BioVendor Group CLIA

Chlamydia

Antibody determination

***Chlamydia pneumoniae* IgA, IgG, IgM**
***Chlamydia trachomatis* IgA, IgG, IgM**

Diagnostic panels:
Respiratory diseases
Sexually transmitted infections
COVID-19

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

CLIA kits are optimized and validated for the determination of antibodies in human serum and plasma

Designed for the platform

Kleeya®

Introduction

Chlamydiota are Gram-negative, obligate intracellular bacteria.

In terms of human health, the most important Chlamydia pathogens are *Chlamydia trachomatis* and *Chlamydia pneumoniae*. *Chlamydia psittaci* is primarily an animal pathogen, which can be transmitted to humans.

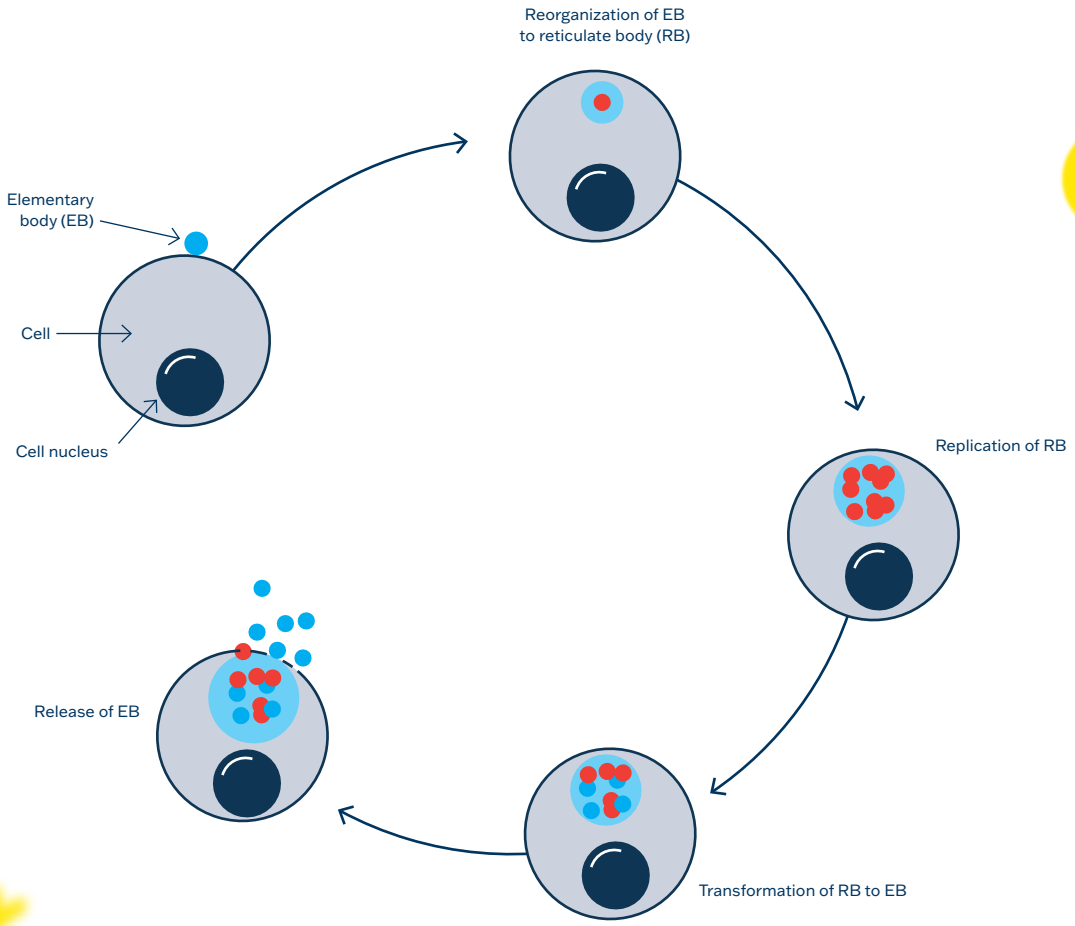
Chlamydia trachomatis is the most common sexually transmitted bacterial pathogen, causing venereal diseases in humans worldwide. The most vulnerable group is young people between 15 and 30 years of age. Urogenital chlamydia infections often occur in the form of “post-gonococcal inflammation”. Cervical chlamydia infection is currently considered to be one of the risk factors for uterine cervix carcinoma.

Chlamydia trachomatis is also the most frequent cause of sterility in both men and women.

Chlamydia pneumoniae is the most widely spread Chlamydiaceae species in the human population. In recent years, the number of acute and chronic infections has increased. Primary infection generally occurs between 5 and 18 years of age. Major clinical symptoms include: rhinitis, sinusitis, otitis media, pharingitis, bronchitis, atypical pneumonia with non-productive cough and indistinctive auscultatory findings.

Chlamydia psittaci can cause human diseases with atypical pneumonia-like (avian strains) or placentitis-like (mammal strains) manifestations.

