



Nevada State Health Division Technical Bulletin



Topic: July 20, 2011 The World Health Organization (WHO) Issued an Explicit "Negative" Policy Recommendation Against the Use of Commercial Serodiagnostic Tests for Diagnosis of Tuberculosis

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Date: July 21, 2011

TO: Nevada Laboratories

The World Health Organization (WHO) issued a [news release](#) and a [policy statement](#) yesterday, warning that serological tuberculosis (TB) tests not be used for testing for active pulmonary or extra-pulmonary TB. The tests referenced by the WHO are not recommended by international guidelines for clinical use, nor are they approved by the U.S. Food and Drug Administration (FDA). They are, however, marketed in many parts of the world, especially in some countries with a high-burden of TB.

The tests evaluated by the WHO rely almost exclusively on antibody recognition of *Mycobacterium tuberculosis* (MTB) antigens by the humoral immune response; as opposed to antigen recognition by the cellular immune response used with interferon-gamma release assays (IGRA). The WHO issued the recommendation based on poor [performance characteristics](#) of the tests and a high proportion of false positive and/or false negative test results due to low specificity and/or sensitivity respectively.

Currently, there are only two IGRA TB blood tests approved by the U.S. Food and Drug Administration for use in the U.S.: the [QuantiFERON® TB Gold](#) (specificity = 99%, sensitivity = 84%); and the [T-SPOT®.TB](#) (specificity = 88%, sensitivity = 90%), both of which exhibit specificities and sensitivities within acceptable standards. In 2010, the CDC published [Updated Guidelines for Using IGRA's to Detect MTB infection in the U.S.](#) This provides recommendations on the proper use of these tests. As with any laboratory test, clinicians must consider the patient's clinical history in combination with the results obtained through testing. The IGRA TB blood test is considered a TB screening test to be utilized in the same manner as the tuberculin skin test (TST).

For more information regarding tuberculosis in Nevada see our website at: http://health.nv.gov/CD_HIV_TBProgram.htm

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