Validating the Analytical Reproducibility of a New Chemiluminescence-based Point-of-need Platform for Multiplex Protein Measurements Across pg/ml To µg/ml Range: MeMed Key® and MeMed BV®

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Background:

MeMed BV® is a test for differentiating between bacterial and viral infection. It is based on computational integration of circulating levels of TNF-related apoptosis-induced ligand (TRAIL), interferon gamma-induced protein-10 (IP-10), and C-reactive protein (CRP). The test result is a score between 0 and 100 that correlates with increasing likelihood of bacterial infection, as established in multiple clinical validation studies. Precise and simultaneous measurement of these three proteins within minutes is a challenge as they range in concentration from pg/ml (TRAIL) to µg/ml (CRP). With this goal in mind, a chemiluminescence-based analyzer called MeMed Key was developed to run the BV test in 15 minutes.

Methods:

The reproducibility studies for each BV measurand and the score were conducted using a panel of 4 clinical serum samples representing infectious bacterial, infectious viral, equivocal and healthy scores. In total, 90 repeat runs were performed for each clinical sample over 5 non-consecutive days on six MeMed Key analyzers, located in three laboratories: Johns Hopkins University School of Medicine, Baylor College of Medicine (Texas Children's Hospital) and MeMed. Studies were performed in accordance with CLSI EP05-A3 Evaluation of Precision of Quantitative Measurement Procedures.

Location	Site 1 / Operator 1					Site 2 / Operator 2					Site 3 / Operator 3															
Analyzer	1					2					3					4					5					6				
Non-consecutive day	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5

Results:

The reproducibility results complied with the pre-established acceptance criteria for the score and individual analytes. The reproducibility coefficient of variation % range observed over the 4 samples was 9.7-12.7%, 4.6-6.2%, and 5.0-11.6% for TRAIL, IP-10 and CRP respectively. The reproducibility standard deviation range for the score was 0.4-9.4 score units.

Conclusions:

MeMed Key can quickly, precisely and in parallel measure proteins in the pg/ml-µg/ml range, supporting its applicability to patient triage. Future studies will address real world use of this platform and test.