Chlamydiota life cycle



Antibody response

The production of specific antibodies is delayed in the case of chlamydial infections. The IgM antibodies are produced in the 2nd and 3rd week after the outbreak of the disease; the production of IgA and IgG antibodies is slower (from the 6th to 8th week).

Antibody response dynamics

IgM

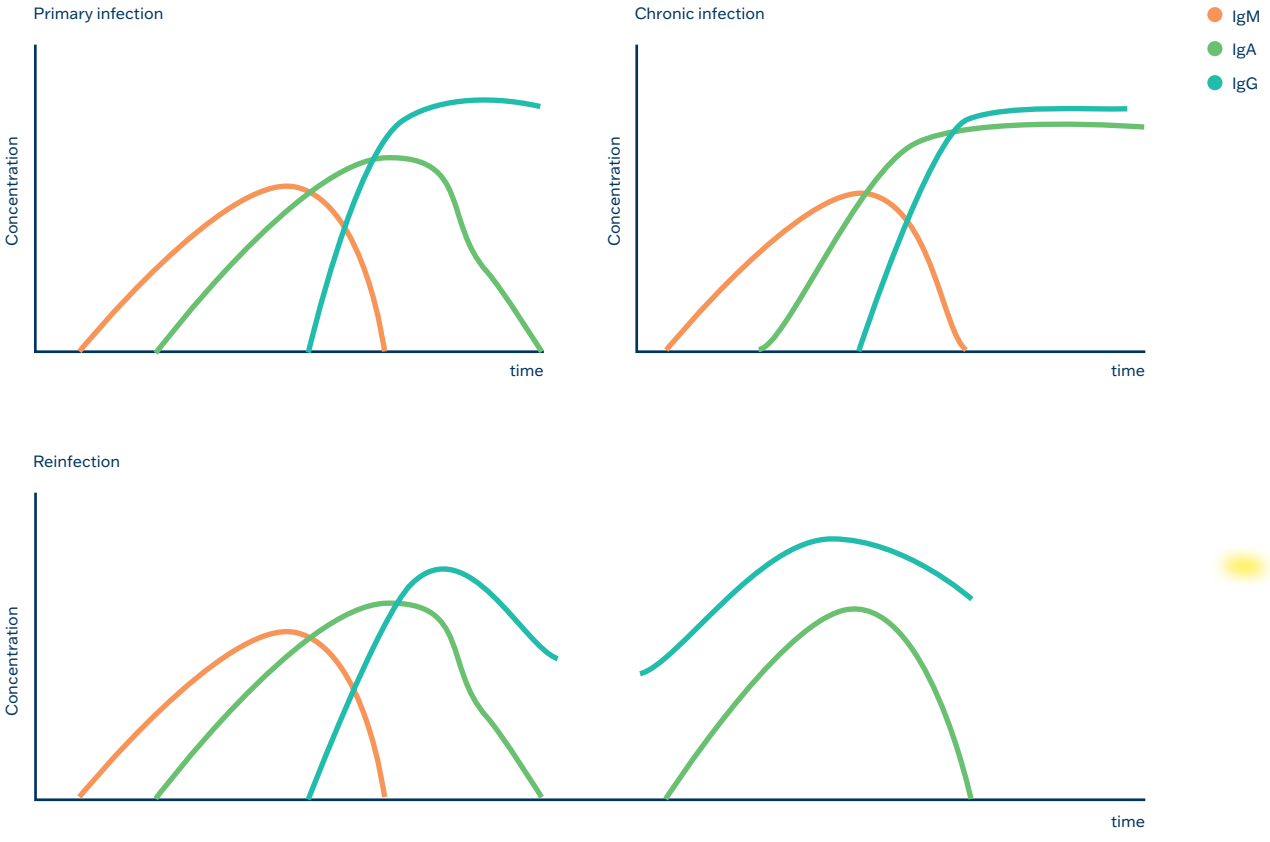
The presence of IgM antibodies in the absence of IgA and / or IgG is evidence of primary infection; IgM antibodies are generally not produced during reinfections.

IgA

These are produced later than IgM antibodies; their increase is typical during re-infections. IgA can be considered as a marker of active infection.

IgG

The isolated occurrence of IgG antibodies without clinical manifestations of the disease is characteristic of the postinfectious stage.



Clinical applications

- Detection of specific antibodies
- Disease stage diagnosis
- Identification of chlamydia infection

Interpretation of serology results

IgM	IgA	IgG	
–	–	–	Negative result
+	–/+	–	Early infection Confirmation by a repeated test after several weeks is recommended
–	–	+	Persistent IgG antibodies after recent infection
–	borderline/ low-positive	+	Recent infection Early reinfection
–	++	+	Ongoing infection (IgM may not be produced at all) Recurrent infection Chronic infection (confirmation should be performed by repeated testing after 1 and 3 months if symptoms persist)
+	+	+	Ongoing infection

Antigens

CLIA *Chlamydia pneumoniae*	CLIA *Chlamydia trachomatis*
Purified and inactivated native antigen	Mix of highly specific recombinant antigens

