



5 October 2022

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

**Positive WHO data received for VISITECT® CD4 test**  
***Test shows high diagnostic accuracy (specificity and sensitivity)***

Omega (AIM: ODX), the specialist medical diagnostics company focused on industry-leading Health & Nutrition, welcomes receipt of the draft Performance Evaluation report for the VISITECT® CD4 Advanced Disease Rapid test, issued by the World Health Organisation ('WHO') on 3 October 2022.

In August 2022, Omega confirmed the sale of its CD4 Business to Accubio Limited ('Accubio') and under the terms of the agreement the Company expects to receive up to an additional £4.0m, contingent on the successful outcome of the clinical study in Kenya, required in order to maintain the test's WHO pre-qualification status. The receipt of the draft Performance Evaluation is an important milestone in completing the pre-qualification process and in releasing the deferred consideration funds to the Company.

The VISITECT® CD4 Advanced Disease Rapid Test was evaluated at the Kenya Medical Research Institute, Kisumu, Kenya on behalf of WHO, where a total of 300 specimens were analysed. The report concluded that the VISITECT® CD4 Advanced test showed high sensitivity of 96.0% (95% CI: 90.1-98.9) and a specificity of 96.0% (95% CI: 92.3-98.3) from whole blood specimens and high sensitivity of 95.0% (95% CI: 88.7-98.4) and a specificity of 97.0% (95% CI: 93.6-98.9) using capillary blood specimens. Repeatability and reproducibility on specimens with reference values <150 or >250 CD4+ T-cells/ $\mu$ L was 100%. These results are in line with management's expectations.

Omega now has until 3 November 2022 to review and comment on the draft report and the results submitted. A summary of the Performance Evaluation report will then be included in the WHO prequalification Public Report if the product successfully meets all WHO prequalification requirements.

**Jag Grewal, CEO of Omega Diagnostics said:** *"We are extremely pleased to receive this draft report, detailing that the test has shown high diagnostic accuracy. Whilst we have no visibility of the WHO pre-qualification requirements, it is encouraging to formally receive these positive results. If the VISITECT® CD4 Advanced Disease test successfully meets all WHO pre-qualification requirements, it will continue to be made available for sale by Accubio and the Company will receive the full £4.0m of deferred consideration. We look forward to updating shareholders on the outcome in due course."*

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**About Omega Diagnostics Group PLC**

Omega manufactures and distributes high quality in-vitro diagnostic products in over 70 countries for use in clinics, laboratories and by healthcare practitioners specialising in the area of health and nutrition.

[www.omegadx.com](http://www.omegadx.com)