VIRCELL MYCOBACTERIUM REALTIME PCR KIT

Rapid detection and differentiation of tuberculosis and major nontuberculous mycobacterial infections directly from respiratory specimens

Summary

An independent prospective multicenter evaluation of the Vircell MYCOBACTERIUM REALTIME PCR KIT has been published in ASM Microbiology Spectrum:

Cano-Fernandez M, Barrado L, Bermudez-Marvalc H, Cabrera-Pineda M, Diaz-De-La-Torre I, Domingo D, Hernandez S. et al. Evaluation of clinical usefulness of a commercial multiplex PCR for diagnosing mycobacterial infections: a multicenter study. Microbiol Spectr. 2026 Jul 13:e0017526. https://pubmed.ncbi.nlm.nih.gov/42439557/

Conducted under real-world conditions, this prospective multicentre study included a large number of specimens. Its findings provide robust scientific evidence supporting the utility of the Vircell multiplex real-time PCR assay for the rapid diagnosis of pulmonary mycobacterial infections. This technical note presents the main study findings and explores their potential application in routine laboratory practice.

The Vircell assay is designed to detect *Mycobacterium tuberculosis* complex and the most clinically relevant nontuberculous mycobacteria directly in respiratory specimens. The study assessed its ability to detect and differentiate *Mycobacterium tuberculosis* complex (MTBC), *Mycobacterium avium* complex (MAC) and *Mycobacterium abscessus* complex (MABSC). A total of 845 respiratory specimens were prospectively collected and analysed across 15 clinical microbiology laboratories serving 24 hospitals in the Madrid region. Results from the Vircell multiplex PCR assay were compared with mycobacterial culture as the reference method and with acid-fast bacilli (AFB) staining.

The assay showed particularly strong performance for MTBC, with 90.3% sensitivity and 98.5% specificity, increasing to 96.3% sensitivity in AFB smear-positive specimens. Specificity exceeded 99% for MAC and MABSC, supporting the very high reliability of positive results for the three targeted complexes. These findings support the incorporation of the Vircell assay into routine diagnostic workflows as a rapid tool for differentiating tuberculosis from major nontuberculous mycobacterial infections directly from respiratory samples.

This differentiation has direct clinical and laboratory relevance. AFB staining can rapidly demonstrate the presence of acid-fast organisms but cannot distinguish MTBC from NTM, while culture-based identification may require several weeks. Earlier molecular differentiation can support timely tuberculosis treatment and infection-control measures or, when MAC or MABSC is detected, guide the selection of further identification and susceptibility-testing procedures.

From a diagnostic-solution perspective, this publication is particularly valuable when the MYCOBACTERIUM REALTIME PCR KIT is offered as part of Vircell's broader mycobacterial molecular portfolio. This portfolio extends beyond direct detection from respiratory specimens and includes the MTBC SPECIES REALTIME PCR KIT for further identification of *Mycobacterium tuberculosis* complex and other *Mycobacterium* species causing human tuberculosis, from culture-positive samples. The portfolio also covers whole-process and analytical AMPLIRUN® controls to support verification and routine quality management, as well as automated extraction systems and middleware for interpretation and connection to LIS.

Technical Note
Vircell Scientific Marketing, September 2026

Introduction

Mycobacterial respiratory infections include disease caused by *Mycobacterium tuberculosis* complex and a broad group of environmental organisms collectively known as nontuberculous mycobacteria (NTM).

Tuberculosis remains a major global cause of infectious morbidity and mortality. At the same time, NTM pulmonary disease is becoming increasingly relevant, particularly among older patients, individuals with structural lung disease and immunocompromised populations. Among the most clinically significant NTM are: *M. avium* complex, *M. abscessus* complex, *M. kansasii* and *M. xenopi*

The diagnosis of NTM pulmonary disease is challenging because its clinical and radiological manifestations frequently overlap with those of tuberculosis. However, the therapeutic and public-health implications differ substantially.

