Fisher HealthCare

KIT 150 TESTS, CAT. NO. 23046500
KIT 300 TESTS, CAT. NO. 23046501

CE

Sure-Vue® Color Staph ID

A Rapid, Color Enhanced Latex Slide Test For The Detection of Clumping Factor and Protein-A Associated with *Staphylococcus Aureus*.

AN AID IN THE IDENTIFICATION OF *Staphylococcus aureus* FROM CULTURE

INTENDED USE

The **Sure-Vue® Color Staph ID** is a rapid, color enhanced latex agglutination test to detect clumping factor and/or Protein-A, two characteristics associated with *Staphylococcus aureus* colonies obtained from culture. **Sure-Vue® Color Staph ID** latex reagent will react with either or both of these characteristics.

SUMMARY AND EXPLANATION

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

The coagulase tube test has long been the standard procedure routinely used for identification of *S. aureus*.[1] Although other procedures require up to 48 hours to complete, this test can be performed as soon as a fresh overnight culture is available. Essers and Radebold have shown that staphylococci can be differentiated by a rapid slide latex agglutination procedure with the same reliability as the tube coagulase method.[2]

Performance characteristics of the **Sure-Vue® Color Staph ID** show 100% detection of coagulase positive, methicillin resistant staphylococci.

PRINCIPLE

The **Sure-Vue® Color Staph ID** is a rapid test utilizing protein-coated latex particles which are capable of simultaneously detecting both clumping factor and Protein A. The aggregation of the smooth latex suspension represents a positive reaction which is visible to the unaided eye within 10-30 seconds, producing a red agglutination in a “blue” background.

REAGENTS AND MATERIALS SUPPLIED

For In Vitro Diagnostic Use Only
Store All Reagents at 2 - 8°C
Bring All Reagents To Room Temperature Before Use
DO NOT FREEZE Any Reagent

KIT COMMPONENT	150 tests	300 tests
Test Latex Reagent Protein-coated latex particles suspended in buffer and 0.02% sodium azide.	1 x 2.6mL	2 x 2.6mL
Control Latex Reagent Non-reactive protein (BSA) coated particles in buffer and 0.02% sodium azide.	1 x 2.6mL	2 x 2.6mL
Positive Control Reagent A formulation of non-viable *S. aureus* in buffer and 0.1% sodium azide	1 x 0.5mL	1 x 0.7mL
Negative Control Reagent A formulation of non-viable *S. epidermidis* in buffer and 0.1% sodium azide.	1 x 0.5mL	1 x 0.7mL
Disposable 8- Well Test Cards	40 each	80 each
Disposable Mixing Sticks	300 each	600 each
Test Instructions	1	1

MATERIALS REQUIRED BUT NOT SUPPLIED

- A timing device

Use the **Sure-Vue® Color Staph ID** Test in accordance with the supplied instructions

PRECAUTIONS

This product should only be used by properly trained individuals. Precautions should be taken against microbial hazards. The toxicity of these reagents has not been determined. Do not pipet by mouth; do not ingest.

STABILITY OF THE REAGENTS

Some settling of the latex particles may occur when stored at 2-8°C for a period of time. After gentle mixing, the **Sure-Vue® Color Staph ID** latex reagents should appear as a purple homogeneous suspension of particles. If non-specific clumping is observed, which is not dispersed by normal resuspension procedures, do not use the reagent. The kit should be discarded upon its expiration date. Do not mix reagents from different kit lots.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Overnight (18-24 hours) culture of a primary plate will provide a fresh, sufficient sized colony specimen (approximately 2mm). Sample the colony with a fresh mixing stick. It is preferable to use nutrient or sheep blood agar for any subculture which is to be tested if contamination of the culture is suspected. An identical sampling maneuver should be followed for any subcultured colony. The colony should be gram-stained to confirm the morphology and gram-positive characteristics of the organism. Catalase reaction is also useful.

Cultures to be tested may be selected from any of the following media:

Columbia Agar	Nutrient Agar
Columbia CNA Agar	Sheep Blood Agar
Mannitol Salt Agar	Tryptic Soy Agar
Mueller-Hinton Agar w/ 5% Blood	Tryptic Soy Agar w/ 5% Blood

Confirm morphologic appearance of suspect *S. aureus* colonies from a suitable solid medium (Trypticase Soy Agar w/5% Sheep Blood) by Gram stain. Once confirmed, perform the agglutination test as follows:

