SeroCP™ CE 0483

Chlamydia pneumoniae causes approximately 10% of community-acquired pneumonia and 5% of pharyngitis, bronchitis, and sinusitis. *C. pneumoniae* infection is ubiquitous. Virtually everyone is infected at some point in their lives and re-infection commonly occurs.
The clinical symptoms of *C. pneumoniae* pulmonary infections are similar to those caused by other respiratory pathogens. Coughing is very common and prolonged. Although pneumonia is often relatively mild, recovery is slow, even with antibiotic therapy.
Considerable knowledge of the epidemiology of *C. pneumoniae* infection has been derived from serological studies. Antibodies against *C. pneumoniae* are rare in children under the age of 5, except in developing and tropical countries. The antibody prevalence increases rapidly between the ages of 5 to 14, reaches 50% at the age of 20 and continues to increase slowly to between 70% and 80% at ages 60 to 70.
The spectrum of *C. pneumoniae* infections has been extended to atherosclerotic vascular disease(1) and its clinical manifestations. Sero-epidemiologic studies have associated *C. pneumoniae* antibodies with coronary artery disease(2), myocardial infarction(2), carotid artery disease and cerebrovascular disease(3).

Diagnosis

Chlamydia pneumoniae is an intracellular pathogen and therefore grows poorly in culture and although highly specific, the technique is time-consuming and technically difficult.
Therefore, routine diagnosis of *Chlamydia pneumoniae* infection is usually based on serology.
There are two patterns of antibody response to acute *C. pneumoniae* infection. In primary infection, the IgM antibodies rise within 2 to 4 weeks. The IgG response is delayed till 6 to 8 weeks after the onset of the illness and the IgA antibody response is weak or absent. In re-infection, IgG and IgA antibodies promptly rise and therefore are the primary diagnostic markers. IgM antibodies are either absent or appear at low titer levels.
Persistent or elevated levels of IgA antibodies are suggested as a diagnostic marker for chronic infections.

The SeroCP™ product line is a well known and established ELISA-based assay for the qualitative detection of antibodies to *C. pneumoniae* in human serum. Since their release, the kits have been used extensively in routine diagnosis and research studies. The assay utilizes highly purified *C. pneumoniae* (TWAR-183) elementary bodies as antigens.

A comprehensive study performed in Germany(4) found the SeroCP™ assay to be 98% specific and 96% sensitive for the detection of specific IgG antibodies to *C. pneumoniae*.

(1) J Infect. (1995);30:21-28
(2) Circulation (2001);103:1064-1070
(3) Stroke (1998);29:404-410
(4) J. Clin. Microbiol. (2002);40:1603-1609

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SeroCP Quant CE 0483

The SeroCP Quant product line is a second generation ELISA-based assay for the semi-quantitative determination of IgG and IgA antibodies to *Chlamydia pneumoniae* in human serum.

SeroCP Quant incorporates 2 unique features:

- Semi-quantitative results: Using the kit's 3 ready to use calibrators - P10, P50 and P100 - a standard curve of arbitrary Binding Units/mL (BU/mL) against absorbent O.D. units is plotted. The standard curve enables close monitoring of the patients' IgG and IgA antibody dynamics.
A significant increase in specific antibody titer in paired sera is accepted as a serological indication of an acute *C. pneunoniae* infection. Thus, quantitative results provide valuable diagnostic information on the state of the infection.

- Well-established correlation with the micro-immunoflourescence (MIF) method: Following a comprehensive comparative study SeroCP Quant BU/mL units, were correlated with SeroFIA™ (MIF) End Point Titer (Table 1 & 2). Hence, SeroCP Quant results can be reported either as BU/mL or as End Point Titer units.

SeroCP Quant is an advanced diagnostic product that enables quantitation of IgG and IgA antibodies previously possible only by MIF titration. Moreover, since it is an ELISA assay, results reading is objective rather than subjective as in the MIF method and the assay can be automated by using a standard ELISA sample processor.

Table 1: The correlation between SeroCP Quant IgG BU/mL and SeroFIA™ IgG End Point Titer.

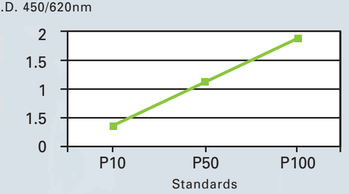
	SeroCP Quant Range of BU/mL	SeroFIA™ End Point Titer
IgG	<10	<1:64 (Neg)
	10-30	1:64
	31-50	1:128
	51-80	1:256
	>80	>1:512

Table 2: The correlation between SeroCP Quant IgA BU/mL and SeroFIA™ IgA End Point Titer.

