T-SPOT.TB

DIAGNOSE WITH CONFIDENCE

TB.
TO FIND
IT IS TO
FIGHT IT.

Oxford Immunotec

TB – a continuing threat to global health

With ~10 million people falling ill in 2020 alone, it is estimated that as much as a quarter of the world's population is infected with Mycobacterium tuberculosis (MTB). TB kills **1.4 million people** every year - making it one of the world's leading causes of death by a single infectious agent[1]

Although incidence is falling by about 2 % per year, the rate of infection is not dropping fast enough.

To confine TB to the history books, a complete toolbox of drugs and tests are essential to accurately identify and treat it.

Latent TB – the "unseen" threat

In order to turn the tide against TB, healthcare practitioners need not only to treat patients with active disease, but crucially, identify and treat the unseen pool of TB in the form of latent TB infection (LTBI).

Correctly diagnosing LTBI increases the chance of:

- Stopping TB before it becomes active disease
- Avoiding additional costs and adverse effects from unnecessary chemoprophylaxis
- Better outcomes for patients

LTBI is hard to identify

The immune system locks MTB inside a granuloma after infection—making it almost impossible to detect, without the right test. However, you can use an individual's own immune response against MTB to give insight into who has the disease.

There are two types of LTBI test which use the immune response to detect the presence of MTB; the tuberculin skin test (TST or purified protein derivative/Mantoux test) or an interferon-gamma release assay (IGRA).

The TST test has several major drawbacks. Patients need to visit the clinic twice; once to administer the test and again to measure the immune response in the form of an induration on the skin. Staff need specialist training for this. The test can also react to BCG vaccination which can lead to false positives in vaccinated individuals. In addition, the test is only moderately sensitive and specific and patients with LTBI can be missed[3].

In contrast, IGRAs work by identifying MTB-specific effector T cells from the blood *in vitro* to diagnose LTBI. These tests are performed in the laboratory, only require one patient visit and, importantly, are unaffected by BCG vaccination.

There are two types of IGRA:

- Non-normalised IGRAs that use ELISA or similar technology
- Normalised IGRA — the T-SPOT.*TB* test — that uses ELISPOT technology

To diagnose LTBI quickly and correctly, you need the right test – T-SPOT.TB

T-SPOT.*TB* – ELISPOT efficacy

The T-SPOT.*TB* test is the only IGRA available that uses a simplified ELISPOT (enzyme-linked immunospot) technology. It is the most sensitive test available[4], suitable for all LTBI testing,

The T-SPOT.*TB* test is ideal to use as a screen for:

Transmission:

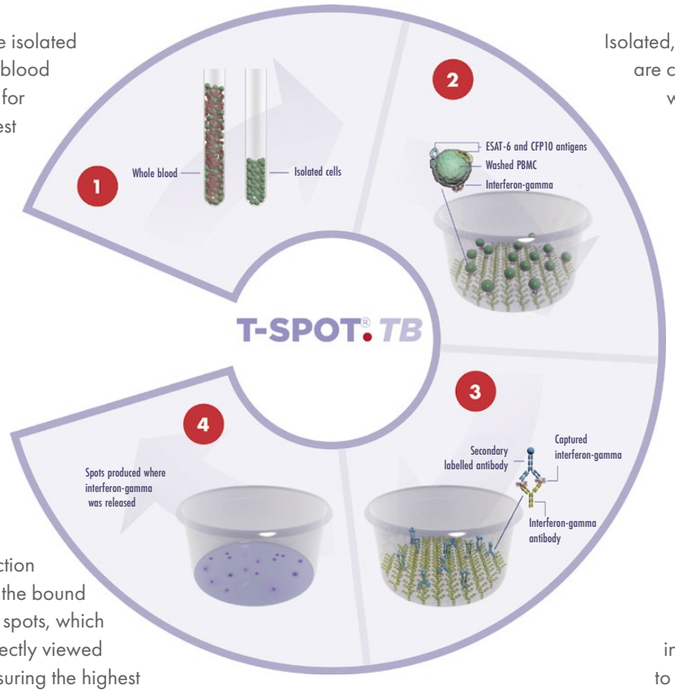
- TB contacts, migrants, health care workers, prisoners, underserved groups and military personnel

Progression/reactivation:

- Prior to biologic treatments, prior to immunosuppressive therapy, HIV infection, chronic renal failure, organ transplant, haematological disorders, paediatrics and alcohol/drug abuse

How the T-SPOT.*TB* test works

Immune cells are isolated from peripheral blood and normalised for cell count and test conditions.



