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ANALYTICAL METHOD FOR THE DETERMINATION OF ICH Q3D ELEMENTAL IMPURITIES (CLASS 1, 2A, 2B, 3 & 4 WITH BISMUTH AND STRONTIUM) BY INDUCTIVELY COUPLED PLASMA MASS SPECTROMETRY (ICP-MS) 2-MEA

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1. PURPOSE:

1.1. To provide a procedure for the assessment of Elemental Impurities via the NexION 350X S/N 85VN5093001 ICP-MS. This procedure was assessed as a full quantitative option-3 procedure as per validation report BSI-RPT-0590 and follows the validation parameters for quantitation procedures as outlined in USP <233>.

1.2. Elements under 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, Ba, Mo, Cu, Cr, and Sn

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

1.2.6. Other: Bi and Sr

2. SCOPE:

2.1. Applies to 2-MEA 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 Quality Control Manager, or other qualified designated individual, is responsible for the control, implementation, training, and maintenance of this method.

3.2. The Trace Metal Specialists and QC analysts are 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-0507, Determination of ICH Q3D Elemental Impurities by ICP-MS in 2-MEA

4.2. BSI-RPT-0590, Determination of ICH Q3D Elemental Impurities by ICP-MS in 2-MEA Validation Report

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

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

4.5. ICH Guideline for Elemental Impurities Q3D Current Step 4 v. (16 December 2014)

4.6. USP <730> PLASMA SPECTROCHEMISTRY

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

4.8. NexION Operation with Syngistix Software Guide4.9. USP <232>, <233>

TABLE 1: LIMITS FOR 2-MEA (50 GRAM/DAY PATIENT EXPOSURE)

Elements	ICH Class	Parenteral PDE Limits (µg/day)	0.1J LOQ (µg/g) in sample	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	0.03	0.09	0.15	0.30	0.45
Cd	1	2.0	0.004	0.012	0.02	0.04	0.06
Hg	1	3.0	0.006	0.018	0.03	0.06	0.09
Pb	1	5.0	0.01	0.03	0.05	0.10	0.15
Co	2A	5.0	0.01	0.03	0.05	0.10	0.15
Ni	2A	20	0.04	0.12	0.20	0.40	0.60
V	2A	10	0.02	0.06	0.10	0.20	0.30
Tl	2B	8.0	0.016	0.048	0.08	0.16	0.24
Se	2B	*50	0.10	0.30	0.50	1.0	1.5
Ag	2B	10	0.02	0.06	0.10	0.20	0.30
Au	2B	100	0.20	0.60	1.0	2.0	3.0
Pd	2B	10	0.02	0.06	0.10	0.20	0.30
Ir	2B	10	0.02	0.06	0.10	0.20	0.30
Os	2B	10	0.02	0.06	0.10	0.20	0.30
Pt	2B	10	0.02	0.06	0.10	0.20	0.30
Rh	2B	10	0.02	0.06	0.10	0.20	0.30
Ru	2B	10	0.02	0.06	0.10	0.20	0.30
Ba	3	700	1.4	4.2	7.0	14	21
Sb	3	90	0.18	0.54	0.90	1.8	2.7
Li	3	250	0.50	1.5	2.5	5.0	7.5
Mo	3	*50	0.10	0.30	0.50	1.0	1.5
Cu	3	*25	0.05	0.15	0.25	0.50	0.75
Sn	3	600	1.2	3.6	6.0	12	18
Cr	3	*50	0.10	0.30	0.50	1.0	1.5
Al	4	*400	0.80	2.4	4.0	8.0	12
Fe	4	*200	0.40	1.2	2.0	4.0	6.0
Mn	4	*25	0.05	0.15	0.25	0.5	0.75
Zn	4	*200	0.40	1.2	2.0	4.0	6.0
Bi	N/A	200	0.40	1.2	2.0	4.0	6.0
Ca	4	750	1.5	4.5	7.5	15	22.5
K	4	2000	4.0	12	20	40	60
Mg	4	200	0.40	1.2	2.0	4.0	6.0
Na	4	2000	4.0	12	20	40	60
Sr	N/A	200	0.40	1.2	2.0	4.0	6.0

