Accreditation of Complex Matrices: Gaps, Challenges, and Insights

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Bucharest, 26-27 May 2025
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What Are Complex Matrices?

- Highly variable over time and space
- Heterogeneous distribution of analytes
- Multi-component compositions
- Often contain interfering substances,
- Require special sample preparation and method validation strategies.

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Why Accreditation Matters in Complex Matrices?

- Ensures reliable results in unpredictable conditions;
- Demonstrates technical competence in handling challenging sample types;
- Builds trust with regulators, clients, and consumers;
- Strengthens traceability, method validation, and uncertainty estimation;

- Promotes continuous improvement in complex testing environments;
- Supports international recognition of results under ISO/IEC 17025.

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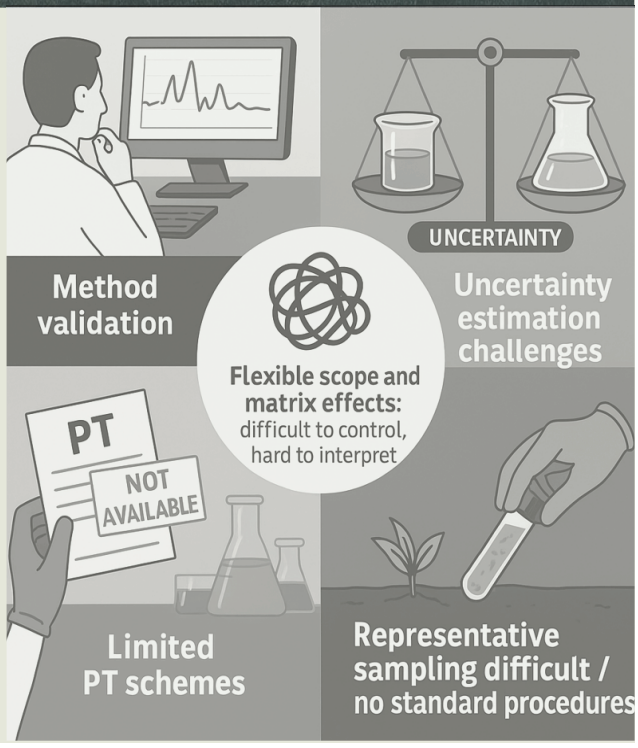
Challenges in Accrediting Complex Matrices

- Lack of standardized methods for complex matrices and non-routine analytes
- Difficulty in ensuring representative sampling and traceability
- Limited proficiency testing (PT) schemes and reference materials
- Complex estimation of measurement uncertainty
- Matrix effects impacting method performance
- Inconsistent interpretation of flexible scope accreditation



Understanding the Challenges of Accrediting Complex Matrices

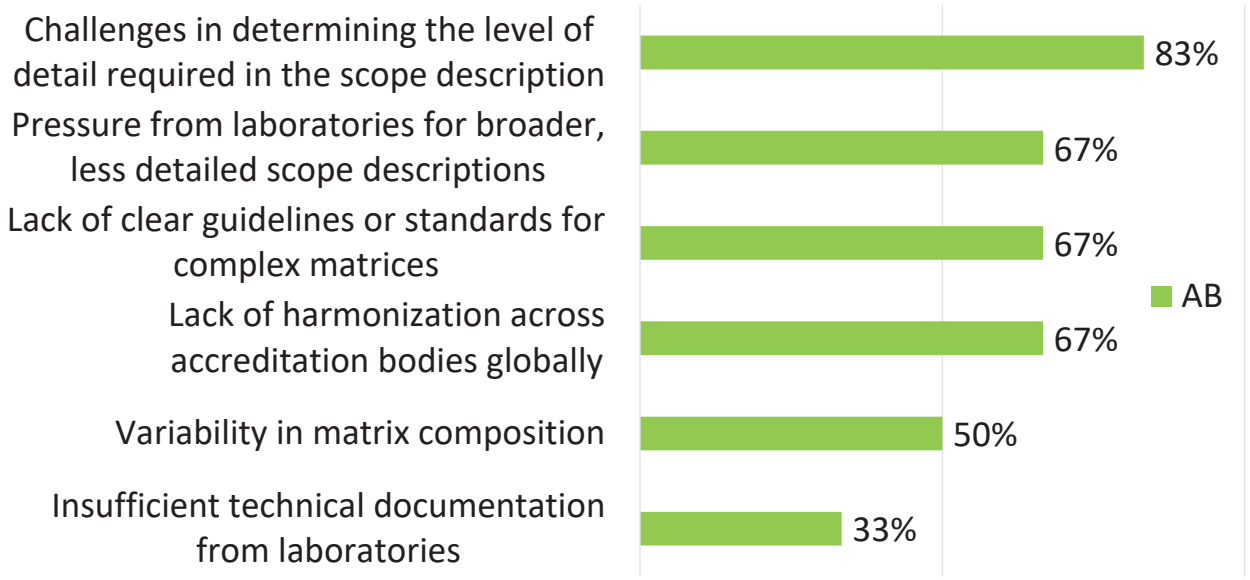
- Two structured surveys developed to explore key challenges
- One survey targeting testing laboratories with accredited complex matrix methods and another targeting accreditation bodies (ABs) assessing such laboratories
- Topics covered: sampling, method validation, uncertainty, PT schemes, reference materials, flexible scope, technical guidance
- 24 responses from ISO/IEC 17025-accredited laboratories
- 7 responses from ISO/IEC 17025 accreditation bodies

