# A large, retrospective study analysed pediatric samples to increase the IGRA reliability metrics in the pediatric populations, especially in very young populations.

T-SPOT.TB Performance in Routine Pediatric Practice in a Low TB Burden Setting (Mandalakas et al., 2018).[1]

## Background

T-SPOT™.TB is an interferon-gamma release assay (IGRA), which is an indirect diagnostic test that looks for an immune system response to the presence of *Mycobacterium tuberculosis* (Mtb). Due to sparse and conflicting evidence, the use of IGRAs has been limited in pediatric patients and HIV-infected children, in clinical practice and in guidelines. The goal of this study was to determine the prevalence of clinically relevant results. Additionally, the study aimed to use this data to look at the associations of these different result classifications with key demographic variables.

## Methods

Associations between initial test outcome and demographics were estimated by bivariate analysis and logistic regression, in samples collected from 2010-2015.

## Results

The T-SPOT.TB test provides evaluable results in 98 % of children, including young children.

- 43,697 samples of children from 1 day to < 17 years old (median age 12.5 years) were examined.

- 5,057 samples (11.6 %) were from children < 5 years old.

- T-SPOT.TB positivity was strongly correlated (r = 0.60; P < 0.0001) with state TB incidence rate.
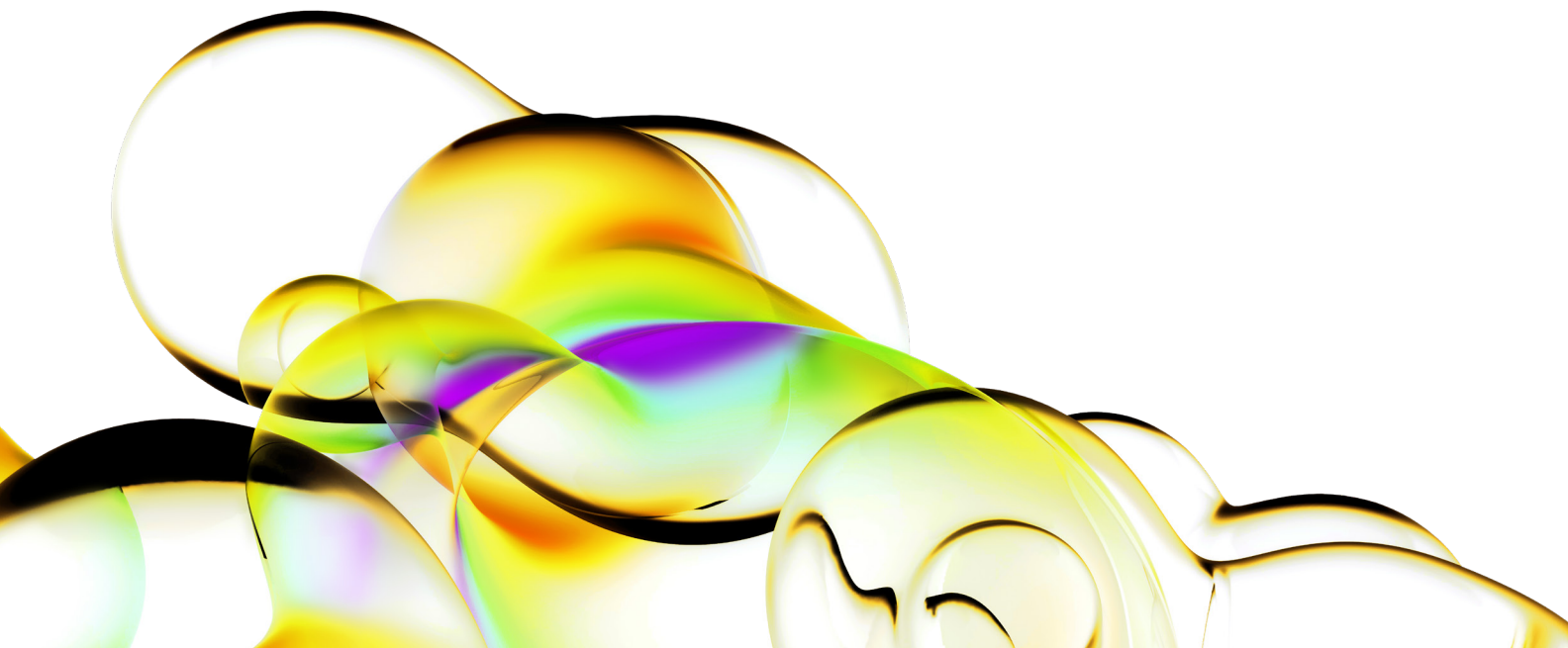
A large, retrospective study analysed pediatric samples to increase the IGRA reliability metrics in the pediatric populations, especially in very young populations.