Tuberculosis is generally managed using standardized first-line treatment regimens and may require immediate respiratory isolation and contact investigation. By contrast, NTM infections often require prolonged and species-specific treatment, with regimens determined by the organism involved, antimicrobial susceptibility and the patient's underlying condition.

Rapid differentiation between MTBC and NTM is therefore essential for appropriate clinical decision-making. Conventional diagnostic methods do not always provide this distinction within a clinically useful timeframe. Acid-Fast Bacilli (AFB) staining is rapid but cannot differentiate MTBC from NTM. Culture remains fundamental but may require several weeks before definitive identification is available. Molecular testing can shorten this diagnostic interval by detecting and differentiating clinically relevant mycobacteria directly from respiratory specimens.

Assay technology and intended positioning

Vircell MYCOBACTERIUM REALTIME PCR KIT is a multiplex real-time PCR assay designed for the simultaneous detection of: *Mycobacterium tuberculosis* complex (MTBC), *Mycobacterium avium* complex (MAC), *Mycobacterium abscessus* complex (MABSC) and *Mycobacterium* genus. The assay includes a human RNase P internal control to monitor the suitability of the sample and molecular process.

Within *Mycobacterium avium* complex, the test considers organisms belonging to the *M. avium–intracellulare* group, including *M. avium* subspecies, *M. intracellulare* and *M. chimaera*.

According to the authors, the assay is best positioned as a rapid complement to microscopy and culture, rather than as a standalone replacement for conventional methods. This positioning is important because, alongside the specific detection of MTBC, MAC and MABSC, the assay includes a genus-level *mycobacterium* target that can indicate the presence of other mycobacterial species not covered by those three complexes.

A positive result can provide early, clinically relevant differentiation. However, a negative result does not exclude infection, particularly when the organism is present below the assay's detection threshold, or detection is affected by low bacillary burden, sample heterogeneity, or pre-analytical or analytical factors.

In routine practice, the assay can therefore be used to accelerate early diagnostic orientation while culture continues in parallel.

Evidence from the publication

Study design

Cano-Fernandez *et al.* conducted a prospective multicenter study between June 2024 and July 2025. The study involved 15 microbiology laboratories processing mycobacterial cultures for 24 hospitals in the Madrid region. A total of 845 respiratory specimens were collected from patients with clinical suspicion of mycobacterial infection and were processed according to each laboratory's routine procedures. A summary of the Study design is shown in Table 1.

Study component	Details from publication
Study design	Prospective multicenter clinical evaluation
Study period	June 2024 to July 2025
Participant laboratories	15
Hospitals represented	24
Total respiratory specimens	845
Main sample type	Sputum (594)
Other sample matrices	Bronchial aspirates (146) Bronchoalveolar lavage samples (98) Bronchial lavage specimens (7)
Reference method	Culture
Additional reference	Acid-fast bacilli staining (AFB)
Molecular assay	MYCOBACTERIUM REALTIME PCR KIT
Extraction workflow	MagXtract® 3200 instrument Vircell Standard Extraction Plate SE001
PCR instrument used	Bio-Rad CFX96 Touch

Table 1: *Overview of the study design for this multicenter evaluation.*

Diagnostic workflow

Each specimen was evaluated using parallel diagnostic methods: acid-fast bacilli staining, mycobacterial culture and the Vircell Multiplex real-time PCR.

For molecular testing, approximately 1 mL of sample underwent thermal inactivation at 95°C for 30 minutes. A 600 µL aliquot was then processed with the MagXtract® 3200 automated system using the pre-dispensed Vircell Standard Extraction Plate Ref. SE001

The extraction procedure included proteinase K digestion and magnetic bead-based purification, producing an 80 µL eluate in approximately 20 minutes per batch. Five microlitres of extracted nucleic acid were automatically transferred to lyophilized PCR tubes before amplification.

Laboratories participating in this multicentre study were additionally queried regarding the use of other molecular assays for MTBC detection.

