

Utilizing Host Immune Response to Differentiate Between Bacterial and Viral Infections

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DiaSorin

LIAISON® MeMed BV® Overview

Clinical and Technical Features

Case Studies



**To treat
or not
to treat?**

LIAISON® MeMedBV

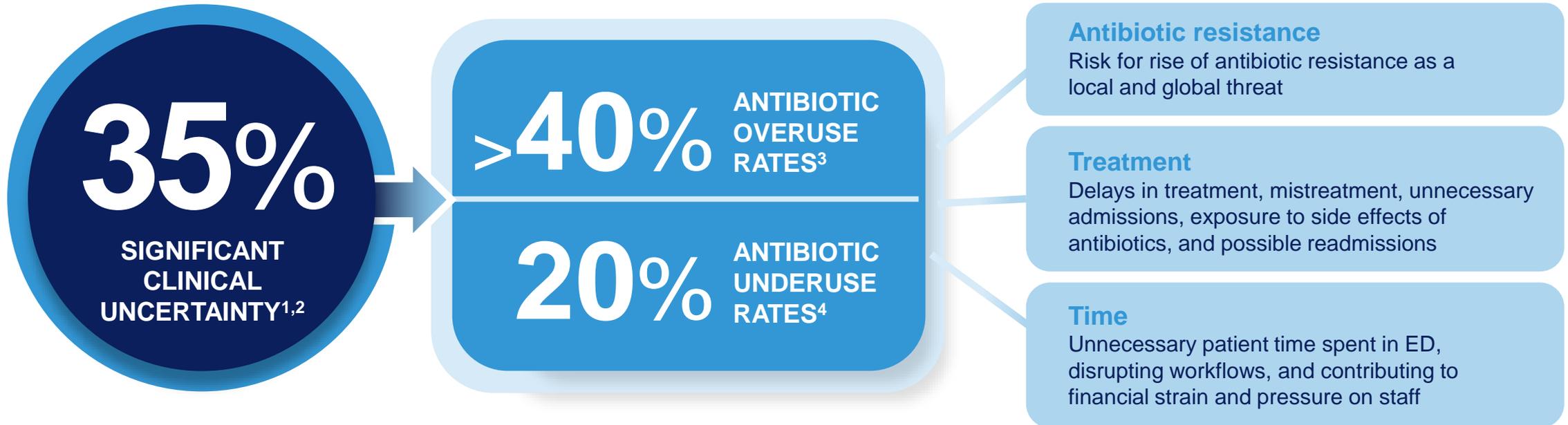
The new test enables physicians to accurately differentiate between bacterial and viral infections, thus supporting fast and more-informed treatment and patient management decisions.

This innovative solution will be soon available on DiaSorin LIAISON® XL and XS systems.



The problem for clinicians

Bacterial and viral infections are often clinically indistinguishable.



Sources: 1. MeMed survey of ED pediatricians (n=42). 2. D Wang, et al. Primary Care Respiratory Medicine (2021). 3. Antibiotic use in the United States: Progress and opportunities — 2018 update, Center of Disease Control and Prevention (CDC). 4. Kornblith, et al. Predictors for under-prescribing antibiotics in children with respiratory infections requiring antibiotics (2018).

The problem for labs

Today's diagnostic methods to distinguish between bacterial and viral infections are imperfect



Prolonged time to results (up to 2 days)



Inaccessible infection sites



Often, no pathogens are detected



Undetected bacterial co-infections



False alarms due to natural flora (detection=disease)

The lack of available tools that can provide an accurate answer within the workflow timeline creates **costly inefficiencies** and plays a major role in the **misuse of antibiotics**—which has local and global implications.

Introducing the revolutionary LIAISON® MeMed BV®

Together, DiaSorin and MeMed Diagnostics Ltd partnered to develop the LIAISON® MeMed BV® test for the LIAISON® family of analyzers—the first CLIA, fully automated and high-throughput assay to identify whether a patient presenting in the ED with a suspected acute infection has a bacterial or viral infection.



