Diagnostic Automation/Cortez Diagnostics, Inc.

IMMUNO DIAGNOSTICS

STAPHSLIDE LATEX TEST KIT

REF A02-STA-53

IVD See External Label 2°C 8°C Σ 25/50Tests

INTENDED USE

The Cortez Diagnostics Inc. Staphslide Latex Test is a slide agglutination assay for the qualitative detection of coagulase (both clumping factor and protein A) to identify *Staphylococcus aureus* to the exclusion of other species of staphylococci. This test is for use on pure culture samples suspected of being *S. aureus*. The Cortez Diagnostics Inc. Staphslide Latex Test does detect methicillin resistant *S. aureus* (MRSA) strains that produce clumping factor and protein A. These materials are intended to be acquired, possessed and used only by health professionals.

SUMMARY AND EXPLANATION

Although staphylococci are commonly found on the skin and mucous membranes, they have been associated with many human and animal infections,[1]. *S. aureus*, coagulase positive staphylococci, has been identified as a cause of suppurative infections, food poisoning, toxic shock syndrome and has been isolated from nearly all anatomical sites.

ASSAY PRINCIPLE

Erythrocytes are lysed by saponin, and the released hemoglobin is deoxygenated by dithionite in a concentrated phosphate buffer.[3] Hb-S when deoxygenated, is insoluble in concentrated phosphate buffer and produces visible turbidity. Since almost all other hemoglobin (i.e., Hb-A, -F, -C, -E, -D) are soluble, blood specimens containing Hb-S are easily identified.

When a positive specimen is identified, the addition of urea to the reaction mixture will cause the solution to become clear if Hb-S is present. If the solution remains turbid after adding urea, a non Hb-S is indicated. Electrophoresis assay is required for conclusive identification. The method presented here is based upon a modified Nalbandian procedure.[4,5]

MATERIALS AND COMPONENTS

Materials Provided with the Kit

Materials	25 Tests	50 Tests
Staphslide Latex Reagent	1.25 ml	2.5 ml
Reactive Control	0.5 ml	1 ml
Nonreactive Control	0.5 ml	1 ml
Test Cards (10-well)	3	5
Disposable Stirrers	25	50

Materials required but not provided

1. Timing Device
2. *S. aureus* organism, ATCC 12600 strain (positive control)
3. *S. epidermidis* organism, ATCC 12228 strain (negative control)
4. Biohazard receptacle

REAGENTS

Latex reagent - Suspended inert plasma-coated latex particles, with 0.1% Sodium Azide as preservative.

Controls (Reactive, Nonreactive) – Suspensions of non-viable control organisms with 0.2% Sodium Azide and 0.2% Gentamicin Sulfate as preservatives.

HANDLING AND PROCEDURAL NOTES

1. In order to obtain reliable and consistent results, the instructions in the package insert must be strictly followed. Do not modify the handling and storage conditions for reagents or samples.
2. Do not use past the expiration date indicated on the kit.
3. Do not interchange components of one kit with those of another kit.

STORAGE

- Store reagent at 2-8°C in an upright position when not in use.
- Do not freeze reagent.
- Test cards and stirrers do not require refrigeration.

INDICATIONS OF DETERIORATION

Bacterial contamination of reagents or specimens may cause false positive results.

WARNINGS AND PRECAUTIONS

For *In Vitro* Diagnostic Use.

1. Cortez Diagnostics Inc. Staphslide Latex Reagent and Controls contains sodium azide. Azides in contact with lead and copper plumbing may react to form highly explosive metal azides. When disposing of reagents containing azide, flush down the drain with large quantities of water to prevent azide build-up.
2. Do not pipet by mouth.
3. Do not smoke, eat, drink or apply cosmetics in areas where patient samples are handled.
4. Any cuts, abrasions or other skin lesions should be suitably protected.

SPECIMEN COLLECTION AND STORAGE

1. Use only pure, 24-hour cultures, grown on 5% sheep blood agar plates.
2. Handle cultures using standard biohazard techniques.
3. Samples to be sent out for testing should be placed on ice packs and packaged like any other biohazardous material that could potentially transmit infection.

PREPARATION FOR THE ASSAY

1. Allow all reagents and samples to warm to room temperature (20-30°C) before use. Remove reagents from foam holders. Do not heat reagents in a water bath.
2. Latex Reagent and Controls are ready for use as supplied. Gently mix the reagents before use; avoid foaming.

ASSAY PROCEDURE – QUALITATIVE

1. Add a drop of the LATEX REAGENT to a well of the test card.
2. Using a disposable stirrer, collect a visible amount of an isolated colony about 2 mm in size from the overnight culture grown on 5% sheep blood agar plate.
3. Emulsify the culture sample in the LATEX REAGENT on the card. Discard the stirrer into an appropriate biohazard container.
4. Add one free-falling drop of REACTIVE or NONREACTIVE CONTROL from the dropper vial supplied. Note the location of each sample by using the numbers located below and to the left of each circle.
5. Gently tilt and rotate the card in a complete circular motion for up to 45 seconds, or until agglutination is evident, whichever comes first. Positive reactions usually occur within 15-20 seconds.
6. View the mixture on the card, using only a high intensity light source. Do not use a magnifying lens.
7. Record the results. Dispose of the card into an appropriate biohazard container.

