



**Instruction for use**

# **EIA Chlamydia pneumoniae IgG**

**REF** ChpG96



**Kit for professional use**



 **TestLine Clinical Diagnostics s.r.o.**  
Křižíkova 68, 612 00 Brno, Czech Republic  
Tel.: +420 541 248 311  
FAX: +420 541 243 390  
E-mail: [info@testlinecd.com](mailto:info@testlinecd.com)  
[www.testlinecd.cz](http://www.testlinecd.cz)  
[www.testlinecd.com](http://www.testlinecd.com)

**CONTENT**

1	Document Records.....	3
2	Intended Purpose .....	3
3	Introduction.....	3
4	Test Principle .....	3
5	Materials Provided.....	4
6	Other Material Required for Test Performance.....	5
7	Storage and Stability .....	5
8	Preparation of Reagents .....	6
9	Preparation of Samples.....	6
10	Assay Procedure .....	7
11	Working Schedule .....	8
12	Quality Control.....	9
13	Results Interpretation.....	10
14	Analytical Performance.....	11
15	Clinical Performance .....	14
16	Safety Precautions .....	15
17	Procedural Notes .....	16
18	References .....	17
19	IFU Symbols.....	18

## 1 Document Records

Revision No.	Version No.	Revision Description
ZM01566	17	Revision according to IVDR requirements

## 2 Intended Purpose

The immunoenzymatic assay is intended for the diagnosis of *Chlamydia pneumoniae* infection using IgG antibodies in human serum or plasma in the general population. The semi-quantitative and quantitative manual assay is designed for professional use in a laboratory.

## 3 Introduction

*Chlamydiae* are gram-negative bacteria, obligate intracellular parasites.

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 species of the genus *Chlamydia* 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, pharyngitis, 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 (mammalian strains) manifestation.

In case of chlamydial infection, the anti-lipopolysaccharide (LPS) antibodies are produced in organism within 5 to 20 days after the beginning of the infection. After that period, antibodies to the species-specific proteins are detectable. Serological methods as ELISA, BLOT, MIF, CFT, etc. are used for *Chlamydia sp.* identification. The stage of the disease (acute, chronic, late phase or seronegativity) can be indicated by the specific IgM, IgA and IgG antibodies determination in blood.

## 4 Test Principle

The kit is intended for detection of specific IgG antibodies in a sample by means of a sandwich type of the EIA method (i.e. a solid phase coated with specific antigen – antibody from the analysed sample – labelled antibody). The labelled antibody (conjugate) is an animal immunoglobulin fraction to human IgG conjugated with horseradish peroxidase. Peroxidase activity is determined in the test by a substrate containing TMB. Positivity is indicated when blue colour appears; after stopping solution has been added, blue changes to yellow. The yellow colour intensity is measured by a photometer at 450 nm, and it is proportional to the concentration of specific IgG antibodies in the sample.

### Antigen Used

Purified and inactivated antigen of *Chlamydia pneumoniae*

## 5 Materials Provided

MICROPLATE		<b>Microtitre Plate</b>	1 pc	
		coated with antigen, 12 x 8 wells in bag with desiccant		
CONTROL	-	CAL1	<b>Negative Control (Calibrator 1) 5 U/ml</b>	1 × 2 ml
		Solution containing no specific human antibodies, ready to use		
CUTOFF		CAL2	<b>CUT-OFF (Calibrator 2) 20 U/ml</b>	1 × 3 ml
		Solution containing specific human antibodies in cut-off concentration, ready to use		
CONTROL	+	CAL3	<b>Positive Control (Calibrator 3) 80 U/ml</b>	1 × 2 ml
		Solution containing specific human antibodies, ready to use		
CAL4			<b>Calibrator 4 (320 U/ml)</b>	1 × 2 ml
		Solution containing specific human antibodies, ready to use		
CONJUGATE			<b>Conjugate</b>	1 × 15 ml
		Solution containing peroxidase labelled animal immunoglobulin to human IgG, ready to use		
DILUENT 2			<b>Sample Diluent 2</b>	1 × 105 ml
		Buffer with protein stabilisers, ready to use		
SUBSTRATE 2			<b>TMB-Complete 2</b>	1 × 15 ml
		Chromogenic substrate solution containing TMB/H <sub>2</sub> O <sub>2</sub> , ready to use		
WASH 20x			<b>Wash Solution</b>	1 × 75 ml
		20× concentrated buffer		
STOP			<b>Stop Solution</b>	1 × 15 ml
		Acid solution, ready to use		
			<b>Instructions for use</b>	1 pc

