



ASX ANNOUNCEMENT

Lumos commences FebriDx® CLIA waiver Pediatric Study

Key Highlights

- Lumos has commenced the FebriDx® CLIA-waiver study for patients 2 to 12 years of age (“pediatric study”) in the United States (US), with the first patient successfully enrolled.
- It is anticipated between 500 – 800 patients will need to be enrolled across approximately 20 sites to achieve a sufficient number of positive bacterial cases for the study, over the next 12 months.
- The Biomedical Advanced Research and Development Authority (BARDA) is supporting the pediatric study with previously announced non-dilutive funding of US\$6,198,459.
- Milestones to date, through first patient enrollment carry payments that total US\$1,000,000.
- A successful study outcome will support the expansion of FebriDx’s use as a diagnostic aid for differentiating bacterial from non-bacterial acute respiratory infections in the US, broadening its patient usage from ages 12 - 64 to include younger children, ages 2 - 12.

MELBOURNE, Australia (22 October 2025) – Lumos Diagnostics Holdings Ltd (ASX: LDX, “Lumos” or the “Company”), a leader in rapid, point-of-care diagnostic technologies, is pleased to announce that in partnership with the U.S. Department of Health and Human Services (HHS), Administration for Strategic Preparedness and Response (ASPR), Biomedical Advanced Research and Development Authority (BARDA) has commenced the FebriDx® CLIA-waived pediatric study in the US, with first patient tested.

This study will assess the use of the FebriDx® device in children aged 2 to 12 years within CLIA-waived settings. It will be conducted across approximately 20 clinical sites in the US. Between 500 and 800 patients are expected to be enrolled to achieve a sufficient number of bacterial cases. The study is expected to run for approximately 12 months, following which a formal submission will be prepared for the U.S. Food and Drug Administration (FDA).

Milestone payments totaling US\$6,198,459 from BARDA to Lumos will be triggered upon the achievement of twelve milestone events, including clinical trial set-up, patient recruitment, FDA submission, and FDA granting of 510(k) clearance and CLIA-waiver categorization for children 2 to 12 years of age. Milestones completed and invoiced to date total \$1,000,000, with US\$400,000 cash received so far.

Currently, FebriDx® is FDA 510(k)-cleared for use in patients aged 12 – 64 years presenting to urgent care or emergency care settings for evaluation of acute respiratory infection who have had symptoms for less than 7 days and within 3 days of fever onset. On 15 August 2025, Lumos—supported by BARDA—submitted an application to the FDA, seeking to expand FebriDx® use from moderately complex settings into CLIA-waived settings. If a CLIA waiver is granted, this expansion would increase Lumos’ US total addressable market 15-fold to over US\$1 billion, providing access to 270,000 clinical sites (currently 18,000), and covering around 80 million annual acute respiratory consultations^{1,2}. The proposed age eligibility extension would enable clinicians, including the 60,000 clinicians treating children 2 to 12 years of age, to access an additional diagnostic aid for differentiating bacterial acute respiratory infections from non-bacterial causes.

Doug Ward, CEO of Lumos Diagnostics, said: *“The commencement of this study marks an important milestone for FebriDx® and our commitment to aiding healthcare professionals in improving infection diagnosis in children. A successful outcome would represent a significant step forward in helping healthcare professionals quickly and confidently differentiate bacterial and non-bacterial acute respiratory infections in children aged 2 to 12 years, supporting better treatment decisions and antibiotic stewardship.”*

This project has been funded in whole or in part with federal funds from the U.S. Department of Health and Human Services (HHS); Administration for Strategic Preparedness and Response (ASPR); Biomedical Advanced Research and Development Authority (BARDA) under contract number 75A50124C00051.

-Ends-

This announcement has been approved by the Lumos Disclosure Committee.

About FebriDx

FebriDx® is a rapid, point-of-care test that helps healthcare professionals differentiate between bacterial and non-bacterial respiratory infections in about 10 minutes, supporting more informed clinical decision-making and potentially reducing unnecessary antibiotic prescribing.

About Lumos Diagnostics,

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

For more information visit lumosdiagnostics.com.

¹ CMS, CLIA Database, 2024 (number of waived sites) and

² Precision Business Insights, US Acute Respiratory Infections, 2024 (80 million annual acute respiratory consultations)

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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