USE LOCATION

Hospital emergency departments



USE POPULATION

Adult and pediatric patients with suspected acute bacterial or viral infection



RESULTS TIME

Results can be returned in as little as **35 minutes**



PERFORMANCE

Greater than 99% viral identification agreement*

99%+

LIAISON® MeMed BV® delivers powerful diagnostics to increase confidence in patient treatment decisions

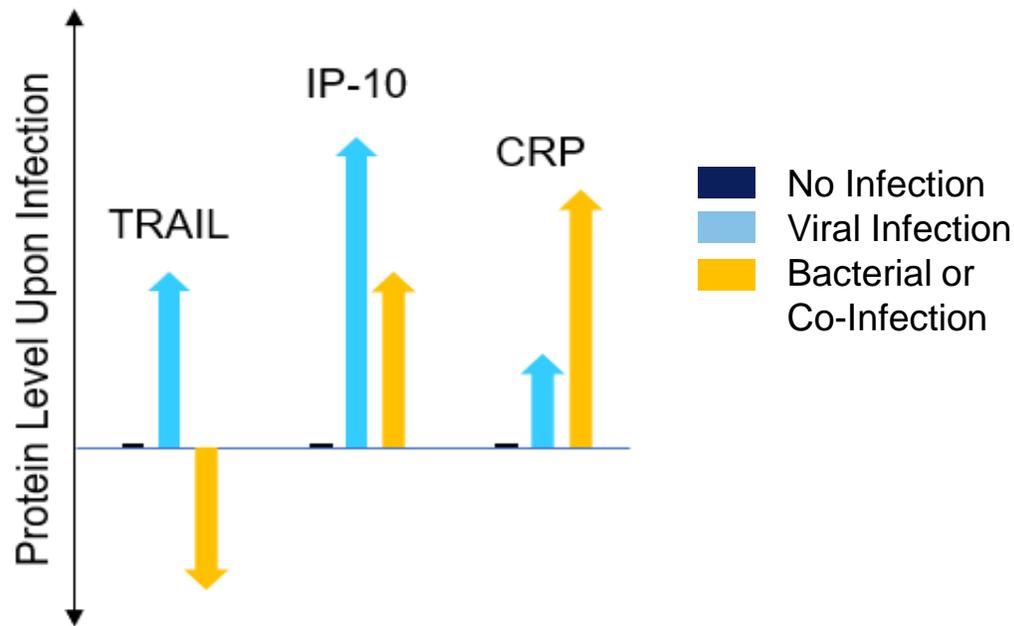
Significantly better performance than other clinical parameters and well-established markers

Improves the quality of a patient's life by optimizing antibiotic use and helps promote antimicrobial stewardship

