

Lower Indeterminate Rates Using Single Lithium-Heparin Tube Blood Collection for the QuantiFERON[®]-TB Gold Plus Test

Background

- *Mycobacterium tuberculosis* (MTB) infection causes tuberculosis (TB); an estimated 10 million people worldwide developed TB in 2019.¹
- The QuantiFERON-TB[®] Gold Plus (QFT-Plus; Qiagen, Germantown, MD) assay is an in vitro diagnostic test that can help detect MTB infection. Blood specimens can be collected (1) in a single lithium-heparin tube and transferred to 4 QFT-Plus assay tubes or (2) immediately into 4 QFT-Plus assay tubes.
- Knowing if 1 method leads to fewer indeterminate results than the other could improve testing efficiency.
- **Objective:** The investigators of this study compared the frequency of indeterminate results for 1-tube versus 4-tube blood collection methods for the QFT-Plus assay.

Methods

- Investigators retrospectively analyzed results of the QFT-Plus assay performed at Quest Diagnostics laboratories.
 - The QFT-Plus assay is an enzyme-linked immunosorbent assay (ELISA) that quantifies the amount of IFN- γ in a blood specimen.
- The blood specimens had been (1) collected into a single lithium-heparin tube and aliquoted to the 4 QFT Plus assay tubes in less than 48 hours (1-tube collection method); or (2) immediately collected into the 4 QFT-Plus assay tubes (4-tube collection method).
- Comparisons of indeterminate rates between groups were performed using the Z-test. $P < 0.05$ or non-overlapping confidence intervals were considered statistically significant.
- Assay results were also examined for follow-up specimens collected using the 1-tube collection method from individuals who initially had indeterminate results.

Results

- Indeterminate results were significantly less common with the 1-tube method (0.8% of >1.8 million specimens) than the 4-tube method (4.2% of >0.3 million specimens).
- MTB positivity rates were similar between the 1-tube method (7%) and the 4-tube method (6%).
- Among 464 patients with initial indeterminate results who were retested within 1 month using the 1-tube collection method, 65% had conclusive results (52% negative and 13% positive).

Conclusions

- The findings of this study demonstrate that the 1-tube collection method has a substantially lower frequency of indeterminate results than the 4-tube collection method.
- Approximately two-thirds of indeterminate results had conclusive results in follow-up specimens collected using the 1-tube collection method.

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Webpage

<https://academic.oup.com/ofid/supplements>

Reference

1. World Health Organization. Global Tuberculosis Report. 2020. https://www.who.int/tb/publications/global_report/en/