*PDE calculated based on manufacturer specification

5. MATERIALS AND EQUIPMENT:

5.1. Equipment
- 5.1.1. Analytical Balance
- 5.1.2. NexION 350X ICP-MS S/N 85VN5093001

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 Solution
- 5.2.7. NexION 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. SiliCycle SiliaPrep Cation Solid Phase Extraction (SPE) cartridge

TABLE 2: REFERENCE STANDARDS

Identification**	Manufacturer	Concentrations / Elements
Pharma-CAL Custom Standard Parenteral STD# 1 IA * AQ0-145-205, document any change in catalog number	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 (50 µg/mL), Tl (8 µg/mL), V (10 µg/mL)
USP232/ICH Q3D Parenteral STD# 2 IA * 140-131-215, document any change in catalog number	SCP Science	Ir, Os, Pd, Pt, Rh, Ru (10 µg/mL); Au (100 µg/mL)
Pharma-CAL Custom Standard Parenteral STD# 3 IA *AQ0-145-211 or AQ0-145-215, document any change in catalog number	SCP Science	Al (400 µg/mL), Ba (700 µg/mL), Cr (50 µg/mL), Cu (25 µg/mL), Fe (200 µg/mL), Li (250 µg/mL), Mn (25 µg/mL), Mo (50 µg/mL), Sb (90 µg/mL), Sn (600 µg/mL), Zn (200 µg/mL)
Bi, Ca, K, Mg, Na, Sr, Ge, Tb, Be, Sc, Y, Re, Te	Perkin Elmer/SCP Science	Bi, Ca, Mg, Sr, Ge, Tb, Be, Sc, Y, Re, Te (1000 µg/mL); K, Na (10,000 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. **Stock Standards**

6.2.1. The stock standards listed in Table 2 will be used to prepare the intermediate standard, which will used for the preparation of calibration standards.

6.3. **Internal Standard**

6.3.1. Prepare a standard solution containing the elements listed in Table 3, using the 1000 µg/mL standard listed in Table 2.

TABLE 3: INTERNAL STANDARD

Identification	Element	Stock Identification	Amount Added (mL)	Final Volume Deionized Water (mL)	Final Concentration (µg/mL)
Internal Standard	Ge	1000 µg/mL	0.05	10.0	5.0
	Tb		0.05		5.0
	Y		0.10		10
	Re		0.10		10
	Be		0.10		10
	Sc		0.10		10
	Te		0.25		25

6.4. **Acid Digestion Mix**

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

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

6.4.2. 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.

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

6.5. **Internal Standard/Complexing Solution**

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

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

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

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

6.5.5. Diluted to a final volume of 50 mL with deionized water and mixed well.

6.5.6. Scale proportionally as needed for use.

6.6. **Intermediate Standard**

6.6.1. Prepare a standard solution containing the elements listed in Table 2, using the standards STD#1 IA, STD#2 IA, STD#3 IA and additional stock standards. Do not allow stock standards to contact concentrated acids while preparing solutions. (Prepare same day)

TABLE 4: INTERMEDIATE STANDARD

Identification	Element	Stock Identification	Amount added (mL)	HCl (mL)	Final Volume DI Water (mL)	Final Concentration (µg/mL)
Intermediate Standard	As	STD# 1 IA AQ0-145-205*	1.0	1.0	10.0	1.5
	Cd					0.20
	Hg					0.30
	Pb					0.50
	Co					0.50
	Ni					2.0
	V					1.0
	Se					5.0
	Ag					1.0
	Tl					0.8
	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 AQ0-145-211*	1.0			70
	Sb					9.0
	Li					25
	Mo					5.0
	Cu					2.5
	Sn					60
	Cr					5.0
	Al					40
	Fe					20
	Mn					2.5
	Zn					20
	Bi	1000 µg/mL	0.20			20
	Ca	1000 µg/mL	0.75			75
	K	10000 µg/mL	0.20			200
	Mg	1000 µg/mL	0.20			20
	Na	10000 µg/mL	0.20			200
	Sr	1000 µg/mL	0.20			20

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

6.7. **0.5J 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 with Be, Sc, Y, Re, Te, Ge, and Tb internal standards. Do not allow stock standards to contact concentrated acids while preparing solutions. Add deionized water to approximately 45 mL before adding Internal Standard/ Complexing Solution. Expiration: 24 hours.