Microbiological findings

The study included 845 respiratory specimens from patients with suspected mycobacterial infection: sputum (n = 594), bronchial aspirates (n = 146), bronchoalveolar lavage (n = 98), and bronchial lavage (n = 7). Median patient age was 66 years, and 50.06% were female. Culture was positive in 301 specimens (35.6%): MTBC (n = 156), MAC (n = 120), and MABSC (n = 25); 238 of these (79.1%) were also AFB-positive. (Table 2).

AFB staining was positive but culture negative in 29 cases. (Table 2). PCR was positive despite negative culture and AFB staining in five cases—three MABSC and two MTBC. Overall, multiplex PCR detected mycobacterial complexes in 245 specimens (29%): identifying MTBC (n = 147), MAC (n = 77), and MABSC (n = 21).

Diagnostic performance

Culture was used as the reference method for calculating sensitivity, specificity, positive predictive value and negative predictive value. (Table 3).

MTBC performance

The Vircell PCR assay showed strong diagnostic performance for MTBC, with 90.26% overall sensitivity, 98.53% specificity, 95.20% positive predictive value and 96.55% negative predictive value. Notably, sensitivity increased to 96.32% among AFB smear-positive specimens.

This performance in terms of sensitivity, specificity and positive predictive value supports the use of the Vircell assay for rapid MTBC detection, particularly in patients with a higher bacillary burden. In this setting, an early molecular result may support timely treatment initiation and infection-control decisions before culture identification becomes available. Furthermore,

Culture result	Number	AFB positive	AFB negative	Multiplex PCR with AFB positive	Multiplex PCR with AFB negative
MTBC	156	138	18	131	8
MAC	120	79	41	60	12
MABSC	25	21	4	15	3
Negative	488	29	459	7	5

Table 2 *Distribution of AFB smear and Vircell Mycobacterium PCR results among culture-positive specimens, stratified by mycobacterial group. Cultures yielding Mycobacterium species outside the assay targets and contaminated cultures were excluded from the analysis.*

comparison of the evaluated PCR panel with other molecular assays routinely used in the participating laboratories for MTBC detection, showed a high degree of concordance with the Vircell PCR assay, particularly among positive samples.

MAC performance

For MAC, overall sensitivity was 61.02%, increasing to 76.92% in AFB-positive specimens. Specificity was 99.37%, and the positive predictive value was 94.74%.

The lower overall sensitivity means that a negative MAC result should not be used independently to exclude infection, particularly in patients with strong clinical or radiological suspicion and a low bacillary burden. This limitation has also been reported by other publications with other NTM PCR assays and likely reflects the heterogeneity and lower bacterial burden often associated with NTM pulmonary disease. The high specificity and positive predictive value nevertheless support the clinical relevance of a positive MAC result in the evaluated population.

NTM therefore accounted for 48.2% of these positive cultures.

Culture additionally identified 37 isolates belonging to NTM species not specifically included among the three targeted complexes. When these isolates were also considered, NTM accounted for 182 of the 338 specimens with positive mycobacterial cultures (53.8%). In this population, NTM were therefore slightly more frequent than MTBC among culture-positive specimens.

These findings show that the diagnostic need is not limited to rapidly confirming tuberculosis or detecting drug resistance. In an AFB smear-positive specimen, it is also essential to determine whether the sample contains MTBC or an NTM, because microscopy cannot provide this differentiation and the clinical, therapeutic and infection-control implications are different.

Target	Sensitivity	Sensitivity in AFB-positive samples	Specificity	PPV	NPV
MTBC	90.26%	96.32%	98.53%	95.20%	96.55%
MAC	61.02%	76.92%	99.37%	94.74%	91.01%
MABSC	72.00%	71.43%	99.58%	85.71%	98.76%
Total as reported	89.66%	89.36%	9748%	94.24%	87.18%

Table 3: *Diagnostic performance of Mycobacterium real-time PCR assay for detection of mycobacteria compared with culture.*

MABSC performance

For MABSC, sensitivity was 72.00% and specificity was 99.58%. The study included only 25 MABSC culture-positive specimens, resulting in wider confidence intervals than those observed for MTBC and MAC. The result should therefore be interpreted as supportive but less precisely estimated.