AB and Laboratory Profile and Sector Distribution

Type of Laboratories:	Main Sectors of Operation:	Type of AB
• 8 Private laboratories • 8 Public or Government laboratories • 7 University or research institutions • 1 Farmer association laboratory	• Food and agricultural matrices • Biological and medical matrices • Environmental matrices • Chemical and pharmaceutical matrices	• 7 AB all having test laboratory accreditation (ISO/IEC 17025) under their scope • Mainly members of European Accreditation.

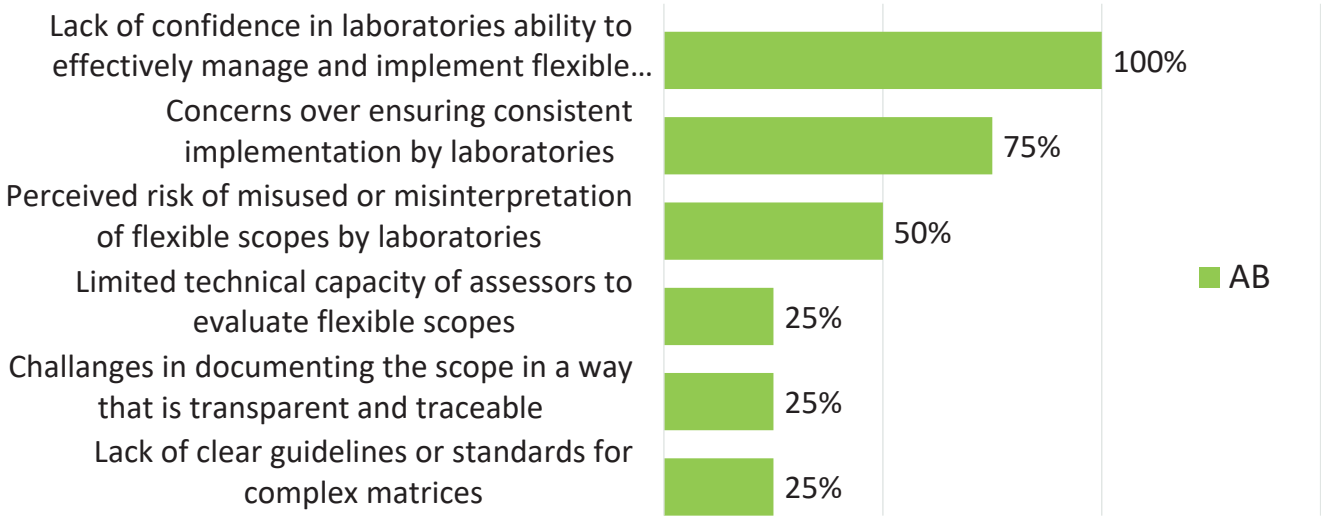
Defining the Scope for Complex Matrices: Key Challenges for ABs

