

Residues after Reprocessing on Orthopedic Implants

By Vacuum Induced Desorption Mass Spectrometry
(VIDMS)

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Contence of the presentation

- Overview of Test Methods
- Tested Implants
- Conditioning of the Implants
- Test Results
- Further Test Plan in the Research Project

Surgical Site Infections(Hip Prosthesis)

Country	No. of operations	No. of SSIs (1)	Percentage of SSIs per 100 operations [95% CI] (2)	No. of operations with a known discharge date
Patient-based data				
Austria	11 703	89	0.8 [0.6-0.9]	11 678
Finland	13 712	239	1.7 [1.5-2.0]	6 477
France	31 465	313	1.0 [0.9-1.1]	31 465
Germany	102 209	976	1.0 [0.9-1.0]	80 322
Hungary	2 909	66	2.3 [1.8-2.9]	2 909
Italy	5 176	76	1.5 [1.2-1.8]	4 238
Lithuania	960	4	0.4 [0.1-1.1]	960
Malta	573	22	3.8 [2.4-5.8]	573
Netherlands	13 893	291	2.1 [1.9-2.3]	13 893
Norway*	22 323	629	2.8 [2.6-3.0]	22 279
Portugal	3 031	27	0.9 [0.6-1.3]	3 031
UK–England	95 997	638	0.7 [0.6-0.7]	95 997

ECDC: Annual epidemiological report for 2014

- Visual Inspection
- Bioburden
- Bacterial Endotoxins
- **Organic Contaminants**
 - Extraction
 - Detection (TOC, THC)
- Inorganic Contaminants
- Particulate Contamination
- Cytotoxicity

- Chemical, film-like Contamination
 - Production Aids
 - Oil, grease, detergents
 - Qualitative and/or quantitative detection
 - Few standards available
 - Requirements specification rather than acceptance criteria (ISO 19227)

Detection Methods

Wipe



Test ink



www.afs.biz

XPS Analysis



www.prevac.eu

ToF-SIMS



www.iontof.com

**Contact angle
measurement**



<http://www.laborpraxis.vogel.de>

**Fluorescence
detection**



www.sita-process.com

TD-GC-MS



www.cassen.ca

FTIR Spektr.



www.agilent.com

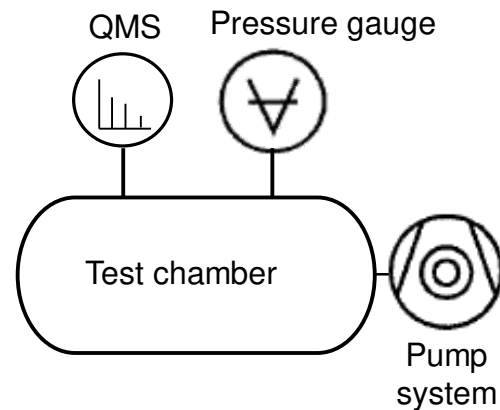
**Simple and non destructive, low amount
of information**

**Complex & destructive,
High amount of information**

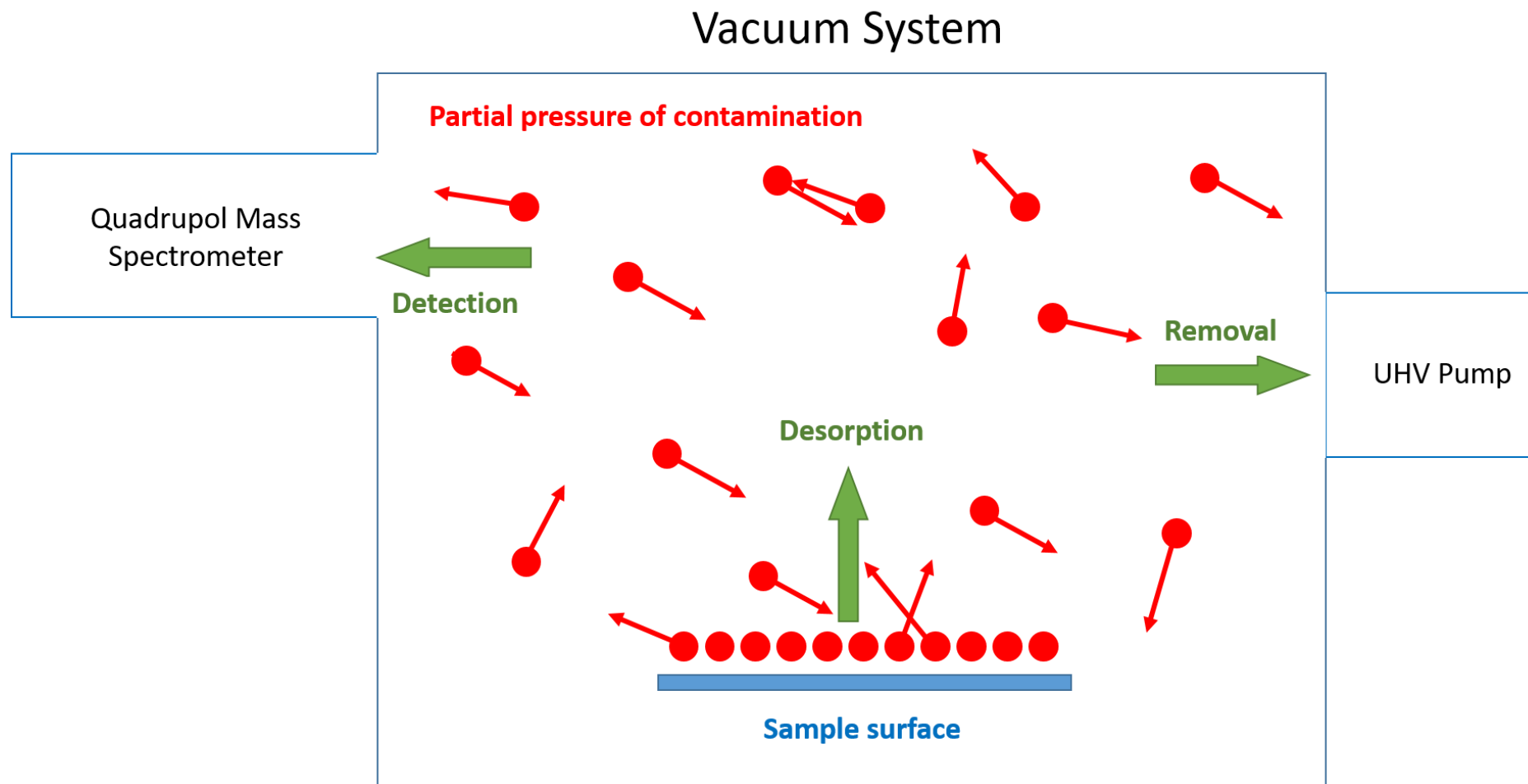
VIDAM

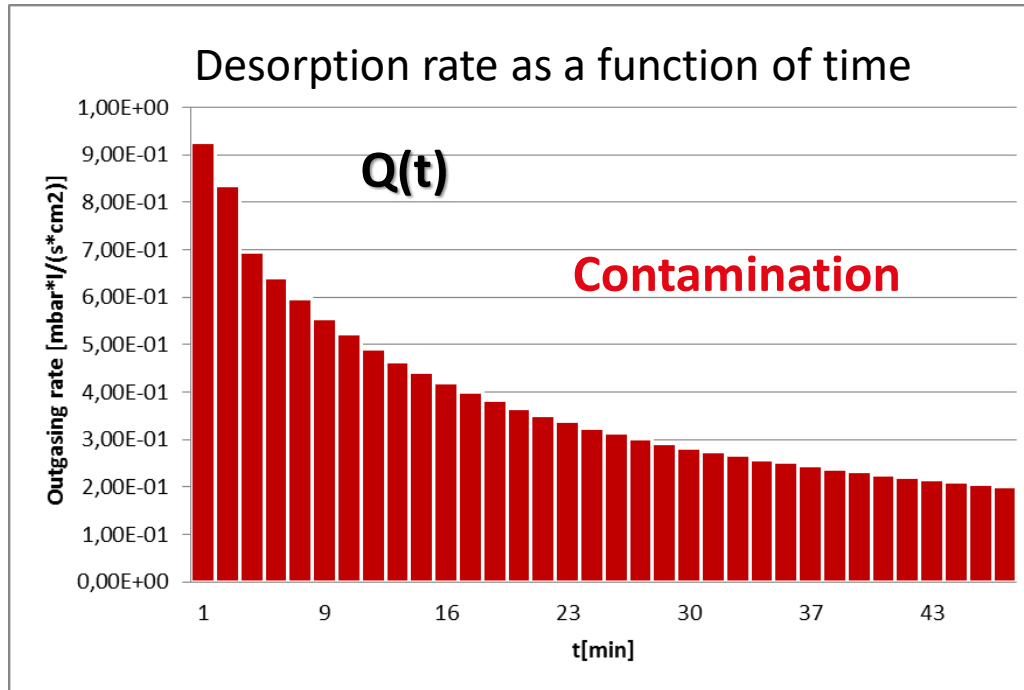


- VIDAM = Vacuum-induced desorption-analysis measurement system
- Developed by VACOM Systems



Basic Principle





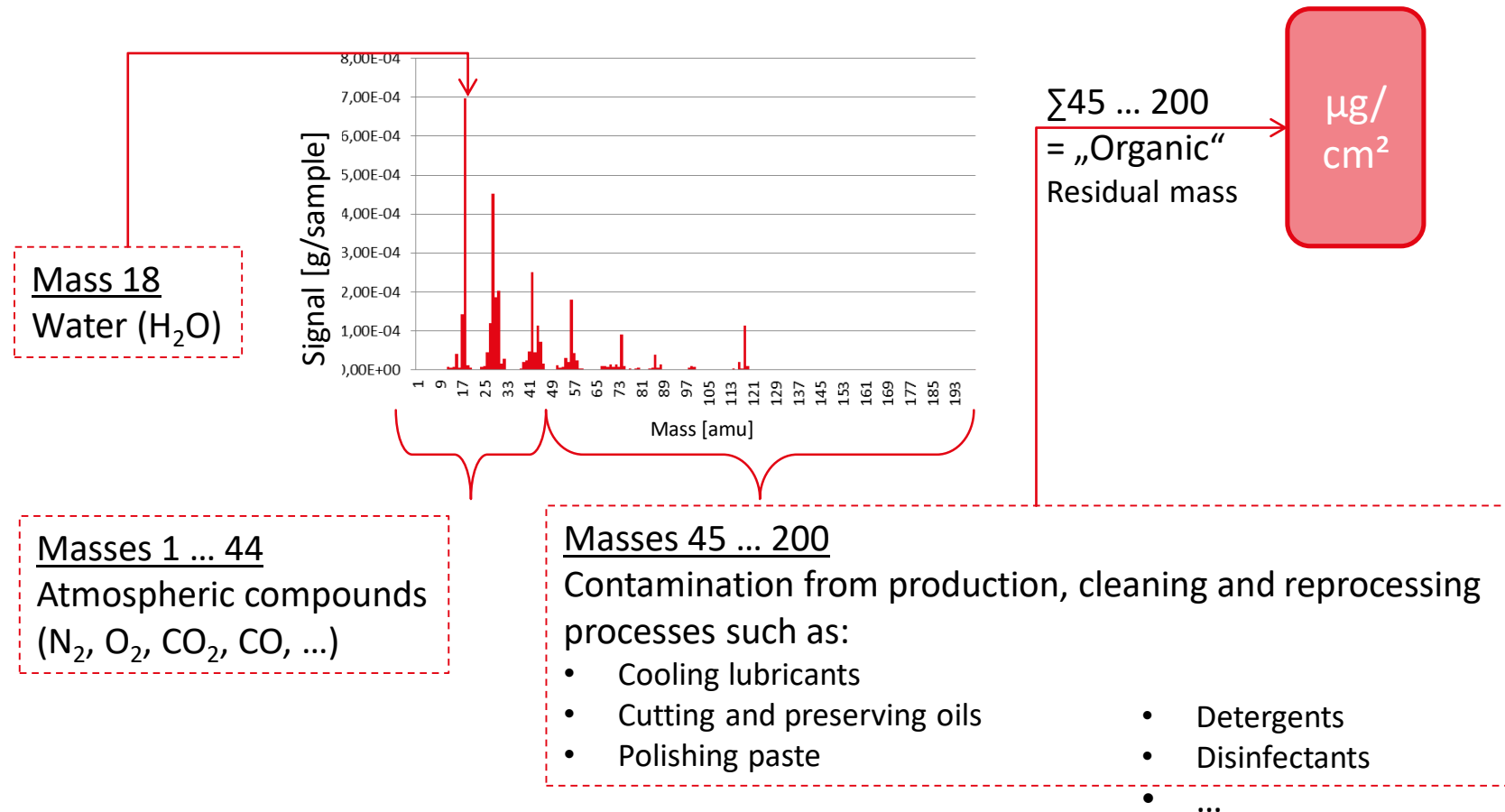
Desorption rate $Q(t)$

Residual contamination on the surface = $\int Q(t)dt$

Each column shown represents the result of a complete mass spectrum (mass = 1-200)

