

High reproducibility of the interferon-gamma release assay T-SPOT™.TB in serial testing.

Determine high reproducibility of T-SPOT.TB in serial testing during a 14-year period (Thomas Meier, et al., 2020)

Background

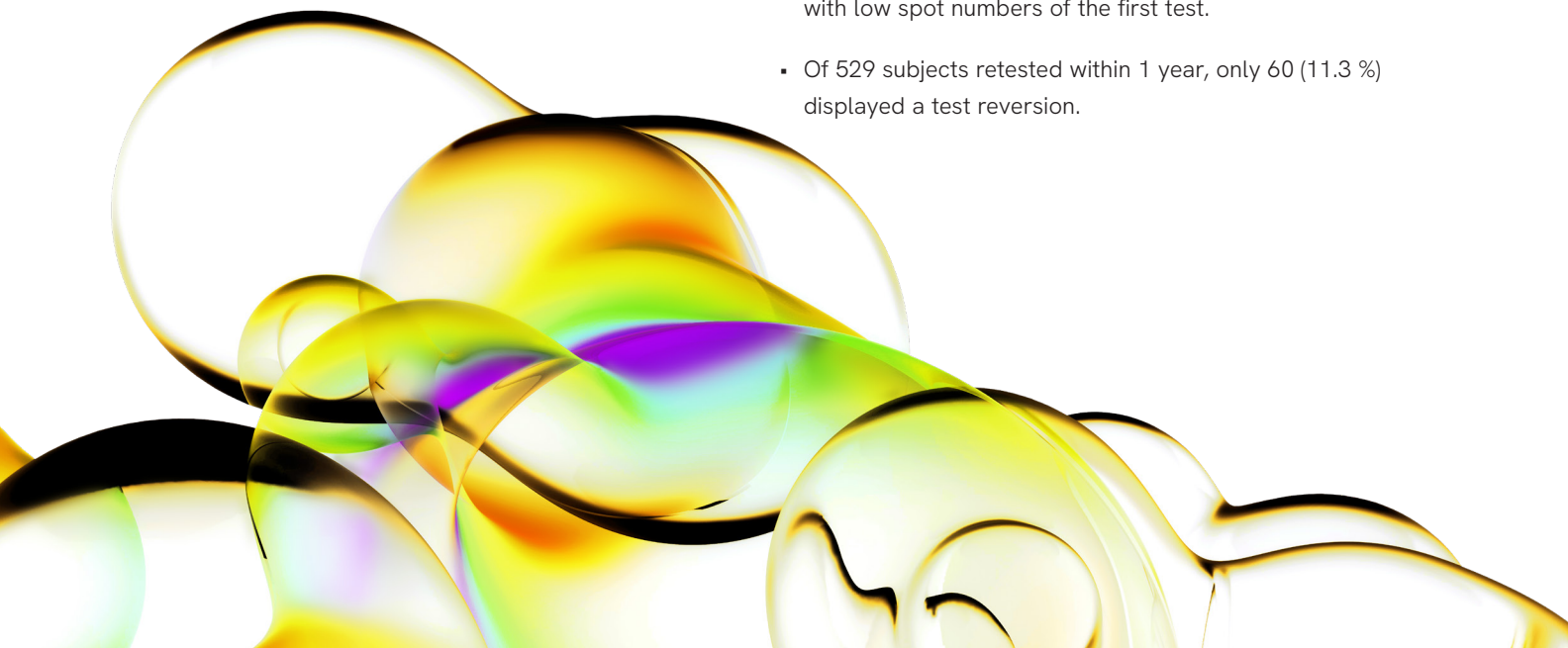
With the increased use of interferon-gamma release assay (IGRA) testing in the last decade, more results of serially tested subjects became available. However, most of the studies addressing the reproducibility of the IGRAs used the QFT, data for the T-SPOT.TB test are still limited. The purpose of this study was to determine the reproducibility of T-SPOT.TB test during a 14-year period and to analyze the mismatching results of serial testing.

Methods

The investigators retrospectively analyzed results of serially tested subjects in a medical laboratory in Germany over a time period of 14 years. From October 2004 to December 2018, a total of 5440 subjects were identified with a second T-SPOT.TB test after a median time interval of 258 days.

Results

- Consistently negative ($n = 4520$) or positive results ($n = 682$) were observed in 5202 (95.6 %) subjects, indicating a high degree of concordance in serial testing ($\kappa = 0.83$).
- Test conversions occurred in 101 of 4621 (2.2 %) subjects with initially negative tests.
- Of 819 subjects with initially positive test results, 137 (16.7 %) had a test reversion which was associated with low spot numbers of the first test.
- Of 529 subjects retested within 1 year, only 60 (11.3 %) displayed a test reversion.



Results

Table 1: T-SPOT.TB test agreement of 5440 serially tested subjects

First T-SPOT.TB	Second T-SPOT.TB	N(%)
Negative	Negative	4520(83.1)
Negative	Positive	101(1.9)
Positive	Positive	682(12.5)
Positive	Negative	137(2.5)

Kappa = 0.83 (95 % CI = 0.80 to 0.85)

Impact of spot number on frequency of test reversions

- In spot range of 32-88 SFC/M, 94 of 273 subjects (34.4 %) had a negative T-SPOT.TB result in the second test.
- In the spot range of 92-288 SFC/M, 34 of 273 (12.5 %) of the tested subjects reverted. In the spot range above 288 SFC/M, the frequency of reversion was only 3.3% (9 of 273).
- The chance for a later test reversion is high for results with low spot numbers (odds ratio = 6.14), whereas at high spot numbers above 288 SFC/M reversions are rarely observed (odds ratio = 0.11).

Table 2: Spot numbers of 819 initially positive tested subjects divided in terciles and rate of T-SPOT.TB test reversions

Sum of ESAT-6 and CFP-10 (SFC/M)	682 subjects serially tested positive (%)	137 subjects with test reversions (%)	Odds ratio (95%CI)
32-88	179(65.6)	94(34.4)	6.14(4.12-9.16)
92-288	239(87.5)	34(12.5)	0.61(0.40-0.93)
>288	264(96.7)	9(3.3)	0.11(0.06-0.22)

Conclusions

During the observation period of 14 years, the T-SPOT.TB test gave reproducible results in 95.6 % of the 5440 serially tested subjects with low frequency of conversions and reversions, which demonstrates a high reproducibility of T-SPOT.TB test in the authors' medical laboratory.

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Reference

1. Meier T, Enders M. High reproducibility of the interferon-gamma release assay T-SPOT.TB in serial testing. Eur J Clin Microbiol Infect Dis. 2021 Jan;40(1):85-93

