



3 February 2022

OMEGA DIAGNOSTICS GROUP PLC
("Omega" or the "Company" or the "Group")

CE-Mark for self-test for VISITECT® COVID-19 antigen test

Omega (AIM: ODX), the specialist medical diagnostics company focused on industry-leading Global Health (CD4 and COVID-19) and Health and Nutrition products announces that it has successfully CE marked its VISITECT® COVID-19 antigen test for self-test use.

The test will provide consumers with an accurate rapid test for the detection of the nucleoprotein of the SARS-CoV-2 virus in nasal swabs only. The VISITECT® COVID-19 antigen test has excellent performance characteristics following independent multi-centre validations, with sensitivity of 93.2% based on 103 samples with cycle threshold (Ct) values <25, and 97.8% specificity, based on 230 RT-qPCR negative samples.

The Company remains in discussions with commercial partners about how best to service the European market and other territories that recognise the CE mark. Omega's commercial offering will be via B2B partners and distributors, and not through a direct-to-consumer strategy.

The CE Mark certificate is conditional upon the submission of additional data and follow-up reports by 31 March 2022 and Omega is working closely with its external study centres to ensure this deadline is met.

Omega remain in the review process under CTDA regulations, which were introduced on 1 November 2021. Further field study data has been recently requested. Omega is seeking this information from external parties but this may not be available prior to the current extended deadline for submission of 10 February 2022.

Jag Grewal, CEO of Omega, commented: *"We are delighted to have reached this milestone, achieving CE Mark for our VISITECT® COVID-19 antigen test for the home-use market. It is frustrating that our test is still awaiting approval under CTDA regulations for sale of the professional-use test in the UK. We will now look to begin the process of filing for approval to sell our home-use product in the UK. In the meantime, we look forward to working with prospective partners to determine the best route to market."*

The information communicated in this announcement is inside information for the purposes of Article 7 of EU Regulation 596/2014.

Contacts:

Omega Diagnostics Group PLC

Jag Grewal, Chief Executive Officer
Chris Lea, Chief Financial Officer

www.omegadiagnostics.com

via Walbrook PR

finnCap Ltd

Geoff Nash / Edward Whiley (Corporate Finance)
Alice Lane / Charlotte Sutcliffe (ECM)

Tel: 020 7220 0500

Walbrook PR Limited

Paul McManus / Lianne Applegarth
Sam Allen

Tel: 020 7933 8780 or omega@walbrookpr.com

Mob: 07980 541 893 / 07584 391 303

Mob: 07502 558 258