BIOSPECTRA
100 Majestic Way, Bangor, PA 18013 / www.biospectra.us

ANALYTICAL METHOD FOR THE DETERMINATION OF ICH Q3D ELEMENTAL IMPURITIES BY INDUCTIVELY COUPLED PLASMA MASS SPECTROMETRY (ICP-MS) IN WATER FOR INJECTION

TABLE OF CONTENTS

1. PURPOSE:

1.1. To provide a procedure for the assessment of Elemental Impurities in Water for Injection products via the NexION 350X S/N 85VN5093001 ICP-MS. This procedure was assessed as a full quantitative option-1 procedure as per validation report BSI-RPT-1031 and follows the validation parameters for quantitation procedures as outlined in USP <233>.

1.2. Elements under USP <232> validated for this test method are as follows:

1.2.1. Class 1: Hg, As, Cd, and Pb

1.2.2. Class 2A: Co, V, and Ni

1.2.3. Class 2B: Tl, Au, Pd, Ir, Os, Rh, Ru, Se, Ag, and Pt

1.2.4. Class 3: Li, Sb, Sn, Ba, Mo, Cu, and Cr

1.2.5. Class 4: Al, Ca, Fe, K, Mg, Na, and Zn

2. SCOPE:

2.1. Applies to Water for Injection and related products manufactured at BioSpectra.

2.2. Applies to the NexION 350X S/N 85VN5093001 ICP-MS located in the Quality Control (QC) Laboratory at the BioSpectra Bangor, PA facility.

3. RESPONSIBILITIES:

3.1. The Executive Director of Quality Control or other qualified designated individual, is responsible for the control, implementation, training, and maintenance of this method.

3.2. The QC Staff is responsible for complying with the requirements of this procedure

3.3. If any abnormalities are determined during routine use of the ICP-MS or during calibration, the QC Managers shall be promptly notified. If necessary, the ICP-MS will be serviced and recalibrated by Perkin Elmer before being approved for use.

4. REFERENCES:

4.1. BSI-PRL-0554, Analytical Method Validation Protocol: Determination of Elemental Impurities in Water for Injection

4.2. BSI-RPT-1031, Analytical Method Validation Report: Determination of Elemental Impurities in Water for Injection

4.3. BSI-SOP-0303, NexION 350X ICP-MS SOP

4.4. BSI-SOP-0304, NexION 350X ICP-MS Care and Maintenance SOP

4.5. ICH Guideline for Elemental Impurities Q3D Current

4.6. USP <730> Plasma Spectrochemistry

4.7. USP <1730> Plasma Spectrochemistry—Theory and Practice

4.8. NexION Operation with Syngistix Software Guide

4.9. USP <232>, <233>

TABLE 1: LIMITS FOR WATER FOR INJECTION PRODUCTS (1,000 GRAM/DAY PATIENT EXPOSURE)

Elements	ICH Class	Parenteral PDE Limits (µg/day)	0.3J LOQ (µg/g) in sample	0.5J Target (µg/g) in sample	1.0J Target (µg/g) in sample	1.5J Target (µg/g) in sample
As	1	15	4.5	7.5	15	22.5
Cd	1	2.0	0.60	1.0	2.0	3.0
Hg	1	3.0	0.90	1.5	3.0	4.5
Pb	1	5.0	1.5	2.5	5.0	7.5
Co	2A	5.0	1.5	2.5	5.0	7.5
Ni	2A	20	6.0	10	20	30
V	2A	10	3.0	5.0	10	15
Tl	2B	8.0	2.4	4.0	8.0	12
Se	2B	80	24	40	80	120
Ag	2B	10	3.0	5.0	10	15
Au	2B	100	30	50	100	150
Pd	2B	10	3.0	5.0	10	15
Ir	2B	10	3.0	5.0	10	15
Os	2B	10	3.0	5.0	10	15
Pt	2B	10	3.0	5.0	10	15
Rh	2B	10	3.0	5.0	10	15
Ru	2B	10	3.0	5.0	10	15
Ba	3	700	210	350	700	1,050
Sb	3	90	27	45	90	135
Li	3	250	75	125	250	375
Mo	3	1,500	450	750	1,500	2,250
Cu	3	300	90	150	300	450
Sn	3	600	180	300	600	900
Cr	3	1,100	330	550	1,100	1,650
Al	4	*25	7.5	12.5	25	37.5
Ca	4	*750	225	375	750	1,125
Fe	4	*200	60	100	200	300
K	4	*500	150	250	500	750
Mg	4	*500	150	250	500	750
Na	4	*500	150	250	500	750
Zn	4	*200	60	100	200	300

