SSI DIAGNOSTICA

Instructions for use

# PNEUMOCOCCAL CWPS ANTIGEN PRODUCTS


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For *in vitro* diagnostic use

## Intended use

The SSI Diagnostica pneumococcal CWPS (cell wall polysaccharide) antigen products Pneumoccoccus CWPS and Pneumoccoccus CWPS Multi are intended for binding antibodies recognising epitopes on the pneumococcal cell wall polysaccharide.

Pneumoccoccus CWPS and CWPS Multi are intended for preabsorbing human serum samples before quantitation of specific pneumococcal capsular polysaccharide antibodies.

Pneumoccoccus CWPS and CWPS Multi may also be used as a coating agent upon performance of an ELISA test.

For use by clinical laboratories by their established procedures. The analytical and clinical performance has not been established by manufacturer.

## Description

Pneumoccoccus CWPS and Pneumoccoccus CWPS Multi are supplied in sealed glass vials containing approximately 10 mg lyophilized purified antigen (a white powder). Before use, the product needs to be dissolved in liquid (see the section “Procedure”). The number of tests that can be performed with one vial depends on the use of the products.

The CWPS1 antigen is a cell wall polysaccharide antigen common to all pneumococcal serotypes.
The CWPS Multi antigen product contains a 1:1 mixture of CWPS1 and CWPS2[1].

The CWPS antigens are produced by purification of CWPS from native fermented pneumococci strains and lot to lot variations can occur. Therefore, SSI Diagnostica recommends customers to order samples for performance testing in the customers own assays before a large quantity of a lot is ordered.
SSI Diagnostica antigen products are for use by laboratory professionals and/or healthcare professionals only.

## Principle

To measure a specific antibody response to a specific pneumococcal CPS (capsular polysaccharide), it is necessary to remove the antibodies against CWPS1 and CWSP2 (CWPS2 explained in WHO recommended assay as 22F capsule, because 22F capsule contains CWPS2) since they offer no protection against pneumococcal invasive diseases. By addition of CWPS to the human serum sample the antibodies against CWPS are removed[2]. By addition of CWPS Multi to the human serum sample the antibodies against CWPS1 and CWPS2F are removed.

## Precautions

- Do not use the CWPS after the expiry date.
- Inspect the vial before use to ensure it is intact. Any damaged vials should be discarded.

## Materials provided

The clear vial contains approximately 10 mg of CWPS1/CWPS2 or CWPS1 as a white powder. The supplied powder must be diluted before use.

## Materials required but not provided

- Sterile Type I ultrapure water, conforming to ASTM, CAP, NCCLS, USP and ISO specifications
- Mixer
- Sodium azide ($NaN_3$; Sigma, S-2002)

## Storage and stability

Store the unopened CWPS and CWPS Multi vials at 2-25 °C. Expiry date of the sealed vial is printed on the label. The stability of the stock solution (10 mg/mL) is 1-2 weeks at 2-8 °C and can be prolonged by addition of sodium azide. The dilution of 1 mg/mL can be stored at -80°C for 10 years.

## Sample collection and storage

For sample collection and storage please follow your local standard procedure.

## Quality control

Before use, check the vial to ensure that there is no damage and/or leak. In case of damage or leak discard the vial.

## Procedure

The procedure described herein is only covering the steps directly related to preparing the stock solution of CWPS or CWPS Multi, and not the procedure for absorption of serum samples.

Prepare stock solution of CWPS or CWPS Multi

- Remove the vial of lyophilised material from the 2-25 °C storage and allow it to come to room temperature (approximately one hour).
- Remove the aluminum crimp seal and septum. Be careful not to let any lyophilised material escape.
- Reconstitute the lyophilised antigen to 10 mg/mL by adding the 1 mL volume of sterile reagent grade water (type 1) to the vial.
- Aliquot the polysaccharide into 1.5 ml cryovials, label with reagent name, date, lot number, initials, and store at –70°C.

The recommended WHO absorption dilution is a final concentration of 10 µg/mL.

Coating of ELISA plates

To test the effect of adsorption CWPS can be used as an ELISA plate coating agent. The stock solution is diluted 1:4000 in coating buffer (2.5 µg/mL).

## Interpretation of results

CWPS and CWPS Multi is not intended for providing a result.

## Disposal

Follow your local procedures and/or national guidelines for disposal of biological materials.

## Limitations

There are no relevant limitations.

## Performance

### Repeatability

| Pneumococcal CWPS antigen products | | |
|---|---|---|
| | Percent (number positive/ actual positive) | 95% confidence interval |
| Repeatability | 100% (144/ 144) | 97%-100% |

Table 1: Repeatability for pneumococcal CWPS antigen products

### Reproducibility

The reproducibility of the pneumococcal CWPS antigen products is 100% (confidence interval 98%-100%). Therefore, all produced pneumococcal CWPS antigen products have a high level of reproducibility throughout time and lots.

## Incident reporting

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the member state in which the user and/or patient is established.

## Quality certificate

SSI Diagnostica's development, production and sales of *in vitro* diagnostics are quality assured and certified in accordance with ISO 13485.

Certificate of analysis can be downloaded from our website:
ssidiagnostica.com

Presafe Denmark A/S

Quality System DS/EN ISO 13485

REF 3459/ 68866

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CE

## References


1. Skovsted, I.C. et al., Purification and structure characterization of the active component in the pneumococcal 22F polysaccharide capsule used for adsorption in pneumococcal enzyme-linked immunosorbent assays, Vaccine. Aug 29;25(35):6490-500, 2007.

2. Training manual for Enzyme linked immunosorbent assay for the quantitation of *Streptococcus pneumoniae* serotype specific IgG (Pn PS ELISA). Prepared by the World Health Organization Pneumococcal Serology Reference Laboratories at the Institute of Child Health (London, England) and the Department of Pathology (Birmingham Alabama, USA, http://www.vaccine. uab.edu/uploads/mdocs/ELISAProtocol(007sp).pdf 2002/2011.


## Information and ordering


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5th edition · May 2022 · 54685

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