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Quantitative PFAS Analysis in Medical Devices Using Triple Quadrupole LC/MS

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Introduction

Per- and polyfluoroalkyl substances (PFAS) are widely used in medical device materials due to their exceptional chemical stability, low friction, and biocompatibility. These properties are critical for ensuring performance and patient safety in applications such as catheters, blood collection devices, contact lenses, and implantable cardiovascular systems. However, the extreme environmental persistence of PFAS and growing evidence of potential health risks have driven increased global regulatory scrutiny.

With the U.S. EPA tightening reporting and oversight requirements and the European Union moving toward a near-total PFAS ban under REACH 2.0, manufacturers are accelerating the transition to PFAS-free, regulation-resilient materials.

Reliable, sensitive analytical methods are therefore essential to monitor PFAS throughout the medical device lifecycle, from raw material qualification to finished product evaluation.

This study presents a comprehensive analytical workflow for 73 native PFAS screening in medical device materials using UHPLC coupled with triple quadrupole LC/MS. The newly launched PFAS analysis UHPLC system, which is purpose-built at manufacturing, with a 1290 Infinity III High-speed pump, and a 1290 Infinity III Hybrid Multisampler for enhanced PFAS readiness and reduced background contamination.

Experimental

Calibration standards and consumables

73 PFAS analytes, 34 surrogate standards and two internal standards (ISTDs) were included in this work.

Calibration standards were prepared in methanol (MeOH), ranging from 0.01 to 50 µg/L with a constant concentration of 1 µg/L surrogates and ISTD added to each level. All consumables used in this study were evaluated and verified for PFAS suitability.

Instrumentation

An Agilent 6475 LC/TQ was used for target acquisition in negative ionization mode. PFAS were separated under 12 minutes using an Agilent ZORBAX RRHD Eclipse Plus C18 column (2.1 x 100 mm, 1.8 µm) installed on an Agilent PFAS analysis UHPLC–1290 Infinity III system, which aggressively reduced fluorinated materials in the flow path with minimizing background contamination. Its Hybrid Mulitsampler with Feed Injection enables large volume high organic injection.

Experimental

Table 1. LC pump conditions and Hybrid Multisampler program

Parameter	Setting			
Mobile Phase A	5 mM ammonium acetate in water			
Mobile Phase B	100% MeOH			
Gradient	Time/min	%A	%B	Flow (mL/min)
	0	95	5	0.4
	1	85	15	0.4
	1.5	45	55	0.4
	5.5	30	70	0.4
	7	20	80	0.4
	12	0	100	0.4
	14.4	0	100	0.4
	14.5	85	15	0.4
Stop Time	14.5 minutes			
Post-time	2.5 minutes			
Hybrid Multisampler program				
Injeciton mode	Feed			
Injection volume	30 µL			
Feed speed	Adaptive, 10% of pump flow			
Flush out mode	Automatic			
Injection path cleaning	Inner wash mode: Extended			
	Outer wash mode: Extended			
	Step	Task	Solution	Duration/Volume
	Draw Sample			
	1	Outer wash	S1 = 50:50 ACN:IPA	15 s
	2	Outer wash	S3 = 100% MeOH	15 s
	Injection			
	1	Inner wash	S1 = 50:50 ACN:IPA	150 µL
	2	Inner wash	S3 = 100% MeOH	150 µL
	3	Seat wash	S1 = 50:50 ACN:IPA	150 µL
	4	Seat wash	S3 = 100% MeOH	150 µL
	5	Reconditioning	S2 =95:5 MPA:MPB	

Sample preparation

Medical device samples—IV tubing, blood collection tubes, and syringes—underwent methanol extraction followed by heat- and ultrasound-assisted (HUA) treatment, filtration and LC/TQ analysis (Figure 1). Matrix-spiked quality control (QC) samples at 1 µg/kg (LSQ), 10 µg/kg (MSQ), and 100 µg/kg (HSQ) were performed in triplicates to evaluate method LOQs, recovery and reproducibility.

