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## Predicting Study Success in Diagnostic Test Evaluation: A Case Study Using Frequentist and Bayesian Approaches

In diagnostic test evaluation, agreement between a candidate method and a reference method is sometimes assessed using a composite comparator method when no gold standard is available. A composite comparator combines the results of multiple assays to derive a final adjudicated classification of the patients.

This work addresses the prediction of study success after a partial testing of an initial subset of the study population. Using a case study of an immunoassay In Vitro Diagnostic (IVD) test evaluation, we leverage the results of the initial testing to predict the outcomes in the remaining samples and quantify the probability of meeting predefined agreement criteria for the positive and negative percent of agreement (PPA/NPA).

Two complementary frameworks are considered: a frequentist approach based on confidence intervals for transition probabilities, and a Bayesian approach using beta-binomial posterior predictive distributions under different prior assumptions. Sensitivity analyses compare pessimistic, likely, and optimistic scenarios for the two frameworks. Additionally, a total probability framework computes the posterior predictive probability of achieving target performance criteria across all possible outcome combinations.

The methodology is illustrated for additional study settings to evaluate the robustness of the approaches, assessing the impact of sampling design, prior assumptions, and uncertainty quantification on decision-making in diagnostic development.

### Special/ Invited session

### Classification

### Keywords

Diagnostic test evaluation, decision-making under uncertainty, Bayesian inference, frequentist methods, sensitivity analysis

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