

recomLine Chlamydia IgG recomLine Chlamydia IgA [IgM]

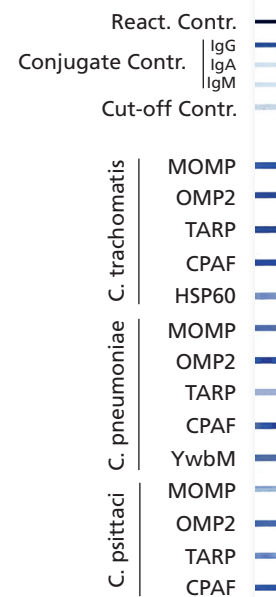
Strip-Immunoassay with antigens produced by recombinant techniques for the detection of IgG, IgA and IgM antibodies against *Chlamydia trachomatis*, *Chlamydia pneumoniae* and *Chlamydia psittaci*

Chlamydia trachomatis is worldwide one of the most causative agents of sexually transmitted diseases with an incidence of about 50 million diseases. Besides the urogenital tract, eyes and the respiratory tract of newborns can be infected by *Chlamydia trachomatis*. The clinical pictures involve primarily urethritis, Trachoma, Lymphogranuloma venereum and can finally cause sterility, conjunctivitis and reactive arthritis.

The importance of the 1986 identified bacterium *Chlamydia pneumoniae* is shown by a serological prevalence of about 50%. *C. pneumoniae* infects mainly the respiratory tract and causes bronchitis, pneumonia and sinusitis amongst others.

Chlamydia psittaci is the causative agent of ornithosis, a rare anthroponosis in Germany. *Chlamydia psittaci* infects usually only persons who have contact to pet birds and farmbirds.

The *recomLine* Chlamydia is the only test system, which allows the detection of the immune response against all three human pathogenic Chlamydia-species in one step and on one strip. Primarily it has been designed as a confirmatory assay but it can also be applied as a screening assay. The *recomLine* Chlamydia comprises of different recombinant, species specific antigens sprayed onto nitrocellulose strips so that it is possible to detect IgG, IgA and IgM antibodies against immunodominant antigens of *C. trachomatis*, *C. pneumoniae* and *C. psittaci*.



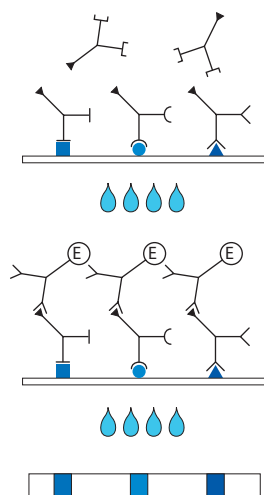
Product advantages

- New recombinant species specific antigens (CPAF, TARP, YwbM (only for *C. pneumoniae*))
- Separate detection of IgG, IgA and IgM antibodies possible
- Safe evaluation due to strip specific controls (cut-off and conjugate control)
- Clarification of the immunestatus of a possible *C. trachomatis*, *C. pneumoniae* and *C. psittaci* - infection in one step and on one strip possible
- The only assay of a specific serological diagnostic of *C. psittaci*
- Easy test procedure; automation possible – easy and objective evaluation and documentation by *recomScan* software
- Test procedure and reagents identical in all MIKROGEN strip tests – reagents exchangeable
- Application as well as screening as confirmation assay possible
- CE label: The *recomLine* Chlamydia tests meet the high standard of the EC directive 98/79/EC on in vitro diagnostic medical devices

Recombinant Chlamydia antigens

Antigen	Species	Characteristics
MOMP	<i>C. tr.</i> , <i>C. pn.</i> , <i>C. ps.</i>	„major outer membrane protein“; immunodominant outer membrane antigen
OMP2	<i>C. tr.</i> , <i>C. pn.</i> , <i>C. ps.</i>	„outer membrane protein 2“; outer membrane protein with high cysteine concentration; universal marker for an infection with the species Chlamydia
TARP	<i>C. tr.</i> , <i>C. pn.</i> , <i>C. ps.</i>	„translocated actin-recruiting protein“; binding actin
CPAF	<i>C. tr.</i> , <i>C. pn.</i> , <i>C. ps.</i>	„chlamydial protease-like activity factor“; virulence factor
HSP60	<i>C. tr.</i>	„heat shock protein 60“, potential indicator for chronically inflammable ascending infection of <i>C. trachomatis</i> (e.g. tubal infection)
YwbM	<i>C. pn.</i>	hypothetical protein; not existing for <i>C. trachomatis</i> and for <i>C. psittaci</i>

