

## 6 September 2021

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

## VISITECT® COVID-19 antigen test self-test submission update All supporting data and documentation now submitted to Omega's European Notified Body

Omega (AIM: ODX), the medical diagnostics company focused on CD4, infectious diseases and food sensitivity, announces that all of the supporting data and documentation relating to its submission for CE marking for self-test use for the VISITECT® COVID-19 antigen test have been filed with its European Notified Body. The submission process has been running in parallel with the Useability Study conducted by Ulster University since mid-July and the conclusion of the Ulster study was the final step in this process. The test is already CE marked for professional-use and once approved would allow the test to be sold in Europe for home-use as well.

As the global market for antigen testing develops, the Company believes self-test approval will be a key requirement, as has already been seen in the UK. The submission is already under review by the Notified Body and the Company will provide a further update on the process as it concludes.

**Colin King, CEO of Omega, said:** "As a result of a lot of hard work by our team and Ulster University, we are very pleased to have submitted all of the information required for self-test use approval for our VISITECT® COVID-19 antigen test. Once approval is granted, we anticipate strong demand for a UK developed and manufactured product.

"Furthermore, we believe we have a high-quality, high-performance product with significant global appeal, including the US market, due to that market's size and high barriers to entry."

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