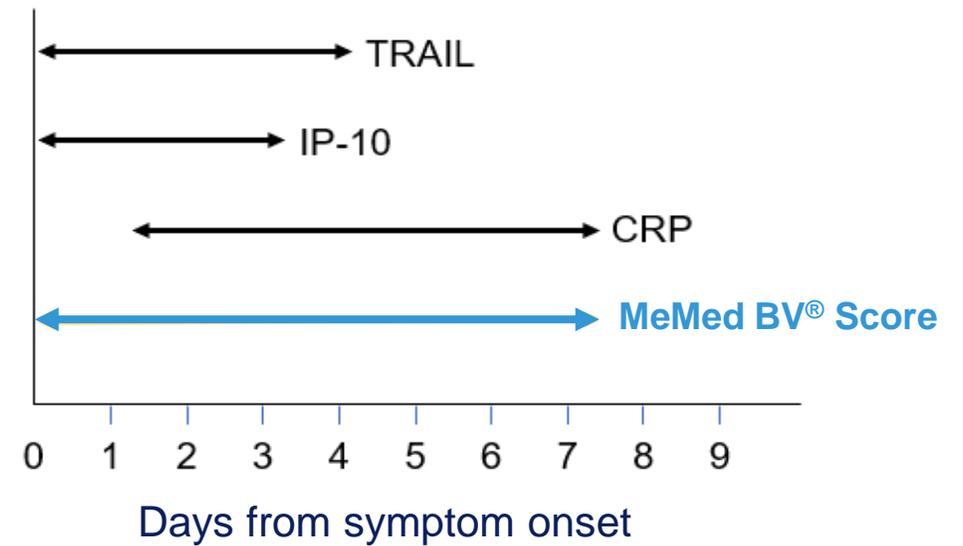
*Data based on Expert Adjudication

Robust behavior of the markers produces a generalizable score

Single Protein Analysis vs MeMed BV[®] Score



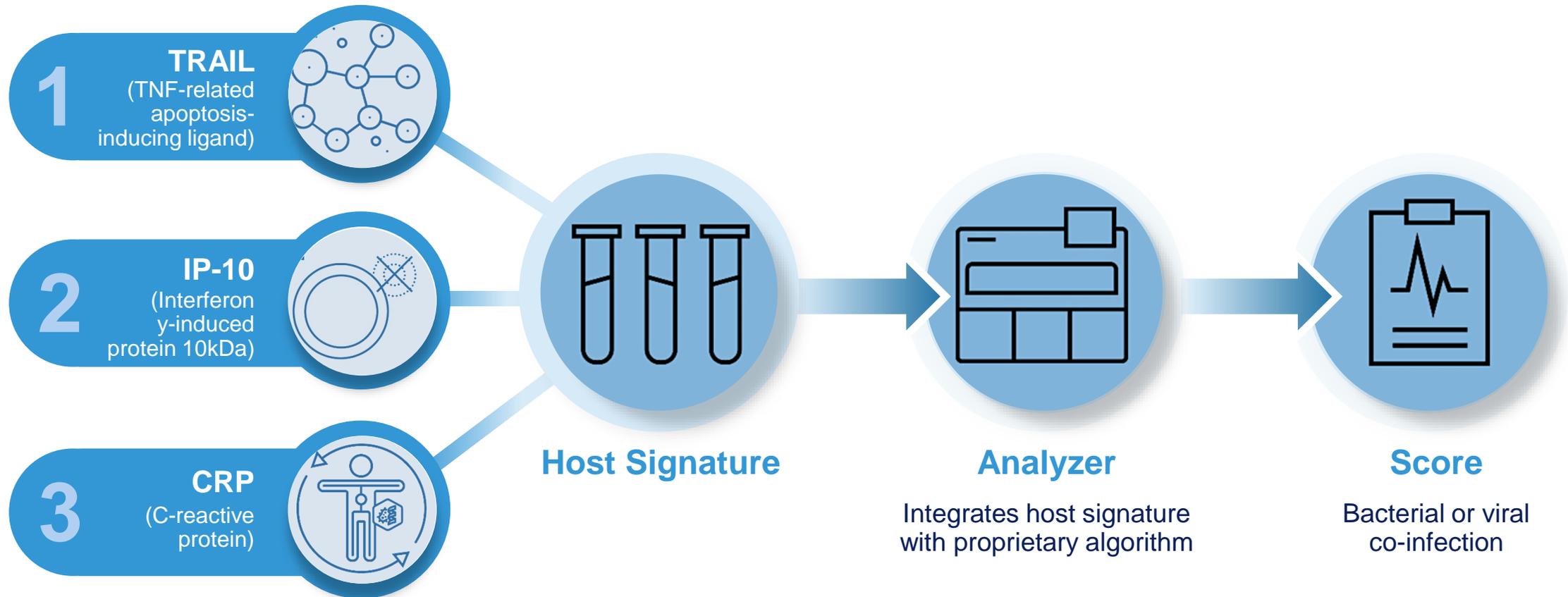
When Biomarker or MeMed BV[®] Score is Useful