A positive MABSC result may provide clinically useful early information because infections caused by the *M. abscessus* complex can require complex, prolonged and highly specific therapeutic approaches.

Relevance of NTM in the study population

The distribution of culture-positive results highlights the diagnostic relevance of NTM in the evaluated population. Among the 301 specimens culture-positive for one of the three specifically targeted complexes, 156 corresponded to MTBC and 145 to MAC or MABSC.

Performance according to AFB smear status

The study demonstrated that assay sensitivity was generally higher in AFB smear-positive samples, particularly for MTBC and MAC.

This relationship reflects the effect of bacillary burden on molecular detection. AFB-positive specimens usually contain a higher concentration of mycobacteria, increasing the probability that target nucleic acid will be present in the aliquot analysed by PCR.

For MTBC, sensitivity increased from 90.26% overall to 96.32% in smear-positive specimens. For MAC, sensitivity increased from 61.02% overall to 76.92% in smear-positive specimens. This result reinforces the value of combined interpretation:

- AFB staining provides rapid evidence of acid-fast organisms and an indirect estimate of bacillary burden.
- PCR provides early differentiation among the targeted complexes.
- Culture confirms viable organisms and permits broader identification and susceptibility testing.

The assay's strongest immediate clinical contribution is therefore likely to occur when an AFB-positive respiratory specimen requires rapid differentiation between tuberculosis and NTM infection.

Why specimens are decontaminated before culture

Respiratory specimens originate from non-sterile anatomical sites and may contain large numbers of commensal bacteria and fungi.

These microorganisms generally grow faster than mycobacteria and can overgrow the culture medium, potentially preventing the recovery or recognition of the target organism. Respiratory specimens therefore undergo digestion and decontamination before culture inoculation. The objectives of this procedure are to liquefy mucus and homogenize the specimen, release mycobacteria trapped within respiratory material, reduce bacterial and fungal contamination and concentrate viable mycobacteria before inoculation.

The procedure depends partly on the relative resistance of MTBC to alkaline decontaminating reagents. However, the conditions must be carefully controlled. Insufficient decontamination can lead to bacterial or fungal overgrowth. Excessive decontamination can reduce mycobacterial viability and compromise culture sensitivity.

This effect is particularly relevant for NTM. The publication explains that some NTM, especially rapidly growing mycobacteria, may be more susceptible than MTBC to the reagents used during decontamination. Viable NTM cells may therefore be damaged or destroyed during processing, reducing their recovery in culture.

In the study, 19 cultures were contaminated with bacteria or fungi and were excluded from the performance analysis. Two of these specimens produced positive PCR results, one for MAC and one for MTBC.

This illustrates the complementary nature of culture and PCR: Culture requires viable organisms capable of growth while PCR detects target nucleic acid and is not dependent on microbial viability.

Interpretation of discrepant results

PCR-positive, culture-negative results

Seven specimens were positive for MTBC by the Vircell PCR assay but negative by culture. Among these specimens four were AFB smear positive, one came from a patient with a previous episode of tuberculosis and in four additional cases they were also positive with another molecular assay used by the participating laboratories (e.g. GeneXpert® MTB/RIF), supporting the PCR findings obtained by the Vircell assay.

These findings reinforce the reliability of at least some PCR-positive, culture-negative results.

Potential explanations include reduced organism viability after treatment, loss of viable organisms during decontamination or sample processing, low concentrations of viable organisms., persistence of mycobacterial DNA from a previous or treated infection and differences between the aliquots used for molecular testing and culture.

The detection of nucleic acid does not always establish active disease. Positive PCR findings should therefore be interpreted alongside the patient's clinical presentation, radiological findings, treatment history and other microbiological results.

