



# Is it Bacterial or Viral?

Addressing an age-old question in 15 minutes!

Adam Voigt – Sr. Clinical Sales Executive

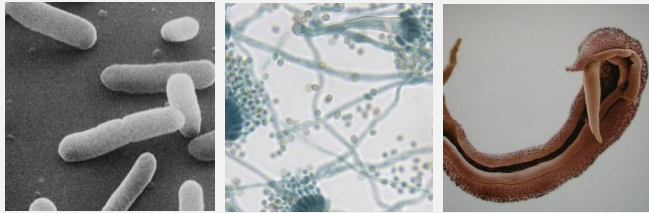




# Infection ID Process

# Opposite Sides of the Coin

## Pathogen



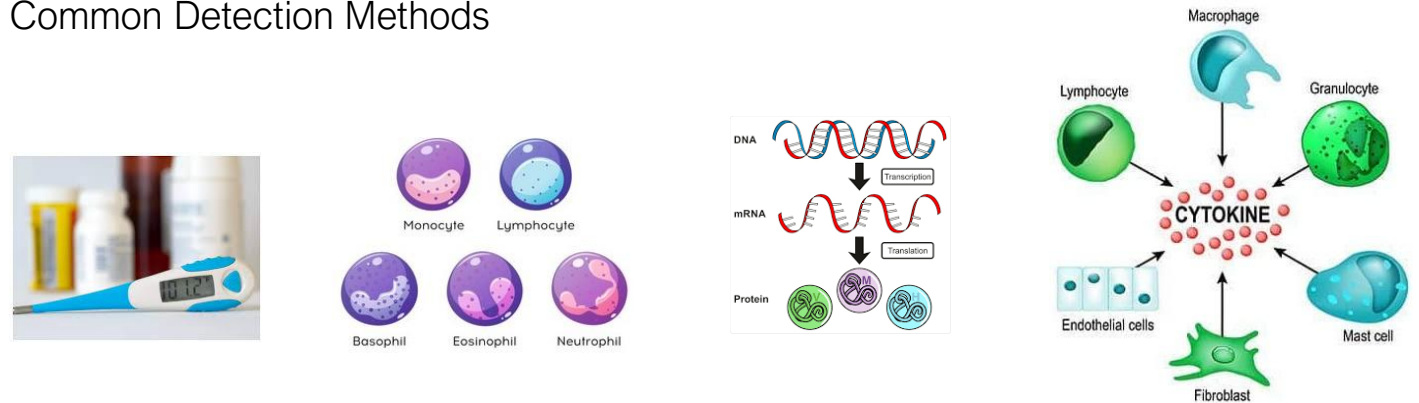
## Common Detection Methods



## Host



## Common Detection Methods



# The Pathogen Alone Does Not Tell the Whole Story

- ~60% of pathogens are never identified, even in severely ill<sup>1</sup>
- Patients were asymptomatic in 40-60% of cases where viral pathogens were identified<sup>2</sup>

## Consequences - Excessive antibiotic use

In 2014, **266.1 million courses** of outpatient antibiotics were dispensed in the U.S.

**>28% of outpatient antibiotics**  
prescribed are unnecessary

**Increased  
antimicrobial resistance**

**Adverse drug effects  
and drug interactions**

Antibiotics are among the most frequently prescribed drugs but are only prescribed correctly about half the time

1. EPIC Study: Jain et al. *N Engl J Med* 2015;373:415-27.

2. BIG-LoVE, Byington et al. *Clin Infect Dis*. 2015 Oct 15;61(8):1217-24

# Conventional tests are important but insufficient to aid in effective patient management

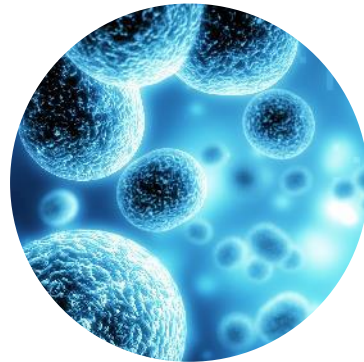
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Prolonged time to results



