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

UK-RTC statement on AbC-19™ rapid antibody test

Lateral flow test data shows potential for companion diagnostic to the Pfizer-BioNTech COVID-19 vaccine
AbC-19™ rapid antibody test was effective in demonstrating immune response following first dose vaccination

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, which presents new data relating to the performance of the AbC-19™ rapid antibody test when used as a companion diagnostic to the Pfizer-BioNTech COVID-19 vaccine. The initial study performed at the University of Birmingham highlighted the effectiveness of the AbC-19™ rapid antibody test in demonstrating immune response following vaccination.

During the study the AbC-19™ Rapid Test was used to test individuals who had been given a single dose of the Pfizer-BioNTech COVID-19 vaccine**.** In total 193 individuals who had received a COVID-19 vaccine were tested for the presence of IgG antibodies to the full trimeric spike using the AbC-19™ test. Of these individuals, a sub-set of 65 patients had been determined to have previously been infected with COVID-19, and 128 had no previous infection. The study also concluded that patients previously infected with COVID-19 showed a stronger immune response to the first dose of the Pfizer-BioNTech COVID-19 vaccine.

Following the study the statement from the UK-RTC said:
"The initial data from the study being performed at the University of Birmingham supports the rationale that vaccination programmes could benefit from determining an individual's antibody status not only after vaccination but also prior to vaccination. Should these results continue to be seen in further studies, and with other vaccines, this demonstrates that the AbC-19™ antibody test could potentially assist in patient stratification and resource management in overburdened international healthcare settings."

The UK-RTC press release is reproduced in full at the end of the statement and can be found here:
https://www.abc19.com/

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Press release from the UK-RTC (issued on 24 February 2021)

The UK-RTC, a consortium of UK diagnostic companies including Abingdon Health, CIGA Healthcare, BBI Solutions and Omega Diagnostics, presents new data examining the performance of the AbC-19™ rapid antibody test when used with 193 individuals that had received a single dose of the Pfizer-BioNTech COVID-19 vaccination. This study was performed at the University of Birmingham.

The sample population included a sub-set of 65 patients that had previously been infected with COVID-19, and 128 that had no previous infection. The highlights of the data/study are as follows:

- *The AbC-19™ rapid antibody test was effective in demonstrating the immune response of patients to the first dose of the Pfizer-BioNTech COVID-19 vaccine,*

- *The study highlighted a differential immune response of two cohorts of patients: those previously infected with COVID-19 and those not infected;*

- *Patients previously infected with COVID-19 showed a stronger immune response to the first dose of the Pfizer-BioNTech COVID-19 vaccine;*

The initial data from the study being performed at the University of Birmingham supports the rationale that vaccination programmes could benefit from determining an individual's antibody status not only after vaccination but also prior to vaccination Should these results continue to be seen in further studies, and with other vaccines, this demonstrates that the AbC-19™ antibody test could potentially assist in patient stratification and resource management in overburdened international healthcare settings.

The AbC-19™ Rapid Test was used to test samples from individuals who had been given a single dose of the Pfizer-BioNTech COVID-19 vaccine. In total 193 individuals who had received a COVID-19 vaccine were tested for the presence of IgG antibodies to the full trimeric spike using the AbC-19™ test.

Of the patients involved in the study, the AbC-19™ rapid test identified 181 (94%) as testing positive for the presence of IgG antibodies to COVID-19, with some samples from those with previous infection demonstrating a positive result as little as 1-4 days post vaccination. Using a cut-off of 13 days post-vaccination (which is the minimum recommendation for determining antibody status using the AbC-19™ rapid test) 137 out of 140 of samples, or 98% of patients, were identified as testing positive for the presence of IgG antibodies.

Using the WHO classification of the lateral flow device test line, results were classified as:

- *0 (negative)*
- *1 (very weak but definitely reactive)*
- *2 (medium to strong reactivity)*

Of the 193 individuals examined, 128 (66%) patients were determined as not having a previous COVID-19 infection and thus naïve samples, with 65 (34%) patients identified as having a previous COVID-19 infection.

When applying the above scoring to the samples taken 13 days after the single vaccination, 43.3% of the naïve samples scored medium to strong test line response with 53.8% showing a weaker response and 2.9% having a negative result. In contrast, those who had previously been infected with COVID-19 had a stronger response in 75% individuals, while 25% showed a weaker response with no negative results. It would be expected for the IgG anti-spike antibody levels to continue to rise with time and following a second vaccination.

Further studies are being performed to expand this data set and are expected to be available in the next few weeks.

About the UK-RTC

The UK Rapid Test Consortium (UK-RTC) was founded in response to a UK Government call for businesses to work together on a rapid antibody test to be rolled out nationally. Led by Abingdon Health, it's members also include, BBI Solutions, CIGA Healthcare and Omega Diagnostics. The Abc-19™ is approved in Europe and the UK for professional use and is available for sale.

About the AbC-19™ Rapid Test

The AbC-19™ Rapid Test is a single use test for the detection of neutralising IgG antibodies to the full trimeric spike protein of the SARS-CoV-2 virus in human capillary whole blood.