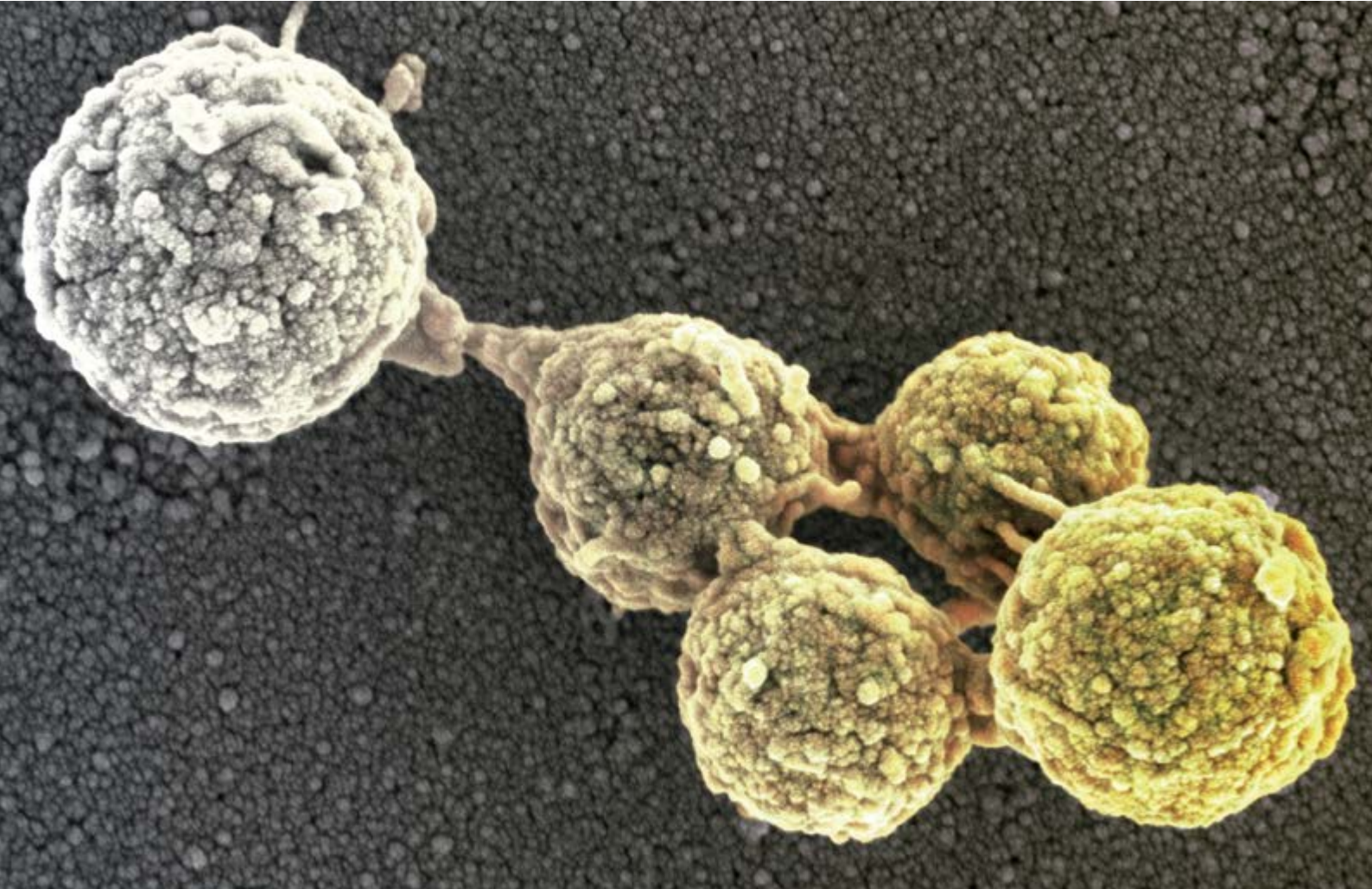


Mycoplasma pneumoniae



Enzyme immunoassays for the diagnosis of **Mycoplasma** infection

ELISA kits are optimized and validated for detection of IgA, IgG and IgM antibodies in human serum and plasma

INTRODUCTION

Mycoplasma pneumoniae is a primary pathogenic agent of the human respiratory tract. It causes pneumonia accompanied by fever, nausea, ague, cough and fatigue. The disease is prolonged but well curable with antibiotics. The pathogen is air-borne, spread especially in dense gatherings of children, particularly during spring and autumn months.

DIAGNOSIS OF INFECTION

Diagnosis of the disease is based on the overall clinical picture, epidemiological anamnesis and laboratory tests. Because it is difficult to cultivate *Mycoplasma pneumoniae*, it is advisable to use the ELISA method for the detection of specific antibodies in human serum or plasma in routine laboratory practice.

