

# MeMed BV in Clinical Practice

Melissa Naiman, PhD, EMT-B | 04.10.26



# Introduction

## Melissa Naiman, PhD, EMT-B



- Employee of Beckman Coulter
  - Senior Director, Acute Care– Medical & Scientific Affairs
- Public Health Policy and Administration
  - Medical device and diagnostic development in academia and industry
    - Research interest: Innovation adoption in healthcare settings

“

Health Statistics represent people with the tears  
wiped off.

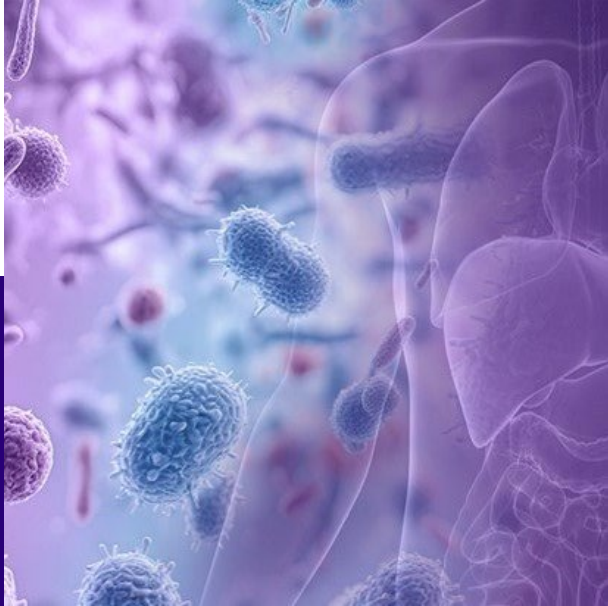
— Sir Austin Bradford Hill (1897-1991)

# Relevance



Diagnostic Uncertainty  $\Rightarrow$  Operational Inefficiency

# Acute Infection: Missed and Mis- Diagnosis



**Antibiotic**  
Over/under use



**Missed**  
Severe infection and sepsis



**Operational Challenges**  
Length of Stay  
Readmissions  
Throughput  
Unnecessary Transfers

# Acute Infection Disposition

#1

Discharge Diagnosis  
from Urgent Care<sup>1</sup>

#5

Reason for ED  
Referrals from UCCs<sup>2</sup>

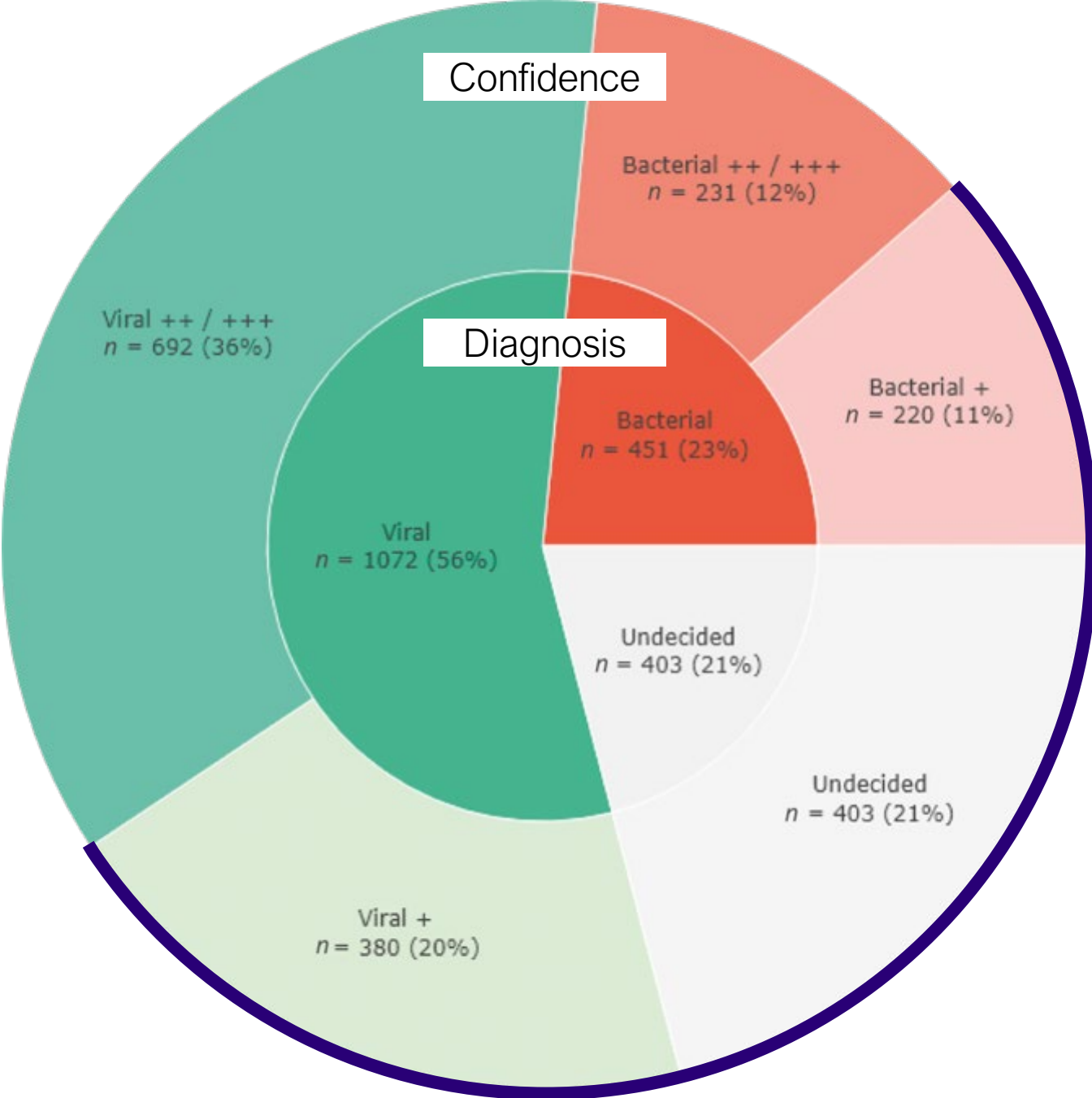
#3

Reason for ED  
Treat-and-Release Visits<sup>3</sup>

#2

Reason for Admission  
from the ED<sup>3</sup>

1. Kathryn A Martinez, Abhishek Deshpande, Elizabeth Stanley, Michael B Rothberg, Antibiotic Prescribing for Respiratory Tract Infections in Urgent Care: A Comparison of In-Person and Virtual Settings, *Clinical Infectious Diseases*, 2025; 80,:1, p7–13.
2. Poyorena C, Patel S, Keim A, Monas J, et. al. Evaluating urgent care center referrals to the emergency department. *J Am Coll Emerg Physicians Open*. 2022 Dec 7;3(6):e12838.
3. A.J. Weiss, H.J. Jiang. Most Frequent Reasons for Emergency Department Visits, 2018. STATISTICAL BRIEF #286. Dec 2021. <https://hcup-us.ahrq.gov/reports/statbriefs/sb286-ED-Frequent-Conditions-2018.jsp>



## Providers Experience Uncertainty *MeMed “Spirit” Study*

### Survey says...

As part of a clinical study, physicians were asked how certain they were about their diagnosis of bacterial vs viral infection.