5 AB reported difficulties in defining the scope for complex matrices. Key contributing factors:



Challenges on Implementing Flexible Scope Schemes by the AB

3 AB don't allow flexible scope in test accreditation. Their main concerns are:



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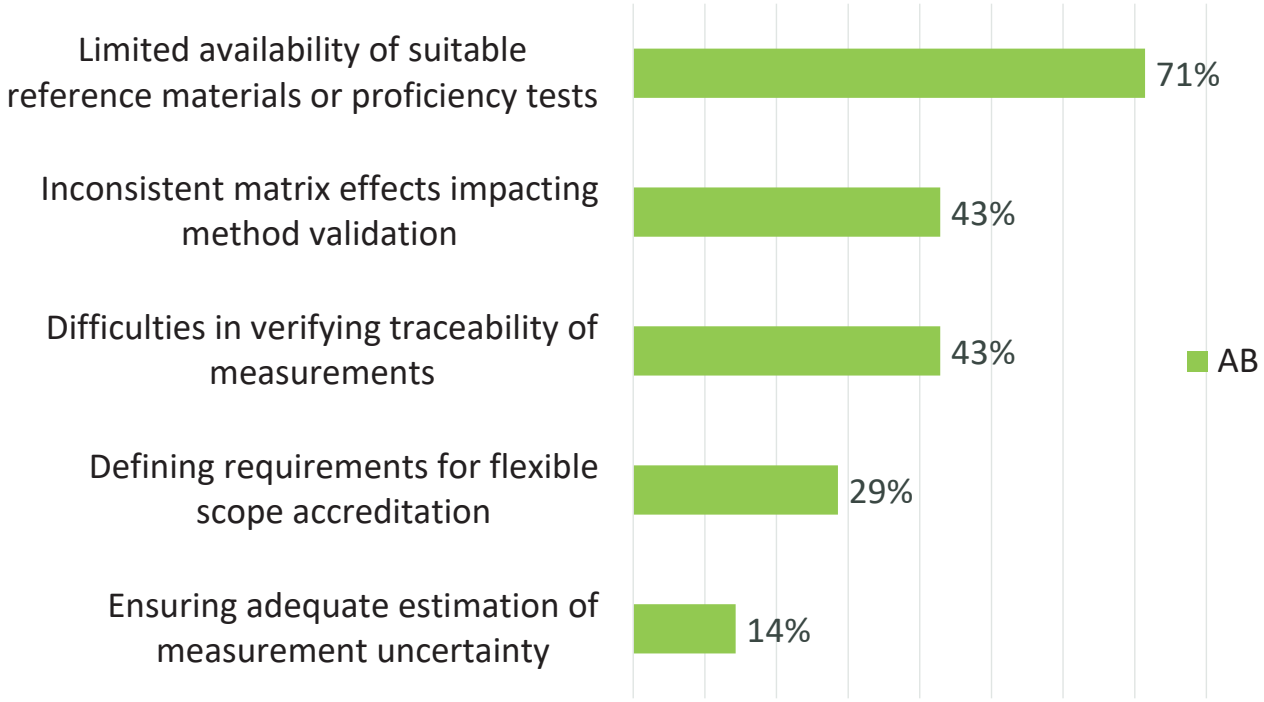
Main Challenges in Accrediting Tests for Complex Matrices - AB



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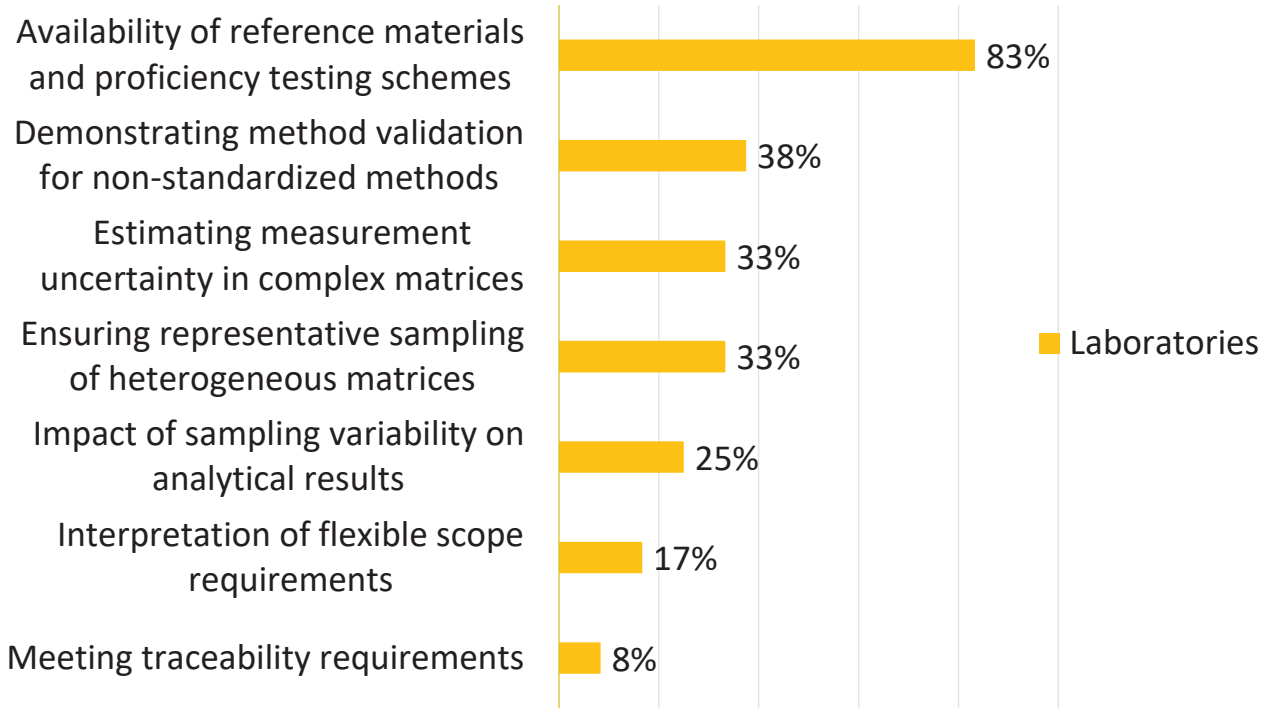
Main Challenges in Accrediting Tests for Complex Matrices - Laboratories