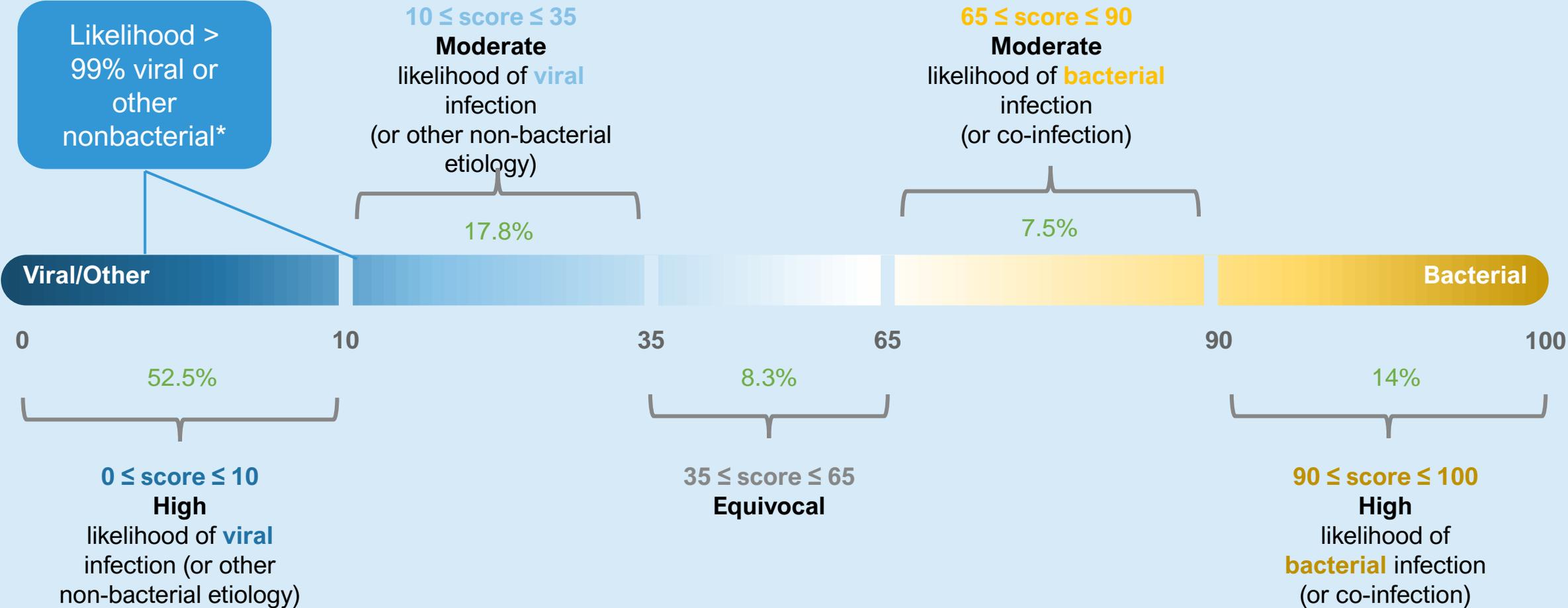
The result is a single qualitative score showing the likelihood of a bacterial or viral infection.

How it works

The LIAISON® MeMed BV® discriminates bacterial and viral infections by leveraging an immune-based protein signature test that measures and computationally **integrates the levels of three host-proteins** (TRAIL, IP-10 and CRP) and assigns a score indicating the likelihood of a bacterial or viral infection.



