BioVendor Group CLIA

Mycoplasma

Antibody determination

***Mycoplasma pneumoniae* IgA, IgG, IgM**

Diagnostic panels: Respiratory diseases

IVD CE 2265

The kits are CE-IVD certified and intended for professional use.

Designed for the platform

Kleeya®

Introduction

Mycoplasma pneumoniae is a primary pathogenic agent of the human respiratory tract. It causes pneumonia accompanied by fever, nausea, ague, cough and fatigue. The disease is prolonged but well curable with antibiotics. The pathogen is airborne, spread especially in dense gatherings of children, particularly during spring and autumn months.

Diagnosis of the disease

Diagnosis of the disease is based on clinical picture, epidemiological anamnesis and laboratory tests. Since a cultivation of *Mycoplasma pneumoniae* is difficult, the detection of specific IgA, IgG and IgM antibodies in human serum or plasma using ELISA, CLIA and BLOT methods is advisable in routine diagnostics.

Antibody determination

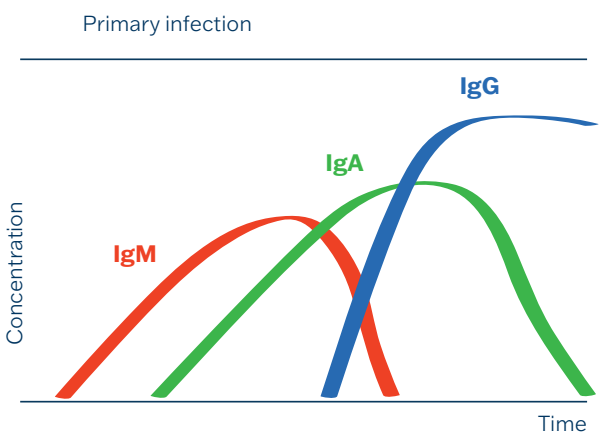
Diagnostic importance of antibody classes

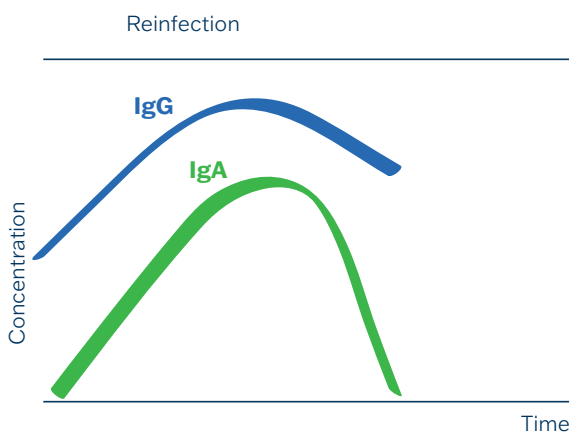
Primary infection is indicated by IgM antibody increase (1–2 weeks after the infection). The antibody level reaches its maximum after 1 month from the beginning of the infection and antibodies may persist in organism for more than 1 year. Specific IgM antibodies are detected in 80% of infected persons under the age of 20 years, at persons older than 20 years it is only 40%. During reinfection the antibody level rarely rises.

IgA antibodies are usually produced later than IgM and their level often decreases earlier. IgA antibodies determination is relevant when IgM antibodies are absent or in case of reinfection.

IgG antibodies may rise already 2–3 weeks after appearance of symptoms. The maximum is reached after a longer period (even 6 months). Antibodies persist more than one year. Some cases of antibody persistence longer than 4 years were reported. In case of reinfection, it is necessary to evaluate dynamics of antibodies in paired samples collected after 1–2 weeks.

It is crucial to examine all three classes of antibodies and sometimes even perform reinvestigation of paired samples for proper evaluation of serological findings.





Clinical applications

– The diagnosis of *Mycoplasma pneumoniae* infection using IgA, IgG and IgM antibodies in human serum or plasma in the general population.

Result interpretation

IgG	IgA	IgM	
–	–	–	No serological evidence of *Mycoplasma pneumoniae* infection
–	+	+	Early phase of acute infection or reinfection
–	+	–	Early phase of acute infection or reinfection
+	+	+	Acute infection
+	–	+	Acute infection (late phase)
+	+	–	Reinfection or infection without IgM production
+	–	–	Past infection or reinfection
–	–	+	Early phase of acute infection

Antigens

Mycoplasma pneumoniae IgA, IgG

Mixture of highly specific recombinant *Mycoplasma pneumoniae* antigens.

Mycoplasma pneumoniae IgM

Purified and inactivated *Mycoplasma pneumoniae* antigen enriched with highly specific immunodominant epitopes.

Test characteristics

Kit	Calibration scale	Diagnostic sensitivity	Diagnostic specificity
CLIA Mycoplasma IgA	0,1–320 U/ml	93.33%	96.10%
CLIA Mycoplasma IgG	0,5–320 U/ml	90.00%	93.45%
CLIA Mycoplasma IgM	2–160 U/ml	88.52%	85.26%

Correlation of methods

CLIA kits were compared to established ELISA kits from TestLine of the BioVendor Group. 96–99% agreement was found among the compared methods.

