



ASX ANNOUNCEMENT

FebriDx® Update - Brazil Market Authorisation and New Study Published

- *Brazil's Health Regulatory Agency, ANVISA, has granted market authorization for the FebriDx test.*
- *FebriDx is a rapid 10-minute point-of-care test to aid healthcare professionals in detecting and differentiating bacterial from viral acute respiratory infections.*
- *FebriDx is now available to healthcare providers in the UK, Europe, Canada, Australia, UAE and Brazil.*
- *Independent meta-analysis of 5 studies involving 2,309 patients concludes FebriDx may have clinical value for rapid screening of patients with suspected COVID-19 in acute care settings.*

MELBOURNE, VIC. (28th February 2022) - Lumos Diagnostics (ASX:LDX), a leader in rapid point-of-care (POC) diagnostic technologies, today announced that it received market authorization for the FebriDx® test from Brazil's Health Regulatory Agency, ANVISA.

FebriDx is a rapid 10-minute point-of-care test that can aid healthcare professionals in detecting and differentiating bacterial from viral respiratory infections from a single fingerstick drop of blood—quickly providing results and helping guide care decisions. FebriDx is an all-in-one test that measures a patient's immune response to acute respiratory infections without any additional instruments or lab equipment. When used as part of a clinical exam, FebriDx can help healthcare professionals manage patients with a wide range of acute respiratory symptoms such as sore throat, cough and sinus congestion.

With ANVISA's market authorization, FebriDx is available to qualified healthcare providers across Brazil, and is also approved by the corresponding regulatory agencies and available to qualified healthcare providers in the UK, Europe, Canada, Australia and UAE. An application for U.S. FDA 510(k) regulatory clearance is under review with an outcome expected during FY2022.

"Historically, it has been difficult for doctors to determine if patients have viral or bacterial infections because the symptoms present nearly identical during a clinical exam," **said Robert Sambursky, MD, president and chief executive officer, Lumos Diagnostics.** "Using FebriDx, clinicians in Brazil can have actionable, lab-quality test results in about 10 minutes. This is a game-changer for diagnosing and managing acute respiratory infections in primary care and urgent care settings."

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For bacterial infections, FebriDx has been shown to provide a 97-99% negative predictive value (NPV), allowing healthcare professionals to confidently rule out bacterial infections for their patients. The ability to rule out bacterial infections is especially important during the respiratory (cold and flu) season because it can help reduce the use of medically unnecessary antibiotics.

Recently, an independent meta-analysis of data from five, investigator-led clinical studies involving 2,309 patients titled “FebriDx for rapid screening of patients with suspected COVID-19 upon hospital admission: systematic literature review and meta-analysis” has been published in the peer-reviewed *Journal of Hospital Infection*. This study concluded that, in addition to its intended use for differentiating bacterial from viral respiratory infections, FebriDx may have clinical value for the rapid screening of patients with suspected COVID-19 in acute care settings.

This announcement has been approved by the Lumos Disclosure Committee.

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About Lumos Diagnostics

Lumos Diagnostics specialises in rapid, cost-effective, and complete point-of-care (POC) diagnostic test technology to help healthcare professionals more accurately diagnose and manage medical conditions. Lumos offers customised assay development and manufacturing services for POC tests and proprietary digital reader platforms. Lumos also directly develops, manufactures, and commercialises novel Lumos-branded POC tests that target infectious and inflammatory diseases.

For more information visit lumosdiagnostics.com.

Forward-Looking Statements

This announcement contains forward-looking statements, including references to forecasts. Forward-looking statements are not guarantees of future performance and involve known and unknown risks, uncertainties, assumptions, and other important factors, many of which are beyond Lumos' control and speak only as of the date of this announcement. Readers are cautioned not to place undue reliance on forward-looking statements.

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