*recom*Well Chlamydia pneumoniae IgG
*recom*Well Chlamydia pneumoniae IgM
*recom*Well Chlamydia pneumoniae IgA

MIKROGEN DIAGNOSTIK

IVD

Instructions for use (English)

1 Purpose

The *recom*Well Chlamydia pneumoniae IgG, IgM and IgA is a qualitative (IgG, IgA, IgM) or quantitative (IgG, IgA) *in vitro* test for the detection and identification of IgG, IgM or IgA antibodies against *Chlamydia pneumoniae* in human serum or plasma. *recom*Well Chlamydia pneumoniae IgG, IgM or IgA is an indirect ELISA. The test can be carried out either manually or automated.

2 Intended use

The *recom*Well Chlamydia pneumoniae is used to detect IgG, IgM and IgA antibodies against proteins on the external membrane of the pathogen *Chlamydia pneumoniae*.
Infections with the pathogen are transmitted aerogenically and can lead to diseases of the upper respiratory tract, the bronchia and the lungs. A correlation with other diseases such as coronary heart disease (CHD) is also known. An infection with *Chlamydia pneumoniae* is usually asymptomatic or produces only minimal symptoms. The prevalence of the pathogen in the adult population is about 50%.
IgM antibodies, followed by IgA antibodies, develop within 2 to 4 weeks of the initial infection while IgG antibodies develop within 6 to 8 weeks. IgG and IgA antibodies can also occur with reinfections and persist for long periods.
The *recom*Well Chlamydia pneumoniae can be used to determine the serological status or to support diagnostics for an acute infection.

3 Test principle

The microtitre plates of the detection test are coated with a purified native complex of proteins from the external membrane of *Chlamydia pneumoniae* elementary and reticular bodies.
Diluted serum or plasma samples are incubated in the wells of the microtitre plates and specific antibodies to the pathogen antibodies attach to the bottom of the cavities.
Unbound antibodies are then washed away.
In a second step, anti-human immunoglobulin antibodies (IgG, IgM or IgA), which are coupled to horseradish peroxidase, are incubated in the wells.
Unbound conjugate antibodies are then washed away.
Specific bound antibody is detected in a colour reaction catalysed by the peroxidase. If an antigen-antibody reaction has taken place, the colour intensity of the solution increases in proportion to the quantity of bound anti-Chlamydia pneumonia IgG, IgM or IgA antibodies. The intensity of the colour can be measured using a photometer and provides information about the concentration of the anti-Chlamydia pneumoniae antibodies in the sample.

4 Reagents

4.1 Package contents

The reagents in one pack are sufficient for 96 assays.
Each set of reagents contains:

WASHBUF 10 X	**100 ml** wash buffer (**10x concentrate**) Contains phosphate buffer, NaCl, detergent. Preservatives: MIT (0.01%) and Oxypyrion (0.1%)
DILUBUF	**125 ml** dilution buffer (**ready to use**) Contains protein, detergent and blue dye. Preservatives: MIT (0.01%) and Oxypyrion (0.1%)
SUBS TMB	**12 ml** chromogenic substrate tetramethylbenzidine (TMB) (**ready to use**)
SOLN STOP	**12 ml** stop solution 24.9% phosphoric acid (H_3PO_4) (**ready to use**)
INSTRU	**1** instructions for use
EVALFORM	**1** evaluation sheet
TAPE	**2 sheets** sealing film

***recom*Well Chlamydia pneumoniae IgG** also contains:

MTP	**12x8 well** microtitre plate (strip marked **red**), Coated with specific *Chlamydia pneumoniae* antigens in a vacuum zipper pouch.
CONTROL + IgG	**450 µl** positive control (**purple** cap), rabbit serum Preservatives: MIT (0.1%) and Oxypyrion (0.1%)
CONTROL ± IgG	**450 µl** cut-off control (**yellow** cap), rabbit serum Preservatives: MIT (0.1%) and Oxypyrion (0.1%)
CONTROL - IgG	**450 µl** negative control (**white** cap), human serum Preservatives: MIT (0.1%) and Oxypyrion (0.1%)
CONJ IgG	**500 µl** goat anti-human IgG peroxidase conjugate, pig anti-rabbit IgG peroxidase conjugate (**101x concentrate**, **red** cap) Preservatives: Thimerosal (<0.02%), MIT (<0.01%) and chloroacetamide (<0.1%)