**64%**

Physicians were uncertain or undecided 64% of the time (1003/1561).

### MeMed BV outperformed Physicians

Physicians: Sensitivity, 66.2%; Specificity, 72.0%

MeMed BV: Sensitivity, 89.7%, Specificity, 92.6%

Klein A, Shapira M, Lipman-Arens S, et al. Diagnostic Accuracy of a Real-Time Host-Protein Test for Infection. *Pediatrics*. 2023 Dec 1;152(6):e2022060441

# Clinical Value



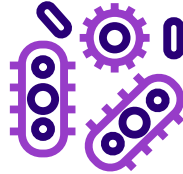
A lab test intentionally designed to differentiate bacterial and viral etiology

# Established laboratory tests were not designed to establish infectious etiology

Established lab tests take too long, fail 60% of the time<sup>1</sup>, and are prone to false positives<sup>2</sup>



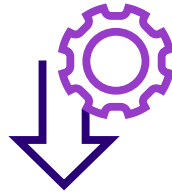
**Inaccessible  
infection sites**



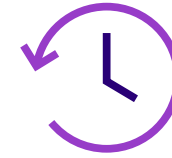
**False alarms due  
to colonization**



**Often no  
pathogens  
are detected**



**Poor performance  
for emerging  
pathogens**

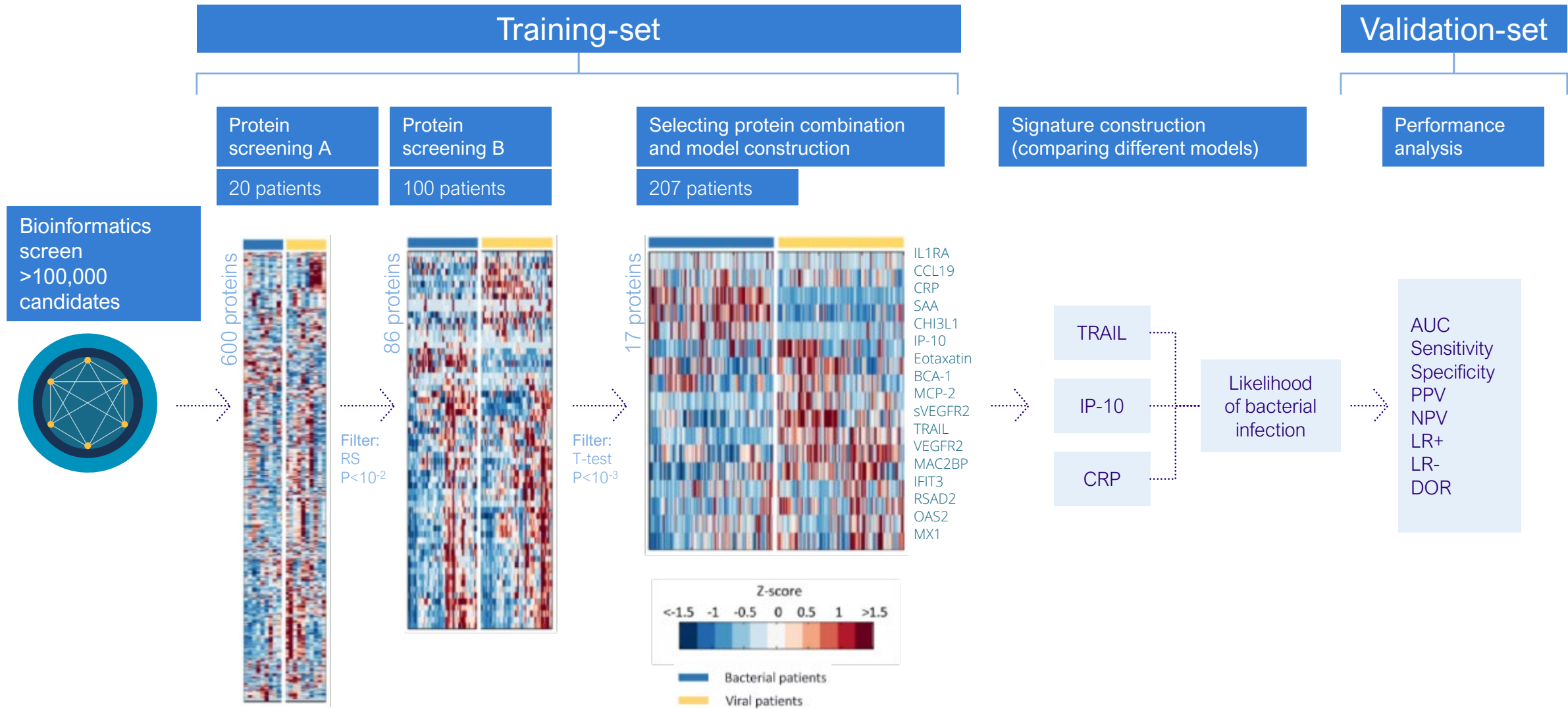


**Prolonged time  
to results**

1. Jain S., Self W Wunderink, et al. Community-Acquired Pneumonia Requiring Hospitalization among U.S. Adults. *N Engl J Med* 2015;373:415-27.

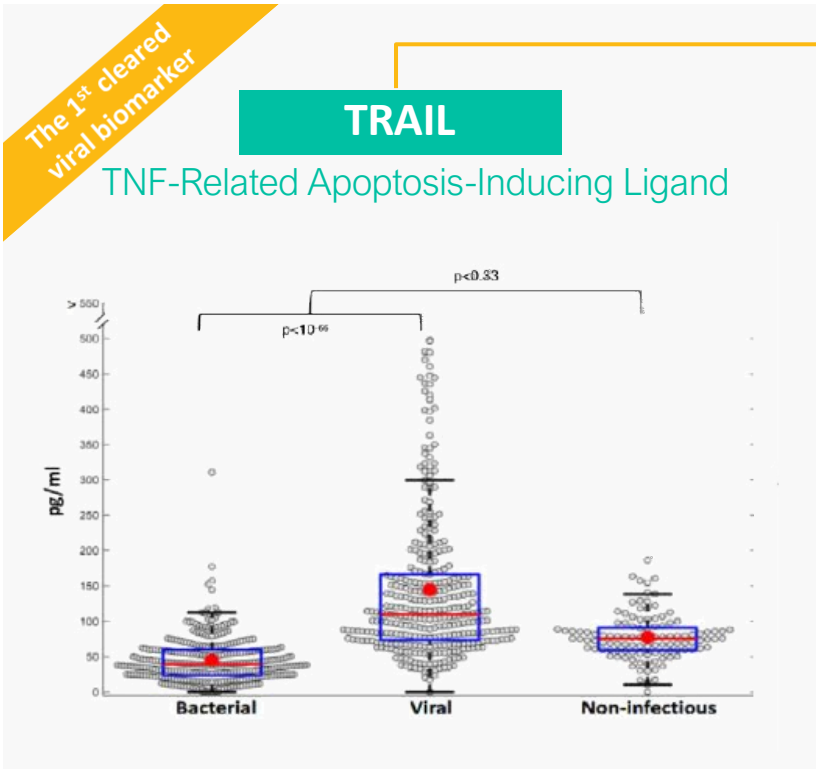
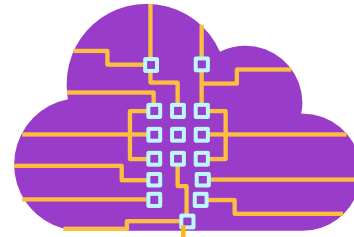
2. Byington C, Ampofo K, Stockmann C, et al. Community Surveillance of Respiratory Viruses Among Families in the Utah Better Identification of Germs-Longitudinal Viral Epidemiology (BIG-LoVE) Study. *Clin Infect Dis*. 2015 Oct 15;61(8):1217-24