Two MAC PCR-positive, culture-negative results were obtained from patients with a documented history of *M. intracellulare* infection. This finding may also reflect persistent DNA or organisms not recovered in the culture aliquot.

Culture-positive, PCR-negative results

A negative PCR result does not exclude mycobacterial infection. Potential explanations include low bacillary burden, heterogeneous distribution of organisms within the specimen, differences between PCR and

culture aliquots, PCR inhibition or inefficient nucleic acid recovery or infection caused by a species outside the targeted complexes.

In this study culture identified 37 isolates corresponding to species not specifically identified in the PCR panel. These included *M. gordonae*, *M. fortuitum*, *M. mucogenicum*, *M. lentiflavum*, *M. scrofulaceum*, *M. celatum*, *M. chelonae*, *M. interjectum*, *M. shottsii* and *M. xenopi*. Only two of these samples were positive by AFB staining. This result supports the continued need for culture when the clinical suspicion of mycobacterial disease remains high.

Clinical and laboratory implications

Rapid diagnostic orientation

The principal clinical value of MYCOBACTERIUM REALTIME PCR KIT is the early differentiation of MTBC from MAC and MABSC directly in respiratory specimens.

One of the assay's most clinically relevant applications is the evaluation of AFB smear-positive respiratory specimens. Microscopy confirms the presence of acid-fast organisms but cannot distinguish MTBC from NTM. This uncertainty may initially lead to respiratory isolation, contact investigation and empirical antituberculosis treatment while culture-based identification is pending.

Early molecular differentiation of MTBC, MAC and MABSC, and generic detection of other mycobacteria can support these decisions on the same day. Detection of MTBC may support the prompt implementation of tuberculosis-specific infection-control measures and appropriate treatment. Conversely, detection of MAC or MABSC may provide early evidence of an NTM infection and support reassessment of measures specifically directed against tuberculosis, while accelerating the investigation and management of the identified NTM complex. In this study, NTM accounted for approximately half of the positive mycobacterial cultures. Unlike assays focused on MTBC and rifampicin resistance, the Vircell assay differentiates and detects NTM.

Support for early tuberculosis decisions

The high MTBC sensitivity observed in AFB smear-positive specimens (96.32%), together with 98.53% specificity, supports rapid action while culture is still pending. In an appropriate clinical context, an early MTBC-positive result may contribute to treatment initiation, respiratory isolation and other infection-control decisions. The result should remain integrated with clinical, radiological and microbiological information.

Earlier orientation for major NTM

Direct detection of MAC or MABSC can provide an early indication that the organism is a major NTM complex rather than MTBC. This may help laboratories prioritize subsequent culture identification and susceptibility-testing procedures and may support earlier specialist assessment. However, molecular detection alone does not establish that ATS/ERS/ESCMID/IDSA criteria for NTM pulmonary disease have been fulfilled.

Complementary use with microscopy and culture

The study supports an integrated workflow in which AFB staining estimates bacillary burden, multiplex PCR provides rapid differentiation among the targeted complexes, and culture confirms viable organisms, detects species outside the panel and enables susceptibility testing. PCR should therefore accelerate diagnostic orientation while culture continues in parallel, rather than replace it.

Laboratory resilience in difficult cultures

PCR can provide useful information when culture is compromised by contamination, loss of organism viability during decontamination, prior antimicrobial treatment or uneven distribution of organisms between aliquots. Conversely, culture remains essential when PCR is negative but clinical suspicion persists, especially for low-burden infection or disease caused by an NTM species outside the assay targets.

Balanced interpretation and study limitations.

