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

## Positive study data for Mologic COVID-19 lateral flow antigen test

Test shows high diagnostic accuracy (specificity and sensitivity) exceeding WHO targets

Omega (AIM: ODX), the medical diagnostics company focused on CD4, infectious diseases and food intolerance, notes the publication of a manuscript entitled: "Accuracy of the Mologic COVID-19 rapid antigen test: a prospective multicentre analytical and clinical evaluation" which provides positive study data relating to Mologic Ltd's ('Mologic') lateral flow antigen test for COVID-19.

The study concludes that the Mologic test, which has been commercialized by Omega as the <u>VISITECT® COVID-19</u> <u>Antigen test</u>, has fulfilled the WHO target diagnostic accuracy with a high sensitivity (93.2%-98.4%) detecting individuals with high viral load infections (Ct<20 and Ct<25).

The VISITECT<sup>®</sup> COVID-19 Antigen test provides healthcare professionals with an accurate rapid test for the detection of the nucleoprotein of the SARS-CoV-2 virus in respiratory swabs in 10 minutes.

The Mologic COVID-19 rapid test was evaluated in a prospective multicentre study across UK sites, where a total of 347 participants were enrolled. The Diagnostic accuracy and clinical performance of the test were investigated by comparing to gold standard RT-PCR results from individuals with and without COVID-19 symptoms attending secondary care facilities in Merseyside, ambulance services in Yorkshire, and drive-through testing facilities in Northumberland, UK.

With data stratified by RT-PCR cycle threshold (Ct), sensitivity was shown to be high in individuals with highest viral loads (i.e. most likely to be highly contagious): 93.2% of samples with a Ct less than 25 and 98.4% of samples with a Ct less than 20. Overall sensitivity (including all cycle thresholds, so individuals with low viral loads as well) and specificity compared to the reference SARS-CoV-2 RT-PCR was 85.0% and 97.8% respectively.

The study also concluded that the Mologic test replicated diagnostic accuracy in a variety of settings important for COVID-19 control (hospitals, ambulatory services, and drive-through centres) and on self-collected swab specimens. The manuscript can be viewed here: <u>https://wellcomeopenresearch.org/articles/6-132/v1</u>

**Colin King, CEO of Omega, commented:** "This is great news for the Mologic test, which we are now producing under our VISITECT<sup>®</sup> brand. It is significant that the test has been shown to have high diagnostic accuracy, but also that this performance is replicated across multiple different settings, different demographics, and on self-collected swab specimens. Rapid diagnostic tests play a crucial role in breaking the spread of infection in the community and we are delighted to be a leading manufacturer of these home-grown tests." Contacts:

**Omega Diagnostics Group PLC** Colin King, Chief Executive Kieron Harbinson, Group Finance Director

finnCap Ltd Geoff Nash/Edward Whiley (Corporate Finance) Alice Lane (ECM)

Walbrook PR Limited Paul McManus Lianne Cawthorne Tel: 020 7220 0500

Tel: 020 7933 8780 or <u>omega@walbrookpr.com</u> Mob: 07980 541 893 Mob: 07584 391 303