DIAGNOSTIC IMPORTANCE OF ANTIBODY CLASSES

IgM: Primary infection is indicated by IgM antibody increase (1-2 weeks after infection), which reaches maximum after 1 month from the beginning of infection. The antibody can persist for more than 1 year. Presence of specific IgM antibody in infected persons under 20 years of age is 80% but only 40% in subjects more than 20 years of age. During reinfection the antibody level rarely rises.

IgA: Specific IgA antibody usually increases later than IgM and often decreases earlier. Its significance becomes obvious when IgM antibody is absent in some patients or in case of reinfection.

IgG: Specific IgG antibody rises 2-3 weeks after symptoms appearance with maximum reached after longer period (about 6 months) and the antibody can persist for more than 1 year, in some cases even more than 4 years. In case of reinfection it is necessary to evaluate dynamics of antibodies by reinvestigation of paired samples collected in the course of 1 to 2 weeks.

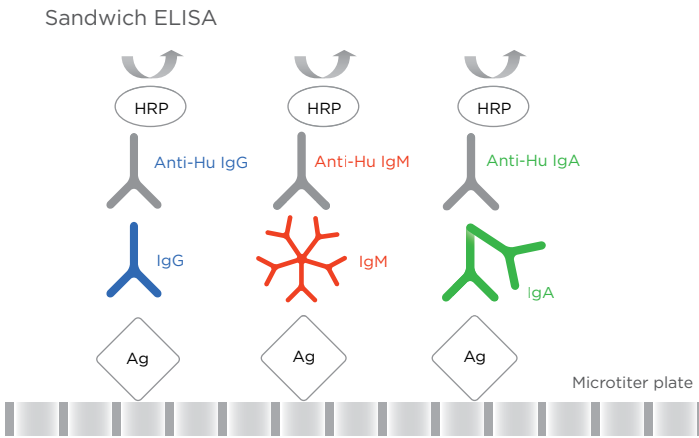
It is advisable to examine each sample for all three antibody classes to evaluate the serological results, eventually to perform reinvestigation of paired samples.

RESULTS INTERPRETATION

| IgM | IgA | IgG | Interpretation |
|-----|-----|-----|-----------------------------------|
| - | - | - | Negative result |
| + | + | - | Acute infections (early phase) |
| - | + | - | Early acute infection without IgM |
| + | + | + | Acute infection (late phase) |
| (+) | (+) | + | Postacute stage |
| - | - | + | Previously infected infections |
| - | + | + | Reinfection |

ELISA

TEST PRINCIPLE



SUMMARY OF 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 minutes at 37 °C |
| 4 | Aspirate and wash the wells 5 times |
| 5 | Add 100 µl Conjugate • Blank = empty well |
| 6 | Incubate 30 minutes at 37 °C |
| 7 | Aspirate and wash the wells 5 times |
| 8 | Add 100 µl Substrate (TMB-Complete) • Including blank |
| 9 | Incubate 30 minutes at 37 °C |
| 10 | Add 100 µl Stopping solution • Including blank |
| 11 | Read colour intensity at 450 nm |

ANTIGENS

Purified and inactivated *M. pneumoniae* antigen enriched with highly specific immunodominant epitopes

CLINICAL APPLICATION

- ▶ Screening test for the detection of infection with *Mycoplasma pneumoniae* in humans
- ▶ Checking of therapy results using the 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 of results (Index of Positivity)
- ▶ Quantitative evaluation of results (U/ml)
- ▶ Easy assay procedure

ADVANTAGES

- ▶ Identical assay procedure
- ▶ High diagnostic specificity and sensitivity
- ▶ High reproducibility
- ▶ High dynamics of antibody response
- ▶ Expiration period of 15 months from date of production
- ▶ Short total assay time
- ▶ Ready for automation
- ▶ Customer support

TEST CHARACTERISTICS

| ELISA | Diagnostic Sensitivity | Diagnostic Specificity |
|--------------------|------------------------|------------------------|
| EIA Mycoplasma IgA | 98.8% | 97.6% |
| EIA Mycoplasma IgG | 97.4% | 97.5% |
| EIA Mycoplasma IgM | 96.7% | 98.8% |

ORDERING INFORMATION

ELISA

| Cat. No. | Product | No. of Tests |
|-----------|-------------------------|--------------|
| MyA096 | EIA Mycoplasma IgA | 96 |
| MyG096 | EIA Mycoplasma IgG | 96 |
| MyM096 | EIA Mycoplasma IgM | 96 |
| SK-MyA096 | SmartEIA Mycoplasma IgA | 96 |
| SK-MyG096 | SmartEIA Mycoplasma IgG | 96 |
| SK-MyM096 | SmartEIA Mycoplasma IgM | 96 |

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

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

