DOCTOR'S DATA INC.

ORDER: [redacted]
TEST: [redacted]
PATIENT: Tamara Rubin
ID: [redacted]
SEX: Female
AGE: 52 **DOB:** 11/20/1969

CLIENT #: [redacted]
DOCTOR: John Salerno DO
Salerno Center
345 East 37th Street #208
New York, NY 10016 U.S.A.

Toxic Metals; urine

TOXIC METALS				
		RESULT µg/g Creat	REFERENCE INTERVAL	WITHIN REFERENCE / OUTSIDE REFERENCE
Aluminum	(Al)	2.5	< 25	
Antimony	(Sb)	0.046	< 0.18	
Arsenic	(As)	13	< 50	
Barium	(Ba)	8.4	< 5	
Beryllium	(Be)	<dl	< 0.01	
Bismuth	(Bi)	0.019	< 1	
Cadmium	(Cd)	1.0	< 0.9	
Cesium	(Cs)	4.8	< 10	
Gadolinium	(Gd)	3.5	< 0.8	
Lead	(Pb)	4.0	< 1.2	
Mercury	(Hg)	0.24	< 1.3	
Nickel	(Ni)	3.3	< 5	
Palladium	(Pd)	<dl	< 0.3	
Platinum	(Pt)	<dl	< 0.1	
Tellurium	(Te)	0.12	< 0.5	
Thallium	(Tl)	0.35	< 0.5	
Thorium	(Th)	<dl	< 0.02	
Tin	(Sn)	0.45	< 5	
Tungsten	(W)	0.090	< 0.4	
Uranium	(U)	0.080	< 0.03	

URINE CREATININE			
	RESULT	REFERENCE INTERVAL	-2SD -1SD MEAN +1SD +2SD
Creatinine	124	30 – 225	

SPECIMEN DATA

Comments:
Date Collected: 06/14/2022
Date Received: 06/17/2022
Date Reported: 06/21/2022
Provoking Agent: CAEDTA 2000MG DMSA 1000MG
Provocation: Post Provocative
Collection Period: 7 hours
Methodology: ICP-MS QQQ, Creatinine by Jaffe Reaction

< dl: less than detection limit
Results are creatinine corrected to account for urine dilution variations. **Reference intervals are based upon NHANES (cdc.gov/nhanes) data if available, and are representative of a large population cohort under non-provoked conditions.** Chelation (provocation) agents can increase urinary excretion of metals/elements.

Introduction

This analysis of urinary elements was performed by ICP-Mass Spectroscopy following acid digestion of the specimen. Urine element analysis is intended primarily for: diagnostic assessment of toxic element status, monitoring detoxification therapy, and identifying or quantifying renal wasting conditions. It is difficult and problematic to use urinary elements analysis to assess nutritional status or adequacy for essential elements. Blood, cell, and other elemental assimilation and retention parameters are better indicators of nutritional status.

- 24 Hour Collections
  "Essential and other" elements are reported as mg/24 h; mg element/urine volume (L) is equivalent to ppm. "Potentially Toxic Elements" are reported as µg/24 h; µg element/urine volume (L) is equivalent to ppb.
- Timed Samples (< 24 hour collections)
  All "Potentially Toxic Elements" are reported as µg/g creatinine; all other elements are reported as µg/mg creatinine. Normalization per creatinine reduces the potentially great margin of error which can be introduced by variation in the sample volume. It should be noted, however, that creatinine excretion can vary significantly within an individual over the course of a day.

If one intends to utilize urinary elements analysis to assess nutritional status or renal wasting of essential elements, it is recommended that unprovoked urine samples be collected for a complete 24 hour period. For provocation (challenge) tests for potentially toxic elements, shorter timed collections can be utilized, based upon the pharmacokinetics of the specific chelating agent. When using EDTA, DMPS or DMSA, urine collections up to 12 hours are sufficient to recover greater than 90% of the mobilized metals. Specifically, we recommend collection times of: 9 - 12 hours post intravenous EDTA, 6 hours post intravenous or oral DMPS and, 6 hours post oral bolus administration of DMSA. What ever collection time is selected by the physician, it is important to maintain consistency for subsequent testing for a given patient.