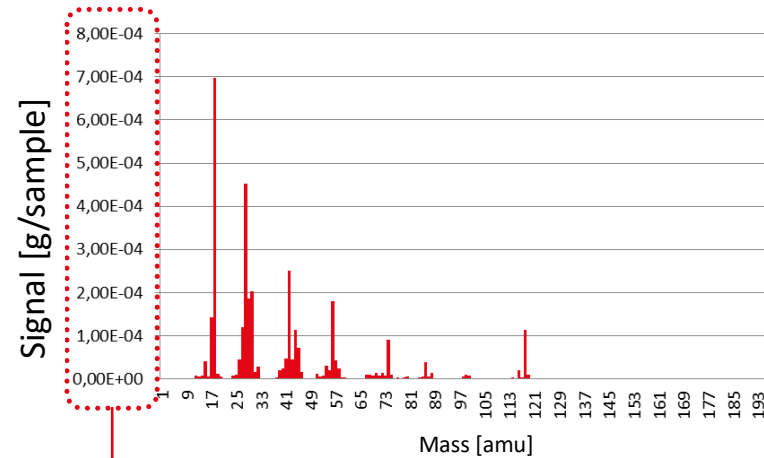
- Allows for non-destructive evaluation without prior preparation of the samples
- Allows for evaluation of any geometry of single samples as well as complete modules or production lots

Interpretation



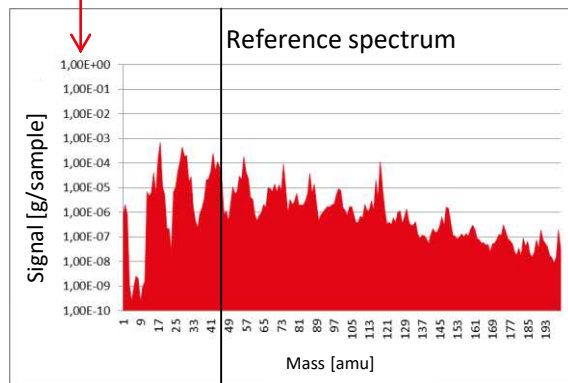
Interpretation

Practical:
logarithmic scale
easier to interpret



$\Sigma 45 \dots 200$
= „Organic“
Residual mass

$\mu\text{g}/\text{cm}^2$

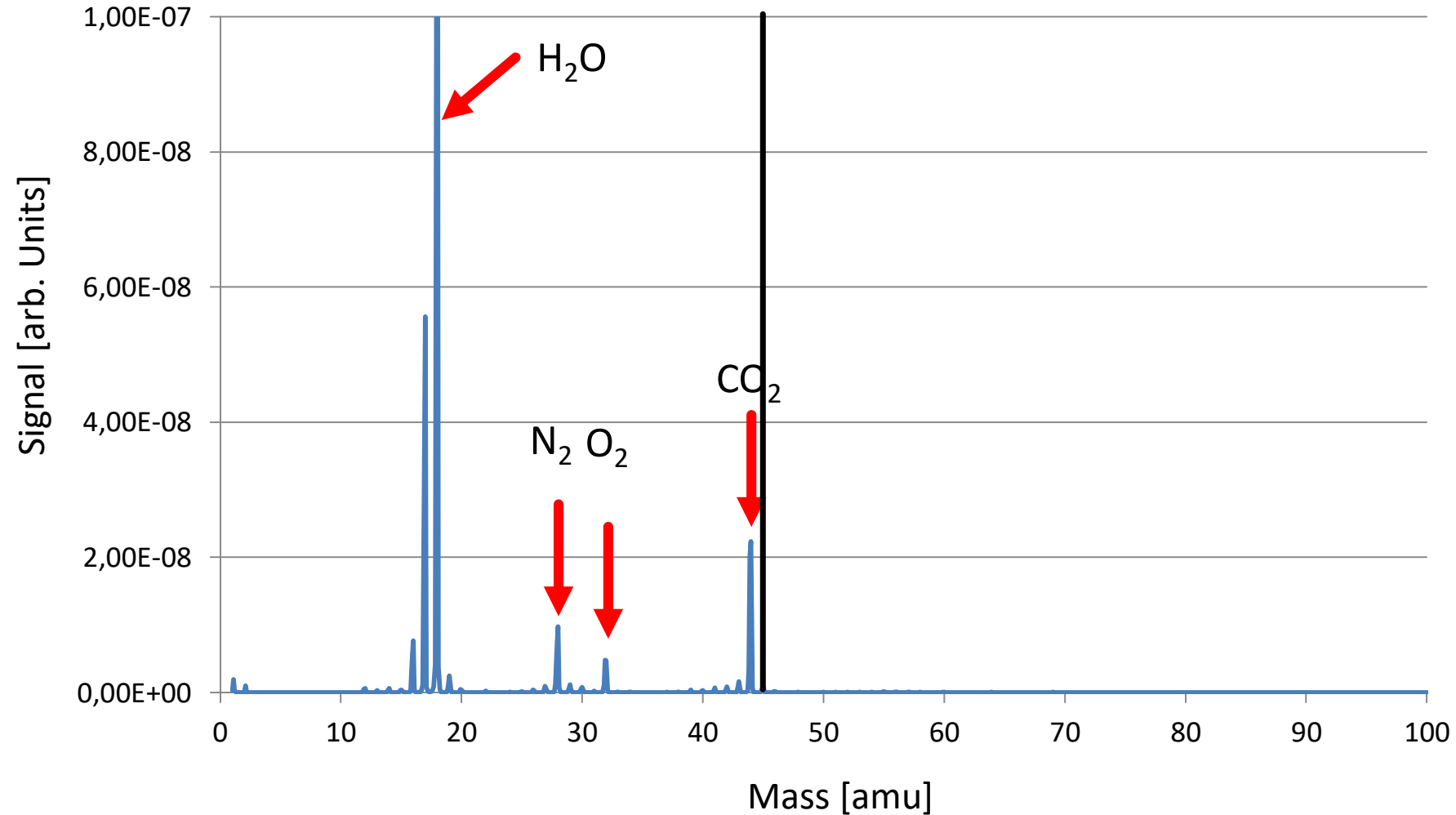


Masses 45 ... 200

Contamination from production, cleaning and reprocessing processes such as:

- Cooling lubricants
- Cutting and preserving oils
- Polishing paste
- Detergents
- Disinfectants
- ...

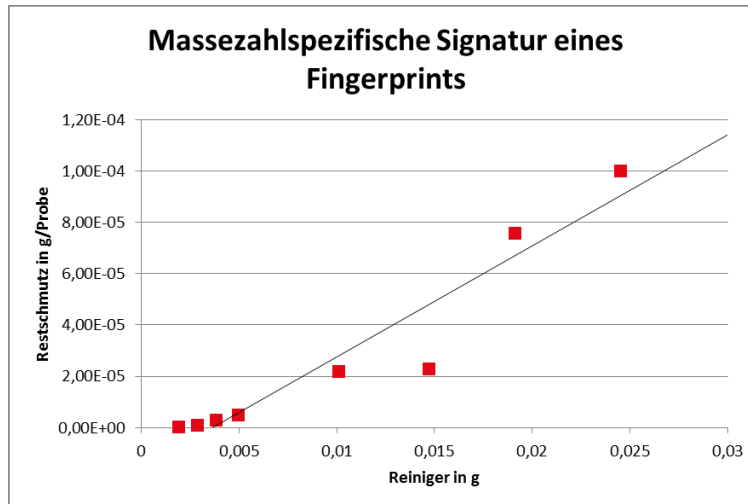
Background – Atmospheric compounds



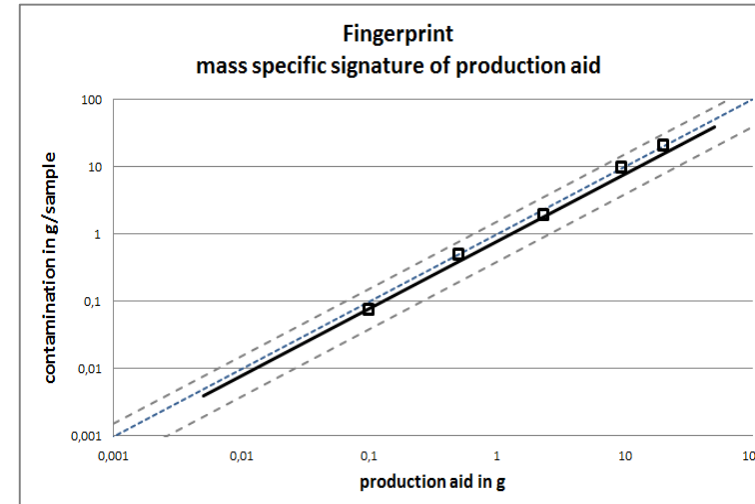
- Time profile for every mass is collected
- Times before and after the measurement are fitted
- Complete amount of material removed for every mass is computed by integration over time taking into account the physical process of pumping
- Results are given as spectrum of residual contamination pumped away
- For substances identified the total amount of contamination on the surface can be given using the specific detection factor (calibration)

Quantification / Calibration

- Mass spectrometric „fingerprint“
- Determination of specific detection factor for example for production aids or detergents by calibration with different amounts of contamination