Inaccessible infection sites



Often, no pathogens are detected



Undetected bacterial co-infections



Pathogen detection doesn't necessarily point to disease cause

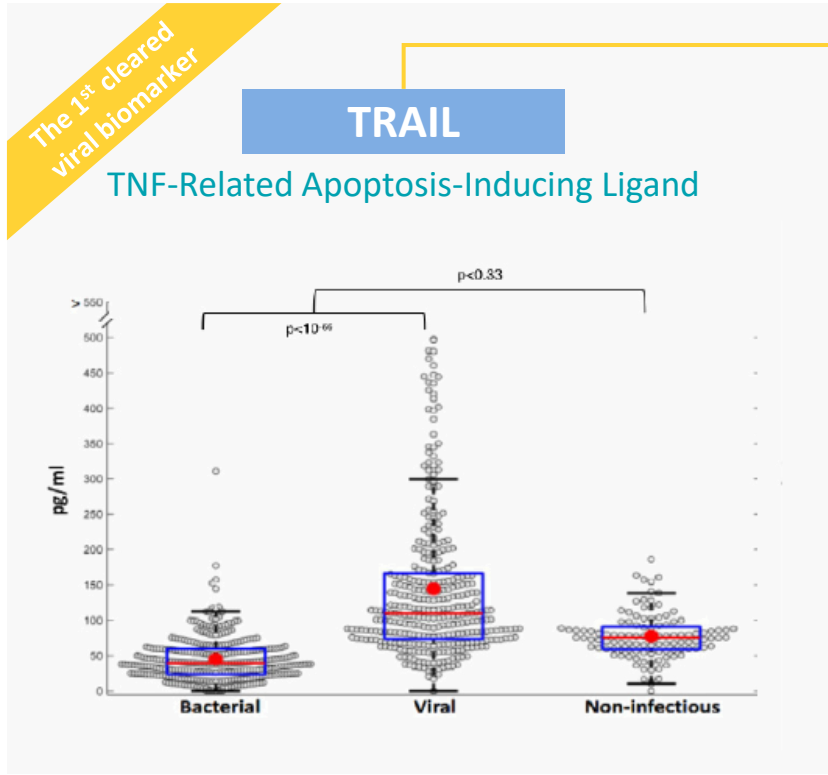
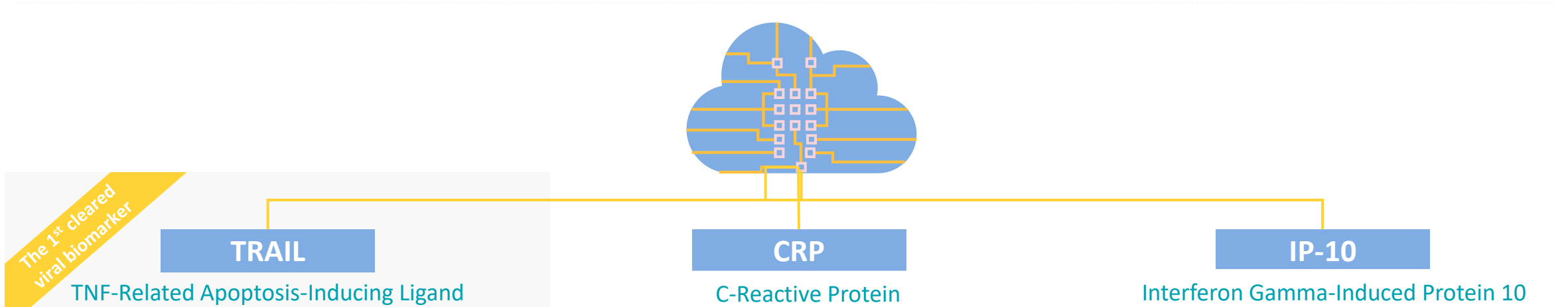


