TAG
Treatment Action Group

TBCAB
GLOBAL TB COMMUNITY ADVISORY BOARD

14 May 2013

Peer M. Schatz
Chief Executive Officer and Managing Director
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RE: Marketing and Use of QuantiFERON-TB Gold for active TB in India and high TB burden countries

Dear Mr. Schatz,

As you know, the Government of India banned the use of serodiagnostic antibody-based tests for TB in 2012. Treatment Action Group (TAG) and members of the Global TB Community Advisory Board (TB CAB) as well as civil society in India have been made aware that Qiagen's QuantiFERON-TB Gold, is now 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" (please see the attached memo, sent to franchisee labs by a leading private network lab in India) and doctors now think this is a better serological test than the antibody enzyme-linked immunosorbent assays that existed until the ban.

The Indian Revised National TB Control Programme (RNTCP) has discouraged the use of interferon-gamma release assays (IGRAs) for TB diagnosis (please see the attached gazette notice by RNTCP), 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 (http://immunoshop.in/news/immucheck-tb-platinum-igra/).

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 (http://www.joii-journal.com/content/3/1/9). 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.

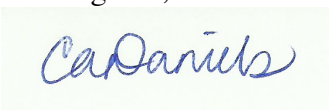
We understand that India is a complicated environment to work in, but hope that you would agree that it does not absolve corporations of ensuring that you and your distributors are following ethical and globally accepted marketing practices.

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.

TAG, the Global TB CAB and other representatives of affected communities 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 Indian Ministry of Health and Family Welfare and Indian regulatory agency.

We look forward to hearing from you about your strategy to address our concerns.

Best regards,



On behalf of:

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cc: Dr Mario Raviglione, Director, Stop TB Department, WHO, Geneva
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