Test characteristics

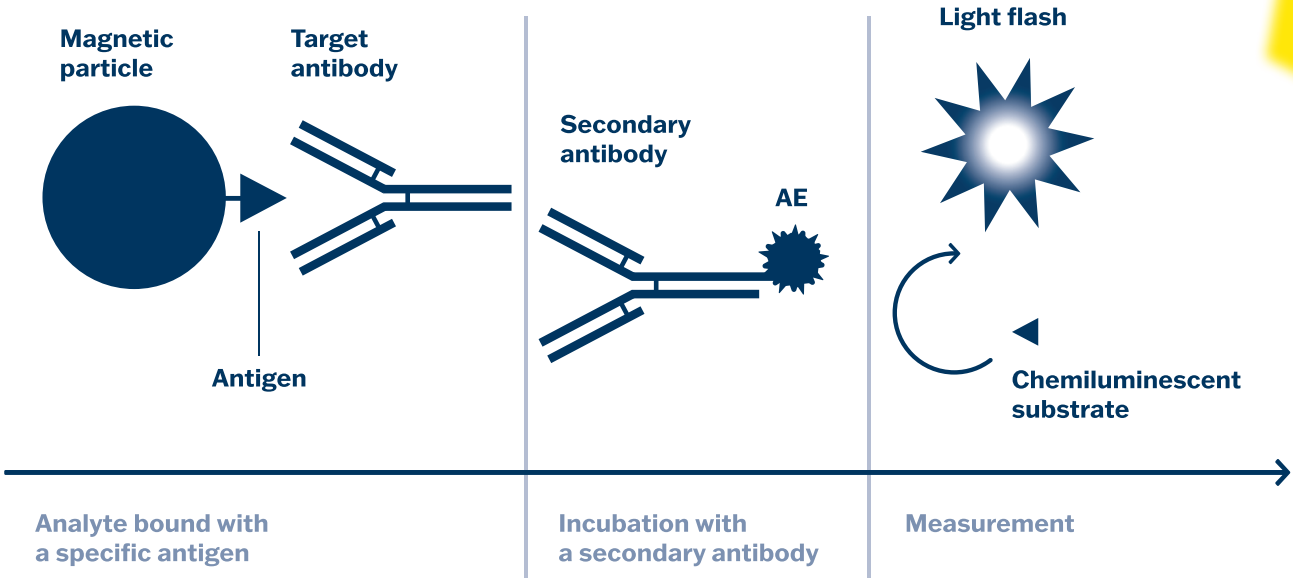
Kit	Calibration scale	Diagnostic sensitivity	Diagnostic specificity
CLIA Chlamydia pneumoniae IgA	5–100 U/ml	99,99 %	98,92 %
CLIA Chlamydia pneumoniae IgG	5–320 U/ml	96,63 %	96,55 %
CLIA Chlamydia pneumoniae IgM	5–100 U/ml	99,99 %	99,99 %
CLIA Chlamydia trachomatis IgA	2–320 U/ml	94.87 %	99.30 %
CLIA Chlamydia trachomatis IgG	0.1–320 U/ml	97.37 %	97.89 %
CLIA Chlamydia trachomatis IgM	0.5–160 U/ml	92.31 %	99.99 %

Correlation of methods

CLIA kits were compared to established ELISA kits from TestLine of the BioVendor Group. 97–99% agreement was found among the compared methods.

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 used to determine specific antibodies IgA, IgG and IgM against *Chlamydia pneumoniae* and *Chlamydia trachomatis* in human serum or plasma on a KleeYa® analyzer. Results are reported in U/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 U/ml

Advantages

- High diagnostic sensitivity and specificity
- Low sample (10 µl) and reagent consumption
- Short test time (30 min)
- Wide measuring range
- 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 used to determine IgA, IgG and IgM antibodies against *Chlamydia pneumoniae* and *Chlamydia trachomatis* in patient serum or plasma on a KleeYa® analyzer.

Kit	Catalogue number	Number of tests
CLIA Chlamydia pneumoniae IgA	CL-CPA100	100
CLIA Chlamydia pneumoniae IgG	CL-CPG100	100
CLIA Chlamydia pneumoniae IgM	CL-CPM100	100
CLIA Chlamydia trachomatis IgA	CL-ChtA100	100
CLIA Chlamydia trachomatis IgG	CL-ChtG100	100
CLIA Chlamydia trachomatis IgM	CL-ChtM100	100

Control set

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

Control set CLIA	Catalogue number	Number of tests
Control set CLIA Chlamydia pneumoniae IgA	CL-CPACON	2 x 20
Control set CLIA Chlamydia pneumoniae IgG	CL-CPGCON	2 x 20
Control set CLIA Chlamydia pneumoniae IgM	CL-CPMCON	2 x 20
Control set CLIA Chlamydia trachomatis IgA	CL-ChtACON	2 x 20
Control set CLIA Chlamydia trachomatis IgG	CL-ChtGCON	2 x 20
Control set CLIA Chlamydia trachomatis IgM	CL-ChtMCON	2 x 20

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