A PROSPECTIVE, MULTI-CENTRE U.S. CLINICAL TRIAL TO DETERMINE ACCURACY OF FEBRIDX® POINT-OF-CARE TESTING FOR ACUTE UPPER RESPIRATORY INFECTIONS WITH AND WITHOUT A CONFIRMED FEVER

Shapiro NI, Self WH, Rosen J, Sharp SC, Filbin MR, Hou PC, Parekh AD, Kurz MC, Sambursky R

***Ann Med.* 2018;50(5):420-9.**

ABSTRACT

BACKGROUND: FebriDx® is a 10-minute disposable point-of-care (POC) test designed to identify clinically significant systemic host immune responses and aid in the differentiation of bacterial and viral respiratory infection by simultaneously detecting c-reactive protein (CRP) and myxovirus resistance protein A (MxA) from a fingerstick blood sample. FebriDx® diagnostic accuracy was evaluated in the emergency room and urgent care setting.

METHODS: A prospective, multicentre, observational cohort study of acute upper respiratory tract infections (URIs), with and without a confirmed fever at the time of enrolment, was performed to evaluate the diagnostic accuracy of FebriDx® to identify clinically significant bacterial infection with host response and acute pathogenic viral infection. The reference method consisted of an algorithm with physician override that included bacterial cell culture, respiratory PCR panels for viral and atypical pathogens, procalcitonin, and white blood cell count.

RESULTS: Among 220 patients enrolled, 100% reported fever 100.5F within the last 72 hours while 55% had a measured hyperthermia (T > 100.4) at the time of enrolment. FebriDx® demonstrated a sensitivity of 95% (95% CI: 77–100%), specificity of 94% (88–98%), PPV of 76% (59–87%), and a NPV of 99% (93–100%).

CONCLUSION: FebriDx® may identify clinically significant bacterial URIs and supports outpatient antibiotic decisions.

The majority of acute upper respiratory infections are self-limiting but remain the most common reasons for antibiotic prescriptions in adults in the U.S. Antibiotic overuse leads to antibiotic resistance, antibiotic-associated infections and increased costs.

The ability to rapidly differentiate viral from bacterial infection is essential for successful outpatient antibiotic stewardship, however historically there has been a lack of rapid and accurate diagnostic tests to assist clinicians with prescribing decisions.

Using CRP alone to guide therapeutic decisions can help to prevent missing a serious bacterial infection but will lead to nearly 40% overtreatment of viral infections. Of 124 patients in this study with a microbiologically confirmed viral infection, 56% had a CRP > 20 mg/L.

FebriDx® is a novel 10-minute POC diagnostic test which aids in the differentiation of viral and bacterial infections through the detection of elevated levels of c-reactive protein (CRP) and myxovirus resistance protein A (MxA) from fingerstick blood.

By combining CRP and MxA into a single test, FebriDx® includes sensitive markers of both bacterial and viral infection. MxA provides the required specificity to the CRP interpretation to allow for guiding therapeutic decisions.

FebriDx® was determined to be an accurate test, with 85% sensitivity, 93% specificity and 97% NPV to rule out bacterial infection for any patient presenting with symptoms and reported fever within the prior 3 days.

FebriDx® is easy to use and reveals greater accuracy than a standalone CRP or PCT test for identifying clinically-important viral and bacterial URI. FebriDx® test supports a delayed antibiotic prescribing strategy for FebriDx®-negative or viral positive patients.

FebriDx® is not currently available in the United States.

FebriDx® is authorized to identify and differentiate viral from bacterial acute respiratory infection; its use for the specific diagnosis of COVID-19 is not authorized by Health Canada.

LUMOS DIAGNOSTICS

Lumos Diagnostics • 7227 Delainey Court • Sarasota, FL 34240 USA **+1 941.556.1850** • **FebriDx.com**