



4 December 2017

Omega Diagnostics and Burnet Institute announce VISITECT® CD4 CE-Marking

Omega Diagnostics, the medical diagnostics company focused on allergy, food intolerance and infectious disease, has announced the CE-Marking of its VISITECT® CD4 point-of-care HIV test. The CE-Marking follows successful performance evaluations in India and the UK.

VISITECT® CD4, co-developed with Burnet Institute, is the world's first instrument-free and affordable rapid test for determining CD4 threshold in people living with HIV. It is designed for use at the point-of-care and provides a means for decentralisation of CD4 testing capacity to where it is most needed.

VISITECT® CD4 will enable those patients in rural locations to access testing more easily and does not require investment in equipment or highly technical scientific staff to operate. The test will now go forward into further regulatory processes that are necessary before being implemented in those regions where HIV remains a significant public health challenge.

Burnet Institute Deputy Director (Partnerships), Associate Professor David Anderson said that achieving CE-Marking was an important step in the roll out of this small, but potentially life-saving diagnostic.

"The Burnet Institute is delighted to witness the commercial release of the VISITECT® CD4 test by our partners at Omega Diagnostics. Despite the adoption of broader HIV treatment access policies in many countries, the fact remains that many people are first diagnosed with advanced disease and low T-cell counts that require additional interventions above and beyond just anti-retroviral therapies. CD4 testing is critical for identifying the patients for whom these extra efforts are needed, and will remain an important tool in HIV treatment and care for many years."

"On behalf of our R&D team at Burnet, I would like to personally thank the Omega Diagnostics team for their persistence and dedication to our shared cause of bringing this vital test to reality – a perfect example of the right industry partnerships being able to help deliver Burnet's vision of equity through better health."

"We expect that the VISITECT® CD4 test will make a real difference in HIV treatment and prevention programs that care for many millions of patients worldwide, which is exactly what we set out to achieve."

Chief Executive Officer of Omega, Mr Andrew Shepherd, said: "We are excited to have achieved this major milestone and hope that VISITECT® CD4 can have a positive impact on the care of people living with HIV throughout the world. It is widely recognised that CD4 testing will continue to play an important role in the management of HIV patients and we are confident that VISITECT® CD4 can address the ongoing challenges of providing access to diagnostic testing in rural locations and reducing the loss of patients to care."

"I'd like to express my sincere thanks to all of the team at Omega who have worked incredibly hard in bringing VISITECT® CD4 to this point. And as the creators of the test, it has been a real pleasure to work with our friends at the Burnet and look forward to future years of partnership in bringing affordable point-of-care tests to those people most in need."

For more information please contact:

Omega Diagnostics Group PLC, Alva, UK
Andrew Shepherd, Chief Executive Officer

Tel +44 1259 763 030
odl@omegadiagnostics.co.uk
www.omegadiagnostics.com

Burnet Institute, Melbourne, Australia
David Anderson, Deputy Director (Partnerships)

Tel +61 408 386 831
david.anderson@burnet.edu.au
www.burnet.edu.au



The VISITECT® CD4 test.

About Omega Diagnostics

Omega is focused on selling a wide range of specialist products, primarily in the immunoassay, in-vitro diagnostics (IVD) market within three segments: Allergy and Autoimmune, Food Intolerance and Infectious Disease. With its global headquarters in Scotland (UK), the group has subsidiaries in Littleport (UK), Reinbek (Germany) and Mumbai (India). It has manufacturing sites in the UK, Germany and India, each possessing ISO 13485 and ISO 9001 and compliant with directive 98/79/EC on IVD Medical Devices.

About Burnet Institute

Burnet Institute is an Australian, unaligned, not-for-profit, independent organisation that links medical research with practical action to help solve devastating health problems. Our mission is to achieve better health for vulnerable communities in Australia and internationally by accelerating the translation of research, discovery and evidence into sustainable health solutions. We are actively involved in research and project activities in a range of Asian, Pacific and African countries.