISD specimens before loading onto the ARCHITECT i2000SR analyzer took up to 13 process steps, ≥20 distinct manual steps and 12 to 20 minutes of staff time. For the ARCHITECT system, TAT from start of testing, including pretreatment and extraction, took 45 to 54 minutes.

The same tests were processed on the Dimension RxL system at a Siemens Healthcare Diagnostics R&D facility. The ISD assays performed on the Dimension system require no manual pretreatment or extraction. Without these manual steps, the tubes can be loaded quickly onto the instrument after a simple pipetting step. Consequently, the TAT for ISD testing on the Dimension RxL system from start of testing took only 16 minutes. The Dimension system reduced average TAT (including sample preparation and processing) by 31 minutes, 66% faster than the ARCHITECT analyzer.



Average TAT (sample preparation and instrument time) was 16 minutes with the Dimension RxL system compared to 47 minutes with the ARCHITECT i2000SR system.

Conclusion: Siemens offers a Lean approach to ISD testing for any routine laboratory

With the Dimension system, there is no need for complex, time-consuming manual pretreatment and extraction protocols. Hence, there is no need for dedicated personnel to perform testing. Additionally, the lack of extensive manual sample processing lowers the probability for human error that could impact the quality of test results. ISD samples can be quickly and simply loaded onto the instrument, without batching, making it possible to perform ISD testing any time of the day. The ISD solutions on the Dimension system enable any lab to efficiently perform ISD testing as part of its daily routine. These solutions help improve transplant patient management with faster TAT, less staff involvement, and lower risk of error.

This study was commissioned by Siemens Healthcare Diagnostics.

To download a copy of the workflow study, please visit www.siemens.com/isd-workflow

References

1. Reducing manual steps, improving turnaround times and creating a lean laboratory environment: ISD testing on the Dimension® integrated chemistry systems. Document on file.

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