Isolated, normalised immune cells are cultured in a 96 well plate with overlapping peptides of ESAT-6 or CFP10. This stimulation causes the release of interferon-gamma (IFN-gamma) from only MTB-specific CD4 and CD8 T cells.

Addition of detection reagent resolves the bound IFN-gamma into spots, which can easily be directly viewed and counted, ensuring the highest accuracy in test evaluation[5].

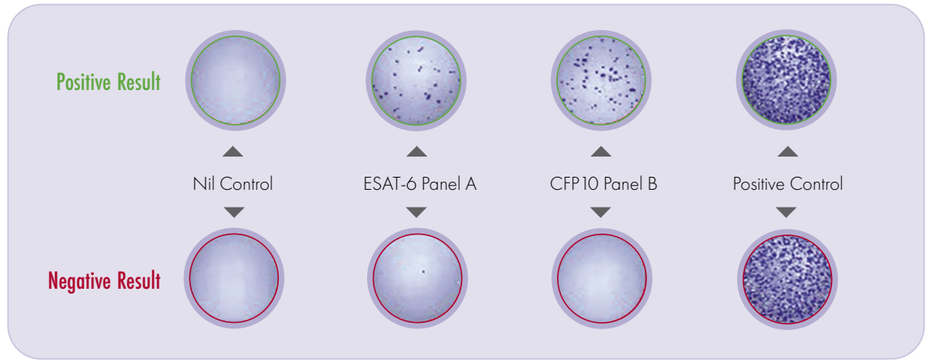
Negative (nil) and positive controls are also used.

Released IFN-gamma binds to the membrane at the base of each well in locations corresponding to each MTB-specific T cell.

Seeing is believing. Be confident in your TB diagnosis

Unlike ELISAs, T-SPOT.*TB* test results can be directly visualised without relying on interpretation from standard curves, giving you the utmost confidence in results.

A small number of cells producing a large amount of IFN-gamma do not produce a false positive result, and even weak spots (e.g. if T cell function is reduced) can be counted.



Spot counts in the nil control are deducted from those in the test panels. A positive result is when the spot counts in either Panel A or Panel B are greater than or equal to 6 more than the nil control[5].

T-SPOT.*TB* – Approved by global health bodies

The T-SPOT.*TB* test is the **only FDA-approved, normalised IGRA available** based on ELISPOT technology and is one of only two IGRAs **recommended by the WHO[6], ATS/CDC/IDSA[4] and the ECDC[7]** for the diagnosis of LTBI.

In addition, the T-SPOT.*TB* test is the only test for TB infection with an **FDA approved borderline[5] zone** to further improve reliability of test results. Spot counts of *5*, *6* or *7* are considered borderline. If the result is outside the borderline zone then you can have full **confidence in the accuracy** of the result. Borderline results can be repeated to further improve accuracy.

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Improve accuracy with the T-SPOT.TB test

The T-SPOT.*TB* test is the only IGRA available that is normalised for both cell number and culture conditions. The test standardises the number of cells and removes serum factors that could adversely affect the test result, making it the **most sensitive and most specific test for TB infection**[4]. You can quickly and reliably diagnose and treat TB infection in all patient groups, including the immunosuppressed[8].

