Institution:_____ Procedure No.:_____

Procedure: **ASI STAPHSLIDE LATEX TEST**		Doc#: 6004-280C CLSI
Effective Date: 09/08	Supersedes Revision/Date: 08/08	Revision: 09/08
Supersedes Procedure #	Prepared by: ASI	Date Adopted:

Review Date:			
Revision Date:			
Signature:			

For in vitro diagnostic use

Catalog Number	Kit Size
280-2-25	25 Tests
280-2-50	50 Tests
280-2	150 Tests

CPT Code: 87449

1 **INTENDED USE:** The **ASI 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 **ASI 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.

2 **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.

3 **PRINCIPLE OF THE PROCEDURE**: The coagulase tube test has long been accepted as the standard procedure routinely used for the identification of *S. aureus* [1]. This and other procedures typically require 24 to 48 hours to complete. Essers and Rodebold have shown that staphylococci can be differentiated by a rapid slide latex agglutination procedure with the same reliability as the tube coagulase method[2]. The **ASI Staphslide Latex Test** is a test of this nature, utilizing plasma-coated latex particles that will simultaneously bind both clumping factor and protein A. The aggregation of the latex reagent upon mixing with a culture sample, within 45 seconds, represents a positive reaction. This test is easily visible to the unaided eye and has been shown to correlate 91% in one study[3] and 100% in another study[4] with the tube coagulase test.

4 **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.

5 **WARNINGS AND PRECAUTIONS**
For *in vitro* diagnostic use

5.1 ASI 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.

5.2 Do not pipet by mouth.

5.3 Do not smoke, eat, drink or apply cosmetics in areas where patient samples are handled.

5.4 Any cuts, abrasions or other skin lesions should be suitably protected.

6 HANDLING AND PROCEDURAL NOTES

6.1 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 reagent or samples.

6.2 Do not use past the expiration date indicated on the kit.

6.3 Do not interchange components of one kit with those of another kit.

7 STORAGE INSTRUCTIONS:

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.

8 INDICATIONS OF DETERIORATION

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

9 SPECIMEN COLLECTION AND STORAGE

9.1 Use only pure, 24-hour cultures, grown on 5% sheep blood agar plates.

9.2 Handle cultures using standard biohazard techniques.

9.3 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.

10 PERFORMANCE OF THE TEST

MATERIALS PROVIDED

	25 Test	50 Tests	150 Tests
STAPHSLIDE LATEX REAGENT	1.25 ml	2.5 ml	3 x 2.5 ml
REACTIVE CONTROL	0.5 ml	1.0 ml	2.0 ml
NONREACTIVE CONTROL	0.5 ml	1.0 ml	2.0 ml
Test Cards (10 well)	3	5	15
Disposable Stirrers	25	50	150

11 ADDITIONAL MATERIALS REQUIRED

11.1 Timing device
11.2 *S. aureus* organism, ATCC 25923 strain (positive control)
11.3 S. epidermidis organism, ATCC 12228 strain (negative control)
11.4 Biohazard receptacle

12 **TEST PROCEDURE**

12.1 PREPARATION FOR THE ASSAY

12.1.1 Allow all reagents and samples to warm to room temperature (20-30 °C) before use. Remove reagent from foam holder. Do not heat reagent in a water bath.

12.1.2 LATEX REAGENT AND CONTROLS are ready for use as supplied. Gently mix the reagents before use; avoid foaming.

12.2 ASSAY PROTOCOL - QUALITATIVE

12.2.1 Add a drop of the LATEX REAGENT to a well of the test card.

12.2.2 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.

12.2.3 Emulsify the culture sample in the LATEX REAGENT on the card. Discard the stirrer into an appropriate biohazard container.

12.2.4 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.

12.2.5 Gently tilt and rotate the card in a complete circular motion for up to 45 seconds, or until agglutination is evident, whichever occurs first. Positive reactions usually occur within 15-20 seconds.

12.2.6 View the mixture on the card, using only a high intensity light source. Do not use a magnifying lens.

12.2.7 Record the results. Dispose of the card into an appropriate biohazard container.

13 **QUALITY CONTROL**: Positive and negative controls should be included in each run of test samples:

13.1 To check for auto agglutination, add one drop of LATEX REAGENT to a slide. No degree of agglutination should occur.

13.2 For a positive control, use either the liquid control or a known *S. aureus* control organism (ATCC 25923 strain) grown overnight at 37 °C on 5% sheep blood agar plates and treat as in the Assay Protocol.

13.3 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.

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 test and contact ASI Technical Support (800) 654-0146.

14 **INTERPRETATION OF RESULTS**

14.1 POSITIVE: Any degree of agglutination as compared to a negative control.

14.2 NEGATIVE: Smooth suspension with no visible agglutination after 45 seconds.

15 LIMITATIONS OF THE PROCEDURE

15.1 The **ASI Staphslide Latex Test** does detect methicillin resistant *S. aureus* (MRSA) strains that produce clumping factor and protein A.

15.2 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.

15.3 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.

15.4 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.

15.5 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.

15.6 Rough strains of staphylococci and yeasts frequently cause nonspecific reactions and should therefore be distinguished by morphological criteria.

15.7 Some streptococci possess plasma protein-binding factors; and several species, such as members of the *enterobacteriaceae*, nonspecifically agglutinate latex particles.

15.8 Gram stains should be performed to insure that only organisms with staphylococcal morphology are tested.

15.9 Media such as mannitol salt agar, containing high salt concentrations, inhibit protein A production and can cause false negative reactions.

15.10 Temperature of the REAGENTS and samples is crucial to test outcome. It should be between 20° and 30°C.

15.11 Reaction times longer than specified might cause false positive results due to a drying effect.

15.12 In accord with all diagnostic methods, a final diagnosis should not be made on the result of a single test, but should be based on a correlation of test results with other clinical findings.

16 REFERENCES

16.1 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.

16.2 Easers L, Rodebold K. 1980. *J Clin Microbiol*, **12**:641-643.

16.3 Miller JM, Miller JD, McAllister S. 1997. Presentation to the American Society for Microbiology. C-201.

16.4 Aldridge KE, Kogos C, Sanders CV, Marier RL. 1984. *Clin Microbiol*, **19**:703-704.

TECHNICAL INFORMATION: (801) 489-8911 or (800) 654-0146