*No PDE limits for Class 4 elements; limits derived from other internal product specifications.

5. MATERIALS AND EQUIPMENT:

5.1. Equipment
- 5.1.1. Analytical Balance
- 5.1.2. NexION 350X ICP-MS S/N 85VN5093001
- 5.1.3. Micropipettes, Rainin or Eppendorf

5.2. Reagents
- 5.2.1. Nitric Acid, Trace metals grade or equivalent
- 5.2.2. Hydrochloric Acid, Trace metals grade or equivalent
- 5.2.3. Sulfuric acid, Trace metals grade or equivalent
- 5.2.4. Deionized (DI) water (Type 1 Ultrapure)
- 5.2.5. Thiourea, 99+ % grade
- 5.2.6. NexION Setup and KED Setup Solution

5.3. Consumable Supplies
- 5.3.1. SCP Digitubes® 15 mL, 50 mL and 100 mL
- 5.3.2. Pipette Tips of various sizes
- 5.3.3. SiliaPrep MB SPE Cartridges, Silica-Based AMPA, 500 mg, 4 mL, 40 - 63 µm, 60 Å

5.4. Personnel
- 5.4.1. All personnel that executed the protocol are trained on ICP-MS or are considered Subject Matter Experts. This test method will be assigned a mark as read training to QC analysts involved with the execution.

TABLE 2: REFERENCE STANDARDS

Identification**	Manufacturer	Concentrations / Elements
Pharma-CAL Standard Parenteral STD# 1 IA 140-131-201*	SCP Science	Ag (10 µg/mL), As (15 µg/mL), Cd (2 µg/mL), Co (5 µg/mL), Hg (3 µg/mL), Ni (20 µg/mL), Pb (5 µg/mL), Se (80 µg/mL), Tl (8 µg/mL), V (10 µg/mL)
USP232/ICH Q3D Parenteral STD# 2 IA 140-131-215*	SCP Science	Au (100 µg/mL); Ir, Os, Pd, Pt, Rh, & Ru (10 µg/mL)
Pharma-CAL Standard Parenteral STD# 3 IA 140-131-221*	SCP Science	Ba (700 µg/mL), Cr (1,100 µg/mL), Cu (300 µg/mL), Li (250 µg/mL), Mo (1,500 µg/mL), Sb (90 µg/mL), Sn (600 µg/mL)
Aluminum Stock Standard	Perkin Elmer	Al (1,000 µg/mL)
Calcium Stock Standard	Perkin Elmer	Ca (1,000 µg/mL)
Iron Stock Standard	Perkin Elmer	Fe (1,000 µg/mL)
Potassium Stock Standard	Perkin Elmer	Ca (1,000 µg/mL)
Magnesium Stock Standard	Perkin Elmer	Ca (1,000 µg/mL)
Sodium Stock Standard	Perkin Elmer	Na (1,000 µg/mL)
Zinc Stock Standard	Perkin Elmer	Ca (1,000 µg/mL)
Pharma-CAL Custom Standard AQ0-086-125* (Internal Standard)	SCP Science	Be, Sc, Y, Re (10 µg/mL); Te (25 µg/mL); Ge, Tb, Bi (5 µg/mL)

* SCP Science catalog numbers ending in 1 denote 125 mL bottle sizes and catalog numbers ending in 5 denote 500 mL bottle sizes.
** Additional standards/custom standards can be used as long as the concentration remains the same in final preparations.