## 6 Other Material Required for Test Performance

Single- and multichannel pipettes  
Disposable tips  
Microplate washer  
Timer  
Incubator (37 °C)  
Microplate reader

## 7 Storage and Stability

Store the kit at +2 °C to +8 °C. Do not freeze. If the kit is stored as described, the labelled expiration date is valid. The expiration date is indicated on the package. The opened kit should be used within three months.

### Sample Preparation and Storage

Samples listed in the intended use may be used for the examination. The following human body liquids can be used for testing: serum and citrate plasma. Anticoagulants in the plasma (except for citrate) as well as bacterially contaminated, haemolytic or chylous samples can affect the test results.

A coagulating blood collection tube is recommended for serum collection. A citrated plasma collection bag is recommended for plasma collection. Other types of plasma (EDTA, heparin) may be used but they are not recommended since anticoagulants may affect the test result.

Follow the manufacturer's instructions when using commercial or other specially modified samples. Clinical samples collected within standard medical procedures into standardized tubes are ready for immediate use. Centrifugation or other separations are not required.

The examined samples can be stored at +2 °C to +8 °C for a maximum of 1 week.

## 8 Preparation of Reagents

Dilute the Wash Solution 1:20 (1 part of solution and 19 parts of distilled water); e.g. 75 ml of the concentrated Wash Solution + 1425 ml of distilled water.

Salt crystals might develop in the bottle with the concentrated Wash Solution. Prior to use, it is necessary to dissolve the crystals by warming the bottle in a water bath. The diluted Wash Solution is stable at +2 °C to +8 °C for one week.

The Controls and the Calibrators are supplied ready to use, do not dilute further!

The Conjugate is supplied ready to use, do not dilute further!

TMB-Complete is a one-component chromogenic substrate solution ready to use, do not dilute further!

### Interchangeability of reagents

The Sample Diluent, TMB-Complete and the Avidity Solution are interchangeable in EIA kits of TestLine Clinical Diagnostics s.r.o., provided they have the identical numeric marking (e.g. Sample Diluent 2, Sample Diluent 3, etc.). The Stop Solution and the Wash Solution are universal in all kits.

## 9 Preparation of Samples

Mix gently the Sample Diluent prior to use.

### Dilution of sera and plasma samples

Dilute well mixed samples 1:101 with the Sample Diluent:

E.g.: 10 µl of sample + 1 ml of the Sample Diluent

Mix well.

## 10 Assay Procedure

Allow all reagents to come to room temperature and mix well. If you do not use a whole microplate, return unnecessary strips into the bag with desiccant. Seal the bag tightly and store at +2 °C to +8 °C. Keep dry!

1. Dispense the controls (calibrators) and the diluted samples according to the working schedule.

### Semiquantitative evaluation in Index of Positivity (IP)

- Leave A1 well empty (blank).
- Pipette 100 µl of the Negative Control (Calibrator 1) into 1 well.
- Pipette 100 µl of CUT-OFF (Calibrator 2) into 2 wells.
- Pipette 100 µl of the Positive Control (Calibrator 3) into 1 well.
- Pipette 100 µl of the diluted samples (see Chapter Preparation of Samples) into the other wells.