# A Better Way

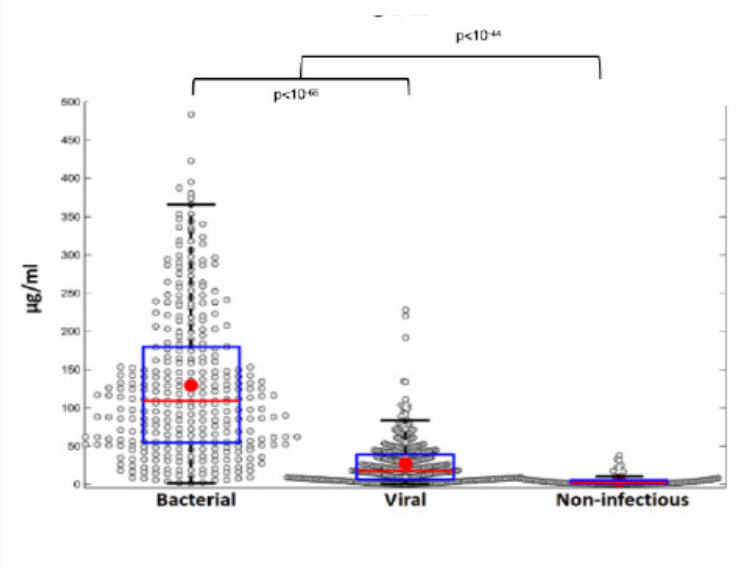
# MeMed BV<sup>®</sup>

- **Accurately distinguishes between bacterial and viral infections**
- Since bacterial and viral infections are clinically indistinguishable, physicians are often challenged to decide whether to treat or not with antibiotics.
- By providing host response information, we help physicians make more informed decisions about how and when to treat.

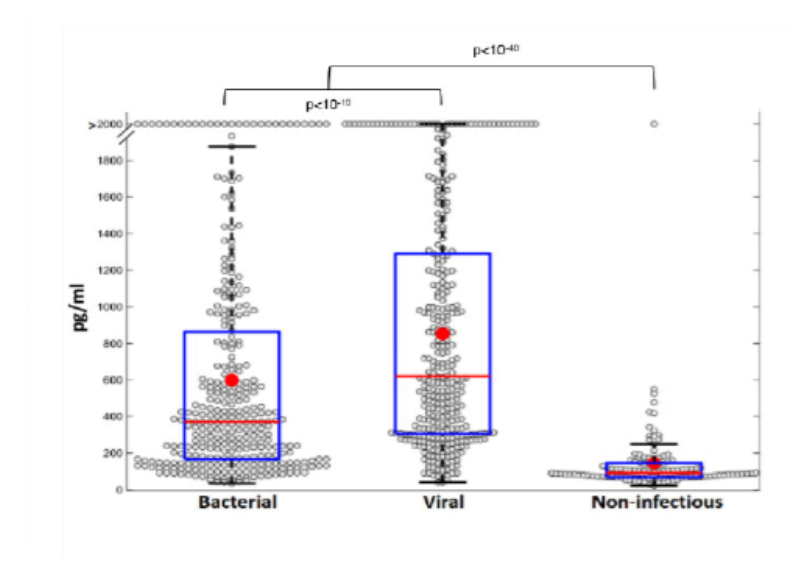
# MeMed BV® = 3 Host proteins + Machine learning