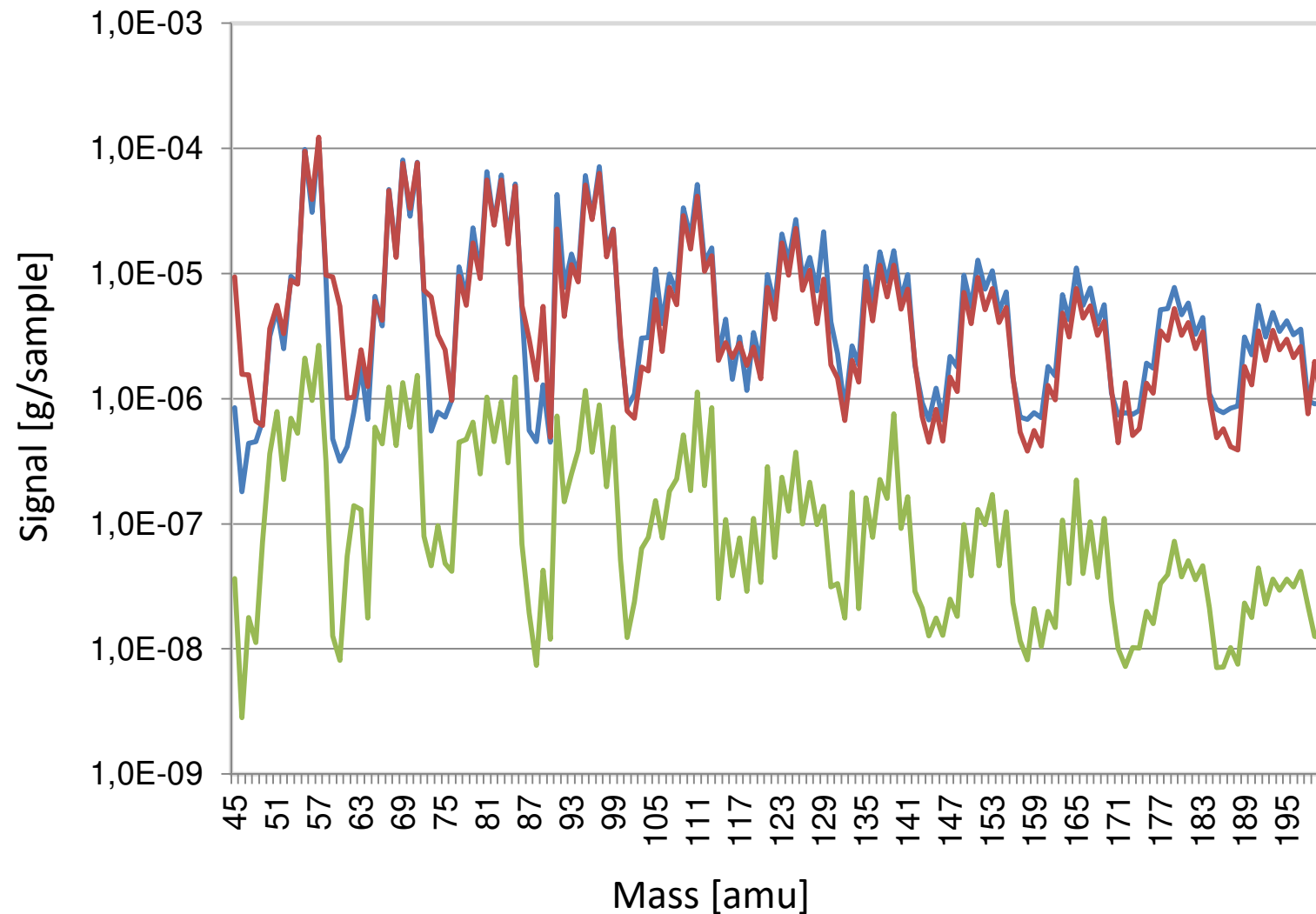
Own data



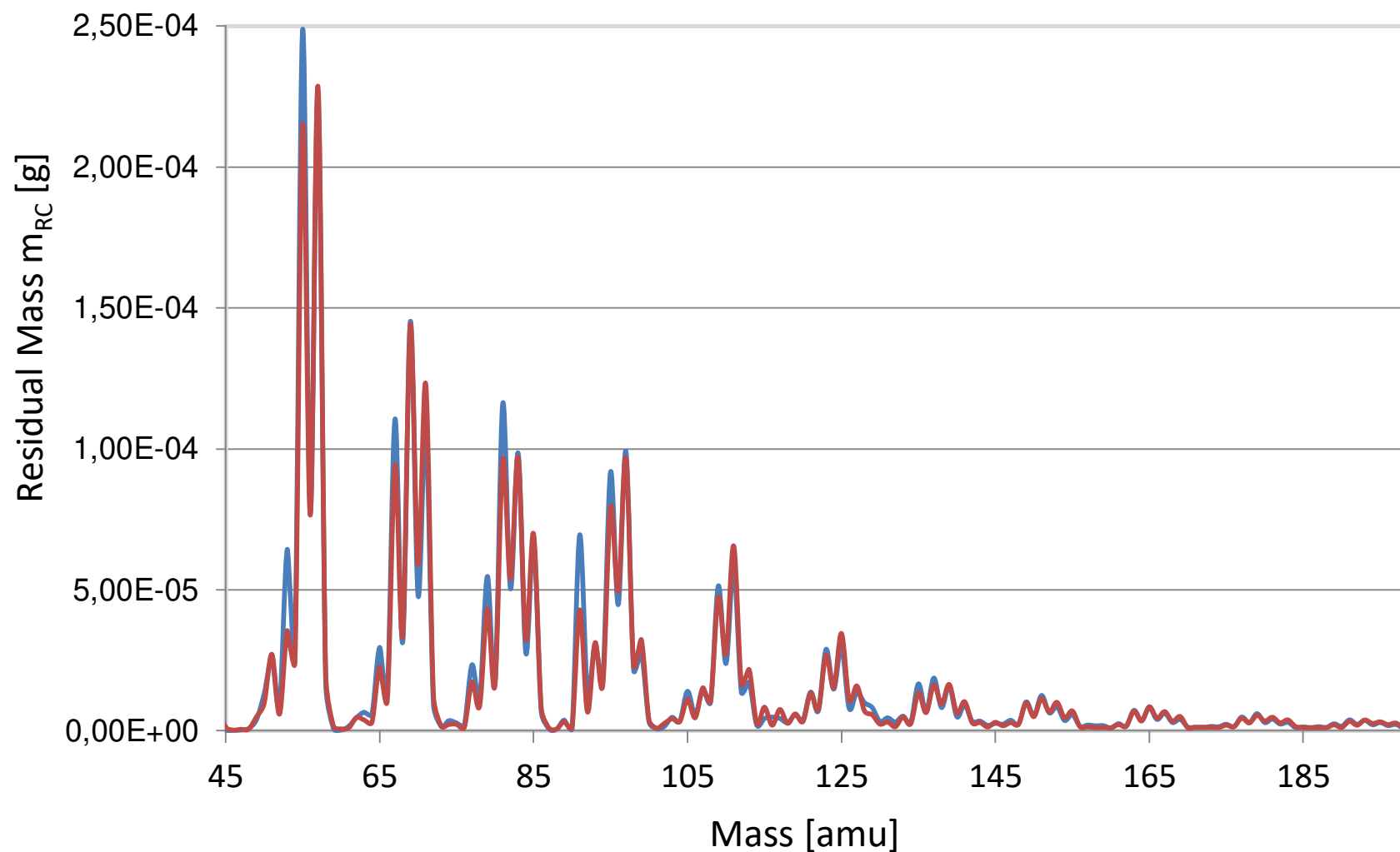
Example provided by VACOM

Specific detection factor is linear and characteristic for the substance

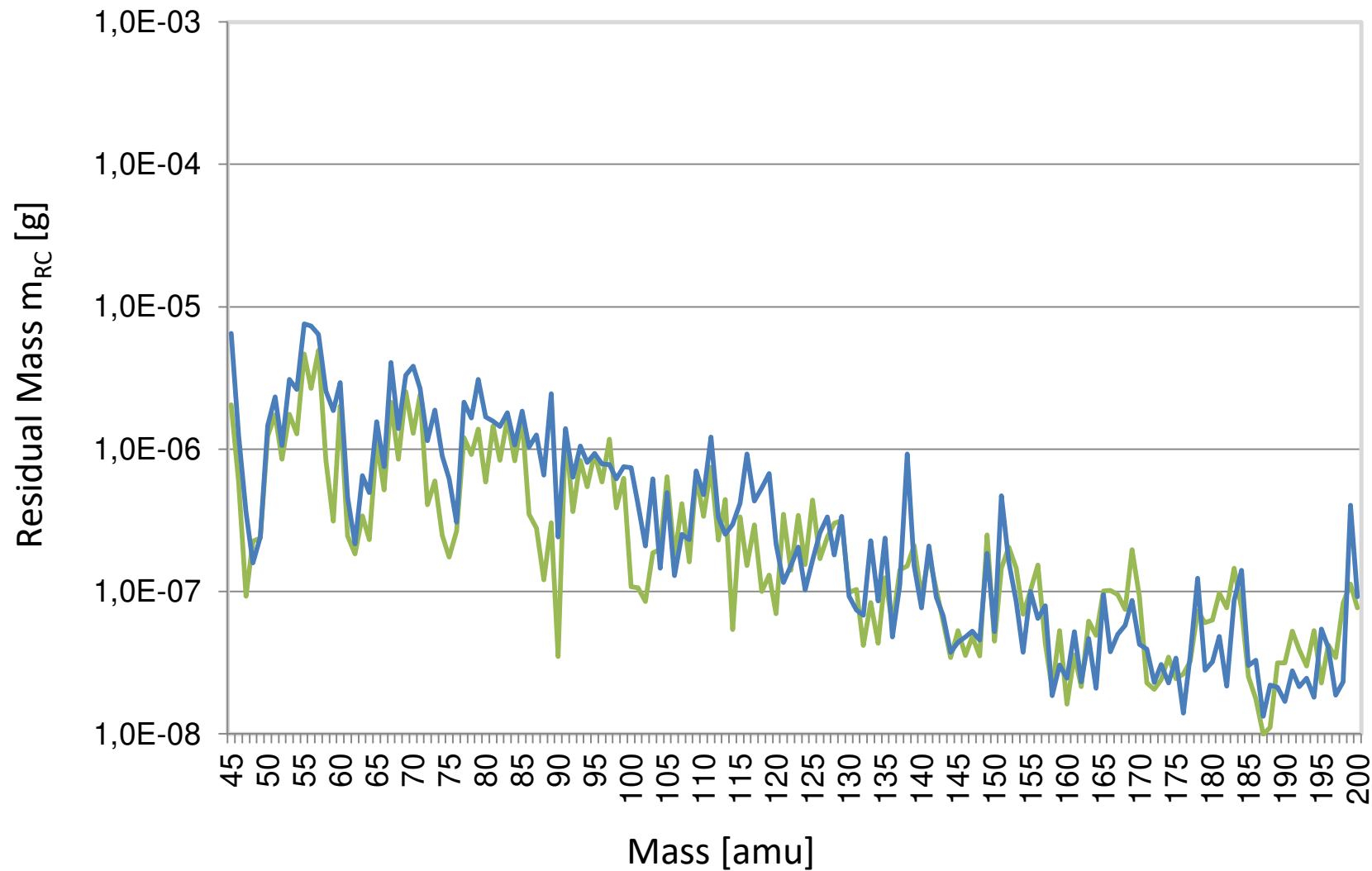
Features - Oil in different amounts



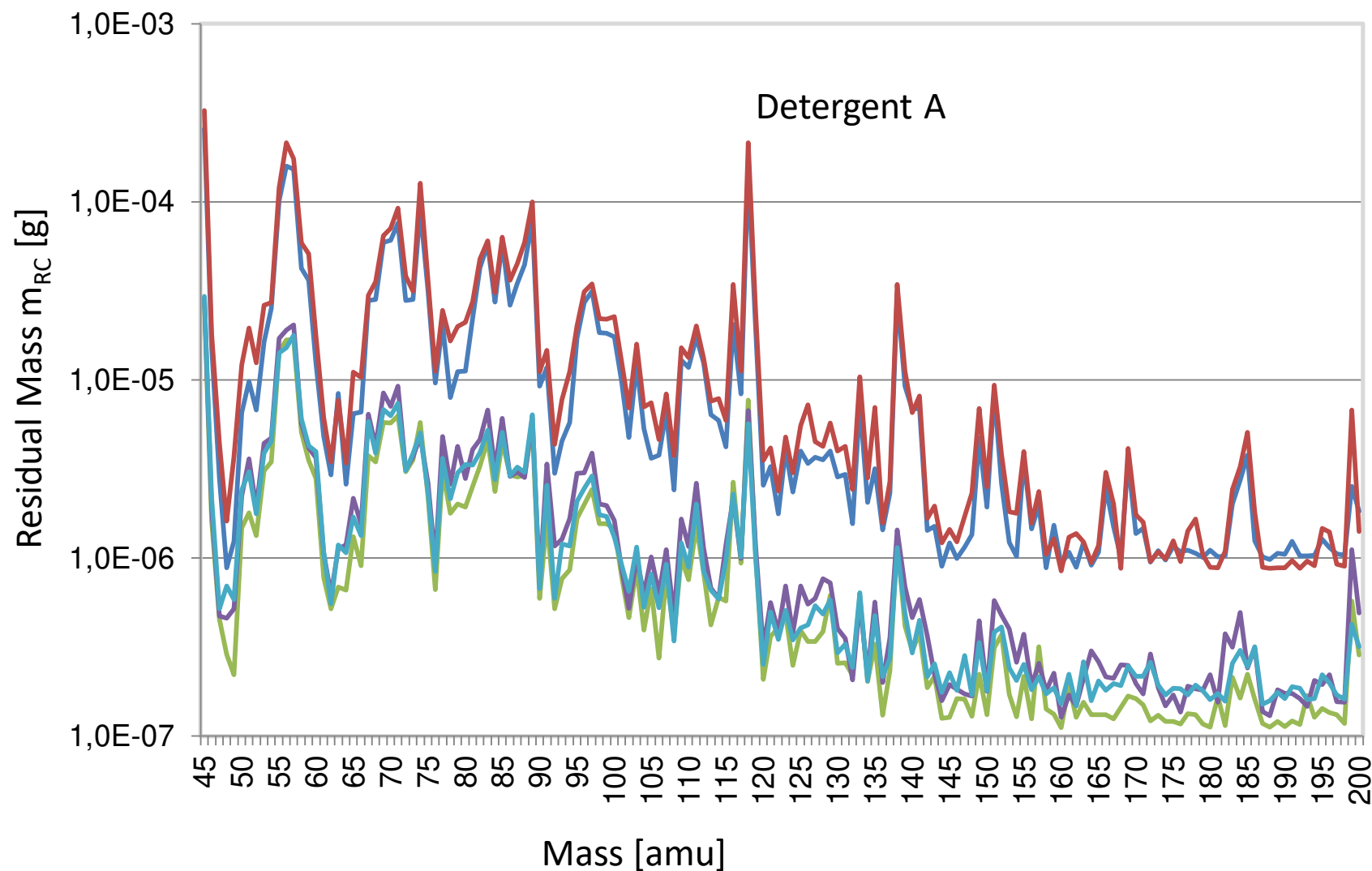
Two slightly different Oils (5 Years of Age)



