



# Quantiferon TB<sup>®</sup> Gold Plus Assay

May 2019 update

The QuantiFERON TB<sup>®</sup> Gold Plus assay was developed in Australia primarily to detect Latent *M.tuberculosis* infection.

## Clinical Background

Tuberculosis (TB) is relatively uncommon in Australia. Active disease may occur:

- Following exposure to a patient with active TB
- By re-activation of latent TB infection (LTBI).

Active TB is diagnosed by clinical signs and symptoms in conjunction with chest x-ray, histology and mycobacteriological (including culture and PCR) findings. Latent TB is diagnosed with a positive QuantiFERON TB<sup>®</sup> Gold Plus in a patient in whom active TB has been excluded.

## What is the QuantiFERON TB<sup>®</sup> Gold Plus assay?

The QuantiFERON TB<sup>®</sup> Gold Plus assay was developed in Australia primarily to detect Latent *M.tuberculosis* infection. It is intended for use in conjunction with risk assessment, radiological and other medical and diagnostic evaluations.

It detects *in-vitro* interferon-gamma (IFN- $\gamma$ ) response by T-lymphocytes when challenged with specific *M.tuberculosis* antigens absent in BCG vaccine strains. The test includes a mitogen control for T-Cell response, and a negative control.

## Specificity and sensitivity of assay

While there is no gold standard test for latent TB, using surrogate reference methods the manufacturer estimates the sensitivity and specificity of the assay to be 95.3% and 97.6%, respectively.

## Interpretation of the Test

<b>Positive response</b>	<ul style="list-style-type: none"><li>▪ TB infection (active or latent)</li><li>▪ Medical and diagnostic evaluations are needed to confirm or exclude active disease</li></ul>
<b>Negative response</b>	<ul style="list-style-type: none"><li>▪ Unlikely latent TB infection</li><li>▪ Does NOT exclude active TB</li></ul>
<b>Indeterminate response</b>	<ul style="list-style-type: none"><li>▪ May be due to a high background level of IFN-<math>\gamma</math>, or heterophile antibodies.</li><li>▪ Medical treatments or conditions that impair immune function can potentially reduce IFN-<math>\gamma</math> responses. The test can only be interpreted in patients capable of generating detectable levels of IFN-<math>\gamma</math> (this is assessed by the Mitogen control).</li><li>▪ In the event of an indeterminate result repeating the test on a different sample is recommended.</li></ul>

## Features of QuantiFERON TB<sup>®</sup> Gold Plus assay

It performs well at all ages, including those < five years.

### In contrast to the previous Mantoux (Skin) test

- It does not expose the patient to TB antigens
- It is not affected by prior BCG vaccination or BCG therapy
- It requires only one attendance for a single blood sample
- Results are available within three – four working days
- It is not subject to performer technique or reader bias
- It is valid in HIV infected patients, or other immunocompromised patients if there is a sufficient mitogen response.



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## Indications for QuantiFERON TB<sup>®</sup> Gold Plus assay

- Pre-employment/baseline check for healthcare workers prior to travel to an endemic country for healthcare related work
- Prior to commencing immunomodulatory drugs (chemotherapy, high dose steroids, other immunosuppressive drugs) to detect latent TB
- Follow-up of exposure to a known case of active TB
- If active TB is suspected however, culture (and/or PCR testing) of appropriate specimens is necessary for a definitive diagnosis.

## Specimen Collection

The QuantiFERON TB<sup>®</sup> Gold Plus kit consists of four tubes (grey, green, yellow and purple caps).



1. Collect exactly 1mL of blood into each tube by filling to between the lines marked at 0.8 and 1.2ml
2. Mixing: Immediately after collection, mix the tubes by inverting 10 times. Mixing should occur prior to incubation. This mixing is critical to solubilise all of the tubes' contents coated on the inner wall of the tubes, and to ensure the tubes' contents are thoroughly integrated into the blood. *Over-energetic shaking may cause gel disruption and aberrant results.*
3. Place tubes back into the bag they were supplied in
4. Store tubes at room temperature until collection by couriers. **Do not centrifuge.**

Specimens must be collected **Monday to Friday** (avoid collecting the day before a public holiday) and must be received in the laboratory by 8pm and within 10 hours of collection. Refer to the instruction sheet contained in the kit. **Kits are available via our Stores Department on 9287 7824.**

## Medicare Rebate

This test is Medicare Rebatable in the following circumstances:

- A person who has been exposed to a confirmed case of active TB
- A person who is infected with human immunodeficiency virus
- A person who is to commence, or has commenced, tumour necrosis factor (TNF) inhibitor therapy
- A person who is to commence, or has commenced, renal dialysis
- A person with silicosis
- A person who is, or is about to become, immunosuppressed because of a disease, or a medical treatment, not mentioned in the bullet points above.

For further information, please contact the Melbourne Pathology Medical Microbiologists on 9287 7700.

## Our Medical Microbiologists



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