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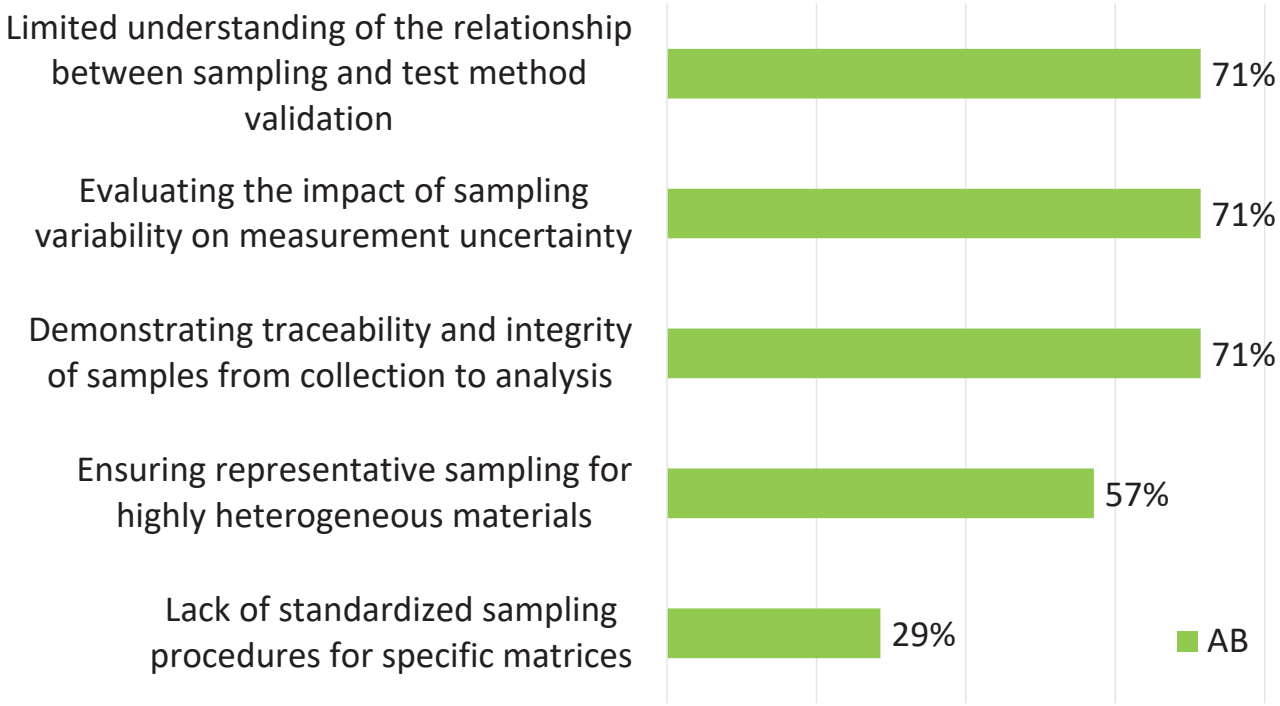
Accreditation Sampling Challenges in Complex Matrices – ABs' Perspective