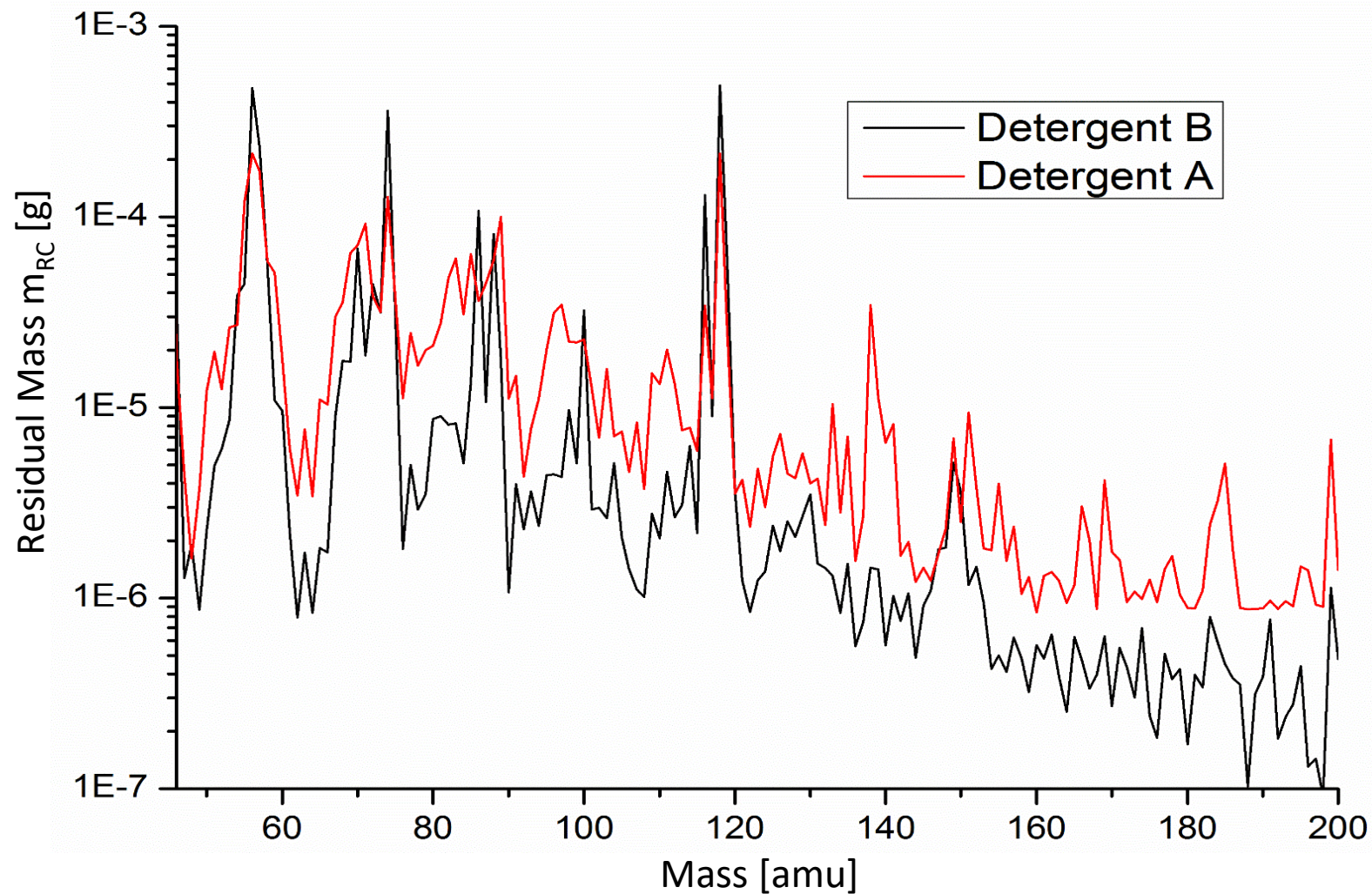
Grease



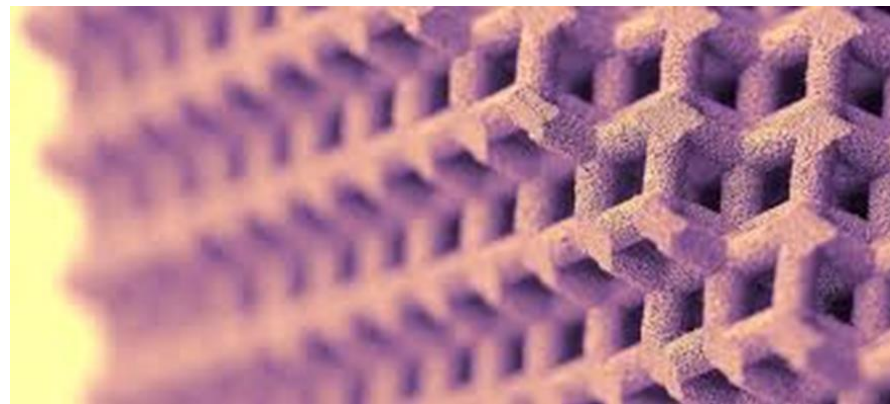
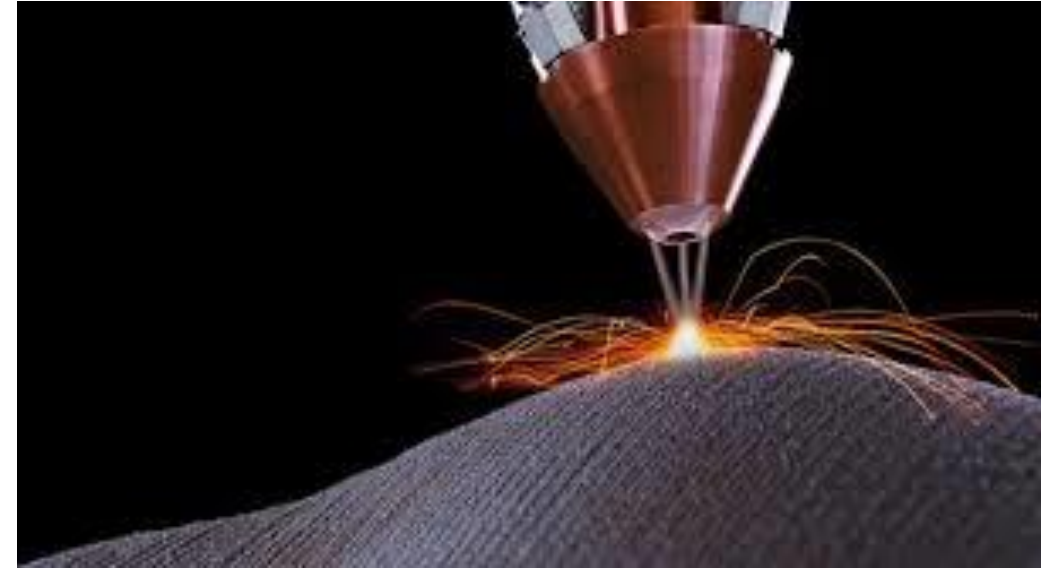
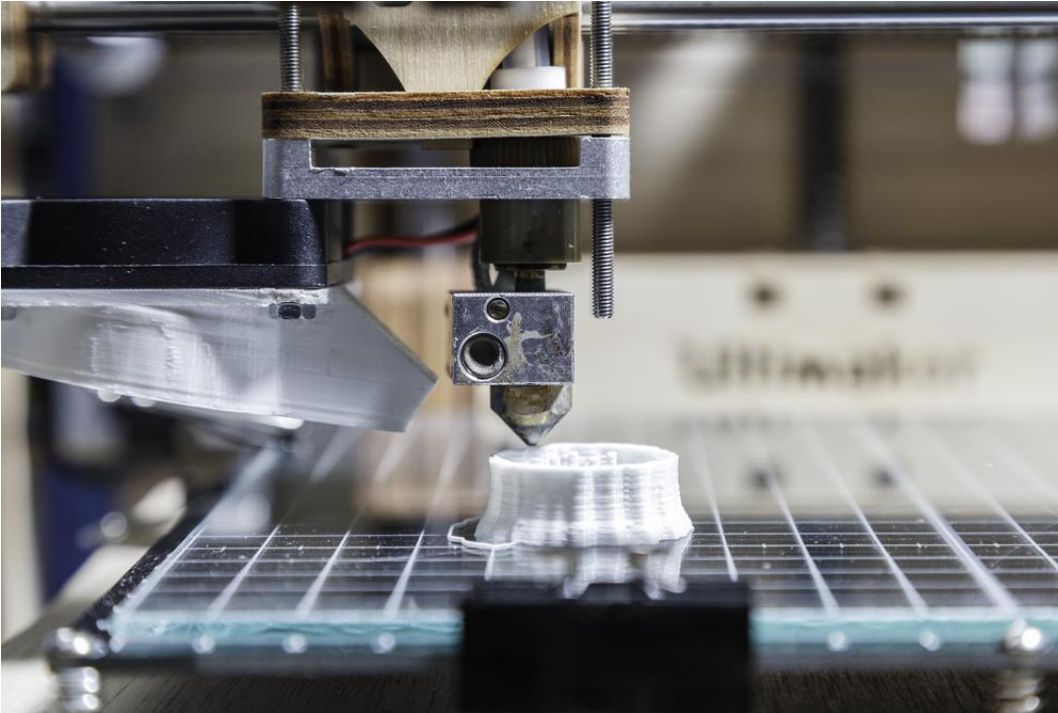
Features - Detergent A in different amounts