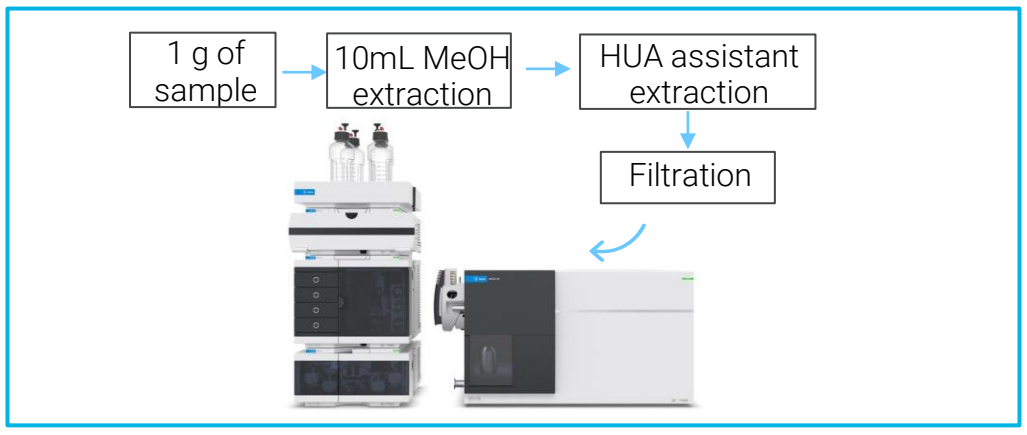

Figure 1. Agilent PFAS analysis UHPLC coupled with 6475A LC/TQ. (note: 10 times dilution was involved.)

Results and Discussion

Ultra-low PFAS background

Achieving ultra-low background levels is critical for PFAS analysis, as contamination introduced by the analytical system, solvents, or sample preparation steps can directly impact method sensitivity.

Figure 3 presents a total ion chromatogram (TIC) overlay of the solvent blank (MeOH) and calibration standard 1 (Cal 1). Solvent blank exhibited negligible PFAS background signals, demonstrating that the PFAS analysis UHPLC effectively minimized background contamination, and is well suited for ultra-trace-level PFAS analysis.

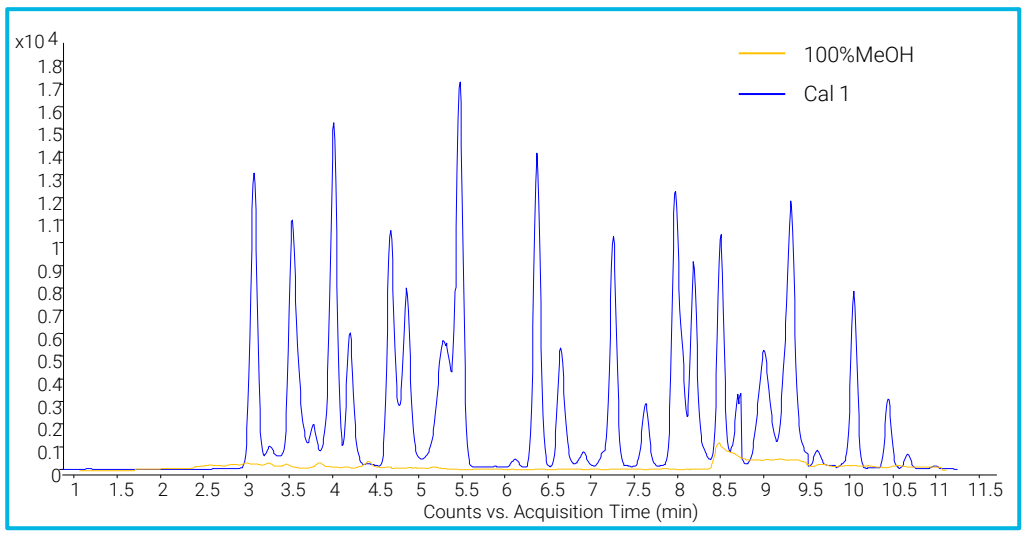

Figure 2. TIC overlay of solvent blank (100% MeOH) and calibration standard 1 with 30µL Feed Injection.

Feed Injection optimization

PFAS analysis UHPLC was equipped with Hybrid Multisampler, enabling Feed Injection of large volume test solution in 100% organic solvent. In this study, calibration standards and sample extract were prepared in MeOH. Injection volume and feed speed were optimized during method development. Figure 3 and 4 show chromatogram performance with different injection volumes for early eluted and late eluted compounds, respectively.

