A new test, based on the measure of three non-microbial host proteins, for the differentiation between bacterial and viral infections.

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R. Alonso, L. Urbina, J. Serrano, P. Catalán, C. Sánchez-Carrillo, P. Muñoz

Department of Clinical Microbiology and Infectious Diseases.
Hospital General Universitario Gregorio Marañón. Madrid. Spain

INTRODUCTION

Bacterial and viral infections are often clinically indistinguishable. Clinical findings are frequently unspecific and do not provide definitive discrimination; this may lead to inappropriate patient management, including misuse of antibiotics, with serious health consequences.

An accurate diagnostic method has high impact on clinical decisions and laboratory efficiency.

This study aimed to investigate the accuracy of a new test (LIAISON® MeMed BV®) to differentiate bacterial from viral infections.

MATERIALS AND METHODS

Between March and September 2022, 123 patients from the emergency department and hospitalization areas of our hospital were preselected for this study. All included patients had a **suspicion of acute infection** (who have had symptoms for less than seven days) which was investigated by the microbiology laboratory. The availability of serum samples from the patients was required for the inclusion.

Bacterial and viral infections were confirmed at the microbiology laboratory by standard culture methods or PCR assays from different samples.

Of the 123 preselected patients, **44 met the inclusion criteria** required by the test (according to the manufacturer the test can not be performed on pregnant women, active malignancy, HIV/HCV/HBV infections, active tuberculosis, inflammatory disease, recent major surgery or trauma/burns among others).

Serum samples were tested with **LIAISON® MeMed BV®** (**DiaSorin** S.P.A., Italy), an automated chemiluminescent immunoassay performed at the **LIAISON XL® instrument** (FIGURE 1) to measure three non-microbial host proteins (TRAIL, IP-10, and CRP) to differentiate between bacterial from viral infections. The test provides a numeric score (BV) that falls into discrete interpretation ranges indicating the likelihood of a bacterial/co-infection immune response versus a likely viral immune response (FIGURE 2).

The BV score and the reference (REF) microbiology diagnostics information (culture/PCR) were compared to evaluate the agreement between the two diagnostic approaches.

FIGURE 1. LIAISON XL® instrument

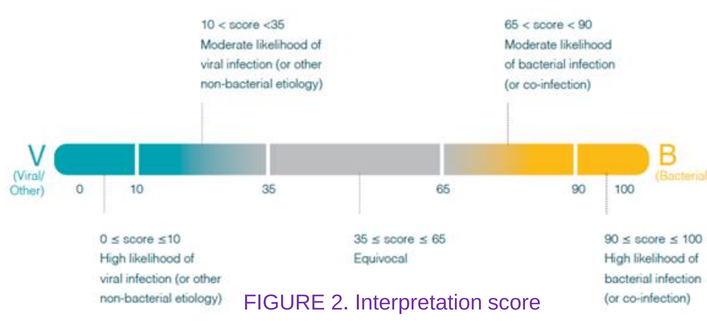

FIGURE 2. Interpretation score

RESULTS

Reference methods provided a diagnosis of **bacterial** and **viral** infections in 19 (43%) and 17 samples (39%) respectively. Eight (18%) specimens were classified as **co-infections** (TABLE 1).

LIAISON® MeMed BV® showed an **overall agreement** with the reference standard aetiology in 36 samples (90%). Specifically, 13 (87%) and 23 (92%) of samples collected from microbiologically confirmed viral and bacterial/co-infected patients respectively, were correctly classified by the test (TABLE 3). **Inconclusive** (Equivocal) results were obtained by LIAISON® MeMed BV® in 4 (9%) of samples analysed (2 viral and 2 co-infection) (TABLE 2). These samples were excluded from the agreement analysis (TABLE 3).

For 4 samples we obtained discordant results. Out of them 2 COVID-19 were classified by the new test as bacterial infections (1 HighBact & 1 ModBact) and 2 sepsis (1 *E. coli* & 1 MSSA) were classified as viral ones (1 HighVir & 1 ModVir).

The test was fully automated, results were available in **45 minutes** and up to 35 samples could be processed per hour with a minimal intervention.

BACTERIAL INFECTIONS (N=19, 43%)
Sepsis (19): MRSA (5), *E.coli* (6), *K. pneumoniae* (2), *E. cloacae* (1), *S. liquefaciens* (1), *L. monocytogenes* (1), *E. faecalis* (1), *S.pneumoniae* (1), *S. canis* (1)
CO-INFECTIONS (VIRAL + BACTERIAL) (N=8, 18%)
COVID-19 + bacterial pneumonia (4); COVID-19 + urinary infection (2); COVID-19 + endocarditis (1); Flu A + Sepsis (1)
VIRAL INFECTIONS (N=17, 39%)
MonkeyPox (10); COVID-19 (6); Flu A (1)

TABLE 1. Classification of infection, from patients included at the study, according to reference laboratory methods (culture and PCR).

		BV SCORE			
		BAC/CO-INFEC	VIR	EQV	TOT
REF	BAC	17	2	0	19
	CO-INFEC	6	0	2	8
	VIR	2	13	2	17
	TOT	25	15	4	44

TABLE 3. Comparison of results from LIAISON® MeMed BV® *vs.* reference (REF). BAC: bacterial infection; VIR: viral infection; CO-INFEC: co-infection. Agreement is shown in green colour, disagreement in red colour and equivocal (undetermined) in orange colour.

LIAISON® MeMed BV® CLASSIFICATION	BV score classification (No)	No. of Patients (%)
Viral	Score 0-10, HighVir (8) Score 10-35 ModVir (7)	15 (34%)
Bacterial or Co-infections (viral+bacterial)	Score 90-100, HighBact (19) Score 65-90, ModBact (6)	25 (57%)
Inconclusive (equivocal)	Score 35-65 (4)	4 (9%)
Total	-	**44**

TABLE 2. LIAISON® MeMed BV® classification of infections. Likelihood of viral (HighVir or ModVir) or bacterial/co-infection (HighBact or ModBact) with respect to the obtained score, is also shown.

CONCLUSIONS

The data have shown the **good performance of the LIAISON® MeMed BV® test to differentiate between viral and bacterial/co-infections in one single diagnostic procedure**. The test can be a convenient tool, to be used in conjunction with other clinical and laboratory parameters, as an **aid to expedite patient management and for treatment decisions, particularly for emergency patients**.

Moreover, due to its full automation and high-throughput this new diagnostic solution could contribute to **optimize the diagnostic pathway** performed by the laboratory.

REFERENCES

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Hospital General Universitario Gregorio Marañón
SaludMadrid
Comunidad de Madrid

33rd ECCMID EUROPEAN CONGRESS OF CLINICAL MICROBIOLOGY AND INFECTIOUS DISEASES
Copenhagen, Denmark
15–18 April 2023