A Step Towards Fieldability: Validating the Analytical Performance of MeMed BV, a Host-Based Test for Differentiating Between Bacterial and Viral Infection, in Whole Blood Specimens

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Background:

Antibiotic overuse drives the emergence and spread of antibiotic resistant bacteria. Despite major advances in molecular diagnostics, differentiating bacterial and viral infections remains a challenge, leading to widespread overuse.

Capability Description: MeMed BV®

MeMed BV® is an FDA-cleared test for differentiating bacterial and viral infections from human blood samples. It is based on computational integration of the levels of three host proteins:

- TNF-related apoptosis-induced ligand (TRAIL)
- Interferon gamma-induced protein-10 (IP-10)
- C-reactive protein (CRP).

The test result is a score between 0 and 100 that correlates with increasing likelihood of bacterial infection (or co-infection).

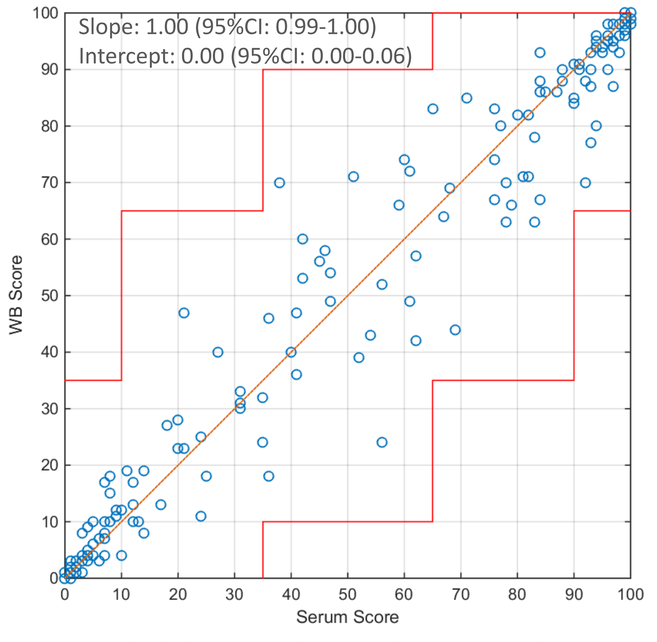
Here, we assessed the analytical performance of MeMed BV using whole blood (WB).

Methods:

Precision for each BV protein measurement and the score were assessed using 3 clinical WB samples representing bacterial, viral and equivocal scores. Each specimen was analyzed in four runs on five MeMed Key® analyzers. The study was performed in accordance with CLSI EP05-A3 Evaluation of Precision of Quantitative Measurement Procedures.

For matrix comparison, paired samples of serum and WB were collected from patients with suspected acute bacterial/viral infection. The study was performed in accordance with CLSI EP35Ed1E Assessment of Equivalence or Suitability of Specimen Types.

Limit of Quantitation was established based on CLSI EP17-A2 Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures.



Blue circles represent individual patient results, orange line represents the regression line, dashed orange line (masked by the regression line here) represents identity line (slope=1, intercept=0), individual results were averages of duplicates, red line marks the borders of non-adjacent bin scores.

Results:

Precision results passed the pre-determined acceptance criteria for the analytes and score. The range of the precision coefficient of variation was 4.6-6.9%, 3.1-5.8%, and 4.0-12.0% for TRAIL, IP-10 and CRP, respectively. The precision standard deviation for the score was 0.0-3.0 score units.

For **matrix comparison**, 216 patients were recruited, aged 1-92 years (median 42.0) and 45.8% female. Passing-Bablok regression analysis of test scores from serum versus WB yielded a slope of 1.00 (95% confidence interval, CI 0.99-1.00) and intercept of 0.00 (95%CI 0.00-0.06) fulfilling pre-defined acceptance criteria (Fig. 1).

Limit of Quantitation was established to be 1mg/L, 100 pg/mL, and 15pg/mL for CRP, IP-10 and TRAIL, respectively; the same values as for serum.

Conclusion:

MeMed BV analytical performance using whole blood (WB) is satisfactory.

Now that the BV test can be run on Key using WB specimens, this bacterial versus viral test can improve the management of acute infections and reduce antibiotic overuse in a wider range of acute care medical settings.

Impact to the Warfighter:

Implementation of BV at military healthcare settings has potential to greatly improve the management of acute infections and reduce antibiotic overuse. Introducing the newly developed WB product can bring the technology closer to the warfighter, as the need for blood processing is eliminated – saving critical time and effort, making the test more suitable to decentralized settings.

MeMed WB | | LinkedIn