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The Role of Biospecimen Science in the Development of Companion Diagnostics

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Biospecimens and the Molecular Diagnostic Development Pipeline

SPECIMEN VARIABILITY
- Failure to control collection variables
- Lack of evidence supporting biobanking practices
- Inadequate quality control metrics for biospecimens
- Failure to prioritize collection by pathologists and sponsors

Differential analyte stability

LOGISTICAL BARRIERS
- Matched samples unavailable
- Metastatic tissue unavailable
- Tissue not collected in accordance with clinical practice
- Informed consent standards are inconsistent
- Lack of financial support for specimen collection

Fewer samples available for R&D

Specimens of poor quality

Specimens that do not represent biology

Sample bias

THEN YOU CANNOT…

Identify markers

Develop and validate assays

Perform bridging studies

Accrue samples during clinical trials

Perform retrospective studies use samples from clinical trials

Meet requirements for regulatory approval

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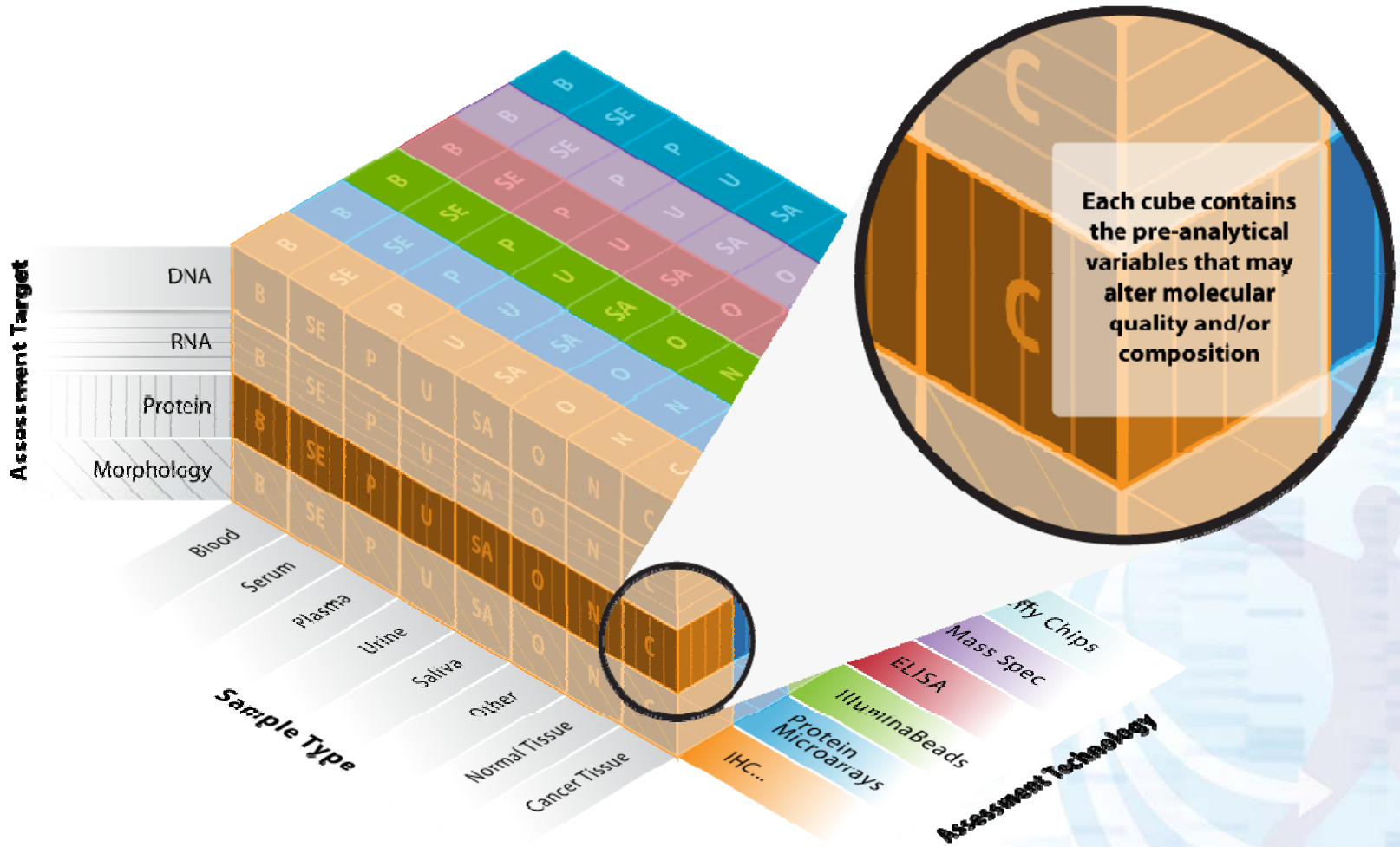
A Framework for Investigating the Pre-Analytical Variables That Affect Specimen Quality



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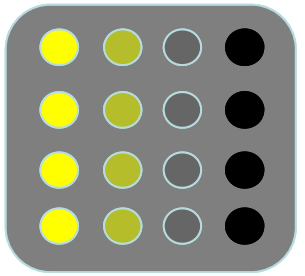
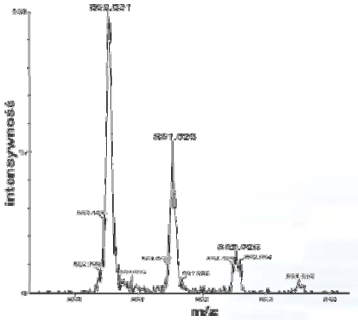
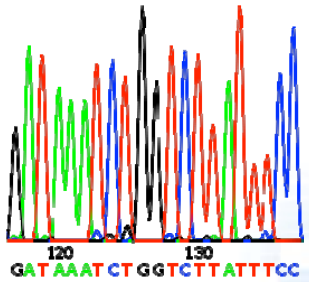
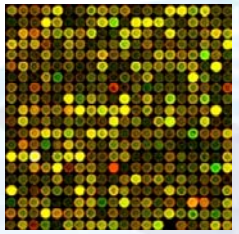
Design of a Biospecimen Science Project



Preanalytical variable







What happens to known analytes as preanalytical factors are varied?
Is there a molecular signature that identifies particular sample handling variables?
Is there a molecular signature that can provide a read-out of biospecimen quality?

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caHUB: A Resource for Biospecimen Science