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Government of India

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Directorate General of Health Services

स्वास्थ्य एवं परिवार कल्याण मंत्रालय

Ministry of Health and Family Welfare

निर्माण भवन, नई दिल्ली - ११० १०८

Nirman Bhawan, New Delhi - 110 108

Dear All,

IMPORTANT

Despite not recommended by any international guideline, the commercial serological tests (which detect antibodies in the blood developed in response to *Mycobacteria tuberculosis* infection) continue to be used extensively especially in the private health sector, with claims about accuracy often based on poor quality and grossly insufficient data. It is estimated that about 1.5 million TB suspects are subjected to serological tests every year in India at an estimated cost of 15 million USD. Results of several meta-analyses have indicated poor performance of these tests, and in 2008, an assessment by TDR (UN special programme for research and training in tropical diseases) found that none of the assays were good enough to replace conventional microbiological tests or as an add-on test to rule out tuberculosis. An updated systematic review commissioned by WHO and TDR in 2010 have re-confirmed these findings. A wrong diagnosis may mean that those with tuberculosis will not get needed therapy and may result in continued spread of the disease, or that those without tuberculosis may be subjected to possible side-effects from unnecessary treatment leading to wasted resources for the patient and consequent impact on livelihood. This has huge epidemiological and socio-economic implications.

The WHO Expert Group and STAG-TB which reviewed this data concluded that **currently available commercial serological tests provide inconsistent and imprecise estimates of sensitivity and specificity and strongly recommended that these tests should not be used for the diagnosis of pulmonary and extra-pulmonary TB (adults and children), irrespective of HIV status.** On the basis of STAG-TB recommendation, WHO is due to release a negative policy —the first of its kind—on current commercial tuberculosis serodiagnostics though being cautious not to stifle research and innovation in this field as a more accurate serological test has the potential to become a 'point of care' test for diagnosing TB.

The National laboratory committee of RNTCP endorsed the WHO expert group recommendations and requested Central TB Division to disseminate the message to all stakeholders involved in TB control in India.

Hence, you are requested to disseminate this message in all the relevant fora, available to you including professional medical associations and to advocate with all the stakeholders including civil society representatives to make this a community movement.

Regards,

Yours sincerely,

Dr. Ashok Kumar,
DDG-TB

To,

- All State TB Officers/District TB Officers/NRLs/IRLs,
- All RNTCP Consultants,
- All Senior Regional Directors (HFW/Gol)
- **All RNTCP Partners**



TB is fully curable with complete course of DOTS