If an essential element is sufficiently abnormal per urine measurement, a descriptive text is included with the report. Because renal excretion is a minor route of excretion for some elements, (Cu, Fe, Mn Zn), urinary excretion may not influence or reflect body stores. Also, renal excretion for many elements reflects homeostasis and the loss of quantities that may be at higher dietary levels than is needed temporarily. For these reasons, descriptive texts are provided for specific elements when deviations are clinically significant. For potentially toxic elements, a descriptive text is provided whenever levels are measured to be higher than expected. If no descriptive texts follow this introduction, then all essential element levels are within acceptable range and all potentially toxic elements are within expected limits.

Reference intervals and corresponding graphs shown in this report are representative of a healthy population under non-provoked conditions. Descriptive texts appear in this report on the basis of measured results and correspond to non-challenge, non-provoked conditions.

Chelation (provocation) agents can increase urinary excretion of metals/elements. Provoked reference intervals have not been established therefore non-provoked reference intervals shown are not recommended for comparison purposes with provoked test results. Provoked results can be compared with non-provoked results (not reference intervals) to assess body burden of metals and to distinguish between transient exposure and net retention of metals. Provoked results can also be compared to previous provoked results to monitor therapies implemented by the treating physician. Additionally, Ca-EDTA provoked results can be used to calculate the EDTA/Lead Excretion Ratio (LER) in patients with elevated blood levels.

CAUTION: Even the most sensitive instruments have some detection limit below which a measurement cannot be made reliably. Any value below the method detection limit is simply reported as "< dl." If an individual excretes an abnormally high volume of urine, urinary components are likely to be extremely dilute. It is possible for an individual to excrete a relatively large amount of an element per day that is so diluted by the large urine volume that the value measured is near the dl. This cannot automatically be assumed to be within the reference range.

This analysis of urinary metals was performed by ICP-Mass Spectroscopy. Urine metal analysis is traditionally used for evaluation of very recent or ongoing exposure to potentially toxic metals. The urinary excretion of certain metals is known to be increased (provoked) to a variable extent after administration of specific chelating agents. Reference values and corresponding graphs are representative of a healthy population under non-provoked conditions; reference values have not been established for provoked urine samples. Reference values are age and sex specific.

For timed, random or first morning urine collections, metals are reported as µg/ gram creatinine. Normalization per creatinine reduces the potentially great margin of error that can be introduced by variation in the sample volume (concentration). It should be noted that creatinine excretion for an individual may vary to some extent over the course of a day, and from day to day. For 24 hour (h) urine collections elements are reported as µg/24 h. Results are also reported as µg element/gram creatinine to ensure clinically useful information in the event that an inaccurate 24 h urine volume was reported to the laboratory.

Descriptive texts appear in this report if detected levels of specific elements are abnormally high by comparison to the unprovoked reference values. If no descriptive texts follow this introduction, potentially toxic metals are within reference limits.

Barium High

Barium (Ba) has not been established to be an essential element. Elevated levels of Ba often are observed after exposure to Ba (a contrast agent) during diagnostic medical tests (e.g. "barium swallow", "upper GI series", "barium enema", etc.). Elevated levels of Ba may interfere with calcium metabolism and potassium retention. Acutely high intake of soluble Ba-salts (nitrates, sulfides, chlorides) can be toxic. Chronic exposure to Ba may be manifested by muscular and myocardial stimulation, tingling in the extremities, and loss of tendon reflexes.

Brazil nuts and peanuts/peanut butter are very high in Ba so urine Ba may be elevated shortly after consumption of these foods; toxic effects would not be anticipated under such conditions. Although Ba is poorly absorbed orally (<5%) it can be very high in peanuts and peanut butter (about 3,000 nanograms/gram), frozen and fast foods such as burgers, fries, and hot dogs (400-500 nanograms/gram). It is noteworthy that Ba intake is much higher in children than adults (Health Canada 2005, www.atsdr.cdc.gov/toxprofiles/tp24-c6.pdf).

