#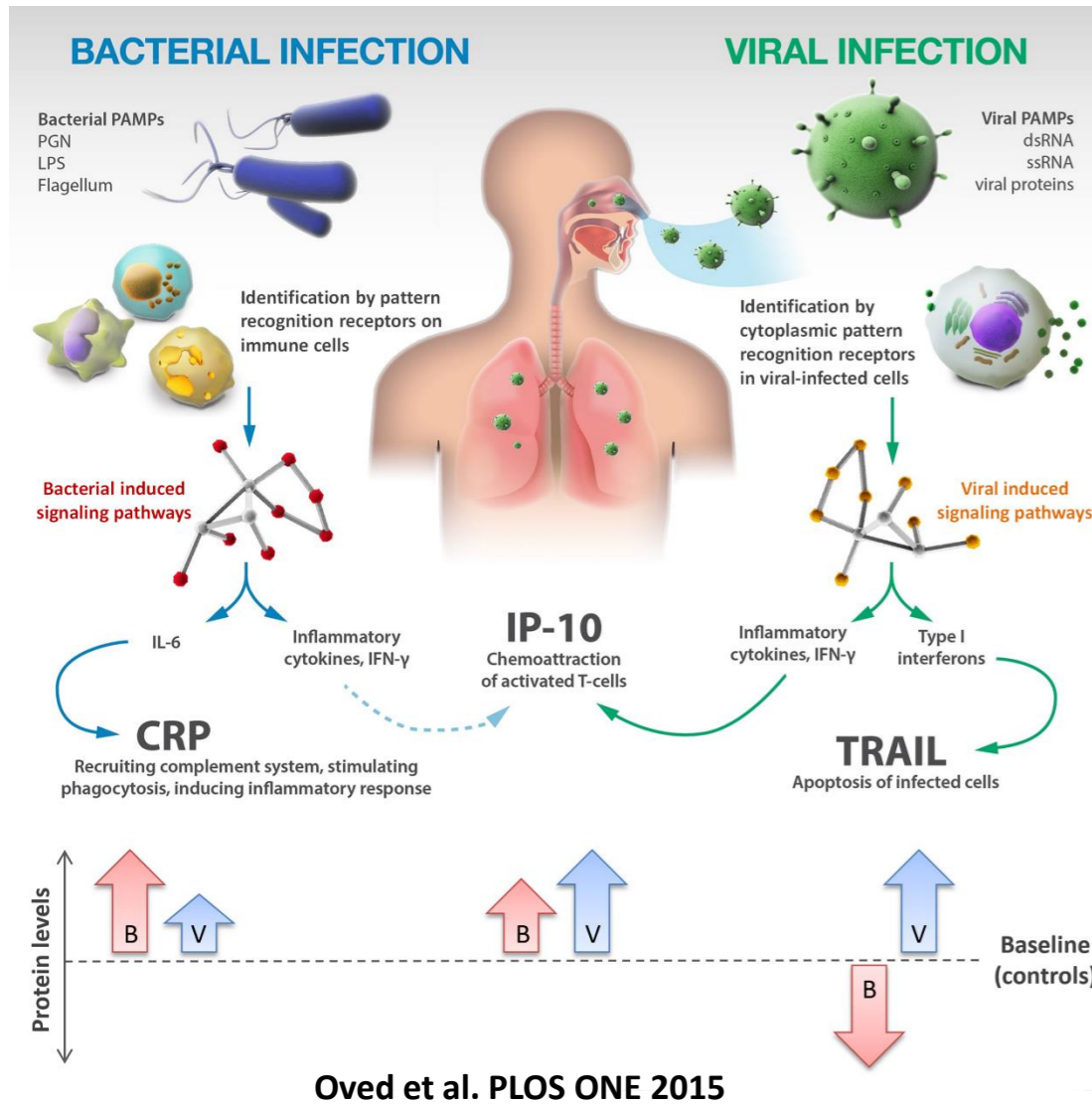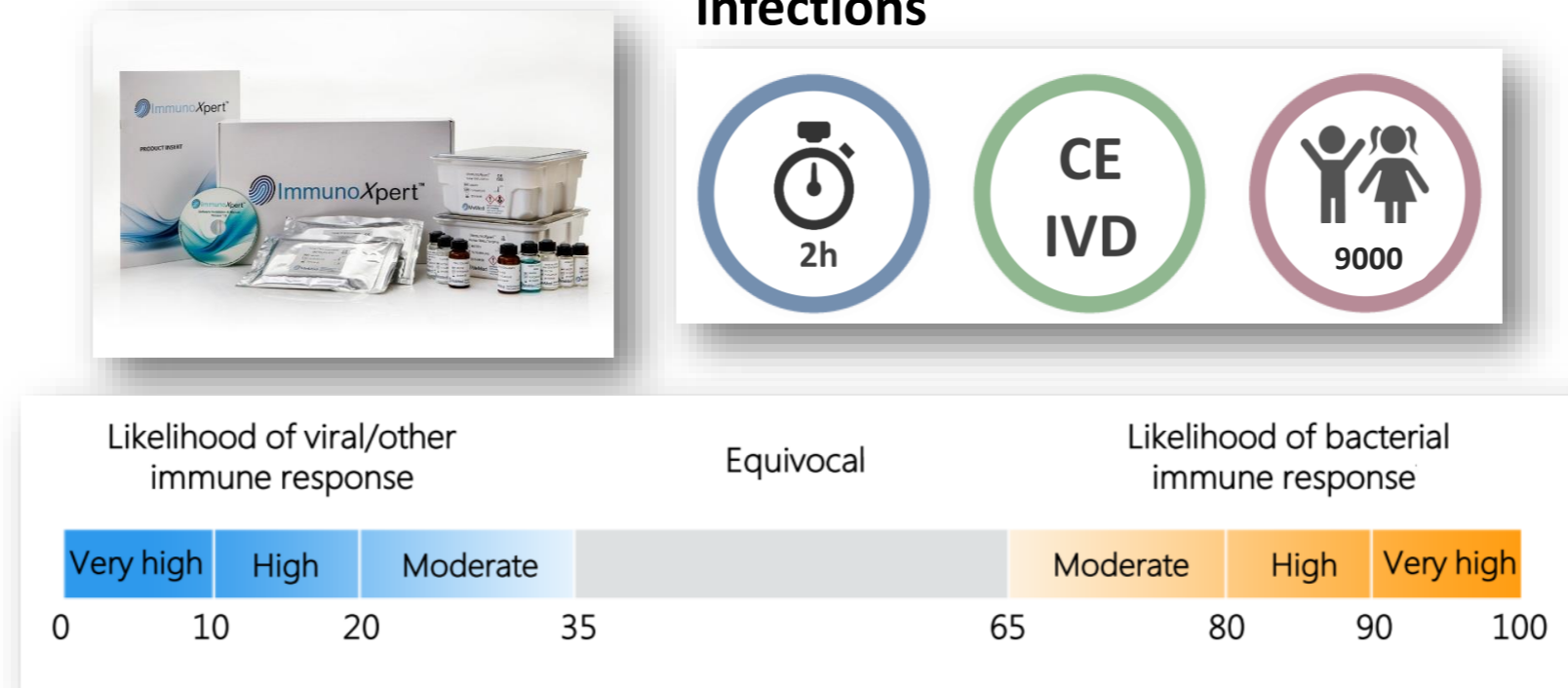 EVALUATING A NOVEL HOST-IMMUNE BASED ASSAY FOR DISTINGUISHING BACTERIAL FROM VARIOUS VIRAL INFECTIONS IN FEBRILE CHILDREN

