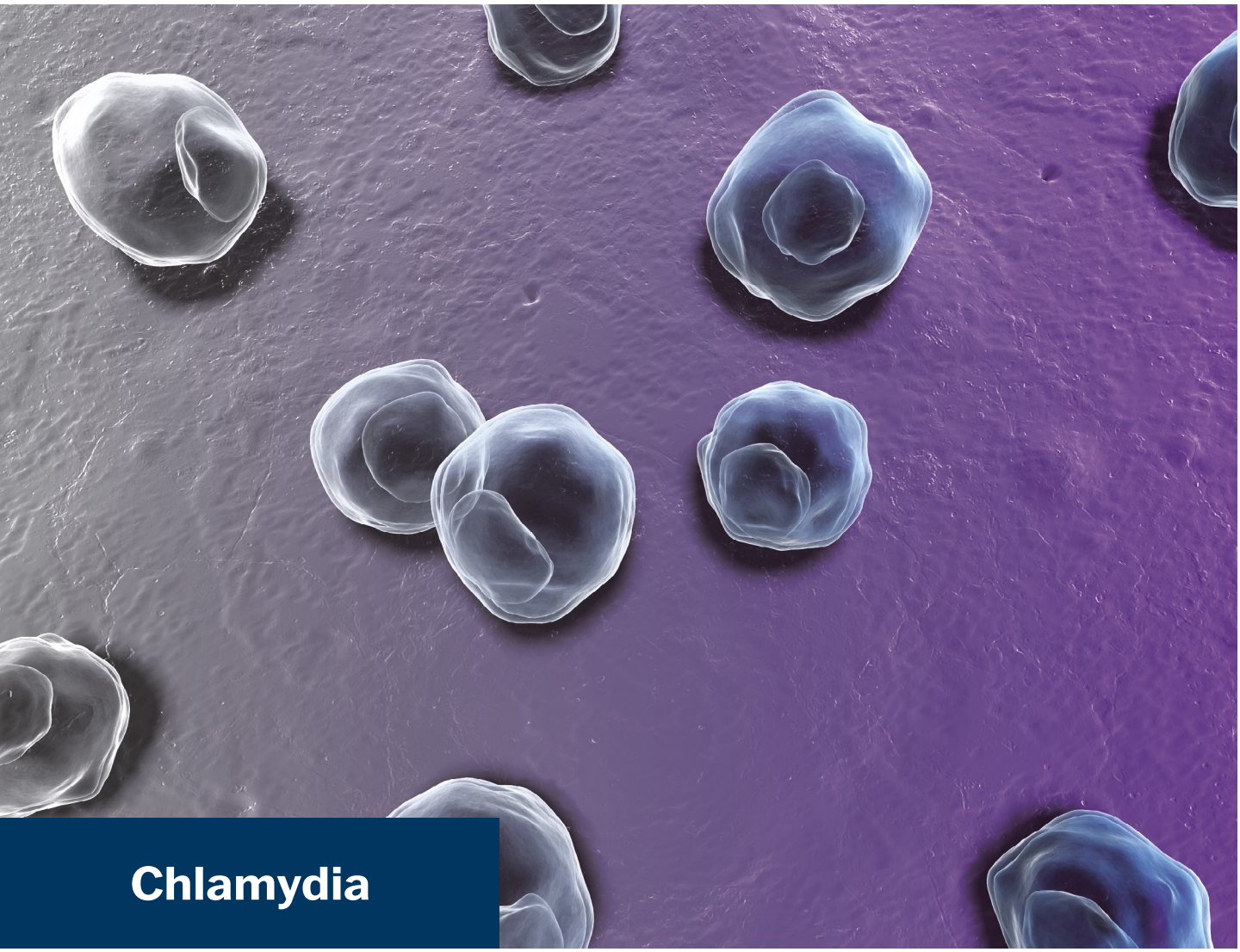


Chlamydia

Enzyme immunoassays for the diagnostics of Chlamydia infection

ELISA, **IMMUNOBLOT**, and **MICROBLOT-ARRAY** kits are optimized and validated for detection of IgA, IgG and IgM antibodies in human serum and plasma

IVD CE 2265

Diagnostic kits are intended for professional use in the laboratory.

BG TestLine®

Introduction

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) manifestation.

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).