Accuracy and analytical sensitivity

High precision ensures consistent and reliable results of each measurement:

		IgA	IgG	IgM
Repeatability	Intra assay (within run)	12.89 %	8.10 %	9.56 %
	Within-laboratory precision	16.07 %	13.53 %	16.66 %

Clinical function

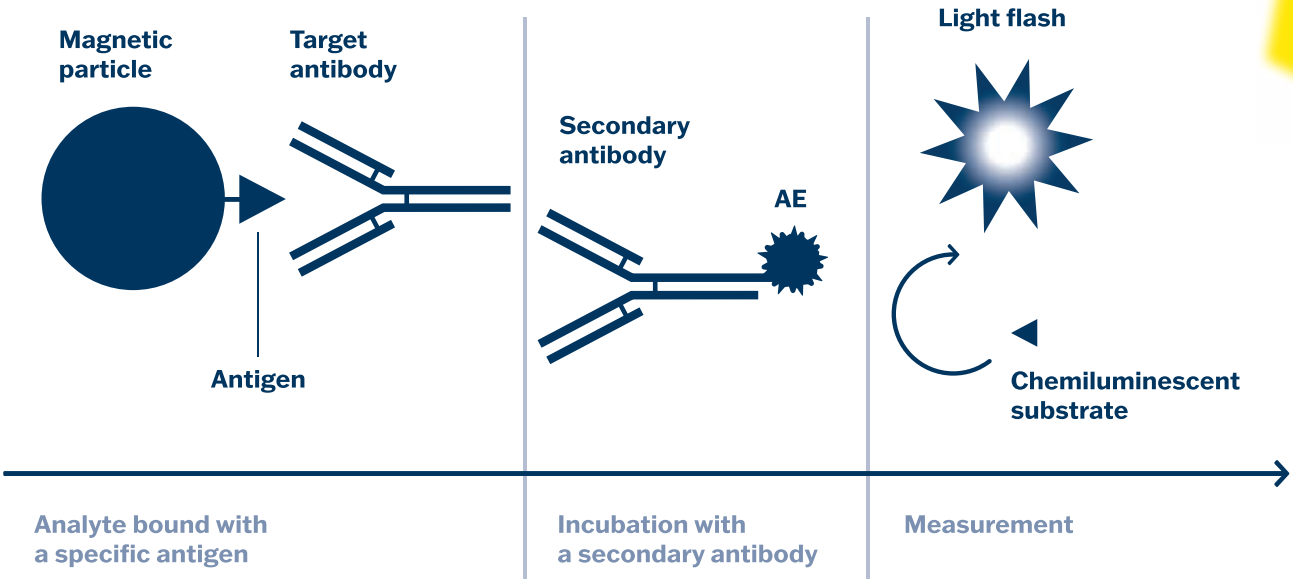
The quality of the CLIA Mycoplasma IgA, IgG, IgM kits were verified within an external clinical performance study at a specialized laboratory according to the strict requirements of the European IVDR directive.

The obtained comparison of clinical samples with the reference commercial kits high level of agreement:

	IgA	IgG	IgM
Comparison with the reference method	95.65 %	92.34 %	86.06 %

How does CLIA method work?

CLIA is a fully automated, fast, specific and sensitive method. It combines the use of magnetic particles for immunocomplex separation of the antigen and flash chemiluminescence for sensitive detection. The use of magnetic particle suspension facilitates automation, significantly shortens reaction times and improves the specificity of the determination. Flash chemiluminescence of acridinium ester provides an intense light signal even at very low concentrations and its intensity is measured in relative units of light (RLU). CLIA kits are designed for use on the KleeYa® automated platform.



CLIA kits

Diagnostic CLIA kits are intended for the monitoring of *Mycoplasma pneumoniae* IgA, IgG, IgM antibodies in human serum or plasma in the general population on a KleeYa® analyzer. Results are reported in IU/ml.

Control set CLIA

Control sera verify the accuracy of results obtained by the CLIA kits.

Ease of use

- Fully automated method
- Kits include all necessary reagents, incl. calibrators
- Working strength reagent solution
- Control sera available as independent sets
- Results in IU/ml

Advantages

- High diagnostic sensitivity and specificity
- Low sample (10 µl) and reagent consumption
- Short test time (30–40 min)
- Full traceability of reagent consumption and number of tests available using RFID tags
- LIS connectivity available
- Superior customer service

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Ordering information

CLIA kits

CLIA diagnostic kits are intended to determination of IgA, IgG and IgM antibodies against *Mycoplasma pneumoniae* in human serum or plasma on a KleeYa® analyser.

Kit	Catalogue number	Number of tests
CLIA Mycoplasma IgA	CL-MyA100	100
CLIA Mycoplasma IgG	CL-MyG100	100
CLIA Mycoplasma IgM	CL-MyM100	100

Control set

Each set contains two vials of positive and two vials of negative control serum with the predetermined level of specific antibodies. They are designed to verify the accuracy of results obtained with CLIA kits.

Kit	Catalogue number	Number of tests
Control set CLIA Mycoplasma IgA	CL-MyACON	2 x 20
Control set CLIA Mycoplasma IgG	CL-MyGCON	2 x 20
Control set CLIA Mycoplasma IgM	CL-MyMCON	2 x 20

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