T-SPOT.® TB

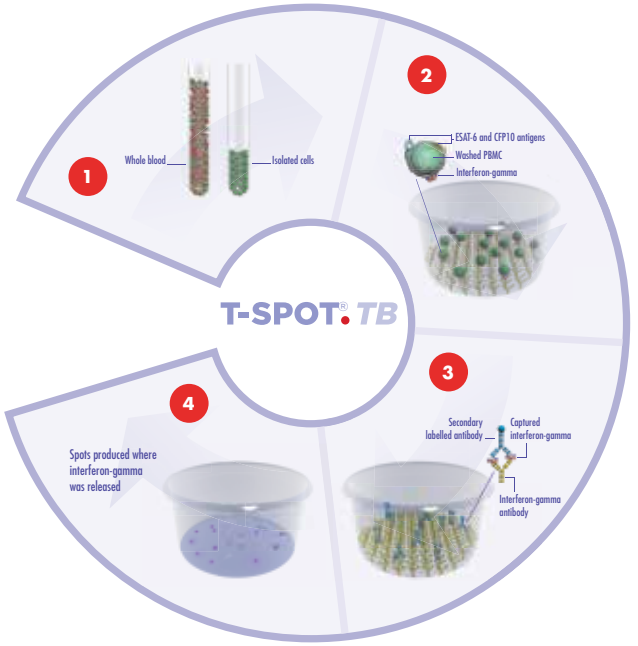
Detecting Tuberculosis Infection

How the T-SPOT.*TB* test helps you[1]

- Identifies a high percentage of infected subjects and is the only interferon-gamma release assay (IGRA) with sensitivity of 98.8%.
- Specificity above 99%. False-positives are rare with the T-SPOT.*TB* test, so unnecessary chemoprophylaxis and follow-up is minimized.
- Is unaffected by BCG vaccination and common non-tuberculous mycobacteria.
- Can be used in testing of all patient groups including those with weakened immune systems (e.g. living with HIV/AIDS, transplant recipients, undergoing biologic therapy), pregnant individuals and very young children.
- Can be drawn into a standard blood collection tube using routine phlebotomy technique.
- Avoids complicated sample collection steps and leaves sample processing steps, including incubation, to the laboratory which ensures the laboratory has full quality control over sample processing.
- Has a sample stability of up to 32 hours, which can allow for overnight shipment.
- Can be processed by the laboratory in 24 hours.
- Has low levels of indeterminate results (1.1%[2] in Oxford Immunotec's own service laboratory).
- Is the only IGRA with a borderline result category, which is intended to safeguard patients by reducing the risk of false-positive and false-negative results around the test cut-off.
- Requires only one patient visit, unlike the TST test which requires two patient visits within 72 hours.
- Reduces the number of false-positive and false-negative results, helping to ensure therapy is targeted at patients who are truly infected, compared to the TST.
- Has been extensively studied in numerous patient populations.
- Has been approved for sale in over 50 countries, including the United States, where it has received pre-market approval from the Food and Drug Administration, Europe, where it has obtained a CE mark, as well as Japan and China.

How the T-SPOT.*TB* test works based on the proprietary T-SPOT technology[1]

- The only IGRA that separates cells from whole blood and standardises the number of these cells used in each patient test, reducing the risk of false-negative and indeterminate test results.
- The only IGRA that washes cells to enable the removal of potentially interfering substances that can affect test results.



1. A blood sample is collected using routine phlebotomy and a standard blood collection tube from which a subset of white blood cells, known as peripheral blood mononuclear cells, are isolated. The cells are washed, counted and normalized to create a standard cell suspension.

2. A standard number of cells are added into specially designed plates and stimulated with TB-specific antigens, ESAT-6 and CFP10. Cells responding to these antigens release interferon-gamma.

3. Interferon-gamma antibodies are used to directly capture interferon-gamma as it is released by the cells. A secondary labelled antibody is added and binds to the captured interferon-gamma.

4. A detection reagent is added and reacts with the secondary labelled antibody. This reaction produces spots, which are a footprint of where the interferon-gamma was released. Spots are then enumerated.

The T-SPOT.*TB* test

- Testing of patients with conditions that weaken the immune system and increase the risk for latent TB reactivation, including: HIV infection, treatment with immunosuppressants, including anti-TNF-α therapy and high-dose steroids, chronic renal disease and cancer chemotherapy.
- Targeted testing of high-risk populations including: Close contacts, migrants, prisoners and patients suspected of TB.
- Pre-employment and regular screening of healthcare professionals.

REFERENCES

1 T-SPOT.*TB* Package Insert (PI-TB-IVD-UK-V3)
2 Year to date (1/12/15) 2015 data at Oxford Diagnostic Laboratories, UK

T-SPOT® *TB*

Oxford Immunotec

LP-TB-UK-V9

info@oxfordimmunotec.com
www.oxfordimmunotec.com