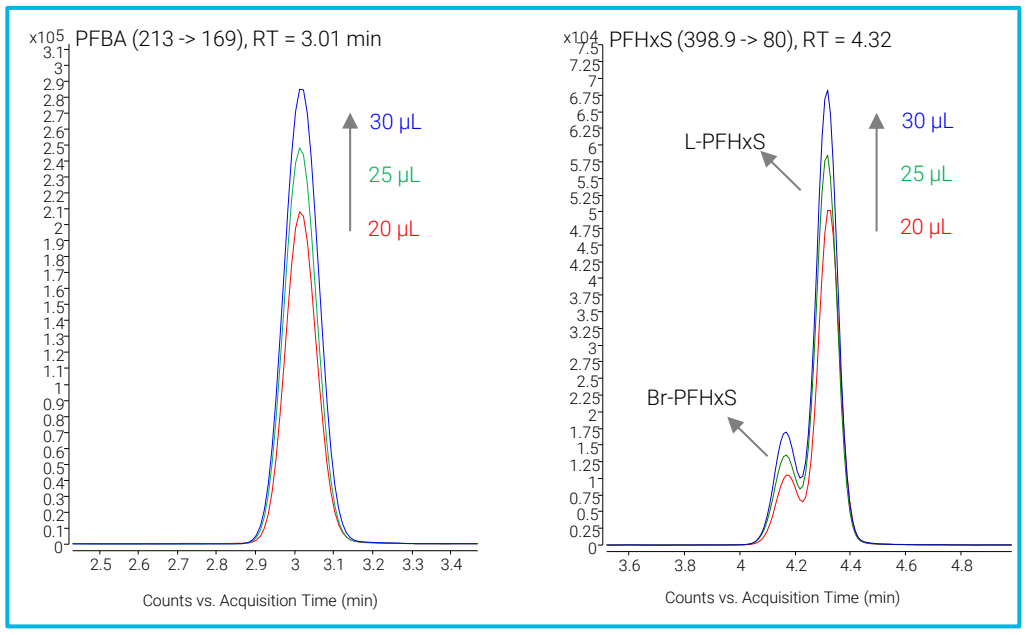

Figure 3. Feed Injection volume optimization for early eluted compound PFBA and PFHxS.

Feed Injection optimization

Perfect peak shape and high abundance were achieved for all the analytes with the injection volume of 30 µL and pump flow at 10%.

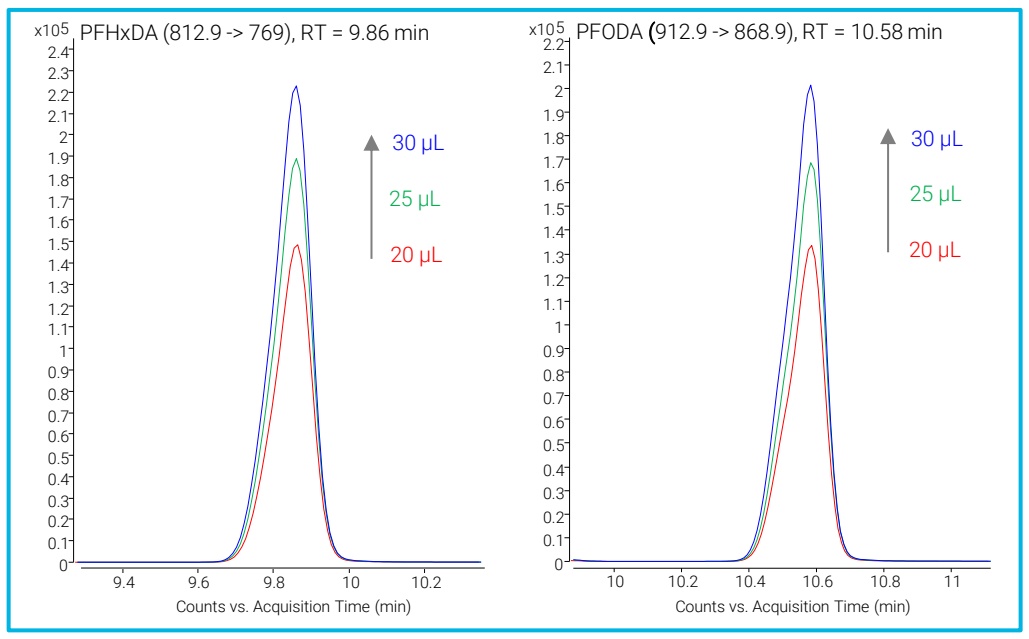

Figure 4. Feed Injection volume optimization for late eluted compound PFHxDA and PFODA.