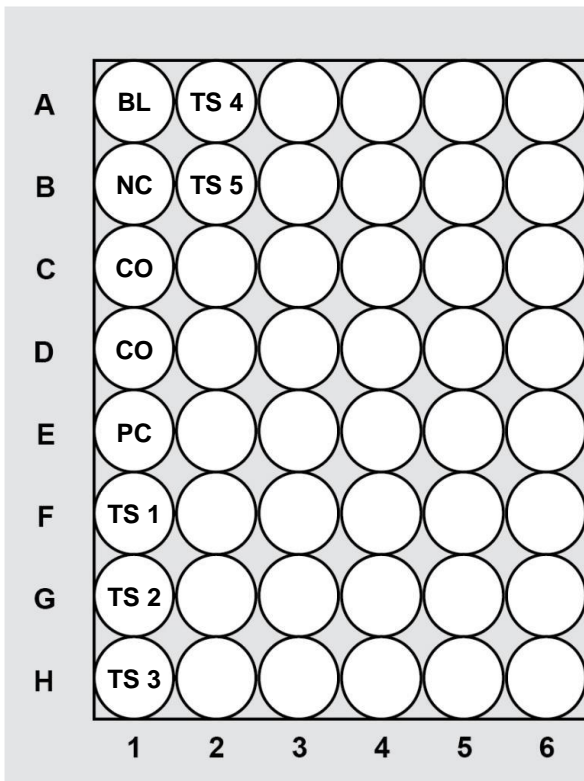
### Quantitative evaluation in Units U/ml

- Leave A1 well empty (blank).
  - Pipette 100 µl of the Negative Control (Calibrator 1) into 1 well.
  - Pipette 100 µl of CUT-OFF (Calibrator 2) into 2 wells.
  - Pipette 100 µl of the Positive Control (Calibrator 3) into 2 wells.
  - Pipette 100 µl of the Calibrator 4 into 2 wells.
  - Pipette 100 µl of the diluted samples (see Chapter Preparation of Samples) into the other wells.
2. Cover the microplate with the lid and incubate at 37 °C for 30 minutes.
  3. Aspirate the content of the wells and wash 5× with the working strength Wash Solution. Fill the wells up to the edge. Finally, tap the inverted microplate thoroughly on an absorbent paper to remove solution remnants.
  4. Pipette 100 µl of the Conjugate into all wells except A1 well.
  5. Cover the microplate with the lid and incubate it at 37 °C for 30 minutes.
  6. Aspirate the content of the wells and wash 5× with the working strength Wash Solution. Fill the wells up to the edge. Finally, tap the inverted microplate thoroughly on an absorbent paper to remove solution remnants.
  7. Pipette 100 µl of TMB-Complete into all wells. Avoid contamination – see Chapter Procedural Notes.
  8. Cover the microplate with the lid and incubate at 37 °C for 30 minutes. Keep out of light.
  9. Stop the reaction by adding 100 µl of the Stop Solution in the same order and intervals as the substrate was added.
  10. Read the colour intensity in wells against blank (A1 well) using photometer set to 450 nm. The absorbance should be read within 30 minutes after stopping the reaction.

# 11 Working Schedule

Semiquantitative evaluation

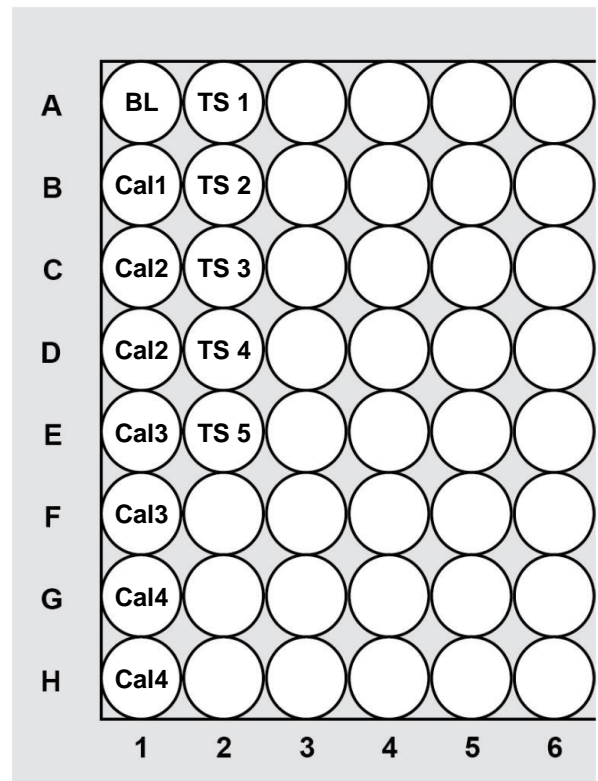
Index of Positivity (IP)



