Clinical Application Note
Simple LIMS/LIS interfacing for Immunosuppressant assays

CSols
laboratory systems integration

Links **4** LIMS

AqcTools™

Kevin Jones, Graham Pratt & Claire Parker
CSols Ltd, The Heath, Runcorn, Cheshire WA7 4QX, UK

Tel: +44 (0)1928 513535 Web: www.csols.com email: kevin.jones@csols.com

Background

Immunosuppressants are a class of drugs that inhibit the body's immune response and are typically administered to prevent the rejection of transplanted organs (e.g. kidney) or tissue (e.g. bone marrow), and may also be used to treat various autoimmune disorders such as Crohn's Disease or rheumatoid arthritis. The first effective immunosuppressant drug was cyclosporine A (CsA), now tacrolimus (FK506), sirolimus (rapamycin) and everolimus are also used separately or in combination treatments. Tandem Mass Spectrometry (TMS) with its ability to analyse all four drugs in a single assay has become the technique of choice for busy laboratories supporting one or many transplant units.

Challenges

When considering transcription free reporting options laboratories often face the following challenges :

• Validating samples to ensure they belong to the correct patient, especially important in referral laboratories receiving samples from many different clinics

• Making sure test request(s) are correctly assigned as all drugs are usually analysed in a single immunosuppressant panel only where only one or two are reported

• Providing a rapid turnaround time (often must be < 3 hours).

• Reducing the number of data processing steps to a minimum to maintain consistent operation during all working shifts independent of user skill.

Sample & Test Request Validation

One way to validate specimens arriving in the laboratory prior to running immunosuppressant analysis is to logon to the LIMS/LIS system and check there. However this can be time consuming for a large number of specimens. **Links for LIMS** users however can make use of the **Links for LIMS** *Instrument Setup* program. In one operation specimens can be checked for the correct patient, test request and can be immediately incorporated into a Sciex Analyst or Cliquid compatible batch run file, avoiding the danger of mix ups and saving precious instrument setup time.

To achieve this **Links for LIMS** automatically conducts host queries to the LIMS/LIS system using specimen barcode IDs and automatically validates and fetches the test code(s) and patient demographics to help laboratory staff. N.B. In busy laboratories specimens may arrive for testing before the specimens are correctly registered in the LIMS/LIS system. In this case **Links for LIMS** can carry out post run validation instead.
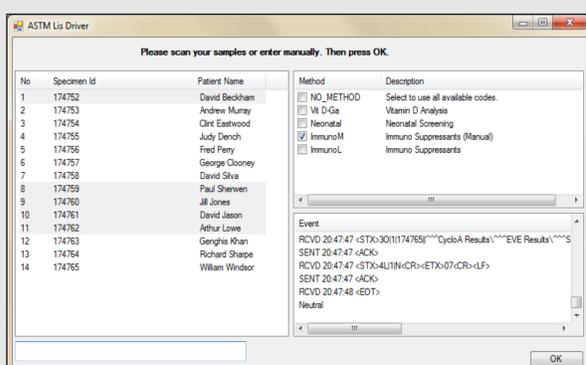

Figure 1: Links for LIMS Setup program

Instrument setup and loading

When creating a Sciex Analyst or Cliquid software compatible instrument batch file, specimen details are automatically merged into a typical method run sequence in order to ensure the positions of standards, blanks and IQCs are consistent with existing laboratory Standard Operation Procedures (SOPs). Where some assays require a second duplicate injection (replicates) repeat entries are made automatically in the batch file and an average calculation scheduled in the **Links for LIMS** method, saving valuable setup time.

Figure 3: Batch run displayed in Analyst showing the validated specimens.

Results Review & Reporting

Once completed all results can be sent directly to **Links for LIMS**. **Links for LIMS** then automatically synchronizes all specimen IDs with data collected earlier and applies any calculations, formatting, flagging or logic rules relevant to the method. The display (Figure 2) is fully configurable allowing results, computed results and demographic information to be displayed. A traffic light colour coding system is also used to identify IQC warnings and failures according to Westgard rules. All IQC data can also be saved to an external database using the CSols **AqcTools** software to support ISO 15189 quality charting requirements.

Summary

Links for LIMS can fully complement a Sciex based Immunosuppressant assay workflow allowing the instrument to be used to its maximum capacity. Eliminating data transcription from both instrument setup and results transfer steps saves between 3% & 5% errors compared to manual processes, and can save many man hours of effort per run.

Further Information

CSols Ltd. The Heath, Runcorn, Cheshire, WA7 4QX, UK
Tel: +44 (0)1928 513535 Fax: +44 (0)7006 061106
Web: www.csols.com Email: links4lims@csols.com