Features - Two different Detergents



Direct Metal Laser Sintering – 3 D Printing

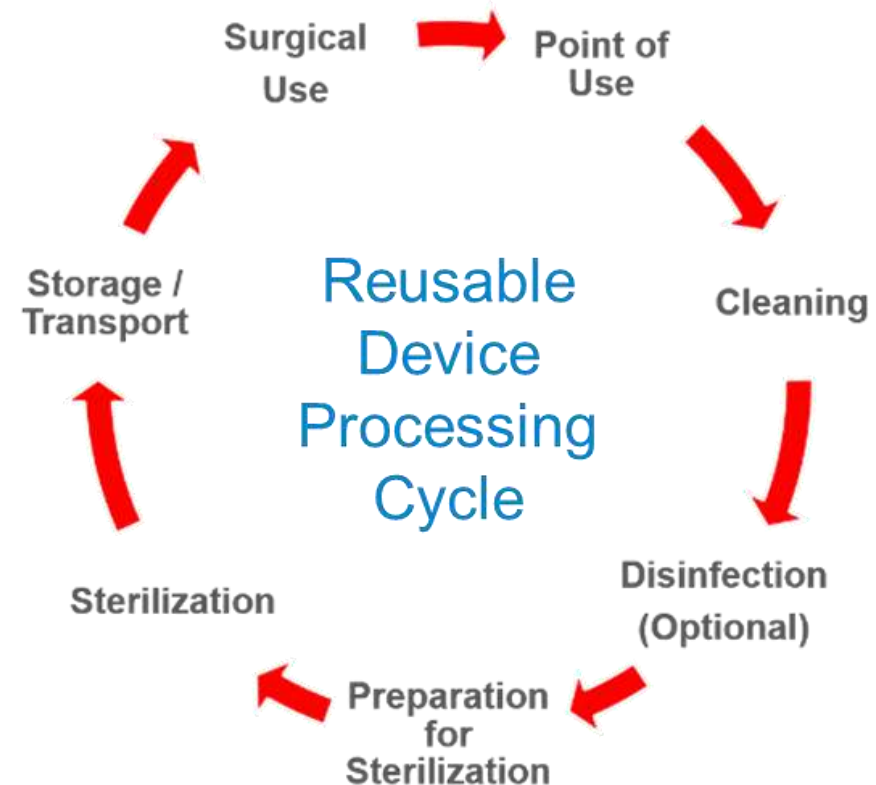


Conditioning of the Test Samples

Repeated Reprocessing of Implants

Materials 3 D printed implants

- Stainless Steel
- Titanium



Conditioning of the Test Samples

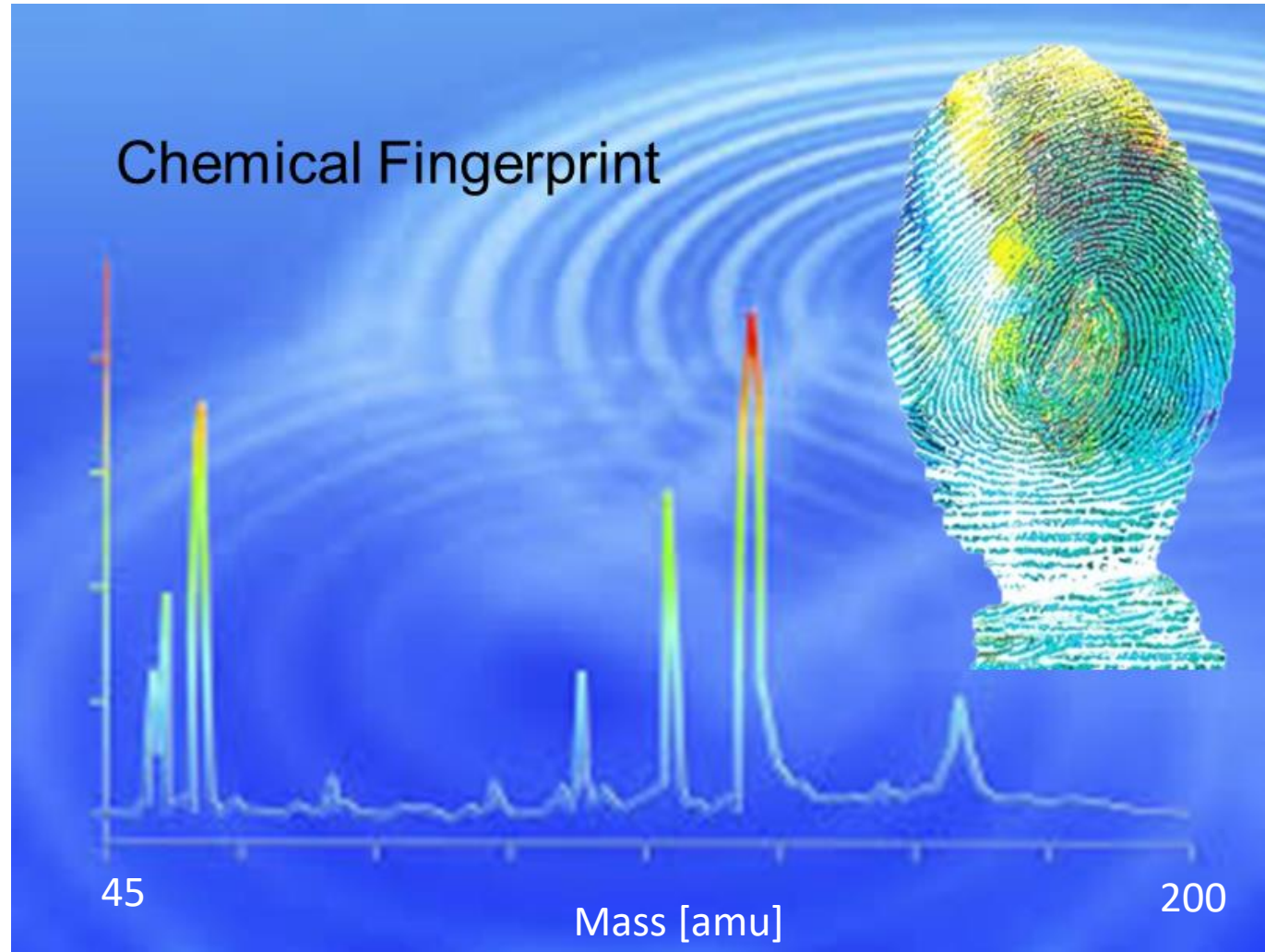
Repeated Reprocessing of Implants

50 times cleaning followed by autoclaving (134°C; 5 minutes)

