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# Indian Experts slam serological TB tests

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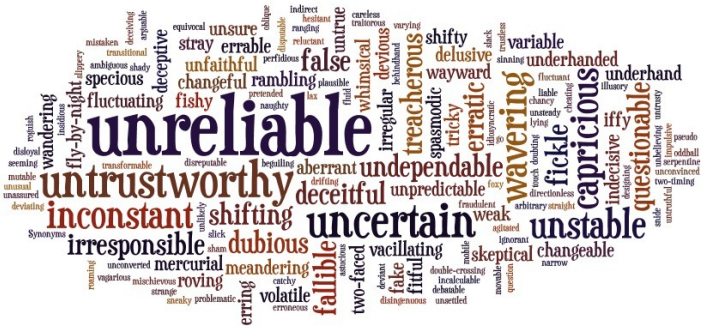


An estimated 1.5 million patients undergo diagnostic tests for Mycobacterium tuberculosis in India every year and this number has been steadily increasing along with the number of confirmed cases. The adverse scenario is further compounded by the lack of reliable serological diagnostic tests.

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The lack of a dependable serological test is so acute that even the World Health Organization (WHO) in its policy recommendation suggested that a ban be implemented on such tests as unreliable serological tests give imprecise results and cause inconsistent diagnosis of TB, thus leading to risk to human lives. This recommendation was taken very seriously and the Indian government recently banned the use of serological tests for TB. Trends in the TB diagnostic markets in India have been rapidly changing and serological tests have recently drawn a lot of criticism from experts.

Dr Madhukar Pai, associate professor, McGill University, Canada, said that, "Repeated results have shown that these tests are inaccurate and misleading and are costly. So, just because doctors are widely using them does not make it right. Popularity of a test or product does not make it valid. You need hard scientific data to show that the tests are valid and accurate."

According to Dr Sanjay Sarin, regional director, global health, central and south Asia Pacific, Becton Dickinson, "It was imperative to ban the serology-based tests, because of their highly variable performance characteristics. These, coupled with poor prescription practices cause preventable and needlessly high cost of care and misdiagnosis leading to poor patient outcomes and increased incidence of disease transmission."

Dr Ranjan K Nanda, scientist, International Center for Genetic Engineering and Biotechnology, opined that, "The tests are neither sensitive nor specific for TB diagnosis. Moreover these tests are not adequately validated using statistically accepted sample size. Due to the wrong diagnosis, heavy doses of antibiotics are prescribed to otherwise healthy subject that may lead to high hepatotoxicity and other adverse effects."

Dr Navin Dang, director, Dr Dang's Laboratory, cited the lack of education among the patients and the unawareness among the doctors as the primary cause. "The whole system is botched up 70 percent of the clients lack awareness. What astonishes me is the fact that, after MBBS, there is no mandatory certification examination for the doctors to practice," he added with a sense of disappointment.

Dr BR Das, president, research and innovation mentor, molecular pathology and clinical research services, SRL, said, "For TB, available serological assays fail to provide reliable diagnostic information. However, there is not much awareness about the flip side of this test for which it is being overused. Besides, the cost of these tests are also quite low which may be another reason for doctors preferring these tests."