



FOR IMMEDIATE RELEASE

A Prospective Multicenter Clinical Trial Demonstrates that FebriDx Can Accurately Identify Clinically Significant Bacterial Infections and May Support Antibiotic Stewardship in the Outpatient Setting

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SARASOTA, FL (May 21, 2018) – [RPS Diagnostics \(RPS®\)](#) today announces publication of a second United States (U.S.) clinical study that supports the accuracy of the FebriDx® test, a 10-minute, single use, disposable, point-of-care diagnostic test capable of identifying clinically significant acute bacterial and viral respiratory tract infections by testing the body’s immune response to infections. The clinical data published in an article entitled, “A prospective, multi-centre US clinical trial to determine accuracy of FebriDx point-of-care testing for acute upper respiratory infections with and without a confirmed fever” on May 18, 2018 in *Annals of Medicine*.

The prospective study enrolled 220 patients with upper respiratory infection (URI) from ten clinical sites in the U.S., including outpatient academic emergency departments and community care centers. Approximately half of the patients were febrile (hyperthermic) when they presented while the balance of the patients reported a history of fever within the prior three days. The FebriDx test’s sensitivity for bacterial infection was higher in the patients confirmed to have a fever (95%) compared with the overall population (85%). FebriDx demonstrated a sensitivity of 95%, specificity of 94%, positive predictive value (PPV) of 76%, and a negative predictive value (NPV) of 99% in febrile patients. Across the entire population, the FebriDx test was found to have a 97% NPV that supports a delayed antibiotic prescribing strategy.

Acute URI, which consists of sinusitis, sore throat, the common cold, and acute uncomplicated bronchitis, is extremely common and leads to frequent outpatient physician visits and antibiotic prescriptions worldwide. According to the U.S. Centers for Disease Control and Prevention (CDC), approximately forty-one million adult ambulatory care visits result in an antibiotic prescription, of which 50% may be unnecessary.

Antibiotic overuse leads to antibiotic-associated infections, increased costs, and adverse events, ranging in severity from mild diarrhea and rash to life-threatening conditions as well as contributes to the growing concerns for antibiotic resistance. Most patients with acute URI present to primary

and urgent care clinics in the outpatient setting, and because of clinician diagnostic uncertainty and pressure from patients or their guardians, lead to an antibiotic prescription. Point-of-care diagnostic testing is a cost-effective way to manage outpatient antibiotic stewardship for acute febrile URI.

“The overuse of antibiotics is a significant and growing problem,” said Robert Sambursky, MD, RPS Diagnostics’ President and Chief Executive Officer. “FebriDx provides clinicians a tool for rapidly measuring an immune response. This information facilitates clinical decision making and reduces unnecessary antibiotic prescribing.”

[FebriDx®](#) is a novel, single use disposable point-of-care (POC) diagnostic test designed to rapidly identify clinically significant host immune responses associated with bacterial and viral URIs and to assist with antibiotic prescribing decisions. The FebriDx test uses proprietary technology to detect a combination of two biomarkers, myxovirus resistance protein A (MxA) – an intracellular protein that becomes elevated in the presence of acute viral infection and C-reactive protein (CRP) – an acute-phase inflammatory protein that is frequently elevated in the presence of bacterial infection. As a standalone test, neither MxA nor CRP alone is sensitive or specific at identifying both viral and bacterial infection; however used together, this combination of biomarkers provides a sensitive and specific way to identify an immune response to a viral or bacterial infection. For more information about the FebriDx test, visit [FebriDx.com](#).

RPS Diagnostics

RPS Diagnostics is an emerging biotechnology company strategically focused on designing, developing, and delivering novel point-of-care tests for infectious diseases and antibiotic stewardship. RPS Diagnostics is a trade name of Rapid Pathogen Screening, Inc., a wholly owned subsidiary of RPS Diagnostics, Inc. RPS products are developed using a unique, innovative, and patented technology platform that the company can utilize to develop a variety of cost-effective tests. RPS tests allow healthcare providers to more accurately diagnose diseases, provide appropriate and timely treatment, and reduce healthcare costs associated with spread of disease and unnecessary treatment methods. The FebriDx test has received HealthCanada approval, Saudi Arabia FDA clearance, Singapore HSA registration, and is CE marked for sale in Europe. At this time, the FebriDx test has not received U.S. FDA clearance and is not commercially available in the United States. For more information on RPS and its products, visit [RPSdetectors.com](#).

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