NEW YORK STATE OF OPPORTUNITY. | **Department of Health**

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Certificate of Analysis

CHEAR Reference Materials
Trace Elements in Human Urine: UE17-14 L and UE17-15 H

The CHEAR Reference Materials, UE17-14 L and UE17-15 H, are intended primarily to promote harmonization of trace element data across biomonitoring studies. Each set of Trace Elements in Human Urine reference material consists of two concentrations: 1.) a "Low" level – UE17-14 L; and 2.) a "High" level – UE17-15 H. Each vial contains approximately 10 mL of urine.

The development of these RMs was overseen by the New York State Biomonitoring Proficiency Testing (PT) Program for Trace Elements at the Wadsworth Center, New York State Department of Health, with support from the NIEHS Children's Health Exposure Analysis Resource (CHEAR).

Assigned Values: Assigned values for 22 trace elements are provided in Table 1. These values have been set based on an interlaboratory study using either 1.) the robust consensus value in accordance with procedures defined in Algorithm A in ISO 13528:2005(E) *Statistical methods for use in proficiency testing by interlaboratory comparison*[1]; or 2.) the arithmetic mean after outlier removal. The expanded uncertainties (U) associated with each value represents a confidence level of 95%; the quality specifications are also provided for elements which are graded in the New York State Biomonitoring PT Program for Trace Elements. Other statistical data from the interlaboratory study (*i.e.,* standard deviation, and n) are provided for informational purposes.

Informational Values: Informational values are provided in Table 2. These data were reported to the PT Program by 1-4 laboratories and may be of interest to the user, however there is insufficient data available to adequately assess the uncertainty associated with the values.

Expiration: An expiration date for this RM has been designated as February 1, 2028. This date is consistent with the expiration of similar NYS RMs, and NIST SRM 3668 and 2668 reference materials for toxic elements in frozen urine.

NOTICE AND WARNING TO USERS

These RMs are a human material product derived from donor volunteers. Handle with caution in the same manner as patient specimens.

Preparation Information: Urine was collected from volunteer donors into polyethylene containers and stored at 4°C. Following collection, urine was acidified to 1% (v/v) with nitric acid and mixed with a sulfamic acid solution (stock solution contained 200 mg/mL sulfamic acid and 10% (v/v) Triton-X 100) to a final concentration of 1% (v/v) to stabilize Hg. Urine was stored frozen at -80°C pending further preparation. The urine was thawed and precipitated salts were removed by centrifugation. Urine supernatants were combined into two separate pools. Each urine pool was supplemented with arsenic (As), barium (Ba), beryllium (Be), cadmium (Cd), cobalt (Co), chromium (Cr), mercury (Hg), manganese (Mn), lead (Pb), thallium (Tl), uranium (U), aluminum (Al), cesium (Cs), copper (Cu), molybdenum (Mo), nickel (Ni), platinum (Pt), antimony (Sb), selenium (Se), tin (Sn), strontium (Sr), tellurium (Te), vanadium (V), tungsten (W), and zinc (Zn) and stirred overnight to ensure thorough mixing prior to aliquoting 10-mL into polypropylene vials. Samples were stored at -80°C.

Long Term Storage: Store at or below –80°C.

Instructions for Use: Prior to analysis, remove the desired number of vials and thaw, mixing thoroughly. These materials should be handled in the same manner as patient specimens, utilizing your laboratory's standard procedures.

Multiple aliquots may be removed from each vial; unused portions may be refrigerated for up to one week, or re-frozen for later use. According to unpublished in-house QC data, thawed urine materials remain stable over at least 20 freeze-thaw cycles, but this will depend on the volume of urine remaining.

References:

1. ISO/FDIS-13528 (2005) Statistical methods for use in proficiency testing by interlaboratory comparisons. International Organization for Standardization, Geneva.

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Table 1 Assigned value, expanded uncertainty (U), standard deviation, and n for 22 trace elements in UE17-14 L and UE17-15 H. For elements that are graded by the New York State Biomonitoring PT Program for Trace Elements, the quality specifications are also given. All values are reported in µg/L.

	UE17-14 L						UE17-15 H				
Element	Assigned Value ± U		SD	Quality Specification	n	Element	Assigned Value ± U		SD	Quality Specification	n
As	12.0 ± 0.4		1.1	± 6.0	21	As	68 ± 2		4	± 14	21
Ba	1.6 ± 0.1		0.1	± 1.0	13	Ba	5.9 ± 0.2		0.4	± 1.2	13
Be	0.50 ± 0.01		0.02	± 1.00	11	Be	1.30 ± 0.04		0.09	± 1.00	12
Cd	0.71 ± 0.03		0.07	± 1.00	19	Cd	1.2 ± 0.1		0.2	± 1.0	20
Co	0.91 ± 0.05		0.11	± 1.50	14	Co	2.4 ± 0.1		0.1	± 1.5	15
Cr	2.3 ± 0.1		0.2	± 3.0	12	Cr	9.1 ± 0.3		0.6	± 3.0	12
Hg	3.3 ± 0.2		0.4	± 3.0	15	Hg	24.1 ± 0.7		1.6	± 7.20	15
Mn	1.1 ± 0.1		0.2	± 0.55	16	Mn	2.1 ± 0.1		0.3	± 0.55	16
Pb	1.40 ± 0.04		0.10	± 1.00	18	Pb	5.1 ± 0.1		0.3	± 1.0	18
Tl	0.310 ± 0.002		0.005	± 0.200	14	Tl	0.75 ± 0.01		0.02	± 0.20	14
U	0.027 ± 0.001		0.003	± 0.030	16	U	0.063 ± 0.001		0.003	± 0.030	16
Element	Assigned Value ± U		SD	2 SD	n	Element	Assigned Value ± U		SD	2 SD	n
Cs	7.5 ± 0.2		0.3	0.6	10	Cs	15.0 ± 0.3		0.5	1.0	10
Cu	18 ± 1		2	4	10	Cu	103 ± 4		8	16	10
Mo	97 ± 1		3	6	14	Mo	284 ± 4		9	18	14
Ni	8.3 ± 0.6		0.9	1.8	9	Ni	13.7 ± 0.6		0.9	1.8	9
Pt	0.23 ± 0.03		0.04	0.08	6	Pt	1.18 ± 0.04		0.05	0.10	6
Sb	0.64 ± 0.03		0.05	0.10	11	Sb	1.27 ± 0.04		0.07	0.14	11
Se	50 ± 3		4	8	7	Se	150 ± 10		13	26	7
Sn	2.5 ± 0.2		0.3	0.6	7	Sn	12.2 ± 0.8		1.1	2.2	7
V	1.3 ± 0.1		0.2	0.4	6	V	6.0 ± 0.6		0.7	1.4	6
W	0.57 ± 0.03		0.04	0.08	8	W	1.26 ± 0.03		0.05	0.10	9
Zn	868 ± 35		56	112	9	Zn	1359 ± 37		55	110	8

Table 2 Informational values for 11 trace elements in UE17-14 L and 12 trace elements in UE17-15 H. All values are reported in µg/L.

UE17-14 L		UE17-15 H	
Element	**Mean***	**Element**	**Mean***
Ag	< 0.302	Ag	< 0.302
B	799	Al*	26
Bi	< 0.230	B	994
Fe	8.85	Bi	< 0.230
I	130	Fe	7.78
Li	15.0	I	100
Mg	13800	Li	16.6
Sr*	119	Mg	28500
Te	0.7	Sr*	281
Th	< 0.00557	Te	2.4
Ti	5.96	Th	< 0.00557
		Ti	24.6

*For those elements where n>1.