# Discovery and Preliminary Validation

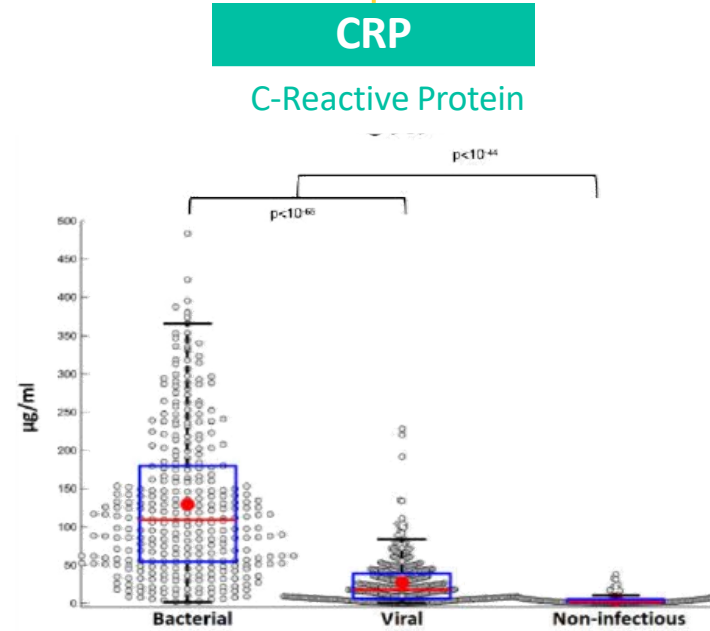


Oved et al. PLoS ONE. 2015 Mar 18; 10(3) e0120012

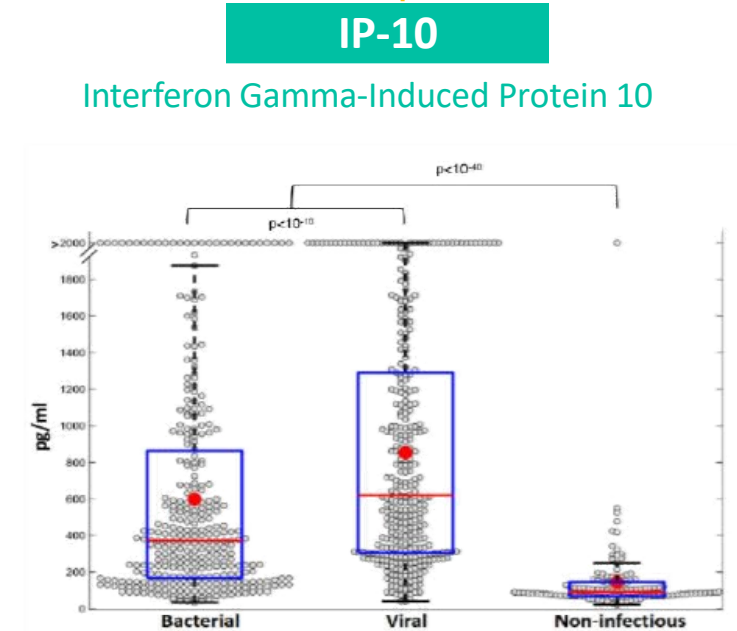
# MeMed BV is designed to establish infectious etiology



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



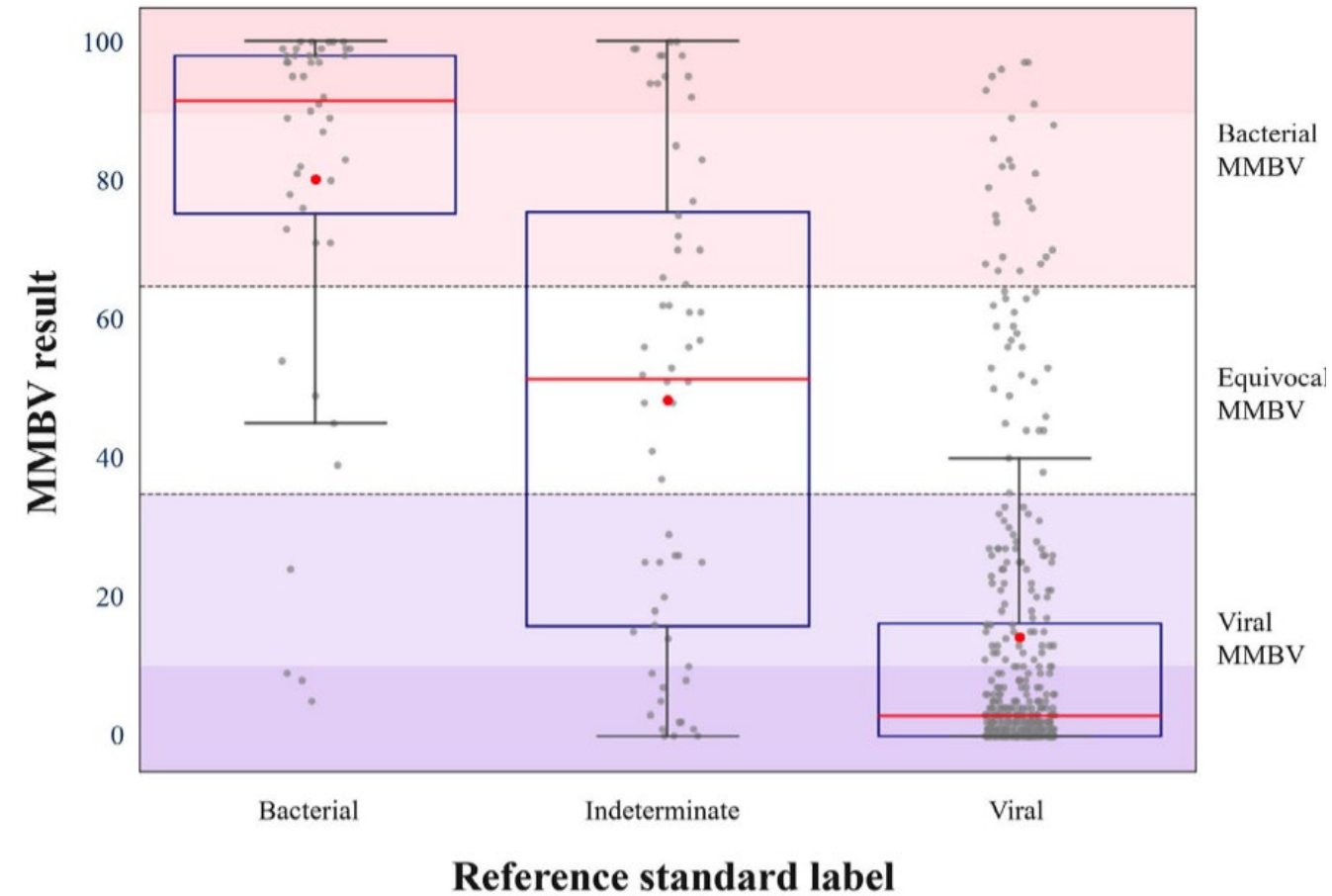
Elevated in **bacterial** infections  
Avg. time to peak 36-50 hours



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

Oved K, Cohen A, Boico O, et al. A novel host-proteome signature for distinguishing between acute bacterial and viral infections. *PLoS ONE*. 2015;10(3):e0120012.





