

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.

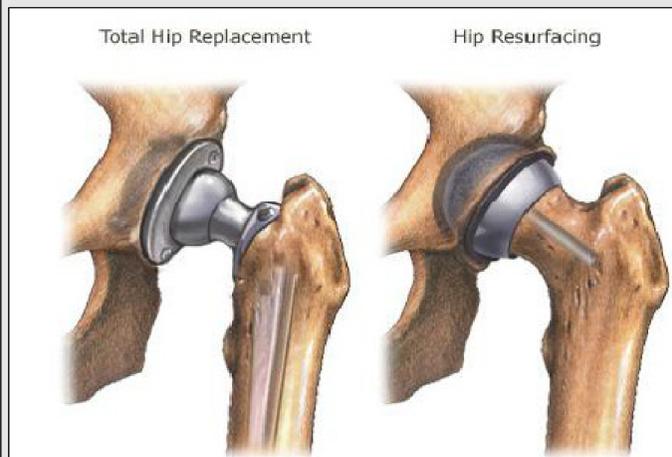


Figure 1: Diagram illustrating different MoM positioning

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 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 to the laboratories' Clinisys WinPath LIS/LIMS system to maintain a high service level to all submitting clinicians across the UK.



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

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 analyser connections in other parts of Surrey Pathology Services.

Sample Name	Cobalt µmol/L	Chromium µmol/L
1 Blank	0.54	14.10
2 Blank	0.67	14.00
3 Blank	0.66	0.00
4 E	7.58	7.67
5 E+5	68.80	100.00
6 E+10	173.00	195.00
7 E+20	338.00	380.00
8 E+50	989.00	990.00
9 E+100	1700.00	1620.00
10 E	7.58	7.67
11 L1 89151	114.00	17.40
12 L2 89152	39.00	381.00
13 SB2 1103129	92.80	215.00
14 SB3 1112891	181.00	415.00
15 13L608756	30.00	32.90
16 13L608757	15.50	19.70
17 13L608790	95.40	44.40
18 13L608791	8.38	10.70
19 13L608792	92.10	59.90
20 13L608793	68.60	54.20
21 13L608795	34.60	18.50
22 13L608796	40.40	56.70
23 13L608835	35.50	46.20
24 13L608839	11.50	18.10
25 13L608840	68.20	91.00
26 13L608841	8.30	78.70
27 13L608842	16.60	22.90
28 13L608843	5.73	10.70
29 SB3 1112891	181.00	415.00
30 13L608844	30.00	28.20
31 13L608845	25.20	34.50
32 13L608846	58.10	69.20
33 13L608850	37.80	17.30
34 13L608853	41.30	39.20
35 13L608854	14.70	8.18
36 13L608855	11.00	12.00
37 13L608856	10.70	19.50
38 13L608857	5.90	34.90
39 13L608858	8.32	30.50
40 13L608859	29.90	28.70

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

To enable communication with Centralink™, Links for LIMS® was installed with a driver 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.

```
Status=Neutral
Status=Establishing
--> 12:58:29 <ENQ>
<-- 12:58:29 <ACK>
Status=Transmitting
--> 12:58:29 <STX>1H|I*||CSols|||||P|20131016125829|<CR><ETX>2E<CR><LF>
<-- 12:58:29 <ACK>
--> 12:58:29 <STX>2P|1<CR><ETX>3F<CR><LF>
<-- 12:58:29 <ACK>
--> 12:58:29 <STX>3Q|1|13L613996|I*||CSols||Co<CR><ETX>7C<CR><LF>
<-- 12:58:29 <ACK>
--> 12:58:29 <STX>4R|1|I*||CSols||12.80|||||P|20131016125829|CPMS1<CR><ETX>81<CR><LF>
<-- 12:58:29 <ACK>
--> 12:58:29 <STX>5R|2|I*||CSols||0.56|||||P|20131016125829|CPMS1<CR><ETX>70<CR><LF>
<-- 12:58:29 <ACK>
--> 12:58:29 <STX>6P|1<CR><ETX>43<CR><LF>
<-- 12:58:29 <ACK>
--> 12:58:29 <STX>7O|1|I*||CSols||Co|S|||||Q|||||F<CR><ETX>21<CR><LF>
<-- 12:58:29 <ACK>
--> 12:58:29 <STX>0M|1|ICDD*ACS.NGV*V1*Q|CM2|69151<CR><ETX>D6<CR><LF>
<-- 12:58:29 <ACK>
--> 12:58:29 <STX>1R|1|I*||CSols||12.50|||||P|20131016125829|CPMS1<CR><ETX>C1<CR><LF>
<-- 12:58:29 <ACK>
--> 12:58:29 <STX>2R|2|I*||CSols||124.00|||||P|20131016125829|CPMS1<CR><ETX>0F<CR><LF>
<-- 12:58:29 <ACK>
--> 12:58:29 <STX>3P|1<CR><ETX>40<CR><LF>
<-- 12:58:29 <ACK>
```

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 LIS/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.

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 laboratories 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 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 (Charing Cross Hospital), Leeds Teaching Hospitals NHS Trust (St. James Hospital), Lund University Hospital, Northumbria Healthcare Trust (Wansbeck General Hospital) & Oxford University Hospital Trust (John Radcliffe Hospital).