



## ASX ANNOUNCEMENT

### FebriDx Paediatric Study 250 Patient Enrolment Milestone Achieved

#### Key Highlights

- Lumos has completed Milestone #7 (tied to total number of enrolled patients to-date) triggering a milestone payment of US\$670,000, bringing the total to US\$2,590,000 in milestone payments to-date. BARDA has committed non-dilutive funding of US\$6,198,459 across the achievement of all 12 milestones.
- A successful outcome will support broadening the use of FebriDx® in the US as a diagnostic tool for differentiating bacterial from non-bacterial acute respiratory infections to include patients aged 2-64 years.

**MELBOURNE, Australia (14 May 2026)** – Lumos Diagnostics Holdings Ltd (ASX: LDX, “Lumos” or the “Company”), a leader in rapid, point-of-care diagnostic technologies, today announced the successful completion of milestone #7: enrollment of 250 patients in the Biomedical Advanced Research and Development Authority (BARDA) funded FebriDx® paediatric clinical study.

The successful completion of this milestone triggers a US\$670,000 milestone payment under Lumos’ agreement with BARDA, which has now been received. Lumos has now received a total of US\$2,590,000 in milestone payments to-date under the BARDA Paediatric Study agreement. If all 12 milestone events, including clinical trial set-up, patient recruitment, US Food and Drug Administration (FDA) submission, and FDA granting of 510(k) clearance and CLIA-waiver categorization for children, are achieved, Lumos will receive a total of US\$6,198,459 from BARDA across the entire agreement.

This study assesses the use of the FebriDx® device in children aged 2 to 12 years within CLIA-waived settings. The study is expected to run for approximately 12 months (from the commencement date on 22 October 2025) to meet statistical endpoint[s], following which a formal submission will be prepared for the FDA.

**Doug Ward, CEO and Managing Director of Lumos Diagnostics, said:**

*“The paediatric study continues to progress, and we look forward to the day that we can support clinicians in accurately assessing acute respiratory infections in younger children.”*

Lumos will continue to provide updates as further milestones are achieved.

This project has been funded in whole or in part with federal funds from the U.S. Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority, 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 after 10 minutes, supporting more informed clinical decision-making and potentially reducing unnecessary antibiotic prescribing.

On 27 March 2026, Lumos, supported by BARDA, was granted by the US FDA, 510(k) clearance with CLIA waiver for FebriDx® use in patients aged 12-64 years. This expands FebriDx®'s US total addressable market 15-fold to over US\$1.0+ billion per annum, providing access to over 300,000 locations covering a broad range of healthcare settings, spanning primary care physician offices, urgent care clinics, retail health & pharmacy clinics and community health centres that hold a Certificate of Waiver, and covers around 80 million acute respiratory consultations per year<sup>1,2</sup>.

### **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](https://lumosdiagnostics.com), which includes access to the full indications for use.

### **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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<sup>1</sup> CMS, CLIA Database, 2024 (number of waived sites) and

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

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