- Odds of test positivity increased with age and peaked with children older than 10 years of age being 2.3 times more likely (OR 2.3; 95 % CI 1.3 – 4.3) to have a positive T-SPOT.TB than children under 1 year of age.

- For each additional year of age, children had a 6 % increased risk of a positive result (OR = 1.06 (95 % CI: 1.05, 1.07, P < 0.0001).

- Invalid results were infrequent, overall (0.6 %), but were more frequent in samples collected at HIV clinics and from younger children (most possibly due to a strong nil (negative) control response).

## Results

The table below outlines the results, stratified by age.

|  | Total results | Positive n (%) | Negative n (%) | Borderline n (%) | Invalid n (%) |
|---|---|---|---|---|---|
| < 1 year | 455 (1) | 11 (2.4) | 433 (95.2) | 3 (0.7) | 8 (1.8) |
| > 1 < 2 years | 964 (2.2) | 13 (1.3) | 937 (97.2) | 7 (0.7) | 7 (0.7) |
| > 2 < 3 years | 1,047 (2.4) | 31 (3.0) | 1,000 (95.5) | 7 (0.7) | 9 (0.9) |
| > 3 < 5 years | 2,591 (5.9) | 106 (4.1) | 2,453 (94.7) | 19 (0.7) | 13 (0.5) |
| > 5 < 10 years | 10,746 (24.6) | 463 (4.3) | 10,101 (94) | 112 (1.0) | 70 (0.7) |
| > 10 < 17 years | 27,894 (63.8) | 1,565 (5.6) | 25,829 (92.6) | 353 (1.3) | 147 (0.5) |
| Total | 43,697 (100) | 2,189 (5.0) | 40,753 (93.3) | 501 (1.1) | 254 (0.6) |

## Conclusions

The T-SPOT.TB test correlated strongly with well-recognized risk factors for TB infection and provided evaluable results in 98 % of children. To optimize the impact of testing on clinical decision-making and patient outcomes, local epidemiology and individual patient risk should be considered when incorporating IGRAs into pediatric guidelines.

Products may not be licensed in accordance with the laws in all countries. Please check with your local representative for availability.

Revvity, Inc. does not endorse or make recommendations with respect to research, medication, or treatments. All information presented is for informational purposes only and is not intended as medical advice.

## Reference

1. Mandalakas, Anna M. MD, PhD*; Highsmith, Heather Y. MD[†]; Harris, Nadine M. MD[‡]; Pawlicka, Anna MBA[§]; Kirchner, H. Lester PhD*[¶] T-SPOT.TB Performance in Routine Pediatric Practice in a Low TB Burden Setting, The Pediatric Infectious Disease Journal: April 2018 - Volume 37 - Issue 4 – p 292-297 doi: 10.1097/INF.0000000000001792
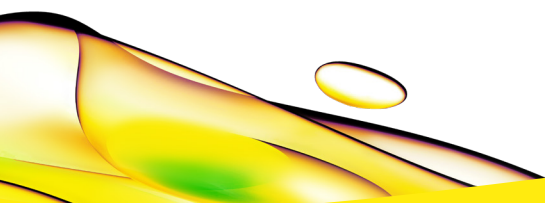
T-SPOT is a trademark of Oxford Immunotec Ltd.

revvity