LIAISON[®] MeMed BV[®] results and interpretation

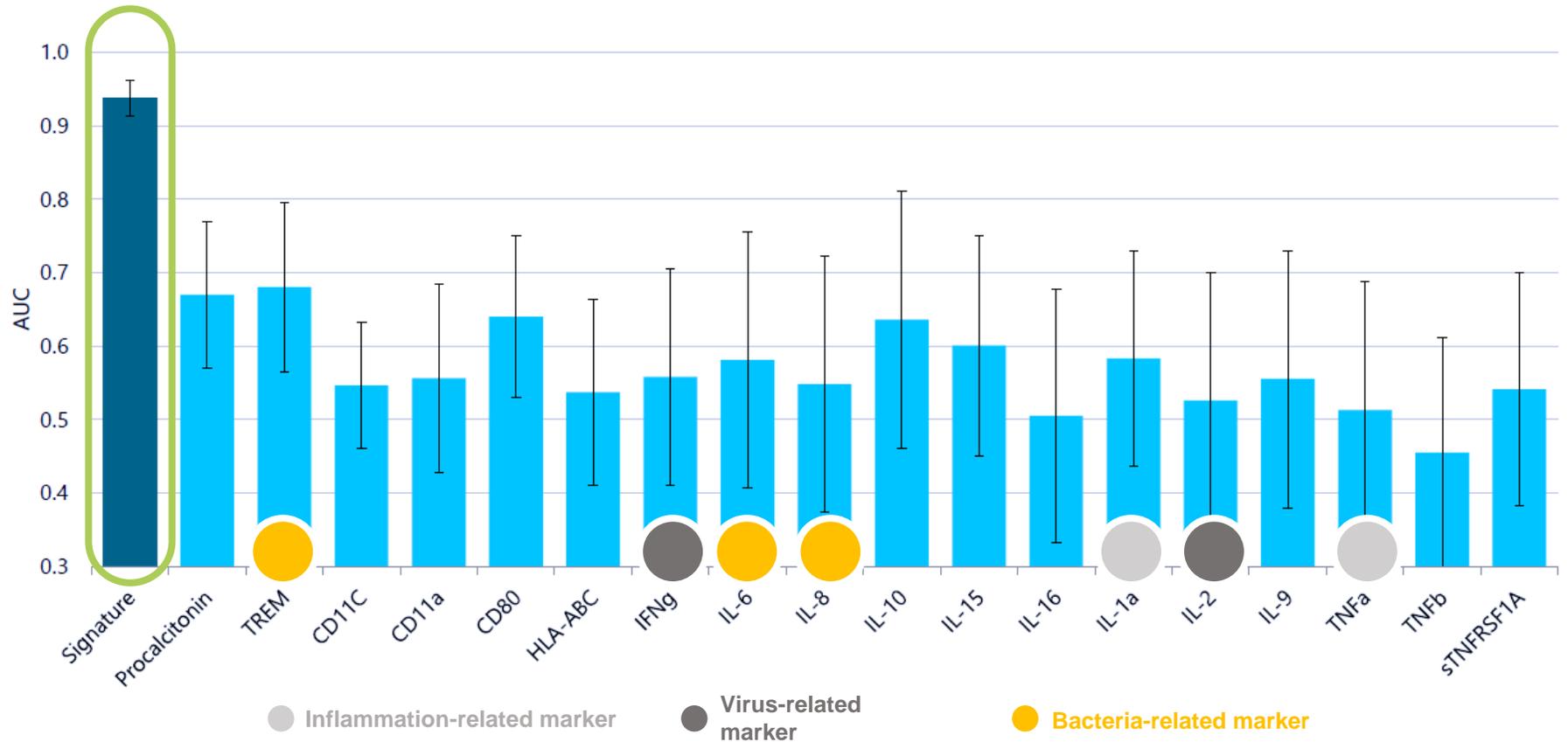


Patient distribution on LIAISON[®] MeMed BV[®] scale

*Likelihood based on Apollo study secondary endpoints results

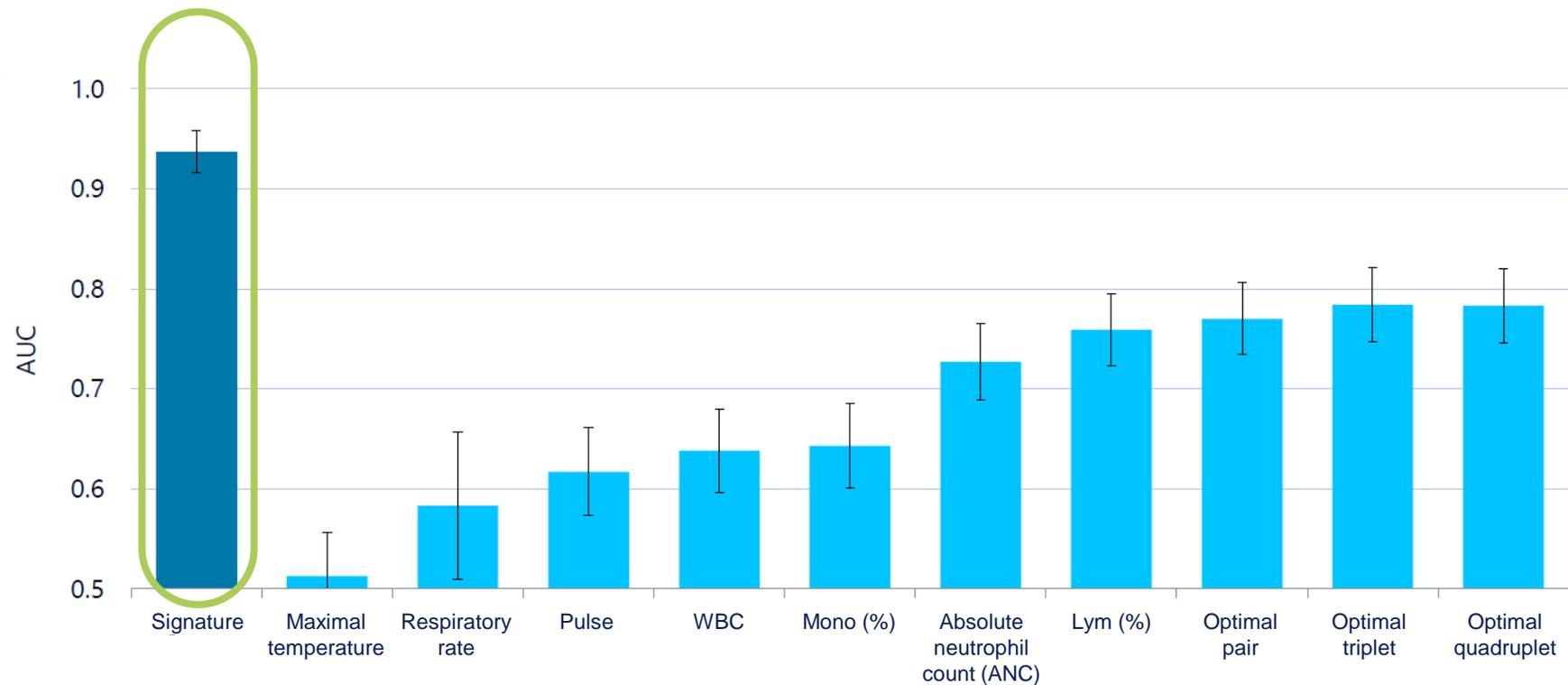
The host-protein signature performance versus laboratory measurements

