The TB test you can trust.

revvity

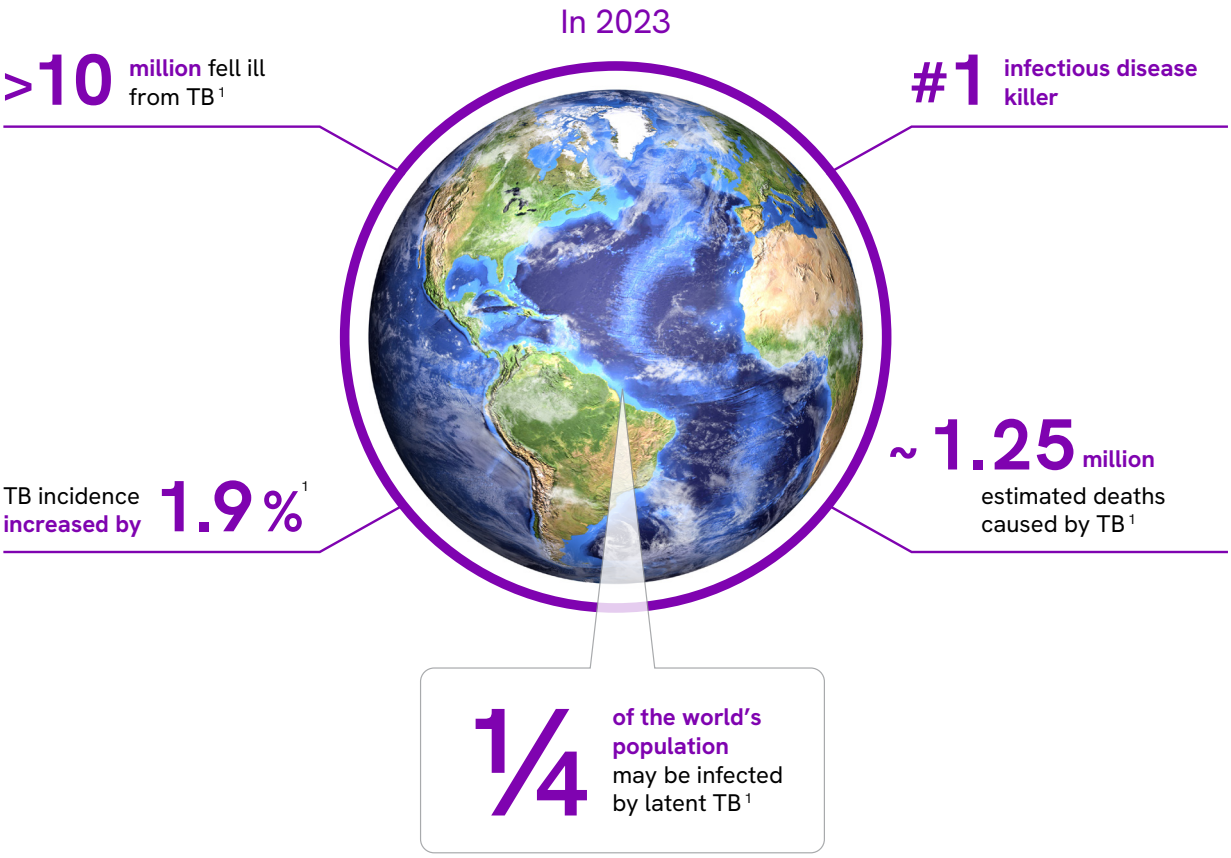
The T-SPOT™.TB test

Tuberculosis (TB): A continuing threat to global health.

More than 10 million people fell ill from TB in 2023 alone and it killed 2.5 million people – making it the world's leading cause of death by a single infectious agent.[1]

Incidence is also now back on the rise by 1.9 % vs 2022, after a decade of decline. It is estimated that as much as a quarter of the world's population is latently infected with *Mycobacterium tuberculosis* (MTB).[1]

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



Why is testing for latent tuberculosis infection important?

For every person with active TB, many more have a latent TB infection. Latent TB is asymptomatic, and it cannot be transmitted to others, however 5 to 10 %[1] of those infected with latent TB may progress to active, symptomatic, contagious TB disease and will transmit the bacteria to others in their community[2].

This process continues to drive the global epidemic of TB. Accurately identifying individuals who are infected with latent TB and treating them before they develop active TB is crucial to global TB management[2,3].

