

In a press release from July 20, 2011, WHO made a statement against the use of non-FDA approved serologic tests marketed for the purpose of diagnosing tuberculosis disease.

Partial information from WHO's report was publicized in the press, however these initial press reports did not properly distinguish between the serologic tests of interest in WHO's study, versus the FDA-approved interferon gamma release assays (IGRA) available in the U.S. (i.e. QuantiFERON-TB Gold In-Tube (QFT-GIT, Cellestis Ltd.) and T-SPOT.TB (T-Spot, Oxford Immunotec Ltd.).

IGRAs are not serologic tests, but rather rely on a whole blood sample from which the activity of the white cells can be measured in terms of the amount of IFN-g that is released or in terms of the number of cells that release IFN-g. IGRAs can aid in diagnosing *Mycobacterium tuberculosis* infection, including both latent tuberculosis infection (LTBI) and active TB disease.

The bottom line is that the WHO press release is not related to the FDA-approved IGRAs that are commercially available in the United States.

For more information please visit: http://www.who.int/tb/laboratory/policy_statements/en