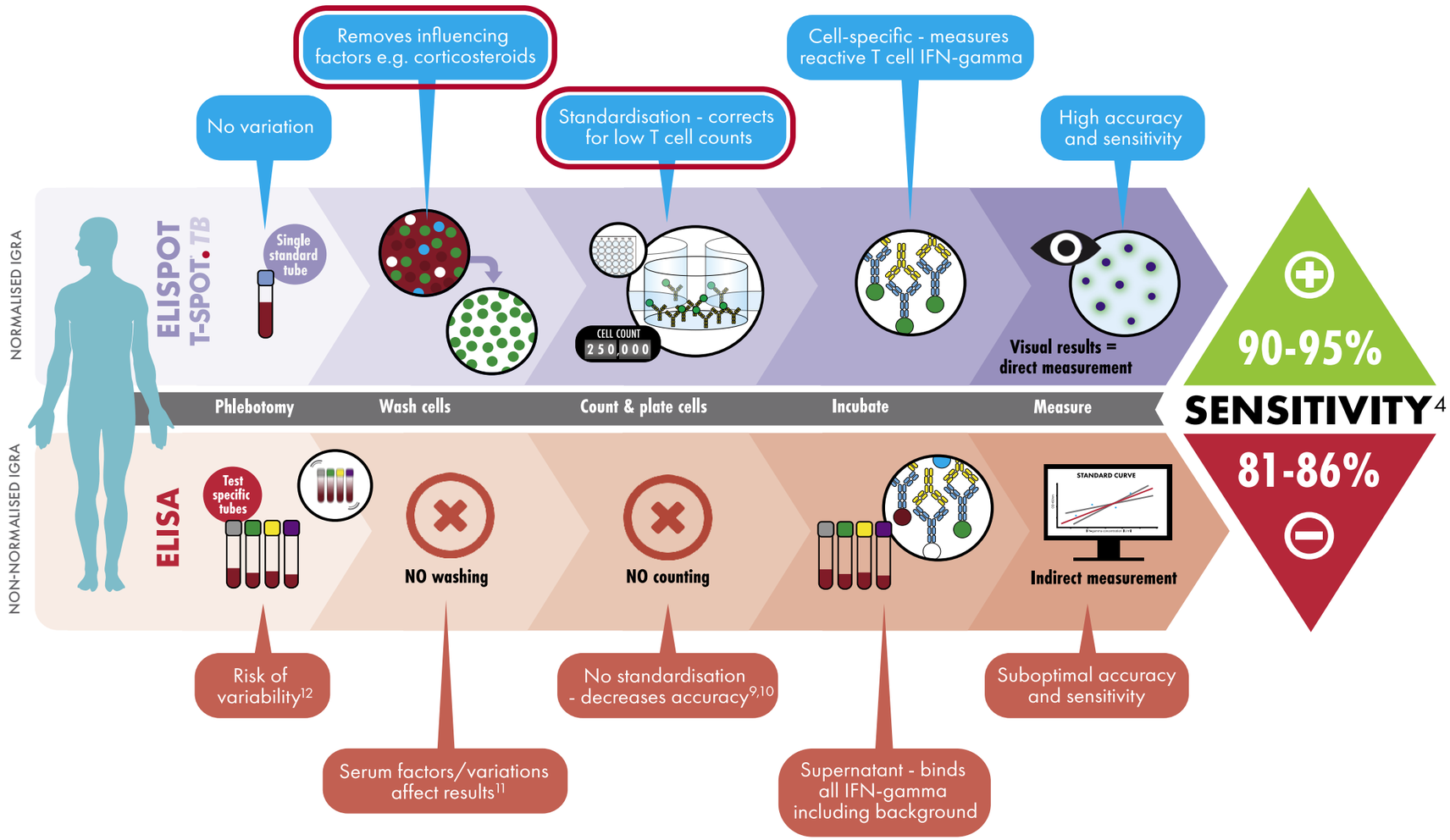
Reduce false results with normalisation

Standardised cell numbers ensure there are always enough cells to get an accurate result. Diagnosis is not affected by changes in blood cell counts - especially important in the immunosuppressed[9,10].

All serum factors, such as corticosteroids and unnecessary blood components are removed, reducing the likelihood of false negative or false positive results[11].

Reduce variability

Uses your normal phlebotomy methods with just a single standard tube and no requirement for additional training. This helps keep variation in test results introduced during sample collection to a minimum. Transport at room temperature makes logistics simple, and the test only starts once the sample has arrived in the lab — under the lab's full quality control[12].



