



Tests for tuberculosis infection: landscape analysis

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New and emerging tests for tuberculosis infection have the potential to improve accuracy, operational characteristics and end-user access. Evaluation of these tests in a standardised design would facilitate their endorsement and programmatic scale-up. <https://bit.ly/327RBky>

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Abstract

Background Only the tuberculin skin test (TST) and two interferon- γ release assays (IGRAs), QuantiFERON-TB Gold In-Tube and T-SPOT.TB, are currently endorsed by the World Health Organization as tests for tuberculosis (TB) infection. While IGRAs are more specific than the TST, they require sophisticated laboratory infrastructure and are costly to perform. However, both types of tests have limited performance to predict development of active TB. Tests with improved predictive performance and operational characteristics are needed.

Methods We reviewed the current landscape of tests for TB infection identified through a web-based survey targeting diagnostic manufacturers globally.

Results We identified 20 tests for TB infection: 15 *in vitro* tests and five skin tests. 13 of the *in vitro* tests are whole-blood IGRAs and 14 use early secreted antigenic target 6 (ESAT-6) and culture filtrate protein 10 (CFP-10), with or without additional antigens. 10 of the tests are based on assays other than an ELISA, such as a fluorescent lateral flow assay that requires less manual operation and shorter assay time and hence is more suitable for decentralisation compared with the existing IGRAs. Four of the five skin tests use ESAT-6 and CFP-10 proteins, while the remaining test uses a new antigen that is specific to *Mycobacterium tuberculosis* complex.

Conclusions New tests have the potential to improve accuracy, operational characteristics and end-user access to tests for TB infection. However, published data in various populations and settings are limited for most new tests. Evaluation of these new tests in a standardised design would facilitate their endorsement and programmatic scale-up.