## MeMed BV is highly accurate

### 95% Accurate

MeMed BV is “right” about the infectious etiology 95% of the time.

*Overall accuracy (ROC-AUC): 95% (95% CI: 90 – 99%)*

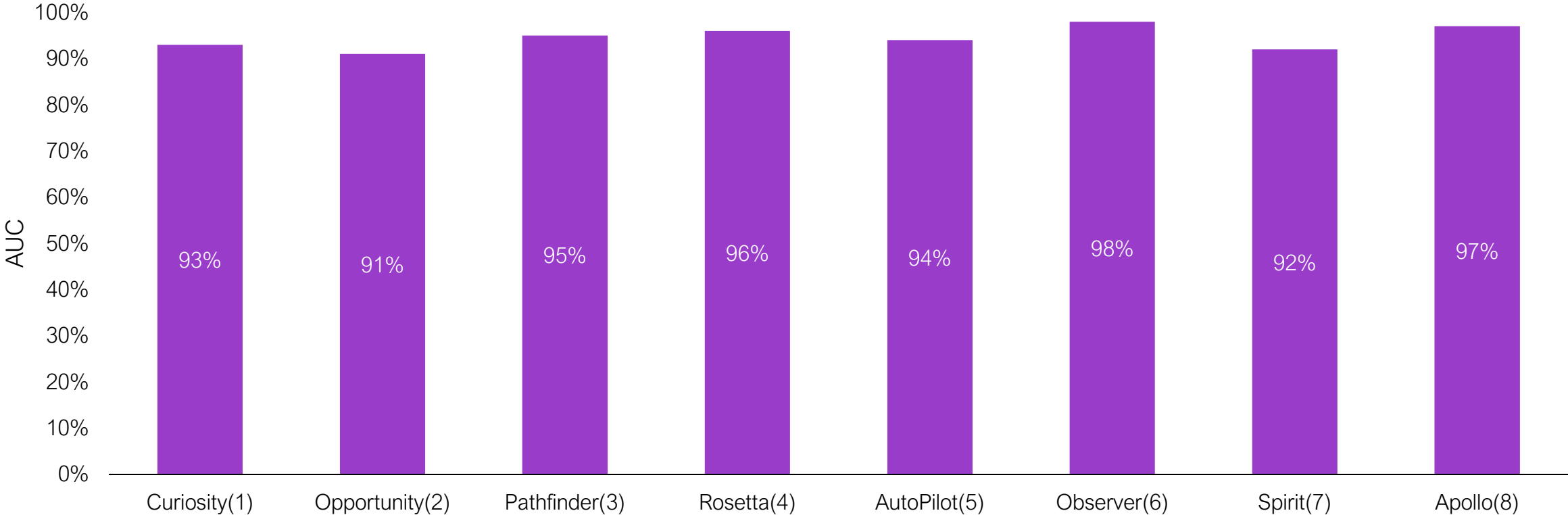
### 99% NPV

Patients with a “viral” score are very unlikely to have a bacterial infection.

*NPV for Bacterial Infection: 98.8% (95% CI: 96.8% - 99.6%)*

Bachur R, Kaplan SL, Arias CA, et al., A rapid host-protein test for differentiating bacterial from viral infection: Apollo diagnostic accuracy study. *JACEP Open*. 2024;5:e13167.

# MeMed BV accuracy is highly reproducible



1. Oved K, Cohen A, Boico O, et al. A novel host-proteome signature for distinguishing between acute bacterial and viral infections. *PLoS ONE*. 2015;10(3):e0120012.
2. van Houten CB, de Groot JAH, Klein A, et al. A host-protein based assay to differentiate between bacterial and viral infections in preschool children (OPPORTUNITY): a double-blind, multicentre, validation study. *Lancet Infect. Dis*. 2017 Apr; 17(4) 431-440
3. Srugo I, Klein A, Stein M, et al. Validation of a novel assay to distinguish bacterial and viral infections. *Pediatrics* 2017 Oct; 140(4).
4. Mor M, Paz M, Amir L, et al. Bacterial vs viral etiology of fever: A prospective study of a host score for supporting etiologic accuracy of emergency department physicians. *PLoS One*. 2023 Jan 30; 18(1) e0281018.
5. Papan C, Argentio A, Porwoll M, et al. A host signature based on TRAIL, IP-10, and CRP for reducing antibiotic overuse in children by differentiating bacterial from viral infections: a prospective, multicentre cohort study. *Clin Microbiol Infect*. 2022 May; 28(5) 723-73.
6. Halabi S, Shiber S, Paz M, et al. Host test based on TRAIL, IP-10 and C-reactive protein for differentiating bacterial and viral respiratory tract infections in adults. *Clin Microbiol Infect*. 2023 Sep; 29(9) 1159-1165 (2023)
7. Klein A, Shapira M, Lipman-Arens S, et al. Diagnostic Accuracy of a Real-Time Host-Protein Test for Infection. *Pediatrics*. 2023 Dec 1;152(6):e2022060441
8. Bachur R, Kaplan SL, Arias CA, et al., A rapid host-protein test for differentiating bacterial from viral infection: Apollo diagnostic accuracy study. *JACEP Open*. 2024;5:e13167.

# Clinical Performance



Real-world evidence of clinical utility

# UCC Prescribing Behavior in Adults *Real-world Evidence*

Helpful in **86%** of cases

MMBV results changed patient management: 20.9% (607/2901)

MMBV result supported decision-making: 65% (1887/2901)