The signature performs significantly better ($P < 10^{-8}$) than individual markers with a well-established role in the host response to infections



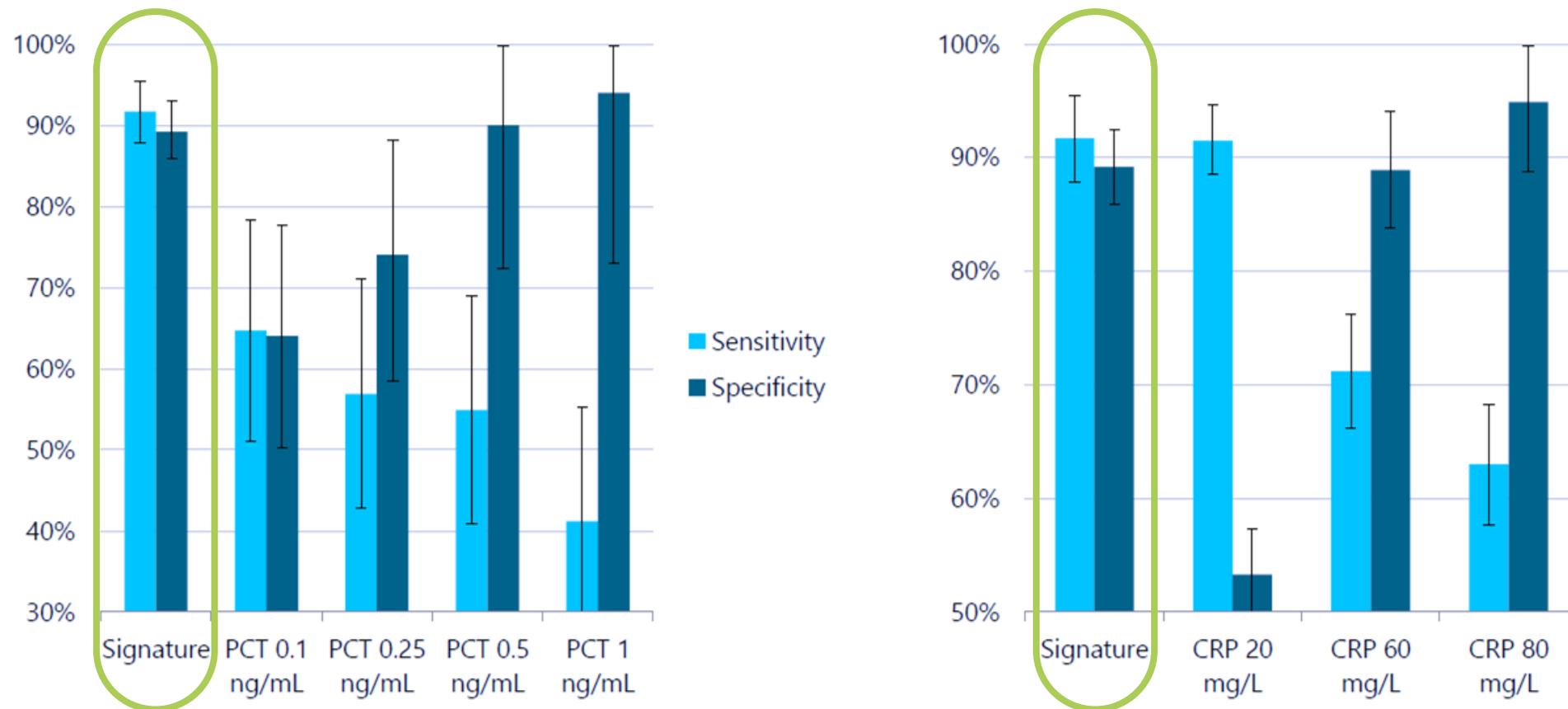
The host-protein signature performance versus clinical parameters