QUALITY CONTROL

Quality control requirements must be performed in accordance with applicable local, state and/ or federal regulations or accreditation requirements and your laboratory's standard Quality Control Procedures. Controls with graded reactivity should be included. If control samples do not yield the expected response, the assay should be considered invalid and the assay repeated. If the repeat assay does not elicit the expected results for the control samples, discontinue use of the kit and contact DACD Technical Support at 818-591-3030.

1. To check for auto agglutination, add one drop of LATEX REAGENT to a slide. No degree of agglutination should occur.
2. For a positive control, use either the liquid control or a known S. aureus control organism (ATCC 12600 strain) grown overnight at 37°C on 5% sheep blood agar plates and treat as in the Assay Protocol.
3. For a negative control, use either the liquid control or a known S. epidermidis control organism (ATCC 12228 strain) grown overnight at 37°C on 5% sheep blood agar plates and treat as in the Assay Protocol."

RESULTS

NEGATIVE: Smooth suspension with no visible agglutination after 45 seconds.
POSITIVE: Any degree of agglutination as compared to the negative control.

LIMITATIONS OF THE PROCEDURE

1. The **Cortez Diagnostics Inc. Staphslide Latex Test** does detect methicillin resistant *S. aureus* (MRSA) strains that produce clumping factor and protein A.
2. Strains of some *S. aureus* which do not possess clumping factor and protein A may give negative results in the test. Additional biochemical tests may be necessary to assist in identification.
3. Occasionally a culture sample may cause LATEX REAGENT to appear stringy or speckled and not demonstrate typical agglutination. This result necessitates further biochemical testing to identify the organism.
4. False positive results may occur with *S. saprophyticus* for protein A and therefore cause misidentification as *S. aureus*. Protein A determinations should not be performed alone, especially on cultures from urine.
5. Less than heavy suspensions of the test organism can be used, but reactions tend to be weaker and slower in agglutinating and may lead to erroneous results.
6. Rough strains of staphylococci and yeasts frequently cause nonspecific reactions and should therefore be distinguished by morphological criteria.
7. Some streptococci possess plasma protein-binding factors; and several species, such as members of the Enterobacteriaceae, nonspecifically agglutinate latex particles.
8. Gram stains should be performed to ensure that only organisms with staphylococcal morphology are tested.
9. Media such as mannitol salt agar, containing high salt concentrations, inhibit protein A production and can cause false negative reactions.
10. Temperature of the REAGENTS and samples is crucial to test outcome. It should be between 20 and 30°C.
11. Reaction times longer than specified might cause false positive results due to a drying effect.
12. In accord with all diagnostic methods, a final diagnosis should not be made on the results of a single test, but should be based on a correlation of test results with other clinical findings.

EXPECTED VALUES

Specimens containing HbS/S, HbS/A, HbS/C, HbS/D, HbS-thalassemia and HbS/N (Baltimore) reportedly produce positive results.[10] Specimens containing normal hemoglobin and HbA/C, HbC/C, HbA/F, and thalassemia reportedly produce negative results.[13] However, low solubility variants such as Hb-H, King's County and Stanley II may show false positive results.[4,5]

The homozygous form of Sickle Cell Disease affects 0.3% of the black population. In America and Africa, HbS/A is the most common hemoglobin variant, approximately 8% in African Americans (heterozygous form) and 30% in African Blacks. The mutation probably originated in Central Africa and spread to countries bordering the Mediterranean Sea, including the non-black people of these areas, e.g. Italy, Greece, Turkey and some of the Arabic nations. The heterozygous state does not cause anemia or shortened red cell life span, but 1 in 6000 African Americans are homozygous for Hb-C.

REFERENCES

1. Kloos WE, Smith PB. 1980 In EH Lennette, A. Bawlows, WJ Hausler, JP Truant (ed.) *Manual of Clinical Microbiology*, 3rd ed., American Society for Microbiology, Washington D.C.
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3. Miller JM, Miller JD, McAllister S. 1997. Presentation to the American Society for Microbiology. C-201.
4. Aldridge KE, Kogos C, Sanders CV, Marier RL. 1984. *Clin Microbiol*, 19:703-704.

WARRANTY

This Product is warranted to perform as described in its labeling and Cortez Diagnostics Inc. literature. Cortez Diagnostics Inc. disclaims any implied warranty of merchantability or fitness for a particular purpose and in no event shall Cortez Diagnostics Inc. be liable for consequential damages.

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