Ba is surprisingly abundant in the Earth's crust, being the 14th most abundant element. High amounts of Ba may be found in soils and in food, such as nuts (e.g. brazil nuts), seaweed, fish and certain plants. Because of the extensive use of barium in industry, human activities add greatly to the release of barium in the environment. As a result barium concentrations in air, water and soil may be higher than naturally occurring concentrations in many locations. It can also enter the air during coal and oil combustion. Barium compounds are used by the oil and gas industries to make drilling mud. Drilling mud simplifies drilling through rocks by lubricating the drill. Barium compounds are also used to make paint, bricks, tiles, glass, and rubber. Soluble Ba compounds are highly toxic and may be used as insecticides. Ba-aluminates are utilized for water purification, acceleration of concrete solidification, production of synthetic zeolites, and in the paper and enamel industries.

Ba levels (and the levels of 16 other elements) in water can be assessed with water testing as provided by DDI. A possible confirmatory test for excessive Ba is measurement of blood electrolytes as hypokalemia may be associated with excessive Ba in the body. Hair elements analysis may provide further evidence of exposure to Ba.

Cadmium High

Urine cadmium (Cd) is higher than expected, but associated symptoms or toxic effects may not be evident. Cadmium accumulates primarily in bone, the liver and kidneys, and it has a half-life of elimination is on the order of years. Zinc and vitamin E may be somewhat protective, N-AC and glutathione may reduce Cd-induced oxidative damage. Cadmium contamination can be insidious with delayed effects that may take years to appear. The exception is acute pneumonitis, dyspnea, and fatigue following exposures to Cd dusts, fumes, or soluble salts.

Virtually all soil, rock, and water contain Cd. Cadmium is present in most foods, with broad variation in concentrations. Although oral bioavailability of ingested Cd is poor, local soil contaminant conditions, soil-to-plant transference, and use of cadmium-containing fertilizers might lead to higher overall oral cadmium dietary exposure. Tobacco naturally accumulates relatively high concentrations of cadmium in its leaves, a significant risk for smokers. Other occupational or environmental sources include: mining and smelting activities, pigments and paints, electroplating, electroplated parts (e.g., nuts and bolts), batteries (Ni-Cd), plastics and synthetic rubber, photographic and engraving processes, old drums from some copy machines, photoconductors and photovoltaic cells, and some alloys used in soldering and brazing.

Symptoms or findings that may be consistent with this urine level of Cd include: hypertension; microcytic, hypochromic anemia (not responsive to iron supplementation); and proteinuria with abnormally high excretion of beta-2-microglobulin per gram creatinine.

Elevated urine Cd may occur after administration of: EDTA, DMPS, DMSA, or D-penicillamine. Blood Cd levels may not accurately depict potential net retention of Cd.(Harrison's Principles of Internal Medicine, 13th ed, p. 2463).

Gadolinium High

This individual's urine level of Gadolinium (Gd) is higher than expected. Gadolinium is one of the most abundant "rare-earth" elements but is never found as a free element in nature. Gadolinium has no known biological role in humans.

Toxicity is rarely associated with Gd due to its poor gastrointestinal absorption (it is suspected that very little Gd is absorbed from the gastrointestinal tract (<0.05%). If exposure to high enough doses and/or if absorption does occur, symptoms of acute toxicity may develop, including abdominal cramps, diarrhea, lethargy, muscular spasms, and even eventual death due to respiratory collapse. Gadolinium salts can cause irritation of the skin and eyes and are suspected to be possible carcinogens. As reported by Perazella (2009) Gadollinium-based contrast (GBC) agents have been linked on occasion with a rare systemic fibrosing condition called nephrogenic systemic fibrosis (NSF) and their use in patients with even mild kidney disease should be avoided (parenteral administration).

Gd is often used in alloys (e.g. chromium, iron). Other technical uses include the phosphors of color television tubes and in making magnets and electronic components such as recording heads for video recorders and in the manufacture of compact disks and computer memory. In medicine Gd, chelated with diethylenetriaminepentaacetic acid (DTPA), is used as a non-radioactive contrasting agent in magnetic resonance imaging and has a half-life in blood of about 90 minutes. However, residual Gd is retained in tissues for quite some time. It is also used in control rods for nuclear reactors and power plants, in making garnets for microwave applications.