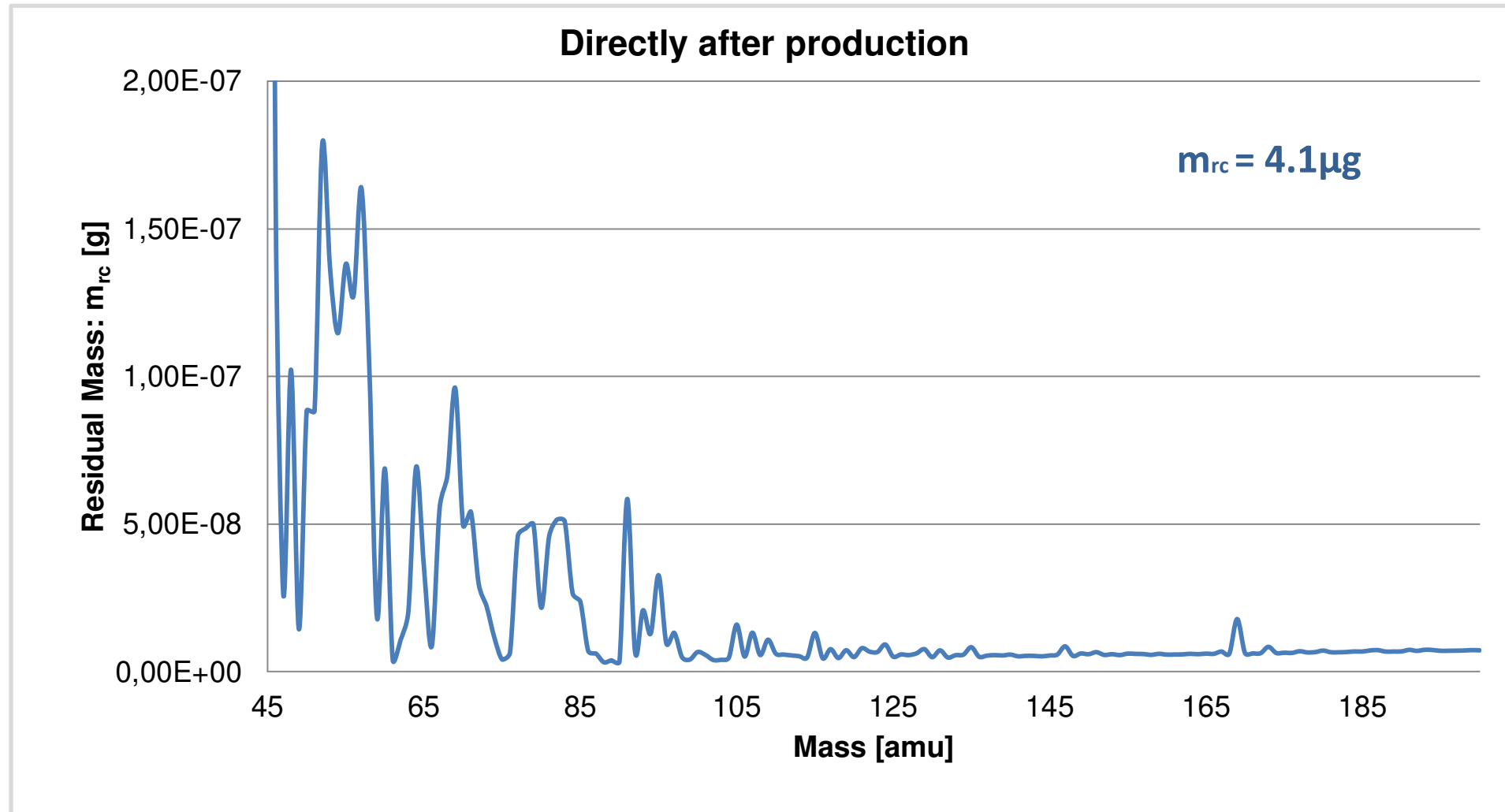
Cleaning was performed by using

- Alkaline detergent
- Enzymatic detergent

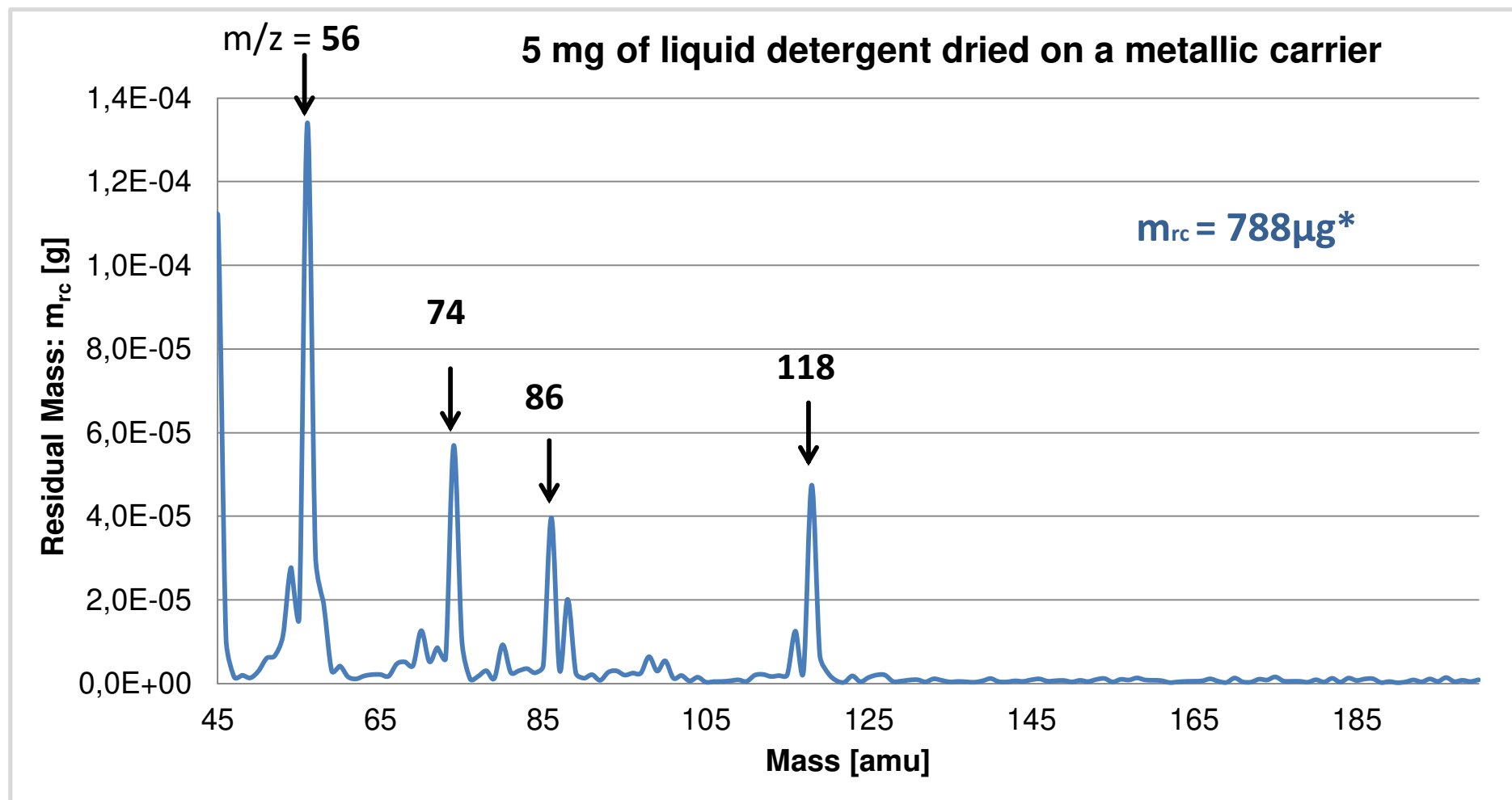
Identification of Contaminants



Titanium - Manufacturing Process Residues



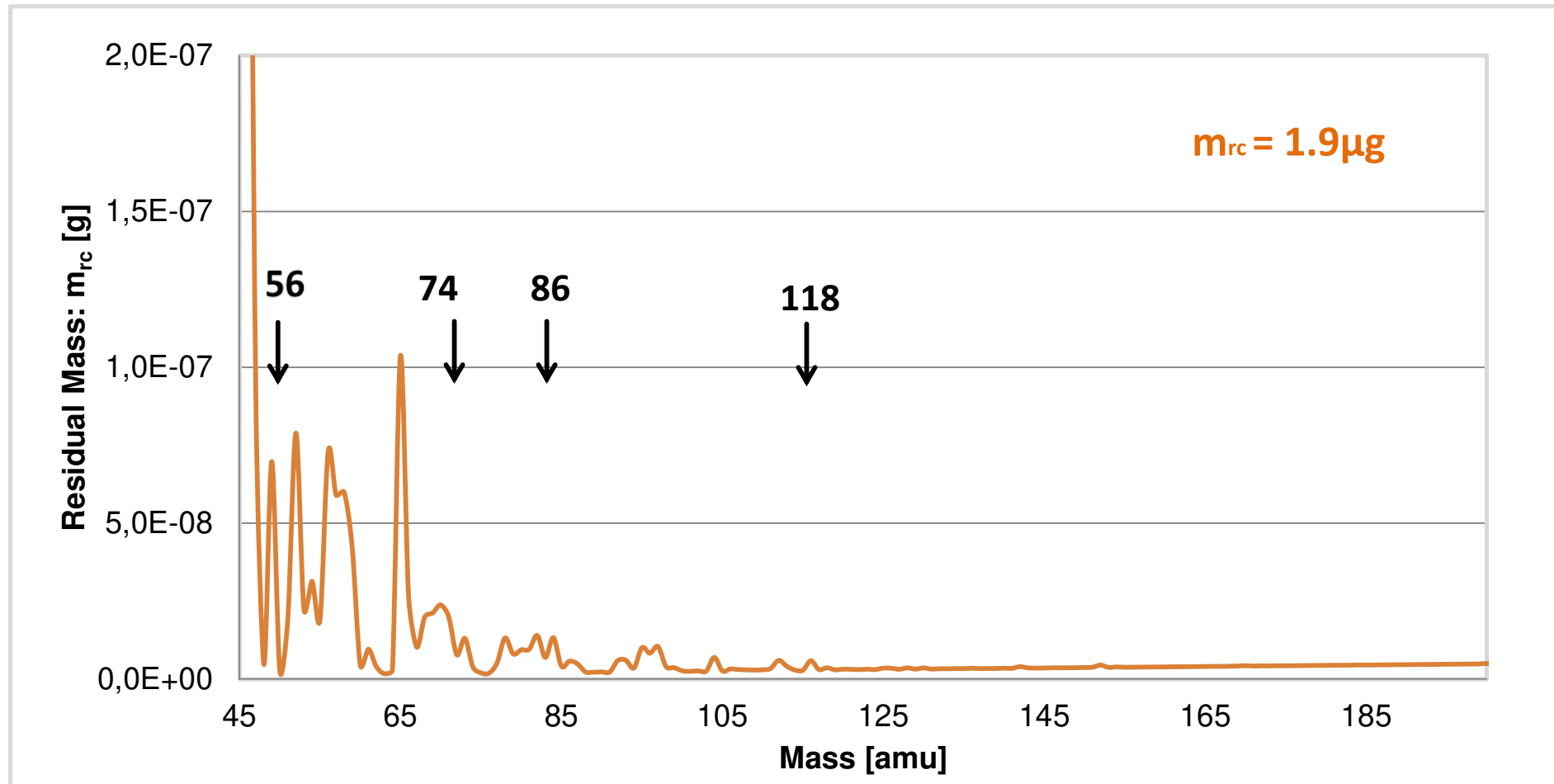
Chemical Fingerprint – Alkaline Detergent



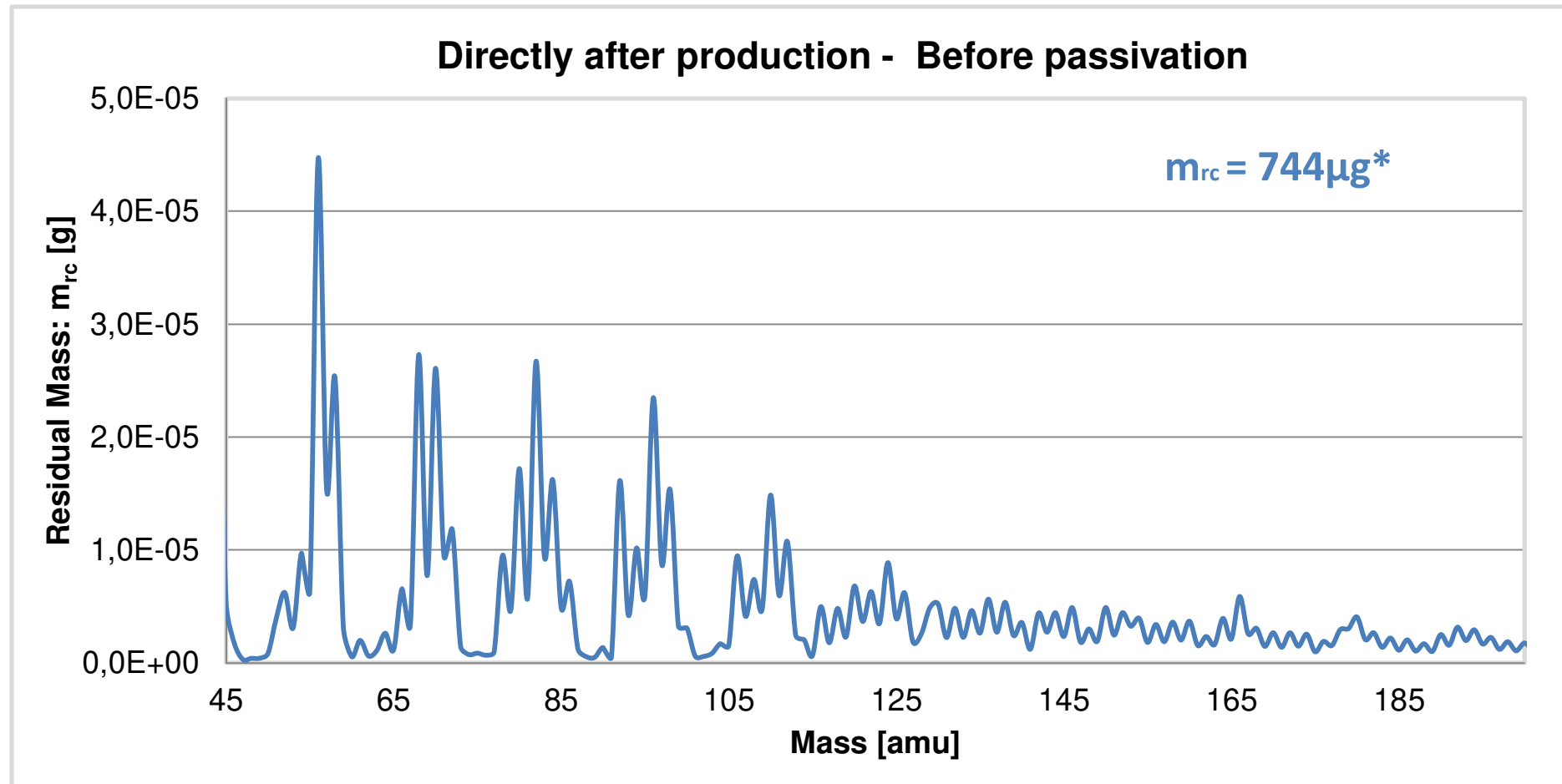
* $m_{rc} = \sum (\text{residual Mass})_{\text{mass} = 45 \rightarrow 200}$

