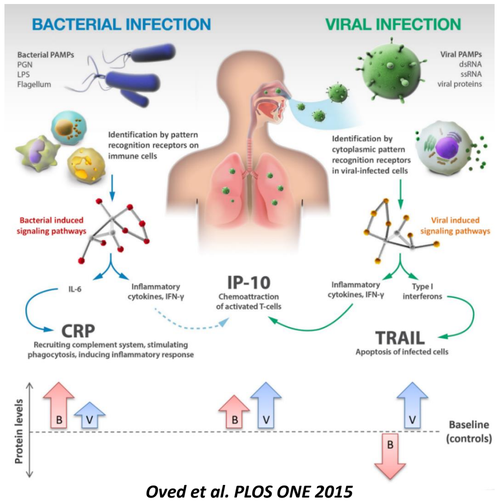
Adoption Of A Novel Host-protein Signature In The Workflow Of Acute Febrile Illnesses At Hillel Yaffe Medical Center

Michal Stein[1], Ma'anit Shapira[1], Kfir Oved[2], Asi Cohen[2], Roy Navon[2], Olga Boico[2], Meital Paz[2], Liat Etshtein[2], Ellen Bamberger[2,3], Eran Eden[2], and Adi Klein[1]

[1]Hillel Yaffe Medical Center, Hadera, Israel; [2]MeMed Diagnostics, Tirat Carmel, Israel;[3]Bnai-Zion Medical Center, Haifa

Background and design

1. A novel host-immune signature for distinguishing between bacterial and viral infections



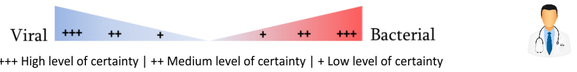
Oved et al. PLOS ONE 2015

2. ImmunoXpert™ - a new IVD assay that was independently validated in external double blind studies

Name	Type	Size	Population	Sensitivity	Specificity	Publication
Curiosity (2009-2013)	Prospective, development and validation	1,002	Adults and pediatrics	94%	93%	Oved et al, PLoS One 2015; Eden et al, JOI, 2016
Pathfinder (2012 – 2016)	Retrospective, external blinded validation	597	Pediatric	94%	90%	Srugo et al, Under review
Opportunity (2013 - 2016)	Prospective, external blinded validation	777	Pediatric	88%	93%	Houten et al, Lancet ID, 2016

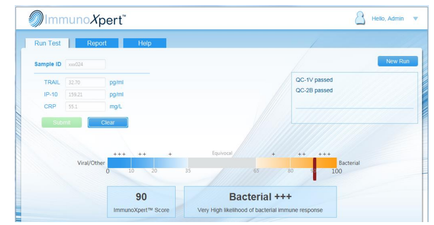
3. Study design

A) Presumed etiology specified by the managing physician



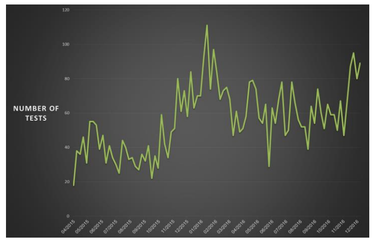
B) A reference standard diagnosis, retrospectively determined by three independent experts based on comprehensive clinical and laboratory investigation, including a nasal swab multiplex PCR panel

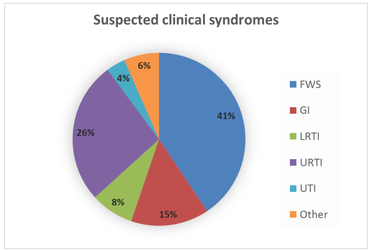
C) ImmunoXpert™ test result



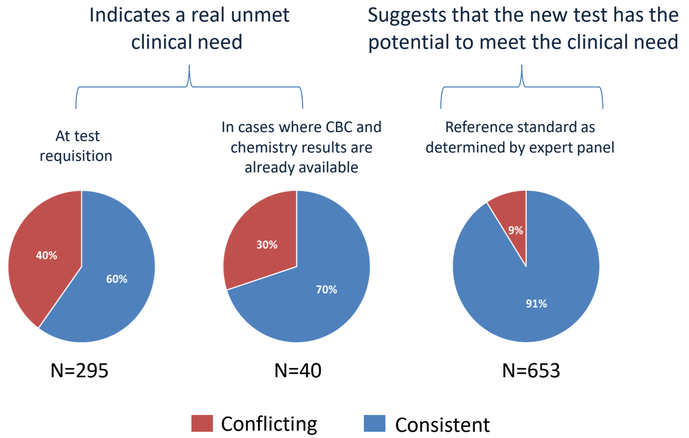
Results and conclusions

4. ImmunoXpert™ adoption curve in one pediatric department





5. Concordance rates of ImmunoXpert™ with physician's initial diagnoses and reference standard diagnoses



6. Conclusions

ImmunoXpert™ is a novel host-based assay that was successfully incorporated into routine care in our department. The higher concordance rate (91%) of the assay with reference standard diagnoses in comparison to the managing physician's initial assessment (60%) suggests that the assay may facilitate timely and accurate diagnosis of acute infections, even before molecular and microbiological results are available. Accordingly, the assay may enhance clinical utility by reducing diagnostic testing and antibiotic misuse.

Corresponding author:
Michal Stein, MD
michals@hy.health.gov.il

27th ECCMID

ESCMID