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ANALYTICAL METHOD FOR THE DETERMINATION OF ICH Q3D ELEMENTAL IMPURITIES (CLASS 1, 2A, 2B, 3, & 4) BY INDUCTIVELY COUPLED PLASMA MASS SPECTROMETRY (ICP-MS) IN POTASSIUM BROMIDE

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1. PURPOSE:

1.1. To provide a procedure for the assessment of Elemental Impurities in Potassium Bromide (KBr) 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-0827 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, Sn, Ba, Mo, Cu, and Cr
  - 1.2.5. Class 4: Ca, Fe and Mg

2. SCOPE:

2.1. Applies to Potassium Bromide 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 Laboratory Technology Manager, 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-0453, Determination of ICH Q3D Elemental Impurities by ICP-MS in Potassium Bromide

4.2. BSI-RPT-0827, Determination of ICH Q3D Elemental Impurities by ICP-MS in Potassium Bromide

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. NexION Operation with Syngistix Software Guide

4.7. USP <232>, Elemental Impurities- Limits

4.8. USP <233>, Elemental Impurities- Procedures

4.9. USP <730> Plasma Spectrochemistry

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

TABLE 1: LIMITS FOR POTASSIUM BROMIDE (10 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	0.45	0.75	1.5	2.25
Cd	1	2.0	0.06	0.10	0.20	0.30
Hg	1	3.0	0.09	0.15	0.30	0.45
Pb	1	5.0	0.15	0.25	0.50	0.75
Co	2A	5.0	0.15	0.25	0.50	0.75
Ni	2A	20	0.60	1.0	2.0	3.0
V	2A	10	0.30	0.50	1.0	1.5
Tl	2B	8.0	0.24	0.40	0.80	1.2
Se	2B	80	2.4	4.0	8.0	12
Ag	2B	10	0.30	0.50	1.0	1.5
Au	2B	100	3.0	5.0	10	15
Pd	2B	10	0.30	0.50	1.0	1.5
Ir	2B	10	0.30	0.50	1.0	1.5
Os	2B	10	0.30	0.50	1.0	1.5
Pt	2B	10	0.30	0.50	1.0	1.5
Rh	2B	10	0.30	0.50	1.0	1.5
Ru	2B	10	0.30	0.50	1.0	1.5
Ba	3	700	21	35	70	105
Sb	3	90	2.7	4.5	9.0	13.5
Li	3	250	7.5	12.5	25	37.5
Mo	3	1500	45	75	150	225
Cu	3	[1]100	3.0	5.0	10	15
Sn	3	600	18	30	60	90
Cr	3	1100	33	55	110	165
Ca	4	[1]500	15	25	50	75
Fe	4	[1]100	3.0	5.0	10	15
Mg	4	[1]100	3.0	5.0	10	15

[1] PDE calculated based on customer specification.

5. MATERIALS AND EQUIPMENT:

5.1. Equipment
  5.1.1. Analytical Balance
  5.1.2. NexION 350X ICP-MS S/N 85VN5093001, or qualified ICP-MS
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. Ultrapure Potassium Bromide, Matrix Modifier, 99.999% grade
  5.2.7. NexION Setup and KED Setup Solution, or equivalent
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
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[1]	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 140-131-211	SCP Science	Au (100 µg/mL); Ir, Os, Pd, Pt, Rh, & Ru (10 µg/mL)
Barium Stock Standard	SCP Science	Ba (1,000 µg/mL)
Copper Stock Standard	SCP Science	Cu (1,000 µg/mL)
Chromium Stock Standard	SCP Science	Cr (1,000 µg/mL)
Lithium Stock Standard	SCP Science	Li (1,000 µg/mL)
Molybdenum Stock Standard	SCP Science	Mo (1,000 µg/mL)
Antimony Stock Standard	SCP Science	Sb (1,000 µg/mL)
Tin Stock Standard	SCP Science	Sn (1,000 µg/mL)
Calcium Stock Standard	SCP Science	Ca (1,000 µg/mL)
Iron Stock Standard	SCP Science	Fe (1,000 µg/mL)
Magnesium Stock Standard	SCP Science	Mg (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)

[1] 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 a separate 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. **Potassium Bromide Matrix Modifier (10% Solution)**

- 6.5.1. Weigh approximately 1.0 gram of Ultrapure Potassium Bromide into a 15 mL Digitube®.
- 6.5.2. Dilute to 10 mL using Deionized Water and mix solution thoroughly.
- 6.5.3. Scale proportionally as needed for use.