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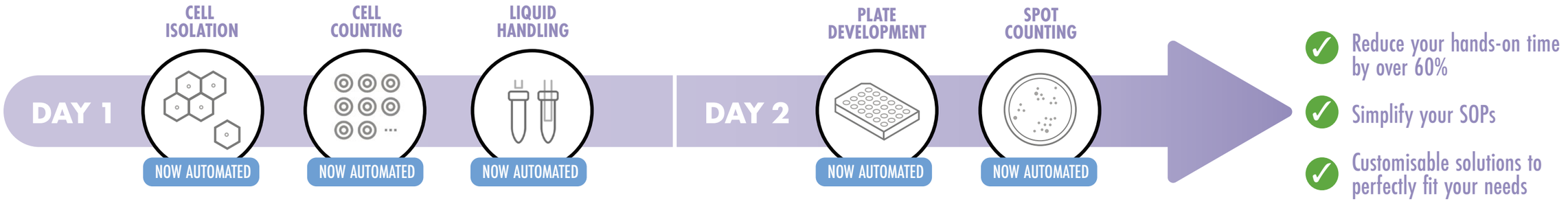
Automation: T-SPOT.TB testing made easy

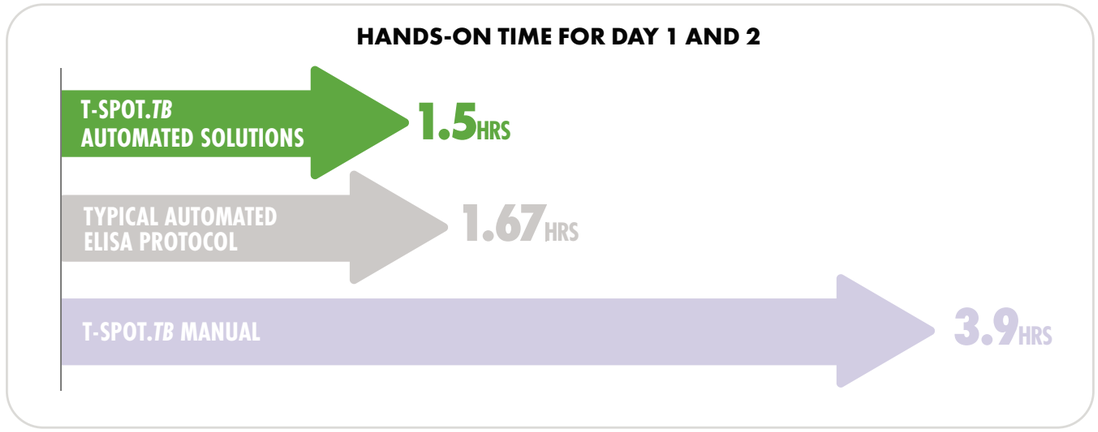
Each process of the T-SPOT.*TB* test is now automated allowing for increased workflow efficiency, and reduced hands-on time. With customisable and scalable solutions for each part of the process, you can select the most cost-effective solution for your specific needs.



Liquid handling steps of the plate development process can be automated.
Each result should be individually validated before reporting.

Increase efficiency with less hands-on time allowing other tasks to be carried out. With our automation solutions, the T-SPOT.*TB* test can easily fit into complex, multi-test workflows and provides the flexibility to comfortably manage high sample-volume days.

Our automation solutions are customisable and scalable – meaning that they can adapt to your changing requirements. By choosing to automate just one, a number, or all of the processes within the T-SPOT.*TB* test workflow, you can select the most cost-effective solution for your specific needs.



N.B. Hands-on time based on 24 samples and time interacting with instruments plus any walk away time under or equal to 15 minutes. Typical automated ELISA protocol based on a 22 sample Dynex DS2® run

'The automated process is more efficient, allowing us to organise the lab better, so technicians can also work on other tests. We also now handle large screenings with our normal staff levels.'

