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Civil society groups urge Qiagen to look into misuse of TB Gold kit

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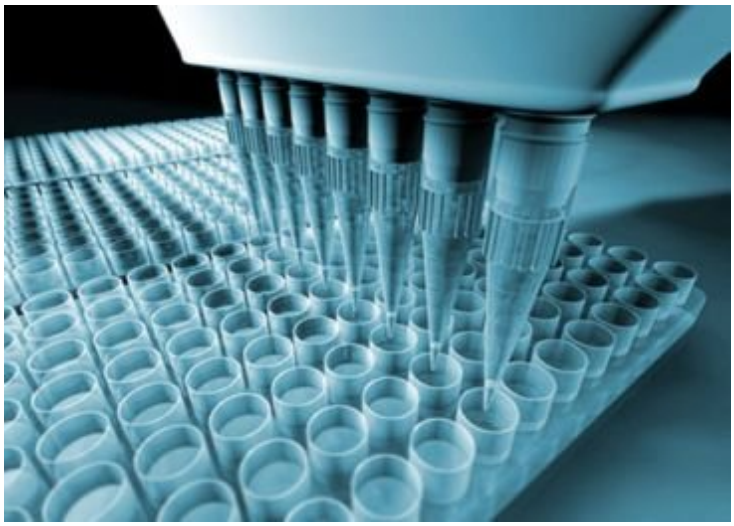

While the government of India banned the use of serodiagnostic antibody-based tests for TB in 2012, the letter from the Treatment Action Group (TAG) and members of the Global TB Community Advisory Board (TB CAB) as well as civil society in India, has pointed towards Qiagen's QuantiFERON-TB Gold, being used to detect active TB disease in the private sector (where serology use was rampant).

"Because of the void created by the serology ban, it appears that private laboratories have essentially replaced the banned serological tests with "TB-Gold" and doctors now think this is a better serological test than the antibody enzyme-linked immunosorbent assays that existed until the ban", says the letter written to Mr Peer M Schatz, chief executive officer and managing director, Qiagen Benelux B.V. on May 14, 2013.

"We urge you and your distributors to market your test as the label indicates and take action to stop the unethical, off-label use of the test for active TB. This is not only relevant for India but also for other high TB burden countries. For instance, we have heard that QuantiFERON-TB Gold is also used in the South African private sector for active TB diagnosis," the letter mentioned.

As per TAG, the Global TB CAB and other representatives of affected communities, they will continue to monitor the situation in India and elsewhere by visiting random labs and talking to distributors and doctors. "We hope that such surveillance confirms that IGRAs are not being promoted for off-label use. We will be obligated to call attention to instances in which this is occurring, and also take up the matter with the the Indian Ministry of Health and Family Welfare and Indian regulatory agency," the letter concluded.

The letter draws its base from a survey titled, 'Perspectives of Quantiferon TB Gold test among Indian practitioners' published in the Journal of Opthalmic Inflammation and Infection in early 2013, that determined the preferences and perspectives regarding the Quantiferon TB Gold test for the diagnosis of tuberculosis (TB) in India. The urvey was distributed among 46

uveitis specialists, rheumatologists, and pulmonologists with a minimum of 2 years experience in the management of tuberculosis, in order to restrict the respondents to specialists who have used this test in their practice in the diagnosis of tuberculosis. Topics included demographics, usage, logistics, effectiveness, and preferences related to the Quantiferon TB Gold test.

The results of the survey were shocking. Among the 37 responders, there were 19 uveitis specialists, 9 rheumatologists, and 9 pulmonologists with the majority having more than 7 years of experience in treating tuberculosis. Latent TB was the most common type of tuberculosis reported by 81% of the responders. Although 92% agree that Quantiferon TB Gold assay is used for the diagnosis of latent TB, only 32% use this test always in their practice. Limiting factors include the higher cost (35.14%), limited data from countries endemic for TB and hence limited interpretation of results (32.43%), the inability to differentiate active and latent TB (32.43%), and technical issues related to the test (18.92%). A combination of the Mantoux test and Quantiferon TB Gold test was the preferred test for investigation in 51% of the responders rather than solo tests.

The Indian Revised National TB Control Program (RNTCP) has discouraged the use of Interferon-Gamma Release Assays (IGRAs) for TB diagnosis, and a World Health Organization policy also states that IGRAs should not be used to diagnose active TB in high burden settings where the prevalence of latent TB infection (LTBI) is very high (nearly 40% of the Indian population is estimated to be latently infected and therefore positive by latent TB tests). "We are concerned that your test, which is indicated for LTBI detection only, is being used in an off-label manner, and are worried about the implications for individuals with suspected TB in India. We understand that you are marketing QuantiFERON-TB Gold as "TB Gold" (and not "Latent TB Gold"), which may lead users to believe it is the gold standard for active TB disease diagnosis."

"There is great potential for this test to become a replacement for antibody blood tests that the Government of India (and WHO) has worked so hard to ban. We are now aware of other IGRAs being sold in India as "TB Platinum" and openly marketed for active TB." the letter explained, "The RNTCP has no program in place for treating people with LTBI, and even in the private sector it is very uncommon to see prescriptions for 6 - 9 months of isoniazid. Most providers in India do not treat LTBI, and there is considerable confusion in the minds of providers about the value and role of TB Gold in the Indian setting (as mentioned earlier, Babu K et al. in J Ophthal Inflamm Infect 2013). So this means that any LTBI test used in India will most likely be used to diagnose active TB disease. Even if private laboratories are educated about the need to restrict IGRAs for LBTI, they have no control over how doctors actually use the end results. We understand that India is a complicated environment to work in, but hope that you would agree that it does not absolve corporations of ensuring that you and your distributors are following ethical and globally accepted marketing practices."