

INTERFERON GAMMA RELEASE ASSAY FOR THE DIAGNOSIS OF TUBERCULOUS

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WHAT ARE THEY?

Interferon-Gamma Release Assays (IGRAs) are whole-blood tests that can aid in diagnosing *Mycobacterium tuberculosis* infection. They do not help differentiate latent tuberculosis infection (LTBI) from tuberculosis disease. Two IGRAs that have been approved by the U.S. Food and Drug Administration (FDA) are commercially available in the U.S:

QuantIFERON®-TB Gold In-Tube test (QFT-GIT);
T-SPOT®.TB test (T-Spot)

HOW DO THEY WORK?

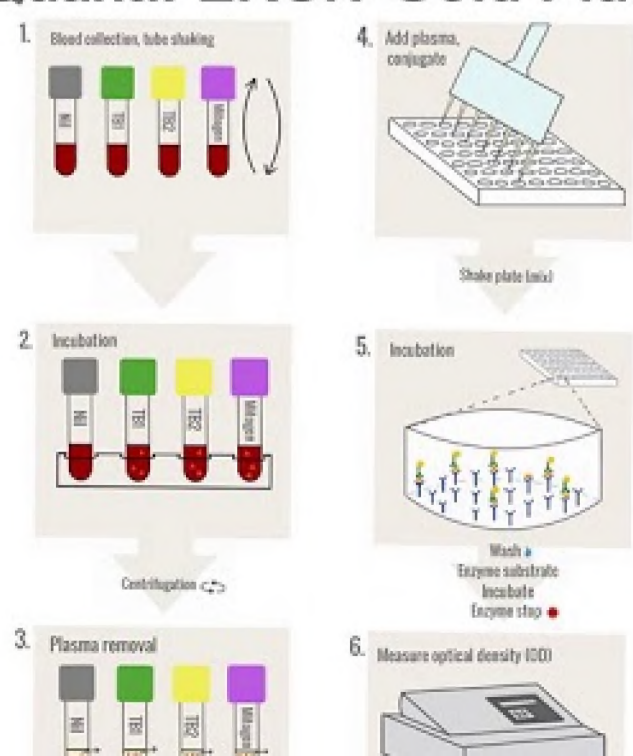
IGRAs measure a person's immune reactivity to *M. tuberculosis*. White blood cells from most persons that have been infected with *M. tuberculosis* will release interferon-gamma (IFN-g) when mixed with antigens (substances that can produce an immune response) derived from *M. tuberculosis*.

To conduct the tests, fresh blood samples are mixed with antigens and controls. The antigens, testing methods, and interpretation criteria for IGRAs differ (see Table 1).

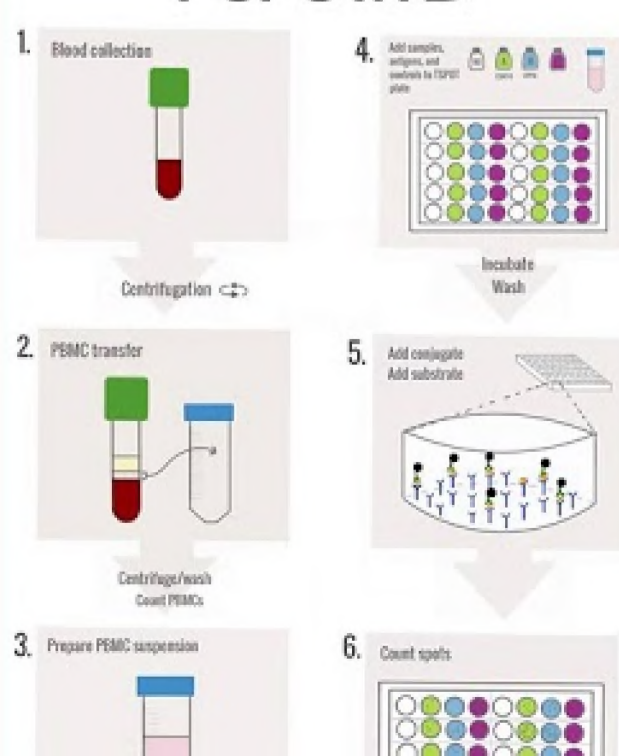
Table1: Differences in Currently Available IGRAs

| | QFT-GIT | T-Spot |
|--------------------------------|---|---|
| Initial Process | Process whole blood within 16 hours | Process peripheral blood mononuclear cells (PBMCs) within 8 hours, or if T-Cell Xtend® is used, within 30 hours |
| <i>M. tuberculosis</i> Antigen | Single mixture of synthetic peptides representing ESAT-6, CFP-10 & TB7.7. | Separate mixtures of synthetic peptides representing ESAT-6 & CFP-10 |
| Measurement | IFN-g concentration | Number of IFN-g producing cells (spots) |
| Possible Results | Positive, negative, | Positive, negative, borderline, invalid |

QuantIFERON Gold Plus



T-SPOT.TB®



WHAT ARE THE ADVANTAGES OF IGRAS?

- Requires a single patient visit to conduct the test.
- Results can be available within 24 hours.
- Does not boost responses measured by subsequent tests.
- Prior BCG (bacille Calmette-Guérin) vaccination does not cause a false-positive IGRA test result.

Can IGRAs Be Given To Persons Receiving Vaccinations?

As with TST, live virus vaccines might affect IGRA test results. However, the effect of live virus vaccination on IGRAs has not been studied. Until additional information is available, IGRA testing in the context of live virus vaccine administration should be done as follows:

- Either on the same day as vaccination with live-virus vaccine or 4-6 weeks after the administration of the live-virus vaccine
- At least one month after smallpox vaccination