BL	Blank (empty well)			
NC	100 µl	CONTROL	-	CAL1
CO	100 µl	CUTOFF	CAL2	
PC	100 µl	CONTROL	+	CAL3
TS 1-x	100 µl	diluted tested sample		

Quantitative evaluation

Units U/ml



BL	Blank (empty well)			
Cal1	100 µl	CONTROL	-	CAL1
Cal2	100 µl	CUTOFF	CAL2	
Cal3	100 µl	CONTROL	+	CAL3
Cal4	100 µl	CAL4		
TS 1-x	100 µl	diluted tested sample		



## 12 Quality Control

Test is valid if:

The absorbance of blank is lower than 0.150.

$$\text{BLANK} < 0.150$$

The absorbance of the Negative Control (Calibrator 1) is lower than half of the mean absorbance of CUT-OFF (Calibrator 2).

$$\boxed{\text{CONTROL}} \mid \boxed{-} \mid \boxed{\text{CAL1}} < 0.5 \times \boxed{\text{CUTOFF}} \mid \boxed{\text{CAL2}}$$

The mean absorbance of CUT-OFF (Calibrator 2) is within a range of 0.150 – 0.900.

$$0.150 < \boxed{\text{CUTOFF}} \mid \boxed{\text{CAL2}} < 0.900$$

The absorbance of the Positive Control (Calibrator 3) is 1.5-fold higher than the mean absorbance of CUT-OFF (Calibrator 2).

$$\boxed{\text{CONTROL}} \mid \boxed{+} \mid \boxed{\text{CAL3}} > 1.5 \times \boxed{\text{CUTOFF}} \mid \boxed{\text{CAL2}}$$

The absorbance of the Calibrator 4 is higher than the absorbance of the Positive Control (Calibrator 3).

$$\boxed{\text{CAL4}} > \boxed{\text{CONTROL}} \mid \boxed{+} \mid \boxed{\text{CAL3}}$$

## 13 Results Interpretation

### Calculation of Index of Positivity (IP)

Divide the absorbance of a tested sample by the mean absorbance of CUT-OFF measured in the same test run:

$$IP = \frac{\text{Absorbance of the sample}}{\text{Mean absorbance of CUT-OFF}}$$

Interpretation of the test results is described in the table (Table 1).

**Table 1 Interpretation of test results**

Index of Positivity (IP)	Evaluation
lower than 0.9	negative
0.9 to 1.1	borderline
higher than 1.1	positive

Examination of borderline samples, i.e. samples with Index of Positivity from 0.9 to 1.1, should be repeated from a new sample collected after 2 to 6 weeks regarding to the disease specifics.

### Quantitative evaluation in Units (U/ml)

Construct a calibration curve by plotting the concentration (X) of the calibrators in U/ml against the corresponding absorbance (Y). Construct the calibration curve by single point cross connection. Read the values of antibody level (U/ml) in samples from the calibration curve. Interpretation of the quantitative test results is described in the table (Table 2).

**Table 2 Quantitative interpretation in Units (U/ml)**

Antibody level (U/ml)	Evaluation
lower than 18	negative
18 to 22	borderline
higher than 22	positive

Examination of borderline samples should be repeated from a new sample collected after 2 to 6 weeks regarding to the disease specifics.

Serological finding can be interpreted only in the context of results of other laboratory tests and patient clinical picture.

## 14 Analytical Performance

### 14.1 Specificity and Sensitivity

Specificity was determined in the panel of negative samples. Sensitivity was determined in the panel of positive samples. The number of samples tested and the results obtained are described in the table (Table 3).

### 14.2 Trueness (bias)

Trueness is the closeness of agreement between the average value obtained from a large number of measurement results and the reference value. Its measure is bias. The nature of the method does not allow quantitative determination of bias (and thus the trueness). The trueness of the method is ensured by clinical parameters such as sensitivity and specificity, comparison with the reference method and batch continuity. The obtained results are described in the table (Table 3).

