

# A Host-response Assay Distinguishes Between Simple *Influenza* Patients and *Influenza* Patients with Bacterial Coinfection

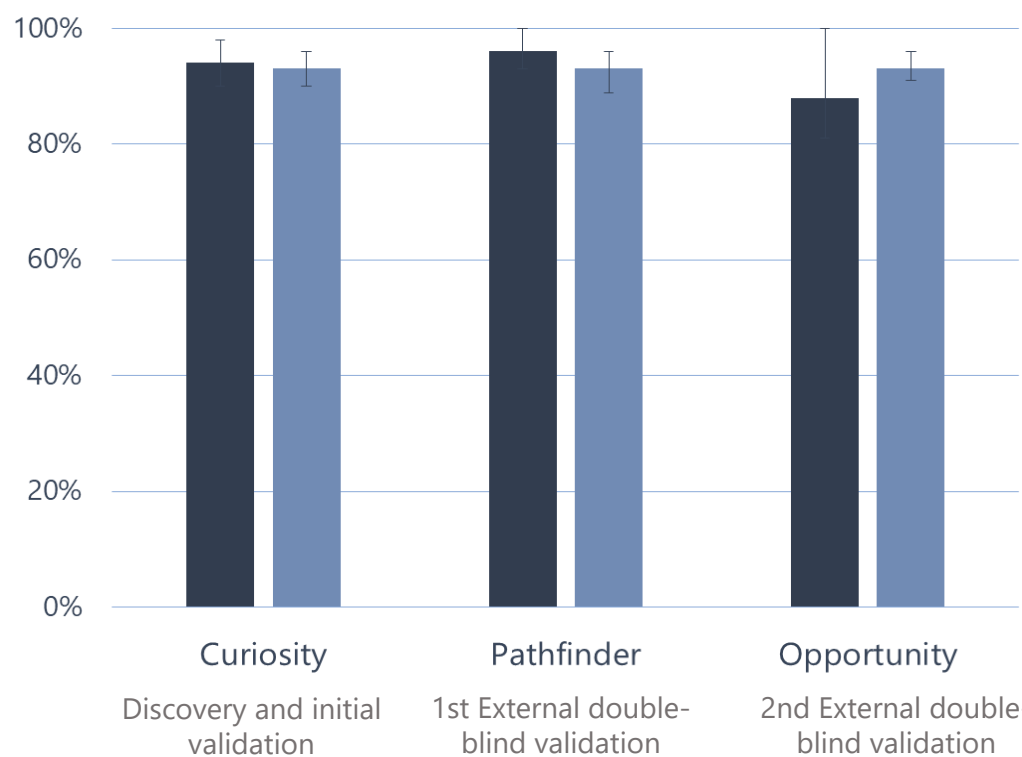
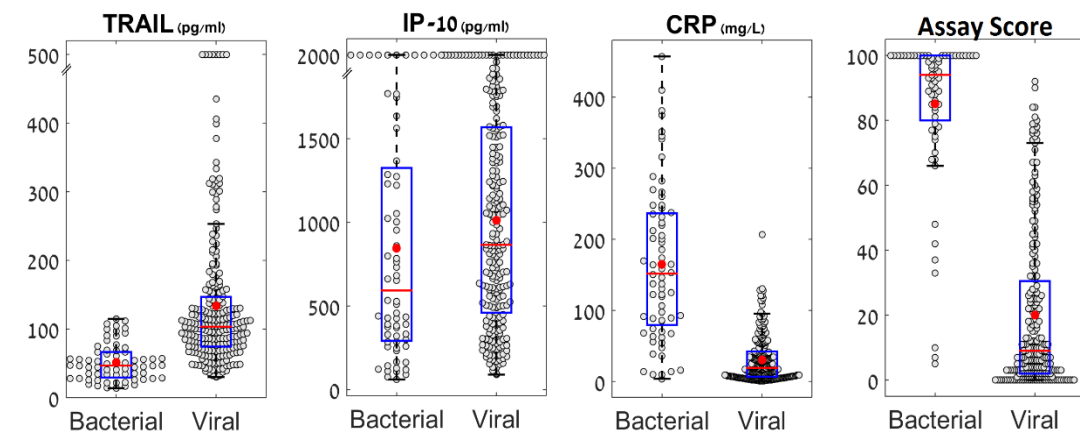
Meital Paz, BSc<sup>1</sup>, Kfir Oved, PhD<sup>1</sup>, Tanya Gottlieb, PhD<sup>1</sup>, Asi Cohen, PhD<sup>1</sup>, Roy Navon, MSc<sup>1</sup>, Niv Mastboim, BSc<sup>1</sup>, Ellen Bamberger, MD<sup>1,2,3</sup>, Tom Friedman, MD<sup>1,4</sup>, Liat Etshtein, MD<sup>1,4</sup>, Olga Boico, PhD<sup>1</sup>, Isaac Srugo, MD<sup>2,3</sup>, Irina Chistyakov, MD<sup>2,3</sup>, Adi Klein, MD<sup>3,5</sup>, Israel Potasman, MD, FIDSA<sup>3,6</sup>, Eran Eden, PhD<sup>1</sup> and Liran Shani, MD<sup>1</sup>

