Evaluation of VACUETTE® NH Trace Element Sodium Heparin tubes for trace elements determination

Background:

Greiner-Bio-One, Austria has sold plastic evacuated tubes (VACUETTE®) for venous blood collection since 1986. In addition to the standard product line, Greiner-Bio-One also has an extensive range of special tubes including tubes for trace element testing.

Sodium heparin activates antithrombins, thus blocking the coagulation cascade and producing a whole blood or plasma sample after centrifugation process.

The tubes are composed of clear plastic. The caps are made of plastic with a rubber stopper.

Study Objective:

Trace elements are inorganic components that are found in the body in a concentration of < 0.01% of the body mass, which are amounts of < 10^{-6} g/g bodyweight. Normal ranges of the tested trace elements are listed below in Table 1.

The aim of evaluation of VACUETTE® NH Trace Element Sodium Heparin tubes was to demonstrate the analytical performance and suitability for trace element testing in blood for a variety of trace elements.

Study design and procedure:

The study and its results are applicable to all VACUETTE® NH Trace Element Sodium Heparin tubes.

For the studies, the following product was used:

Sample	Draw Volume	Description
456080	6 ml	VACUETTE® Trace Element NH Sodium Heparin

In total, 120 tubes were filled to the fill line with Millipore water (filling was carried out without any metal-containing devices). After filling, the tubes were inverted 8 times. Standards, controls and the samples were measured by ICP-MS. The tubes were tested for the following trace elements:

Results

The maximum, mean, and standard deviation of testing results of VACUETTE® NH Trace Element Sodium Heparin are shown in Table 1.

Table 1

Element	Normal range in		Maximal contamination level in VACUETTE® NH Trace Element Sodium Heparin tube [ppb]	Mean contamination in VACUETTE® NH Trace Element Sodium Heparin tube [ppb]	SD of mean contamination in VACUETTE® NH Trace Element Sodium Heparin tube [ppb]
	whole blood [ppb] [1]	Plasma/Serum [ppb] [1]			
Ag Silver	N.A.	<0.3	≤ 1.00*	0.87	0,10
Al Aluminium	< 5	5	7.30	2.05	2.057
As Arsenic	< 12	12	≤ 1.00*	0.87	0.10
Ba Barium	100	80	≤ 1.00*	0.87	0.10
Be Beryllium	< 3.8	4	≤ 1.00*	0.87	0.10
Bi Bismuth	N.A.	< 0.5	≤ 1.00*	0.66	0.34
Cd Cadmium	<1.0	N.A.	≤ 1.00*	0.39	0.35
Cr Chromium	3-6	< 0.4	≤ 1.00*	0.87	0.10

Element	Normal range in		Maximal contamination level in VACUETTE® NH Trace Element Sodium Heparin tube [ppb]	Mean contamination in VACUETTE® NH Trace Element Sodium Heparin tube [ppb]	SD of mean contamination in VACUETTE® NH Trace Element Sodium Heparin tube [ppb]
	whole blood [ppb] [1]	Plasma/Serum [ppb] [1]			
Co Cobalt	0.5-3.9	0.6	≤1.00*	0.87	0.10
Cu Copper	1.6-1190	< 1400	≤ 1.00*	0.87	0.10
Hg Mercury	1.0	N.A.	≤ 0.50*	0.30	0.15
I Iodine	N.A.	40-80	3.00	1.89	0.60
Li Lithium	N.A.	< 70	1.50	0.87	0.10
Mn Manganese	6.0-11.0	0.3-1.1	≤ 1.00*	0.87	0.10
Mo Molybdenum	1-10	< 6	≤ 1.00*	0.87	0.10
Ni Nickel	0.05-1.05	< 1.2	≤ 1.00*	0.87	0.10
Pb Lead	< 100	N.A.	1.70	0.28	0.13
Se Selenium	60-125	55-103	≤ 1.00*	1.00	0.00
Sb Antimony	< 3.0	N.A.	2.90	1.26	0.56
Sn Tin	N.A.	< 5	≤ 1.00*	0.87	0.10
Te Tellurium	0.15	N.A.	≤ 1.00*	0.87	0.10
Th Thorium	< 0.5	< 0.04	1.00*	0.87	0.10
Tl Thallium	< 0.8	N.A.	≤ 0.50*	0.27	0.13
U Uranium	0.1	< 60	≤ 0.20*	0.20	0.00
Zn Zinc	400-750	700-1500	6.00	2.11	2.20

[1] see Ref (1)
N.A. Not available

*Detection limit of ICP-MS:
for Hg, Pb, Tl, U: 0.2-0.5 ppb day-dependent
for all other trace elements: 0.80-1.00 ppb day-dependent

Apart from Aluminium, Iodine, Zinc, Lead, and Antimony, the maximum contamination was found to be 1ppb. As antimony is used for production of the PET material, it can be detected in the trace element tube. The mean and standard deviation indicate the range in which that trace element can be found. Due to the contamination level found for Aluminium (Al) it is not recommended to do testing for Al in that tube. For Pb testing, a blank value determination is recommended in order to obtain reliable values and rule out day-dependent deviations. The contamination level for Iodine and Zinc, however, is far below the reference range.

All values demonstrated above in Table 1 refer to typical average results found in GBO-studies.

Conclusion:

From these results, it can be concluded that the Greiner VACUETTE® NH Trace Element Sodium Heparin is suitable for trace element analysis (except Al not recommended) in blood/plasma for the tested trace elements. Blank measurements are always beneficial for assessing very low trace element contents.

References:

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(5) FDA Approval Greiner Trace Element Tubes
(6) CLSI C38A: Control of Preanalytical Variation in Trace Element Determinations, Approved Guideline