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EDITORIAL

Making IGRA testing easier: First performance report of QIAreach QFT for tuberculosis infection diagnosis

Tuberculosis (TB), with around 1.4 million deaths, is one of the most important leading killer for infectious diseases in the world. Moreover, a quarter of the world population is estimated to live with TB infection (TBI).[1,2] TBI is considered the reservoir of active TB, therefore, diagnosing and treating TBI is a crucial component of the End TB Strategy to achieve TB control.[3] So far, the diagnosis of TBI is based on tuberculin skin test and on interferon (IFN)-γ release assays (IGRAs) such as T-SPOT. TB and Quantiferon-TB Plus (QFT-Plus).[4] However, costs, complexity, and supply chain requirements hamper the implementation of current tests for TBI in decentralized settings. Therefore, there is an urgent need for accelerating the scale-up of such assays to inform test-and-treat algorithms for TBI.[5]

The QIAreach QFT test is a novel and simplified version of QFT-Plus. Indeed, it uses a single tube corresponding to the TB2 tube of the QFT-Plus. However, unlike QFT-Plus, the test provides a qualitative result through a fluorescence lateral flow reader, which is transportable, easy to use and does not need highly trained personnel.[6,7] The assay time to result (TTR) is around 20 minutes. Therefore, the QIAreach QFT test has the potentials to be a point-of-care test.

The paper of Fukushima et al[7] aimed to evaluate the accuracy of the QIAreach QFT test for the detection of TBI compared to the commercial QFT-Plus test in both immunocompetent and immunocompromised individuals. The authors evaluate the tests' clinical performance in patients with active TB, used as a surrogate for TBI. Compared to QFT-Plus, which was used as reference standard, QIAreach QFT showed a 99% overall concordance and an optimal accuracy with 100% sensitivity and 98% specificity, similar to QFT-Plus 4. Interestingly, QIAreach QFT also scored positive in samples with IFN-γ level falling in the so-called uncertainty zone of the QFT-Plus.[8] IFN- γ level inversely correlated with TTR, suggesting that the TTR may be used as a surrogate marker for the IFN-γ concentrations. The QIAreach QFT test also scored positive in individuals with CD4 counts $<$200 cells/μl, thus showing potential for immunocompromised individuals.

Multicenter studies are needed to validate these results, and to evaluate the QIAreach in immunocompromised individuals. Moreover, data on precision, repeatability and reproducibility, as well as costs analyses are needed to fully understand the potential of this platform. However, these optimal pilot performances, together with the technical advantages of the test (a single 1 mL of blood is needed), the short TTR, the portability and the multipurpose design of the platform allowing for diagnosing relevant diseases other than TB,[9] make the QIAreach QFT test a promising tool for TBI screening in peripheral settings for easier identification of people eligible for TB preventive therapy. This tool may be useful for TBI screening based on the new suggestions proposed by the WHO, and could support contact investigation to early identify individuals at risk for acquiring TBI also in high TB prevalence countries.[5,10]

The further development and availability of tests for predicting the risk of progression from TBI to active disease will complete the portfolio for maximizing the impact of TB preventive treatment strategies.

Declaration of Competing Interests

PM and LP have nothing to declare. DG is a consultant for QIAGEN and Biomerieux and gave lectures for Diasorin.

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P. Miotto[a,*], D. Goletti[b], L. Petrone[b]
[a] *Emerging Bacterial Pathogens Unit, Div. of Immunology, Transplantation and Infectious Diseases, IRCCS San Raffaele Scientific Institute, Milano, Italy*
[b] *Translational Research Unit, National Institute for Infectious Diseases "Lazzaro Spallanzani"-IRCCS, Rome, Italy*

[*] Corresponding author at: Emerging Bacterial Pathogens Unit, Div. of Immunology, Transplantation and Infectious Diseases, IRCCS San Raffaele Scientific Institute, Dibit 2, Building San Gabriele 1, Via Olgettina, 60, 20132 Milano, Italy.
E-mail address: miotto.paolo@hsr.it (P. Miotto).
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