	SeroCP Quant Range of BU/mL	SeroFIA™ End Point Titer
IgA	<10	<1:32 (Neg)
	10-35	1:32
	36-65	1:64
	66-110	1:128
	>110	>1:256

Standard curve

- Assures the quantitative capability of the assay
- Assures reproducibility of the assay



SeroMP™ CE

Mycoplasma pneumoniae causes 15% to 20% of community-acquired pneumonia in older children and adults and a variety of respiratory tract infections in younger children. It is spread by close personal contact and has a long incubation period.
M. pneumoniae infections occur sporadically throughout the year while outbreaks tend to occur in the late summer and the fall. Epidemics tend to occur every 4-8 years in the general population but tend to be more frequent within closed populations e.g., army camps, dormitories, nursing-homes etc.
The spectrum of *M. pneumoniae* infections extend to endocarditis and myocarditis, where it appears to be an important cause of death in infected patients.

Typical symptoms include fever, coughing, bronchitis, a sore throat, headaches and generalized malaise. Since clinical examination does not allow differentiating between the etiological agents responsible for primary atypical pneumonia, diagnosis of *M. pneumoniae* infection relies mainly on laboratory tests.

The SeroMP™ product line is Savyon Diagnostics' third generation kit for semi-quantitative determination of antibodies to *Mycoplasma pneumoniae* in human serum. This assay utilizes as antigen a unique enriched P1 membrane protein preparation of *M. pneumoniae*. Semi-quantitation of the results is obtained by utilizing 3 ready to use calibrators - P10, P50 and P100.

Diagnosis

Mycoplasma pneumoniae culture is successful in only 40-90% of cases and requires 2-3 weeks to grow. The organism also resides in the respiratory tract for several weeks without causing infection. Therefore, isolation of the organism may not indicate acute infection.
The routine laboratory methods for diagnosis of *M. pneumoniae* infection are based primarily on serological analysis of the patient's serum. ELISA methods provide high sensitivity and specificity and enable a differential determination of specific IgM, IgG and IgA antibodies.
The presence of IgM antibodies in a single serum sample provides evidence for an acute, either current or recurrent, infection. A negative result does not rule out an acute infection, since the specimen may have been collected before detectable antibody is present or after the antibody level has decreased below detectable levels.
A significant change in IgG and/or IgA antibodies titers (particularly in elderly populations), between paired samples drawn 2-3 weeks apart, should be sought in order to confirm *M. pneumoniae* infection. Detection of IgA antibodies is of diagnostic value in coronary artery disease patients. It was reported that high IgA antibody titers independently and significantly can predict an increased hazard of death or MI events in patients with severe, angiographically-defined coronary artery disease. This finding provides further evidence for the association between *M. pneumoniae* and coronary artery disease.

The table presents results of a comprehensive in-house study. For sensitivity study, 317-paired sera were collected from a population with community-acquired pneumonia. The first serum sample of each patient was obtained within 48 hours after hospitalization or visit to the emergency room. Average interval between first and second sample was 31 days. For specificity study, serum samples from 99 blood donors were collected. Consensus results represent agreement of at least 2 commercial methods for IgM and IgG and the only commercial method available for IgA.

SeroMP™ / Consensus results	IgM		IgG		IgA	
	Pos.	Neg.	Pos.	Neg.	Pos.	Neg.
Pos.	45	1	39	2	12	1
Neg.	2	49	0	38	9	35
Sensitivity (%)	97.8		95.1		92.3	
Specificity (%)	96		100		79.5	

SeroPertussis™

CE

Whooping Cough (Pertussis), caused by the bacterium Bordetella pertussis, is a relatively mild disease in previously vaccinated adults but has a significant mortality rate in infants.
The incidence of this disease in developed countries declined dramatically after vaccines were introduced in the mid 1940s. However, since 1980 the incidence of pertussis has been rising and today it is regarded as a re-emerging disease.
Infants and young children continue to have the highest rates of pertussis, although these rates have not increased. However, the incidence among adolescents and adults has increased substantially.
Investigations of outbreaks have documented that adults develop infection and then transmit the organism to susceptible children or other adults. Thus, previously immunized adults and adolescents are the main source of transmission of Bordetella pertussis.
Though vaccination is highly effective for young children, immunity diminishes in many adolescents and adults implicating that a different vaccination routine is required.
It is rather difficult to diagnose pertussis infection in adults since the infection may have an atypical presentation with a modified clinical course. This may lead to misdiagnosis and delayed treatment or lack of treatment all together.