In addition, we must also promote screening and treatment of persons at greatest risk of developing active disease. At risk populations are the most likely to progress from latent TB infection

to active TB disease, and as such the World Health Organization (WHO) recommends that these groups should be tested and treated for latent TB infection in order to prevent transmission[2]. At risk populations include, but are not limited to: immunosuppressed and paediatric patients, people living with HIV and close contacts of an active case.

Accurately detecting latent TB increases the likelihood of achieving the following outcomes:

Stopping TB	Avoiding	Improving
before the infection becomes an active disease	additional costs and adverse effects from developing active TB	patient outcomes

Methods for testing latent TB

Two types of latent TB tests utilize the immune response to detect MTB: skin tests (tuberculin or specific TB antigens) and interferon-gamma release assays (IGRAs). The skin tests have significant drawbacks, including the requirement for two clinic visits, specialized staff training, potential reactivity to BCG vaccination leading to false positives, and only moderate sensitivity and specificity, potentially resulting in missed latent TB cases.[4]

In contrast, IGRAs function by identifying MTB-specific effector T cells from the blood *in vitro* for latent TB detection. These tests are conducted in the laboratory, necessitate only one patient visit, and crucially remain unaffected by BCG vaccination.[5, 6]

There are two different IGRAs:

1. **ELISPOT IGRA (the T-SPOT.TB test)**

   Where peripheral blood mononuclear cells (PBMCs) are isolated, washed and counted to purify them from the whole blood prior to cell stimulation.

2. **ELISA/CLIA IGRAs:**

   Where the cell stimulation is performed in the whole blood.

Why choose the T-SPOT.TB test?

The T-SPOT technology allows for:

High sensitivity (98.8 %) and specificity (>99 %) providing accurate results[5]

Low indeterminate results, few repeat tests[12]

Maintains performance in the immunosuppressed [9, 13]

The T-SPOT.TB test has three crucial steps that have recently been acknowledged by the WHO for ensuring reproducibility and mitigating the impact of pre-analytical variables.[7] These steps include isolating, washing, and counting the PBMCs before the test is performed.

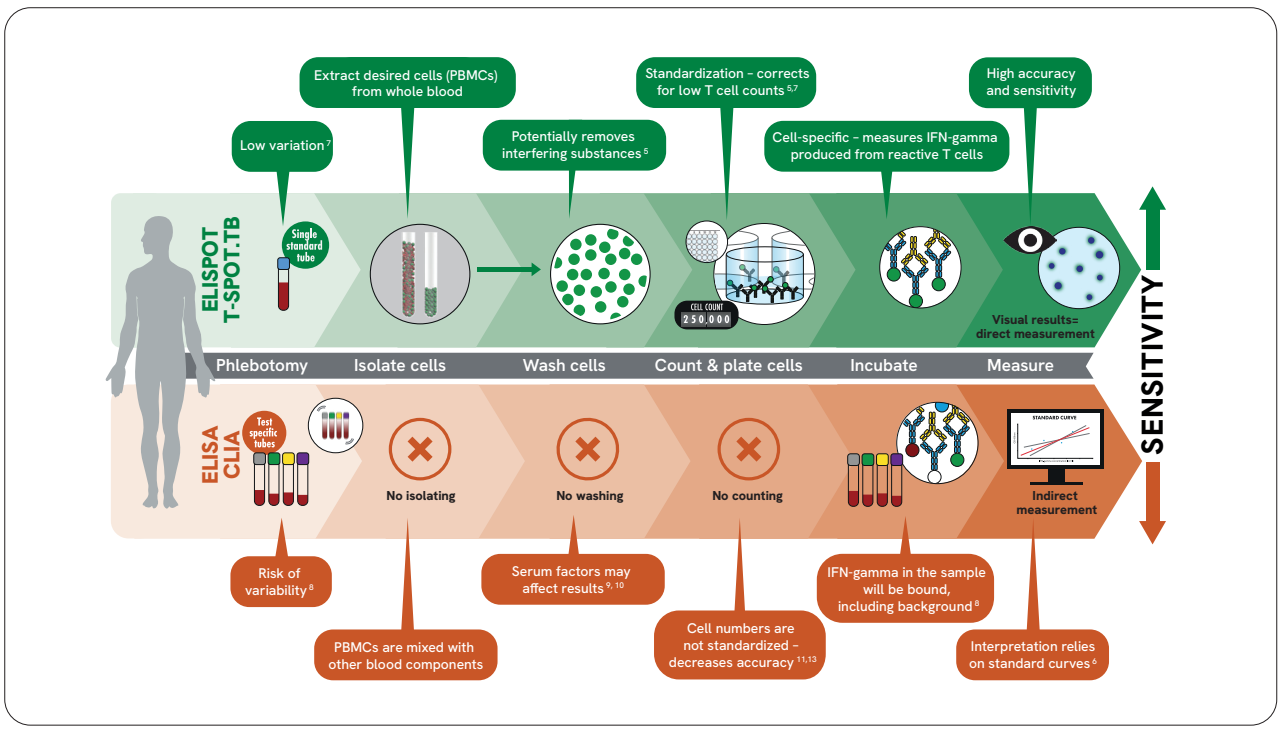
Shifting from traditional whole blood sample testing, the T-SPOT.TB test provides precision and reliability, allowing more control in your TB infection testing.

