



18 March 2019

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

CE-Mark for VISITECT® CD4 Advanced Disease test

Omega (AIM: ODX), the medical diagnostics company focused on allergy, food intolerance and infectious disease, announces that it has CE-Marked its VISITECT® CD4 Advanced Disease test for monitoring people living with HIV.

The VISITECT® CD4 Advanced Disease test utilises a cut-off of 200 CD4 cells/mm³ of blood, a level at which patients' immune systems are so weakened by HIV that they are at risk of infection by other life-threatening diseases.

The technical file supporting the CE-Mark will form the basis of the additional regulatory approvals that the Company will seek through the UNITAID-funded Expert Review Panel for Diagnostics ("ERPD"), hosted by the Global Fund to Fight AIDS, Tuberculosis and Malaria. The ERPD outcome is a time-limited, risk-based recommendation on eligibility for procurement whilst the Company undergoes the World Health Organisation Prequalification programme. This programme aims to ensure that clinical diagnostics, medicines and vaccines meet global standards of quality, safety and efficacy, in order to optimise the use of health resources and improve health outcomes.

Colin King, Chief Executive of the Group, commented: *"We are pleased to have reached the milestone of attaining the CE-Mark for our VISITECT® CD4 Advanced Disease test within the timeframe we previously set out. Together with our currently commercialized VISITECT® CD4 350 test, we intend to provide easy to use, clinically relevant CD4 testing to less advantaged communities around the world. We look forward to working with the Global Health community to bring this unique test to the market to make a positive impact on the lives of many people living with HIV."*

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

Contacts:

Omega Diagnostics Group PLC

Bill Rhodes, Interim Non-Executive Chairman

Colin King, Chief Executive

Kieron Harbinson, Group Finance Director

Tel: 01259 763 030

www.omegadiagnostics.com

finnCap Ltd

Geoff Nash/James Thompson (Corporate Finance)

Camille Gochez (ECM)

Tel: 020 7220 0500

Walbrook PR Limited

Paul McManus

Lianne Cawthorne

Tel: 020 7933 8780 or omega@walbrookpr.com

Mob: 07980 541 893

Mob: 07584 391 303