

Evaluation of VACUETTE® Trace Elements 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.

VACUETTE® Trace Elements Sodium Heparin tubes and VACUETTE® Trace Elements No Additive tubes are composed of clear plastic. The safety caps are made of plastic with a rubber stopper.

The VACUETTE® Trace Elements Sodium Heparin tube contains sodium heparin. The additive activates antithrombin, thus blocking the coagulation cascade and producing a whole blood sample or plasma sample after centrifugation. The VACUETTE® Trace Elements No Additive tube contains no additive resulting in a serum sample for testing purposes.

Study Objective:

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

The aim of this evaluation of VACUETTE® Trace Elements Sodium Heparin tubes and VACUETTE® Trace Elements No Additive tubes is to demonstrate their analytical performance and suitability for trace element testing in blood for a variety of trace elements.

Study design and procedure:

The study presents results from a random sampling of VACUETTE® Trace Element tubes (for the purpose of periodic monitoring). Its results are applicable to VACUETTE® Trace Elements Sodium Heparin tubes and VACUETTE® Trace Elements No Additive tubes.

For the studies, the following products were used:

Sample	Draw Volume	Description
456080	6 ml	VACUETTE® Trace Elements Sodium Heparin
456016	6 ml	VACUETTE® Trace Elements No Additive

In total, 20 VACUETTE® Trace Elements Sodium Heparin tubes and 10 VACUETTE® Trace Elements No Additive tubes were filled to the fill line indicator with Millipore water (filling was carried out without any metal-containing devices). After filling, all tubes were inverted 8 times. Standards, controls and the samples were measured by ICP-MS. The tubes were tested for the trace elements included in Table 1.

Results

The maximum contamination level for VACUETTE® Trace Elements Sodium Heparin and VACUETTE® Trace Elements No Additive tubes following ICP-MS measurement are shown in Table 1.

Table 1

Element	Normal range in		Maximal contamination level in VACUETTE® Trace Elements Sodium Heparin tube [ppb]	Maximal contamination level in VACUETTE® Trace Elements No Additive tube [ppb]
	whole blood [ppb] ¹	Plasma/Serum [ppb] ¹		
Ag Silver	N.A.	<0.3	≤ 1.00*	≤ 1.00*
Al Aluminium	< 5	5	≤ 2.00*	≤ 2.00*
As Arsenic	< 12	12	≤ 1.00*	≤ 1.00*
Ba Barium	100	80	≤ 1.00*	≤ 1.00*
Be Beryllium	< 3.8	4	≤ 1.00*	≤ 1.00*
Bi Bismuth	N.A.	< 0.5	≤ 1.00*	≤ 1.00*
Cd Cadmium	<1.0	N.A.	≤ 0.20*	≤ 0.20*
Cr Chromium	3-6	< 0.4	≤ 1.00*	≤ 1.00*
Co Cobalt	0.5-3.9	0.6	≤1.00*	≤ 1.00*
Cu Copper	1.6-1190	< 1400	≤ 1.00*	≤ 1.00*
Hg Mercury	1.0	N.A.	≤ 0.20*	≤ 0.20*
I Iodine	N.A.	40-80	≤ 2.00*	≤ 2.00*
Li Lithium	N.A.	< 70	≤ 1.00*	≤ 1.00*
Mn Manganese	6.0-11.0	0.3-1.1	≤ 1.00*	≤ 1.00*
Mo Molybdenum	1-10	< 6	≤ 1.00*	≤ 1.00*
Ni Nickel	0.05-1.05	< 1.2	≤ 1.00*	≤ 1.00*
Pb Lead	< 100	N.A.	≤ 0.20*	≤ 0.20*
Se Selenium	60-125	55-103	≤ 2.00*	≤ 2.00*
Sb Antimony	< 3.0	N.A.	2.70	1.30
Sn Tin	N.A.	< 5	≤ 1.00*	≤ 1.00*
Te Tellurium	0.15	N.A.	≤ 1.00*	≤ 1.00*
Th Thorium	< 0.5	< 0.04	≤ 1.00*	≤ 1.00*
Tl Thallium	< 0.8	N.A.	≤ 0.20*	≤ 0.20*
U Uranium	0.1	< 60	≤ 0.20*	≤ 0.20*
Zn Zinc	400-750	700-1500	≤ 1.00*	≤ 1.00*

¹ see Ref (1)

N.A. Not available

*Detection limit of ICP-MS:

for Cd, Hg, Pb, Tl, U: 0.2-0.5 ppb day-dependent

for all other trace elements: 0.80-2.00 ppb day-dependent

Apart from Aluminium, Iodine, Selenium, and Antimony and the highly toxic elements such as Cadmium, Mercury, Lead, and Thallium, the maximum contamination of all other trace elements was found to be 1 ppb. The maximum contamination of the highly toxic elements (Pb, Cd, Hg, Tl, U) was below 0.2 ppb. Taking into consideration the slight day-to-day variation in the detection limit (reproducibility), the contamination level of Aluminium, Iodine and Selenium (Al, I and Se) was 2 ppb. These contamination levels for Al, I and Se, however, are below the ranges normally found in the body. Antimony is used for production of the PET-material, therefore it can be detected in the trace element tubes, which may make these tubes unsuitable for testing of this element. Before determination of trace element all devices used in collection, transportation and storage should be evaluated. A blank measure for each tube lot must be carried out beforehand.

Conclusion:

From these results, it can be concluded that the Greiner VACUETTE® Trace Elements Sodium Heparin tubes and the VACUETTE® Trace Elements No Additive tubes are suitable for trace element analysis in blood/plasma for the tested trace elements. Blank measurements may be beneficial in accurately assessing trace element contents.

References:

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- (4) Guder W.G., Narayanan S., Wisser H., Zwata B., Samples: From the Patient to the Laboratory. Wiley-VCH, third revised edition (2003)
- (5) FDA Approval Greiner Trace Element Tubes
- (6) CLSI C38A: Control of Preanalytical Variation in Trace Element Determinations, Approved Guideline