



Sample Report DD001

CLIENT #: 12345
DOCTOR: Erlo Roth, MD
Doctor's Data, Inc.
3755 Illinois Ave.
St. Charles, IL 60174 U.S.A.

DOB:

AGE: 60

Implant Metal Profile; whole blood

| METALS | | | | | |
|------------|------|------------------------|-----------------------|---------------|----------|
| | | RESULT / UNIT ng/mL | REFERENCE INTERVAL | NO IMPLANT | EXPOSURE |
| Cobalt | (Co) | 3.5 | < 0.80 | | |
| Chromium | (Cr) | 3.7 | < 0.80 | | |
| Titanium | (Ti) | 2.2 | < 2.0 | | |
| Vanadium | (V) | 0.09 | < 0.50 | | |
| Molybdenum | (Mo) | 0.95 | < 3.0 | | |
| Nickel | (Ni) | 2.8 | < 3.0 | | |

This test assesses the circulating blood levels of the six metals that are most commonly associated with orthopedic and dental metal prostheses or implants. Metal debris may be associated with excessive physical wear or corrosion of the metal alloys. The greatest release of the metals occurs when prostheses entail metal-on-metal (M/M) bearing surfaces. Many studies have shown that the released metal debris may be associated with localized tissue damage to bone and soft tissue, sensitivity reactions, and remote adverse effects on normal physiological and biochemical functions. The reported blood metal levels should not be solely used to make conclusions regarding the integrity of metals prosthesis devices.

Cobalt (Co), chromium (Cr), and molybdenum (Mo) These three metals constitute the most commonly used alloys that have been used in orthopedic prostheses such as hip, knee and shoulder replacements (about 60:30:7, respectively). The blood levels of Co and Cr, as well as deposition in remote tissues, will be elevated to some extent indefinitely in every patient who has had M/M hip replacement or femoral head resurfacing. Co is the most abundant metal released by wear from the bearing surfaces. The release of the metal debris is highly dependent on device design, surgical technique, level of physical activity and other factors that affect the health of involved bone and surrounding soft tissue. Very high blood levels of the metals are typically associated with failure of the prostheses; if symptoms are present referral to an orthopedist is warranted for further evaluation. Systemic adverse effects of the metals may be associated with excessive oxidative stress, inflammation, low levels of glutathione, compromised redox capacity, and detoxification (Phases I and II), and abnormal arterial permeability. Signs and symptoms of cobaltism include visual and auditory impairment, tinnitus, vertigo, impaired immune and renal function, cardiomyopathy, cognitive dysfunction/dementia, mood disorders, hypothyroidism, peripheral neuropathy and skin rashes. It should be noted that benign high blood Co levels may be associated with very high B-12 supplementation, and supplementation with trivalent Cr and Mo may contribute to high blood levels of the latter metals.

Titanium (Ti) vanadium (V) and nickel (Ni) Several grades of pure Ti and Ti-alloys have been used extensively for dental implants, and orthopedic devices such as plates, rods, screws, wires, and inter-bone stems. Although used because of their relative high biocompatibility, Ti and Ti-alloys are susceptible to various types of corrosion even when completely imbedded within bone; corrosion releases Ti and Ti-alloy metals. The released metals may be persistently high in circulation and accumulate in the immediate periprosthetic bone and soft tissue, as well as remote tissues and organs. Elevated blood Ti levels associated with prostheses are not necessarily associated with Toxicity. However; there is a dearth of clinical data regarding potential adverse health effects. The lack of clinical studies is disconcerting since it has been reported that serum Ti levels can be 18 times greater 10 years post-surgery than at baseline; the M/M hip prostheses in the subjects consisted of Ti-alloy acetabular sockets (bearing) and Ti femoral stems. In an animal model Ti released from within bone concentrated primarily in the spleen and lungs, and to a lesser extent in the heart, kidneys and liver. Ti may have adverse effects in blood, fibrotic tissues and osteogenic cells after transport through the circulatory or lymphatic systems. Blood levels of V, a minor component of some Ti alloys, are expected to be higher than normal (<1ng/mL) with Ti-alloy prostheses in good condition (1-2 ng/mL), and even higher with significant prosthesis wear (>5 mg/mL). A case report indicated V toxicity associated with a broken Ti alloy femoral stem and a blood V level of 5.8 ng/mL. The patient exhibited sensory-motor axonal neuropathy and bilateral sensorineural hearing loss, and did not have alloy bearing surfaces. It should be noted that isolated high blood levels of V may likely be associated with high supplementation with V. Nickel-containing Ti-alloys have been used primarily in dentistry. Much concern has been raised regarding the established cytotoxic, allergic and genotoxic activity of Ti-Ni alloys.

References available upon request.

SPECIMEN DATA

Comments:

Date Collected: 01/02/2018

Time Collected: 07:30 am

Methodology: ICP-MS

Date Received: 01/03/2018

Fasting: Yes

Date Reported: 01/04/2018