***recom*Well Chlamydia pneumoniae IgM** also contains:

MTP	**12x8 well** microtitre plate (strip marked **green**) Coated with specific *Chlamydia pneumoniae* antigens in a vacuum zipper pouch.
CONTROL + IgM	**450 µl** positive control (**black** cap), rabbit serum Preservatives: MIT (0.1%) and Oxypyrion (0.1%)
CONTROL ± IgM	**450 µl** cut-off control (**colourless** cap), rabbit serum Preservatives: MIT (0.1%) and Oxypyrion (0.1%)
CONTROL - IgM	**450 µl** negative control (**white** cap), human serum Preservatives: MIT (0.1%) and Oxypyrion (0.1%)
CONJ IgM	**500 µl** goat anti-human IgM peroxidase conjugate, pig anti-rabbit IgG peroxidase conjugate (**101x concentrate**, **green** cap) Preservatives: Thimerosal (<0.02%), MIT (<0.01%) and chloroacetamide (<0.1%)

***recom*Well Chlamydia pneumoniae IgA** also contains:

MTP	**12x8 well** microtitre plate (strip marked **blue**) Coated with specific *Chlamydia pneumoniae* antigens in a vacuum zipper pouch.
CONTROL + IgA	**450 µl** positive control (**brown** cap), rabbit serum Preservatives: MIT (0.1%) and Oxypyrion 0.1%)
CONTROL ± IgA	**450 µl** cut-off control (**orange** cap), rabbit serum Preservatives: MIT (0.1%) and Oxypyrion (0.1%)
CONTROL - IgA	**450 µl** negative control (**white** cap), human serum Preservatives: MIT (0.1%) and Oxypyrion (0.1%)
CONJ IgA	**500 µl** goat anti-human IgA peroxidase conjugate, pig anti-rabbit IgG peroxidase conjugate (**101x concentrate**, **blue** cap) Preservatives: Thimerosal (<0.02%), MIT (<0.01%) and chloroacetamide (<0.1%)

4.2 Additionally required reagents, materials and equipment

- Deionised water
- Test tubes
- Vortex mixer or other rotatory device
- 8 channel pipette or washer with pump
- Clean measuring cylinders, 50 ml and 1000 ml
- Micropipettes with single-use tips, 10 µl and 1000 µl
- 10 ml pipette or dispenser
- Incubator 37°C
- Microtitre plate photometer
- Timer
- Disposable protective gloves
- Waste container for biohazardous substances

5 Shelf life and handling

- Store reagents between +2°C and +8°C before and after use, **do not freeze**.
- Before starting the test, let all reagents sit at room temperature (+18°C to +25°C) for at least 30 minutes.
- The dilution buffer, wash buffer, substrate and stop solution for the *recom*Well tests can be used for different batches and parameters. In doing so, pay attention to the shelf life of these components.

- The control sera and conjugates are batch specific and must not be used for different parameters or batches.
- Before use, mix the concentrated conjugates, controls and patient samples thoroughly. Avoid foam formation.
- All MIKROGEN microtiter plates are provided with break-apart strips.
- The sealing films are intended for single use.
- The packages have an expiry date, after which a guarantee of quality can no longer be given.
- Keep the kit components away from direct sunlight throughout the test procedure. Note: The substrate solution (TMB) is light sensitive.
- The test must only be performed by trained, authorised and qualified personnel.
- Substantial changes made by the user to the product or the directions for use may compromise the intended purpose of the test specified by MIKROGEN.
- Cross-contamination of the patient samples or conjugates in the kit can lead to false test results. Add patient samples and conjugate solution carefully. Make sure that any incubated liquids are not carried over to other wells.
- Automation is possible. Further details are available from MIKROGEN.