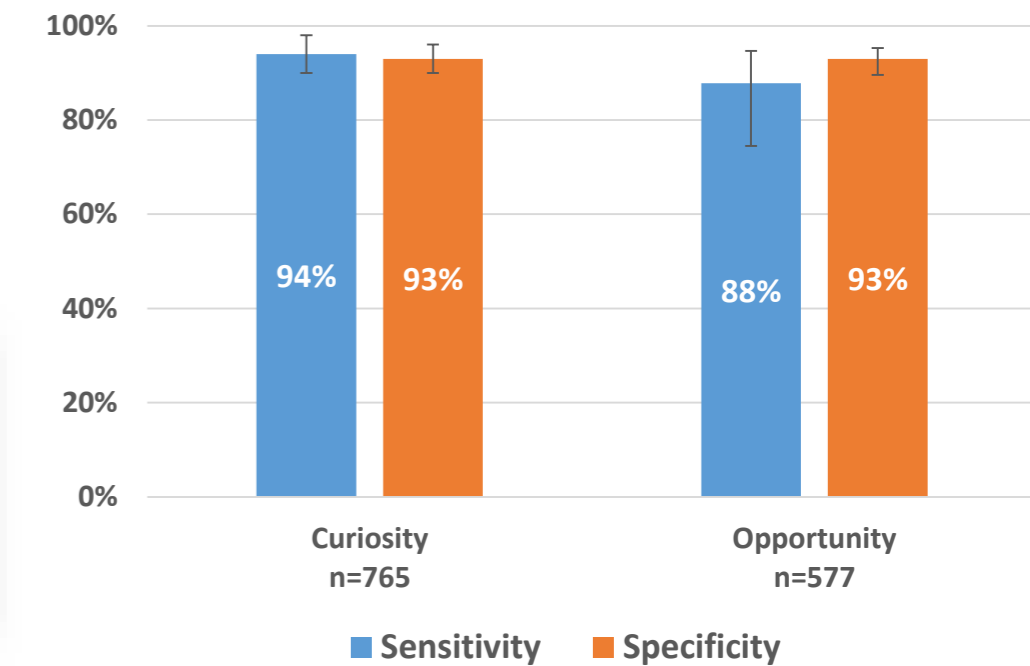Eran Eden[a], Isaac Srugo[b,c], Asi Cohen[a], Roy Navon[a], Olga Boico[a], Tanya Gottlieb[a], Ellen Bamberger[a,b,c], Meital Paz[a], Liat Etshtein[a], Liran Shani[a], Michal Stein[d], Adi Klein[d] and Kfir Oved[a]