6. PROCEDURE:

6.1. All standards will be prepared volumetrically from stock solutions purchased from certified vendors. If the vendor supplied stock standard is within 2% of the nominal value as per the certificate of analysis, then the nominal value will be used to calculate the concentration of the standard. If the stock standard certificate of analysis value is greater than or less than 2% of the nominal value, then the certificate of analysis value will be used for the stock standard concentration.

6.2. Acid Digestion Mix

[2:1] Nitric Acid (HNO_3): Sulfuric Acid (H_2SO_4)

6.2.1. Caution: Combining nitric acid and sulfuric acid generates excessive heat. Never seal cap tightly before solution has completely cooled.

6.2.2. To prepare, add 50 mL of nitric acid to a 100 mL Digitube® and then slowly add 25 mL of sulfuric acid. Solution can be placed in a cold-water bath to aid cooling.

6.2.2.1. Scale as necessary for use (Prepare same day).

6.3. Internal Standard/Complexing Solution

6.3.1. Weigh approximately 1.0 gram of Thiourea into a 50 mL Digitube®

6.3.2. Add approximately 20 mL of deionized water and mix to dissolve.

6.3.3. Filter solution through a SiliaPrep Cation Solid Phase Extraction (SPE) cartridge into a separate 50 mL digitube.

6.3.4. Add 2.5 mL of Internal Standard Intermediate followed by 25 mL of hydrochloric acid.

6.3.5. Dilute to a final volume of 50 mL with deionized water and mix well.

6.3.6. Scale proportionally as needed for use.

6.4. 2% Thiourea Solution

6.4.1. Weigh approximately 1.0 gram of Thiourea into a 50 mL Digitube®

6.4.2. Add approximately 20 mL of deionized water and mix to dissolve.

6.4.3. Filter solution through a SiliaPrep Cation Solid Phase Extraction (SPE) cartridge into aseparate 50 mL digitube.

6.4.4. Dilute to a final volume of 50 mL with deionized water and mix well.

6.4.5. Scale proportionally as needed for use.

6.5. Intermediate Standard Preparation

6.5.1. Prepare a standard solution containing the elements listed in Table 3, using the standards STD#1 IA, STD#2 IA, STD#3 IA, and additional single source stock standards.

6.5.2. Prepare by adding stock standards to a 15 mL Digitube®.

6.5.3. Add DI Water to approximately 8 mL and pipette 1.0 mL hydrochloric acid (HCl).

6.5.4. Dilute to final volume using DI Water.

TABLE 3: INTERMEDIATE STANDARD

Identification	Element	Stock Identification	Amount Added (mL)	HCl (mL)	Final Volume (mL)	Final Concentration (µg/mL)
Intermediate Standard	As	STD# 1 IA 140-131-201*	1.0	1.0	10	1.5
	Cd					0.20
	Hg					0.30
	Pb					0.50
	Co					0.50
	Ni					2.0
	V					1.0
	Tl					0.80
	Se					8.0
	Ag					1.0
	Au	STD# 2 IA 140-131-215*	1.0			10
	Pd					1.0
	Ir					1.0
	Os					1.0
	Pt					1.0
	Rh					1.0
	Ru					1.0
	Ba	STD# 3 IA 140-131-221*	1.0			70
	Sb					9.0
	Li					25
	Mo					150
	Cu					30
	Sn					60
	Cr					110
	Al	1,000 µg/mL Al Std	0.025			2.5
	Ca	1,000 µg/mL Ca Std	0.750			75
	Fe	1,000 µg/mL Fe Std	0.200			20
	K	1,000 µg/mL K Std	0.500			50
	Mg	1,000 µg/mL Mg Std	0.500			50
	Na	1,000 µg/mL Na Std	0.500			50
	Zn	1,000 µg/mL Zn Std	0.200			20

* SCP Science catalog numbers ending in 1 denote 125 mL bottle sizes and catalog numbers ending in 5 denote 500 mL bottle sizes.

