

M. tuberculosis complex + non-tuberculous mycobacteria

Multiplex

Tuberculosis is a contagious, chronic and granulomatous disease caused mainly by the specie *M. tuberculosis*. This disease was declared in 1993 as a "global health emergency" due to its magnitude as a public health problem.

Tuberculosis usually affects the lungs, but it can also affect other parts of the body such as the brain, kidneys or spine. Only people who suffer from pulmonary tuberculosis transmit the infection. Primary infection leads to active disease in approximately 10% of infected people and in 80% of cases in the period of two years. In the remaining 90%, the immune system controls the infection and the individual is not infectious or asymptomatic.

It is estimated that one third of the world population has latent tuberculosis; that is, these people are infected with the bacillus, but (still) have not become ill or can transmit the infection. In this clinical state, TB bacilli can remain inactive for years (latent TB). However, when the immune system weakens, the latent infection can be reactivated. In a person infected with HIV, the risk of reactivation of latent TB is more than 10% per year, compared to a lifetime risk of 10-20% for HIV negative people.

Mycobacteria are a group of microorganisms that constitute one of the most serious health problems worldwide. Three groups can be defined within the genus *Mycobacterium*:

- 1) Tuberculosis complex that produces tuberculosis and is formed by the species *M. tuberculosis*, *M. bovis* (including *M. bovis* BCG), *M. africanum*, *M. microti*, *M. caprae*, *M. canettii*, *M. pinnipedii*, *M. mungi* and *M. suricattae*;
- 2) *M. leprae* that produces leprosy;
- 3) Other non-tuberculous mycobacteria (NTM) of the *Mycobacteria* other than tuberculosis that are opportunistic and produce non-tuberculous symptoms with less pathogenic power.

The isolation of NTM is increasingly frequent and its differentiation from the *M. tuberculosis* complex is of great clinical and public health importance, since it defines the isolation of patients in special rooms of health centres and the study of patient contacts.

The symptoms of active tuberculosis will depend on where mycobacteria develop within the body. The general symptoms of tuberculosis include fatigue, weight loss, fever and night sweats. Active pulmonary tuberculosis can cause breathing difficulties, chest pain and bloody expectorations. The symptoms of tuberculosis in other parts of the body depend on the area or organ affected.

Over a year, a tubercular patient can infect 10 to 15 people through close contact. If they do not receive the appropriate treatment, up to two thirds of the tubercular patients die.

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VIASURE M. tuberculosis complex + non-tuberculous mycobacteria Real Time PCR Detection Kit is designed for the diagnosis of pulmonary Tuberculosis caused by *M. tuberculosis* or *M. tuberculosis* complex species and NTM infections caused by strains classified as non-tuberculous mycobacteria in clinical samples.

After DNA isolation, the detection of the genus mycobacterium is performed by the amplification of a region of the 16S rRNA, the detection of *M. tuberculosis* complex is performed by the amplification of the insertion sequences IS6110 and IS1081 and the detection and differentiation of *M. tuberculosis* specie is performed by the amplification of a fragment of the TbD1 region using specific primers and fluorescent-labeled probes.

Analytical sensitivity

VIASURE M. tuberculosis complex + non-tuberculous mycobacteria Real Time PCR Detection Kit has a detection limit of ≥ 10 DNA copies per reaction for the insertion sequences IS6110 and IS1081, the 16S rRNA and the TbD1 region (Figures 1, 2 and 3).

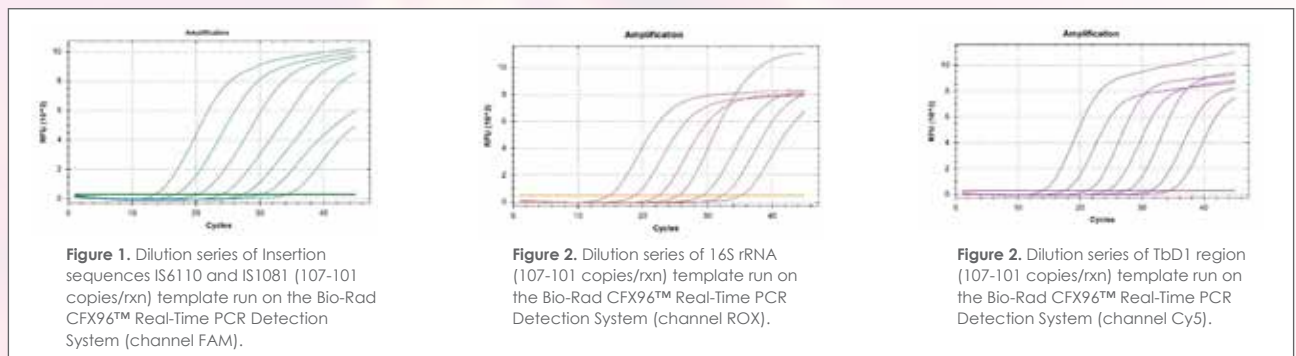


Figure 1. Dilution series of Insertion sequences IS6110 and IS1081 (107-101 copies/rxn) template run on the Bio-Rad CFX96™ Real-Time PCR Detection System (channel FAM).

Figure 2. Dilution series of 16S rRNA (107-101 copies/rxn) template run on the Bio-Rad CFX96™ Real-Time PCR Detection System (channel ROX).

Figure 2. Dilution series of TbD1 region (107-101 copies/rxn) template run on the Bio-Rad CFX96™ Real-Time PCR Detection System (channel Cy5).

VIASURE M. tuberculosis complex + non-tuberculous mycobacteria Real Time PCR Detection Kit contains in each well all the components necessary for real time PCR assay (specific primers/probes, dNTPS, buffer, polymerase) in a stabilized format, as well as an internal control to monitor PCR inhibition.

Two regions of the Insertion sequences IS6110 and IS1081 are amplified and detected in FAM channel, a fragment of the 16S rRNA is detected in ROX channel, a fragment of TbD1 region is amplified in Cy5 channel and the internal control (IC) is detected in HEX, VIC or JOE channel (depending on the equipment used select the proper detection channel, see Annex 2).

References.

VIASURE M. tuberculosis complex + non-tuberculous mycobacteria Real Time PCR Detection Kit:

- 6 x 8-well strips, low profile _____ VS-MTD106L
- 6 x 8-well strips, high profile _____ VS-MTD106H
- 12 x 8-well strips, low profile _____ VS-MTD112L
- 12 x 8-well strips, high profile _____ VS-MTD112H

- 96-well plate, low profile _____ VS-MTD113L
- 96-well plate, high profile _____ VS-MTD113H
- 9 x 4-well strips, Rotor-Gene® _____ VS-MTD136
- 18 x 4-well strips, Rotor-Gene® _____ VS-MTD172



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For more information and use procedure, read the instructions for use included in this product.



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