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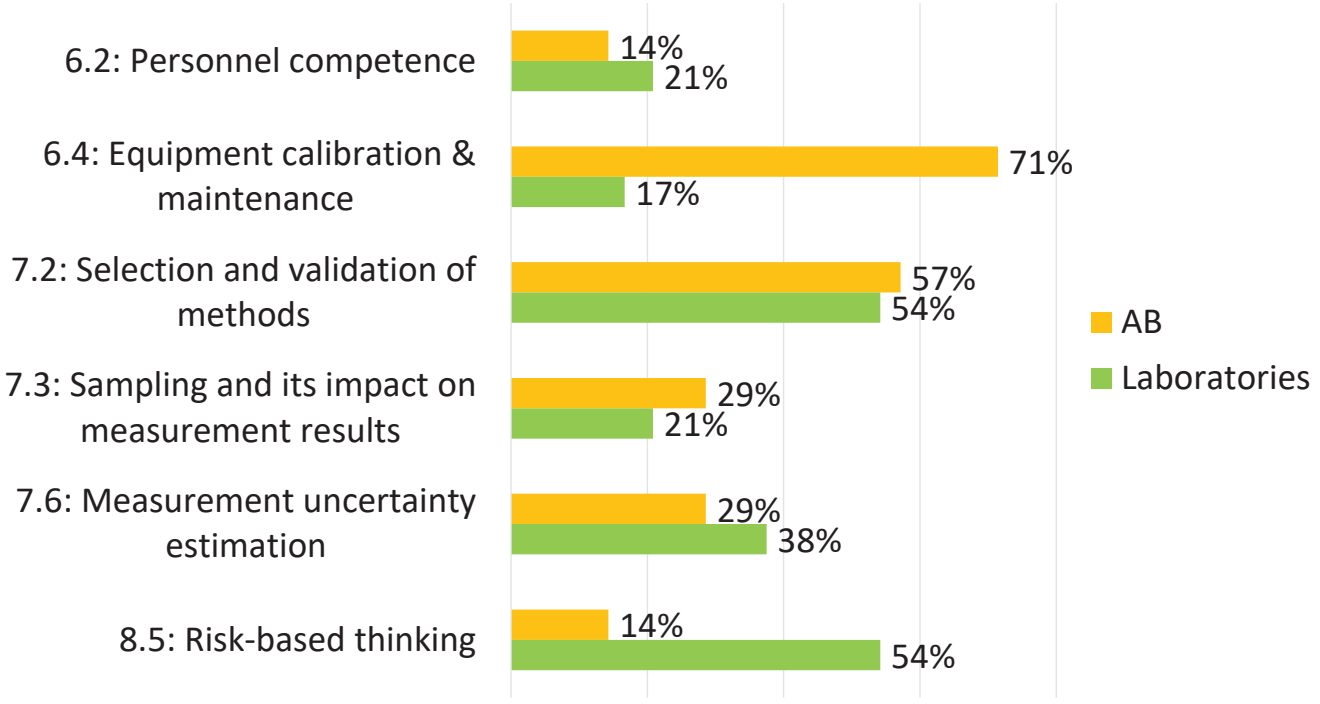
ISO/IEC 17025 Clauses Most Challenging in Complex Matrices



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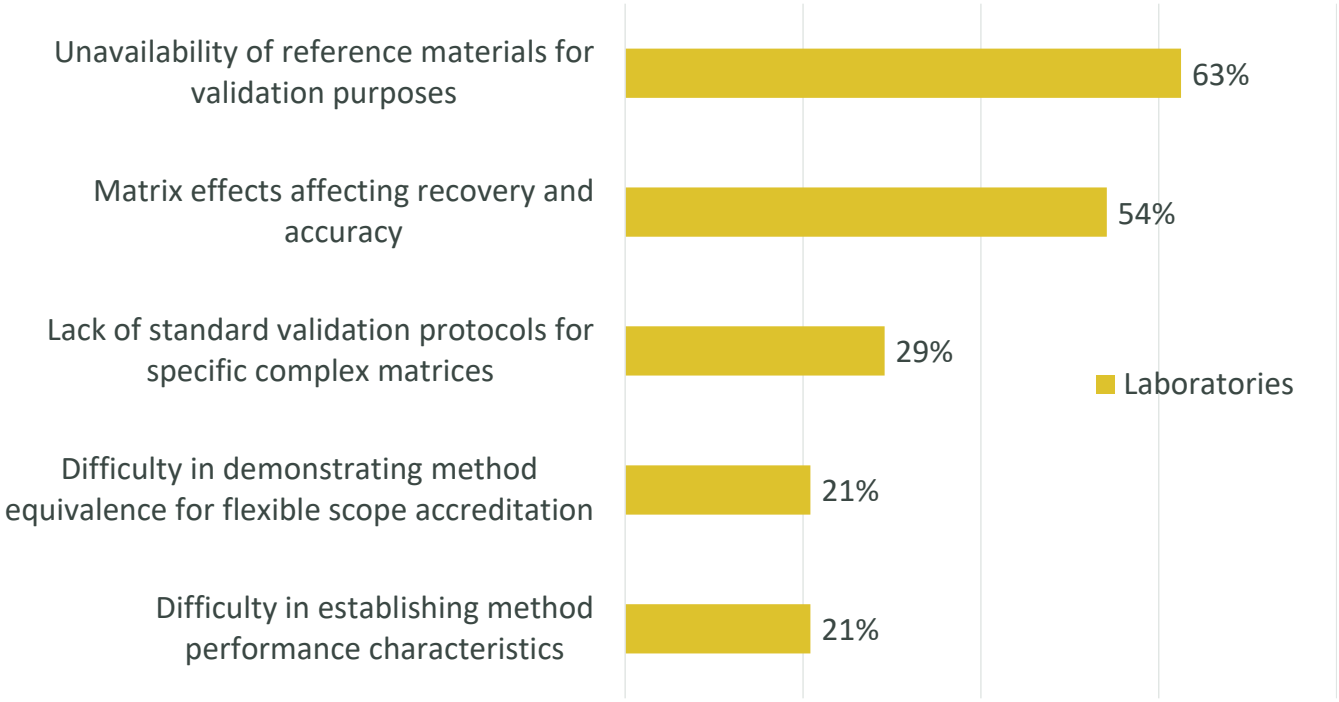
Main difficulties Faced by the Laboratories in Method Validation for Complex Matrices