Titanium – After 50 Reprocessing Cycles

alkaline detergent

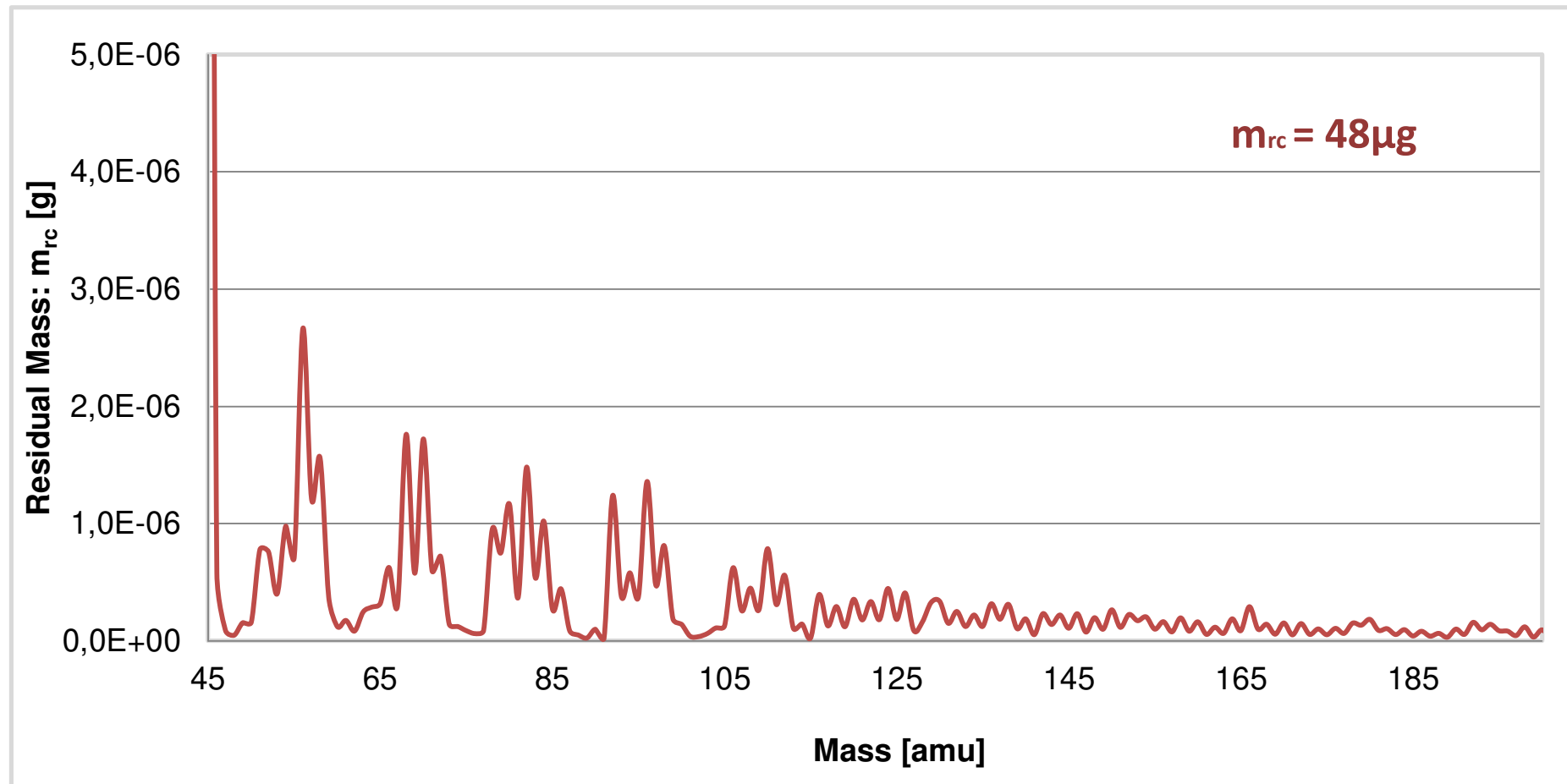


Stainless Steel – Manufacturing Process Residues



* $m_{rc} = \sum (\text{residual Mass})_{m/z = 45 \rightarrow 200}$

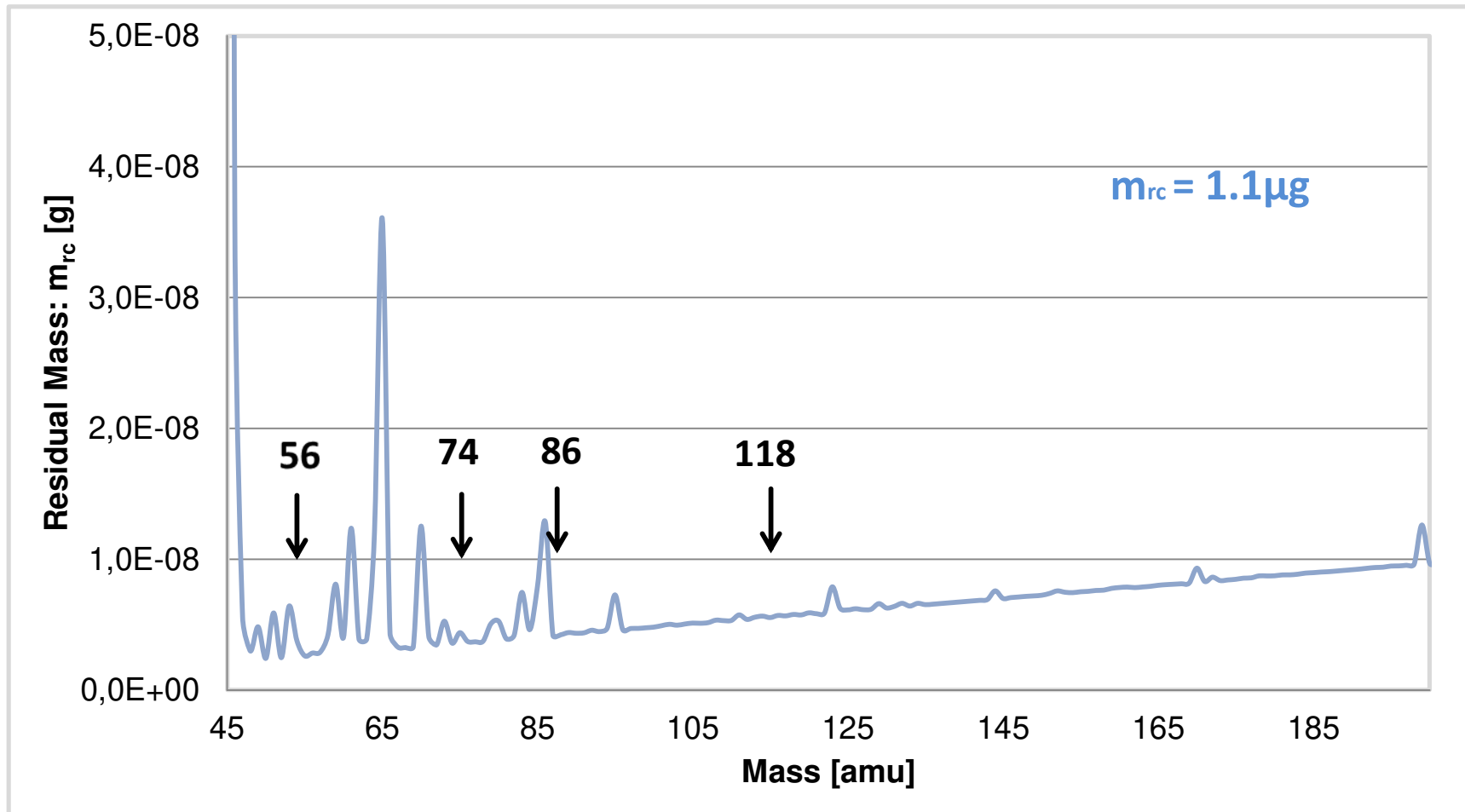
Stainless Steel – Post Passivation



Stainless Steel –

Post Passivation and 50 Reprocessing Cycles

alkaline detergent



Total Residue Summary

alkaline detergent

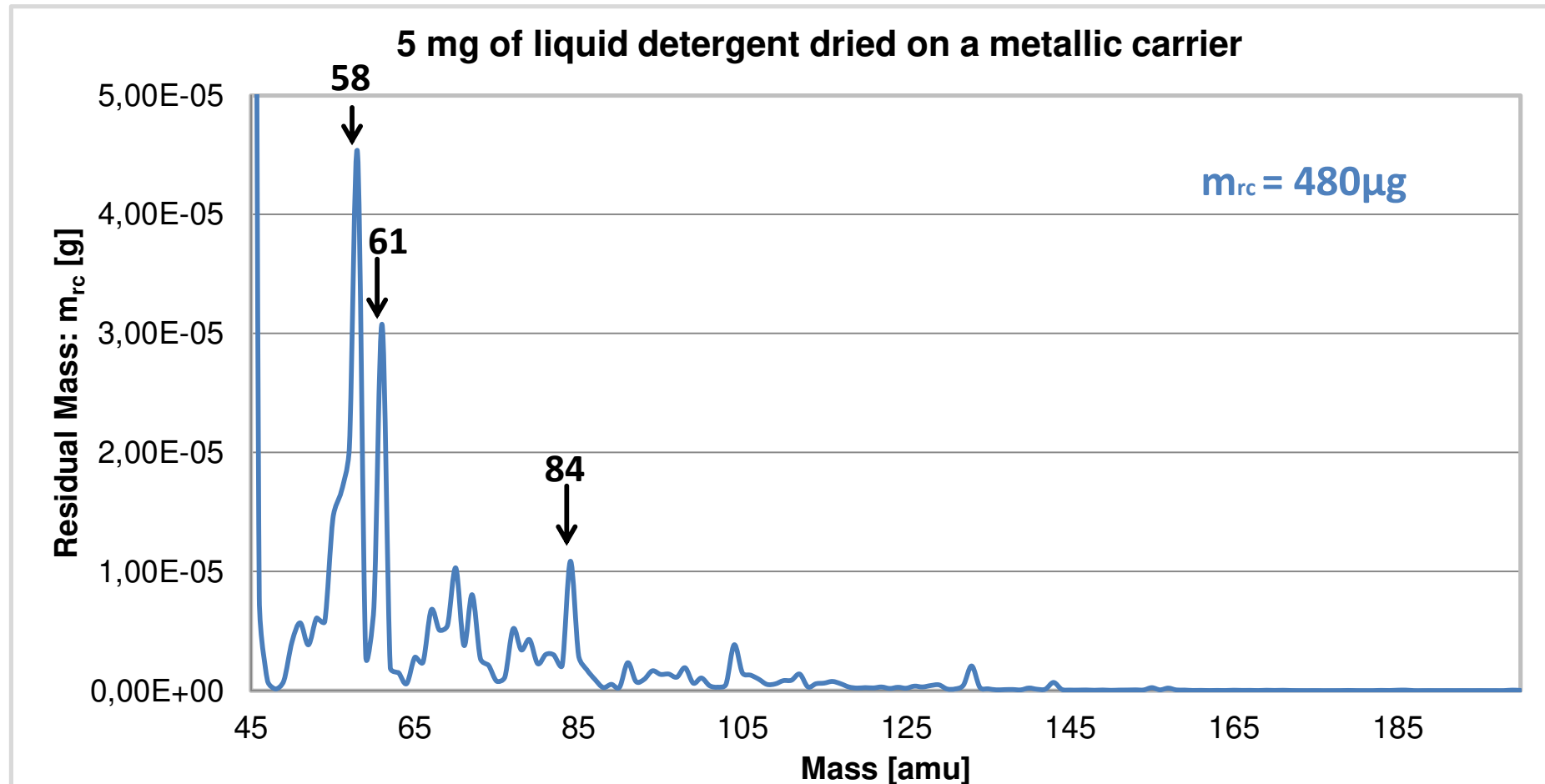
Timepoint	Titanium (µg)	Stainless Steel (µg)
Post Manufacturing	4.1	744
Simulated Passivation	N/A	48
1 Processing Cycle	3.7	3.8
50 Reprocessing Cycles	1.9	1.1
Acceptance Criteria	500	500

Cytotoxicity Summary (alkaline detergent)*

Sample	Cell growth %	Grade
Post manufacturing (Ti)	61	2
Post manufacturing (Ti)	60	2
Post passivation (Ti)	83	0
Post passivation (Ti)	81	0
<u>After 1 Cycle (Ti)</u>	83	0
<u>After 1 Cycle (Ti)</u>	82	0
Post manufacturing (SS)	29	4
Post manufacturing (SS)	28	4
Post passivation (SS)	104	0
Post passivation (SS)	90	0
After 1 Cycle (SS)	87	0
After 1 Cycle (SS)	83	0

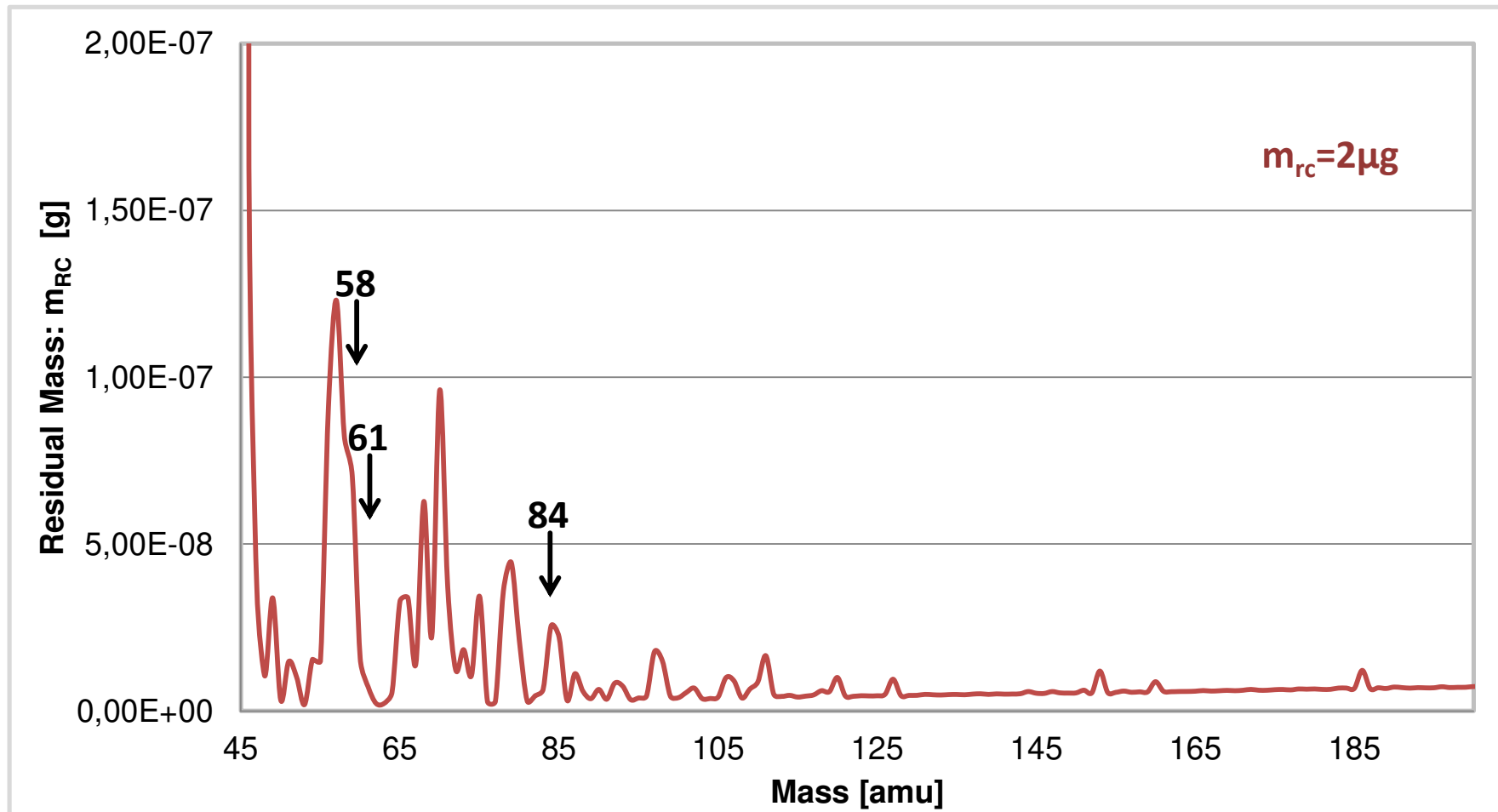
*Preliminary data - ongoing investigation

