



15 June 2021

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

**Statement re. Media Comment**

Omega (AIM: ODX), the medical diagnostics company focused on CD4, infectious diseases and food intolerance, notes the recent media comment that Mologic Ltd have requested for Porton Down to evaluate their lateral flow antigen test with an independent party observing.

This process has no implications on the UK Government manufacturing contract that Omega has in place with the Department of Health and Social Care ("DHSC"). Under that contract Omega will provide manufacturing capacity for COVID-19 lateral flow antigen tests utilising the key pieces of manufacturing equipment loaned by the UK Government for that purpose and Omega will manufacture whichever test is approved for use by the DHSC. As clarified on [7 June 2021](#) the ability to supply tests that are produced within the UK remains a key priority for the DHSC and to that end the DHSC have facilitated initial commercial discussions between Omega and a number of companies with lateral flow antigen tests to potentially provide UK manufacturing services.

As already announced on [8 June 2021](#) Omega is in the process of seeking CE marking of its VISITECT® COVID-19 Antigen test, as a self-test.. Final preparations for a submission to the U.S. Food and Drug Administration (FDA) requesting Emergency Use Authorization (EUA) for this test is also underway.

Recently published study data confirms that Mologic's lateral flow antigen test, being commercialised by Omega as the [VISITECT® COVID-19 Antigen test](#), demonstrates high diagnostic accuracy (specificity and sensitivity) fulfilling WHO target accuracy with a high sensitivity (93.2%-98.4%) detecting individuals with high viral load infections (Ct<20 and Ct<25). The test has also been independently verified in a 665-person study in Germany by FIND a global not-for-profit foundation and a WHO collaborating centre. The test was shown to demonstrate best-in-class performance with 100% specificity and 96.4% sensitivity (Cycle threshold <25) compared with laboratory PCR testing.

Further details of the study and the FIND report can be seen using the links below:

<https://www.londonstockexchange.com/news-article/ODX/positive-data-for-covid-19-antigen-test/14998113>

<https://www.londonstockexchange.com/news-article/ODX/positive-data-for-mologic-covid-19-antigen-test/14963499>

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