6.6. **Intermediate Standard Preparation**

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

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

6.6.3. Add DI Water to approximately 8 mL and pipette 1.0 mL Hydrochloric Acid (HCl).

6.6.4. Dilute to 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 140-131-211	1.0			10
	Pd					1.0
	Ir					1.0
	Os					1.0
	Pt					1.0
	Rh					1.0
	Ru					1.0
	Ba	1,000 µg/mL Ba Std	0.700			70
	Sb	1,000 µg/mL Sb Std	0.090			9.0
	Li	1,000 µg/mL Li Std	0.250			25
	Mo	1,000 µg/mL Mo Std	1.500			150
	Cu	1,000 µg/mL Cu Std	0.100			10
	Sn	1,000 µg/mL Sn Std	0.600			60
	Cr	1,000 µg/mL Cr Std	1.100			110
	Ca	1,000 µg/mL Ca Std	0.500			50
	Fe	1,000 µg/mL Fe Std	0.100			10
	Mg	1,000 µg/mL Mg Std	0.100			10

6.7. 0.5J Calibration Standard Preparation

6.7.1. 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.

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

6.7.3. Add 0.500 mL of Potassium Bromide Matrix Modifier and swirl to mix.

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

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

6.7.6. Do not allow intermediate standard to contact concentrated acids while preparing solutions. (Standards are to be prepared fresh for each analysis; if calcium is not needed for analysis, standards are stable for 24 hours.)

TABLE 4: 0.5J CALIBRATION STANDARD

Identification	Element	Intermediate Standard (mL)	KBr Matrix Modifier (mL)	Acid Mix (mL)	Internal Standard/ Complexing Solution (mL)	Final Volume (mL)	Final Concentration (µg/L)
0.5J Calibration Standard	As	0.050	0.500	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						10
	Sn						60
	Cr						110
	Ca						50
	Fe						10
	Mg						10

6.8. 1.5J Calibration Standard Preparation

6.8.1. 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.

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

6.8.3. Add 0.500 mL of Potassium Bromide Matrix Modifier and swirl to mix.

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

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

6.8.6. Do not allow intermediate standard to contact concentrated acids while preparing solutions. (Standards are to be prepared fresh for each analysis; if calcium is not needed for analysis, standards are stable for 24 hours.)

TABLE 5: 1.5J CALIBRATION STANDARD

Identification	Element	Intermediate Standard (mL)	KBr Matrix Modifier (mL)	Acid Mix (mL)	Internal Standard/ Complexing Solution (mL)	Final Volume (mL)	Final Concentration (µg/L)
1.5J Calibration Standard	As	0.150	0.500	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						30
	Sn						180
	Cr						330
	Ca						150
	Fe						30
	Mg						30

6.9. **2.0J Calibration Standard Preparation**

6.9.1. 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.

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

6.9.3. Add 0.500 mL of Potassium Bromide Matrix Modifier and swirl to mix.

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

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

6.9.6. Do not allow intermediate standard to contact concentrated acids while preparing solutions. (Standards are to be prepared fresh for each analysis; if calcium is not needed for analysis, standards are stable for 24 hours.)

TABLE 6: 2.0J CALIBRATION STANDARD

Identification	Element	Intermediate Standard (mL)	KBr Matrix Modifier (mL)	Acid Mix (mL)	Internal Standard/ Complexing Solution (mL)	Final Volume (mL)	Final Concentration (µg/L)
2.0J Calibration Standard	As	0.200	0.500	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						40
	Sn						240
	Cr						440
	Ca						200
	Fe						40
	Mg						40

6.10. **Calibration Blank**

6.10.1. Prepare a solution containing 5.0% HNO_3, 2.5% H_2SO_4, 1.0% HCl, and 0.04% (400µg/mL) Thiourea as described in Table 7 below.
6.10.2. To a separate 50 mL Digitube®, add approximately 35 mL of DI Water.
6.10.3. Add 0.500 mL of KBr Matrix Modifier and swirl to mix.
6.10.4. Add 3.75 mL of Acid Mixture then dilute to 45 mL using DI Water.
6.10.5. Add 1.0 mL of internal standard/complexing solution and dilute to volume using DI Water.
6.10.6. Do not allow Internal Standard Solution to contact concentrated acids.