Calibration performance

All 73 analytes demonstrated excellent linearity with $R^2 > 0.992$ across a minimum of five calibration levels (2-3 orders of magnitude). Surrogate recoveries ranged from 70–130%, and ISTD response RSD was ≤ 20% throughout the batch analysis.

Figure 5 shows representative calibration curves for four key compounds–PFOA, PFNA, PFOS and PFHxS, covered from EPA, EU and other regulatory lists.

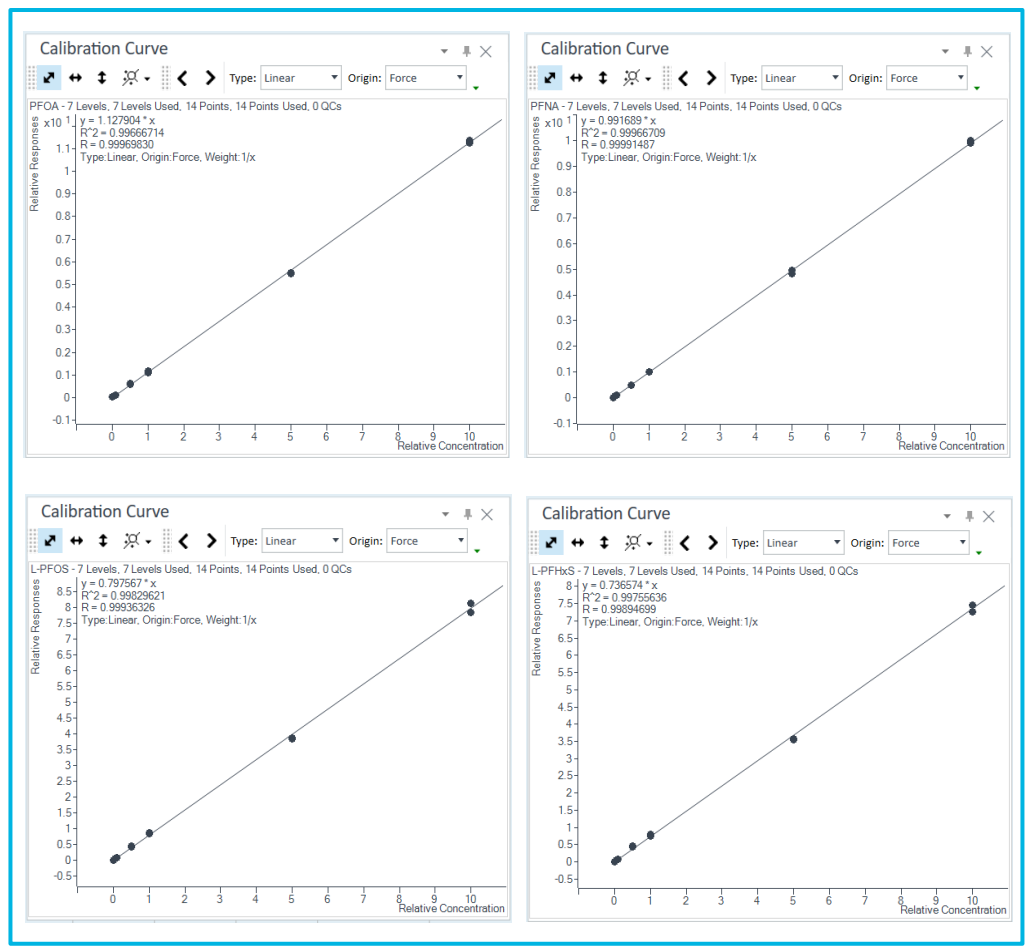

Figure 5. Calibration curve for PFOA, PFNA, PFOS and PFHxS.