Test Principle and Procedure



1st Incubation

A test strip loaded with Chlamydia antigens is incubated with diluted serum or plasma in a dish for **1 hour**.

wash 3 times

2nd Incubation

Peroxidase conjugated anti-human antibodies (IgG, IgA or IgM specific) are added. Incubate for **45 minutes**.

wash 3 times

Color reaction

8 minutes after addition of the coloring solution, insoluble colored bands develop at the sites on the test strips occupied by antibodies.

Examples

Determination of the immunostatus of different patients after infection with *Chlamydia trachomatis*, *Chlamydia pneumoniae* and *Chlamydia psittaci* on one test strip.

<i>C. trachomatis</i>						<i>C. pneumoniae</i>						<i>C. psittaci</i>						interpretation
Cut-off	MOMP	OMP2	TARP	CPAF	HSP60	MOMP	OMP2	TARP	CPAF	YwbM	MOMP	OMP2	TARP	CPAF	YwbM			
IgG	3+	2+	2+	2+	-	pos	+	+	+	-	-	pos	-	+	+	+	pos	<i>C. trachomatis</i> and <i>C. pneumoniae</i> infection
IgM	+	+	2+	-	-	pos	+	-	+	-	-	pos	-	-	-	-	neg	
IgA	+	-	+	-	-	pos	-	-	-	-	-	neg	-	-	-	-	neg	
IgG	-	-	-	-	-	neg	3+	-	+	-	2+	pos	-	-	-	-	neg	former <i>C. pneumoniae</i> infection
IgM	-	-	-	-	-	neg	+/-	-	-	-	-	neg	-	-	-	-	neg	
IgA	-	-	-	-	-	neg	-	-	-	-	-	neg	-	-	-	-	neg	
IgG	+	2+	-	-	+	pos	+/-	2+	-	-	-	neg	+	+	-	+	pos	<i>C. psittaci</i> and former <i>C. pneumoniae</i> / <i>C. trachomatis</i> infection
IgM	-	-	-	-	-	neg	-	-	-	-	-	neg	-	-	-	-	neg	
IgA	-	-	+/-	-	-	neg	-	-	-	-	-	neg	2+	-	-	-	pos	

Evaluation

Diagnostic Sensitivity

recomLine Chlamydia IgG, IgA [IgM]	<i>C. trachomatis</i>		<i>C. pneumoniae</i>		<i>C. psittaci</i>	
	IgG (n=82)	IgA (n=39)	IgG (n=82)	IgA (n=20)	IgG (n=8)	IgA (n=8)
positive	80	37	80	20	6	8
borderline	2	2	1	0	2	0
negative	0	0	1	0	0	0
sensitivity %	100*	100*	99*	100	100*	100

Diagnostic Specificity

recomLine Chlamydia IgG, IgA [IgM]	<i>C. trachomatis</i>			<i>C. pneumoniae</i>			<i>C. psittaci</i>		
	IgG (n=110)	IgA (n=134)	IgM (n=137)	IgG (n=51)	IgA (n=87)	IgM (n=137)	IgG (n=93)	IgA (n=96)	IgM (n=137)
negative	110	134	137	51	87	137	93	96	137
borderline	0	0	0	0	0	0	0	0	0
positive	0	0	0	0	0	0	0	0	0
specificity %	100	100	100	100	100	100	100	100	100

* incl. borderline results

Due to very low number of defined IgM positive samples, no sensitivity has been calculated.

Article-No

6172 **recomLine Chlamydia IgG**
Reagents for 20 determinations

6173 **recomLine Chlamydia IgA [IgM]**
Reagents for 20 determinations

Storage

At +2°C - +8°C