Reference methods and commutablereference materials for clinical measurements

Despite 60 to 70% of medical decisions are based on an in vitro diagnostic test, results are not always traceable to internationally recognized references. As different methods are available to measure the same biomarkers, results will not always be the same depending on the method used. Given that uncertainties are not always assessed and/or are too large, the consequence is that there is a doubt on results. To assess and improve the reliability and comprability of clinical measurements, the input of metrology is critical. While CRMs can help improving the agreement between the different methods through common calibration, assigning reference method target values to quality control materials makes it possible to monitor methods accuarcy. A prerequisite for this is however that calibrators and EQA materials be commutable, that is to say mimic real samples in an acceptable manner depending on their intended use. In this presentation, different examples will be taken to highlight the importance of reference methods and commutability in the field of clinical diagnostics and especially general biochemistry tests.

Reference measurement systems for biomarkers : towards biometrology

Absolute quantification of protein biomarker is made difficult by many factors. Indeed, the low amount of sample usually available, together with the complexity of biological matrices and the number of potential interferents makes it necessary to develop efficient purification techniques. As different isoforms can have different clinical significance, structural heterogeneity of proteins complicates the situation even further and requieres having highly specific quantification techniques. Through different case studies, this presentation will highlight a number of challenges associated with protein asbolute quantifcation but also the benefit of establishing traceability chains in clinical diagnostics.