

SMALL SAMPLE SIZE CAPABILITY INDEX FOR ASSESSING VALIDITY OF ANALYTICAL METHODS

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Analytical method's capability evaluation can be a useful methodology to assess the fitness of purpose of these methods for their future routine application. However, care on how to compute the capability indices has to be made. Indeed, the commonly used formulas to compute capability indices such as Cpk , will highly overestimate the true capability of the methods. Especially during methods validation or transfer, there are only few experiments performed and, using in these situations the commonly applied capability indices to declare a method as valid or as transferable to a receiving laboratory will conduct to inadequate decisions.

In this work, an improved capability index, namely $Cpk-tol$ and the corresponding estimator of proportion of non conforming results ($\pi_{Cpk-tol}$) is proposed. Through Monte-Carlo simulations, they have been shown to greatly increase the estimation of analytical methods capability in particular in low sample size situations as encountered during methods validation or transfer. Additionally, the usefulness of this capability index is illustrated through several case studies.