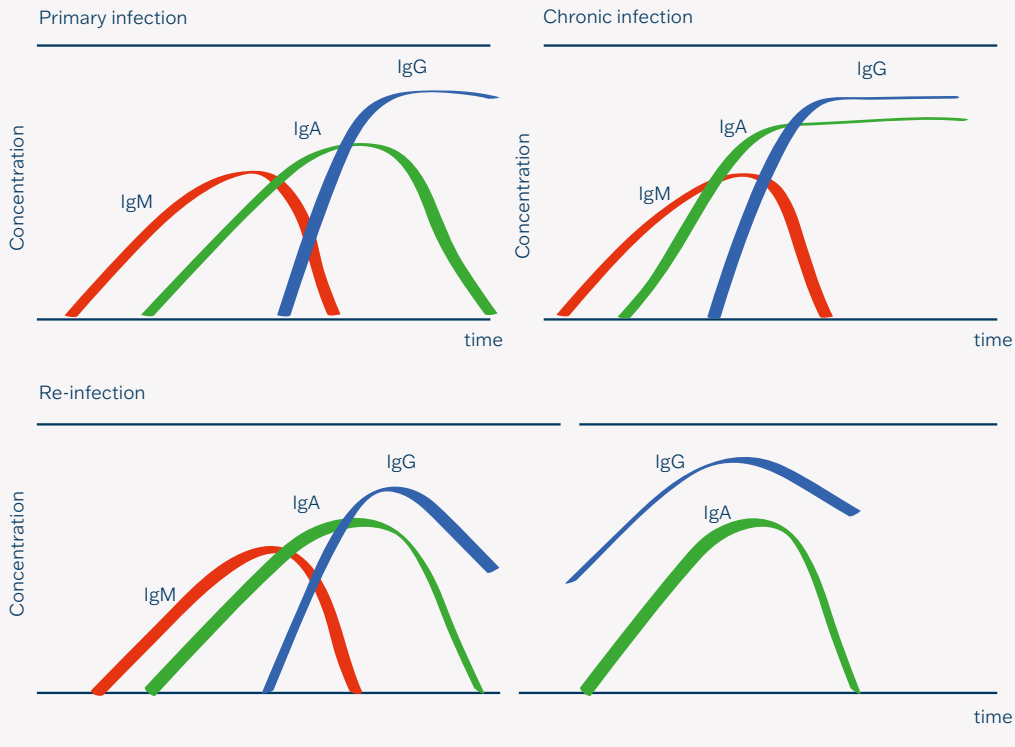
Production of antibodies IgA, IgG and IgM

IgM: Occurrence of IgM antibodies without the IgA and/or IgG antibodies being present is the evidence of primary infection; IgM antibodies are generally not produced during re-infections.

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

IgG: Isolated occurrence of IgG antibodies without clinical manifestations of the disease is characteristic of the post-infectious stage.

Detected seroconversion or quadruple increase of antibodies in pair sera (the first sample at the beginning of the illness, the second sample 2 to 3 weeks later) are a clear identification of active infection. Antibodies against Chlamydia can persist for a long time (months, or even years), yet it does not mean that it is an active infection.



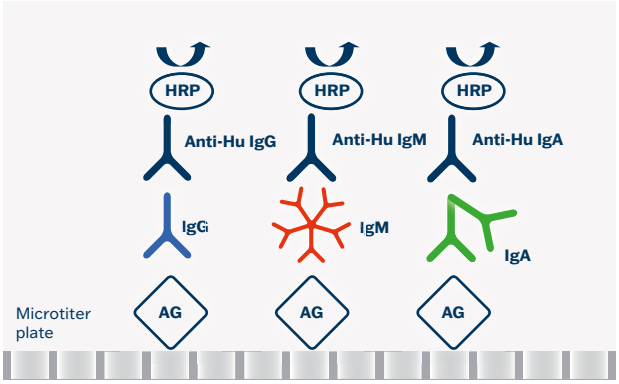
Results Interpretation

IgG	IgA	IgM	Interpretation
–	–	–	Negative result.
–	– / +	+	Eventual incipient infection. In order to confirm the results it is necessary to repeat the test
+	–	–	Persistent IgG antibodies after previous infection.
+	border line/low +	–	Previous infection. Beginning of reinfection.
+	++	–	On-going infection. (IgM not necessarily produced) Repeated infection. Chronic infection. (Chronicity confirmed by tests repeated after the 1st and 3rd month; occurrence of clinical symptoms)
+	+	+	On-going infection.

ELISA

Test Principle

The assays are based on a sandwich type of ELISA method.



