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Assessment of the Diagnostic Accuracy of Three Commercial Interferon-gamma Release Assays for Mycobacterium tuberculosis

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Description

The diagnostic accuracy of interferon-gamma release assays for detecting *Mycobacterium tuberculosis* infection has been a focal point of tuberculosis diagnostics, especially given the limitations of traditional methods like the tuberculin skin test. IGRAs measure the release of interferon-gamma from sensitized T-cells in response to specific Mtb antigens, providing a more specific and reliable diagnostic tool for both latent tuberculosis infection and, to some extent, active TB. These assays were assessed for their sensitivity, specificity, and overall diagnostic accuracy under varying clinical and demographic conditions [1]. The study enrolled a diverse cohort of participants, including individuals with confirmed active TB, those with presumed latent TB infection, and healthy controls with no history of TB exposure. Participants included adults and children from high-burden and low-burden TB regions to ensure that the assays were evaluated across a range of epidemiological and immunological contexts. The diagnosis of active TB was confirmed through microbiological evidence, such as positive sputum cultures or polymerase chain reaction tests, while latent TB infection was defined based on exposure history and positive TST results.

Blood samples were collected and processed according to the manufacturers' protocols for each assay. QFT-Plus involves a whole blood assay with antigens stimulating both CD4+ and CD8+ T-cells, providing a more comprehensive immune response profile. T-SPOT.TB employs enzyme-linked immunospot technology to count the number of IFN-γproducing T-cells in response to specific antigens, offering a cellular-level resolution. LIAISON® IGRA-TB, a newer assay, uses chemiluminescence immunoassay technology for IFN-γquantification. These assays target Mtb-specific antigens like ESAT-6 and CFP-10, which are absent in the Bacille Calmette-Guérin vaccine and most nontuberculous mycobacteria, thereby improving specificity. The sensitivity of the three assays was evaluated based on their ability to detect active TB cases. QFT-Plus demonstrated a sensitivity of 87%, comparable to T-SPOT.TB, which showed a sensitivity of 89%. LIAISON® IGRA-TB exhibited slightly lower sensitivity at 83%. These findings indicate that all three assays perform well in detecting active TB, with T-SPOT.TB showing a slight advantage. However, sensitivity varied depending on factors such as age, immune status, and TB burden [2]. For instance, in immunocompromised patients, including those with HIV infection, the sensitivity of all assays decreased, though T-SPOT.TB retained better performance due to its ability to detect low-frequency T-cell responses, Specificity, critical for distinguishing TB infection from prior BCG vaccination or exposure to environmental mycobacteria, was assessed in healthy controls with no TB exposure. QFT-Plus and T-SPOT.TB demonstrated high specificity, at 98% and 97%, respectively. LIAISON® IGRA-TB had a specificity of 96%, slightly lower but still within an acceptable range. This high specificity supports the use of IGRAs in low-burden settings where false positives from BCG vaccination or environmental mycobacteria are a concern.

Despite the promising performance of these assays, certain limitations were noted. The reduced sensitivity in immunocompromised individuals, including those with HIV or diabetes, underscores the need for supplementary diagnostic tools in these populations. Additionally, while IGRAs can detect immune responses to Mtb antigens, they cannot differentiate between active and latent TB, necessitating further clinical and microbiological evaluation for definitive diagnosis. Efforts to combine IGRAs with other biomarkers or imaging techniques may address this limitation and improve diagnostic accuracy.

Another consideration is the variability in performance across different TB burden settings. In high-burden regions, where repeated Mtb exposure is common, the interpretation of IGRA results may be complicated by boosting effects or transient immune responses. Conversely, in low-burden settings, the high specificity of IGRAs makes them valuable tools for identifying true infections and guiding targeted treatment. Future research should focus on improving IGRA sensitivity in immunocompromised populations and exploring their utility in monitoring treatment efficacy. The integration of IGRAs with molecular diagnostics, such as nucleic acid amplification tests, could provide a comprehensive diagnostic approach that combines the strengths of both methods. Additionally, developing point-of-care IGRA platforms could enhance accessibility and enable widespread use in resource-limited settings.

The evaluation of QuantiFERON-TB Gold Plus, T-SPOT.TB, and LIAISON® IGRA-TB demonstrates that all three assays offer high diagnostic accuracy for detecting *Mycobacterium tuberculosis* infection. While T-SPOT.TB showed a slight edge in sensitivity, particularly in challenging subgroups, QFT-Plus and LIAISON® IGRA-TB provided comparable performance with operational advantages in automated settings. The choice of assay may depend on specific clinical and logistical factors, including population characteristics, laboratory infrastructure, and cost considerations. These findings underscore the critical role of IGRAs in advancing TB diagnostics and highlight the potential for further innovations to enhance their diagnostic utility in diverse healthcare settings.

References

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