



ASX ANNOUNCEMENT

U.S. Food and Drug Administration Deprioritises Emergency Use Authorization Application for CoviDx

SARASOTA, Fla. (22 September 2021) – Lumos Diagnostics (ASX:LDX), a leader in rapid point-of-care (POC) diagnostic technologies, has received correspondence from the U.S. Food and Drug Administration (FDA) indicating that the FDA has deprioritised Lumos' request for Emergency Use Authorization (EUA) for the CoviDx™ SARS-CoV-2 Rapid Antigen Test (CoviDx™) and has ceased review of the EUA at this time. The Company is in active dialogue with the FDA and is preparing additional data in support of the application. The CoviDx test is currently available in Europe through its CE Mark approval and is undergoing regulatory review in other markets.

“While we are clearly disappointed with the delay, we appreciate the effort the FDA put into reviewing our application as part of its efforts to manage the COVID-19 pandemic,” said Rob Sambursky, President and CEO of Lumos Diagnostics. “We believe CoviDx™ has an important role in the rapid identification of patients potentially infected with COVID-19, and Lumos will continue to work with the FDA to secure regulatory clearance for CoviDx”.

Lumos is also completing development of its ViraDx™ point of care test which simultaneously tests for COVID-19 and influenza and has the potential to satisfy an even greater public health need for monitoring patients by the two most common acute respiratory viral infections in the community.

This announcement has been approved by the Lumos Disclosure Committee.

###

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 on Lumos Diagnostics, visit lumosdiagnostics.com, and for more information on CovidX visit, <https://lumosdiagnostics.com/products/covidx/>.

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.

Media Contacts (U.S. and Global):

Jennifer Christiansen – Lumos Diagnostics
jennifer.christiansen@lumosdiagnostics.com
+1 920 784 3153

Media Contact (Australia):

Haley Chartres – H[^]CK
haley@hck.digital
+61 423 139 163

Investor Contact:

Matthijs Smith – Lumos Diagnostics
ir@lumosdiagnostics.com
+61 411 137 080
+61 3 9087 1598

Company Registered Office:

Lumos Diagnostics Holdings Ltd
Level 4, 100 Albert Rd
South Melbourne, VIC 3205
+61 3 9087 1598