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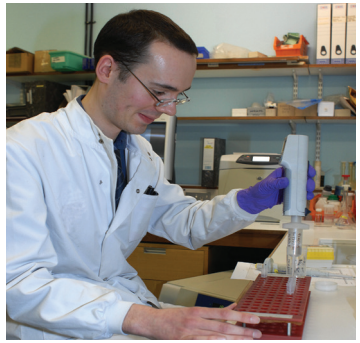
Chromium and Cobalt for Metal on Metal Hip Replacements

Trace Elements Laboratory
Blood Sciences, Sandwell Hospital



BCPS
NHS Pathology Serving the Black Country

Provided by Sandwell and West Birmingham NHS Trust, The Dudley Group NHS Foundation Trust, The Royal Wolverhampton NHS Trust and Walsall Healthcare NHS Trust.

Sample Collection

- It is not necessary to use an indwelling cannula when collecting the blood as the amounts of chromium and cobalt leaching from stainless steel needles has been found to be negligible. A single 0.5 mL EDTA or sodium heparin whole blood sample is required for both tests
- Plasma/serum is not recommended as there is a small risk that the separation process may contaminate the specimen. In addition, there is a marked difference in the normal chromium content of plasma and whole blood so it is important that the two types of specimen are not used interchangeably when serially monitoring patients

Sending Specimens for Analysis

- Send specimens by 1st class post, at ambient temperature, to the address on the back of this leaflet
- Prior to dispatch, store samples at 4 °C

Turnaround Times

We aim to analyse and report results within 3 working days of receipt of the specimen.

Reference Ranges

Chromium:

Normal (individuals without hip replacements):	< 40 nmol/L
MHRA Threshold (7 ppb):	135 nmol/L

Cobalt:

Normal (individuals without hip replacements):	< 10 nmol/L
MHRA Threshold (7 ppb):	120 nmol/L

It should be noted that this laboratory, in agreement with other NHS SAS Trace Elements Laboratories, is reporting results in nmol/L. The unit used in the MHRA document, MDA/2020/033 (see below), ppb ('parts per billion' ug/L) was felt to be inappropriate in the context of modern clinical chemistry.

Analysis

Analysis of both cobalt and chromium is performed simultaneously by inductively-coupled plasma mass spectrometry (ICP-MS). Typical between-batch variation is 7.2% for chromium at 113 nmol/L and 3.0% for cobalt at 95 nmol/L. Assay performance is monitored by participation in the NEQAS Trace Elements EQA scheme.

Clinical Use of Blood Chromium and Cobalt

In some individuals with metal-on-metal (MoM) replacement hip joints, and similar prostheses, it has become evident that release of metal debris from the devices may occur, leading to elevated blood metal ion concentrations and local soft tissue reactions. These can result in destruction of nearby muscle and bone and in a small number of cases, complete failure of the joint.

In response to concerns regarding this, the MHRA issued a Medical Devices Alert (MDA/2010/033) in 2010. This recommended that certain groups of patients deemed to be at high risk of soft tissue reactions, undergo regular monitoring, including measuring blood concentrations of cobalt and chromium. If the metal ion concentrations exceed the MHRA threshold of 7 ppb (135 nmol/L for chromium or 120 nmol/L for cobalt), repeat testing 3 months later is advised together with other further investigations (e.g., imaging studies)

Very recently, updated guidance was released recommending monitoring of blood cobalt and chromium in all patients with MoM hip joints regardless of the size of the implant or whether the patient is symptomatic. Annual monitoring is recommended for most groups with less frequent monitoring in low risk groups. The thresholds of blood cobalt and chromium indicating adverse soft tissue reactions in the original 2010 guidance have remained in place.

It should be noted that, whilst elevated blood chromium and cobalt concentrations reflect varying degrees of wear to the hip implant, it is currently not possible to interpret these results with respect to any potential toxicity effects on the patient.