

Press Release

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UK's NICE Recommend replacing Mantoux with TB blood tests for Key Patient Groups

Oxford, UK, 24 March 2011

The National Institute for Health and Clinical Excellence (NICE) released new clinical guidelines for the use of innovative TB blood tests called interferon-gamma release assays (IGRAs) for diagnosing latent tuberculosis infection (LTBI) on 24th March 2011.

Previous guidelines for diagnosis of LTBI released by NICE in 2006 recommended the use of a two step approach, starting with the Mantoux skin test and then only using IGRAs to confirm positive results.

In recognition of the mounting clinical evidence in favour of IGRA technology, the new guidelines recommend going straight to an IGRA test in a number of specified indications including:

- In an outbreak situation when large numbers of individuals may need to be screened
- Recent arrivals from high incidence countries who are from 16 to 34 years old
- The immunocompromised and some HIV subjects
- New NHS employees who have recently arrived from high incidence countries or who have had contact with patients in a setting where TB is highly prevalent
- Hard to reach populations

In addition, the new guidelines recommend that an IGRA test be considered for initial use in individuals for whom Mantoux testing may be less reliable, such as those who have been BCG vaccinated, and for use in individuals whose Mantoux test result is positive.

These interventions are designed to identify subjects with LTBI so that they can be treated before they convert to active disease. This proactive approach will help to reduce the rates of active TB disease in the UK which have been rising over the past decade.

Until recently, the only test available to identify LTBI has been the Mantoux skin test which has been used for over 100 years and suffers from a variety of problems such as a high false negative rate amongst the immunocompromised and a high false positive rate amongst those who have been BCG vaccinated. The new IGRA tests recommended in these guidelines have been designed to overcome the deficiencies of the Mantoux test.

Oxford Immunotec Chief Executive, Peter Wrighton-Smith commented:

“I very much welcome the new guidelines from NICE which recognise the superior accuracy and convenience of IGRA testing in many populations. I am optimistic that the adoption of these guidelines will help to reverse the steadily increasing rates of TB seen in the UK over the past decade.”

For more information, please visit www.IGRAguidelines.com

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Notes to Editors:

About Oxford Diagnostic Laboratories

www.tbtestingservices.com

Oxford Diagnostic Laboratories is the TB blood testing service run by Oxford Immunotec in the UK and USA. It is the only dedicated IGRA testing laboratory in the UK and US and offers customers a simple, reliable and cost-effective way of accessing IGRA technology.

Oxford Diagnostic Laboratories exclusively runs the T-SPOT[®].*TB* test.

About Oxford Immunotec

www.oxfordimmunotec.com

Oxford Immunotec Ltd., the T cell measurement company, is headquartered near Oxford, UK; its US operations are based in Marlborough, MA. The company develops and sells clinical diagnostic products based on its patented T-SPOT[®] technology, the first FDA-approved method for directly quantifying antigen-specific T cells.

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

About T-SPOT[®].*TB* test

The T-SPOT.*TB* test is an Interferon Gamma Release Assay (IGRA) used for diagnosing TB disease and latent TB infection and is the first product from Oxford Immunotec using T-SPOT technology. The product offers unrivalled sensitivity with results unaffected by a patient's immune status.

The T-SPOT.*TB* test is approved for sale in Europe, USA, Canada and over 40 other countries worldwide and is designed to replace the 115 year old tuberculin skin test. It offers a substantially more accurate and effective tool for controlling the spread of TB, addressing a market exceeding \$1bn.

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