### 14.3 Precision: Repeatability – Intra-assay (within run)

The precision is defined as the closeness of agreement between measured values obtained by replicate measurements on the same object under specified conditions. The Intra-assay repeatability is expressed as agreement level among sample replicates within a run of the assay (in one batch). The obtained results are described in the table (Table 3).

### 14.4 Precision: Reproducibility – Inter-assay (between-run)

Reproducibility is a measure of precision under a defined set of conditions which include the inter-assay, expressed as agreement level among sample replicates within runs of the assay in one batch. The obtained results are described in the table (Table 3).

### 14.5 Accuracy

Accuracy is defined as the closeness of agreement between the measured value and the reference value. It is expressed as an achievable measure of the combined uncertainty. The obtained results are described in the table (Table 3).

### 14.6 Analytical sensitivity – limits of detection and quantitation

The analytical sensitivity is the maximum binary dilution of CUT-OFF or international standard samples, respectively, giving absorbance significantly different from the background. The value is expressed as an index of positivity and/or a concentration in units. This value is a minimum limit of detection and quantification. The obtained results are described in the table (Table 3).

### 14.7 Measuring Range

The measuring range of the kit lies between values where the lower limit is determined by the analytical sensitivity value and the upper limit depends on the measuring capability of the equipment used.

### 14.8 Linearity

The linearity is the ability of the method to obtain final values proportional (directly or after mathematical transformation) to the concentration of analyte in the sample; it is expressed as the range in which the method provides linear results. The obtained results are described in the table (Table 3).

### 14.9 Hook effect

Hook effect is an immunological phenomenon that causes falsely low results in the presence of an excess amount of analyte. Its presence is detected by serial dilution of a highly positive sample (Table 3).

### 14.10 Comparison with the reference method

Comparison with the reference method was performed. The results of both methods are comparable, considering the differences of both methods and completely meeting the requirements if the agreement in the classification of the samples is at least 90% (Table 3).

**Table 3 Analytical Performance**

Parameter	Value
Sensitivity (n 91)	98.89%
Specificity (n 93)	94.38%
Trueness (bias)	N/A
Precision: Repeatability	4.77%
Precision: Reproducibility	8.78%
Accuracy	10.52%
Analytical sensitivity	IP 0.04
	0.79 U/ml
Linearity interval	IP 0.16–9.88
	5.00–320.00 U/ml
Hook effect	Not observed
Comparison with the reference method	At least 90%

N/A – not applicable

### 14.11 Interference

Two samples (one negative plasma pool and one positive plasma pool) were spiked with potentially interfering substances. Results of interference testing are shown in the table (Table 4).

**Table 4 Interference Results**

<b>Interfering substance</b>	<b>The result was not affected up to concentration:</b>
Bilirubin	0.4 mg/ml
Triacylglycerols	20 mg/ml
Haemoglobin	5 mg/ml
Biotin	3500 ng/ml

### 14.12 Cross-reactivity

The population is predominantly IgG positive, which does not allow testing for cross-reactivity. Therefore, cross-reactivity of antibodies cannot be excluded. However, the use of high-quality antigen ensures high specificity of the test (see the respective value in the specificity table).

## 15 Clinical Performance

### 15.1 Diagnostic specificity and diagnostic sensitivity

Diagnostic specificity was determined in the panel of negative samples. Diagnostic sensitivity was determined in the panel of positive samples. The number of samples tested and the results obtained are shown in the table (Table 5).

### 15.2 Positive and negative predictive value

A positive predictive value is probability that a person is actually affected by infection if the result was positive. A negative predictive value is probability that a person is actually healthy if the result was negative. The results obtained are shown in the table (Table 5).

### 15.3 Likelihood ratio of the kit

The likelihood ratio of the kit for a positive test is the ratio of probability that an individual from affected population is diagnosed as positive by the test and probability that a healthy individual is misdiagnosed as positive.

