

RNS Miscellaneous



CE-Mark for Mologic COVID-19 antibody test

OMEGA DIAGNOSTICS GROUP PLC

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

CE-Mark of Mologic COVID-19 lateral flow antibody test

Omega (AIM: ODX), the medical diagnostics company focused on CD4, infectious diseases and food intolerance, announces that it has CE-Marked Mologic Ltd's ('Mologic') lateral flow antibody test for COVID-19 for sale under Omega's VISITECT[®] brand.

The Mologic lateral flow antibody test is a Point-of-Care test that differentiates itself by testing for three antibodies - IgA, IgG and IgM - picking up positive patients at an earlier stage than most other tests. This test will be used in the primary care settings, such as GP surgeries and for other professional use and has been subject to successful independent validation by the Liverpool School of Tropical Medicine and St George's, University of London. Mologic is currently applying for World Health Organization (WHO) emergency use listing for the lateral flow antibody test and Omega will provide an update when Mologic receives a final decision.

Omega will be the legal manufacturer of the test and will be able to manufacture up to 100,000 tests per week initially out of its Alva facility in Scotland, which is currently undergoing refurbishment to increase capacity as planned. Omega will commercialise the test as a VISITECT[®] branded product and expects to announce the product's full marketing launch later this month.

As previously announced, partnering with Mologic is separate from, and additional to, the announcement made by the Company on 9 April 2020 relating to the UK Rapid Test Consortium (RTC).

Colin King, CEO of Omega, commented: *"We are pleased to have reached this significant milestone of CE-Marking Mologic's lateral flow antibody test as we continue to support efforts to combat the effects of COVID-19. This approval will allow us to commence in-country registrations and product evaluations. We also look forward to WHO emergency use approval in due course, which will open up opportunities for the test to access global tenders where this approval is required."*

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

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