Elevated in **Viral** infections  
Avg. time to peak 0-6 hours

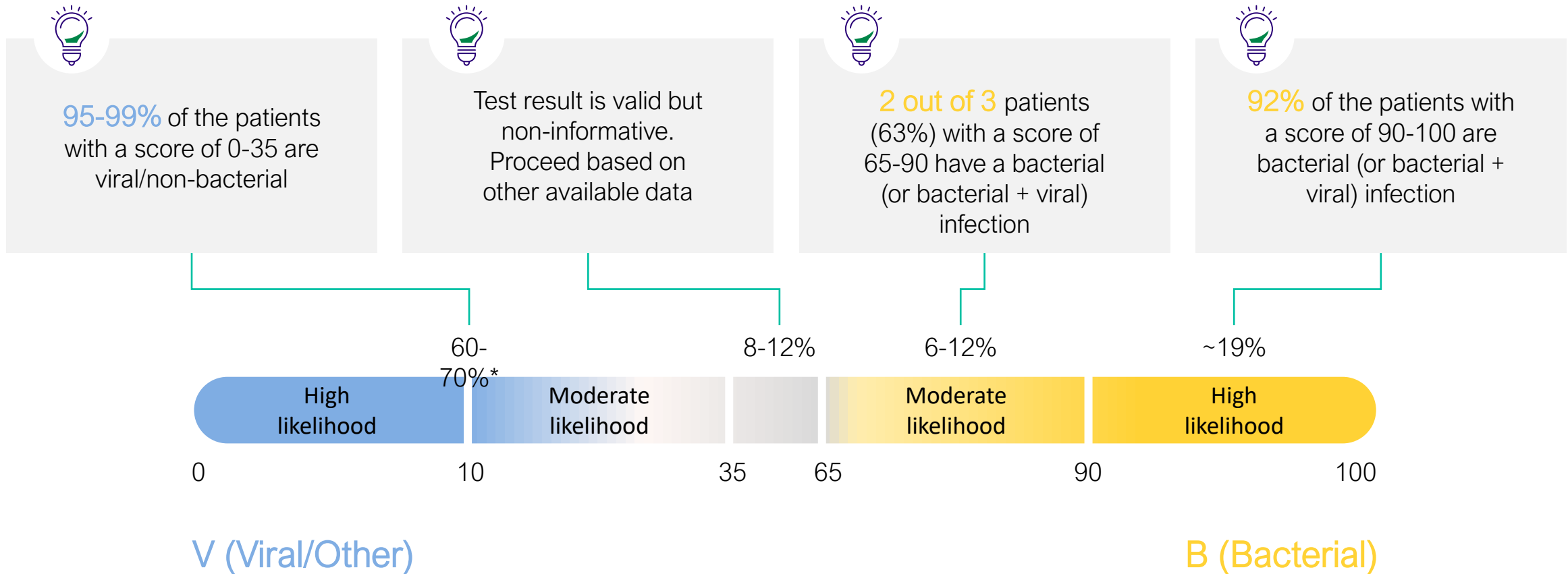


Elevated in **bacterial** infections  
Avg. time to peak 36-50 hours



Elevated in **infections**  
Avg. time to peak 12 hours

# The MeMed BV score interpretation



\* BV Results bin distribution

\*\* Data is based on published studies and data on file: signature measures of accuracy for diagnosing bacterial vs. viral infections – in a combined cohort of three validation studies (Curiosity, Opportunity, Pathfinder) and dependent on bacterial prevalence in the population

# MeMed Key® - rapid, highly sensitive measurements within your laboratory workflow

Quick turnaround time  
15 minutes  
from **Whole blood** or serum sample

Small volume  
150µl of blood sample  
or 100µl of serum

Connects to the LIS  
for easy and convenient test result  
transmission from the lab

Compact  
H 9.84 W 9.84 D 13.5 in.; Wt. 17 lb.



# MeMed BV - When to order the test?

## Indications:



Clinical suspicion of bacterial vs. viral infection



Adults and pediatric patients (>3m)