[a]MeMed Diagnostics, Tirat Carmel, Israel, [b]Bnai-Zion Medical Center, Haifa, [c]Technion – Israel Institute of Technology, Haifa, Israel, [d]Hillel Yaffe Medical Center, Hadera, Israel.

Background

1. A novel host-immune signature

Oved et al. PLOS ONE 2015

2. A new IVD assay for distinguishing between bacterial and viral infections

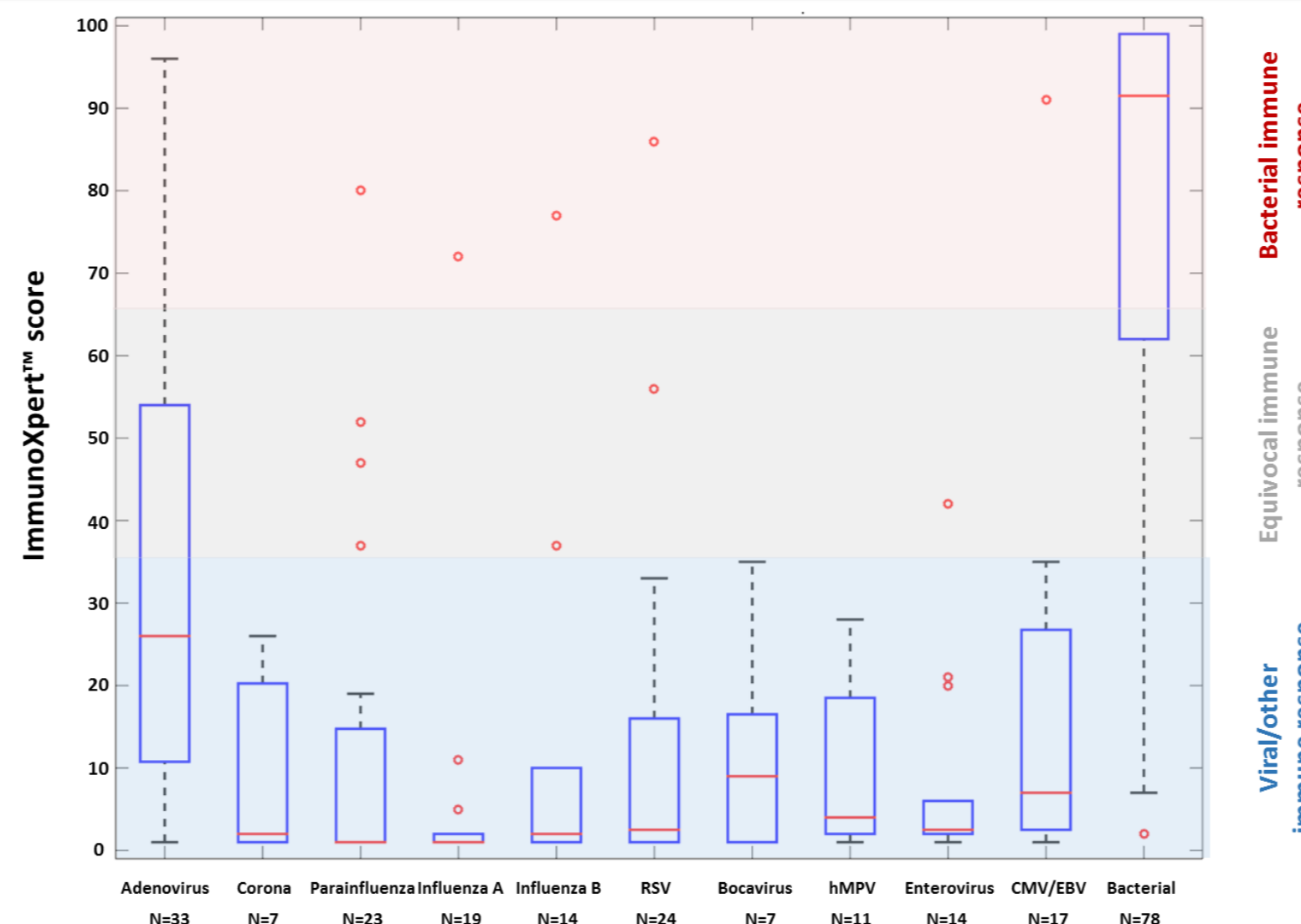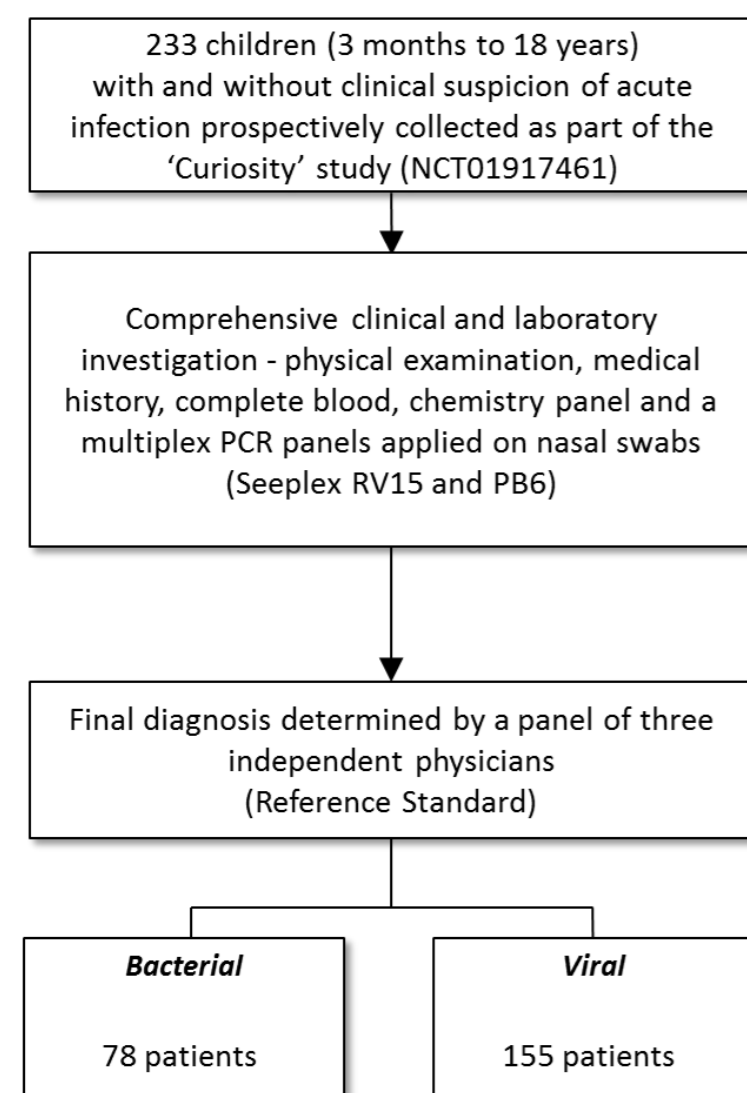| Likelihood of viral/other immune response	Equivocal	Likelihood of bacterial immune response
Very high — High — Moderate		Moderate — High — Very high