TABLE 7: CALIBRATION BLANK

Description	KBr Matrix Modifier (mL)	Acid Mix (mL)	Internal Standard/ Complexing Solution (mL)	Final Volume (mL)
Cal Blank	0.500	3.75	1.0	50

6.11. **Method Blank Preparation**

6.11.1. Refer to Calibration Blank

6.12. **Sample Preparation**

6.12.1. Samples are stable for 24 hours.
6.12.2. Weigh approximately 100 mg of the sample into a 50 mL Digitube®.
6.12.3. Add 20 mL of deionized water and swirl solution to dissolve solid.
6.12.4. Add 0.500 mL of KBr Matrix Modifier and swirl to mix.
6.12.5. Add 3.75 mL of Acid Digestion Mixture and swirl solution periodically to evolve gasses that are produced during the reaction.
6.12.6. Add deionized water to approximately 45 mL and then transfer 1.0 mL of Internal Standard/ Complexing Solution.
6.12.7. Dilute to a final volume of 50 mL with deionized water and mix thoroughly.

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:
$M_c = M_u - [M_{(rm)} \times (A_{(i.e.)}/A_{(rm)})]$

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
$A_{(i.e.)}$ = Percent Abundance of Interfering Element (i.e.) 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 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. 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 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	Not Applicable
1.5J Check Std 1	QC Check	Not Applicable
Method Blank	Sample	Not Applicable
Sample(s) 10 or less	Sample	Not Applicable
1.5J Check Std 2	QC Check	Not Applicable

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, 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 "KBr_EI_Profile.mth" for elemental impurities testing.

7.8.5. The internal standard recovery can vary in the samples and final bracketing check standard. This is caused by the sample matrix differing greatly from the standards and a suppressive or enhancement effect occurs depending on ionization energy potential. The matrix modifier is added to assist with this effect.

TABLE 9: ICP-MS PARAMETERS

ICP-MS System	Perkin Elmer NexION350X Inductively Coupled PlasmaMass 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	109Ag	185Re	KED	0.60-4.0
24Mg	45Sc	KED	6.0-40	111Cd	125Te	KED	0.12-0.80
44Ca	45Sc	KED	30-200	113Cd	125Te	KED	0.12-0.80
51V	45Sc	KED	0.60-4.0	118Sn	125Te	KED	36-240
52Cr	45Sc	KED	66-440	119Sn	125Te	KED	36-240
53Cr	45Sc	KED	66-440	120Sn	125Te	KED	36-240
56Fe	45Sc	H_2 DRC	6.0-40	121Sb	125Te	KED	5.4-36
57Fe	72Ge	KED	6.0-40	123Sb	125Te	KED	5.4-36
58Ni	72Ge	KED	1.2-8.0	135Ba	89Y	KED	42-280
59Co	72Ge	KED	0.30-2.0	137Ba	89Y	KED	42-280
60Ni	72Ge	KED	1.2-8.0	138Ba	89Y	KED	42-280
62Ni	72Ge	KED	1.2-8.0	188Os	209Bi	KED	0.60-4.0
63Cu	72Ge	KED	6.0-40	189Os	209Bi	KED	0.60-4.0
65Cu	72Ge	KED	6.0-40	190Os	209Bi	KED	0.60-4.0
75As	72Ge	H_2 DRC	0.90-6.0	191Ir	209Bi	KED	0.60-4.0
75As	72Ge	KED	0.90-6.0	192Os	209Bi	KED	0.60-4.0
77Se	89Y	H_2 DRC	4.8-32	193Ir	209Bi	KED	0.60-4.0
78Se	89Y	H_2 DRC	4.8-32	194Pt	209Bi	KED	0.60-4.0
92Mo	89Y	KED	90-600	195Pt	209Bi	KED	0.60-4.0
95Mo	89Y	KED	90-600	196Pt	209Bi	KED	0.60-4.0
97Mo	89Y	KED	90-600	197Au	209Bi	KED	6.0-40
98Mo	89Y	KED	90-600	199Hg	209Bi	KED	0.18-1.2
99Ru	89Y	KED	0.60-4.0	200Hg	209Bi	KED	0.18-1.2
101Ru	89Y	KED	0.60-4.0	202Hg	209Bi	KED	0.18-1.2
103Rh	89Y	KED	0.60-4.0	203Tl	209Bi	KED	0.48-3.2
105Pd	185Re	KED	0.60-4.0	205Tl	209Bi	KED	0.48-3.2
106Pd	185Re	KED	0.60-4.0	206Pb	209Bi	KED	0.30-2.0
107Ag	185Re	KED	0.60-4.0	207Pb	209Bi	KED	0.30-2.0
108Pd	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/g (ppm) according to Table 11 below. Report the average result for multiple isotopes of the same element that are above the LOQ concentration.

TABLE 11: RESULT REPORTING

Result	Reporting
If < LOQ	Report as < LOQ
If ≥ LOQ and < 1.0 ppm	Report to two (2) decimal places
If ≥ LOQ and ≥ 1.0 ppm	Report to whole number