



ASX ANNOUNCEMENT

Publication of Data from DISRUPT Clinical Trial in JAMA

MELBOURNE, Australia (19 October 2022) – Lumos Diagnostics (ASX: LDX), (“Lumos” or the “Company”) is pleased to announce that results of its DISRUPT clinical trial of FebriDx[®] as an aid to differentiate bacterial from viral acute respiratory infections (ARI’s) has been published in the peer-reviewed journal JAMA Open Network. The authors concluded that the “rapid diagnostic test demonstrated performance that may inform clinicians when assessing for bacterial or viral etiology of ARI symptoms.”

The DISRUPT trial was a prospective, blinded, multicentre, observational study of FebriDx’s performance in identifying bacterial versus viral acute respiratory infections. Participants were enrolled between October 2019 and April 2021 at 20 outpatient sites throughout the United States. The trial included 496 ARI patients with a clinically adjudicated final diagnosis, and 170 subjects without an ARI. Participants with ARIs were diagnostically tested with FebriDx as well as multiplex-PCR (polymerase chain reaction) testing and culture algorithm designed to identify 28 different pathogens.

The results of this trial have been published in the peer-reviewed journal JAMA Open Network as an Original Investigation entitled “*Diagnostic accuracy of a bacterial and viral biomarker Point-of-Care test in the outpatient setting*” ([doi:10.1001/jamanetworkopen.2022.34588](https://doi.org/10.1001/jamanetworkopen.2022.34588)). In this study FebriDx demonstrated sensitivity of 93.2% and specificity of 88.4% for bacterial infections, providing a negative predictive value (NPV) of 98.7%. For viral ARIs, FebriDx demonstrated sensitivity of 70.3%, specificity of 88.0% and an NPV of 66.7%.

The publication describes that acute respiratory infections (ARIs) account for more than 150 million outpatient visits in the US each year. The similarity in the presenting symptoms for bacterial and viral ARI’s makes diagnosis difficult. As a consequence, clinicians have tended to overprescribe antibiotics to ensure that they do not miss a bacterial infection that has the potential to progress to a serious infection or sepsis. Many ARI visits are associated with antibiotic prescription with approximately 50% considered to be unnecessary or inappropriate. Diagnostic uncertainty is a key contributor to this antibiotic overuse.

“The publication of this important clinical study in JAMA reflects the quality of clinical data supporting our FebriDx product,” said Doug Ward, Chief Executive Officer of Lumos Diagnostics. “While we were clearly disappointed with the recent outcomes of our regulatory application and appeal to the FDA for clearance to market FebriDx in the US, we continue to believe that it has an important role in global healthcare.”

FebriDx is not available for sale in the US.

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 or febridx.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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