6.6. 0.5J Calibration Standard Preparation

6.6.1. Prepare a solution containing the elements listed in Table 4 below in 5.0% HNO_3, 2.5% H_2SO_4, 1.0% HCl and 0.04% (400 µg/mL) Thiourea.

6.6.2. Add 0.050 mL of intermediate standard to separate 50 mL Digitube® followed by addition of approximately 35 mL of deionized water.

6.6.3. Add 3.75 mL of Acid Mixture then dilute to 45 mL using deionized water.

6.6.4. Add 1.0 mL of internal standard/complexing solution and dilute to volume using deionized water.

6.6.5. Do not allow intermediate standard to contact concentrated acids while preparing solutions. (Standards are stable for 24 hours)

TABLE 4: 0.5J CALIBRATION STANDARD

Identification	Element	Intermediate Standard (mL)	Acid Mix (mL)	Internal Standard/ Complexing Solution (mL)	Final Volume (mL)	Final Concentration (µg/L)
0.5J Calibration Standard	As	0.050	3.75	1.0	50	1.5
	Cd					0.20
	Hg					0.30
	Pb					0.50
	Co					0.50
	Ni					2.0
	V					1.0
	Tl					0.80
	Se					8.0
	Ag					1.0
	Au					10
	Pd					1.0
	Ir					1.0
	Os					1.0
	Pt					1.0
	Rh					1.0
	Ru					1.0
	Ba					70
	Sb					9.0
	Li					25
	Mo					150
	Cu					30
	Sn					60
	Cr					110
	Al					2.5
	Ca					75
	Fe					20
	K					50
	Mg					50
	Na					50
	Zn					20

6.7. 1.5J Calibration Standard Preparation

6.7.1. Prepare a solution containing the elements listed in Table 5 below in 5.0% HNO_3, 2.5% H_2SO_4, 1.0% HCl and 0.04% (400 µg/mL) Thiourea.

6.7.2. Add 0.150 mL of intermediate standard to separate 50 mL Digitube® followed by addition of approximately 35 mL of deionized water.

6.7.3. Add 3.75 mL of Acid Mixture then dilute to 45 mL using deionized water.

6.7.4. Add 1.0 mL of internal standard/complexing solution and dilute to volume using deionized water.

6.7.5. Do not allow intermediate standard to contact concentrated acids while preparing solutions. (Standards are stable for 24 hours)

TABLE 5: 1.5J CALIBRATION STANDARD

Identification	Element	Intermediate Standard (mL)	Acid Mix (mL)	Internal Standard/ Complexing Solution (mL)	Final Volume (mL)	Final Concentration (µg/L)
1.5J Calibration Standard	As	0.150	3.75	1.0	50	4.5
	Cd					0.60
	Hg					0.90
	Pb					1.5
	Co					1.5
	Ni					6.0
	V					3.0
	Tl					2.4
	Se					24
	Ag					3.0
	Au					30
	Pd					3.0
	Ir					3.0
	Os					3.0
	Pt					3.0
	Rh					3.0
	Ru					3.0
	Ba					210
	Sb					27
	Li					75
	Mo					450
	Cu					90
	Sn					180
	Cr					330
	Al					7.5
	Ca					225
	Fe					60
	K					150
	Mg					150
	Na					150
	Zn					60

6.8. 2.0J Calibration Standard Preparation

6.8.1. Prepare a solution containing the elements listed in Table 6 below in 5.0% HNO_3, 2.5% H_2SO_4, 1.0% HCl and 0.04% (400 µg/mL) Thiourea.