Fever within the past 7 days



Symptom duration less than 7 days



## Patient populations to focus on:

**1** Respiratory Tract Infection

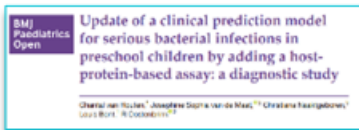
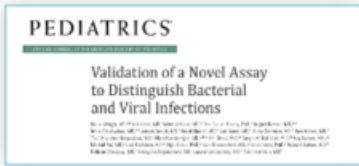
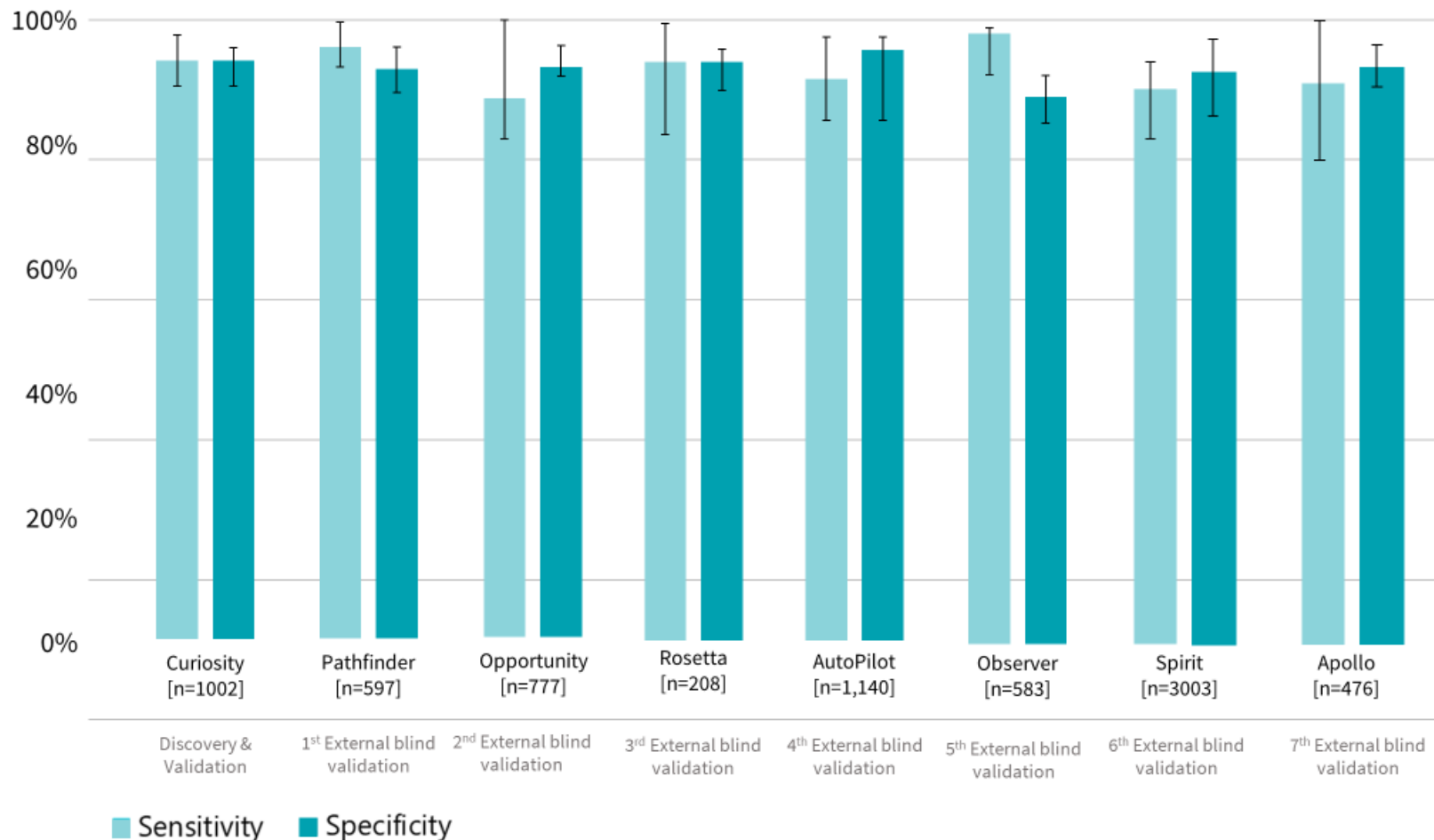
**2** Suspected sepsis\*

**3** Fever without localizing signs or symptoms

Limitations include immunocompromised patients

\* Suspected sepsis is defined as hemodynamically stable patients with 2 or more SIRS criteria and fever in the last 7 days

# BV<sup>®</sup> high performance independently confirmed in unprecedented blinded validation and real-world evidence of >20,000 patients



- Oved, K. et al. PLoS One (2015)
- Srugo, I. et al. Pediatrics (2017)
- van Houten, C. B. et al. Lancet Infect. Dis. (2016)
- Mor, M. et al. PLoS One (2023)
- papan et al. CMI (2021)
- Halabi et al. CMI (2023)
- Klein et al. Pediatrics (2023)
- Bachur et al. JACEP Open (2024)

# FDA clearance: MeMed BV<sup>®</sup> high performance further established in large double blind, pivotal study focused on EDs and Urgent Cares

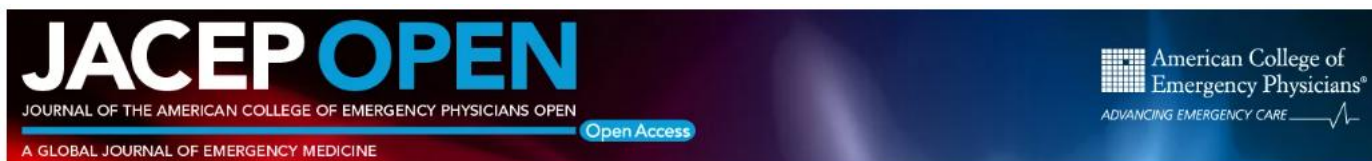
## Participating Medical Centers



## “Apollo” Clinical Study (NTC04690569)

- Achieved FDA 510k clearance
- 9 EDs & 3 UCCs
- May 2019- Aug 2020
- 563 Patients (Adults & Pediatrics)
- Suspected of acute bacterial/viral infection, temp w/in last 7 days and symptoms <7days

<b>AUC %</b>	0.95 (0.90 to 0.99)
<b>Sensitivity %</b>	90.0 (76.4 to 96.6)
<b>Specificity %</b>	92.8 (89.5 to 95.1)



# Thank you!

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