

2 July 2013

Mr. Manoj Monga  
Director  
Immunoshop India Pvt. Ltd.  
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Navi Mumbai-400614, India  
[manojmonga@immunoshop.com](mailto:manojmonga@immunoshop.com)

**RE: Marketing and Use of TB Platinum for active TB in India and high TB burden countries**

Dear Mr. Monga,

You may have seen our recent open letter to Qiagen about their marketing of Quantiferon TB Gold in India (please see letter attached or at <http://www.treatmentactiongroup.org/tb/advocacy/marketing-and-use-quantiferon-tb-gold>). As you know, the Government of India banned the use of serodiagnostic antibody-based tests for TB in 2012, following a negative policy by the World Health Organization about these tests. Treatment Action Group (TAG) and members of the Global TB Community Advisory Board (TB CAB) as well as civil society in India are now concerned about reports that blood-based interferon gamma release assays (IGRAs) are being used to detect active tuberculosis (TB) disease in the private sector, where serology use was rampant. As we mentioned to Qiagen, the void created by the serologicals ban is being filled with tests such as TB Gold and your product, TB Platinum.

We are concerned that your test, which is indicated only for latent TB infection (LTBI) detection, is being or will be used in an off-label manner, and are worried about the implications for individuals with suspected TB in India. In fact, your advertisement (<http://immunoshop.in/news/immucheck-tb-platinum-igra/>) explicitly markets your product as: “Immucheck TB Platinum – The IGRA test method will be a boon for detection of active TB and LTBI and thus for containment of its transmission!!!!!!” This is clearly not consistent with the WHO policy that discourages use of IGRAs for active TB diagnosis in low and middle income countries, and is also not in line with the Indian Revised National TB Control Programme (RNTCP)’s advertisements (published in several newspapers) which discourage use of IGRAs for diagnosing TB disease in India. We are also not aware of any published data on TB Platinum to support the claims in your advertisements.

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. A

large proportion of the Indian population (estimated to be 40%) is latently infected with TB, and IGRA tests cannot separate latent infection from active TB disease. Thus, the concerns we outlined in our open letter to Qiagen apply to your product as well.

We urge you to market your test as the label indicates and take action to stop the unethical, off-label use and advertising of the TB Platinum test for active TB. This is not only relevant for India but also for other high TB burden countries.

TAG, the Global TB CAB and other representatives of affected communities will continue to monitor the situation in India and elsewhere by randomly visiting laboratories 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 to take up the matter with the Indian Ministry of Health and Family Welfare and Drug Controller General of India (DCGI), the Indian regulatory agency.

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

Best regards,

A handwritten signature in blue ink that reads "Car Daniels". The signature is written in a cursive style and is set against a light green rectangular background.

On behalf of:

Polly Clayden, United Kingdom  
Alberto Colorado, United States  
Mike Frick, United States  
Sergey Golovin, Russian Federation  
Mark Harrington, United States  
Giselle Israel, Brazil  
Bactrin Killingo, Kenya  
Blessina Kumar, India (also on behalf of the India CAB)  
Erica Lessem, United States  
Lindsay McKenna, United States  
Natalia Sidorenko, Russia  
Khairunisa Suleiman, South Africa  
Ezio Tavora dos Santos Filho, Brazil  
Wim Vandeveld, South Africa

for the Global Tuberculosis Community Advisory Board (TB CAB)

cc: Dr Mario Raviglione, Director, Stop TB Department, WHO, Geneva  
Dr. V. M. Katoch, Director General, Indian Council of Medical Research  
Dr GN Singh, Drug Controller General of India, New Delhi

Dr RS Gupta, Deputy Director General – TB, Central TB Division, Ministry of Health and Family Welfare, New Delhi

Dr KS Sachdeva, Chief Medical Officer, Central TB Division, Ministry of Health and Family Welfare, New Delhi

Dr Reba Kanungo, President, Indian Association of Medical Microbiologists

Dr Ram Gopalakrishnan, President, Clinical Infectious Diseases Society of India

Dr K Vijayakumar, President, Indian Medical Association

Dr Darivianca Lalloo, CEO, Partnership for TB Care and Control, India