TABLE 5: 0.5J CALIBRATION STANDARD

Identification	Element	Intermediate Standard (mL)	Acid Digestion Mix (mL)	Internal Standard/ Complexing Solution (mL)	Final Volume DI Water (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
	Se					5.0
	Ag					1.0
	Tl					0.80
	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					5.0
	Cu					2.5
	Sn					60
	Cr					5.0
	Al					40
	Fe					20
	Mn					2.5
	Zn					20
	Bi					20
	Ca					75
	K					200
	Mg					20
	Na					200
	Sr					20

6.8. **1.5J 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 with Be, Sc, Y, Re, Te, Ge, and Tb internal standards. Do not allow standards to contact concentrated acids while preparing solutions. Add deionized water to approximately 45 mL before adding Internal Standard/ Complexing Solution. Expiration: 24 hours.

TABLE 6: 1.5J CALIBRATION STANDARD

Identification	Element	Intermediate Standard (mL)	Acid Digestion Mix (mL)	Internal Standard/ Complexing Solution (mL)	Final Volume DI Water (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
	Se					15
	Ag					3.0
	Tl					2.4
	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					15
	Cu					7.5
	Sn					180
	Cr					15
	Al					120
	Fe					60
	Mn					7.5
	Zn					60
	Bi					60
	Ca					225
	K					600
	Mg					60
	Na					600
	Sr					60

6.9. **2.0J Calibration Standard Preparation**

6.9.1. Prepare a solution containing the elements listed in Table 7 below in 5.0% HNO_3, 2.5% H_2SO_4, 1.0% HCl and 0.04% (400 µg/mL) Thiourea with Be, Sc, Y, Re, Te, Ge, and Tb internal standards. Do not allow standards to contact concentrated acids while preparing solutions. Add deionized water to approximately 45 mL before adding Internal Standard/ Complexing Solution. Expiration: 24 hours.

TABLE 7: 2.0J CALIBRATION STANDARD

Identification	Element	Intermediate Standard (mL)	Acid Digestion Mix (mL)	Internal Standard/ Complexing Solution (mL)	Final Volume DI Water (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
	Se					20
	Ag					4.0
	Tl					3.2
	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					20
	Cu					10
	Sn					240
	Cr					20
	Al					160
	Fe					80
	Mn					10
	Zn					80
	Bi					80
	Ca					300
	K					800
	Mg					80
	Na					800
	Sr					80

6.10. **Calibration Blank**

6.10.1. Prepare a solution containing 5.0% HNO_3, 2.5% H_2SO_4, 1.0% HCl and 400 µg/mL Thiourea with Be, Sc, Y, Re, Te, Ge, and Tb internal standards as per Table 8 below. Do not allow Internal Standard/Complexing Solution to contact concentrated acids. Add deionized water to approximately 45 mL before adding Internal Standard/ Complexing Solution. Expiration: 24 hours.

TABLE 8: CALIBRATION BLANK

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

6.11. **Method Blank Preparation**

6.11.1. Add 20 mL of deionized water and 3.75 mL of Acid Digestion mixture to a 50 mL Digitube.®

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

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

6.12. **Sample Preparation**

6.12.1. Weigh approximately 500 mg of the sample into a 50 mL Digitube®

6.12.2. Add 20 mL of deionized water and swirl solution to mix.

6.12.3. Add 3.75 mL of Acid Digestion mixture.

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

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

6.12.6. Samples are stable for 24 hours.

6.13. Isobaric Overlap Corrections

6.13.1. 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:

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

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

6.13.3. Multiplier used in the correct equation may differ slightly from the multiplier used inthe 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 DCN 16-001923 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 9.

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. The drift between the bracketing standard checks must 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 9: 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. The elements arsenic and selenium are analyzed using hydrogen reaction gas in order to remove poly atomic interferences. A hydrogen DRC flow rate of approximately 5 mL/min should be used.

