

TB OR NOT TB?

Multiplex molecular solution for the differentiation of tuberculosis and non-tuberculous *Mycobacterium*

MYCOBACTERIUM REALTIME PCR KIT

Real-time PCR multiplex kit for the detection of nucleic acids from *Mycobacterium tuberculosis* complex (MTBC), *Mycobacterium avium* complex (MAC), *Mycobacterium abscessus* complex (MABSC), and other non-tuberculous mycobacteria (NTM) in human sputum samples.

- 5 targets Multiplex PCR - **one single reaction tube** per sample.
- **Endogenous human control** for monitoring the carry-over of amplification inhibitors, sample DNA integrity and the correct amplification set-up.
- Suitable for **5-channel qPCR cyclers**: FAM, HEX (VIC), Q705 (Cy5.5), Texas Red (ROX) and Cy5.
- Fast and reliable **results in under 2 hours**.
- **Lyophilized** master mix and positive control to ensure stability and reduce transportation costs.
- **Different kit presentations** for greater user convenience: pre-dispensed divisible plate and strips.



Ref. RTPCR016-LPD, 96 tests



Ref. RTPCR0016-LP, 24 tests

VIRPLEX

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Multiplex molecular solution

Why is this kit clinically relevant?

Mycobacteria are resilient bacteria due to their unique cell wall structure, making them highly resistant to environmental stress and certain antibiotics. While *Mycobacterium tuberculosis* causes tuberculosis (TB), nontuberculous mycobacteria (NTM) are responsible for chronic lung infections, especially in immunocompromised individuals and those with cystic fibrosis.

NTM incidence is rising globally, particularly in high-income regions, with *Mycobacterium avium* complex (MAC), *M. abscessus* complex (MABSC), *M. kansasii*, and *M. intracellulare* being the most common species.

- In some countries, NTM infections are more prevalent than tuberculosis.^{1,2}
- Conventional rapid diagnostic methods such as smear microscopy struggle to differentiate TB from NTM, leading to delays in treatment.³
- Proper identification of MAC and MABSC is essential for effective treatment and epidemiological control.⁴

More TB diagnosis with VIRPLEX

Complements the solution for the diagnosis of tuberculosis:

MTBC Species Real-Time PCR Kit

- Multiplex PCR detecting 7 different subspecies from the MTB complex in two reaction tubes per sample (*M. tuberculosis*, *M. africanum*, *M. microti*, *M. caprae*, *M. bovis*, *M. bovis* BCG and *M. canettii*). It can be used in culture isolates or smear positive samples.
- Lyophilized format for improved stability and reduced shipping costs.

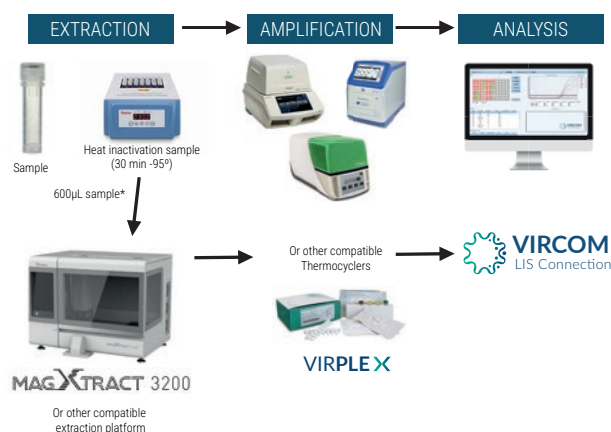
Kit performance

	Sensitivity	Specificity	No. of samples
<i>Mycobacterium abscessus</i> complex	100%	100%	101
<i>Mycobacterium avium</i> complex	100%	100%	100
<i>Mycobacterium tuberculosis</i> complex	100%	100%	109
Non-tuberculous mycobacterium	98%	100%	102

Integration with laboratory workflow

To ensure an efficient and complete diagnostic process, VIRPLEX kits integrate with the following solutions:

- Extraction with MagXtract, optimizing process efficiency and accuracy. Manual extraction or other automated extraction are compatible.
- Amplification and detection with CFX / Azure or other compatible thermal cyclers.
- Automated data analysis with VIRCOM, which facilitates the interpretation of results and streamlines decision making.



Information and related products

Description	Class	Reference	Content
MYCOBACTERIUM REALTIME PCR KIT	CE ₀₁₂₃ IVDR	RTPCR016-LP	24 tests
MYCOBACTERIUM REALTIME PCR KIT	CE ₀₁₂₃ IVDR	RTPCR016-LPD	96 tests
MTBC SPECIES REALTIME PCR KIT	RUO	RTCPCR022-LP-R	24 tests
AMPLIRUN® MYCOBACTERIUM AVIUM DNA CONTROL	RUO	MBC086-R	1 vial
AMPLIRUN® MYCOBACTERIUM TUBERCULOSIS DNA CONTROL	CE ₀₁₂₃ IVDR	MBC034	1 vial
AMPLIRUN® TOTAL MDR-TB VERIFICATION & CONTROL PANEL (SPUTUM)	CE	MBTC027	10 vials

¹ Jarcho-MacDonald, A., Smith, M., Seagar, A. L., Russell, C. D., Claxton, P., Laurensen, I. F., & Moncayo-Nieto, O. L. (2022). Changing Incidence and Characteristics of Nontuberculous Mycobacterial Infections in Scotland and Comparison With Mycobacterium tuberculosis Complex Incidence (2011 to 2019). *Open forum infectious diseases*, 10(1), ofac665. <https://doi.org/10.1093/ofid/ofac665>

² Kendall BA, Varley CD, Choi D, Cassidy PM, Hedberg K, Ware MA, Winthrop KL. Distinguishing tuberculosis from nontuberculous mycobacteria lung disease, Oregon, USA. *Emerg Infect Dis*. 2011 Mar;17(3):506-9. doi: 10.3201/eid1703.101164. PMID: 21392445; PMCID: PMC3166013.

³ Chindam A, Vengaldas S, Sriniv VR, Syed U, Kilaru H, Chenimilla NP, Kilaru SC, Patil E. Challenges of diagnosing and treating non-tuberculous mycobacterial pulmonary disease [NTM-PD]: A case series. *J Clin Tuberc Other Mycobact Dis*. 2021 Aug 30;25:100271. doi: 10.1016/j.jctube.2021.100271. PMID: 34541338; PMCID: PMC8441069.

⁴ Camarena Miriana, J. J., & González Pellicer, R. (2011). *Micobacterias atípicas y su implicación en patología infecciosa pulmonar*. *Enfermedades Infecciosas y Microbiología Clínica*. Recuperado de www.elsevier.es/elsevier