Chemical Fingerprint – Enzymatic Detergent



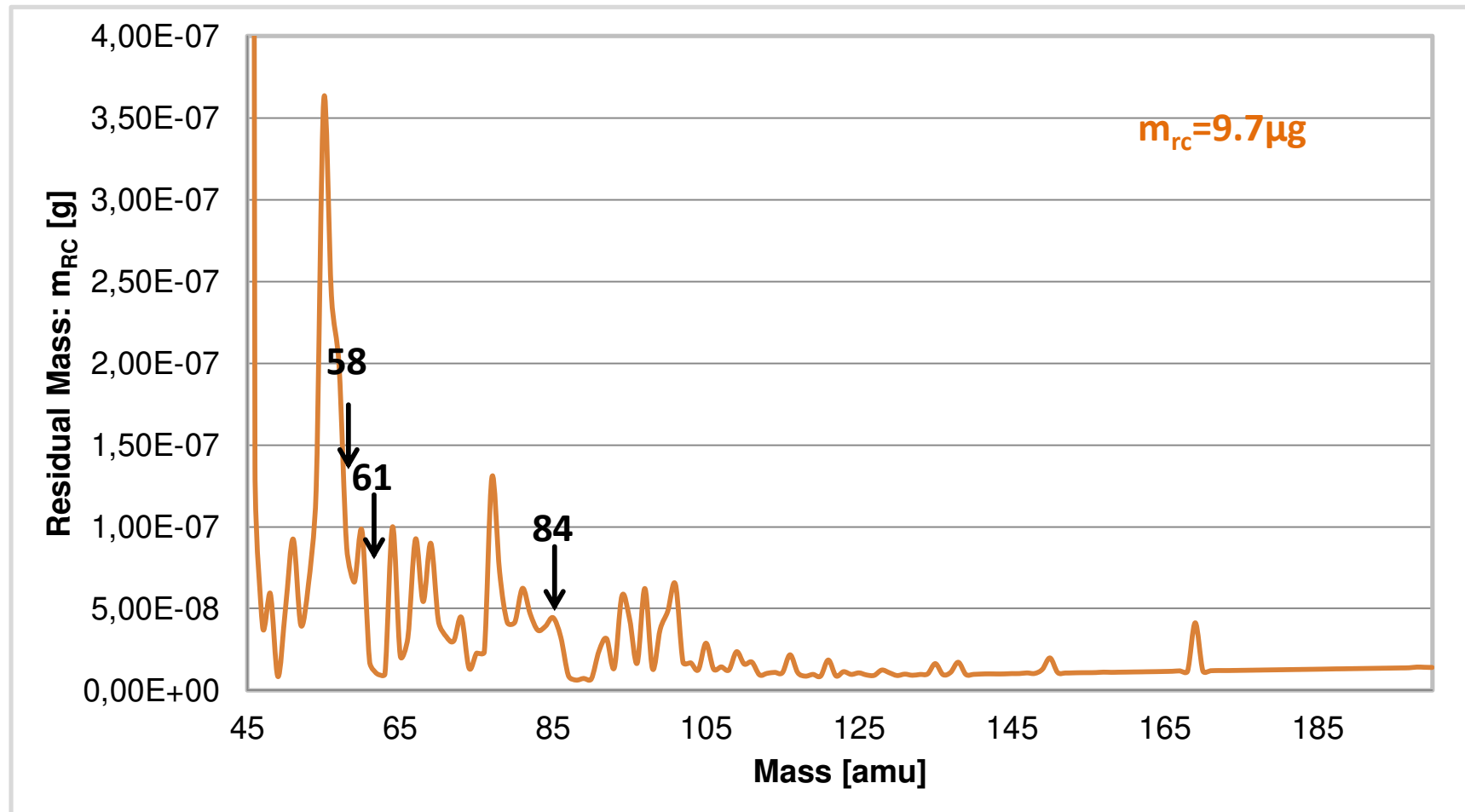
Titanium – After 1 Reprocessing Cycle

Enzymatic Detergent



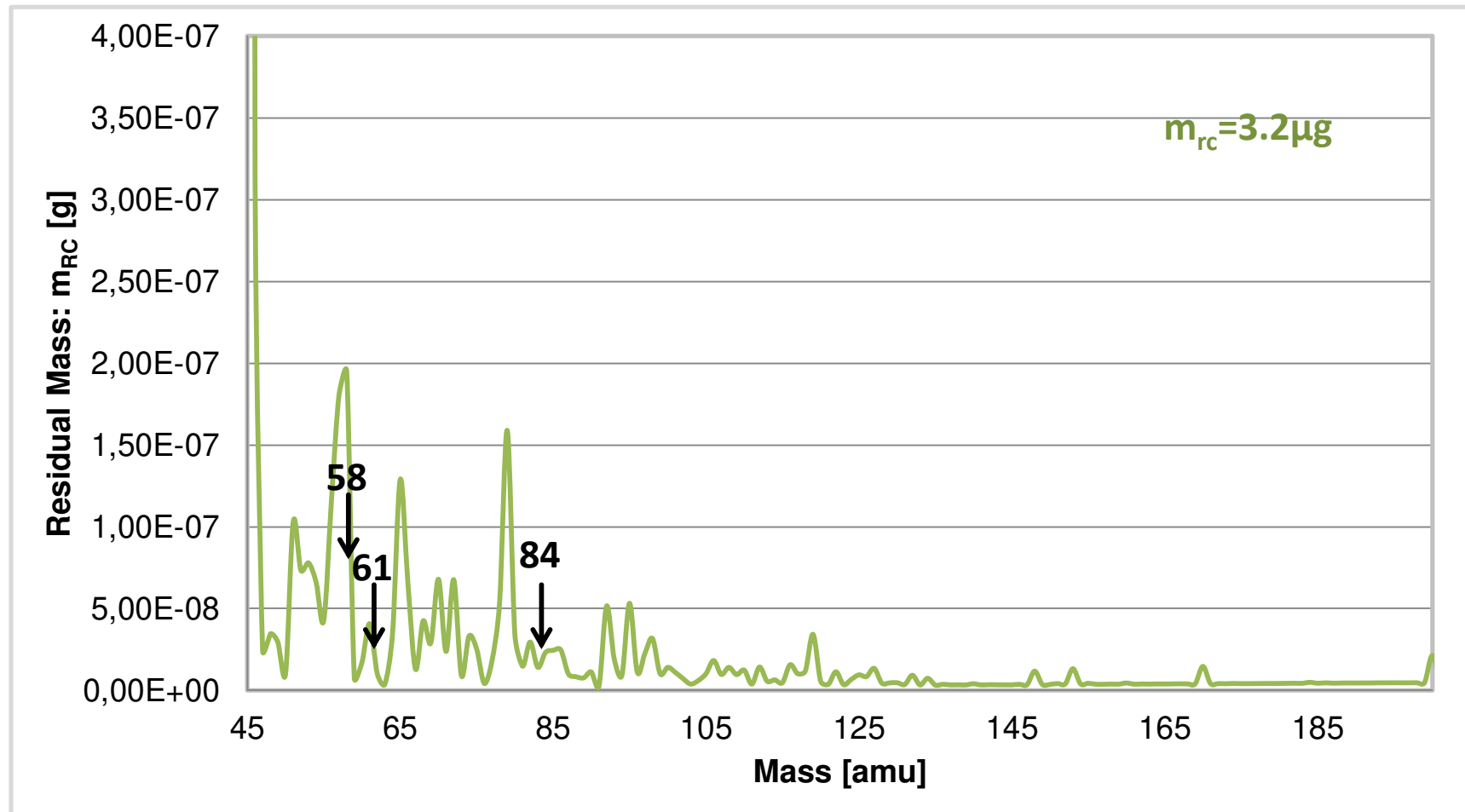
Titanium – After 50 Reprocessing Cycles

Enzymatic Detergent



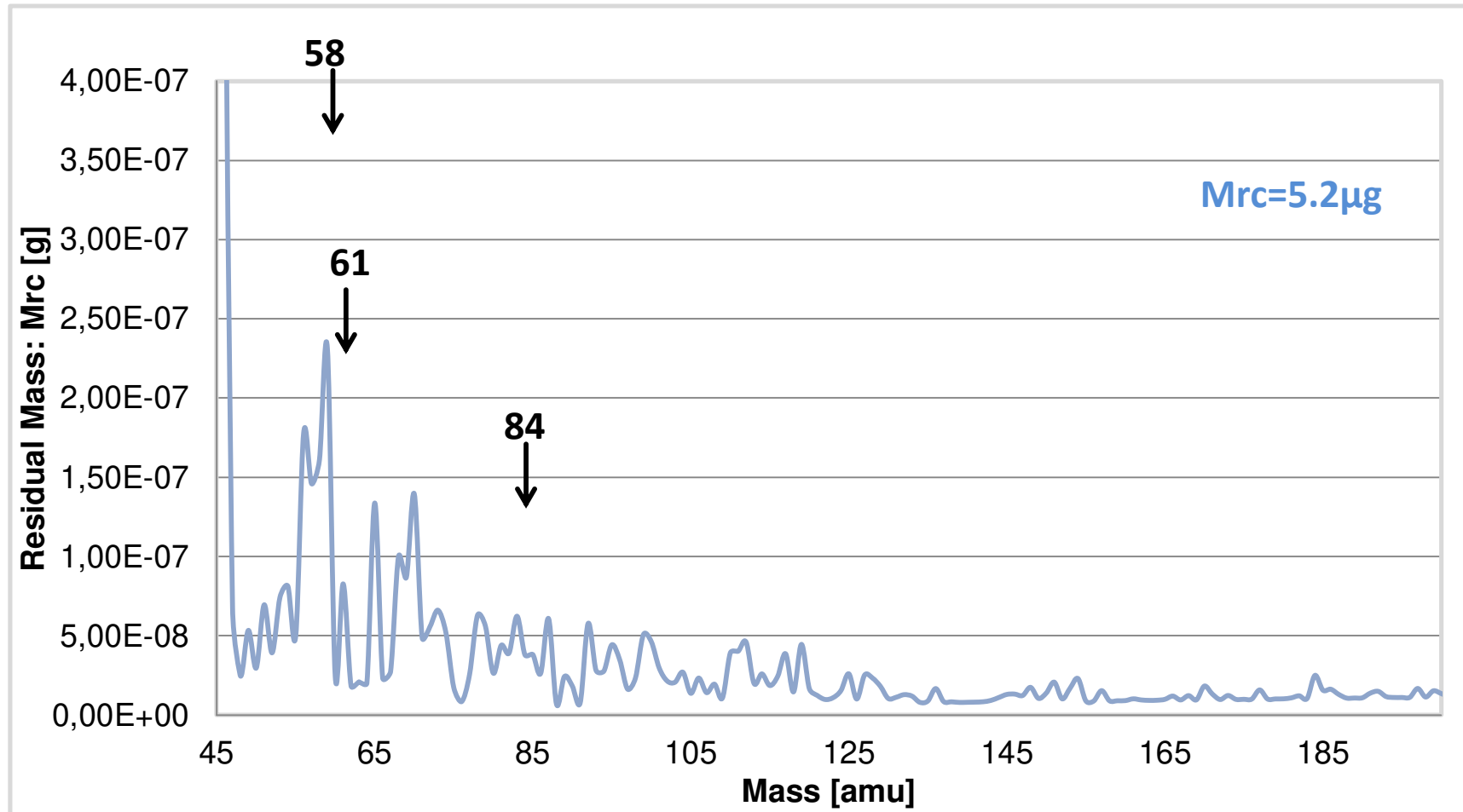
Stainless Steel – After 1 Reprocessing Cycle

Enzymatic Detergent



Stainless Steel – After 50 Reprocessing Cycles

Enzymatic Detergent



Total Residue Summary

Enzymatic Detergent

Timepoint	Titanium (µg)	Stainless Steel (µg)
Post Manufacturing	4.1	744
Simulated Passivation	N/A	48
1 Processing Cycle	2.0	3.2
50 Reprocessing Cycles	9.7	5.2
Acceptance Criteria	500	500

- Evaluation of efficiency of cleaning processes including analysis of single steps
- Release of manufacturing lots of devices (implants)
- Incoming inspection
- Analysis of residual sterilants
- Analysis of reprocessed devices
- Qualification of packaging materials and processes
- Cleaning of delicate devices
- Together with cytotoxicity testing definition of acceptance criteria for residual contamination

Conclusion - VIDMS

- Innovative method to measure residues on complex devices
- Appropriate „extraction“ and analysis for device surface residual characterization
- Relation to other methods of characterization to be investigated

Work funded by:
No. 144131



- Further Test Plan in the Research Project
 - Confirmation of the cytotoxicity results for alkaline and enzymatic detergent
 - Extending the data base of fingerprints of more detergents
 - Tests on implants coming from loaner trays

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