Summary Protocol

Step		Test steps
	1.	Dilute samples – serum/plasma 1:101 (10 µl + 1 ml)
	2.	Pipette controls and diluted samples 100 µl – blank = empty well
	3.	Incubate 30 min. at 37 °C
	4.	Aspirate and wash the wells 5 times
	5.	Add 100 µl Conjugate – blank = empty well
	6.	Incubate 30 min. at 37 °C
	7.	Aspirate and wash the wells 5 times
	8.	Add 100 µl Substrate (TMB-Complete) – Including blank
	9.	Incubate 30 min. at 37 °C
	10.	Add 100 µl Stopping solution – Including blank
	11.	Read colour intensity at 450 nm

Antigens

EIA Chlamydia IgA, IgG, IgM
Inactivated and highly purified LPS antigen from *Chlamydia* sp. strains.

EIA Chlamydia pneumoniae IgA, IgG, IgM
Inactivated and purified antigen from a strain of *Chlamydia pneumoniae*

EIA Chlamydia pneumoniae REC IgA, IgG
Mixture of highly specific recombinant antigens (MOMP, OMP2, OMP4, OMP5 and p54)

EIA Chlamydia trachomatis IgA, IgG, IgM
Mixture of highly specific recombinant antigens from a strain of *Chlamydia trachomatis* with high content of MOMP

Clinical Application

- Screening test for detection of human infection caused by the *Chlamydia* sp.
- Checking therapy results by using quantitative (semiquantitative) determination

User Comfort

- Ready-to-use components
- Colour-coded components
- Interchangeable components
- Breakable colour-coded microplate strips
- CUT-OFF and calibrators included
- Semiquantitative evaluation (Index of Positivity) or quantitative evaluation (U/ml) of results
- Easy assay procedure

Advantages

- High diagnostic efficiency, good reproducibility and high dynamics of tests
- Identical assay procedure, total assay time 1.5 hours
- The possibility of independent verification using Certified control sera, complete customer support

Test Characteristics

ELISA	Diagnostic sensitivity	Diagnostic specificity
EIA Chlamydia IgA	98.8%	96.6%
EIA Chlamydia IgG	98.9%	98.9%
EIA Chlamydia IgM	95.9%	95.2%
EIA Chlamydia pneumoniae IgA	98.8%	99.0%
EIA Chlamydia pneumoniae IgG	98.9%	94.4%
EIA Chlamydia pneumoniae IgM	94.7%	99.9%
EIA Chlamydia pneumoniae REC IgA	99.0%	99.2%
EIA Chlamydia pneumoniae REC IgG	96.6%	98.8%
EIA Chlamydia trachomatis IgA	97.2%	97.7%
EIA Chlamydia trachomatis IgG	97.9%	97.6%
EIA Chlamydia trachomatis IgM	96.3%	99.2%

Types of kits

SmartEIA kits are designed for automated processing using the Agility® analyser.

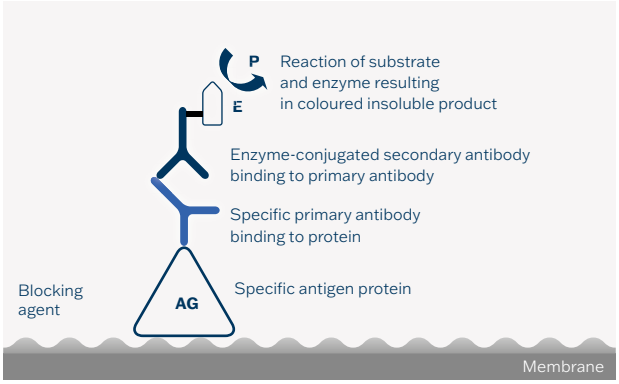
EIA

SmartEIA

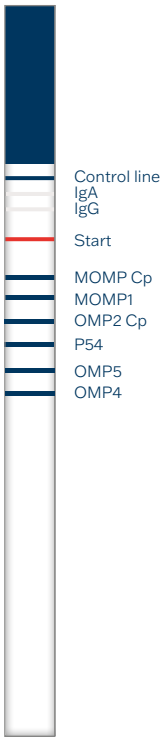
IMMUNOBLOT

Test Principle

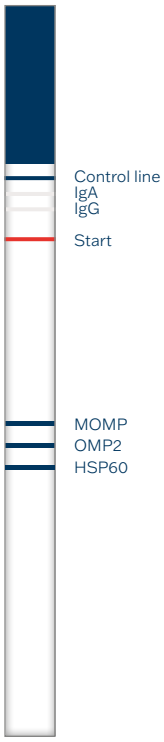
Recombinant antigens are transferred to a nitrocellulose membrane using a micro-dispensing method.



