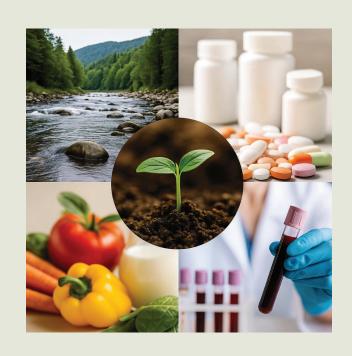






What Are Complex Matrices?

- 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.







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;



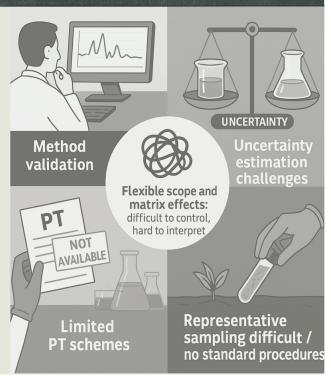
- Promotes continuous improvement in complex testing environments;
- Supports international recognition of results under ISO/IEC 17025.

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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:

- 8 Private laboratories
- 8 Public or Government laboratories
- 7 University or research institutions
- 1 Farmer association laboratory

Main Sectors of Operation:

- Food and agricultural matrices
- Biological and medical matrices
- Environmental matrices
- Chemical and pharmaceutical matrices

Type of AB

- 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 in determining the level of detail required in the scope description Pressure from laboratories for broader, less detailed scope descriptions

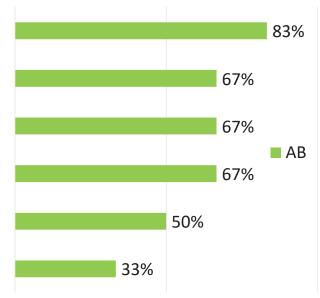
Lack of clear guidelines or standards for complex matrices

Lack of harmonization across accreditation bodies globally

Variability in matrix composition

Insufficient technical documentation

from laboratories



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Challenges on Implementing Flexible Scope Schemes by the AB

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

Lack of confidence in laboratories ability to effectively manage and implement flexible...

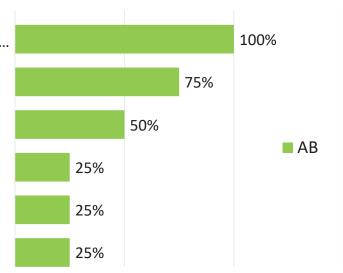
Concerns over ensuring consistent implementation by laboratories

Perceived risk of misused or misinterpretation of flexible scopes by laboratories

Limited technical capacity of assessors to evaluate flexible scopes

Challanges in documenting the scope in a way that is transparent and traceable

Lack of clear guidelines or standards for complex matrices







Main Challenges in Accrediting Tests for Complex Matrices - AB

Limited availability of suitable 71% reference materials or proficiency tests Inconsistent matrix effects impacting 43% method validation Difficulties in verifying traceability of 43% AB measurements Defining requirements for flexible 29% scope accreditation Ensuring adequate estimation of 14% measurement uncertainty

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Main Challenges in Accrediting Tests for Complex Matrices - Laboratories

Availability of reference materials and proficiency testing schemes

Demonstrating method validation for non-standardized methods

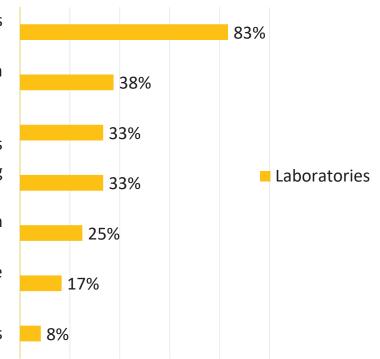
Estimating measurement uncertainty in complex matrices

Ensuring representative sampling of heterogeneous matrices

Impact of sampling variability on analytical results

Interpretation of flexible scope requirements

Meeting traceability requirements





Accreditation Sampling Challenges in Complex Matrices – ABs' Perspective

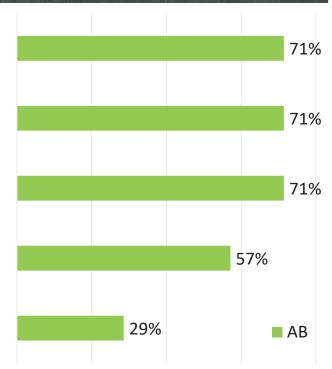
Limited understanding of the relationship between sampling and test method validation

