DIAGNOSTIC ACCURACY OF FEBRIDX®: A RAPID TEST TO DETECT IMMUNE RESPONSES TO VIRAL AND BACTERIAL UPPER RESPIRATORY INFECTIONS

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ABSTRACT

C-reactive protein (CRP) and myxovirus resistance protein A (MxA) are associated with bacterial and viral infections, respectively. We conducted a prospective, multicenter, cross-sectional study of adults and children with febrile upper respiratory tract infections (URIs) to evaluate the diagnostic accuracy of a rapid CRP/MxA immunoassay to identify clinically significant bacterial infection with host response and acute pathogenic viral infection. The reference standard for classifying URI etiology was an algorithm that included throat bacterial culture, upper respiratory PCR for viral and atypical pathogens, procalcitonin, white blood cell count, and bandemia. The algorithm also allowed for physician override. Among 205 patients, 25 (12.2%) were classified as bacterial, 53 (25.9%) as viral, and 127 (62.0%) negative by the reference standard. For bacterial detection, agreement between FebriDx® and the reference standard was 91.7%, with FebriDx® having a sensitivity of 80% (95% CI: 59–93%), specificity of 93% (89–97%), positive predictive value (PPV) of 63% (45–79%) and a negative predictive value (NPV) of 97% (94–99%). For viral detection, agreement was 84%, with a sensitivity of 87% (75–95%), specificity of 83% (76–89%), PPV of 64% (63–75%), and NPV of 95% (90–98%). FebriDx® may help to identify clinically significant immune responses associated with bacterial and viral URIs that are more likely to require clinical management or therapeutic intervention and has potential to assist with antibiotic stewardship.

Most upper respiratory tract infections do not require antibiotic treatment and the inappropriate use of antibiotics for viral URIs has been linked to the development of antibiotic resistance, antibiotic-associated infections, increased costs, and drug toxicities.

Rapid diagnostic tests to assist clinicians with antibiotic prescribing decisions are lacking, which has hampered antibiotic stewardship efforts. CRP levels > 20mg/L can identify a clinically significant immune response but cannot reliably differentiate between viral and bacterial etiology.

FebriDx® is a new rapid point-of-care diagnostic test designed to provide clinicians with actionable, and accurate data on the likely etiology of URIs and assist with antibiotic prescribing decisions. FebriDx® provides qualitative results for elevated levels of CRP and MxA from fingerstick blood.

FebriDx® was sensitive and specific for identifying clinically-important viral and bacterial infections in febrile outpatients with URIs with a negative predictive value (NPV) of 97% for bacterial infections.

Standalone CRP testing concluded 38% of patients in the study with confirmed viral infections had elevated CRP ≥ 20 mg/L which could contribute to overtreatment.

By combining CRP and MxA into a single test, FebriDx® has potential to assist clinicians with rapidly distinguishing between viral and bacterial URIs and promoting antibiotic stewardship.

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