**78%** alignment to MMBV Score

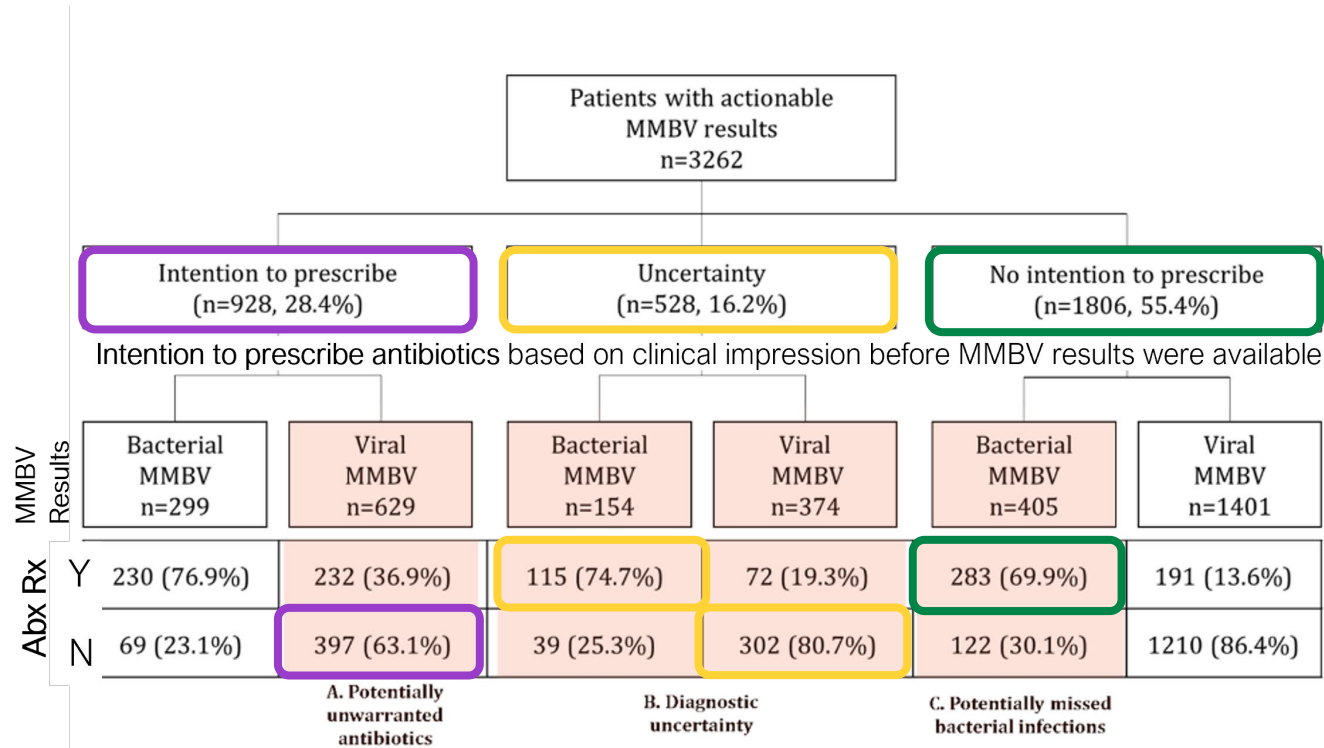
Physician adherence to MMBV results: 77.8% (2537/3262)

## Population

3920 MMBV test orders for adult patients

- 10 UCCs with 144 physicians
- Mostly fever (34.5%) and URI (18.3%)

Kalmovich B., et al. BMC Med. 2026 Feb 04; 23(1) 63



# UCC Prescribing Behavior in Peds *Real-world Evidence*

Helpful in 84% of cases

MMBV results changed patient management: 19.8% (332/1677)

MMBV result supported decision-making: 64.2% (1076/1677)

78% alignment to MMBV Score

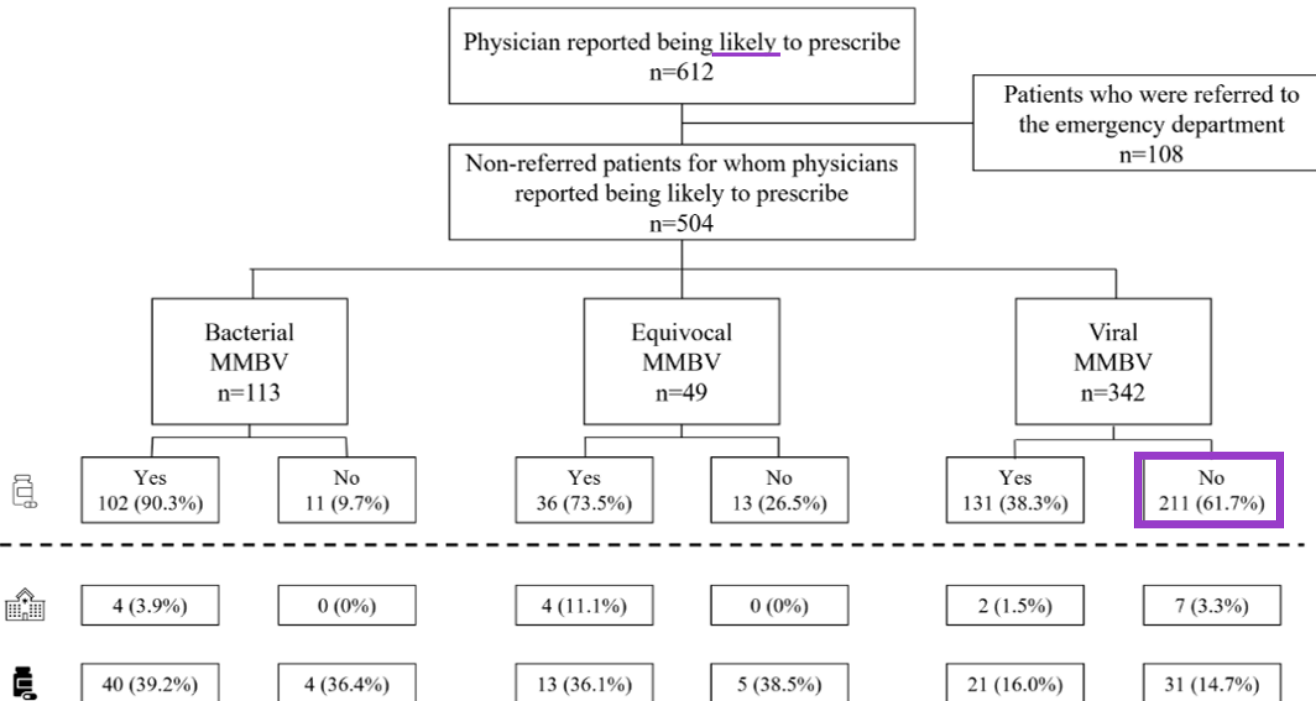
Physician adherence to MMBV results: 77.6% (1564/2016)

