



Harnessing the power of T cell measurement

Press Release

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Study results confirm utility of T-SPOT[®].TB as a rapid rule out test for tuberculosis disease

Oxford, UK; 19th April 2007 – Oxford Immunotec Ltd, the T cell measurement company, today announced the publication of a recent study demonstrating the use of T-SPOT.TB with non-blood samples and its use as a rule out test for active TB disease.

In the study, reported in the American Journal of Critical Care Medicine, Jafari et al investigated the potential use of T-SPOT.TB to diagnose pulmonary TB using bronchoalveolar lavage ('BAL') fluid. The study showed that using T-SPOT.TB in this way could identify cases that are missed by conventional methods such as sputum smear and PCR.

Diagnosis of TB is extremely difficult. Pathogen detection methods such as microscopy (called 'smear') and PCR, although quick, lack sensitivity. The most sensitive (although not foolproof) method, bacterial culture, takes two to six weeks to give a result which produces an unacceptable delay in diagnosis. This study demonstrated that T-SPOT.TB was able to identify active pulmonary TB within 24 hours using BAL, even in cases missed by conventional methods.

In the study, 37 patients with suspected pulmonary TB were enrolled. Of these, diagnosis of active TB was confirmed via culture for 8 patients and a further 4 were finally diagnosed as having active TB notwithstanding a negative culture result. The remaining 25 patients were diagnosed as having alternate non-TB diagnoses. All 37 patients were then tested using T-SPOT.TB on both blood and BAL samples. T-SPOT.TB was 100% specific and sensitive in identifying the 12 active pulmonary TB cases and excluding those patients who did not have TB. The sensitivity of T-SPOT.TB was found to be higher than that for PCR. As a result the authors concluded that T-SPOT.TB could be used to test BAL as an effective 'rule in' test for active pulmonary TB. The role of T-SPOT.TB in diagnosing active TB has also recently been highlighted in another recent publication by Gooding et al. In this study T-SPOT.TB was able to accelerate the diagnose of TB infection over alternative approaches leading to the early initiation of effective treatments.

Commenting on the results, Dr Peter Wrighton-Smith, Chief Executive Officer of Oxford Immunotec said, "This study has demonstrated the clinical utility of our platform with non-blood samples in

addressing a significant problem for clinicians. Through our ability to identify cases of active pulmonary disease in smear negative patients, clinicians can adopt the correct treatment regime quickly avoiding the onward transmission of disease. This 'rule in' test using samples taken directly from the site of infection represents an important addition to the clinician's armoury "

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Notes to editors:

About Oxford Immunotec

www.oxfordimmunotec.com

Oxford Immunotec, the T cell measurement company, is headquartered near Oxford, UK. The Company develops and sells clinical diagnostic products based on its patented T-SPOT[®] technology, the first regulatory approved method for directly quantifying antigen-specific T cells.

T-SPOT is a simple and extremely accurate method of studying a person's cellular immune response to infection and can be applied to diagnose and monitor any major disease driven by a T cell response.

About T-SPOT[®].TB

T-SPOT.TB is an *in vitro* T cell measurement assay used for diagnosing TB disease and latent TB infection and the first product from Oxford Immunotec using the T-SPOT technology. The product is extremely robust in that it gives a result every time and offers unrivalled and maintained sensitivity in high risk and immunocompromised patient groups. T-SPOT.TB is approved for sale in Europe, Canada & over 40 other countries worldwide and is designed to replace the 115 year old Tuberculin Skin Test. As such it offers a substantially more accurate and effective tool for controlling the spread of TB, addressing a market exceeding \$1bn.

Unlike the traditional Tuberculin Skin Test, the T-SPOT.TB test incorporates a positive control, allowing the user to distinguish between a genuine negative result and one which is indeterminate (i.e. an inconclusive result) as a result of a technical failure.

T-SPOT is a trademark of Oxford Immunotec.

Journal Reference

Jafari et al – American Journal of Respiratory Critical Care Medicine; vol 174 – pp1048-1054

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Gooding et al – Journal of Infection; doi:10.1016/j.jinf.2006.11.002

Published November 2006