The publication provides strong prospective, multicentre evidence, but the results should be interpreted within the following constraints:

- The evaluation included respiratory specimens only. Performance cannot be extrapolated directly to extrapulmonary matrices without additional validation.
- All participating laboratories were located in the Madrid region. The multicentre design improves real-world representativeness, but local prevalence and NTM epidemiology may affect predictive values and generalisability to other settings.
- Culture was used as the reference method, although culture can be affected by contamination, prior treatment, low organism viability and decontamination-related loss, particularly for some NTM. Apparent PCR-positive/culture-negative results are therefore not necessarily false-positive molecular results.
- Sensitivity was lower for MAC (61.02% overall) and MABSC (72.00%) than for MTBC, and negative results require caution in low-burden or strongly suspected NTM disease. The MABSC estimate was based on only 25 culture-positive specimens and consequently had wider confidence intervals.
- The panel directly differentiates MTBC, MAC and MABSC, but it does not identify every clinically relevant NTM. Culture detected 37 isolates belonging to species outside the targeted complexes, reinforcing the need to maintain culture and broader identification methods.
- Comparison with other rapid molecular assays was available only for a subset of samples and was not performed systematically using one uniform comparator across all centres.
- Systematic clinical and radiological correlation was not available. The study therefore evaluates microbiological performance and diagnostic usefulness, but cannot determine whether every molecular detection represented active disease, colonisation or persistent DNA after previous infection or treatment.
- The PCR results were not reported to clinicians and did not influence patient management. The study therefore did not directly measure changes in time to treatment, isolation decisions, length of stay or patient outcomes.

Conclusion

Prospective multicentre studies of this scale are uncommon in diagnostic assay evaluation. The inclusion of 845 respiratory specimens processed across 15 laboratories under real-world clinical practice conditions provides strong evidence supporting the use of MYCOBACTERIUM REALTIME PCR KIT as a rapid molecular tool for the direct detection and differentiation of MTBC, MAC and MABSC, together with genus-level detection of other mycobacteria.

The assay demonstrated its strongest performance for MTBC, with 90.3% sensitivity, increasing to 96.3% in AFB smear-positive specimens, and 98.5% specificity. Sensitivity was 61.0% for MAC, rising to 76.9% in AFB-positive samples, and 72.0% for MABSC. Specificity exceeded 99% for both NTM targets, supporting high confidence in positive results. The lower sensitivity observed for NTM is consistent with the lower and more heterogeneous bacillary burden commonly associated with these infections.

The results also highlight the growing diagnostic relevance of NTM, which accounted for approximately half of the positive mycobacterial cultures in the evaluated population. In AFB smear-positive specimens, early differentiation of MTBC from major NTM complexes can support timely decisions regarding tuberculosis-specific isolation, contact investigation and treatment while culture continues in parallel. This broader differentiation provides clinically relevant information that complements molecular assays focused on MTBC and rifampicin resistance. Nevertheless, NTM detection alone does not establish active disease and must be interpreted alongside clinical, radiological and microbiological findings.

Integration with MagXtract® 3200 automated extraction and amplification on the open Bio-Rad

CFX96 Touch real-time PCR platform provides laboratories with a standardized and flexible workflow. This approach substantially reduces the time to clinically relevant mycobacterial differentiation compared with culture-based identification, while preserving the essential role of culture for comprehensive species identification and antimicrobial susceptibility testing.

Vircell as a full *Mycobacterium* molecular portfolio partner, not a single-test supplier

Vircell provides a comprehensive molecular portfolio for mycobacterial diagnosis, covering direct detection, species differentiation, automated extraction, quality controls and workflow connectivity, detailed in Table 4.

Direct detection from respiratory specimens

MYCOBACTERIUM REALTIME PCR KIT provides simultaneous detection of *Mycobacterium* genus and direct differentiation of MTBC, MAC and MABSC. It is positioned for rapid first-line molecular orientation while microscopy and culture proceed in parallel.

Further identification from positive cultures

MTBC SPECIES REALTIME PCR KIT (RTPCR022) extends the workflow beyond initial complex-level detection by enabling further molecular identification from culture-positive material. It detects and differentiates the main members of the *Mycobacterium tuberculosis* complex, including *M. tuberculosis*, *M. africanum*, *M. microti*, *M. caprae*, *M. bovis*, *M. bovis* BCG and *M. canettii*. Together, the two PCR Vircell assays connect rapid direct detection with a subsequent characterisation, providing laboratories with a more complete diagnostic picture than an isolated test result.