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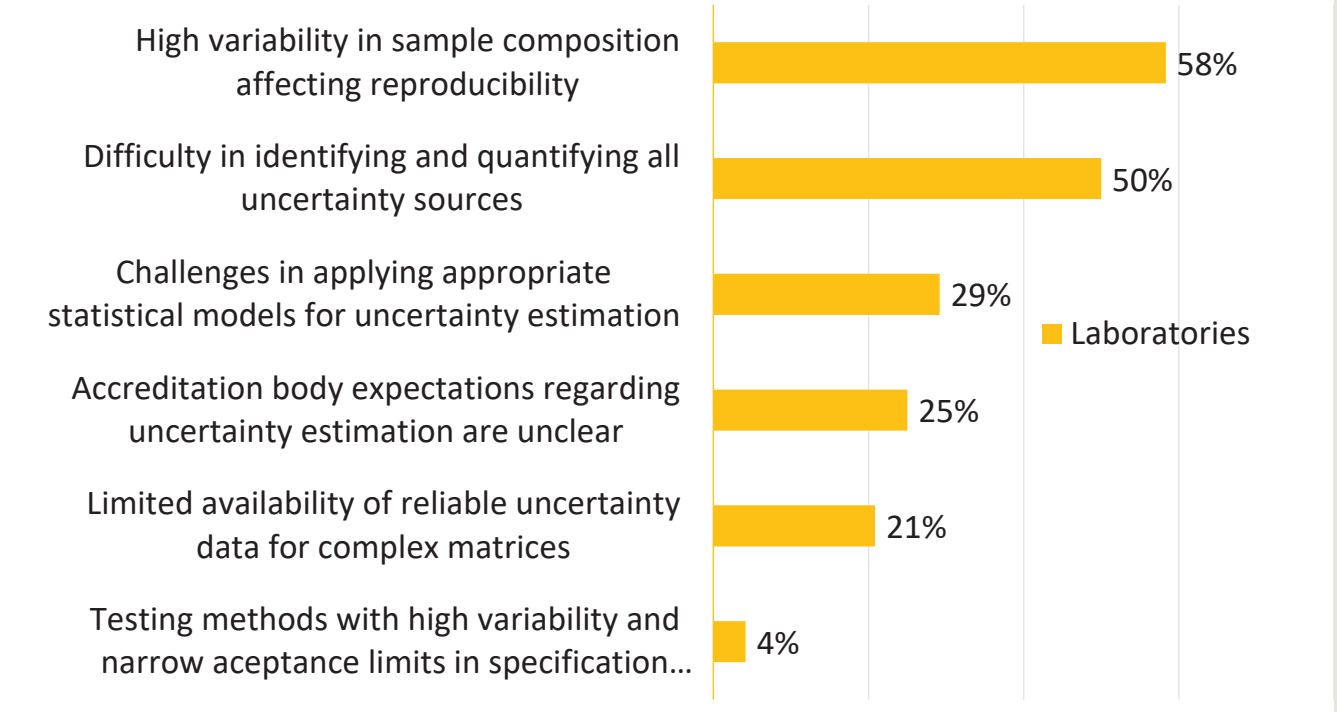
Key Issues Laboratories Face Regarding the Estimation of MU in Complex Matrices