6 Warnings and safety precautions

- Only use for *in vitro* diagnostics.
- All blood products must be treated as potentially infectious.
- The microtitre wells have been coated with inactivated whole-cell lysate, bacterial or viral antigens.
- After adding patient or control material, the microtitre wells must be considered to be potentially infectious and handled accordingly.
- To prepare the control material, blood is used from donors who have been confirmed to have no antibodies to HIV 1/2 or HCV and no HBs antigen. Because an infection cannot be reliably ruled out, however, the control material must be handled with the same care as a patient sample.
- Suitable single-use gloves must be worn throughout the entire test procedure.
- The conjugates and the wash and dilution buffers contain the antimicrobial agents and preservatives thimerosal, MIT (methylisothiazolinone), Oxypyrion and chloroacetamide. Avoid contact with the skin or mucous membranes.
- Phosphoric acid is an irritant. Use caution and avoid contact with skin and mucous membranes.
- All discarded fluids must be collected. All collection reservoirs must contain suitable disinfectants for inactivation of human pathogens. All reagents and materials coming into contact with potentially infectious samples must be treated with suitable disinfectants or be disposed of according to laboratory guidelines. The concentration specifications and incubation times of the manufacturer must be taken into consideration.
- Use microtitre wells only once.
- Do not replace or mix the reagents with reagents of other manufacturers.
- Read through and carefully follow all instructions before performing the test. Deviations from the test protocol described in the instructions for use can lead to false results.

7 Sampling and preparation

7.1 Sample material

The sample material can be either serum or plasma (EDTA, citrate, heparin, CPD) and must be separated as soon as possible after collection to avoid haemolysis. Microbial contamination of the sample must absolutely be avoided. Non-soluble substances must be removed from the sample prior to incubation.
Use of heat-inactivated, icteric, haemolytic, lipaemic or cloudy samples is not recommended.
Caution!
If the tests are not carried out immediately, the sample material can be stored for up to 2 weeks at +2°C to +8°C. It is possible to store the samples for longer periods at -20°C or lower. Repeated freezing and thawing of the samples is not recommended due to the risk of false results. More than 3 freezing and thawing cycles should be avoided.

7.2 Preparation of solutions

The detection reagents are sufficient for 96 measurements. The quantities specified below apply to the processing of one 8-well microtitre plate strip. If using several microtitre plate strips at the same time, each of the specified quantities must be multiplied by the number of microtitre plate strips used. Device-specific dead volume must be taken into account. Dilution buffer, substrate and stop solution are ready to use.

7.2.1 *Preparation of the wash buffer*
The wash buffer concentrate is diluted **1 + 9** with deionised H_2O. For each 8-well microtitre plate strip, 5 ml concentrate are mixed with 45 ml deionised H_2O. The ready-to-use wash buffer can be stored for four weeks between +2ºC and +8ºC or for one week at room temperature.

7.2.2 *Preparation of the conjugate solution*
For each 8-well microtitre plate strip, 1 ml dilution buffer is added to 10 µl IgG peroxidase conjugate (red cap) or 10 µl IgM peroxidase conjugate (green cap) or 10 µl IgA peroxidase conjugate (blue cap) in a clean tube and then mixed well (dilution **1 + 100**). The conjugate solution must be prepared shortly before use; the ready-to-use conjugate solution must not be stored.

