Improving turnaround times for trace element screening of hip replacement patients using the CSols Links for LIMS® system with a Thermo Scientific X Series ICP-MS Mass Spectrometer

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Overview

Metal-on-Metal (MoM) hip replacement devices are used extensively to help patients with hip damage caused by arthritis or fracture. Both the ball and socket components can be made of metal. The metal’s durability makes the devices last longer than ones made from other materials while the larger ball is more stable and less likely to dislocate.

However, in 2012 following increasing concerns about incidents of pain and inflammation from a small number of patients the UK’s Medical and Healthcare Related Devices Agency (MHRA) issued a Medical Device Alert (MDA/2012/036) advising that screening should be undertaken on all patients with MoM hip replacements.

This alert advises clinicians to screen patients to determine whether further investigations are required. This screening step involves the measurement of two of the device’s constituent metals, chromium and cobalt, in whole blood samples. These metal ions are present in the blood due to their release from the metal wear debris which cause soft tissue necrosis and adversely affect the results of revision surgery. If they are found at concentrations greater than 7 µg/L then further investigations such as imaging are required to determine whether the replacement hip-joint is failing or not.

The Supra-Regional Assay Service (SAS) laboratories in Guildford routinely carry out a wide range of trace element testing and scaled up their facilities to address the increase in testing resulting from the MHRA alert. Improvements were made not only to the method and equipment used for analysis but also to the result delivery service.

CSols Links for LIMS® software was used to electronically report results of analysis but also to the result delivery service. However in 2012 following increasing concerns about incidents of pain and inflammation a Medical Device Alert (MDA/2012/036) advising that screening should be undertaken on all patients with MoM hip replacements.

Method

CSols Links for LIMS® software was installed onto a networked laboratory workstation PC that was connected to two Thermo Fisher Scientific X Series ICP-MS instruments running the PlasmaLab® software system. A uni-directional data connection was used via the Siemens CENTRALINK™ middleware to allow direct communications with the Clinisys WinPath LIS/LIMS system. A CENTRALINK™ system was already being used to support clinical analyst connections in other parts of Surrey Pathology Services.

Sample type filtering was also setup in WinPath to correctly reconcile sample results with their correct sample type and laboratory reference ranges, for all sample types managed by the laboratory including urine, serum and whole blood.

Data transfer was instigated after importing instrument results into Links for LIMS® and both unknown and QC results were transferred to CENTRALINK™ and onto WinPath, using a function key in the software.

Discussion & Conclusion

The acquisition and deployment of the CSols software has helped the SAS Trace Element Laboratory to manage a significant increase in sample numbers for cobalt and chromium analysis, which has arisen from the MHRA directive. In 2008/09 the laboratory measured cobalt and chromium in about 100 samples, usually for nutritional reasons, but in 2013/14 the number of requests for this assay had increased to 12,000.

The direct transfer of data without time consuming manual transcription has also helped the management of an increase in testing across all of the elements the laboratory routinely measures. It has had the added bonus of reducing the time for analysis which is one of the key performance indicators used to measure the laboratory’s efficiency.

About Supra-Regional Assay Service (SAS)

The Guildford SAS laboratory has existed since the foundation of the SAS in 1973 to meet both Health Service and academic needs. Prior to the formation of the SAS the laboratory was a Regional Centre. The SAS Trace Elements Centre was opened on 30th April 2014.

Figure 1: Diagram illustrating different MoM positioning

Figure 2: One of the Thermo Fisher X Series ICP-MS Instruments at SAS Guildford

Figure 3: Links for LIMS® Report Results program showing results. Imported from the Thermo PlasmaLab® Software after automatic conditional formatting, filtering and QC flagging, ready for LIS/LIMS upload.

To enable communication with CENTRALINK™ Links for LIMS® was installed with a drive that supported the ASTM 1394 communications protocol and with a software utility that provided a ‘heartbeat’ to maintain an active link with CENTRALINK™ at all times.

Figure 4: Example ASTM message log showing communication Between Links for LIMS® and CENTRALINK™

The Links for LIMS® software was configured to read data from a number of elemental assays including the chromium and cobalt assay. The correct US/LIMS test codes as well as formatting and rounding settings were stored in the Links for LIMS® method.

Links for LIMS® sample type filtering was used to distinguish unknown samples from IQC (Internal quality controls), EQA (External quality assurance control specimens), standards and blanks. Red, Yellow, Green colour flagging was also used to indicate the quality of QC results. In addition to the Links for LIMS® configuration, CENTRALINK™ was configured to ‘pass through’ all results direct to WinPath and also to copy IQC results to the CENTRALINK™ Levey-Jennings charting facility.

Figure 5: Processing results in the SAS Laboratory Reception

The Centre accommodates the Trace Element Laboratory and the Trace Elements External Quality Assessment Scheme (TEQAS). The SAS Trace Elements Centre is managed as part of Surrey Pathology Services, a collaboration of the Royal Surrey County, Frimley Park and Ashford & St. Peter’s Hospital Trusts.

Other CSols Clinical Biochemistry clients include:

- Central Manchester NHS Trust (Manchester Royal Infirmary MRI)
- Falun Hospital, Galway University Hospital, Heart of England NHS Trust (Heartlands Hospital), Imperial College Healthcare Trust (Chelsea and Westminster Hospital, Leeds Teaching Hospitals NHS Trust (St. James’s Hospital), Lund University Hospital, Northumbria Healthcare Trust (Wansbeck General Hospital) & Oxford University Hospital Trust (John Radcliffe Hospital).

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