Staph Test Latex Kit DD-43

PRINCIPLE

The intended use of the Staphylococcus Latex Test kit is a rapid slide agglutination test for the screening and identification of isolated Staphylococcus Aureus colonies that produce clumping factor and/or protein A from other species of staphylococci that do not possess these factors.

CLINICAL SIGNIFICANCE

Plasma coagulase tests are commonly used in the identification of S. Aureus cultures. Two distinct factors are involved independently.

1. Cell associated clumping factor or bound coagulase which reacts with fibrinogen causing aggregation of the organisms. The usual test for this is the slide coagulase test.

2. Extracellular staphylocoagulase or free coagulase which activates prothrombin, and in so doing initiates clot formation with the plasma. The usual test for this is the tube coagulase test.

Approximately 97% of human isolates of S. *aureus* may produce coagulase, clumping factor and/or Protein A. The Staphylococcus latex test kit detects the presence of both clumping factor and protein A by using fibrinogen and human IgG coated latex particles in a rapid slide procedure. The test is therefore more sensitive than a slide coagulase test alone but may be less specific since some non-S. *aureus* species may non-specifically agglutinate latex particles. To eliminate these cases, and thereby improve the specificity of the test, a control reagent which is latex particles that are not coated with either fibrinogen or human IgG is provided in the test kit and should be used.

Over 95% of pathogenic strains of S. *aureus* produce protein A, either with or without clumping factor. Protein A has a high affinity for the Fc moiety of IgG. To this end, the S. *aureus* latex reagent has been designed to react with those species of Staphylococci possessing either clumping factor, protein A or a combination of both through rapid, strong agglutination of the latex particles.

WARNINGS AND PRECAUTIONS

For *in vitro* diagnostic use only. For professional use only.

All patient samples and reagents should be treated as potentially infectious and the user must wear protective gloves, eye protection and laboratory coats when performing the test.

Non disposable apparatus must be sterilised after use by an appropriate method.

Disposable apparatus must be treated as biohazardous waste and autoclaved or incinerated.

Spillages of potentially infectious material should be absorbed and disposed of as above. The site of spillage must be sterilised with disinfectant or 70% alcohol.

Do not pipette by mouth.

Components from human origin have been tested and found to be negative for HIV, HCV and HbsAg. Nonetheless the reagent must be treated as potentially infectious and appropriate precautions should be taken when handling and on disposal. The product also contains aqueous buffer salts including sodium azide as preservative - see material safety data sheet.

Analytical precautions:

Do not modify the test procedure.

All reagents are ready to use **do not** dilute or modify the reagents in any way.

Allow all reagents and samples to reach room temperature (18-30°C) before use.

STANDARD KIT PRESENTATION

Sufficient test and control latex reagent for 50/100 tests using vial dropper supplied.

Sample mixer sticks for 50/100 tests.

Reaction cards for 50/100 tests.

Instructions for use.

MATERIAL, EQUIPMENT REQUIRED BUT NOT PROVIDED.

Sterile loops

Timer

Recommended CL2 safety cabinet.

STORAGE AND SHELF LIFE

Store all reagents upright at 2-8C. Do not modify the test procedure. Do not use the reagents beyond the stated expiry date. DO NOT FREEZE THE REAGENTS. Reagents are ready to use, **do not** modify the reagents in any way. Allow all reagents and samples to reach room temperature (18-30C) before use. Hold the dropper bottle vertically to allow correct drop size to form.

RECOMMENDATIONS AND CONTROLS

Discard the reagent if the suspension becomes rough, (i.e. shows signs of auto-agglutination) or fails to agglutinate with cultures known to contain clumping factor or Protein A. Do not touch the reaction areas on the cards. Do not interpret agglutination that appears after 60 seconds as a positive result. Prolonged rocking can result in false-positive reactions with some coagulase-negative isolates. Microbiological contamination of reagents must be avoided as this may reduce the life of the product and cause erroneous results.

SPECIMEN AND SAMPLE PREPARATION

Consult a standard microbiological textbook for methods relating to specimen collection and the preparation of primary cultures on agar plates. The use of fresh overnight cultures is recommended and may be tested directly from the plate if there is sufficient growth. If there is insufficient growth subculture to enriched media such as blood agar base or nutrient agar and incubate overnight at 37C. Organisms grown on high salt media, such as mannitol salt agar, may show signs of roughness or stringiness when mixed with the test reagents. Any discrepancies can be eliminated by parallel use of the control latex with the test latex. Alternatively, sub-culturing to blood agar base or nutrient agar to avoid the problem. It is recommended that the culture should be Gram-stained in association with the latex test to confirm the staphylococcal morphology of the organisms.