7.8.4. The instrument method is stored under the Approved Test Method Folder labelled as "2-MEA_EI_Profile.mth" for elemental impurities testing.

TABLE 10: ICP-MS PARAMETERS

ICP-MS System	Perkin Elmer NexION350X Inductively Coupled Plasma Mass Spectrometry (ICP-MS) with Syngistix Software
Sweeps/Reading	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% HNO_3, 2.5% HCl, 0.04% Thiourea (or as applicable to mitigate carry over)

TABLE 11: LINEAR RANGE AND CORRESPONDING TUNE MODE

Isotope	Internal Standard	Mode	Linear Range (µg/L)	Isotope	Internal Standard	Mode	Linear Range (µg/L)
7Li	45Sc	STD	5.0-100	107Ag	125Te	KED	0.20-4.0
23Na	45Sc	KED	40-800	108Pd	89Y	KED	0.20-4.0
24Mg	45Sc	KED	4.0-80	109Ag	125Te	KED	0.20-4.0
27Al	45Sc	KED	8.0-160	111Cd	125Te	KED	0.04-0.80
39K	45Sc	KED	40-800	113Cd	125Te	KED	0.04-0.80
51V	45Sc	KED	0.20-4.0	118Sn	125Te	KED	12-240
44Ca	45Sc	KED	15-300	119Sn	125Te	KED	12-240
52Cr	45Sc	KED	1.0-20	120Sn	125Te	KED	12-240
53Cr	45Sc	KED	1.0-20	121Sb	125Te	KED	1.8-36
55Mn	45Sc	KED	0.50-10	123Sb	125Te	KED	1.8-36
57Fe	45Sc	KED	4.0-80	135Ba	159Tb	KED	14-280
58Ni	45Sc	KED	0.40-8.0	137Ba	159Tb	KED	14-280
59Co	45Sc	KED	0.10-2.0	138Ba	159Tb	KED	14-280
60Ni	45Sc	KED	0.40-8.0	188Os	185Re	KED	0.20-4.0
62Ni	45Sc	KED	0.40-8.0	189Os	185Re	KED	0.20-4.0
63Cu	45Sc	KED	0.50-10	190Os	185Re	KED	0.20-4.0
65Cu	45Sc	KED	0.50-10	191Ir	185Re	KED	0.20-4.0
67Zn	45Sc	KED	4.0-80	192Os	185Re	KED	0.20-4.0
68Zn	45Sc	KED	4.0-80	193Ir	185Re	KED	0.20-4.0
75As	89Y	H_2 DRC	0.30-6.0	194Pt	185Re	KED	0.20-4.0
77Se	89Y	H_2 DRC	1.0-20	195Pt	185Re	KED	0.20-4.0
78Se	89Y	H_2 DRC	1.0-20	196Pt	185Re	KED	0.20-4.0
87Sr	89Y	KED	4.0-80	197Au	185Re	KED	2.0-40
88Sr	89Y	KED	4.0-80	199Hg	185Re	KED	0.06-1.2
95Mo	89Y	KED	1.0-20	200Hg	185Re	KED	0.06-1.2
97Mo	89Y	KED	1.0-20	202Hg	185Re	KED	0.18-1.2
98Mo	89Y	KED	1.0-20	203Tl	185Re	KED	0.16-3.2
99Ru	89Y	KED	0.20-4.0	205Tl	185Re	KED	0.16-3.2
101Ru	89Y	KED	0.20-4.0	206Pb	185Re	KED	0.10-2.0
103Rh	89Y	KED	0.20-4.0	207Pb	185Re	KED	0.10-2.0
105Pd	89Y	KED	0.20-4.0	208Pb	185Re	KED	0.10-2.0
106Pd	89Y	KED	0.20-4.0	209Bi	185Re	KED	4.0-80

8. REPORTING

8.1. Any result below the 0.1J target concentration will be reported as less than the corresponding LOQ value listed in Table 1, except for 202Hg where the LOQ is 0.3J. Results above the LOQ concentration will be reported in µg/g and to 2 significant figures. Report the average result for multiple isotopes of the same element that are above the LOQ concentration.