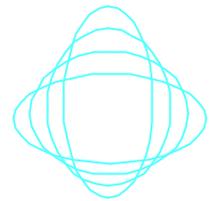




ELIZEN

PNEUMOCOCCUS IgG

Immunopotency Level



ZenTech

Immuno-enzyme assay for the determination of anti-pneumococcus IgG antibodies in human serum

ELISA immunoassay (96 determinations)

Code number : E-DG-96



Help to decide VACCINATION for at risk people

ELIZEN Pneumococcus IgG assay is useful for the :

- ▶ **Definition of the level** of immuno-protection in patient by testing anti-Pneumococcus IgG concentration
- ▶ **Help in decision** to perform pneumococcal vaccination or immunoglobulin treatment
- ▶ **Follow-up** of the immunological response to vaccination allowing switching treatment with e.g. IVIG-immunoglobulin an follow-up of such treatment

- Easy to use : automate available, results in less than 2 hours
- Only 10 µl of patient sample needed (pediatric)
- Detection of the 23 most frequent pathogenic serotypes
- Detection of antibodies in serum containing low levels as well as high levels in hyper-immune sera obtained after vaccination
- Help to decide vaccination for at risk people

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Pneumococcus Ab

Streptococcus pneumoniae is a common host of the oropharyngeal flora. Diplococcus Gram positive, its capsule confers its virulence and antigenicity. Antibodies against the polysaccharidic antigens of the capsule are protective of the infection. The rate of *Streptococcus pneumoniae*'s carriers, varies from age, season and environment infectious or not.

Pneumococcus are the major cause of pneumonia acquired in communities and a frequent source of acute otitis of the middle ear, sinusitis and pharyngitis. Pneumonia, which are caused by pneumococcus, are reported to be the fifth cause of death in the United States. In Belgium, the incidence of worrying infections caused by pneumococcus is 20.000 cases/year. The mortality rate is evaluated at 2.000 deaths/year. (Peterman et al, *Tijdschr Geneesk* 1999;54:1196-1200). The yearly incidence of pneumococcal bacteraemia is highest in the age group ≥ 65 years and in children < 4 years (Flamaing et al, *J Antimicrob chemother* 2002; 50(1):43-50).

Assay description

The assay allows the detection of anti-polysaccharidic antibodies capsule of the 23 most frequent serotypes (95 % isolated strains in North Europe - Belgium).

This method allows the detection of antibodies in serum or plasmatic fractions containing low levels (concentration 1.000 times lower than the mean encountered by healthy individuals) and in hyper-immune sera obtained after vaccination. By the use of an accurate cut-off, this assay helps to decide vaccination for at risk people (children, aged people, patients with cardiac insufficiency, broncho-pneumopathies, ...).

This assay allows to monitor the state of immuno-protection of the patient , follows efficiency of the immunity response after vaccination and helps to decide the vaccination and/or treatment by IV gammaglobulins.

Principle of the test

The method is based on immuno-enzymatic reaction. Patients serum or plasma prior diluted is added into the wells coated with polysaccharidic capsule of 23 *Pneumococcus* strains.

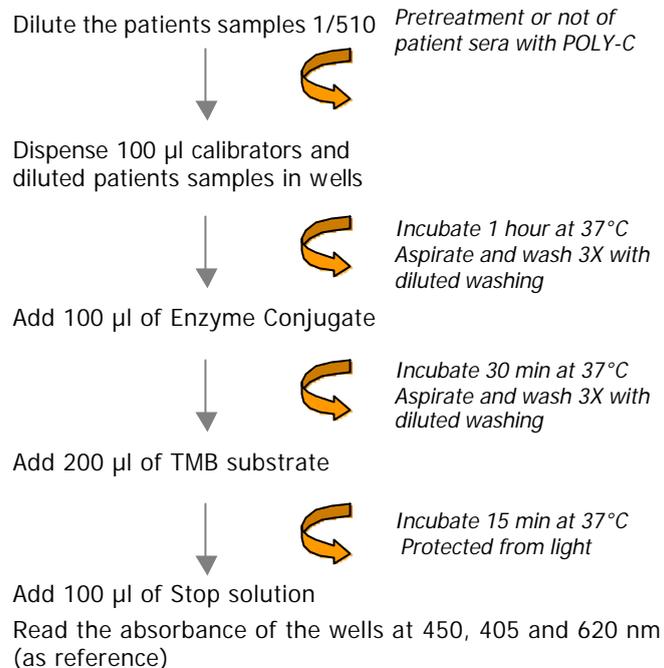
After carefully washing of the microplate wells, horse radish peroxydase coupled to monoclonal anti-human IgG is added in each well. The monoclonal antibody anti-hIgG-HRP reacts with the complexes adsorbed on the solid phase.

After washing, the chromogen solution is added in the wells and incubated. The reaction is stopped, the absorbance, proportional to the concentration of antibodies anti-pneumococcus, is measured at 450 nm with a spectrophotometer. By the use of a standard calibration curve, data are expressed in mU/ml .

For more details see at :

<http://www.zentech.be/diagnostic/PNEUMOCCOQUE/Pneumococcus.html>

Assay Scheme



23 most frequent serotypes

Based on differences in the composition of the polysaccharide capsule, about 90 serotypes are identified. The majority of pneumococcal disease in infants is associated with a small number of these serotypes, which may vary by region. Current data suggest that the 11 most common serotypes cause at least 75% of invasive disease in all regions.

Pneumococcal serotypes antigens							
P23/ P7							
Calibrated in antiserum FDA 89-SF standard							
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6B</u>	<u>7F</u>	<u>8</u>
<u>9N</u>	<u>9V</u>	10A	11A	12F	<u>14</u>		
15B	17F	<u>18C</u>	<u>19F</u>	19A			
	20	22F	<u>23F</u>	33F			

> FDA 89-SF Pneumococcal Reference Serum containing underlined serotypes

> **VACCINE A** used in ELIZEN Pneumococcus IgG is based on black and underlined serotypes (23 serotypes)

> **VACCINE B** is based on colored serotypes