8 Test procedure

No.	Implementation	Note
1	Before starting the test, allow all reagents to sit at +18°C to +25°C (room temperature) for at least 30 minutes.	To avoid condensation forming in the microtitre plate, it must be equilibrated to room temperature **in a sealed bag**. Remove the required number of strips, reseal the plate in the bag and store it in the fridge. Before use, the control sera and patient samples as well as the concentrated conjugates must be mixed thoroughly and then briefly centrifuged if possible to collect any liquid on the base of the tubes.
2	Preparation of the samples and controls Pipette **10 µl** of sample or control into each **1 ml** of the dilution buffer and mix well (dilution **1+100**).	**The samples and controls must always be diluted immediately prior to carrying out the test.** All controls must be run with each assay and these must also be diluted in the same way as the patient samples.
3	Sample incubation Pipette **100 µl** of either diluted sample or diluted control into each well and incubate for **1 hour** at +**37°C**.	At least one value must be prepared for the negative control, positive control and the patient samples. The cut-off control must be prepared in duplicate. Preferably pipette one cut-off control each at the start and at the end of the series. For manual processing, carefully cover the microtitre plate with fresh sealing film. Use the +37°C incubator.
4 a) b) c)	Wash Carefully remove the sealing film. Remove all fluid from the wells. Fill each well with **300 µl** ready-to-use wash buffer (see 7.2.1) → 8.4b	It is recommended to carry out this step with an appropriate ELISA washer. Be certain all wash buffer is completely removed between wash steps. Aspirate or shake out and tap. Carry out the wash steps 8.4b and 8.4c a total of **four times**.
5	Incubation with conjugate Add **100 µl** diluted conjugate solution (see 7.2.2) and incubate for **30 minutes** at +**37°C**.	For manual processing, carefully cover the microtitre plate with unused sealing film.
6	Wash (see 8.4b and 8.4c)	Carry out the wash steps a total of **four times**.
7	Substrate reaction Pipette **100 µl** ready-to-use substrate solution into each well and incubate for **30 minutes** at **room temperature**. The time is calculated from the time substrate solution is pipetted into the first well.	It is not necessary to cover the plate. Protect from direct sunlight.
8	Stopping the reaction Add **100 µl** ready-to-use stop solution per well.	Do not remove the substrate solution before adding the stop solution! Follow the same pipetting scheme used for pipetting the substrate solution.
9	Absorbance measurement Using a microtitre plate photometer, measure the absorbance of the individual wells at 450 nm and the reference wavelength of 620 nm (620 to 650 nm allowed).	Measure absorbance against an air blank. The reading must be completed within 60 minutes of stopping the reaction.
Caution! **Incubated liquids must not be carried over to other wells. Avoid splashing when removing and attaching the sealing film.**		

9 Results

9.1 Evaluation

Cut-off (threshold) = the mean is formed using the absorbance values of the two cut-off controls (at the start and the end of the series).

9.1.1 *Qualitative analysis*

Grey area	Lower limit Upper limit	= cut-off = cut-off + 20% (cut-off ×1.2)
Negative	Samples with absorbance values **below** the grey area	
Borderline	Samples with absorbance values **in** the grey area	
Positive	Samples with absorbance values **above** the grey area	

9.1.2 *Quantitative evaluation*

The corresponding antibody activity in **units per ml** is allocated to the absorbance values using a formula. The measurement unit U/ml is an arbitrary unit that does not have any direct relationships to (international) reference values.

U/ml sample	(absorbance of sample / absorbance of cut-off) × 20
Grey area	Lower limit = 20 U/ml Upper limit = 24 U/ml
Negative	U/ml sample < 20
Borderline	20 ≤ U/ml sample ≤ 24
Positive	U/ml sample > 24

Samples with a borderline test result should be tested again within two to four weeks. If they are again borderline after the second test, it is recommended to collect and test another sample after some time.

The linearity of the test could be confirmed during the evaluation within the following measurement range:
IgG: 20 U/ml to 65 U/ml ($R^2 = 0.95$)
IgA: 20 U/ml to 56 U/ml ($R^2 = 0.95$)
IgM: No serum > 35 U/ml found among 1000 sera with suspected pneumonia in the performance assessment; no linearity determination possible.

With an absorbance ≥ 3.0 or with a measurement above this linear range, either the result should be given for IgG as > 65 U/ml or for IgA as > 56 U/ml or the sample should be diluted and tested again. We recommend initially using a final dilution of 1:500 and then further dilution steps if necessary.

9.1.3 *Validation – Quality control*

The test can be analysed if the following conditions are met:

- The individual absorbance values for the duplicate measurement of the cut-off control do not deviate from their mean by more than 20%.
- Absorbance of the negative control ≤ 0.150
- Absorbance of the cut-off control – absorbance of the negative control ≥ 0.050 ($E_{Cutoff} - E_{neg.\ Contr.} \geq 0.050$)
- Absorbance of the positive control > absorbance of the cut-off control ($E_{pos.\ Contr.} > E_{Cutoff}$)

The controls are used to validate the test results as defined in this section. Determining specific antibodies relative to the cut-off control in U/ml increases the reproducibility of the results because any fluctuations caused by carrying out the test are integrated. Evaluating the positive control and the negative control is not required to validate the test. However, the evaluation can be carried out for purposes of internal quality control if required. In this case, the results should be within the target range stated on the certificate of analysis or on the label.

