



**3 November 2021**

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

**Update on new CTDA Regulations**

Omega (AIM: ODX), the specialist medical diagnostics company focused on industry-leading Global Health (CD4 and COVID-19) and Health and Nutrition products, notes the UK Health Security Agency's Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021 ("CTDA") which were implemented on 1 November 2021.

The new CTDA Regulations required all suppliers of COVID-19 tests to submit information regarding their products for desktop review prior to 31 October 2021 if they wished their products to remain on sale in the UK after this date. This is a new requirement over and above the requirement for the CE Mark secured for Omega's VISITECT® professional-use COVID-19 Antigen test ("LFT") earlier this year.

Omega submitted all documentation ahead of the published deadlines and paid the necessary fee, however, in line with the vast majority of available tests on the market Omega's existing LFT has yet to be approved under CTDA.

This new legislation is not expected to cause a delay in the supply of Omega's VISITECT® professional-use COVID-19 Antigen test to DAM Health clinics in the UK under the agreement announced on 1 November 2021. Omega currently remains free to supply LFTs to DAM Health's clinics throughout Europe and DAM Health are able to distribute Omega's LFT throughout Europe.

The Company will update shareholders as soon as they receive a further update from the UK Health Security Agency.

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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](http://www.omegadx.com)