

Wellcogen S. Pneumoniae

See package insert for more information

Reagent Reconstitution:

Reconstitute the Polyvalent Positive Control using 1.2mL of sterile distilled water. After the addition of water, allow the bottle to stand for a few minutes and then swirl to mix. Store refrigerated until the expiration date of the kit.

Quality Control:

The following procedure should be carried out initially with each shipment of test kits and with each run of test samples. In practice a run may be defined as a testing period of up to 24 hours. POSITIVE Control: Check the performances of the latexes using a drop of Polyvalent Positive Control, either in place of the test sample or in addition to it after no reaction has taken place in 3 minutes. Definite agglutination should be obtained with the Test Latex reagent and there should be no significant agglutination with the control Latex.

NEGATIVE Control: For tests with body fluid specimens, a sample of normal body fluid should be used in place of the test sample. For tests with blood cultures, a sample of uninoculated media is important as false-positives can occur with some formulations of blood culture media.

Specimen Collection and Storage:

Body fluid samples should be tested as soon after collection as possible. If the fluid cannot be tested immediately it may be stored overnight at 2-8°C. If bacteriological analysis are required on the sample, these should be set up prior to performing the latex test, to avoid contaminating the sample.

Blood cultures may be sampled and tested after 18-24 hours incubation at 37°C and/or as soon as bacterial growth is observed.

Preparation of Clinical Specimens:

Body fluid samples must be heated before testing by the Wellcogen procedure to minimize non-specific reactions. The following procedures are recommended:

1. For CSF and urine, heat the sample for 5 minutes in a boiling water bath. Cool the sample to room temperature and clarify by centrifugation or membrane filtration prior to testing.
2. For serum, add 3 volumes 0.1M disodium ethylenediaminetetra-actetate (EDTA) pH 7.4 per 1 volume serum, heat the sample for 5 minutes in a boiling water bath and clarify as above.

Blood cultures. Centrifuge a 1-2mL sample to pellet the red blood cells, for example at 1000 g for 5-10 minutes. Perform the latex test on the supernatant. If a non-specific reaction occurs with a blood culture supernatant, heat the sample in a boiling water bath for 5 minutes, cool to room temperature, clarify by centrifugation and repeat the test.

Test Procedure:

1. Process the sample as described.
2. Shake the latex reagents.

3. For each test sample place 1 drop of Test Latex in one circle on a Reaction Card, and 1 drop of Control Latex in a separate circle. Ensure that the dropper bottles are held vertically to dispense an accurate drop.
4. Using a Disposable Dropper, dispense 1 drop of Test Sample next to each drop of latex.
5. Mix the contents of each circle with a mixing stick and spread to cover the complete area of the circle. Use a separate stick for each circle and discard it for safe disposal after use.
6. Rock the card slowly and observe for agglutination for 3 minutes, holding the card at normal reading distance from the eyes. The patterns obtained are clear cut and can be read under all normal lighting conditions.
7. Discard the used Reagent Card for safe disposal.

Reading of Results:

A positive reaction is indicated by the development of an agglutinated pattern within 3 minutes of mixing the latex particles.

In a negative reaction the latex does not agglutinate and the milky appearance remains substantially unchanged throughout the test.

Interpretation of Results:**Positive Result:**

Clear agglutination of the Test Latex accompanied by a lack of agglutination of the Control Latex indicates the presence of pneumococcal antigen in the body fluid or blood culture supernatant.

Negative Result:

Lack of agglutination in both reagents means that no pneumococcal antigen is detectable in the test sample – it does not eliminate the possibility of pneumococcal infection, and if symptoms persist it may be desirable to perform the test on subsequent or alternative specimens.

Non-Interpretable Result:

Visible agglutination of the Control Latex, whether stronger or weaker than the Test Latex, indicates a non-specific reaction. In most cases, non-specific reaction with body fluids may be eliminated by heating and clarifying the sample. If a non-specific reaction occurs with a blood culture supernatant, heat the sample in a boiling water bath for 5 minutes, cool to room temperature, clarify by centrifugation and repeat the test.