9.2 Test interpretation

Possible results			Interpretation
IgM	IgA	IgG	
+	+	+	Serological evidence of an acute infection.
+	+	-	Serological evidence of an acute infection. Check the IgG status after two to four weeks.
+	-	+	Serological evidence of an acute infection.
-	+	+	Serological evidence of an acute infection.
+	-	-	Serological evidence of an early stage of infection. Check the IgM, IgA and IgG status after two to four weeks.
-	+	-	Serological evidence of an early stage of infection or a solitary persistent IgA. Check the IgM, IgA and IgG status after two to four weeks.
-	-	+	Serological evidence of a previous or existing infection. With clinical suspicion of an infection, check IgA and IgG after two to four weeks.
-	-	-	No serological evidence of an existing or past infection. With clinical suspicion of an infection, check IgM, IgA and IgG after two to four weeks.

An acute *Chlamydia pneumoniae* infection is likely if the IgG titre clearly increases over the course of the infection.

10 Limits of the method, restrictions

- Serological test results must always be viewed within the context of the clinical presentation. The therapeutic consequences of the serological finding must be related to the clinical data.
- A negative result does not rule out the possibility of a *Chlamydia pneumoniae* infection. In case of clinical suspicion of infection with *Chlamydia pneumoniae* and negative serological results, further sampling and testing should be carried out again after 2 weeks.
- False negative results can occur if the serum samples are collected very soon after an infection.
- A positive result *recom*Well Chlamydia pneumoniae test result does not mean that active disease is present in every case.
- To diagnose a *Chlamydia pneumoniae* infection, in each case the clinical presentation and, if necessary, the medical history must also be considered along with the laboratory values.
- To evaluate the *Chlamydia pneumoniae* immune status, the results of the IgM, IgA and IgA detection should always be considered together.
- We generally recommend checking positive and borderline ELISA results in a confirmatory test.

11 Performance characteristics

11.1 Seroprevalence of *Chlamydia pneumoniae* antibodies in blood donors

n = 200	*recom*Well Chlamydia pneumoniae IgG	*recom*Well Chlamydia pneumoniae IgA	*recom*Well Chlamydia pneumoniae IgM
Positive	69	5	0
Borderline	10	4	0
Negative	121	191	200
Seroprevalence (positive and borderline)	39.5%	4.5%	0%

Origin of the samples: Bavarian Red Cross

11.2 Diagnostic performance (positive and negative agreement with MIF) (MI, MC Phoon 2011)

IgG:
A routine collective of 81 sera with suspected atypical pneumonia was analysed with a commercial **M**icro**I**mmuno**F**luorescence test (MIF IgG) and used as the reference for the test development of *recom*Well Chlamydia pneumoniae (evaluation MIF ≥1:32=positive and <1:32=negative, based on the recommendation of the reference laboratory for chlamydia); positive samples n=42, negative samples n=39.

Positive and borderline (%) n=42 as per MIF test (IgG)≥1:32	*recom*Well Chlamydia pneumoniae (IgG)	Confirmation of *recom*Well IgG positive results with *recom*Line (IgG)	Commercially available test A	Commercially available test B
Positive agreement	83.3%	73.8%	97.6%	100%

Negative (%) n=39 as per MIF test (IgG)<1:32	*recom*Well Chlamydia pneumoniae (IgG)	Confirmation of *recom*Well IgG positive results with *recom*Line (IgG)	Comparative test A	Comparative test B
Negative agreement	74.4%	92.3%	43.6%	46.2%

IgA:
A sera collective of patients who were admitted to hospital with various diagnoses and for whom atypical pneumonia was diagnosed as an incidental finding was analysed (IgA positive n=16 with MIF test (IgA) ≥ ++; IgG positive and simultaneously IgA negative n=13 with MIF test (IgA) < ++). For some of these patients bacterial pneumonia was confirmed by radiographic examination.
Two control collectives were included in the test evaluation.
Collective 1: negative control group (n=26, MIF < ++, Jena Hospital);
Collective 2: potentially cross-reacting control group (n=3, *Chlamydia trachomatis* IgG-positive in the MIF test, *Chlamydia pneumoniae* MIF test (IgG) <1:32 and simultaneously MIF test (IgA) negative).