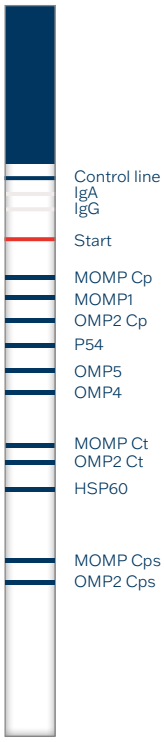
BLOT-LINE Chlamydia pneumoniae



BLOT-LINE Chlamydia trachomatis



BLOT-LINE Chlamydia



Clinical Application

- Detailed determination for the presence of anti-Chlamydia specific antibodies
- Confirmation of ambiguous results
- Confirmation for ELISA tests

Antigens

Chlamydia pneumoniae

MOMP Cp – dominant major outer membrane protein (species specific) – structural protein; metabolic function

MOMP1 – isoform, produced by posttranslational modification

OMP2 Cp – outer membrane protein (species specific) – structural protein of Chlamydia outer membrane complex

OMP4 – outer membrane protein

OMP5 – outer membrane protein

P54 – immunodominant outer antigen, highly specific to *Ch. pneumoniae* – sensitive marker for diagnosis of acute infection

Chlamydia trachomatis

MOMP Ct – dominant major outer membrane protein (species specific) – structural protein; metabolic function

OMP2 Ct – outer membrane protein (species specific) – structural protein of *Chlamydia* outer membrane complex

HSP60 – heat shock protein (GroEL); marker of chronic infection

Chlamydia psittaci

MOMP Cps – dominant major outer membrane protein (species specific) – structural protein; metabolic function

OMP2 Cps – outer membrane protein (species specific) – structural protein of *Chlamydia* outer membrane complex

Summary Protocol

Step		Test steps
	1.	Pipette Universal solution 2.5 ml
	2.	Strips soaking 10 min. at room temperature – Shaker
	3.	Aspirate
	4.	Dilute samples – serum/plasma 1:51 (30 µl + 1.5 ml)
	5.	Pipette Controls and diluted samples 1.5 ml
	6.	Incubate 30 min. at room temperature – Shaker
	7.	Aspirate samples and wash strips with 1.5 ml of Universal solution 3-times for 5 min. – Shaker
	8.	Pipette Conjugate 1.5 ml
	9.	Incubate 30 min. at room temperature – Shaker
	10.	Aspirate Conjugate and wash strips with 1.5 ml of Universal solution 3-times for 5 min. – Shaker
	11.	Pipette Substrate solution (BCIP/NBT) 1.5 ml
	12.	Incubate 15 min. at room temperature – Shaker
	13.	Aspirate Substrate solution and wash strips with 2 ml of distilled water 2-times for 5 min. – Shaker
	14.	Sticking and evaluation of strips

User Comfort

- Ready-to-use components, colour-coded strips
- Positive and Negative controls
- Control of reaction course and Conjugate control are present on the strip
- Interchangeable components
- Easy assay procedure
- Possibility of software evaluation

Advantages

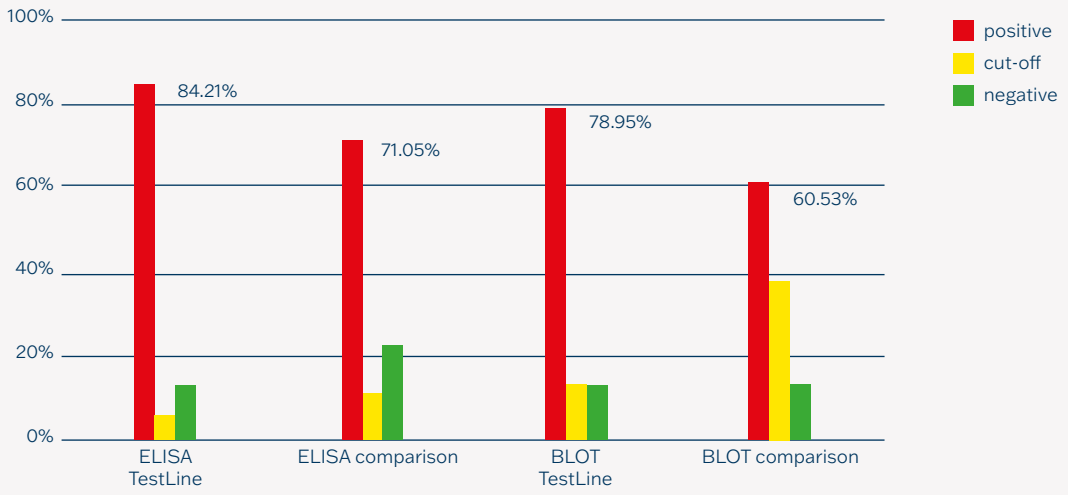
- Easy interpretation and reproducibility of results
- High diagnostic specificity and sensitivity
- Easy evaluation of the test
- Compatibility with all commercial immunoblot processing systems
- Customer support