Results and Discussion

Method sensitivity–LOQs

Method LOQs were established based on matrix-spiked QC levels (LSQ, MSQ and HSQ), while simultaneously fulfilling compound identification criteria. Method LOQs distribution is illustrated in Figure 6. In total, 64 out of 73 targets obtained LOQs at 1 µg/kg, including all 40 mandatory PFAS listed in EPA Method 1633 for multiple environmental matrices, confirming high sensitivity of the workflow for PFAS quantitation in medical device materials using the PFAS-ready LC/TQ system.

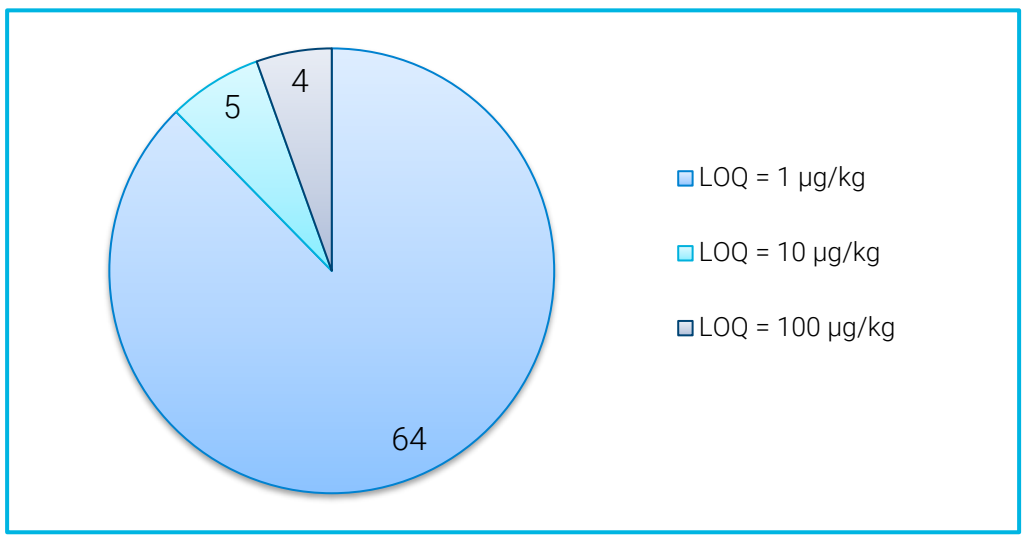

Figure 6. Method LOQs distribution for all analytes.

Extraction efficiency–QC recovery

Sample extraction efficiency was assessed using recoveries of LSQ, MSQ and HSQ. Over 87% of analytes demonstrated recoveries within the acceptable 65–135% range at all QC levels, indicating high extraction efficiency across diverse chemical class. Key compounds—including PFOA, PFOS, PFNA and PFHxS—obtained recoveries between 97-105%. Figure 7 displays the recoveries across all QC levels for the selected 20 compounds.

