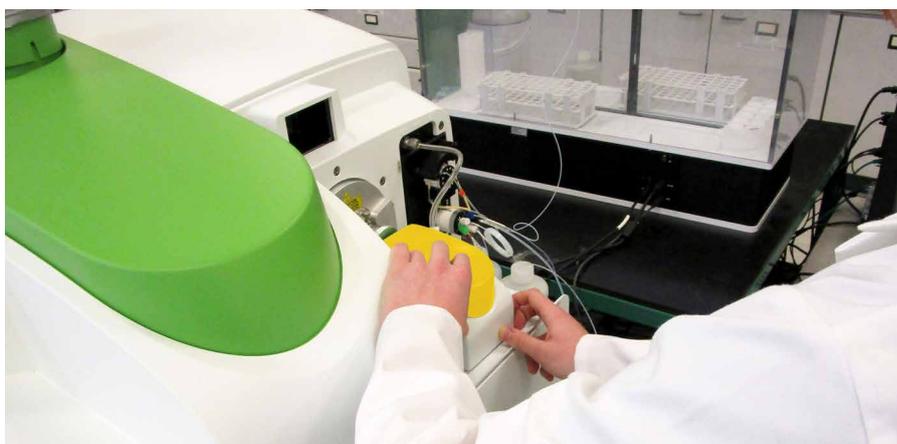


TRACE METAL BIOANALYSIS AND BIOMARKER QUANTIFICATION

Critical requirements for quantitative bioanalytical applications

Trace metal bioanalysis by inductively coupled plasma mass spectrometry (ICP-MS) offers a quantitative and highly selective approach to elemental bioanalysis for pharmacokinetics studies (PK) involving metal containing drugs or for the quantification of metals during biomarker or biomonitoring studies



The quantification of trace metals or other elements at very low levels, (even down to parts-per-trillion (ppt)) in clinical samples is a critical requirement for quantitative bioanalytical applications including bioanalysis supporting preclinical or clinical PK studies, biomarkers or biomonitoring of trace metals in biological samples.

Metal bioanalysis for preclinical and clinical studies

Metal containing drugs are currently being evaluated for a range of therapeutic applications including cancer, arthritis, diabetes and cardiovascular diseases. Examples include the use of platinum in cis-platin anti-cancer drugs or gold in Rheumatoid Arthritis drugs. Medical devices such as implants or pacemakers may also impart metal elements such as titanium or chromium or nickel that may leach from the device. Determining these metals in preclinical and clinical samples is vital to the successful development of metal containing drugs, however, the analysis of these elements at very low detection limits, in complex biological matrices, can present challenges.

Biomarker quantification

Recently there has also been increased interest in identifying biomarkers that can give high specificity and sensitivity to aid diagnosis of a disease. If biomarkers can be

established to predict likelihood of risk of developing the disease perhaps decades before they would typically develop then this assist healthcare providers in determining suitable treatment programs. The use of metals as potential biomarkers has been applied across multiple disease areas including neurodegenerative processes such as those associated with Alzheimer's Disease (AD) where it has been suggested that heavy metals or toxic elements could play a role in early development of the disease. In these studies, zinc, copper and iron have been studied in order to establish possible diagnostic biomarkers. Copper, lead and zinc have been studied as potential breast cancer biomarkers and also potentially linked to cardiovascular diseases.

Human biomonitoring

Metal bioanalysis is key to Human biomonitoring (HBM) studies where the measurement of biomarkers (parent chemical and/or its biotransformation products) in human biological fluids or tissues is used as a tool for quantifying human exposure to chemicals in order to inform public health, risk assessment, and risk management decisions.

Our metal bioanalysis expertise

Our bioanalysis experts provide regulatory compliant laboratory services to support preclinical, clinical PK studies, biomarker and biomonitoring studies. We deliver accurate and robust data for element specific quantitative bioanalytical evaluation of metals or other elements at very low levels, even down to parts-per-trillion (ppt) with few matrix interferences.

Our clinical assay team are adept at method development and validation and apply this technology to quantification of metal elements across a wide range of clinical samples including plasma, serum, whole blood and other matrices.

FOR MORE INFORMATION

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Intertek offers a range of technologies including ICP-MS in a Good Laboratory Practice (GLP) or Good Clinical Practice (GCP) compliant environment to determine levels of trace metals and other inorganic elements in clinical samples to support drug discovery, drug development and the safety assessment of implantable medical devices



METAL BIOANALYSIS SERVICES

- Rapid discovery phase bioanalysis
- Method development
- Method validation (GLP/GCP)
- GLP/GCP quantitative analysis
- Biomarker studies
- Biomonitoring studies
- Method transfer
- Statistical support
- Elemental mapping of tissue samples with electron microscopy (SEM-EDX)

Inductively coupled plasma with mass spectrometry detection

Inductively coupled plasma with mass spectrometry (ICP-MS) detection is an established technique which allows detection of a wide range of elemental species at trace levels and can be used in bioanalytical (e.g PK) or biomarker applications. When coupled with appropriate sample preparation procedures, excellent sensitivity and low levels of detection are achieved (down to ppb).

We develop reliable methods for the simultaneous quantification of multiple elements (e.g. selection from Li, Be, B, Al, Sc, Ti, V, Cr, Mn, Fe, Ni, Co, Cu, Zn, Ga, Ge, As, Se, Rb, Sr, Mo, Ag, Cd, Sn, Sb, Te, Cs, Ba, Hg, Tl, Pb and Bi) in clinical samples with the use of appropriate internal standards.

Meeting regulatory and quality requirements

Intertek offers a range of technologies including ICP-MS in a Good Laboratory Practice (GLP) or Good Clinical Practice (GCP) compliant environment to determine levels of trace metals and other inorganic elements in clinical samples to support drug discovery, drug development and the safety assessment of implantable medical devices. In addition, our UK facility has an on-site Class II Bio sample handling laboratory and a Human Tissue Licence, enabling the handling of clinical and diagnostic specimens.

Bringing quality and safety to life, we apply our Total Quality Assurance expertise to support your bioanalysis or biomarker programs with a focus on developing the best possible methodologies for your requirements that comply with the latest industry guidance.

FOR MORE INFORMATION



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