The signature exceeds the best-performing combination of clinical parameters ($P < 10^{-15}$)



Performance comparison to PCT and CRP

The signature performed significantly better than both PCT and CRP individual markers, showing the most pronounced diagnostic accuracy to differentiate bacterial and viral infections



Case Studies



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CASE STUDY 1: 83-Year-Old Woman



Clinical Examination



Temperature
38.5°C



HR 85
beats/min



RR 20
breaths/min

- Appears well
- No acute distress
- Revealed rales (crackles) bilaterally but greater on the right



CASE STUDY 1: 83-Year-Old Woman

Diagnostic Testing

Lab Tests

- Respiratory panel (COVID-19, flu, RSV)
- Complete Blood Count (CBC)
- Basic Metabolic Panel (BMP)
- Urinalysis (UA)
- Urine culture
- **NEW-LIAISON® MeMed BV®**

Other Tests

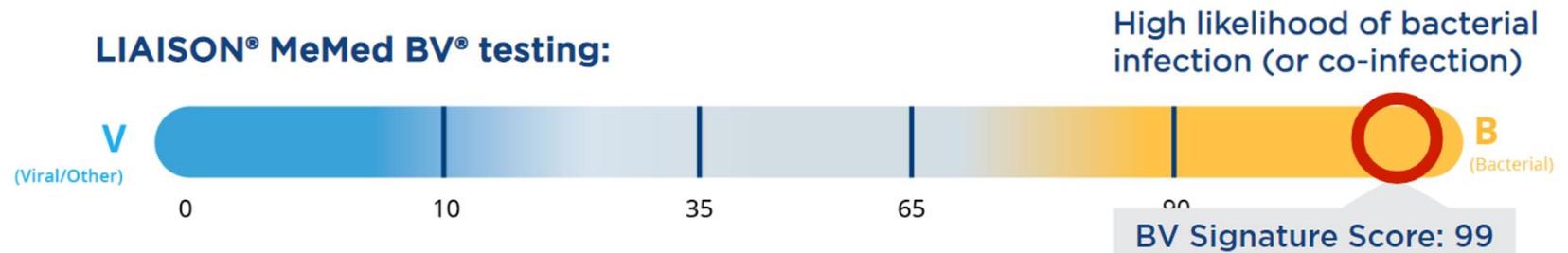
- Chest x-ray
- Electrocardiogram (ECG)
- CRP



Results

- Normal: Respiratory mini panel, BMP, UA, ECG
- High Normal: White Blood Count (WBC) 11K
- Elevated: Absolute Neutrophil Cells (ANC) 9K
- Chest x-ray revealed RUL infiltrated
- Moderately Elevated: CRP 23 mg/dL

LIAISON® MeMed BV® testing:



CASE STUDY 1: 83-Year-Old Woman



Clinical Course of Action

- Admitted to the hospital
- Prescribed amoxicillin-clavulanate plus azithromycin
- Extended respiratory pathogen panel performed: negative
- Blood culture performed: negative



Further Evaluation

- Fever and rales resolved over 3 days
- Discharged home
- Follow-up chest x-ray after 6 weeks showed resolution of pulmonary infiltrate

CASE STUDY 1: 83-Year-Old Woman



LIAISON® MeMed BV® Testing Final Diagnosis

Timely Bacterial-Viral Discrimination

- LIAISON® MeMed test permitted detection of bacterial pneumonia when history, physical examination and some laboratories suggested viral pneumonia
- Consistent with CXR showing RUL infiltrate
- Antibiotics administered in a timely manner

LIAISON® MeMed BV® testing:



CASE STUDY 2: 5-Month-Old Girl



Initial Clinical Presentation



Previously healthy



No medications



Vaccines up to date

- Poor appetite, vomited twice
- Normal urination
- Has a 2-year-old sibling who had an upper respiratory tract infection with fever one week prior to the present illness



CASE STUDY 2: 5-Month-Old Girl



Clinical Examination



Temperature
40°C



HR 180 bpm BP
96/64 mmHg



RR 60
O₂ Sat 97%

- Physical exam revealed decreased breath sounds bilaterally and crepitation on the right
- Fontanelles were slightly depressed and pulsatile