6.8.2. Add 0.200 mL of intermediate standard to separate 50 mL Digitube® followed by addition of approximately 35 mL of deionized water.

6.8.3. Add 3.75 mL of Acid Mixture then dilute to 45 mL using deionized water.

6.8.4. Add 1.0 mL of internal standard/complexing solution and dilute to volume using deionized water.

6.8.5. Do not allow intermediate standard to contact concentrated acids while preparing solutions. (Standards are stable for 24 hours)

TABLE 6: 2.0J CALIBRATION STANDARD

Identification	Element	Intermediate Standard (mL)	Acid Mix (mL)	Internal Standard/ Complexing Solution (mL)	Final Volume (mL)	Final Concentration (µg/L)
2.0J Calibration Standard	As	0.200	3.75	1.0	50	6.0
	Cd					0.80
	Hg					1.2
	Pb					2.0
	Co					2.0
	Ni					8.0
	V					4.0
	Tl					3.2
	Se					32
	Ag					4.0
	Au					40
	Pd					4.0
	Ir					4.0
	Os					4.0
	Pt					4.0
	Rh					4.0
	Ru					4.0
	Ba					280
	Sb					36
	Li					100
	Mo					600
	Cu					120
	Sn					240
	Cr					440
	Al					10
	Ca					300
	Fe					80
	K					200
	Mg					200
	Na					200
	Zn					80

6.9. Calibration Blank

6.9.1. Prepare a solution containing 5.0% HNO_3, 2.5% H_2SO_4, 1.0% HCl and 0.04% (400 µg/mL) Thiourea as described in Table 7 below.

6.9.2. To a separate 50 mL Digitube®, add approximately 35 mL of DI Water.

6.9.3. Add 3.75 mL of Acid Mixture then dilute to 45 mL using DI Water.

6.9.4. Add 1.0 mL of internal standard/complexing solution and dilute to volume using DI Water.

6.9.5. Do not allow Internal Standard Solution to contact concentrated acids.

TABLE 7: CALIBRATION BLANK

Description	Acid Mix (mL)	Internal Standard/ Complexing Solution (mL)	Final Volume (mL)
Cal Blank	3.75	1.0	50

6.10. Method Blank Preparation

6.10.1. Refer to Calibration Blank

6.11. Sample Preparation

6.11.1. Samples are stable for 24 hours.

6.11.2. Weigh approximately 10 grams of the sample into a 50 mL Digitube®.

6.11.3. Add 3.75 mL of Acid Digestion Mixture and swirl solution periodically to acidify the solution and mix thoroughly.

6.11.4. Add deionized water to approximately 45 mL and then transfer 1.0 mL of Internal Standard/Complexing Solution.

6.11.5. Dilute to a final volume of 50 mL with deionized water and mix thoroughly.

6.12. Isobaric Overlap Corrections

6.12.1. An isobaric interference results from equal mass isotopes of different elements present in the sample solution. Analysis sequences that are processed utilizing multi-element standards will require the use of correction equations to compensate for known isobaric overlaps originating from the elemental standard and sample. The following correction equations should be used:

KED Mode:

$M_c(58) = M_u(58) \times 1 - M_{(rm)}(57) \times 0.13208$
$M_c(98) = M_u(98) \times 1 - M_{(rm)}(99) \times 0.14655$
$M_c(106) = M_u(106) \times 1 - M_{(rm)}(111) \times 0.09766$
$M_c(108) = M_u(108) \times 1 - M_{(rm)}(111) \times 0.06953$
$M_c(120) = M_u(120) \times 1 - M_{(rm)}(125) \times 0.01273$
$M_c(123) = M_u(123) \times 1 - M_{(rm)}(125) \times 0.12588$
$M_c(190) = M_u(190) \times 1 - M_{(rm)}(195) \times 0.00036$
$M_c(192) = M_u(192) \times 1 - M_{(rm)}(195) \times 0.02315$
$M_c(196) = M_u(196) \times 1 - M_{(rm)}(202) \times 0.005023$