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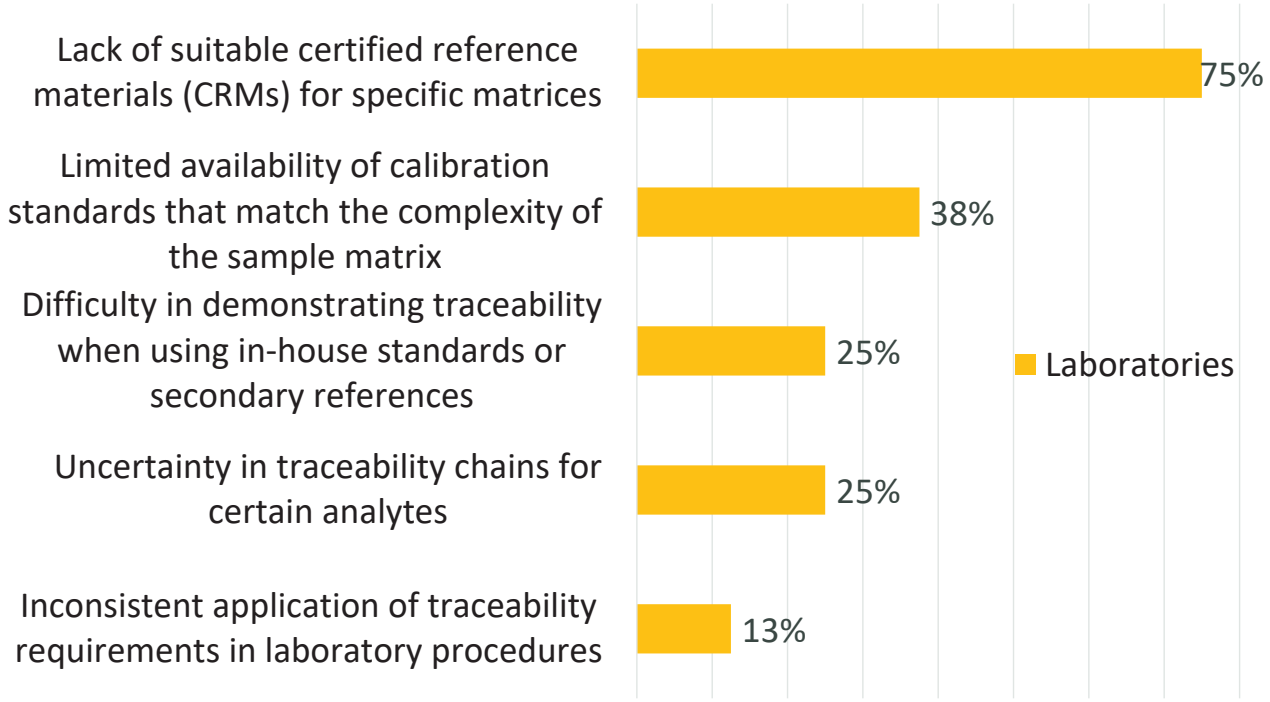
Key Issues Laboratories Face Regarding Metrological Traceability in Complex Matrices



