

Banned serological tests being replaced by IGRAs

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Following a negative policy by the World Health Organization about serodiagnostic antibody based tests, the Indian government banned their usage for tuberculosis (TB) in 2012.

However, more recently few reports have emerged revealing 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. Taking serious view on that, the Treatment Action Group (TAG) and members of the Global TB Community Advisory Board (TB CAB) as well as civil society in India have expressed concerns.

The group in its letter addressed to Mr Manoj Monga, director, Immunoshop India, has pointed out towards the company's product, 'Immucheck TB Platinum' being used as an alternative to the banned serological tests for active TB in India and high TB burden countries.

Also referring to its earlier letter written to Qiagen, TAG mentioned about the void created by the serologicals ban and that being filled with tests such as TB Gold from Qiagen.

"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, said the TAG.

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.

TAG has therefore asked the Immunoshop to market their 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.

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, warned the group.