



ASX RELEASE

Lumos Pilot Manufacturing to Commence in Carlsbad

- *Lumos to manufacture test cartridges for a hormone monitoring platform for use in several international clinical studies.*
- *Hormone monitoring platform is being included as part of a novel “at-home” In-Vitro Fertilisation (IVF) testing procedure which utilises a unique test cartridge and customised Lumos digital reader.*
- *Purchase orders received totalling US\$270k follows the successful completion of a \$US320k manufacturing validation program and CE-Mark regulatory certification;*

MELBOURNE, VIC. (23 AUGUST 2022): Lumos Diagnostics (ASX: LDX), a leader in rapid point-of-care (POC) diagnostic technologies, is today announcing that it has received US\$270k in purchase orders for the manufacture of a unique, multi-assay, rapid diagnostic cartridge to be used in combination with a customised Lumos digital reader platform as part of a novel hormone monitoring platform.

The hormone monitoring platform will be used by IVF patients at-home and within the clinical environment as part of several clinical studies to be conducted across Asia Pacific, Europe and the USA. The clinical studies will assess the impact of the use of the hormone monitoring platform on clinical workflows and decision making. The studies are being conducted as a pre-cursor to a potential market launch in 1H FY2024.

The commencement of pilot manufacturing at the Lumos Carlsbad Californian facility was contingent on Lumos successfully completing a US\$320k manufacturing validation program and the product receiving CE-Mark certification. The manufacturing validation program required a series of assay batches to be manufactured by Lumos and tested to show concordance with critical clinical acceptance criteria which was completed in May 2022.

“The receipt of this initial purchase order to manufacture and supply product is the culmination of years of development work and validates our recent site rationalisation efforts in the US. The commencement of pilot manufacturing signals a successful transition of a commercial services assay development project to commercialisation and is yet another example of the benefits derived from our mature digital reader technology” said Doug Ward, Lumos CEO. “We look forward to providing on-going support and product supply to our partners as they begin to execute on their go-to-market strategy.”

This announcement has been approved by the Lumos Disclosure Committee.

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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 <https://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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