The likelihood ratio of the kit for a negative test is the ratio of probability that an individual from affected population is misdiagnosed as negative by the test and probability that a healthy individual is diagnosed as negative. The results obtained are shown in the table (Table 5).

### 15.4 Expected values in population

Expected values in population are established based on the value results in a file of samples declared as negative and a file of samples declared as positive for the presence of specific antibodies. The results obtained are shown in the table (Table 5).

**Table 5 Clinical performance**

Parameter	Value	95% Confidence Interval (CI)
Diagnostic sensitivity (n 91)	98.89%	93.96–99.97%
Diagnostic specificity (n 93)	94.38%	87.37–98.15%
Positive predictive value (n 91)	94.68%	88.02–98.25%
Negative predictive value (n 93)	98.82%	93.62–99.97%
Likelihood ratio of the kit for a positive test	17.602	-
Likelihood ratio of the kit for a negative test	0.012	-
Expected values in healthy population	IP 0.30	IP 0.26–0.34
Expected values in affected population	IP 2.73	IP 2.55–2.91

## 16 Safety Precautions

The kit is intended for in vitro diagnostic use only.

The sera used for controls were tested and found to be negative for HIV 1 and HIV 2, HBsAg, HCV, TPHA. In spite of this fact, they still need to be handled as potentially infectious materials.

Some reagents contain the toxic component sodium azide or gentamicin, but in very low concentrations. Avoid contact with skin.

The Stop Solution contains diluted acid solution. Avoid contact with eyes and skin.

It is necessary to observe the local safety rules and regulations.

### First aid

In case of contact with eyes, flush with copious amount of water and seek medical assistance. In case of contact with skin and clothing, remove all the contaminated clothes. Wash the skin with soap and plenty of running water. In case of contact with solutions containing plasma or clinical samples, disinfect the skin. In case of accidental ingestion, flush the mouth with drinking water and seek medical assistance.

### Remnants disposal

All the materials used for performing the test must be treated as potentially infectious due to the contact with biological materials. Therefore, they need to be disposed together with biological waste.

### Expired kit disposal

Disassemble the kit and dispose the components as biological material. Discard the packaging material as required by local regulations.

## 17 Procedural Notes

In order to obtain reliable results, it is necessary to **strictly follow the Instructions for Use**. Always use clean preferably disposable tips and glassware.

**Microtitre Plate** – in order to prevent water condensation on the surface of the microplate, always allow the bag with the microplate to warm up to room temperature before opening.

**Wash Solution** – use high quality distilled water for preparing the working strength Wash Solution.

**Washing procedure** – keep to the prescribed number of wash cycles and fill the wells to the upper edge. The soak time (i.e. interval between two different wash cycles during which the wells stay filled up with the Wash Solution) should be approx. 30-60 seconds.

**TMB-Complete** – the vessel used for multichannel pipetting should not be used for other reagents. Do not return the surplus TMB-Complete from the pipetting vessel into the vial.

Non-reproducible results might be caused by improper methodology as following:

- insufficient mixing of reagents and samples before use
- improper replacement of vial caps
- using the same tip for pipetting different reagents
- reagent exposure to excessive temperature; bacterial or chemical contamination
- insufficient washing or filling of the wells (the wells should be filled to the upper edge), improper aspiration of Wash Solution remnants
- contamination of the well edges with Conjugate or samples
- using reagents from different kit lots
- contact of reagents with oxidants, heavy metals and their salts

### Technical limitation of samples

Materials of a human origin from donor population listed in the intended use were used for manufacture and development of the kit. Kits are intended for use in general population, unless otherwise stated.

When using samples from other specific populations (comorbid, immunocompromised, pregnant, paediatric population), the risk of a specific effect on the result of the applied test due to e.g. interference or cross-reactivity should be considered in the context of expert knowledge and current scientific knowledge.

### Other notes

The kit might be used for sequential examinations. When preparing working strength solutions, use only the amount of reagents needed for the analysis.

The kit might be used in all types of automatic EIA analysers. If necessary, TestLine Clinical Diagnostics s.r.o. can offer a certified modification of the Instructions for Use for the specific type of analyser.