0   10   20   35   65   80   90   100

4. Study goal

To evaluate the assay's ability to assign correct infection classification (viral or bacterial) in children infected with ten different types of viral strains as well as in bacterially infected children

3. Assay validated in several clinical studies

Curiosity n=765: Sensitivity 94%, Specificity 93%
Opportunity n=577: Sensitivity 88%, Specificity 93%

'Curiosity' study - Oved et al. *PLOS ONE* 2015; Eden et al. *Journal of Infection* 2016.
'Opportunity' study – van-Houten et al *Lancet Infectious Diseases* 2016.

Design and Results

233 children (3 months to 18 years) with and without clinical suspicion of acute infection prospectively collected as part of the 'Curiosity' study (NCT01917461)

↓

Comprehensive clinical and laboratory investigation - physical examination, medical history, complete blood, chemistry panel and a multiplex PCR panels applied on nasal swabs (Seeplex RV15 and PB6)

↓

Final diagnosis determined by a panel of three independent physicians (Reference Standard)

Bacterial 78 patients   **Viral** 155 patients

- ImmunoXpert™ correctly classified 90% of bacterial cases and 91% of viral cases, when compared to the expert panel diagnoses (13% of patients had an equivocal response).

- Assay classified all coronavirus, bocavirus, human metapneumovirus, and enterovirus cases correctly.

- In the case of adenovirus, which is known to trigger a bacterial-like inflammatory host response, the assay correctly classified 83% of the patients. In comparison, CRP (cut-off: 40 mg/l) correctly classified only 42% of adenovirus infections.

- The assay may aid clinicians in determining infection etiology in febrile children. Importantly, it may assist in distinguishing between adenovirus and bacterial infections, which can be associated with similar clinical presentation.