Test Characteristics

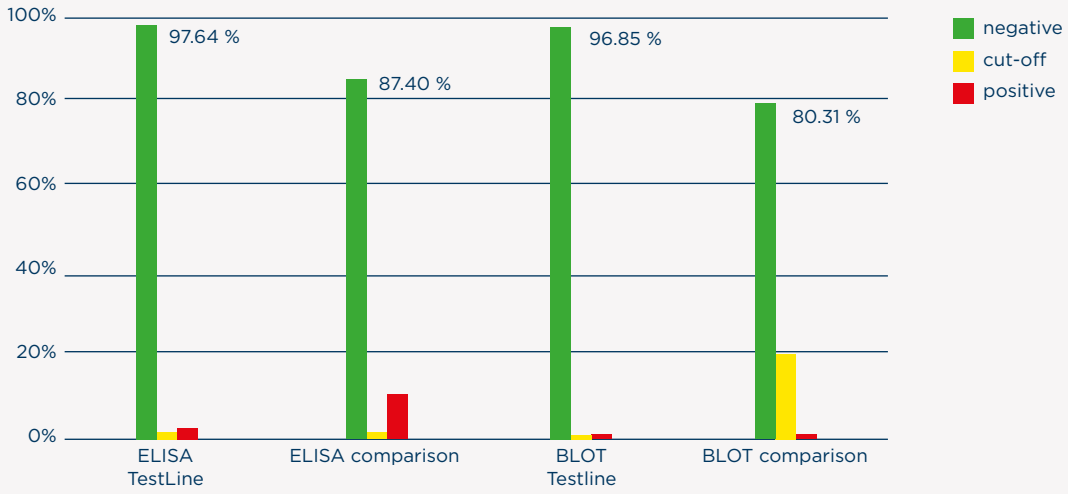
Pathogen	Diagnostic Sensitivity	Diagnostic Specificity
Chlamydia pneumoniae IgA	95.5%	93.6%
Chlamydia pneumoniae IgG	95.3%	94.3%
Chlamydia pneumoniae IgM	85.0%	94.7%
Chlamydia trachomatis IgA	97.4%	96.4%
Chlamydia trachomatis IgG	97.1%	98.0%
Chlamydia psittaci IgA	99.0%	99.0%
Chlamydia psittaci IgG	99.0%	99.0%

Comparative study

Reactivity of different diagnostic kits in a group of positive samples

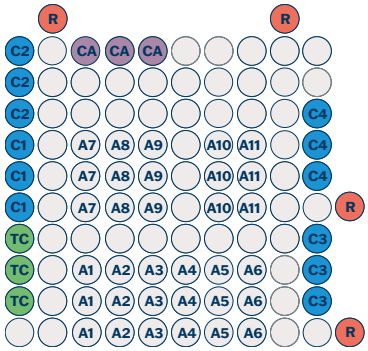


Reactivity of different diagnostic kits in a group of negative samples



MICROBLOT-ARRAY

Distribution of antigens and control spots



Description of antigens

A1 – MOMP Cp
A2 – MOMP1 Cp
A3 – OMP2 Cp
A4 – p54
A5 – OMP5 Cp
A6 – OMP4 Cp
A7 – MOMP Ct
A8 – OMP2 Ct
A9 – HSP60
A10 – MOMP Cps
A11 – OMP2 Cps

Description of control spots

- **R** – Reference
- **TC** – Test control
- **CA** – Conjugate control IgA
- **CG** – Conjugate control IgG
- **CM** – Conjugate control IgM
- **C1** – Calibration 1
- **C2** – Calibration 2
- **C3** – Calibration 3
- **C4** – Calibration 4