*recom*Well Chlamydia pneumoniae IgA	*Chlamydia pneumoniae* – seronegative as defined by MIF test (IgA) < ++ n=42 (13 +26 +3)	*Chlamydia pneumoniae* – seropositive as defined by MIF test (IgA) ≥ ++ n=16
Positive agreement	-	87.5%
Negative agreement	83.3%	-

For IgM no sensitivity could be determined because clinically defined IgM-positive sera are not available.

11.3 Analytical specificity

The analytical specificity is defined as the suitability of the test to precisely determine the analytes in the presence of potential interference factors in the sample matrix or cross-reactions with potentially interfering antibodies.
a) Interference: Control studies on potentially interfering factors have shown that the test performance is not influenced by anticoagulants (sodium citrate, EDTA, heparin, CPD) and haemolysis of the sample. Interference due to lipaemia or bilirubinaemia of the sample may occur in isolated cases.
b) Cross-reactions: Potential interference by antibodies against EBV may rarely occur. Potential interference due to other conditions that can be attributed to atypical activity of the immune system (antinuclear autoantibodies, pregnancy) can be ruled out as far as possible. Exception: In rare cases interference with a rheumatoid factor can lead to false positive results in the *recom*Well Chlamydia pneumoniae IgG. Occasionally, *Chlamydia trachomatis* IgG positive sera can also show false positive results in *recom*Well Chlamydia pneumoniae IgG.

To determine the analytical specificity to potentially interfering antibodies, the following sera were included:
Blood donors (n=200)
- Sera from patients with pneumonia, suspected to be caused by *Mycoplasma pneumoniae*, IgM-positive (n=10)
- *Chlamydia trachomatis* IgG-positive sera (n=20)
- *Chlamydia trachomatis* IgG- and IgA-positive sera (n=10)
- Rheumatoid factor-positive sera (n=50)
- EBV-IgM-positive sera (acute EBV infection) (n=29)
- Icteric sera (n=9)
- Lipaemic sera (n=10)

Positivity (positive and borderline) in %	*recom*Well *Chlamydia pneumoniae*			Commercially available Comparative test A			Commercially available Comparative test B		
	IgG	IgA	IgM	IgG	IgA	IgM	IgG	IgA	IgM
Blood donors (n=200)	39.5	4.5	0	74	38	1	63	54.5	7
Mycoplasma pneumoniae, IgM-positive (n=10)**	30	0	0	40	30	10	40	30	40
Chlamydia trachomatis IgG- (n=20) or IgG,IgA-positive (n=10)***	73.3	3.3	0	83.3	33.3	0	86.7	60	6.7
Rheumatoid factor sera (n=50)	56	22	4	n.t.*	n.t.	n.t.	76	70	12
EBV sera IgM-positive (n=29)****	41.4	3.4	24.1	48.3	34.5	27.6	51.7	60	96.6
Icteric sera (n=9)	88.9	11.1	0	100	55.6	0	100	77.8	100
Lipaemic sera (n=10)	70	20	0	90	90	0	90	100	20

* not tested
** tested with a commercially available *Mycoplasma pneumoniae* ELISA
*** tested with the *recom*Line Chlamydia
**** tested with the *recom*Line EBV

11.4 Precision

	*recom*Well Chlamydia pneumoniae IgG	*recom*Well Chlamydia pneumoniae IgA	*recom*Well Chlamydia pneumoniae IgM
Intra-assay variance*	CV < 6.1%	CV < 9.9%	CV < 5.3%
Inter-assay variance**	CV < 5.2%	CV < 10.4%	CV < 8.2%

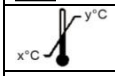
* Three positive or borderline patient samples were tested in 10, 11 or 12 wells each in a diagonal arrangement on a microtitre plate. The coefficient of variation (CV) was calculated for the U/ml of the samples.
** Three positive or borderline patient samples with different absorbance values were examined on three different days in four-fold determination. The coefficient of variation (CV) was calculated for the U/ml of the samples.