CASE STUDY 2: 5-Month-Old Girl



ED Evaluation

- Clinical assessment and vital signs were repeated with findings similar to those at the pediatrician
- **Imaging:** Chest x-ray - bilateral perihilar infiltrates
- **Laboratory testing:**
 - Blood cultures obtained
 - Negative viral molecular panel C-19, flu A/B, RSV
 - White Blood Count (WBC) 20K (elevated)
 - Absolute Neutrophil Count (ANC) 14.6K (elevated)
 - CRP 10 mg/dL (elevated)



CASE STUDY 2: 5-Month-Old Girl



ED Assessment

- Possible pneumonia
- Mild dehydration
- Chest X-ray and elevated temperature, HR, RR, WBC, ANC and CRP are consistent with bacterial infection but can also be seen in viral infection



ED Plan

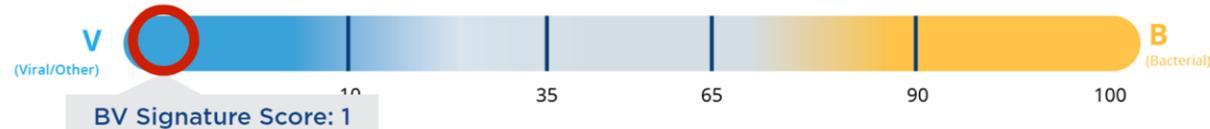
- LIAISON® MeMed BV® test, followed by chest CT if necessary to distinguish bacterial vs viral infection
- Additional molecular respiratory testing

CASE STUDY 2: 5-Month-Old Girl



Results

LIAISON® MeMed BV® testing:
High likelihood of viral infection
(or other non-bacterial etiology)



Clinical Course of Action

Molecular Respiratory testing:
Positive for adenovirus and metapneumovirus

- Supportive care administered
- Fever, tachycardia, tachypnea resolved
- Discharged home

DIAGNOSIS: Viral bronchiolitis caused by adenovirus and metapneumovirus

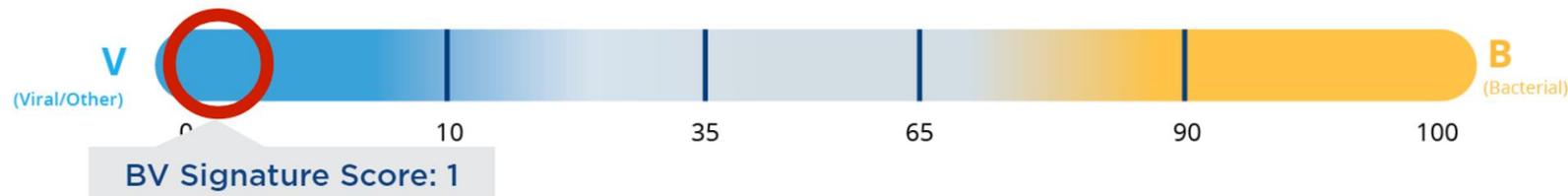
CASE STUDY 2: 5-Month-Old Girl



LIAISON® MeMed BV® Testing Final Diagnosis

- Viral bronchiolitis caused by adenovirus and metapneumovirus
- LIAISON® MeMed BV® score indicated very low chance of bacterial pneumonia
- A chest CT scan was not needed
- Antibiotic treatment was not required

LIAISON® MeMed BV® testing:



Clinical Case Summaries

1

Timely antibiotic administration

Patient with pneumonia without initial localized signs.

Patient management was changed, and antibiotics administered in a timely manner.

2

Antibiotic use not necessary

Clear viral etiology

BV signature prevented antibiotic use, currently it required reviewing CXR a second time.

The BV signature can impact clinical decision pathway and patient management.

Improving clinical certainty around treatment decisions

Situation

- Lack of a true, objective decision-making tool to distinguish between bacterial and viral infections leads to overuse of antibiotics
- Costs valuable time, money and peace of mind

Solution

- LIAISON® MeMed BV® delivers fast differentiation between bacterial and viral
- Transforms treatment of infectious diseases and improves confidence/satisfaction for clinician and patient

Science

- LIAISON® MeMed BV® automatically measures, analyzes and integrates the levels of three host immune proteins to show likelihood of a bacterial immune response versus viral

Performance summary:

**Greater than 99%
viral identification
agreement***



99%+

LIAISON® MeMed BV®
delivers powerful diagnostics
to increase confidence in
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Questions ???

Thank You