Protocol Summary

Step	Test steps
1.	Pipette Universal solution 150 µl
2.	Strips soaking 10 min. at room temperature
3.	Aspirate
4.	Dilute samples – serum/plasma 1:51 (10 µl + 500 µl)
5.	Pipette Controls and diluted samples 100 µl
6.	Incubate 30 min. at room temperature
7.	Aspirate samples and wash strips with 150 µl of Universal solution 3-times for 5 min.
8.	Pipette Conjugate 100 µl
9.	Incubate 30 min. at room temperature
10.	Aspirate samples and wash strips with 150 µl of Universal solution 3-times for 5 min.
11.	Pipette Substrate solution (BCIP/NBT) 100 µl
12.	Incubate 15 min. at room temperature
13.	Aspirate Substrate solution and wash strips with 200 µl of distilled water 2-times for 5 min.
14.	Dry and evaluate strips

User Comfort

- Low sample consumption
- Antigens spotted in triplicate – minimizing statistical variation
- Fully automatic assay processing and results evaluation
- Parallel testing of multiple markers simultaneously
- High sensitivity

Test Characteristics

Pathogen	Diagnostic Sensitivity	Diagnostic Specificity
Chlamydia pneumoniae IgA	94.4%	94.3%
Chlamydia pneumoniae IgG	94.6%	96.0%
Chlamydia trachomatis IgA	94.1%	96.0%
Chlamydia trachomatis IgG	92.7%	98.3%
Chlamydia psittaci IgA	100.0%	100.0%
Chlamydia psittaci IgG	80.0%	99.0%

Ordering Information

ELISA

Cat. No.	Product	No. of wells
ChA096	EIA Chlamydia IgA	96
ChG096	EIA Chlamydia IgG	96
ChM096	EIA Chlamydia IgM	96
ChpA96	EIA Chlamydia pneumoniae IgA	96
ChpG96	EIA Chlamydia pneumoniae IgG	96
ChpM96	EIA Chlamydia pneumoniae IgM	96
CpAR96	EIA Chlamydia pneumoniae REC IgA	96
CpGR96	EIA Chlamydia pneumoniae REC IgG	96
ChtA96	EIA Chlamydia trachomatis IgA	96
ChtG96	EIA Chlamydia trachomatis IgG	96
ChtM96	EIA Chlamydia trachomatis IgM	96
SK-ChA096	SmartEIA Chlamydia IgA	96
SK-ChG096	SmartEIA Chlamydia IgG	96
SK-ChM096	SmartEIA Chlamydia IgM	96
SK-ChpA96	SmartEIA Chlamydia pneumoniae IgA	96
SK-ChpG96	SmartEIA Chlamydia pneumoniae IgG	96
SK-ChpM96	SmartEIA Chlamydia pneumoniae IgM	96
SK-CpAR96	SmartEIA Chlamydia pneumoniae REC IgA	96
SK-CpGR96	SmartEIA Chlamydia pneumoniae REC IgG	96
SK-ChtA96	SmartEIA Chlamydia trachomatis IgA	96
SK-ChtG96	SmartEIA Chlamydia trachomatis IgG	96
SK-ChtM96	SmartEIA Chlamydia trachomatis IgM	96

SmartEIA kits are designed for automated processing using the Agility® analyser

Ordering Information

IMMUNOBLOT

Cat. No.	Product	No. of Tests
CAL020	BLOT-LINE Chlamydia IgA	20
CGL020	BLOT-LINE Chlamydia IgG	20
CpAL20	BLOT-LINE Chlamydia pneumoniae IgA	20
CpGL20	BLOT-LINE Chlamydia pneumoniae IgG	20
CpML20	BLOT-LINE Chlamydia pneumoniae IgM	20
CtAL20	BLOT-LINE Chlamydia trachomatis IgA	20
CtGL20	BLOT-LINE Chlamydia trachomatis IgG	20
BD-CAL024	BlueBLOT-LINE Chlamydia IgA	24
BD-CGL024	BlueBLOT-LINE Chlamydia IgG	24

The BlueBLOT-LINE kits are designed for automatic processing using BlueDiver® analyser

Microblot-Array

Cat. No.	Product	No. of Tests
CAMA096	Microblot-Array Chlamydia IgA	96
CGMA096	Microblot-Array Chlamydia IgG	96

BG TestLine®

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CERTIFIED LR ISO 9001 · ISO 13485

Company is certified to the quality management system standards ISO 9001 and ISO 13485 for in vitro diagnostics.

V10/2022