Here's how:

- Only one standard blood collection tube needed throughout the T-SPOT.TB process
- Isolates PBMCs from whole blood, washes and counts them:

1. Isolate cells	Extract the desired cell population (PBMCs) from whole blood
2. Wash cells	Enables removal of potential interfering substances from whole blood
3. Count cells	Ensures the required number of cells are used to produce reportable and accurate results regardless of individual patient cell counts

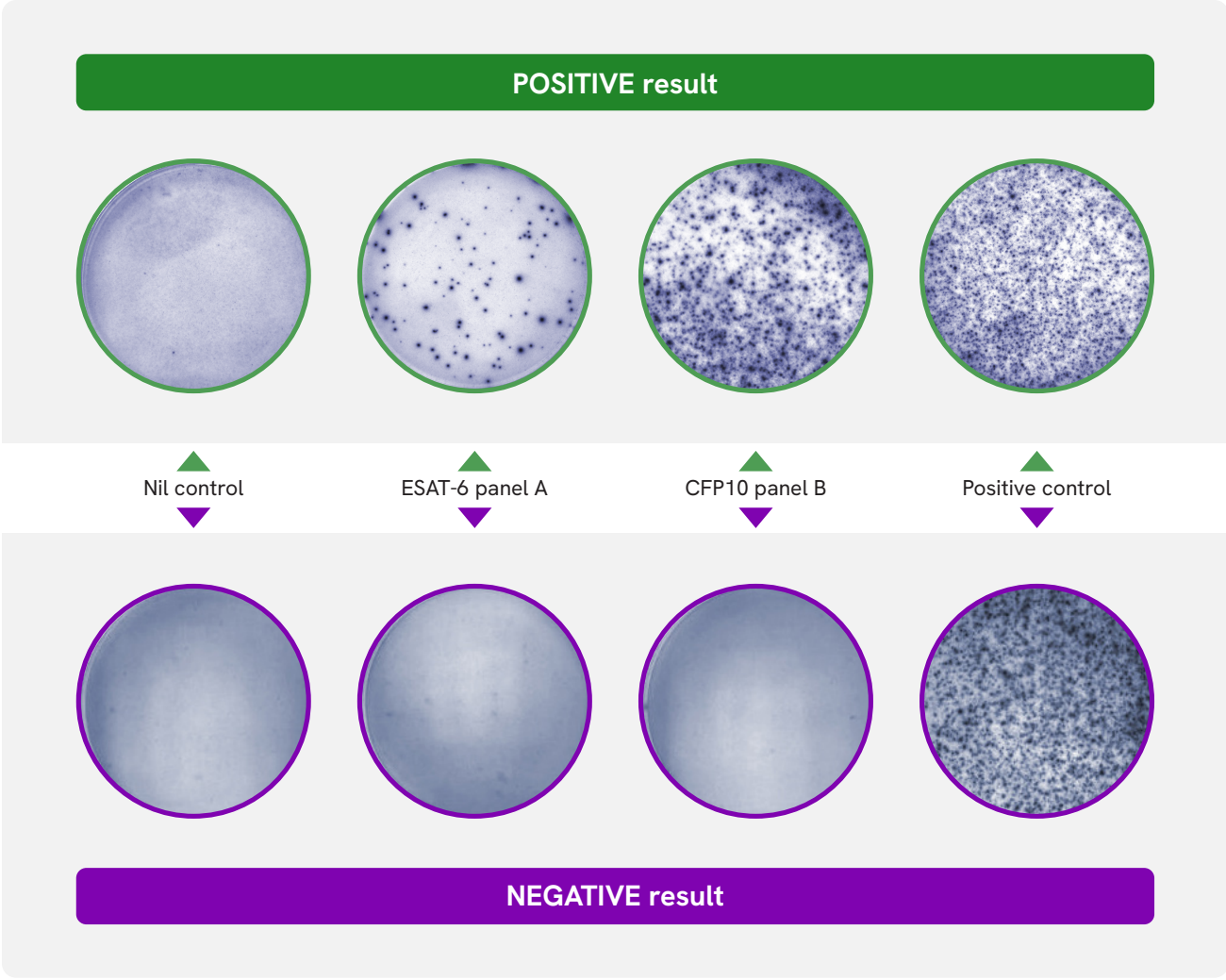
- Directly visualize the results without relying on interpretation from standard curves



