Partners in Health Care Innovation

INDEPENDENT PEER-REVIEWED STUDY DEMONSTRATES THAT T-SPOT®.*TB* ASSAY OUTPERFORMS TUBERCULIN SKIN TEST IN PREDICTING TUBERCULOSIS DISEASE

July 19, 2010

The authors of a recent studyi published in the American Journal of Respiratory and Critical Care Medicine concluded that the T-SPOT.*TB* test is better than the tuberculin skin test (TST) at predicting which patients will develop active TB.

There are significant practical difficulties in designing studies to show the predictive value of assays for the later development of active TB disease. Such studies require population cohorts with high rates of TB infection, high conversion rates to active disease and the absence of preventive therapy for TB infection.

This landmark study overcame these difficulties by examining a unique cohort of silicosis patients, Who have an elevated risk of developing active TBii, iii, and by excluding those who received preventive therapy.

The study compared the predictive value of test results of the T-SPOT.*TB* test and TST for the development of active disease in over 300 subjects over a 4 year period.

The T-SPOT.*TB* test was shown to be more sensitive than the TST at identifying subjects who would later convert to active disease. A significant proportion (7.9%) of T-SPOT.*TB* test positive persons developed TB even within the follow-up period. The T-SPOT.*TB* test only missed one subject who was later diagnosed with active TB disease, although the diagnosis was not confirmed by culture or histology. In contrast the TST was negative (even using the most sensitive 5mm cut-off) in four subjects who converted to active TB disease during the follow-up period. Two of these were confirmed to have TB by culture or histology. Statistical analysis of these results showed that a positive TSPOT.*TB* test predicted the subsequent development of active TB while TST did not.

Since only a few of the subjects had received a BCG vaccination, the superior performance of the TSPOT.*TB* test was not related solely to the higher specificity of the test. Importantly, the greater discrimination of the T-SPOT.*TB* test was largely due to the higher sensitivity of this test compared to the TST.

Commenting on these results, Dr. Peter Wrighton-Smith, CEO of Oxford Immunotec said “This landmark paper is the first significant study to be published on the predictive value of the T-SPOT.*TB* test. It is well known that the T-SPOT.*TB* test is both more sensitive and more specific than the TST. This study has confirmed that this greater accuracy translates into a higher predictive value for the TSPOT.*TB* test over the TST.” He continued “The use of the T-SPOT.*TB* test, in place of the TST, to identify those TB infected persons most at risk of developing active TB disease, should greatly increase the efficacy and cost-effectiveness of TB control programs worldwide.”

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