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Clinical Study Demonstrates that RPS Diagnostics' FebriDx Rapid Point-of-Care Blood Test Can Accurately Distinguish Between Acute Bacterial and Viral Respiratory Infections in the Outpatient Setting

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SARASOTA, FL (October 12, 2017) – RPS Diagnostics, Inc. (RPS®) today announces publication of a United States multicenter, prospective clinical study that demonstrates the accuracy of the FebriDx® test, a commercially-ready, 15-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.

Acute upper respiratory infections (URI) are the most common reason for oral antibiotic prescriptions in the U.S. Thirty to fifty percent of antibiotics used in the outpatient setting are inappropriate, resulting primarily from misuse of antibiotics to treat viral URI. Overuse of antibiotics leads to the development of antibiotic resistance, antibiotic-associated secondary infections, drug allergies, and increased costs. Proper antibiotic stewardship requires that clinicians use antibiotics for URIs only when adequate evidence for bacterial infection exists. However, there is a lack of available rapid diagnostic tests to assist primary and urgent care clinicians in the identification of clinically significant bacterial respiratory infections that necessitate antibiotic therapy, thus limiting outpatient antibiotic stewardship efforts.

Defining a **clinically significant bacterial infection** that requires treatment is important to help drive antibiotic stewardship. Bacterial colonization without infection occurs when microorganisms are detected without a significant associated systemic host response. The inability to differentiate bacterial colonization or local infection without an associated systemic host response from a clinically significant infection with an associated host response may result in unnecessary antibiotic prescriptions.

The FebriDx test uses proprietary technology to detect a combination of two biomarkers, myxovirus resistance 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. In isolation, neither MxA nor CRP

alone is sensitive or specific at identifying both viral and bacterial infection. The addition of MxA to the analysis confers specificity to the CRP interpretation such that, taken together, it provides a sensitive and specific way to identify an immune response to a viral or bacterial infection.

“A combination of diagnostic uncertainty and both patient and parental pressures to prescribe antibiotics lead to unnecessary antibiotic prescriptions and directly contribute to the growing antibiotic resistance crisis, said Robert Sambursky, MD, RPS Diagnostics’ President and Chief Technology/Medical Officer. “What makes FebriDx unique is its ability to shift antibiotic stewardship into the outpatient setting by providing tangible results for patients within 15 minutes without any ancillary equipment. These rapid results facilitate patient and practitioner confidence in clinical management and therapeutic decisions that could lead to withholding antibiotic prescriptions as part of a watchful waiting strategy.”

A prospective, multicenter, cross-sectional study of adults and children with URIs was performed to evaluate the diagnostic accuracy of the FebriDx test to identify clinically significant bacterial infections with host response and acute pathogenic viral infection in patients who presented with a history of fever in the outpatient setting. The clinical data published in an article entitled, “Diagnostic Accuracy of FebriDx: A Rapid Test to Detect Immune Responses to Viral and Bacterial Upper Respiratory Infections” on October 7, 2017 in the Journal of Clinical Medicine.

This study enrolled 370 patients, 205 symptomatic patients with URI and 165 asymptomatic patients from 10 clinical sites in the U.S., including academic emergency departments and community care centers. For bacterial detection, agreement between FebriDx and the reference standard was 92%, with FebriDx having a sensitivity of 80% and specificity of 93%. Bacterial sensitivity increased further in patients that had a confirmed fever at the time of enrollment. Most importantly, FebriDx demonstrated a negative predictive value (NPV) of 97% for bacterial infection. For viral detection, agreement was 84%, sensitivity ranged between 86-87%, specificity was 83-88%, and the NPV was 93-95% depending on the comparator method. Additionally, 38% of viral infections generated elevated CRP and would lead to antibiotic overtreatment if the CRP result was used independently of MxA.

“Robust clinical evidence as depicted in this trial will go a long way to support the international commercial launch of the FebriDx test that is anticipated for mid 2018,” said Doug Lawrence, RPS Diagnostics’ Chief Executive Officer.

Point-of-care diagnostic testing may help primary and urgent care clinicians cost-effectively manage patients presenting with clinical evidence of an acute febrile URI. For more information about the FebriDx test, visit FebriDx.com.

RPS Diagnostics

RPS Diagnostics (RPS) is an emerging developer, manufacturer, and marketer of cost-effective point-of-care (POC) tests for systemic infectious disease and antibiotic stewardship. RPS Diagnostics is a trade name of Rapid Pathogen Screening, Inc., a wholly owned subsidiary of RPS Diagnostics, Inc. The company's innovative and patented FebriDx® test is a rapid, disposable, in-office test that uses a fingerstick blood sample to help identify a clinically significant immune response and differentiate bacterial from viral causes for fever in acute respiratory infection. With a 97% negative predictive value, FebriDx delivers results in 15 minutes and can be used to help triage infectious patients during the initial office visit, providing clinicians with actionable information that can be used to limit unnecessary antibiotics. The FebriDx test has received HealthCanada approval, Saudi Arabia and Singapore HSA registration, and is CE marked for sale in Europe. At this time, the FebriDx test has not received U.S. Food and Drug Administration (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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