12 Literature

1. K.S. Rahman, E.U. Chowdhury, A. Poudel, A. Ruettger, K. Sachse, B. Kaltenboeck; *Defining species-specific immunodominant B cell epitopes for molecular serology of Chlamydia species*; Clin Vaccine Immunol., 2015 May, 22 (5): 539-52
2. R. Dumke, C. Schnee, M.W. Pletz, J. Rupp, E. Jakobs, K. Sachse, G. Rohde, CAPNETZ Study Group; *Mycoplasma pneumoniae and Chlamydia spp. Infection in Community-Acquired Pneumonia, Germany, 2011-2012*; Emerging Infectious Diseases Vol. 21, No. 3, March 2015
3. L. Conklin, J. Adjemain, J. Loo, S. Mandal, C. Davis, S. Parks,T. Parsons, B. McDonough, J. Partida, K. Thurmann, M. H. Diaz, A. Benitez, T. Pondo, C. G. Whitney, J.M. Winchell, N. Kendig, C. Van Beneden; *Investigation of a Chlamydia pneumoniae Outbreak in a Federal Correctional Facility in Texas*; Clin Infect Dis. 2013 September; 57(5): 639-647
4. M. C. Phoon, G. W. J. Yee, W-P. Koh, V. T. K. Chow; *Comparative Seroepidemiologic Analysis of Chlamydophila Pneumoniae Infection using Microimmunofluorescence, Enzyme Immunoassay and Neutralization Test: Implications for Serodiagnosis*; Indian J. Microbiol (Apr-June 2011) 51 (2); 223-229
5. V. Forsbach-Birk, U. Simnacher, K.-I. Pfrepper, E. Soutschek, A. O. Kiselev, M. F. Lampe, T. Meyer, E. Straube, A. Essig; *Indentification and Evaluation of a combination of chlamydial antigens to support the diagnosis of severe and invasive Chlamydia trachomatis infections*; Journal Compilation 2009 European Society of Clinical Microbiology and Infectious Diseases; 2009
6. N. Wellinghausen, E. Straube, H. Freidank, H. von Braun, R. Marre, A. Essig; *Low prevalence of Chlamydia pneumoniae in adults with community-acquired pneumonia*; Int J Med Microbiol. 2006 Nov; 296 (7); 485-91. Epub 2006 Aug 4.
7. S. Mukhopadhyay, A. P. Clark, E. D. Sullivan, R. D. Miller, J. T. Summersgill; *Detailed Protocol for Purification of Chlamydia pneumoniae Elementary Bodies*; Journal of Clinical Microbiology, July 2004, p. 3288-3290
8. L. A. Campbell, C.-C. Kuo, J. T. Grayston; *Structural and Antigenic Analysis of Chlamydia pneumoniae*; Infection and Immunity, Jan. 1990, p. 93-97

We will be pleased to send you additional literature on chlamydia diagnosis upon request.

13 Explanation of symbols

Σ	Content is sufficient for <n> formulations Number of formulations
WASHBUF 10 X	Wash buffer (**10x concentrate**)
DILUBUF	Dilution buffer
SUBS TMB	Chromogenic substrate tetramethylbenzidine
SOLN STOP	Stop solution
TAPE	Sealing film
MTP	Microtiter plate
CONTROL + IgG	Positive control IgG
CONTROL ± IgG	Cut-off control IgG
CONTROL - IgG	Negative control IgG
CONJ IgG	IgG peroxidase conjugate
CONTROL + IgM	Positive control IgM
CONTROL ± IgM	Cut-off control IgM
CONTROL - IgM	Negative control IgM
CONJ IgM	IgM peroxidase conjugate
CONTROL + IgA	Positive control IgA
CONTROL ± IgA	Cut-off control IgA
CONTROL - IgA	Negative control IgA
CONJ IgA	IgA peroxidase conjugate
TVALUE	Target value and/or target range in U/ml
EVALFORM	Evaluation sheet
INSTRU	Instructions for use
	Follow the instructions for use
CONT	Contents, contains
IVD	In vitro diagnostic agent
LOT	Batch/version number
	Do not freeze
REF	Order number
	Use by Expiry date
	Store between x°C and y°C
	Manufacturer

14 Manufacturer and version dates

***recom*Well Chlamydia pneumoniae IgG** ***recom*Well Chlamydia pneumoniae IgM** ***recom*Well Chlamydia pneumoniae IgA**	Article no. 6104 Article no. 6105 Article no. 6106
Instructions for use Valid from	GARECP005EN 2023-06

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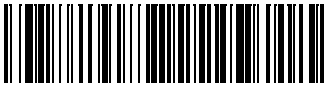

GARECP005