



30 July 2020

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

Update on progress of UK-Rapid Test Consortium
CE Marking of COVID-19 lateral flow antibody test for professional use

Omega (AIM: ODX), the medical diagnostics company focused on CD4, infectious diseases and food intolerance, notes the press release issued today by the UK Rapid Test Consortium ("UK-RTC"), of which Omega is a partner, on developing its COVID-19 lateral flow antibody test (the "AbC-19™ Rapid test").

Further to the announcement on 29 June 2020 confirming design-freeze, Abingdon Health Limited, as lead partner of the UK-RTC, has today confirmed that it has CE-Marked the AbC-19™ Rapid test for professional use.

To achieve self-testing accreditation, pre-approval from the MHRA is required to perform self-test usability studies. The planned study will be performed by Ulster University using approximately 2,000 volunteers and, once complete, will allow the UK-RTC to seek final approval from the MHRA for self-test use. In addition, the test will also be subject to further independent evaluation.

The Company is currently transferring the manufacturing process from Abingdon Health Limited to its Alva facility and expects to complete the work to prove equivalent performance and the capability to manufacture at scale by the end of August. The Company plans to have an initial AbC-19™ Rapid test production capacity in place in September to produce 100,000 tests per week scaling up to 200,000 tests per week capacity in October. If demand through the UK-RTC was to go above 200,000 tests per week, either from the UK Government, or from other third parties, the Company would allocate additional capacity to meet that demand as well.

The UK-RTC is reproduced in full at the end of this statement.

Colin King, CEO of Omega, commented: *"I am delighted that our consortium partner, Abingdon Health has delivered another key milestone as promised and it is even more impressive that this has been achieved within such a compressed timeline to meet very stringent technical requirements set by the MHRA. Omega is focused on ensuring it completes the technical transfer in a timely manner and plays its part in the fight against this pandemic."*

The information communicated in this announcement is inside information for the purposes of Article 7 of EU Regulation 596/2014.

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Press Release from the UK-RTC (issued on 30 July 2020)

UK-RTC AbC-19™ Rapid Test receives CE mark for professional use

The UK-RTC is delighted to announce that the AbC-19™ Rapid test for IgG antibodies to the SARS-COV-2 virus (COVID-19) has achieved CE mark for professional use. To achieve this CE mark the technical performance of the AbC-19™ Rapid test has met the technical performance for a rapid test as stipulated by the Medicines and Healthcare products Regulatory Agency (“MHRA”). The test is now available for distribution for use by professionals.

Three production scale batches of the product have undergone validation and verification. With regards to test performance, the devices showed sensitivity of 98.03% (95% confidence interval 95.03% to 99.46%) and specificity of 99.56% (95% confidence interval 98.40% to 99.95%). These figures have been calculated following analysis of a total of 450 samples taken from individuals pre-September 2019 (negatives) and 203 patients who had symptoms of COVID19, or tested positive for COVID-19 using RT-PCR techniques, and tested positive by a commercially available antibody ELISA test (EuroImmune™). Results are from analyses performed at Ulster University and Abingdon Health laboratories.

If the population is assumed to have a 10% incidence of COVID19, the AbC-19™ Rapid test shows a 99.40% accuracy.

The AbC-19™ Rapid test is now CE marked for professional use and is ready for high volume manufacture by the UK-RTC. The next steps include further independent evaluation. In addition, performance study approval will be sought from the MHRA to facilitate the self-test usability studies to be performed with Ulster University, using around 2000 volunteers to seek necessary approvals for self-testing via the MHRA which is expected in the coming months.

This is a great achievement for an extremely complex project. It has been completed in a very short time period compared to a normal test development programme. The UK-RTC has been committed to delivering this vital test to the UK public, to assist in the management of COVID-19 infections, to aid further understanding of the disease, and is now ready to provide this test.

About the UK-RTC

The UK-RTC was formed in April 2020, when Omega signed a Memorandum of Understanding with Abingdon Health Limited, BBI Solutions Limited, CIGA Healthcare Limited, in conjunction with the University of Oxford, in order to jointly develop and manufacture a COVID-19 Rapid Test as part of the UK Government's five pillar national testing strategy for COVID-19.