

PERFORMANCE OF QUANTIFERON GOLD-IN-TUBE (QFT GIT) TEST FOR RESEARCH APPLICATIONS IN A TUBERCULOSIS (TB) ENDEMIC AREA.

Debbie Abrahams, Sebastian Gelderbloem, Hassan Mahomed, Jane Hughes, Lebohang Makhethe, Tony Hawkrigde, Greg Hussey, Willem Hanekom.

South African TB Vaccine Initiative, University of Cape Town, South Africa

Aims:

We aim to determine longitudinal changes in QFT GIT results in adolescents in a high TB endemic area.

Method:

We are conducting a prospective epidemiological study to determine the two year incidence of TB infection and disease in adolescents.

- Adolescents are enrolled, evaluated at baseline (Day 0), and half followed up at 2 years, while the other half is followed up every 6 months (Day 180) for 2 years.
- At each visit, blood is collected for QFT GIT and a clinical evaluation performed. Performance of the QFT GIT was assessed by assaying 48 donors using 3 different kits from 3 different lot numbers.

Quantitative results were obtained using Cellestis standards at the suggested concentrations and WHO standards at higher concentrations.

Results:

5,000 adolescents have been enrolled and 2601 of these adolescents have had both QFN GIT and tuberculin skin (TST) tests performed. The agreement between positive TST (>10mm) and QFT GIT (≥ 0.35 IU/ml) was 81.5% ($\kappa = 0.63$).

In 426 participants, 88.7% of the QFT GIT results at baseline and at 6 months remained unchanged. QFT GIT results on 9.2% adolescents converted from negative Day 0 to positive Day180, while 2.1% reverted from positive Day 0 to negative Day 180.

The assessment of quantitative changes in IFN- γ (Interferon gamma) over time was not possible, because 57% of the positive results (≥ 0.35 IU/ml) for Day0 were above 4IU/ml, and 70.2% of the positive results for Day 180 were above 4IU/ml, which is the highest IFN- γ standard of the kit.

In 48 participants, repeating the test 3 times, using 3 different kits showed noteworthy variability between kits.

Discussion:

Qualitative results may be adequate in a clinical setting, but may be sub-optimal when quantitative results are used. To obtain quantitative results, we therefore recommend diluting the collected plasma or an IFN- γ standard at higher concentration be introduced.