Commutability, An Important Characteristic Of Reference Materials
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Title
Commutability, an Important Characteristic of Reference Materials

Purpose
Reference materials are key components for establishing and verifying the accuracy of measurements. They must meet certain criteria, including homogeneity and stability. Additionally, commutability is another critically important characteristic of reference materials. This presentation will provide an overview on commutability and its importance in clinical testing, and describes current challenges and activities for determining the commutability of a reference material.

Methods
In this overview, examples describing the importance and the impact of noncommutability will be described and strategies and approaches to determine commutability will be provided.

Results
The importance of commutability became apparent in situations where assays became inaccurate after calibration with a reference material. In these situations, the reference material is considered “non-commutable” and thus unsuitable for calibration or assessment of accuracy. Commutability is determined by assessing the closeness of agreement of measurement results between a routine method and a reference method measuring reference materials and patient samples. Ideally, reference materials show the same relationship as patient samples, in which case no bias is introduced when using this reference material as calibrator or trueness control. Non-commutability is frequently observed with matrix-based reference materials. These are produced by extensively modifying blood or using synthetic blood products and are used by assays optimized for measurements in unmodified patient samples. To present only little is known about factors affecting the commutability of a reference material. Thus, the commutability can neither be predicted nor extrapolated from one assay to another. To ensure that commutability is determined appropriately and consistently, standard protocols describing the experimental design and statistical data evaluation and interpretation are needed. The Clinical and Laboratory Standards Institute established such a protocol and the International Federation of Clinical Chemistry and Laboratory Medicine is currently working on developing an advanced protocol.

Conclusions
Commutability is an important characteristic of a reference material. Non-commutability, when not recognized, can lead to inaccurate, non-comparable patient results.