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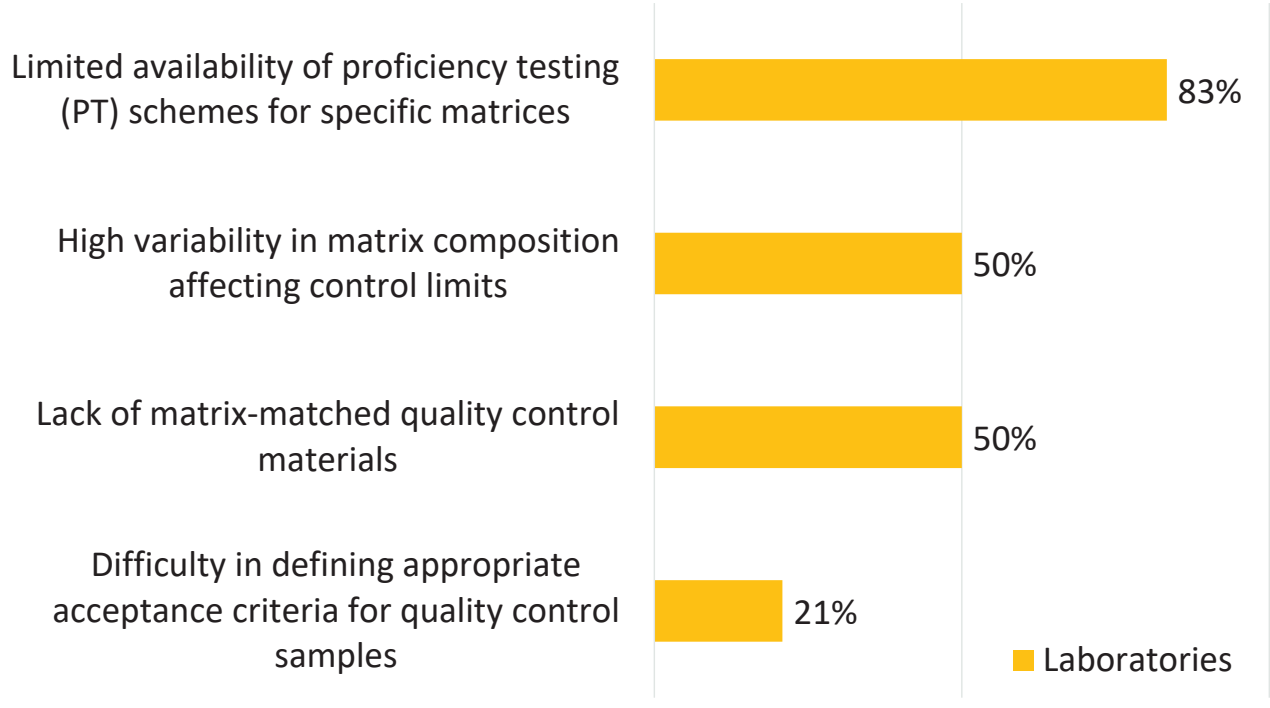
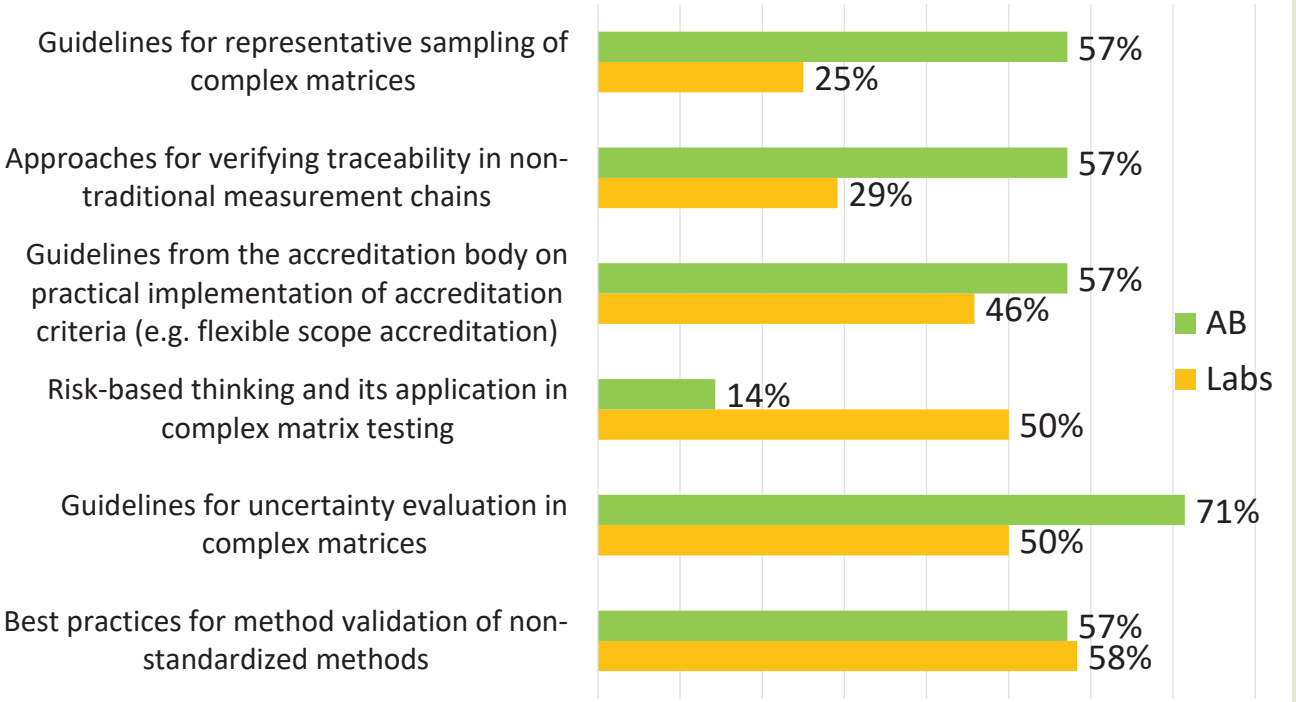
Key Issues Laboratories Face Regarding Quality Control in Complex Matrices



Technical Guides Identified by AB and Laboratories



Key Conclusions

- Accreditation of complex matrices presents shared challenges for both laboratories and accreditation bodies
- Uncertainty estimation, method validation, sampling, and traceability are consistent pain points
- Laboratories request more flexibility, while ABs emphasize the need for traceability and control
- Both groups agree on the lack of guidance and limited availability of PT schemes and CRMs

Recommendations for Moving Forward

- Develop sector-specific technical guides (sampling, validation, uncertainty and risk management)
- Expand and diversify PT schemes and CRM
- Encourage AB to promote flexible scope schemes with clearly defined rules.
- Facilitate collaboration between laboratories and accreditation bodies to harmonize expectations
- Facilitate cooperation amongst accreditation bodies to harmonize accreditation approaches to complex matrices and specific sectorial fields.
- Encourage training and capacity building focused on real-world matrix complexity

Thank you

Open for Questions & Discussion