Improved Detection and Diagnosis: Revolutionizing NTM Infection Management

Nontuberculous mycobacterial infections are now more commonly detected than tuberculosis in the United States, due to rising prevalence numbers along with a greater awareness due to improvements in detection, culture, and diagnosis.

The economic and health-related quality of life burden of NTM-lung disease (NTM-LD) expenditures were found to be:

- 155% greater for patients with NTM-LD than control group 1 year after diagnosis
- 66% greater for patients with NTM-LD than control group 2 years after diagnosis [14,15]

Nontuberculous mycobacteria (NTM) refers to all the species in the family of mycobacteria that may cause human disease, but do not cause tuberculosis (TB) or leprosy. In a U.S. study from 2010, it was estimated that approximately 30 people per 100,000 population were infected with these lesser-known "cousins" of TB and leprosy. In fact, for unknown reasons, data from across the globe notes an increase in case rates of infection over time.

Like tuberculosis (TB), nontuberculous mycobacteria (NTM) infection often affects the lungs. People who have damaged lung tissue from diseases such as emphysema, bronchiectasis, adult cystic fibrosis or previous infection appear to be at greater risk for developing a NTM infection. People who have a suppressed immune system, such as those who receive strong immunosuppressant medications like prednisone or newer immunosuppressants like TNF inhibitors, have a greater risk of developing an NTM infection. The infection may affect all organs of the body, not just the lungs. People with HIV may also develop NTM infections.

> *"The patient profile has changed through the years, making it important to evaluate the implications of all and varying symptoms, and consider testing for NTM"*

Background

Nontuberculous Mycobacteria (NTM) are environmental organisms that can be found in soil, dust, and water including natural water sources (such as lakes, rivers, and streams) and municipal water sources (such as water that people drink or shower in). NTM can form difficult-to-eliminate biofilms, which are collections of microorganisms that stick to each other, and adhere to surfaces in moist environments, such as the insides of plumbing in buildings. Although anyone can get an NTM infection, NTM are opportunistic pathogens placing some groups at increased risk, including those with underlying lung disease or depressed immune systems. These pathogens are typically not transmitted person-to-person. However, person-to-person transmission of *M. abscessus* has been reported in patients with cystic fibrosis.

Nontuberculous mycobacteria (NTM) are mycobacteria other than *M. tuberculosis* (the cause of tuberculosis) and *M. leprae* (the cause of leprosy). NTM lung disease can often be missed due to its nonspecific or overlapping symptomatology in patients with underlying structural lung disease, resulting in NTM being undiagnosed or misdiagnosed. Despite increasing prevalence, the index of suspicion for NTM lung disease remains low, making early diagnosis an ongoing challenge.

If not diagnosed early enough and left unchecked, NTM lung disease can lead to a decline in lung function, worsening symptoms, and a decrease in overall quality of life for patients. *Early diagnosis is critical in the appropriate management of nontuberculous mycobacterial (NTM) lung disease.*

NTM can be divided into two groups based on how long they take to grow in a culture

Mycobacterium avium complex, also referred to as MAC, consists of two species of mycobacteria, which are considered to be “slow growers” (may need >14 days to grow). They include *Mycobacterium avium* and *Mycobacterium intracellulare*. These species, which can be difficult to differentiate, can cause disease and are found in various environmental settings across the globe. Several different syndromes are caused by *Mycobacterium avium* complex. For those who are immuno-compromised, it can often take the form of a pulmonary pathogen. Disseminated infections are usually associated with HIV infection. In HIV infected persons, manifestations may include night sweats, weight loss, abdominal pain, fatigue, diarrhea and anemia. Less commonly, pulmonary disease in non-immunocompromised persons is a result of infection with MAC.

Mycobacterium abscessus complex (MAbC) is one of the most clinically relevant species among nontuberculous mycobacteria and considered to be a “rapid grower” (usually grow within 7 to 10 days). MAbC’s prevalence has increased over the last two decades. These changes can be explained by high rates of antimicrobial resistance seen in MAbC, and patients experience multiple relapses with low cure rates. The higher prevalence of MAbC's results in chronic lung disease.

Nontuberculous mycobacterial infections are an increasingly important contributor to human disease, causing a wide range of infection from localized soft-tissue infiltration to disseminated life-threatening conditions. Having a ubiquitous presence in nature can make it challenging to discern NTM biological sample contamination from a true NTM infection in certain specimen types. The clinical and radiographic features are non-specific; microbiologic diagnosis is cumbersome and insufficiently informative. Treatment is complex, requiring multi-drug regimens with substantial associated toxicity, administered for a prolonged period. Defining treatment milestones is difficult; clinical outcomes are often disappointing.

About the Assay

Name: Nontuberculous Mycobacteria Real-time PCR Panel

Panel/Test Code: 33350

CPT Codes: 87551, 87552 and 87561

Turn-around-time: 24-48 hours after receipt of specimen.

Sample Type(s): The specimen type is lower respiratory (BAL, Bronchial / Trach Washings, and Sputum samples).

Tube/Container type: Sterile screw cap tube.

Shipping information: Can be shipped at ambient or frozen temperature Monday through Friday. Specimens shipped at ambient temperature must be received within 7 days of collection.

Results:

MA(C)omplex PCR assay
(non-specific detection)
Qualitative
Mycobacterium avium
- subsp. *paratuberculosis*
- subsp. *hominissuis*
- subsp. *sylvaticum*

Mycobacterium intracellulare
- subsp. *chimaera*

Mycobacterium colombiense

MAb(C)omplex PCR assay
(subspecies-specific detection)
Quantitative
Mycobacterium abscessus
- subsp. *abscessus*
- subsp. *bolletii*
- subsp. *massiliense*

Mycobacterium spp. PCR assay
(BR-Myco / "pan"-Myco)
Qualitative
MAbC members
MAC members
M. chelonae
M. fortuitum
M. gordonae
M. kansasii
M. malmoense
M. phlei
M. scrofulaceum
M. simiae
M. smegmatis
M. terrae
M. tuberculosis
M. xenopi

The Mycobacterium spp. assay will detect *M. tuberculosis*; however, it does not differentiate species. If *M. tuberculosis* is suspected and a Detected result is returned, the sample should be re-tested for *M. tuberculosis* using an independent method.

Summary

The Eurofins Viracor PCR assay for Nontuberculous Mycobacterium allows for the detection & differentiation of MAC, MAbC & mycobacteria species by RT-DNA PCR, direct from clinical samples.

This product is intended for use in the diagnosis of NTM infections, the genus mycobacterium, & sub / species identification of NTM infections alongside clinical data of the patient and other laboratory tests outcomes.

About Viracor

With over 35 years of diagnostic expertise in infectious disease, immunology and allergy testing for immunocompromised and critical patients, Eurofins Viracor is passionate about delivering accurate, timely and actionable results, never losing sight of the connection between the testing it performs and the patients it serves.

Eurofins Viracor is a subsidiary of Eurofins Scientific (EUFI.PA), a global leader in bio-analytical testing, and one of the world leaders in genomic services. For more information, please visit eurofins.com and eurofins-viracor.com

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