Imke Friedrichs MD
Doctor of Medical Microbiology, Virology and Infectious Disease Epidemiology

Zohreh Davami
Head of Microbiology Department, Frankfurt Main

Laborarztpraxis
Dres. Walther, Weindel und Kollegen

'We have been using T-SPOT technology for several years and are satisfied with the quality of the results. Since we started with the automated solution we have been able to process more samples per day and thus meet the demands of large screenings'

Dr Isabelle Rozet Piales
Laboratoire Eylau-Unilabs

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Improve testing logistics and efficiency

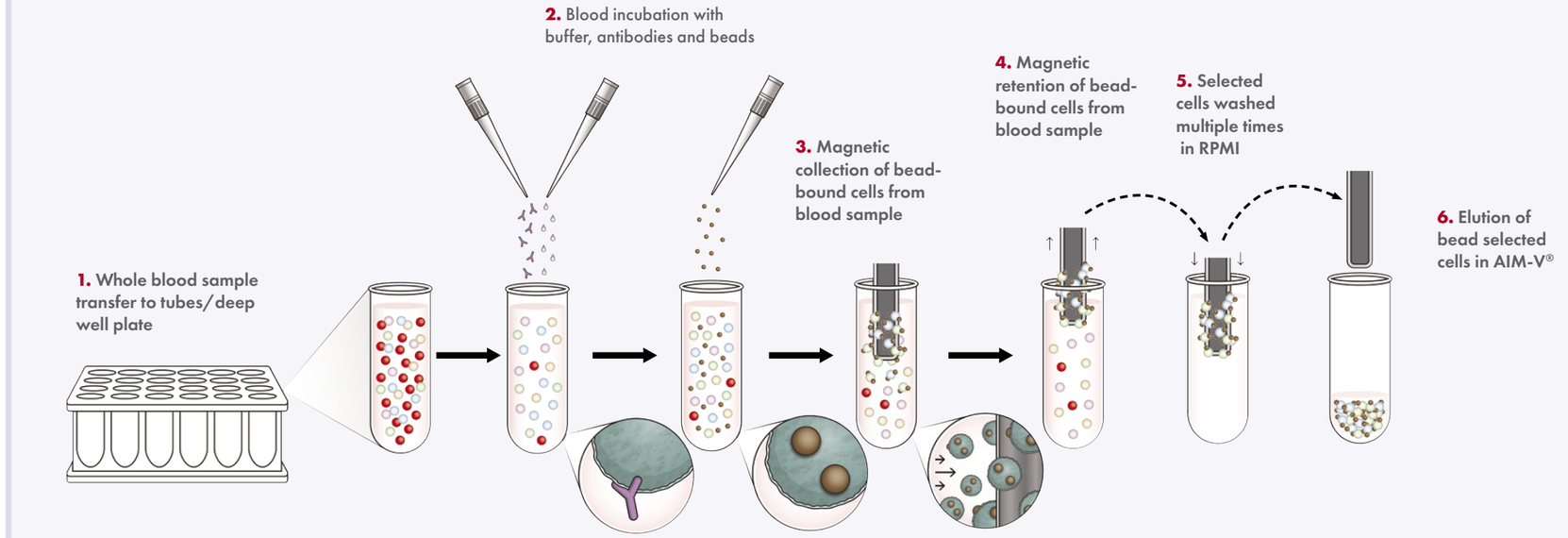
T-Cell *Select*™

The 54 hour sample stability[13] of the T-Cell *Select* reagent kit gives greater flexibility in the laboratory and samples can be shipped from further away.

The T-Cell *Select* reagent kit is used to automate the isolation of immune cells from peripheral blood samples using positive immunomagnetic selection.

Longer sample storage

- Batch samples for efficient testing
- Late arriving samples can be stored overnight for next day processing
- Ambient temperature sample storage



CE marked for the isolation of mononuclear immune cells directly from whole blood

Positive selection using magnetic bead technology

Complete kit of reagents, including all antibodies, buffer and beads required for use with cell-mediated immune assays

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Maximise the sensitivity and specificity of your TB tests with T-SPOT.TB

The most accurate test for TB infection[4], even for harder to diagnose patients who have low T cell counts[14], reduced T cell function[9] or who are on corticosteroids.[8]

Please visit our website: www.tspot.com/uk/

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