

Oxford Immunotec TB test gets nod in Japan

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Singapore: Oxford Immunotec, a medical diagnostic company developing tests in the fields of infectious and immunological disease, announced that the T-SPOT.TB test has received regulatory approval from the Japanese Ministry of Health, Labour and Welfare (MHLW).

The T-SPOT.TB test is a laboratory-based cellular blood test that is intended for use as an aid in the diagnosis of *Mycobacterium tuberculosis* infection and disease. The T-SPOT.TB test improves accuracy and eliminates the logistical challenges often seen with the existing tests for TB infection.

Clinical studies were performed in Japan to obtain this approval. In these studies the test sensitivity (positivity in infected subjects) was 97 percent and the test specificity (negativity in non-infected subjects) was 99 percent.

Oxford Immunotec also announces the inclusion of T-SPOT.TB in the clinical lab fee schedule of reimbursed tests and into the public health government subsidy for contact tracing.

Commenting on the approval, Dr Peter Wrighton-Smith, CEO, Oxford Immunotec, said, "Japan has one of the highest TB rates in the developed world and the accurate and reliable identification of tuberculosis infection, possible with the T-SPOT.TB test, will be an important component of helping to reduce TB rates there." He continued, "Japan has been one of the last major developed-world countries in which we have received regulatory approval. T-SPOT.TB is now sold in over 40 countries worldwide".