EDTA effectively chelates Gd therefore urinary Gd might be higher than average post-Ca-EDTA provocation, particularly in patients who have had Gd-enhanced MRIs.

Lead High

This individual's urine lead (Pb) is higher than expected which means that Pb exposure is higher than that of the general population. A percentage of assimilated Pb is excreted in urine. Therefore the urine Pb level reflects recent or ongoing exposure to Pb and the degree of excretion or endogenous detoxification processes.

Sources of Pb include: old lead-based paints, batteries, industrial smelting and alloying, some types of solders, Ayruvedic herbs, some toys and products from China and Mexico, glazes on(foreign) ceramics, leaded (anti-knock compound) fuels, bullets and fishing sinkers, artist paints with Pb pigments, and leaded joints in municipal water systems. Most Pb contamination occurs via oral ingestion of contaminated food or water or by children mouthing or eating Pb-containing substances. The degree of absorption of oral Pb depends upon stomach contents (empty stomach increases uptake) and upon the essential element intake and Pb status. Deficiency of zinc, calcium or iron increases Pb uptake. Transdermal exposure is significant for Pb-acetate (hair blackening products). Inhalation has decreased significantly with almost universal use of non-leaded automobile fuel.

Lead accumulates in extensively in bone and can inhibit formation of heme and hemoglobin in erythroid precursor cells. Bone Pb is released to soft tissues with bone remodeling that can be accelerated with growth, menopausal hormonal changes, osteoporosis, or skeletal injury. Low levels of Pb may cause impaired vitamin D metabolism, decreased nerve conduction,and developmental problems for children including: decreased IQ, hearing impairment, delayed growth, behavior disorders, and decreased glomerular function. Transplacental transfer of Pb to the fetus can occur at very low Pb concentrations in the body. At relatively low levels, Pb can participate in synergistic toxicity with other toxic elements (e.g. cadmium, mercury).

Excessive Pb exposure can be assessed by comparing urine Pb levels before and after provocation with Ca-EDTA (iv) or oral DMSA. Urine Pb is higher post-provocation to some extent in almost everyone. Whole blood analysis reflects only recent ongoing exposure and does not correlate well with total body retention of Pb. However, elevated blood Pb is the standard of care for diagnosis of Pb poisoning (toxicity).

Uranium High

This individual's urine uranium (U) is higher than expected which indicates higher than expected exposure to U. Renal excretion accounts for most U that is excreted from the body. Uranium is considered mildly toxic for two reasons, low-level radioactivity and moderate biochemical toxicity.

Uranium is a radioactive element with 10 isotopes with half lives exceeding one hour. U238 constitutes about 99% of the naturally-occurring U and this is the isotope measured at DDI and reported for this individual. U238 has a half-life of 4.5 X 10 to the ninth years. It decays by alpha emission to produce thorium, Th234, the initial step in a decay chain that eventually leads to lead. Alpha, beta and gamma emissions occur during this decay process. Because of the very long half-life, the radioactivity danger is only slight. However, exposure to enriched or nuclear fuel grade U (high in U235) does pose a health hazard. The measured result (U238) does not reflect or imply exposure to enriched U235.

The toxochemical effects of U may be more severe than the radiochemical effects for U238. Uranium has four valences (3,4,5 or 6), can combine with phosphate, citrate, pyruvate, malate, lactate, etc. in body tissues, and usually is transported in the blood as a carbonate complex. Uranium that is not excreted in urine can accumulate in bone and kidney tissues as well as in the spleen and liver. In excessive amounts, it can be nephrotoxic. Inhaled U accumulatesin lung tissue. Fatigue is the most common symptom associated with chronic, low-level (natural) U exposure (DDI observations).

Uranium is more common than mercury, silver or cadmium in the earth's rock strata, and may be present, at low levels, in ground (drinking) water. Most commercial use of U is for nuclear fuel, but it may be present in ceramics or colored glass, especially ancient or antique, yellow-colored glassware.

Hair elements analysis may provide further information regarding temporal exposure to U.Whole blood U analysis may provide confirmation of very recent or ongoing exposure to uranium.