



alethia™

Mycoplasma Direct

Improves decision making
for physicians by providing a
convenient and timely result for
Mycoplasma pneumoniae

When Your Current Method Doesn't Provide Clear Results, it's time to change the way you test.

There are an estimated 2 million cases of *Mycoplasma pneumoniae* annually in the US. Of these, X-rays only identify 30% of positives¹ and serology may only detect about 25%².

Alethia™ Mycoplasma Direct takes the guessing out of an accurate identification of *Mycoplasma pneumoniae* infection with a targeted diagnosis from day one of symptoms.

- Report results with certainty and empower physicians to properly treat their patients.
- Single target molecular testing is more sensitive than X-ray, serology and multiplex molecular.
- With minimal hands-on time and an easy to collect throat swab, your lab can deliver qualitative results in less than one hour.

Is your health system missing positives?

- How well do you maximize the use of your financial and technical resources?
- How well does your current test method detect *Mycoplasma pneumoniae*?

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Results that Matter

- Improve patient outcomes by reducing the chance of a missed positive and minimizing risk of spreading the disease.
- Alethia Mycoplasma direct can deliver targeted detection so physicians can treat patients appropriately.

Improved performance over traditional methods

- Definitive diagnosis of Mycoplasma cannot be made on the basis of image alone. A combination of clinical and radiographical findings can significantly improve accuracy of disease diagnosis.³
- Chest X-rays may be negative, particularly in patients presenting in early disease course and among the elderly.⁴ *Mycoplasma pneumoniae* is often difficult to recognize on X-rays.⁵

Product Specifications

Alethia™ Mycoplasma Direct DNA amplification assay is a qualitative in vitro diagnostic test for the direct detection of DNA from *Mycoplasma pneumoniae* in human throat swabs obtained from patients suspected of having *Mycoplasma pneumoniae* infection.

Turnaround Time

Less than one hour

Shelf Life

18 months

Sample Type

Throat swabs placed in a non-nutritive transport medium

Sample Storage

- Samples should be placed in a non-nutritive transport medium containing pledget and held at 2-29 C during transport
- Samples may be held at room temperature (19-29 C) for up to 24 hours or refrigerated (2-8 C) for up to 14 days prior to testing

Kit Storage

Kits should be stored at 2-27 C

Performance

Performance characteristics of the assay were compared to culture.

96.0% PPA

97.7% NPA per PI

Catalog Number

Alethia™ Myco Direct
Test - 480250

CPT Codes

87581

Alethia™ Myco Direct

External Control - 479890

References

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2. Nilsson, A. C., Björkman, P., and Persson, K. Polymerase chain reaction is superior to serology for the diagnosis of acute Mycoplasma pneumoniae infection and reveals a high rate of persistent infection. *BMC Microbiology* 8.1 (2008): 93.
3. Susan D. et al. *RadioGraphics*, 2001; Vol121, Nov:121-131.
4. Long B, et al. *J Emerg Med*. Nov 2017; 53(5):642-652 <https://www.ncbi.nlm.nih.gov/pubmed/28941588>
5. *American Journal of Roentgenology*. 2000;174: 37-41. 10.2214/ajr.174.1.1740037. <https://www.ajronline.org/doi/10.2214/ajr.174.1.1740037>

Ready to get a handle on Mycoplasma testing? Let's talk.

Contact a specialist at 1-888-763-6769.

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