



LUMOS
DIAGNOSTICS

ASX ANNOUNCEMENT

Lumos and BARDA to Partner to Support FebriDx® bacterial/non-bacterial point-of-care test CLIA Waiver Study and Application

Key highlights:

- Lumos awarded US\$2,984,571 in non-dilutive funding from the Biomedical Advanced Research and Development Authority (BARDA) (US) to support the coming FebriDx® CLIA waiver study and US FDA application
- Total contract value, if all contract options are exercised, is US\$8,258,774
- FebriDx® can aid clinicians with appropriate antibiotic use decisions and will hopefully improve antibiotic stewardship
- The partnership aims to expand authorized testing to CLIA-waived, point-of-care settings, including U.S. physician offices, urgent care clinics, or other outpatient clinics, where empiric antibiotic prescription is common practice
- BARDA will support the CLIA waiver study, comparing test usage among untrained users in a CLIA-waived setting to trained users and also provide regulatory expertise and support for the application to obtain a CLIA-waiver from the FDA

MELBOURNE, Australia 3 October 2024 – Lumos Diagnostics (ASX: LDX), (“Lumos” or the “Company”) a leader in rapid, point-of-care (POC) diagnostic technologies, is pleased to announce that it has been awarded US\$2,984,571 from the Biomedical Advanced Research and Development Authority (BARDA), part of the U.S. Department of Health and Human Services’ Administration for Strategic Preparedness and Response, to support the planned Clinical Laboratory Improvement Amendments (CLIA)-waiver clinical study and regulatory submission for Lumos’ FebriDx® bacterial/non-bacterial test.

Lumos’ CEO and Managing Director, Doug Ward commented, *“Since early clinical practice, doctors have relied primarily on clinical observation to determine whether patients require antibiotics for acute respiratory conditions. FebriDx® is a powerful diagnostic which can provide a quick and clear clinical evaluation, and in doing so, can reduce over-prescription of antibiotics.*

We are honored to have the opportunity to partner with BARDA on the CLIA waiver study and regulatory submission for FebriDx®. BARDA’s expertise and the associated funding will support our objective of expanding the test’s utility - from its current use case in moderate/high complexity labs - to US CLIA-waived

point-of-care settings, including physician offices, urgent care clinics, or other outpatient clinics. Should this goal be achieved, FebriDx's ability to improve antibiotic stewardship will be vastly expanded."

"The non-dilutive funding received under this contract will be applied to complement those funds raised under the entitlement offer recently open to Lumos shareholders."

About the FebriDx diagnostic test

FebriDx is a visually read, all-in-one, integrated, single-use test that is designed to assess whether an acute respiratory infection is bacterial or non-bacterial in origin. This test can help aid clinicians with their decisions about antibiotic use and therefore has the potential to improve antibiotic stewardship.

The test includes a lateral flow test strip, a built-in retractable safety lancet, blood collection and transfer tube, and buffer delivery system. FebriDx qualitatively detects elevated levels of two proteins created by the body's immune response that help differentiate between bacterial (C-reactive protein [CRP]) and non-bacterial (Myxovirus resistance protein A [MxA]) infections in a fingerstick blood sample. This assay currently has 510(k) Clearance¹ for moderate and high-complexity use settings.

Under this partnership, BARDA will support Lumos' planned clinical study, comparing test usage among untrained users in CLIA-waived settings to trained users and will provide regulatory expertise and support for the submission to obtain a CLIA-waiver from the FDA. This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. 75A50124C00051.

Waived tests include test systems that are simple to use and have low risk for erroneous results². This partnership has the potential to impact patient care by expanding testing to CLIA-waived, point-of-care settings, including physician offices, urgent care clinics, or other outpatient clinics. FebriDx provides a result in about 10 minutes. Faster results for a bacterial or non-bacterial result can aid providers to make more informed decisions about patient treatment—which may lead to reduction of inappropriate antibiotic use.

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This announcement has been approved by the Lumos Disclosure Committee.

¹ <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K230917>

² <https://www.cdc.gov/labquality/waived-tests.html>

About Lumos Diagnostics

Lumos Diagnostics specializes 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 customized assay development and manufacturing services for POC tests and proprietary digital reader platforms. Lumos also directly develops, manufactures, and commercializes 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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