



DIFFERENT APPROACHES TO QUANTIFYING ENDOGENOUS BIOMARKERS IN BIOLOGICAL MATRICES

- The matrix used to prepare calibration standards should be as similar as possible to the study samples containing analytes
- In principle, when calibration standards are prepared using a surrogate matrix, it is necessary to simultaneously develop a bioanalytical method that is not influenced by the blank matrix
- To address suitability, the blank matrix should demonstrate:
 - Compatibility with the surrogate matrix showing precision and accuracy, recovery, and stability
 - No matrix effect or interference when compared to the biological matrix
 - Specificity from isomeric endogenous compounds
- For a ligand binding biomarker assay, it is important to determine whether the variability of the assay is within the scope of the intended use in order to define the appropriate acceptance criteria that will allow the measurement of the biomarker within the acceptable tolerability for the study