Integrated automated extraction

The workflow evaluated in the publication used the MagXtract® 3200 with the pre-dispensed Vircell Standard Extraction Plate SE001. Automated magnetic-bead extraction and PCR setup support standardisation, traceability and efficient batch processing within an open real-time PCR workflow.

Quality-control support

Vircell AMPLIRUN® controls complement the molecular assays with characterised materials for verification, analytical quality control, operator training and routine monitoring. Whole-process controls can challenge extraction and amplification together, while analytical controls can support target-specific PCR checks according to the laboratory's quality plan.

Open-platform flexibility

The evaluated assay was amplified on a Bio-Rad CFX96 Touch, illustrating a workflow that can be implemented on an open real-time PCR platform. This gives laboratories greater flexibility than a single closed-cartridge approach and allows the mycobacterial solution to be integrated into broader molecular testing infrastructure. Together, these components position Vircell as a portfolio partner for the mycobacterial molecular pathway: rapid direct detection, downstream identification, automated extraction and quality-control support.

The value proposition is therefore not limited to one multiplex assay, but to a connected workflow that laboratories can adapt to their diagnostic algorithms, throughput and quality requirements.

Middleware communication system

VIRCOM Molecular supports end-to-end traceability and standardized data management throughout the molecular workflow. It enables full integration with the laboratory information system (LIS) and provides automatic, straightforward interpretation of results, including amplification curves and Ct values. Human error is reduced through scanner-based data entry, automatic creation of run templates with the corresponding controls, recording of reagent lots and expiry dates, colour-coded identification of positive and negative results, and a guided result-validation wizard.

Description	Reference	Class	Pack size
MYCOBACTERIUM REALTIME PCR KIT	RTPCR016-LPD	CE0123 IVDR	96 Tests
MYCOBACTERIUM REALTIME PCR KIT	RTPCR016-LP	CE0123 IVDR	24 Tests
MTBC SPECIES REALTIME PCR KIT	RTPCR022-LP-R	RUO	24 Tests
MagXtract® 3200	MAGXTRACT3200	CE	
STANDARD EXTRACTION PLATE	SE001	CE IVDR	96 Tests
STANDARD EXTRACTION TUBE	SE002	CE IVDR	96 Tests
VIRCOM PCR	VPCOM		
AMPLIRUN® TOTAL MDR-TB VERIFICATION & CONTROL PANEL (SPUTUM)	MBTC027	CE	5x2 vials
AMPLIRUN® TOTAL MTB CONTROL (SPUTUM)	MBTC013	CE	10 vials
AMPLIRUN® TOTAL MTB INH RESISTANT CONTROL (SPUTUM)	MBTC015	CE	2x5 vials
AMPLIRUN® TOTAL MTB RIF RESISTANT CONTROL (SPUTUM)	MBTC014	CE	2x5 vials
AMPLIRUN® MYCOBACTERIUM AVIUM DNA CONTROL	MBC086-R	RUO	1 vial
AMPLIRUN® MYCOBACTERIUM INTRACELLULARE DNA CONTROL	MBC087-R	RUO	1 vial
AMPLIRUN® MYCOBACTERIUM KANSASII DNA CONTROL	MBC095-R	RUO	1 vial
AMPLIRUN® MYCOBACTERIUM TUBERCULOSIS DNA CONTROL	MBC034	CE0123 IVDR	1 vial
AMPLIRUN® MYCOBACTERIUM ULCERANS DNA CONTROL	MBC094-R	RUO	1 vial

Table 4. *Vircell molecular portfolio for the diagnosis of mycobacterial infections.*

Recommended message for end users

1. Detect and differentiate early.

Use MYCOBACTERIUM REALTIME PCR KIT for rapid molecular differentiation of MTBC, MAC and MABSC, together with genus-level detection of other *Mycobacterium* species, directly from respiratory specimens

2. Interpret AFB and PCR together.

AFB staining indicates the presence and approximate burden of acid-fast organisms; PCR adds early differentiation among the targeted complexes.

