Regulatory Story

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Omega Diagnostics Group PLC - ODX CE-Mark of COVID-19 ELISA antibody test
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OMEGA DIAGNOSTICS GROUP PLC
("Omega" or the "Company" or the "Group")

CE-Mark of COVID-19 ELISA antibody test

Omega (AIM: ODX), the medical diagnostics company focused on CD4, infectious diseases, food intolerance and allergy testing, announces that it has CE-Marked Mologic Ltd's ('Mologic') first generation ELISA[1] antibody test for COVID-19.

The CE-Mark follows successful independent validation of Mologic's ELISA test by the Liverpool School of Tropical Medicine and St George's, University of London. Ongoing validations are being performed by Public Health England, NHS Scotland and in the Republic of Ireland.

Omega will use its ELISA manufacturing facility in Littleport, Cambridgeshire to manufacture up to 46,000 COVID-19 tests per day. Omega and Mologic will now finalise a longer-term supply agreement to commercialise this test which will be used on patient samples sent by hospitals or GPs for laboratory testing.

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), which is to jointly develop and manufacture a Point-of-Care COVID-19 lateral flow antibody test which could be used 'at-home' and which will be manufactured in Omega's Alva facility in Scotland.

Colin King, CEO of Omega commented: "*We are pleased that Omega has been able to CE-Mark Mologic's ELISA antibody test and it is testimony to the teams within both companies that we have reached this milestone in such a short timescale.*"

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

[1] *ELISA (Enzyme Linked Immuno-Sorbent Assay) tests are one of the most tested and proven laboratory technologies used by the global diagnostic industry and remain the principle reference point from which rapid diagnostics are coordinated, especially serological tests, including tests for COVID-19.*

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