Annex 1. Data requirements

Index test (s):

Commercial blood-based in-vitro interferon-gamma release assay (IGRA) tests used for TB infection (TBI) diagnosis.

Reference test (s):

Quantiferon-TB Gold, Quantiferon-TB Gold in Tube, T-SPOT.TB, or the tuberculin skin test (TST).

Research questions (PICO format):

- **Sensitivity**: In persons with active TB, what is the sensitivity of the index test(s) compared to WHO endorsed reference tests?
- **Specificity**: In persons at very low risk of TBI, what is the specificity of the index test(s) compared to WHO endorsed reference tests?
- **Agreement (concordance)**: In patients with active TB, or persons at very low risk of TB, or those tested for TBI, what is the agreement between the index and the reference test(s)?
- **Reproducibility:** What is the within-person reproducibility of the index test(s) in patients tested on repeated occasions (same samples, and/or same time, and/or different times)?

Eligible studies

An eligible study must fulfill criteria “a” through “d” (for the reproducibility outcome “e” is added and “b” and “d” are not required):

a) Assessed >= 1 index tests, supplied as a commercial kit, and followed manufacturer instructions.
b) Compared >= 1 index tests with >= 1 reference tests, in terms of:
    - Sensitivity or
    - Specificity or
    - Agreement (concordance)
c) All tests were performed in a blind manner (no knowledge of other test results).
d) All tests were performed simultaneously (or same samples for blood-based tests), and intervals specified.
e) For the reproducibility outcome, studies must have assessed >= 1 index tests in the same subjects >= 2 occasions within 4 weeks.