

30 April 2021

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

## Launch of VISITECT® COVID-19 Antigen & Update Rapid diagnostic test for visual detection of SARS-CoV-2 antigen

Omega (AIM: ODX), the medical diagnostics company focused on CD4, infectious diseases and food intolerance, announces that it has launched its VISITECT® COVID-19 Antigen test, a rapid point-of-care diagnostic test for the detection of active COVID-19 infections.

The launch of the product is the final stage in the commercial roll-out of the product following successful CE marking announced last month. This lateral flow test is easy to use with throat and nasal swabs, or nasal only, and provides a visual read out in 10 minutes. The VISITECT® COVID-19 Antigen test has demonstrated excellent performance characteristics through independent multi-centre validation studies. The test has sensitivity of 98.4% on samples with a cycle threshold (Ct) of < 20 (85% overall sensitivity on samples with Ct values ranging from 9.8 to 43) and specificity of 97.8%.

For further information please visit: VISITECT® COVID-19 Antigen Test | Omega Diagnostics

The Company remains in discussion with a number of potential commercial partners looking to order the test and to distribute the test on Omega's behalf and the Company will update shareholders in due course.

## **Update re. Government contract**

Further to the announcement on 11 February, regarding a contract with the Department of Health and Social Care ("DHSC") to provide manufacturing capacity for COVID-19 lateral flow antigen tests, the Company confirms that it is waiting for confirmation on which test has successfully passed DHSC's performance evaluations. The DHSC have recently stated that they are in the process of assessing which of these tests are suitable for home-use and thus can obtain the appropriate self-test approval. Once a suitable test has been approved the DHSC will license the test for Omega to manufacture. Omega is not in control of this process but will provide a further update once a test is confirmed.

Whilst waiting to receive this confirmation, Omega is currently supporting the Government with additional cassetting and pouching services for other COVID-19 antigen lateral flow tests that are being deployed in the UK.

The Company has made good progress towards establishing a lateral flow production capacity of approximately two million tests per week from its Alva facility in Scotland. The completion of that capacity target, and more importantly full utilisation of this capacity, is dependent on the confirmation above from the UK Government. In the meantime, Omega is currently using its own capacity to produce its own tests and following today's launch, the Company expects, together with the test to be licensed from the UK Government as above, to rapidly move towards full utilisation of its capacity of 2 million test per week.

From its site in Alva the Company is currently producing VISITECT® CD4 Advanced Disease tests, AbC-19<sup>™</sup> COVID-19 Rapid Antibody tests and, following launch, the VISITECT® COVID-19 Antigen test.

**Colin King, CEO of Omega commented:** "I am delighted to announce the launch of the VISITECT® COVID-19 Antigen test. We look forward to updating shareholders on our commercial discussions as they conclude. I am pleased to say that we are now producing a wide range of our own tests from our Alva site and we look forward to being notified which test we will produce under the UK Government contract, which will then see us move to production of up to two million tests a week. In the meantime, there is much ongoing activity; not only are we producing our own tests, but we are also

producing AbC-19 Rapid tests for the UK-RTC in anticipation of forthcoming orders as well as providing additional cassetting and pouching services to the UK Government for other COVID-19 antigen lateral flow tests."

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