The correction equations can be derived from the following equation:
$M_c = M_u - [M_{(rm)} \times (A_{(ie)}/A_{(rm)})]$

Where:

M_c = Corrected Count Rate for the analyte
M_u = Uncorrected count rate for the analyte
$M_{(rm)}$ = Count Rate of Reference Mass (rm) for the Interfering Element
$A_{(ie)}$ = Percent Abundance of Interfering Element (ie) at the analyte mass
$A_{(rm)}$ = Percent Abundance of Interfering Element at the Reference Mass (rm)

Example:

$M_c(58) = M_u(58) \times 1 - M_{(rm)}(57) \times (0.28 / 2.12)$

6.12.2. All correction coefficients were calculated based on the Agilent Technologies 2016 Relative Isotopic Abundance Table.

6.12.3. Multiplier used in the correction equation may differ slightly from the multiplier used in the Syngistix instrument method due to rounding.

7. INSTRUMENT PROCEDURE:

7.1. Perform the ICP-MS daily performance check prior to beginning the analytical sequence. Refer to NexION 350X ICP-MS SOP BSI-SOP-0303 for Daily Check procedures.

7.2. A calibration curve of no less than two standards and a blank must be used. The calibration correlation coefficient (R) must be ≥ 0.99.

7.3. Set up the sequence as per Table 8.

7.4. Confirm the calibration by analyzing the 1.5J standard after the calibration. The calibration check must recover ± 20% of the calculated theoretical concentration for multi-element analysis and ± 10% for single element determinations.

7.5. The check standard must be verified after the calibration. A re-analysis of the check standard will be performed a minimum of once every 10 samples and at the end of the analytical run.

7.6. Bracketing standard checks must recover NMT 20% of the calculated theoretical concentration for multi-element analysis. Additionally, the drift (calculated as absolute difference) between the bracketing standard checks are to be NMT 20% for each target element.

7.7. The sample concentration is calculated as:

$$\text{Conc. } (\mu g/g) = \frac{\text{Solution Conc. } (\mu g/L) \times \text{Solution vol. } (L.) \times \text{Dilution Factor}}{\text{Sample Mass (g)}}$$

TABLE 8: EXAMPLE SAMPLE ANALYSIS SEQUENCE

ID	Type	Level
Cal Blank	Cal Blank	Level 1
0.5J Cal Std	Cal Std	Level 2
1.5J Cal Std	Cal Std	Level 3
2.0J Cal Std	Cal Std	Level 4
Cal Blank Check	QC Check	N/A
1.5J Check Std 1	QC Check	N/A
Method Blank	Sample	N/A
Sample(s) 10 or less	Sample	N/A
1.5J Check Std 2	QC Check	N/A

7.8. Instrument Setup and Parameters

7.8.1. Instrument settings are only listed as guidelines. Settings may be changed in order to accommodate changes in sample matrix or hardware configurations.

7.8.2. The AMS-II makeup gas must be engaged during analysis using a minimum dilution gas ratio of 15%.

7.8.3. Aluminum, arsenic, iron, and selenium can be analyzed using hydrogen reaction gas in order to remove poly atomic interferences. A hydrogen DRC flow rate of approximately 4 mL/min should be used.

7.8.4. The instrument method is stored under the Approved Test Method Folder labelled as "WFI_EI_Profile.mth" for elemental impurities testing.

7.8.5. Instrument method can be truncated from the full EI instrument method in order to selectively analyze metals as long as parameters match the full method.