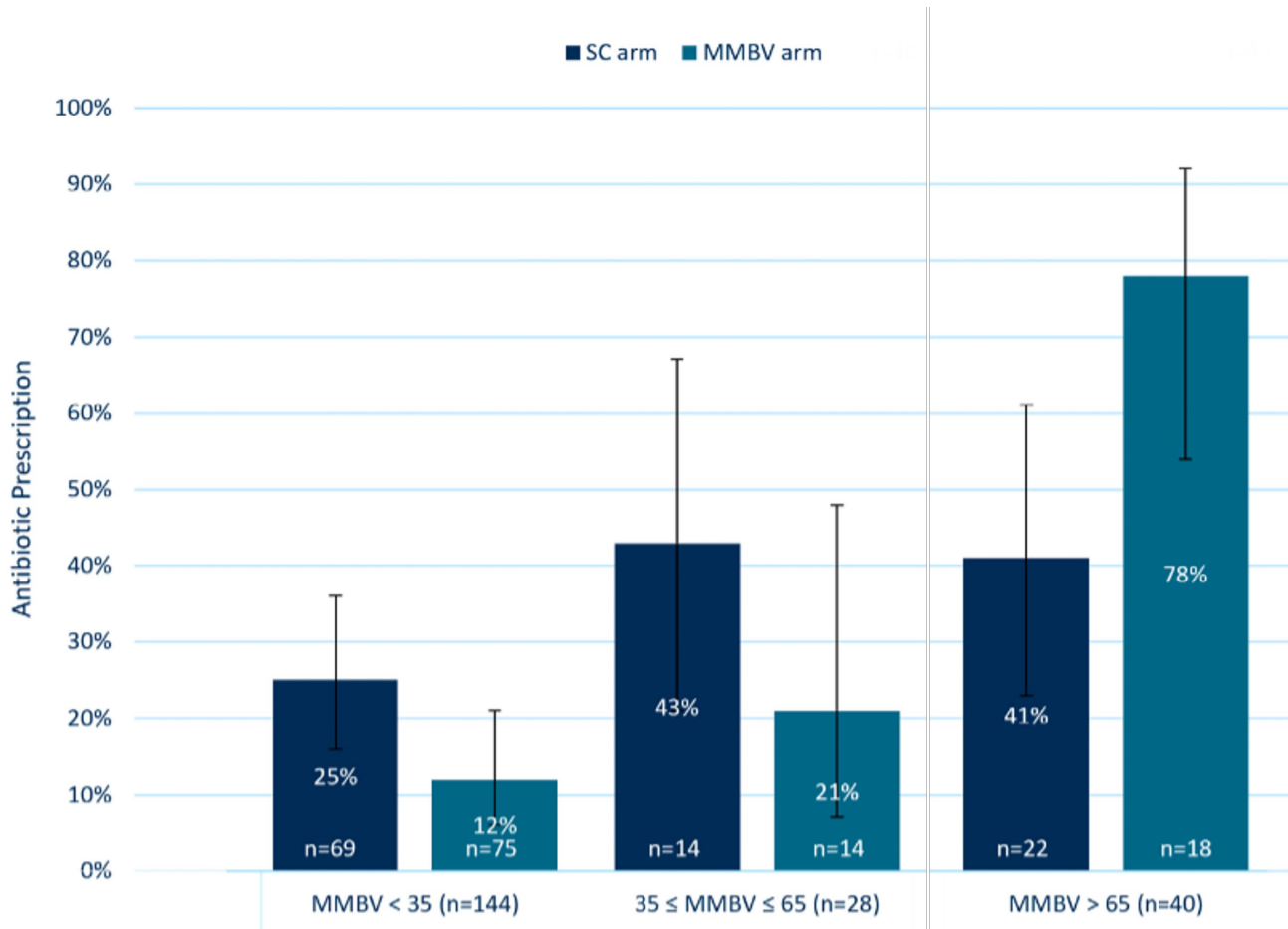
## Population

2016 MMBV test orders for pediatric patients

- 10 UCCs with 156 physicians
- Most common signs & symptoms: fever (93.1%) and cough (30.1%)

Kalmovich B., et al. *Pediatrics* (2026) 157 (1): e2024069961





## ED Prescribing Behavior *RCT (Interim Results)*

### Key Results

Viral score = 50% reduction in antibiotic prescriptions

Bacterial score = 24% increase in antibiotic prescriptions

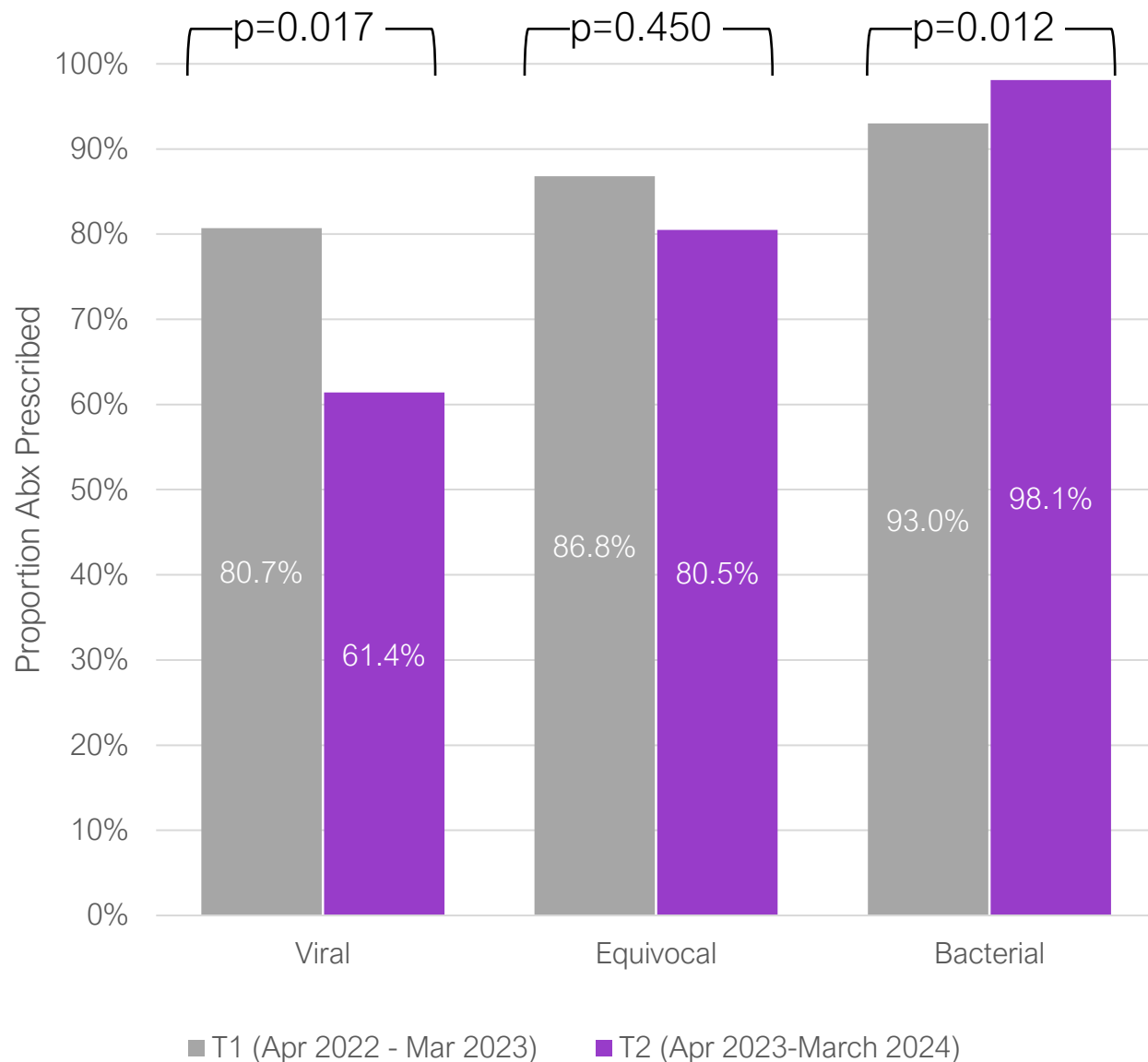
### Safety Endpoint

Test adherence was associated with fewer hospitalizations in 7-day follow-up.