Evaluating the impact of sampling variability on measurement uncertainty

Demonstrating traceability and integrity of samples from collection to analysis

Ensuring representative sampling for highly heterogeneous materials

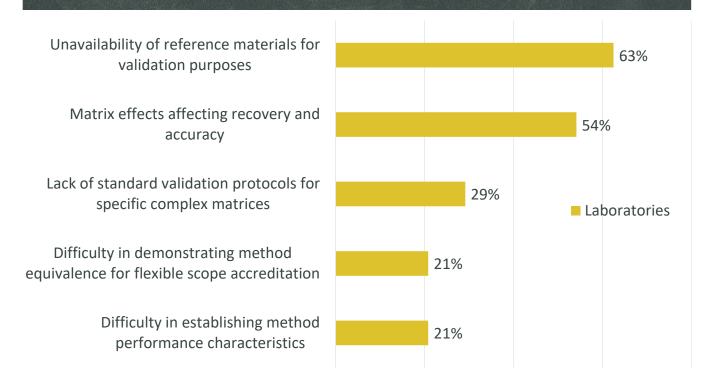
Lack of standardized sampling procedures for specific matrices



I Eurachem ISO/IEC 17025 Clauses Most **Challenging in Complex Matrices** 6.2: Personnel competence 6.4: Equipment calibration & 71% 17% maintenance 7.2: Selection and validation of 57% methods AB Laboratories 7.3: Sampling and its impact on 29% measurement results 7.6: Measurement uncertainty 29% 38% estimation 14% 8.5: Risk-based thinking



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



I Eurachem Key Issues Laboratories Face Regarding the **Estimation of MU in Complex Matrices** High variability in sample composition 58% affecting reproducibility Difficulty in identifying and quantifying all 50% uncertainty sources Challenges in applying appropriate 29% statistical models for uncertainty estimation Laboratories Accreditation body expectations regarding 25% uncertainty estimation are unclear Limited availability of reliable uncertainty 21% data for complex matrices Testing methods with high variability and 4% narrow aceptance limits in specification...



Key Issues Laboratories Face Regarding Metrological Traceability in Complex Matrices

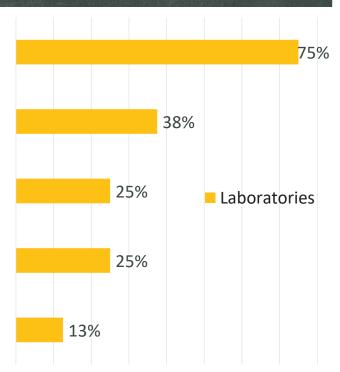
Lack of suitable certified reference materials (CRMs) for specific matrices

Limited availability of calibration standards that match the complexity of the sample matrix Difficulty in demonstrating traceability when using in-house standards or

Uncertainty in traceability chains for certain analytes

secondary references

Inconsistent application of traceability requirements in laboratory procedures



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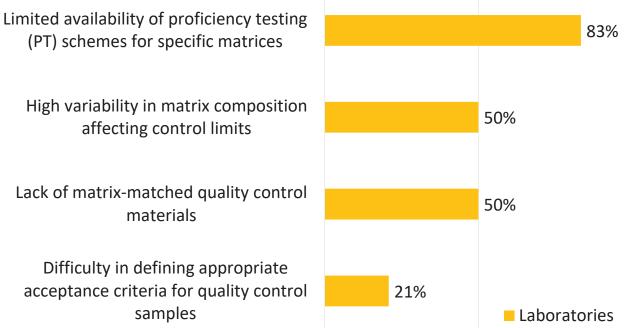
Key Issues Laboratories Face Regarding Quality Control in Complex Matrices

(PT) schemes for specific matrices

affecting control limits

Lack of matrix-matched quality control materials

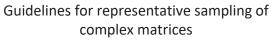
Difficulty in defining appropriate acceptance criteria for quality control samples







Technical Guides Identified by AB and Laboratories



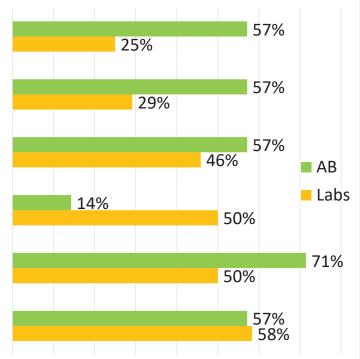
Approaches for verifying traceability in nontraditional measurement chains

Guidelines from the accreditation body on practical implementation of accreditation criteria (e.g. flexible scope accreditation)

Risk-based thinking and its application in complex matrix testing

Guidelines for uncertainty evaluation in complex matrices

Best practices for method validation of nonstandardized methods



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Key Conclusions

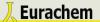
- Accreditation of complex matrices presents shared challenges for both laboratories and accreditation bodies
- Uncertainty estimation, method validation, sampling, and traceability are consistent pain points
- Laboratories request more flexibility, while ABs emphasize the need for traceability and control
- 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