Diagnosis

Pertussis-like coughing can be caused by other pathogens, e.g., Mycoplasma pneumoniae, Chlamydia pneumoniae and adenoviruses. Therefore, the diagnosis of pertussis, particularly in the vaccinated population, relies mainly on laboratory confirmation.
Culture of Bordetella pertussis is laborious, insensitive and highly dependent on sample collection (nasopharigeal sample that is difficult to obtain) and transportation (samples should be processed immediately). Also, pertussis is not suspected in adults until they have had a prolonged period of coughing. Thus, very little organism is left in the nasopharynx when the culture is obtained and consequently no organism is isolated. Similarly, the PCR assay sensitivity rapidly decreases during the disease's progression.
ELISA-based serology is the main approach used for laboratory diagnosis with Pertussis toxin (PT) and filamentous hemagglutinin (FHA) as the preferred antigen combination.
The detection of specific IgA and IgM antibodies is indicative of acute infection and is useful for the differential diagnosis of pertussisform syndromes of longer duration. For Pertussis-like primary infection, IgM is the preferred marker, while in pre-exposed persons, IgA is the preferred marker. IgG antibodies can be used to diagnose active infection and distinguish acute infection from immunization level when paired sera are available and a rise in antibody level can be demonstrated.

The **SeroPertussis™** product line utilizes purified Bordetella pertussis extract, enriched with PT and FHA, as antigens for detecting specific antibodies to Bordetella pertussis in human serum.

SeroPertussis™ IgG is a semi-quantitative assay using 3 ready to use calibrators - P10, P50 and P100 - to draw a calibration curve correlating O.D. readings and arbitrary BU/ml units.

SeroPertussis™ IgA/IgM is a qualitative assay designed to provide flexibility in detecting IgA and/or IgM antibodies.

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RTI Panel

RTI panel advantages:

- Ready to use controls and calibrators
- Unified reagents - Wash buffer, TMB Substrate, Stop Solution and Conjugate Diluent - for all assays
- Automation compatibility with ELISA sample processors
- Convenience - Based on break-apart 8 wells strip format, equally suited for both high or low volume use

Ordering information

Cat. No.	Product	Kit Configuration
A192-01	SeroCP™ IgM	96 Tests
B192-01	SeroCP™ IgM	192 Tests
A191-01	SeroCP™ IgG	96 Tests
B191-01	SeroCP™ IgG	192 Tests
A193-01	SeroCP™ IgA	96 Tests
B193-01	SeroCP™ IgA	192 Tests
A291-01	SeroCP Quant IgG	96 Tests
A293-01	SeroCP Quant IgA	96 Tests
511-01	SeroFIA™ IgG Chlamydia	105 Tests
512-01	SeroFIA™ IgM Chlamydia	105 Tests
513-01	SeroFIA™ IgA Chlamydia	105 Tests
570-01	SeroFIA™ C. Psittaci	105 Tests
580-01	SeroFIA™ C. Trachomatis	105 Tests
590-01	SeroFIA™ C. Pneumoniae	105 Tests
A261-01M	SeroMP™ IgG	96 Tests
A262-01M	SeroMP™ IgM	96 Tests
A263-01M	SeroMP™ IgA	96 Tests
A1261-01M	SeroMP™ Recombinant IgG	96 Tests
A1262-01M	SeroMP™ Recombinant IgM	96 Tests
A1263-01M	SeroMP™ Recombinant IgA	96 Tests
A231-01	SeroPertussis™ IgG	96 Tests
A233-10	SeroPertussis™ IgA/IgM	96 Tests

Sero-Line assays procedure:

Add controls, calibrators and diluted samples to microtiter plate wells coated with antigens
▼
Incubate 1h at 37°C
▼
Wash 3 times
▼
Add HRP-Conjugate
▼
Incubate 1h at 37°C
▼
Wash 3 times
▼
Add TMB-Substrate
▼
Incubate 15 min at room temperature
▼
Add Stop Solution
▼
Read absorbance and interpret results

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Serodiagnosis of atypical Respiratory Tract Infections

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