| Author, Year | Country  (TB Burdena) | %  Male | Mean Age in Years (SD) | % HIV | % BCG | Study Population Comments | Test (N) | Reliability Measure | Result | Quality Rating |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Cummings 2009132 | United States (L) | NR | 28 | NR | 7 | U.S. HCWs at low risk of TB in a single institution. | QFT-GIT (3-Gen)  N=182  N analyzed at 4 weeks=85 | Test-retest | 2 of 5 positive results on first test were confirmed on subsequent testing  At 4 weeks: 85 (47%) of 182 HCWs who had an initial test had the second test; 84 of 85 had consistent results (98.8%) | Poor |
| Dorman, 2014127 | United States (L) | 25 | Median: 36 (IQR: 28 to 48) | 0.4 | 9 | U.S. HCWs at 4 U.S. health care institutions | T-SPOT.*TB* and QFT-GIT  N=130 | Reproducibility  Test-retest | Number of discordant results in participants who had 2 samples drawn simultaneously:  QFT-GIT: 10/172 (5.8%)  T-SPOT.*TB*: 10/153 (6.5%)  Test-retest at 2 weeks:  T-SPOT.*TB*: 9/111 (8.1%) tests changed from negative to positive and 10/19 (52.6%) changed from positive to negative  QFT-GIT: 10/134 (7.5%) results changed from negative to positive and 5/15 (33.3%) changed from positive to negative | Good |
| Dilektasli 201075 | Turkey (I) | 36.7 | 39 | NR | 90.3 | Study included multiple groups, including those with pulmonary TB, close contacts of people with TB, and healthy controls. | T-SPOT.*TB*  N=91 | Interrater reliability | Interrater reliabilityb=96% (k=0.92; p<0.05)  Manual read vs. automated Elispot reader=85.8% (k=0.73; p<0.05) | Fair |
| Franken, 2009128 | Netherlands | NR | NR | NR | NR | Immigrants who were close contacts of smear-positive TB patients. | T-SPOT.*TB*  N=313 | Interrater reliabilityb | Kappas for agreement among 6 raters were all >0.6 | Fair |
| Mancuso, 2012123 | United States (L) | 66 | 21.8 | NR | 3.5 | U.S. military recruits at low risk of exposure to TB. | TST  N=1826 | Interrater reliabilityb | Kappa=0.79 | Fair |
| O’Shea, 2014131 | Nepal (H) | 166 | NR Range: 18 to 21 | 0.9 | 63 | Nepalese military recruits who had left Nepal and recently entered the U.K. | T-SPOT.*TB* and QFT-GIT N=166 | Test-retest | Test-retest at 1 week:  T-SPOT.*TB*: kappa for agreement between initial test and retest: 0.66 (95% CI, 0.50 to 0.83)  QFT-GIT: kappa for agreement between initial test and retest: 0.48 (95% CI, 0.26 to 0.7) | Fair |
| Villarino 2000114 | United States (L) | 37 to 81c | 50 | NR | NR | 2 study populations: persons with pulmonary TB and those at low risk of exposure to TB. | TST (PPD S2)  N=1189 | Interrater reliabilityb | Kappa=0.52 to 0.78 across all groups | Fair |
| Villarino 1999113 | United States (L) | 38 | 26 | NR | NR | Persons at low risk for TB. | TST (PPD S1)  N=127 | Interrater reliabilityb | Kappa=0.69 | Fair |
| Whitworth, 2012129 | United States (L) | 49 | NR; all ≥18 | NR | 28 | Subjects with self-reported positive TST recruited from U.S. Air Force and CDC staff located in San Antonio, TX, and Atlanta, GA | QFT-GIT (3-Gen)  N=91 | Interlaboratory reliabilityd | Across 3 labs, 7/91 (7.7%) subjects had discordant results (none had indeterminate results); kappas of pairwise lab sample comparisons ranged from 0.87, 0.89, and 0.93 | Good |
| Whitworth, 2014130 | United States (L) | 46 | NR; all ≥18 | NR | 21 | Subjects with self-reported positive TST recruited from U.S. Air Force and CDC staff located in San Antonio, TX, and Atlanta, GA | QFT-GIT (3-Gen)  N=146 | Interrater reliability | 2 samples from each participant both processed via manual read and automated ELISA; across all 4 tests, 88.6% were concordant (16% concordant positive and 72.6% concordant negative) and 11% were discordant.  Discordance by method:  Automated vs. automated: 4.8% (kappa=0.85)  Manual vs. manual: 6.9% (kappa=0.80)  Automated vs. manual: 3.4% to 9.0% across comparisons (kappa=0.73 to 0.90) | Good |

a TB burden according to World Health Organization classification. (L) Low <10 cases/100,000; (I) Intermediate 10–99 cases/100,000; (H) High >100 cases/100,000.

b Agreement between first and second observer.

c Among the population with pulmonary TB, 81% were male. Among the population at low risk of exposure to TB, 37% were male.

d To measure interlaboratory reliability, three tubes of blood were collected from each subject so that the assay could be completed at three different laboratories noted to have “extensive experience and demonstrated proficiency.”

**Abbreviations:** BCG=bacille Calmette-Guérin; CDC=Centers for Disease Control and Prevention; HIV=human immunodeficiency virus; HCW=health care worker; IQR=intraquartile range; NR=not reported; N=number analyzed; QFT-GIT=QuantiFERON-TB Gold In-Tube (3rd generation test); PPD-S1 or S2=purified protein derivative standard 1 or standard 2; SD=standard deviation; TB=tuberculosis; TST=tuberculin skin test; U.K.=United Kingdom; U.S.=United States.