### Population

214 adults presenting with acute infection and **discharged** from ED or UC

# Prescription Rate Over Time



## ED Prescribing Behavior in Adults *Real-world Evidence*

### Key Results

Viral MMBV = 23.9% reduction in antibiotic rx

Bacterial MMBV = 5.5% increase in antibiotic rx

No difference in 7-day ED return visit rates

### 80% alignment to MMBV Score

Aligned with MMBV Score in 79.6% of cases in T2 (post-educational intervention)

### Population

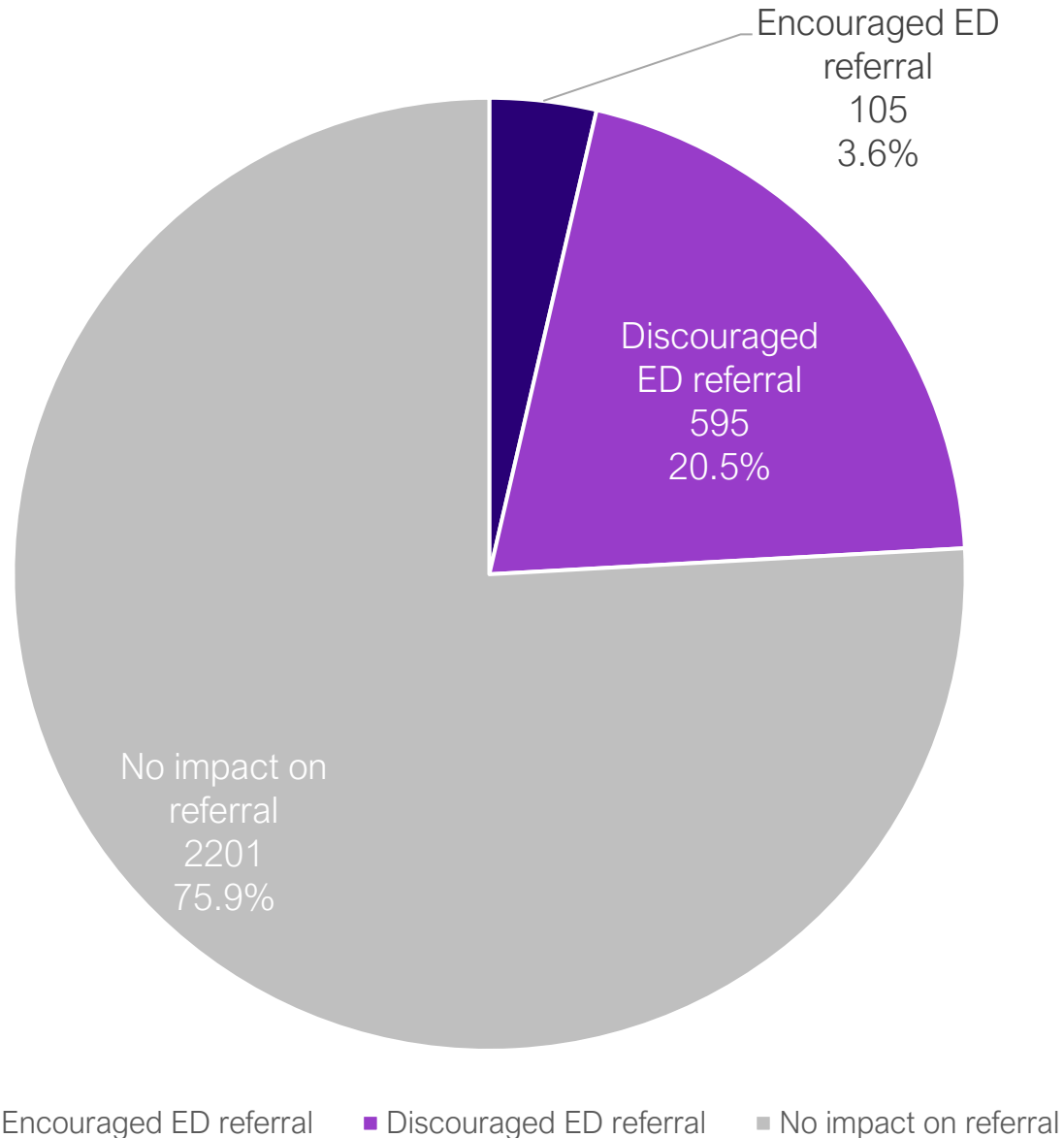
681 adults presenting to the ED with blood culture and MeMed BV results

LoVerde A, Ghitan M, Bodenstein H, et al. *JACEP Open*. 2026;6(6):100255.

# Operational Benefits



Safe risk stratification matches appropriate resources to clinical need for acute infection patients



## UCC Referrals to ED in Adults *Real-world Evidence*

### Up to 40% reduction in ED referrals

A total of 394 patients were referred to the ED

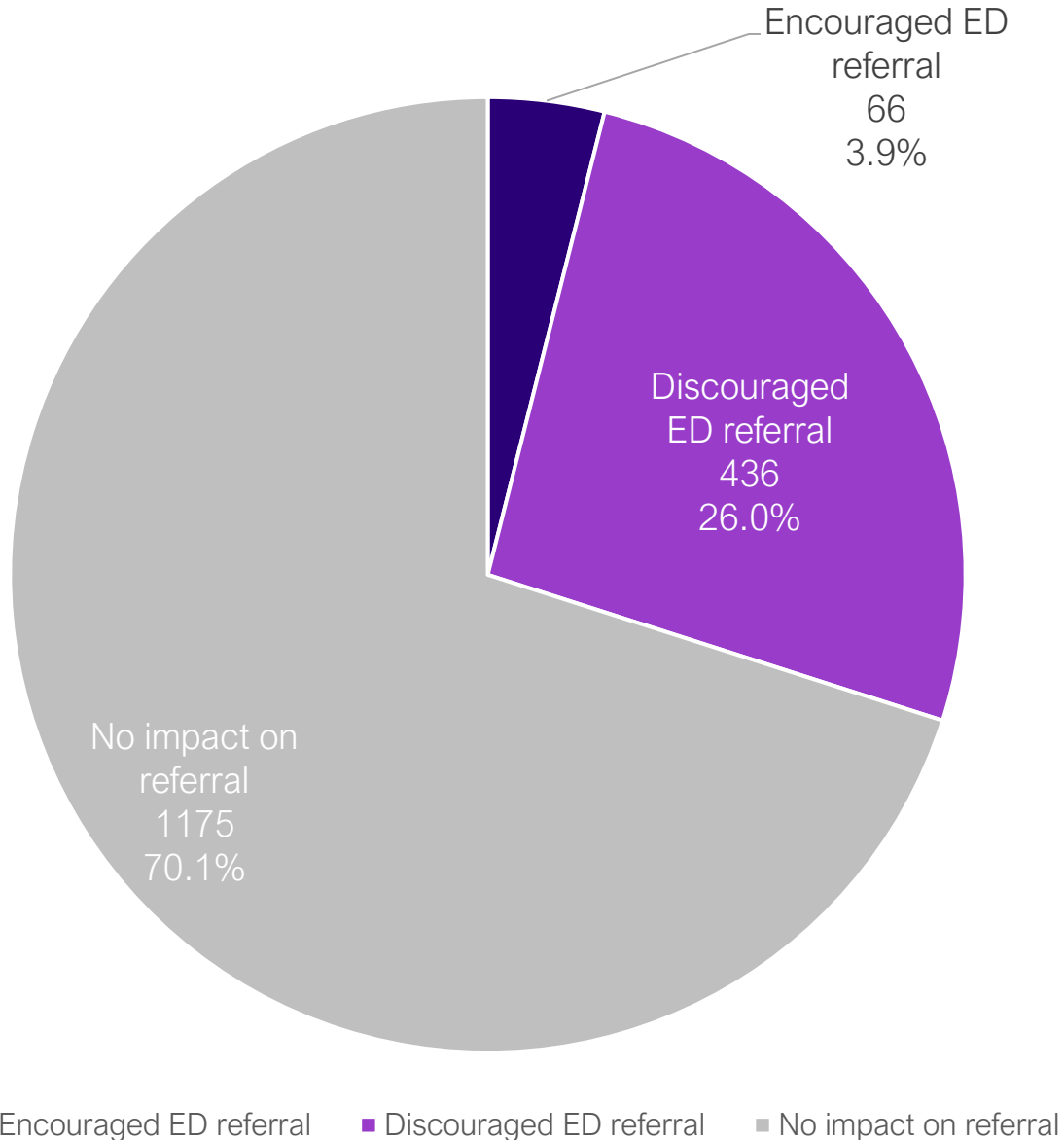
The MMBV Score discouraged an ED referral in 595 cases

