

Retrospective Performance Analyses of Over 2 Million US QuantiFERON Blood Sample Results

Background

- The Centers for Disease Control and Prevention has estimated that up to 15 million US residents have latent tuberculosis (TB) infection.¹
- Latent TB can be detected with blood-based interferon gamma release assays, such as QuantiFERON-TB® Gold In-Tube (QFT-GIT) assay and an updated version introduced in 2018: the QuantiFERON-TB® Gold Plus (QFT-Plus) assay.
- The newer QFT-Plus uses a second tube (TB2) that may improve sensitivity, but further studies are warranted.
- **Objective:** In this study, the investigators examined the performance of the QFT-Plus and QFT-GIT assays to detect TB across >2 million patient specimens submitted for screening.

Methods

- This retrospective analysis included patient results from QFT-Plus and QFT-GIT testing performed at Quest Diagnostics November 2018 to December 2019.
 - All 50 states and other territories were represented in the study population.
- The blood specimens were collected in 1 of 3 ways:
 - In a single lithium-heparin tube, followed by aliquoting within 48 hours to 4 QFT Plus assay tubes (1-tube collection method)
 - Directly into 4 QFT-Plus assay tubes (4-tube collection method)
 - Directly into 3 QFT-GIT assay tubes
- Proportions of positive, negative, and indeterminate results, as well as conversion/reversion results for serial testing, were determined.
- Assays and patient subgroups were compared using the Z-test.

Results

- Over 2.3 million test results were analyzed across the 3 collection methods. The overall proportion of TB positive results was 7%:
 - 7.2% for the QFT-Plus 1-tube collection method (1.9 million specimens)
 - 6.0% for the QFT-Plus 4-tube collection method (0.3 million specimens)
 - 7.5% for the QFT-GIT method (0.1 million specimens)
- The proportion of positive results was higher among
 - Males than females (7.6% vs 6.6%)
 - Persons >65 years old (10.0%) compared to other age groups
- The proportion of indeterminate results was lower with the QFT-Plus 1-tube collection method (0.8%) than with the QFT-Plus 4-tube collection method (4.2%) and the QFT-GIT method (2.7%).
- Most indeterminate QFT-Plus results could be resolved by retesting within a month (64%) or later (77%).

Conclusions

- The findings of this study show that the QFT-Plus 1-tube collection method has a substantially lower rate of indeterminate results than the 4-tube collection method.

Article published in *Microbiology Spectrum*

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Citation

Bi C, Clark RB, Master R, et al. *Microbiol Spectr*. Published online July 26, 2021. doi:10.1128/Spectrum.00096-21

Webpage

<https://journals.asm.org/doi/full/10.1128/Spectrum.00096-21>

Reference

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