



17 November 2020

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

UK-RTC Update

Omega (AIM: ODX), the medical diagnostics company focused on CD4, infectious diseases and food intolerance, notes the press release issued today by the UK Rapid Test Consortium ("UK-RTC"), of which Omega is a partner.

The UK-RTC press release announces that Abingdon Health ("Abingdon") has received confirmation from the US Food and Drug Administration ("FDA") that Abingdon has completed the notification process under the FDA's Policy for Coronavirus Disease Tests During the Public Health Emergency ("the Policy").

The Policy states that the FDA does not intend to object to a manufacturer distributing serology tests to laboratories that are certified under CLIA¹ certification to perform high complexity testing where the test has been validated and while the manufacturer is preparing its Emergency Use Authorization ("EUA") request.

Abingdon has submitted an EUA to the FDA for the AbC-19™ Rapid Test as a point of care test and the Company looks forward to learning how the EUA procedure progresses.

A full copy of the UK-RTC press release is at the bottom of this announcement.

¹ *CLIA or the Clinical Laboratory Improvement Amendments (42 CFR Part 493) are those regulations that were established in 1988 for the regulation and quality assurance of human specimens within clinical laboratory environments.*

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Press release from the UK-RTC (issued on 17 November 2020)

York, U.K. 17 November 2020: Abingdon Health ("Abingdon" or "the Company"), UK-based developer and manufacturer of lateral flow tests and smartphone reader solutions, today announces that it has been notified by the US Food and Drug Administration (FDA) that it has completed the Section IV.D notification process. This enables the Company to distribute its UK-RTC AbC19™ Rapid Test in the USA to laboratories certified under CLIA and to healthcare

workers, for point of care testing covered by a laboratory's CLIA certification for high complexity testing. Distribution of the test will be through CIGA Healthcare, a member of the UK-RTC.

Section IV.D of the FDA's Policy for Coronavirus Disease Tests During the Public Health Emergency (Revised) states that the FDA does not intend to object to a manufacturer distributing serology tests to laboratories that are certified under CLIA certification to perform high complexity testing where the test has been validated and while the manufacturer is preparing its Emergency Use Authorization ("EUA") request. An EUA has been submitted to the FDA for the AbC-19™ Rapid Test as a point of care test and dialogue with the FDA is progressing.

Leigh Thomas, SVP Director of Global Sales of Abingdon Health said, "Today's news allows us to immediately make the AbC19™ Rapid Test available to CLIA testing labs in the United States and is the latest milestone on the path to receiving an EUA for the AbC19™ Rapid Test. Abingdon Health and our consortium partners in the UK-RTC remain committed to the wide deployment of the AbC19™ Rapid Test and continue to work with regulators both in the UK and internationally. "

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About Abingdon Health

Abingdon is a UK-based developer and manufacturer of lateral flow tests and smartphone reader solutions. Abingdon offers development and manufacturing services for customers looking to develop new assays or looking to transfer existing laboratory-based assays to a lateral flow format. Abingdon takes projects from initial concept through to routine and large-scale manufacturing. Abingdon is headquartered in York, England.

About UK RTC

The UK-RTC was established by Abingdon Health, Omega Diagnostics, BBI Solutions, CIGA Healthcare and Oxford University.

About AbC19™ Rapid Test

The AbC-19™ IgG lateral flow assay is targeted at IgG antibodies to the full spike protein of SARS-CoV-2 (COVID19) to indicate a measure of immune response (aligned with neutralizing antibodies).