### MMBV Safely Discouraged Referrals

3.5% 7-day hospitalization rate in ED-discouraged cases

Kalmovich B., et al. *BMC Med.* 2026 Feb 04; 23(1) 63

## MMBV Impact on Referral Decisions



## UCC Referrals to ED in Peds *Real-world Evidence*

### Up to 41% reduction in ED referrals

A total of 303 patients were referred to the ED

The MMBV Score discouraged an ED referral in 436 cases

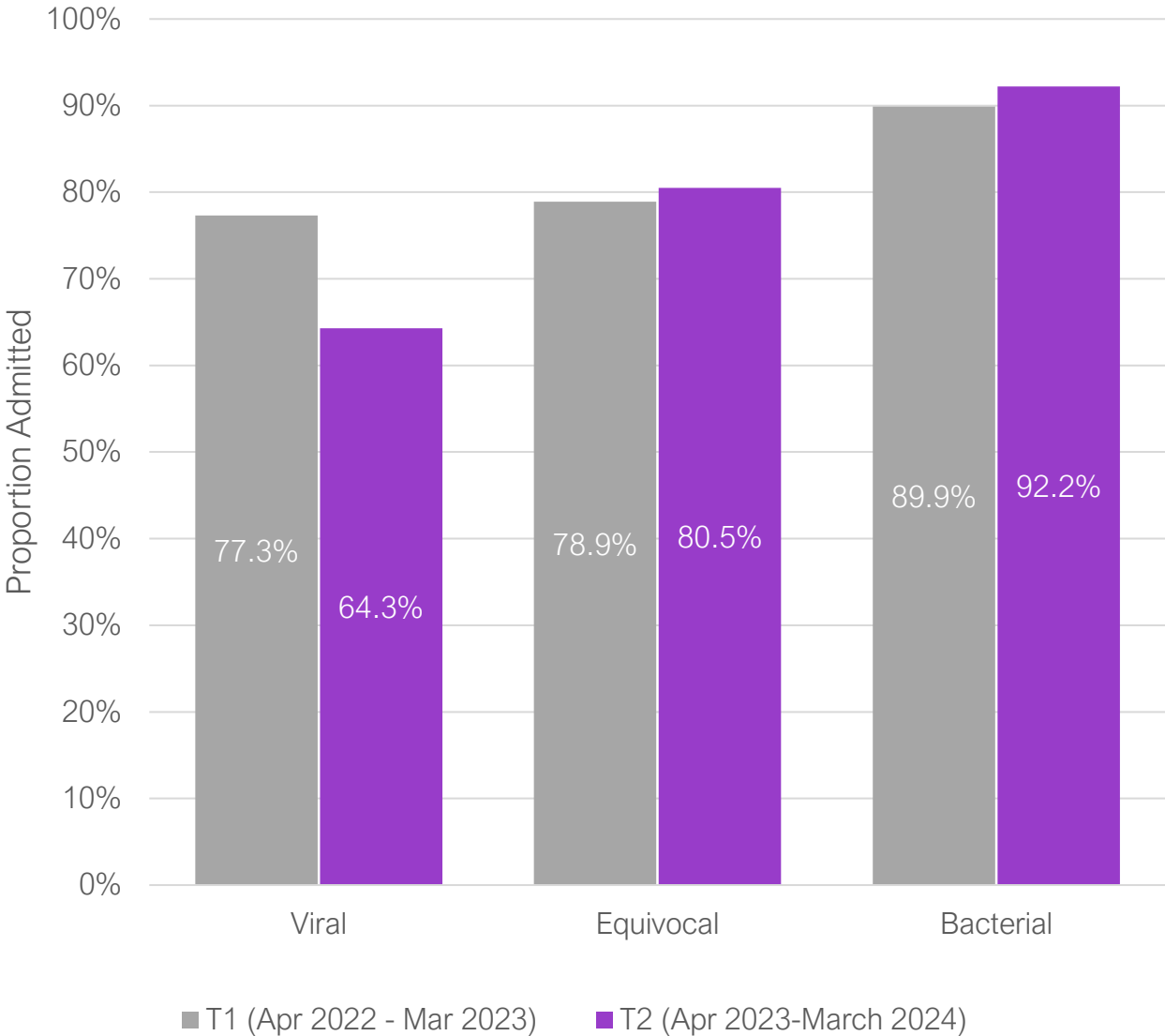
### MMBV Safely Discouraged Referrals

4.7% 7-day hospitalization rate in ED-discouraged cases

- No difference to No Impact cases (4.7% vs 4.9%;  $P = .91$ )
- Significantly lower than Encouraged referral cases (4.7% vs 55.6%;  $P < .0001$ )

Kalmovich B., et al. *Pediatrics* (2026) 157 (1): e2024069961

# MMBV Impact on ED Admission Rate



## ED Admissions in Adults *Real-world Evidence*

### 20% reduction in hospitalizations

19.9% reduction in hospitalization in Viral MMBV group among adults presenting to the ED with blood culture orders

### ~\$562,200 estimated institutional cost savings

\$4,073.96 cost savings/patient (institutional data)

### Cost neutral implementation

Blood cultures + MeMed BV Testing + Antibiotics:

- T1: 50,217
- T2: 49,130

LoVerde A, Ghitan M, Bodenstein H, et al. *JACEP Open*. 2026;6(6):100255.


# Implementation

Workflow and population considerations



# MeMed BV Unique Features

- MeMed BV Signature (CRP/IP-10/TRAIL) broadly cleared, maximizes clinical applications
  - Cleared for use on patients who have exhibited fever or other symptoms of acute infectious disease  $\leq 7$  days.
- Diverse ages maximize addressable population
  - Pediatrics 90 days and older
  - Adults with no age restriction
- Diverse analyzer options maximize accessibility
  - MeMed Key: Stand-alone, ~4 tests/hour
  - Access 2 Immunoassay System: Benchtop analyzer, ~100 tests/hour
  - Dxl 9000 Access Immunoassay Analyzer: High-throughput analyzer, ~450 tests/hour
- Potential value for rural and under-resourced facilities
  - Better risk stratification for acute infection patients could reduce unnecessary referrals and/or transfers



## Stakeholders/Key Decision Makers to Approach in Your Health System

- ED Medical Director
- Antimicrobial Stewardship Committee Members
- Value Analysis Committee Members
- Director of Emergency Services
- VP Quality
- Chief Nursing Officer
- Chief Medical Officer



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