



# Considerations around validation of methods for hybrid LC–MS/MS assays using non-primary matrices

## TRENDS IN HYBRID LC-MS/MS ASSAYS

What molecules do you analyze using hybrid LC–MS/MS?



#### What matrices do you use for hybrid assays?





44%

Urine



50% Tissue



Cerebral spinal fluid



For hybrid LC–MS assays, how frequently do you use surrogate matrices?



#### What process goes into how you select a surrogate matrix?



### **TRENDS IN VALIDATION FOR HYBRID ASSAYS**

Currently, do you believe industry-standard guidance for method development and validation for hybrid assays is:







None, ICH M10 does not require validation in non-primary matrices



Full validation, non-primary matrices should be treated the same as primary matrices



Qualification, non-primary matrices are not equivalent to primary matrices, but application of the method should be considered and some validation parameters should be established prior to sample analysis



I am not sure





Pharma | Biotech

11%

Private Research Foundation

4%

Vendor | Manufacturer

5%

Managing Director | Senior managing Dir

Student

1%

This infographic has been created as part of a Bioanalysis Zone feature in association with ICON.