Visualize and be confident in your results

Unlike ELISAs or CLIAs, T-SPOT.TB test results can be directly visualized without relying on interpretation from standard curves, giving you confidence in the 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.[5]



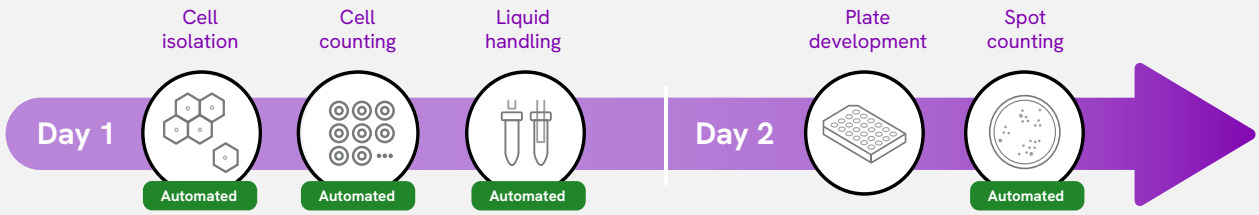
Spot counts in the nil control are deducted from those in the test panels. A positive result is when the spot counts in either Panel A or Panel B are greater than or equal to 6 more than the nil control.[5]

The TB test you want.
The automation you need.

Automate your workflow

T-SPOT.TB enables accurate TB infection testing[5] and when paired with our automation solutions you get efficient laboratory workflows without compromising on clinical performance.[14]

This powerful combination not only simplifies T-SPOT.TB testing but also provides confidence in the result.



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

Reduce manual sample handling for a more efficient workflow.

Multiple steps of the T-SPOT.TB test are now automated allowing for increased workflow efficiency and optimized hands-on time.

With our range of solutions, you can select the most cost-effective combination for your specific needs.

"We have been convinced users of the T-SPOT.TB test for many years and are very satisfied with the performance and results, especially in patients with immunosuppression.

The new automation solutions not only enable more flexible sample logistics and laboratory organisation, but also lead to a higher cell yield with consistently high cell quality."

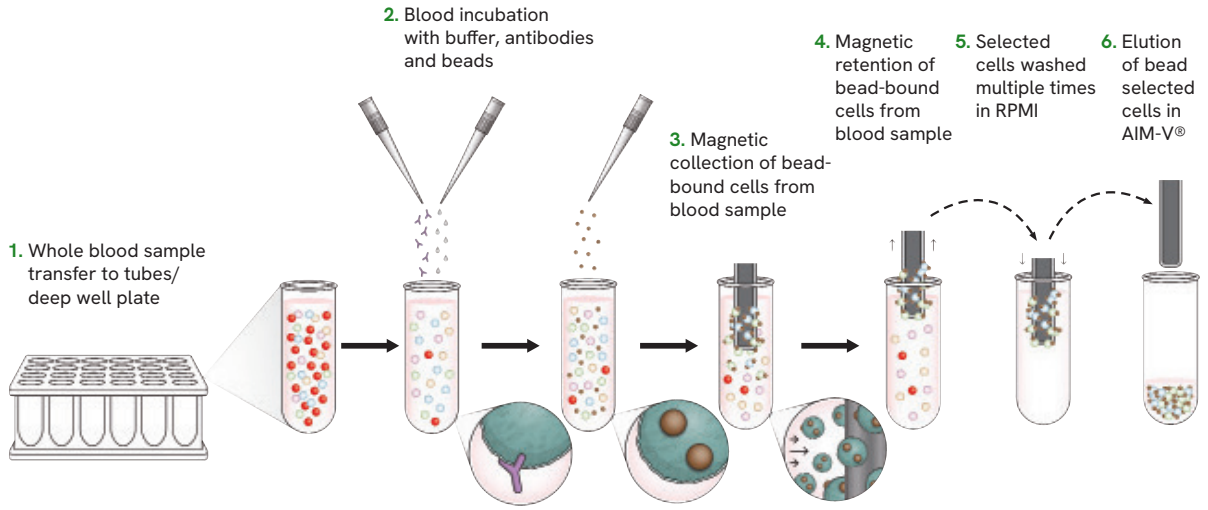
Dr Martin Obermeier
Director and Head of Laboratory, MIB
Medical and Infectious Diseases Centre Berlin