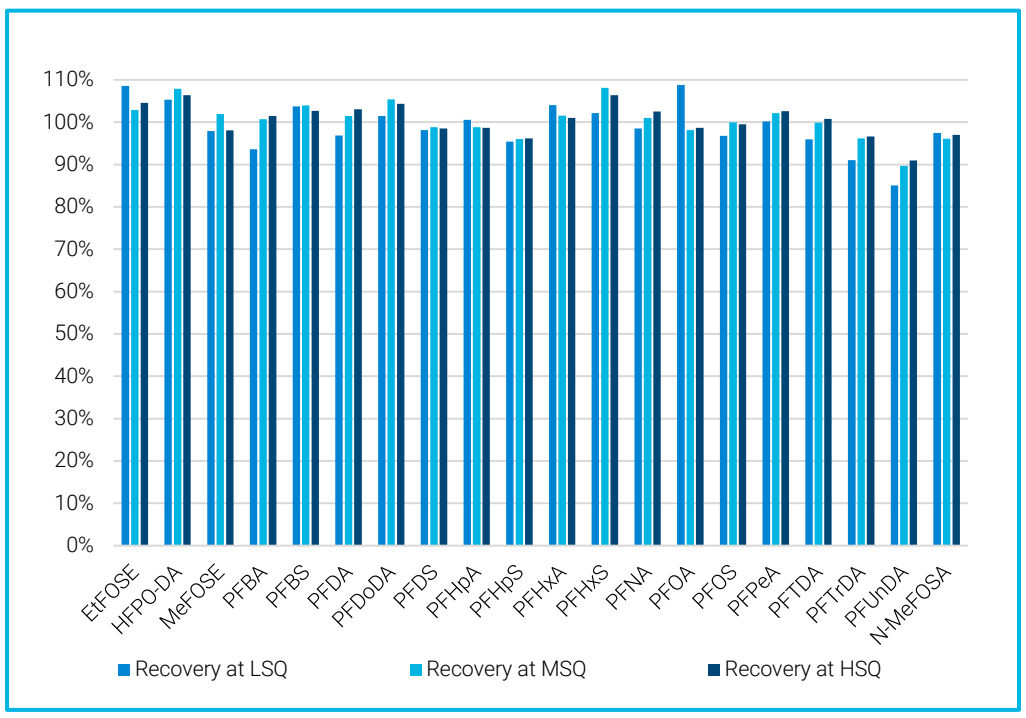

Figure 7. QC recoveries for selected 20 PFAS compounds.

Method reproducibility

Method reproducibility was evaluated based on the relative standard deviation of QC recoveries ((n = 6; three technical preparations with two injections per preparation) from each level. Notably, all analytes show %RSD below 20 across LSQ, MSQ and HSQ in Figure 8, demonstrating excellent reproducibility of the end-to-end workflow suitable for routine PFAS analysis in medical device materials.

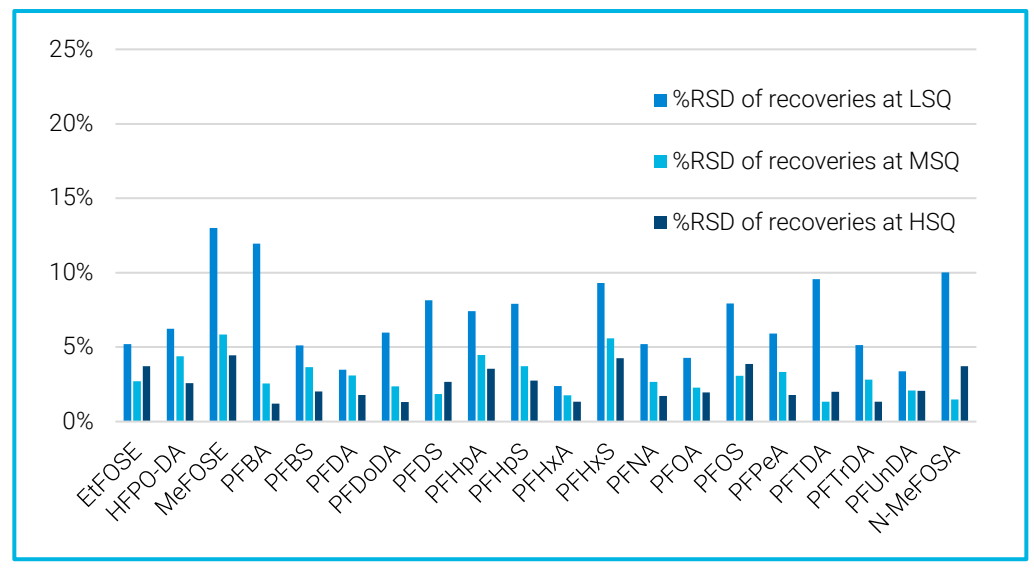

Figure 8. %RSD of recoveries across all QC levels for selected 20 PFAS compounds.

Conclusions

- Streamlined workflow: Employs a fast and straightforward protocol using heat and ultrasound-assisted (HUA) solvent extraction, boosting lab productivity.
- Ultra-low background and exceptional sensitivity: The Agilent PFAS analysis UHPLC–6475 TQ system delivered ultra-trace level of PFAS background and offered superior sensitivity at ppt levels for most analytes via Feed Injection, enabling precise quantification of PFAS in medical device materials.
- Reliable data for regulatory support: Validated analytical data provides strong evidence to regulatory bodies in establishing safe PFAS monitoring guidelines for industrial applications.

References

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2. ISO 10993-12 Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials, 2021. https://www.iso.org/standard/75769.html.

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