<sup>1</sup>MeMed Diagnostics, Tirat Carmel, Israel, <sup>2</sup>Department of Pediatrics, Bnai-Zion Medical Center, Haifa, Israel, <sup>3</sup>Ruth and Bruce Rappaport Faculty of Medicine, Technion-Israel Institute of Technology, Haifa, Israel, <sup>4</sup>Rambam Health Care Campus, Haifa, Israel, <sup>5</sup>Department of Pediatrics, Hillel Yaffe Medical Center, Hadera, Israel, <sup>6</sup>Infectious Diseases, Bnai Zion Medical Center, Haifa, Israel

## Background

A new host-response assay (ImmunoXpert™) that integrates the levels of three proteins (TRAIL, IP-10, and CRP) was shown to exhibit high performance in distinguishing between bacterial and viral disease in two double-blind validation studies.

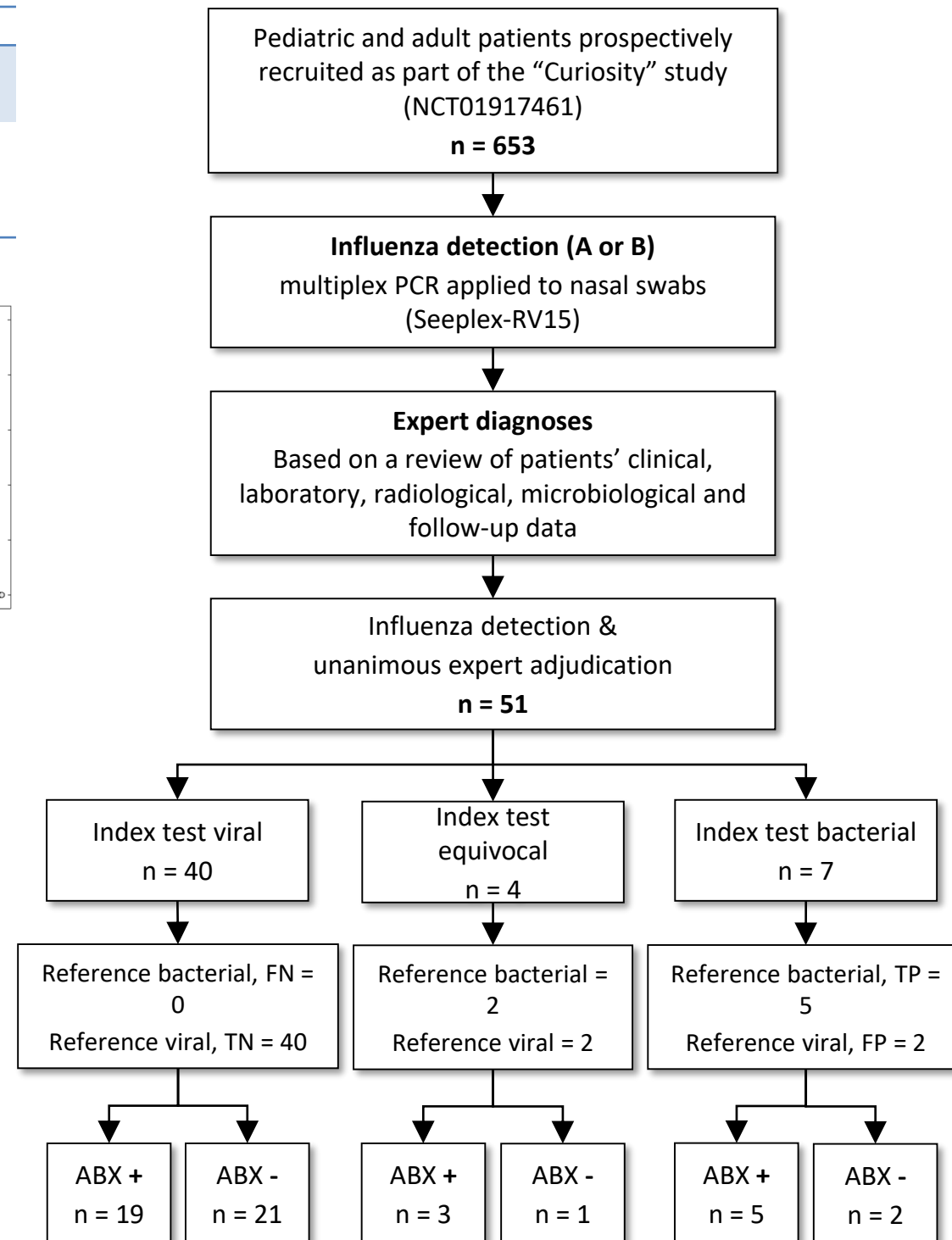
Name	Curiosity	Pathfinder	Opportunity
<b>Target population</b>	Adults & pediatric with acute infection	Pediatric with acute infection	Pediatric with FWS or RTI
<b>Potentially eligible patients (n)</b>	1002	597	777



## Design

Sub-analysis goal:

To evaluate ImmunoXpert™ ability to differentiate between simple influenza and influenza with bacterial coinfection.



**Flow through of febrile patients with positive influenza detection.**

FP, false-positive; TN, true-negative; TP, true-positive; FN, false-negative. The index test is available in Europe as ImmunoXpert™ (CE-IVD), not yet cleared by the FDA.

## Results and conclusions

- Antibiotics (ABX) were prescribed to all 7 cases of influenza with bacterial coinfection and to 20/44 cases adjudicated as simple viral infections, indicating an overuse rate of 45%
- The assay correctly classified 5 of the 7 viral with bacterial coinfection cases as well as 40 of the 44 simple viral cases supporting the assay's potential to reduce antibiotic overuse 5-fold (from 45% to 4/44=9%, P<0.001).

	Abx group	Non Abx group	P value
Age (years)	26.38	11.43	0.09
Maximal temperature (°C)	39.28	39.15	0.58
Respiratory rate (RR/min)	27.44	26.21	0.85
Time From symptoms (days)	4.07	3.13	0.10
Hospitalization duration (days)	1.69	1.04	0.28
WBC (X10 <sup>3</sup> )	8.83	8.71	0.27
Neut(%)	61.73	67.57	0.14

No clinical difference between the ABX and the Non-ABX groups

## Conclusions

The host-response assay can differentiate between simple influenza and influenza patients with bacterial coinfection, with potential to reduce antibiotic overuse. Utility studies are warranted to demonstrate that the assay can safely assist physicians in correct management of influenza patients.



ID Week 2018