3. Continue culture in parallel.

Maintain culture for recovery of viable organisms, detection of species outside the PCR panel, definitive identification and antimicrobial susceptibility testing.

4. Act on positive results in context.

A positive MTBC result may support timely tuberculosis treatment and infection-control decisions. Positive MAC or MABSC results can guide further NTM investigation, but must be correlated with clinical, radiological and microbiological criteria.

5. Do not use a negative PCR result alone to exclude disease.

Low bacillary burden, sample heterogeneity, inhibition, suboptimal nucleic-acid recovery or an NTM outside the targeted complexes may produce a negative result despite ongoing infection.

6. Build a complete workflow.

Combine Vircell direct-detection and culture-identification assays with MagXtract® automated extraction and AMPLIRUN® quality controls for a standardised, traceable and flexible mycobacterial molecular solution.

References

1. Cano-Fernandez M, Barrado L, Bermudez-Marvalc H, Cabrera-Pineda M, Diaz-De-La-Torre I, Domingo D, Hernandez S, et al. Evaluation of clinical usefulness of a commercial multiplex PCR for diagnosing mycobacterial infections: a multicenter study. Microbiol Spectr. 2026; e00175-26. doi:10.1128/spectrum.00175-26.

2. Aguilera Franco M, Sampedro Padilla A, Gutierrez-Bautista JF, Gonzalez Martinez A, Cobo F, Gutierrez-Fernandez J, et al. Evaluation of the Mycobacterium RealTime Kit Vircell assay for detecting Mycobacterium species in clinical specimens. Pathogens. 2025;14:429. doi:10.3390/pathogens14050429.

3. Johansen MD, Herrmann J-L, Kremer L. Non-tuberculous mycobacteria and the rise of Mycobacterium abscessus. Nat Rev Microbiol. 2020;18:392–407. doi:10.1038/s41579-020-0331-1.

4. Ratnatunga CN, Lutzky VP, Kupz A, Doolan DL, Reid DW, Field M, et al. The rise of non-tuberculosis mycobacterial lung disease. Front Immunol. 2020;11:303. doi:10.3389/fimmu.2020.00303.

5. Daley CL, Iaccarino JM, Lange C, Cambau E, Wallace RJ Jr, Andrejak C, et al. Treatment of nontuberculous mycobacterial pulmonary disease: an official ATS/ERS/ESCMID/IDSA clinical practice guideline. Eur Respir J. 2020;56:2000535. doi:10.1183/13993003.00535-2020.

6. Kim J-U, Ryu D-S, Cha C-H, Park S-H. Paradigm for diagnosing mycobacterial disease: direct detection and differentiation of Mycobacterium tuberculosis complex and non-tuberculous mycobacteria in clinical specimens using multiplex real-time PCR. J Clin Pathol. 2018;71:774–780. doi:10.1136/jclinpath-2017-204945.

7. Broncano-Lavado A, Barrado L, Lopez-Roa P, Cacho J, Domingo D, Hernandez S, et al. Clinical evaluation of nontuberculous mycobacteria (NTM) elite agar, a new medium for the isolation of NTM: a multicenter study. J Clin Microbiol. 2023;61:e00036-23. doi:10.1128/jcm.00036-23.

8. Martin I, Pfyffer GE, Parrish N, Carroll KC, Pfaller MA, Landry ML, et al. Mycobacterium: general characteristics, laboratory detection, and staining procedures. In: Manual of Clinical Microbiology. 12th ed. Washington, DC: ASM Press; 2019. p. 558–575.

9. Buijtels PCAM, Petit PLC. Comparison of NaOH-N-acetyl cysteine and sulfuric acid decontamination methods for recovery of mycobacteria from clinical specimens. J Microbiol Methods. 2005;62:83–88. doi:10.1016/j.mimet.2005.01.010.