Simplify your workflow while maintaining clinical performance with the T-Cell Select kit

Enhance testing operations and streamline efficiency using T-Cell Select™, which extends sample stability post-venipuncture to an impressive 54 hours at room temperature (18–25 °C)[14]. This innovation offers several advantages, including:

- Batch samples working to lab schedule
- Store samples overnight reducing the need for extended working hours
- Receive samples from further away facilitating centralization of testing
- Greater flexibility to plan your clinics according to your requirements
- No compromising on performance [14]

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



- 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.

Approved by global health bodies

The T-SPOT.TB test is recommended by the World Health Organization (WHO)[7], European Centre for Disease Prevention and Control (ECDC)[15] and Centres for Disease Control and Prevention (CDC)[16]. It is also approved by the Food and Drug Administration (FDA) as a diagnostic aid for latent tuberculosis.

Be confident in the result with the T-SPOT.TB test

Whether you are conducting routine TB screening or pursuing a comprehensive diagnosis for vulnerable patients, the T-SPOT.TB test ensures confidence in the obtained results. It also provides the laboratory with efficient workflows without compromising on the clinical performance.

Choose the T-SPOT.TB test for accurate IGRA testing.

The TB test you can trust.

The T-SPOT.TB test

Revvity are experts in immune responses to tuberculosis infection, using the market leading ELISPOT IGRA, giving access to high quality TB testing.

References

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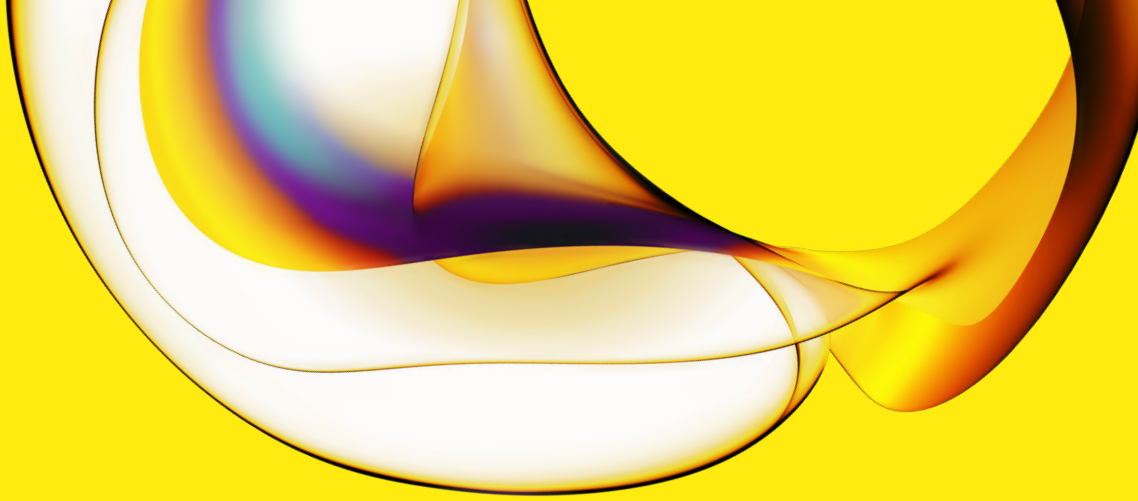

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BRCH-MPN914-01 Ver.1

BRCH-MPN914-01 (DOC-4143) Ver. 1

Approved By:

(CO-634) Update to TB.Brochure (BRCH-MPN914-01 (DOC-4143))

Description

Updating a few of the stats on page 2 to align with new TB report from WHO and reference at back to 2024 from 2023.

Justification

This is needed to align with up to date report by WHO. WHO publish a report yearly on previous TB data (Cases, impact, death...etc). As we use it as a source, we need to update it yearly. NOTE: Although the brochure has claims these have not been updated from v0 therefore both Scientific Affairs and Regulatory are not required for claim review as per WI 01-002.08. Statistics and Branding update only from v0 to v1 therefore CD/GB to review only. LKS 26Nov24

Assigned To:	Initiated By:	Priority:	Impact:
Kirsty Whigham	Sophie Francis	Low	Minor

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Author	Effective Date	CO#	Ver.	Status
Kirsty Whigham	November 27, 2024 12:21 PM GMT	CO-634	1	Published
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