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ASIA EDITION

Oxford Immunotec invents Cell-Mediated (T cell) immune response detection kit

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Submits Emergency Use Authorization request to the FDA and CE Marks for T-SPOT® COVID to detect SARS-CoV-2 Infection

Oxford Immunotec Global PLC, a global, high-growth diagnostics company, announced that it has released the T-SPOT.*COVID* test, a CE marked ELISPOT based test intended for qualitative detection of a cell mediated (T cell) immune response to SARS-CoV-2 in human whole blood. The company has filed an EUA request to the FDA for the test.

Serology does not give the full picture of the adaptive immune response to SARS-CoV-2 infection. Antibodies are not always produced in response to SARS-CoV-2 infection, or may be delayed. Antibodies can also wane quickly after infection and reports show T cells may be more long-lived than the antibody response. In the absence of an antibody response, the T cell response may be protective from SARS-CoV-2 infection.

In a clinical study using samples collected in the US, the T-SPOT.*COVID* test was proven to detect a SARS-CoV-2 cell mediated (T cell) immune response in PCR positive individuals, even with negative serology test results. The T-SPOT*COVID* test therefore complements results obtained by antibody serology to give a more comprehensive view of an individual's adaptive immune response to SARS-CoV-2 infection. The test could also be used, for example, alongside serology tests to support clinical assessment of individuals who present with suspected COVID-19 but are PCR negative.

In the study, the T-SPOT.*COVID* test had a positive agreement with PCR-results of 96.6% (84/87) in SARS-CoV-2 infected individuals <60 days after first PCR positive result. At >60 days (with the furthest time point after first positive PCR test result being >240 days) positive agreement remained high at 83.3% (40/48). The T-SPOT.*COVID* test detected substantially more people with previous positive PCR results than serology in the cohort, whose positivity rate was lower and declined faster over time.

The Company developed the T-SPOT.*COVID* test as an evolution of its T-SPOT® *Discovery* SARS-CoV-2 assay, research use only test used to gain insights about the immune response to SARS-CoV-2.

Dr. Peter Wrighton-Smith, CEO of Oxford Immunotec, said, "The T-SPOT® Technology platform is a standardised way of

measuring T cells. It has been proven in clinical use for over 18 years with another major infectious disease, tuberculosis, which kills around 1.5 million people every year. Our T-SPOT.*COVID* test is tailored specifically for the detection and measurement of an individual's T cell response to SARS-CoV-2 infection. Having the ability to determine an individual's immune response to SARS-CoV-2 has the potential to support a wide range of needs in our battle against the COVID-19 pandemic."