**The producer cannot guarantee that the kit will function properly if the assay procedure instructions are not strictly adhered to.**



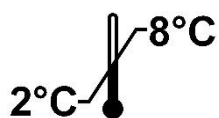
## 18 References

1. Brade L, Brunnemann H, Ernst M, Fu Y, Kosma P, Näher H, Persson K, Brade H. Occurrence of antibodies against chlamydial lipopolysaccharide in human sera as measured by ELISA using an artificial glycoconjugate antigen. *FEMS Immunol Med Microbiol.* 1994. 8 (1): 27–42.
2. Brade L, Holst O, Kosma P, Zhang YX, Paulsen H, Krause R, Brade H. Characterization of murine monoclonal and murine, rabbit, and human polyclonal antibodies against chlamydial lipopolysaccharide. *Infect Immun.* 1990. 58 (1): 205–213.
3. Grayston JT, Kuo CC, Wang SP, Altman J. The new Chlamydia psitacci strain, TWAR, Isolated in acute respiratory tract infections. *New Eng J Med.* 1986. 315 (3): 161–168.
4. Hahn DL, Peeling RW, Dillon E, McDonald R, Saikku P. Serologic markers for C. pneumoniae in asthma. *Ann Allergy Asthma Immunol.* 2000. 84 (2): 227–233.
5. Halvorsen DS, Børvik T, Njølstad I, Gutteberg TJ, Vorland LH, Hansen JB: Chlamydia pneumoniae IgA – and IgG antibodies in young survivors of myocardial infarction. A comparison of antibody detection by a microimmunofluorescence test and an enzyme immunoassay. *J Intern Med.* 2002. 251 (2): 142–147.
6. Hejnar P, Koukalová D. Serodiagnostics of chlamydial infections-significance of positivity in IgA and/or IgM antibody classes only. *Biomed Papers.* 2002. 146 (2): 33–35.
7. Hermann C, Gueinzus K, Oehme A, Von Aulock S, Straube E, Hartung T. Comparison of quantitative and semiquantitative enzyme-linked immunosorbent assays for immunoglobulin G against Chlamydia pneumoniae to a microimmunofluorescence test for use with patients with respiratory tract infections. *J Clin Microbiol.* 2004. 42 (6): 2476–2479.
8. Patton D, Askienazy-Elbhar M, Henry-Suchet J, Campbell LA, Cappuccio A, Tannous W, Wang SP, Kuo CC. Detection of Chlamydia trachomatis in fallopian tube tissue in women with postinfectious tubal infertility. *Am J Obstet Gynecol.* 1994. 171 (1): 95–101.
9. Stephens RS, Tam MR, Kuo CC, Nowinski RC. Monoclonal antibodies to Chlamydia trachomatis: antibody specificities and antigen characterization. *J Immunol.* 1982. 128 (3): 1083–1089.
10. Yuan Y, Zhang YX, Watkins NG, Caldwell HD: Nucleotide and Deduced Amino Acid Sequences for the Four Variable Domains of the Major Outer Membrane Proteins of the 15 Chlamydia trachomatis Serovars. *Infect Immun.* 1989. 57 (4): 1040–1049.

## 19 IFU Symbols

---

---



Temperature limitation

---



Keep dry

---



Expiry date

---



Lot number

---



Manufactured by

---



Consult instructions

---



Catalogue number

---



Number of tests

---














In vitro diagnostic medical device

---

---

## Summary of EIA Chlamydia pneumoniae IgG Protocol

Step No.	Symbol	Test steps
1		Dilute samples serum/plasma 1:101 (10 µl + 1 ml)
2		Pipette Controls (Calibrators) and diluted samples – 100 µl Blank = empty well
3		Incubate at 37 °C for 30 min
4		Aspirate and wash the wells 5×
5		Pipette Conjugate – 100 µl Blank = empty well
6		Incubate at 37 °C for 30 min
7		Aspirate and wash the wells 5×
8		Pipette Substrate (TMB-Complete) – 100 µl Including blank
9		Incubate at 37 °C for 30 min
10		Pipette Stop Solution – 100 µl Including blank
11		Read colour intensity at 450 nm