TABLE 9: ICP-MS PARAMETERS

ICP-MS System	Perkin Elmer NexION350X Inductively Coupled Plasma Mass Spectrometry (ICP-MS) with Syngistix Software
Sweeps/Readings	20
Replicates	3
Nebulizer Gas	Argon
Collision Gas	Helium
Reaction Gas	Hydrogen
Dilution Gas	Argon
Sample and Skimmer Cone	Platinum
Sample Rinses	Rinse-1: 60 sec at 45 rpm 5.0% HNO_3, 2.5% HCl, with 0.04% Thiourea or as applicable to mitigate carry over

TABLE 10: LINEAR RANGE AND CORRESPONDING TUNE MODE

Isotope	Internal Standard	Mode	Linear Range (µg/L)	Isotope	Internal Standard	Mode	Linear Range (µg/L)
7Li	9Be	STD	15-100	106Pd	185Re	KED	0.60-4.0
23Na	45Sc	KED	30-200	107Ag	185Re	KED	0.60-4.0
24Mg	45Sc	KED	30-200	108Pd	185Re	KED	0.60-4.0
27Al	45Sc	STD	1.5-10	109Ag	185Re	KED	0.60-4.0
27Al	45Sc	H_2 DRC	1.5-10	111Cd	125Te	KED	0.12-0.80
39K	45Sc	KED	30-200	113Cd	125Te	KED	0.12-0.80
44Ca	45Sc	KED	45-300	118Sn	125Te	KED	36-240
51V	45Sc	KED	0.60-4.0	119Sn	125Te	KED	36-240
52Cr	45Sc	KED	66-440	120Sn	125Te	KED	36-240
53Cr	45Sc	KED	66-440	121Sb	125Te	KED	5.4-36
56Fe	45Sc	H_2 DRC	12-80	123Sb	125Te	KED	5.4-36
57Fe	72Ge	KED	12-80	135Ba	89Y	KED	42-280
58Ni	72Ge	KED	1.2-8.0	137Ba	89Y	KED	42-280
59Co	72Ge	KED	0.30-2.0	138Ba	89Y	KED	42-280
60Ni	72Ge	KED	1.2-8.0	188Os	185Re	KED	0.60-4.0
62Ni	72Ge	KED	1.2-8.0	189Os	185Re	KED	0.60-4.0
63Cu	72Ge	KED	18-120	190Os	185Re	KED	0.60-4.0
65Cu	72Ge	KED	18-120	191Ir	185Re	KED	0.60-4.0
66Zn	72Ge	KED	12-80	192Os	185Re	KED	0.60-4.0
67Zn	72Ge	KED	12-80	193Ir	185Re	KED	0.60-4.0
68Zn	72Ge	KED	12-80	194Pt	185Re	KED	0.60-4.0
75As	72Ge	H_2 DRC	0.90-6.0	195Pt	185Re	KED	0.60-4.0
75As	72Ge	KED	0.90-6.0	196Pt	185Re	KED	0.60-4.0
77Se	89Y	H_2 DRC	4.8-32	197Au	185Re	KED	6.0-40
78Se	89Y	H_2 DRC	4.8-32	199Hg	185Re	KED	0.18-1.2
95Mo	89Y	KED	90-600	200Hg	185Re	KED	0.18-1.2
97Mo	89Y	KED	90-600	202Hg	185Re	KED	0.18-1.2
98Mo	89Y	KED	90-600	203Tl	209Bi	KED	0.48-3.2
99Ru	89Y	KED	0.60-4.0	205Tl	209Bi	KED	0.48-3.2
101Ru	89Y	KED	0.60-4.0	206Pb	209Bi	KED	0.30-2.0
103Rh	125Te	KED	0.60-4.0	207Pb	209Bi	KED	0.30-2.0
105Pd	185Re	KED	0.60-4.0	208Pb	209Bi	KED	0.30-2.0

8. REPORTING

8.1. Any result below the 0.3J target concentration will be reported as less than the corresponding LOQ value listed in Table 1. Results above the LOQ concentration will be reported in µg/kg andto 2 significant figures. Report the average result for multiple isotopes of the same element thatare above the LOQ concentration.