



11 March 2022

The information contained within this announcement is deemed by the Company to constitute inside information as stipulated under the Market Abuse Regulation (EU) No. 596/2014. Upon the publication of this announcement via the Regulatory Information Service, this inside information is now considered to be in the public domain.

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

Update on validation under CTDA legislation

Omega (AIM: ODX), the specialist medical diagnostics company focused on industry-leading Health & Nutrition and Global Health (CD4 and COVID-19) products, has been informed by the UK Health Security Agency that the application for approval of the professional-use VISITECT® COVID-19 Antigen test under the Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021 ("CTDA") has been unsuccessful, and accordingly the product will not be available for sale in the general UK market.

Some supporting data provided by third-party development partners and submitted for the Desktop Review used comparator RT-qPCR (Quantitative reverse transcription PCR) results from studies conducted in late 2020 and early 2021 and pre-date the CTDA regulations. Certain of these comparator tests were not CE-marked and/or did not meet the sensitivity/specificity requirements subsequently specified in the CTDA regulations. These results therefore had to be excluded from the review and, as a consequence, there are now insufficient test results to meet the CTDA requirements. Currently, with insufficient demand for the professional-use test, the Company does not plan to commission further studies at this time.

The Directors believe that the self-test market is much more relevant in terms of opportunity and Omega continues to work closely with its external study centres to ensure the 31 March 2022 deadline is met for the submission of the outstanding self-test CE Mark data.

Jag Grewal, CEO of Omega, commented: *"Whilst this is clearly disappointing, our plans do not include any contribution from COVID-19 antigen tests, as we focus the business on driving growth in our Health & Nutrition division."*

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About Omega Diagnostics Group PLC

Omega manufactures and distributes high quality in-vitro diagnostic products for use in hospitals, clinics, laboratories and healthcare practitioners in over 75 countries and specialise in the areas of health and nutrition and global health.

www.omegadx.com