RECOMMENDED PROCEDURE

Please read the analytical precautions before commencing the test

1. Shake the test latex reagent bottle well to obtain an even suspension and expel any air in the dropper tube.
Place one drop of reagent in the centre of a reaction circle on an agglutination slide for each culture to be tested.

2. Using a sterile loop, or mixing stick provided, pick off 4 - 5 colonies from a fresh overnight culture plate of the organism to be investigated, and emulsify in the drop of reagent on the slide by rubbing thoroughly without damaging the surface of the card.

3. Spread the sample and reagent to approx. half the area of the card and discard the mixing stick for safe disposal. Rotate the slide gently and observe for agglutination. Do not rotate for more than 1 minute. View only using normal laboratory lighting. Do not employ the use of magnifiers of bench lights.

4. In the case of rough or stringy samples, carry out the above procedure using the control latex and using the same sample culture.

The patterns obtained are clear cut and can be recognised under any normal lighting conditions.

5 Dispose of the card into disinfectant – **do not re-use.**

INTERPRETATION OF RESULTS

POSITIVE RESULT: Indicated by the clearly visible aggregation of the latex particles within 60 seconds accompanied by a clearing of the milky background. This will normally occur within a few seconds of mixing.

NEGATIVE RESULT: Indicated by a substantially unchanged milky appearance without any visible signs of aggregation of the latex particles after 60 seconds. Faint traces of granularity may be detected in negative patterns, due to the particulate nature of reagents and the visual acuity of the operator.

Agglutination of the test latex reagent without agglutination of the control reagent indicates the presence of either clumping factor or protein A. If the control reagent also shows agglutination, then other biochemical tests will be necessary.

LIMITATIONS OF THE METHOD

Specimens grown on high-salt-supplemented media such as mannitol-salt agar tend not to emulsify well giving 'rough' or 'stringy' reactions and may be relatively weak in their protein A and coagulase content.

Some species of staphylococcus other than *S.aureus* (notably *S. intermedius* and *S.hyicus*) may give positive results in conventional coagulase tests and may also agglutinate latex reagents. If necessary, these species may be identified by biochemical test procedures, but they are not considered to be of major clinical significance in man.

Rare species such as *S.lugdunensis* and *S.schleiferi* have been reported as clumping factor positive. Novobiocin resistant strains may also give false positive results using latex based tests. Several species such as *E.coli* and *C.albicans* are capable of non-specifically agglutinating latex particles. Organisms that possess immunoglobulin or plasma protein binding factors may also agglutinate the test reagent latex.

To eliminate potential interference from these organisms a Gram stain should be performed so that only organisms with staphylococcal morphology are tested.

PERFORMANCE CHARACTERISTICS

A blind trial was carried out by the Leicester PHLS.

Two hundred and fourteen reference strains were tested. These represented a number of commonly isolated species together with certain rare species. These included 40 known Novobiocin resistant strains and 20 known clumping factor positive species not represented in the summary below.

Sensitivity 15/15 = 100%,

Specificity 128/134 = 95.5%

INTERFERING SUBSTANCES

See Limitations of Method

DISCLAIMER

The user is responsible for the performance of the reagent by any method other than those mentioned in the Recommended Techniques. Any deviations from the **Recommended Procedures** should be validated prior to use.

QUALITY CONTROL

Testing should be run with each shipment and new kit lot number received. Each laboratory should follow their state and local requirements. Under normal circumstances it will become apparent in day-to-day testing if the reagent fails to operate properly. The latex suspension should always be inspected for granularity as it is dropped onto the test card. Some granularity can be removed by shaking vigorously but if there is evidence of autoagglutination, the suspension should not be used.

A control latex is provided and should be used to verify that the organism under test does not agglutinate latex particles non-specifically. The user should periodically check:

1. The test reagent agglutinates with a known *S.aureus* strain
2. The test and control reagents do not auto agglutinate in normal saline solution.

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TABLE OF SYMBOLS

SYMBOL	DEFINITION
LOT	Batch Number
IVD	*In-vitro* Diagnostics
REF	Catalogue reference
	Store at
	Expiry date
	Manufacturer
	Date of Manufacture
	Read the instructions for use
	Single Use Only, not for reuse
	Number of Tests