

Product specification affigene® Cp/Mp tracer

Technical specification

Code No	71001306 (48 tests)
Intended use	Separate detection of <i>Chlamydomphila pneumoniae</i> (Cp) and <i>Mycoplasma pneumoniae</i> (Mp) DNA in clinical samples
Regulatory status	CE labelled according to IVD Directive 98/79/EC Annex II List B for the complete process from sample preparation to result
Total kit size	48 determinations
Flexible run size	8-48 determinations per run (6-46 clinical samples)
Ready to use	All reagents provided in a ready-to-use format
Compatible profiles	Compatible profiles with other affigene® tender/ tracer assays enabling multitarget runs
Contamination prevention	UDG technology, Single-use reagents
Prev. of false neg. results	Internal Control introduced during sample preparation
Software provided	Results reported by the affigene® analysis software
Sample	Broncho Alveolar Lavage (BAL) and throat swabs
PCR instrument compatibility	Validated according to CE/IVD standards for: Mx3000P/Mx3005P (Stratagene) iCycler iQ/iQ5 (BioRad) Rotor-Gene 3000/6000 (Corbett Research) ABI 7300 (Applied Biosystems)
Sample preparation compatibility	Validated according to CE/IVD-standards for: affigene® DNA extraction (Cepheid AB) NucliSens easyMAG (bioMérieux)

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Performance characteristics

Limit of Detection (LOD) Using affigene® DNA extraction:

Throat swabs 200 µl protocol:

Cp: 14.4 geq/PCR (95% confidence interval: 9.2-32.0 geq/PCR)

Mp: 2.4 geq/PCR (95% confidence interval: 1.5-5.0 geq/PCR)

BAL 200 µl protocol:

Cp: 12.0 geq/PCR (95% confidence interval: 7.7-26.3 geq/PCR)

Mp: 2.7 geq/PCR (95% confidence interval: 1.7-6.2 geq/PCR)

Using easyMAG:

Throat swabs 500 µl protocol:

Cp: 2.8 geq/PCR (95% confidence interval: 1.8-6.0 geq/PCR)

Mp: 6.7 geq/PCR (95% confidence interval: 4.1-35.7 geq/PCR)

BAL 200 µl protocol:

Cp: 3.7 geq/PCR (95% confidence interval: 2.5-8.7 geq/PCR)

Mp: 4.2 geq/PCR (95% confidence interval: 2.5-11.1 geq/PCR)

Separate detection Cp and Mp separately detected without cross-reactivity

Subtype Inclusivity All clinically relevant variants detected.

Exclusivity and Microorganism Interference

No cross-reactivity with relevant pathogens: *Aspergillus fumigatus*, *Bordetella parapertussis*, *Bordetella pertussis*, *Bordetella bronchiseptica*, *Chlamydia psittaci*, *Chlamydia trachomatis*, *Citrobacter freundii*, *Haemophilus influenzae*, *Klebsiella pneumoniae*, *Legionella pneumophila*, *Micrococcus luteus*, *Mycoplasma faucium*, *Mycoplasma buccale*, *Mycoplasma hyorhinis*, *Mycoplasma orale*, *Mycoplasma penetrans*, *Mycoplasma primatum*, *Mycoplasma fermentans*, *Salmonella typhimurium*, *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Pseudomonas aeruginosa*, *Neisseria meningitidis* and *Adenovirus HAdV-2*, human DNA, bacterial or fungal DNA

Robustness 200/200 replicates of a sample at a concentration of 43 geq/PCR for Cp and 7 geq/PCR for Mp (approximately threefold concentration of LOD) were determined positive for either Cp or Mp DNA as well as for Internal Control.