PROCEDURE

ENSURE THAT REAGENTS ARE AT ROOM TEMPERATURE

1. Just prior to use, resuspend the Test Latex Reagent and Control Latex Reagent by gentle but thorough inversion of each for a few seconds.
2. Add one drop (~17 µL) of the Test Latex Reagent directly to a reaction well, in the top row of the card, for each unknown and control organism to be tested.
3. Add one drop of the Control Latex Reagent directly to a corresponding, adjacent reaction well, in the bottom row of the card.
4. Use a fresh mixing stick to apply one fresh colony to a reaction well containing Test Latex Reagent. Mix for approximately **10 seconds**, emulsifying the colony in the latex reagent. Spread to cover the entire circle.
5. Use a fresh mixing stick to apply one fresh colony (similar in size and morphology as used with the Test Latex Reagent) to the adjacent well containing the Control Latex Reagent. Mix for approximately **10 seconds,** emulsifying the colony in the latex reagent. Spread to cover the entire circle.
6. Rotate the slide using a rocking motion for **30 seconds**. Reactive samples may be recorded as soon as agglutination is evident. Negative results should not be reported until thirty seconds of rotation.
7. Repeat the procedure, steps 2 through 6, for each specimen to be tested.
8. Notify **biokit USA** if the expected results are not obtained with appropriate controls.

QUALITY CONTROL

Visually evaluate the latex reagents each time they are used to verify the absence of any aggregation or autoagglutination. Suspensions of non-viable control organisms are provided for quality control, but if preferred the laboratory may substitute freshly cultured, known control organisms. Liquid controls provided are used by testing one drop in the same manner as one colony would be tested (Steps 4-6 above).

- The Test Latex Reagent must show agglutination with *S. aureus* and absence of agglutination with *S. epidermidis*.

- The Control Latex Reagent should not agglutinate with either organism.
- To ensure performance of the Control Latex Reagent American Type Culture Collection (ATTC) strain # 49453 *Staphylococcus saprophyticus*, may be used. Colonies grown from the viable organism should show agglutination with the Control Latex Reagent and Test Latex reagent, indicating a non-interpretable result.*

*This reference material may be purchased on-line at www.atcc.org or by calling 800-638-6597. Cultures are also provided by ATCC through a link on the Clinical Laboratory Standards Institute website at www.clsi.org.

Good Laboratory Practices to Follow:

1. Refer to test instructions before proceeding.
2. Allow the reagents to reach room temperature before using.
3. RESUSPEND the latex reagent before dispensing into the circles.
4. Do not reuse any circle on the card.
5. Use a fresh mixing stick to deliver and mix each specimen.
6. Do not allow the tip of either latex vial to touch a specimen.
7. Follow appropriate microbiological procedures in handling and disposing of the material used in the performance of the test.
8. Replace the proper caps on their respective vials.

INTERPRETATION OF RESULTS

This test is considered positive when red agglutination with change of the background color to "blue" (slight to significant) is determined by the unaided eye. Strain variations and the concentration of the cell suspension will affect the degree of agglutination and color change. This test is considered negative when no agglutination occurs and the appearance of the latex remains unchanged (homogeneous purple) throughout the test well.

Some reactions may occur as colored specs or as rough, stringy or thread-like aggregates. When accompanied by a background that shows no color change, they should be interpreted as a negative. If a color change (reddish aggregates with a "blue" background) is evident, they should be read as a positive.

Some strains of MRSA cause a stringy reaction accompanied by a definite color change from purple to blue. These strains will *not* agglutinate the Control Latex Reagent and should be interpreted as a positive result.

When agglutination is noted with Control Latex Reagent, then the corresponding Test Latex result is considered Non-interpretable. In such cases, the organism should be identified using alternate methods such as testing for the presence of free coagulase or heat-stable DNAse. **Users verifying positive results by an alternate method may elect to eliminate the use of the Control Latex Reagent. However, the specificity of the test system can decrease to 92%.**

The test is considered invalid if either control gives an unexpected result or the expiration date of the reagents has been exceeded.

LIMITATIONS

1. When specimens have been grown on high salt-containing media and the culture is older than 48 hours, rough, stringy and non-interpretable results may occur. In these instances, the concentration of coagulase and Protein-A may be reduced and produce a false negative.
2. Staphylococci isolated from urine specimens which give weak-to-moderate reaction or stringy reaction may be *S. saprophyticus.* .When such is suspected, further identification of isolates may be conducted using biochemical tests and novobiocin sensitivity (*S. saprophyticus* is resistant to novobiocin).
3. Although other catalase-positive staphylococci, such as *S. hyicus* and *S. intermedius* can agglutinate the latex reagent, they are rarely associated with human infection.[3]
4. Some laboratories have reported erroneous results when using wooden mixing sticks. Plastic sticks are provided.
5. Rough strains of staphylococci and yeasts frequently cause non-specific reactions and should therefore be distinguished by morphological criteria.

EXPECTED VALUES

Within 30 seconds of the initial mixing of the latex reagent and fresh specimen, agglutination **and** color change indicate a positive result. If no agglutination **and** color change is observed by 30 seconds after the initial mixing, coagulase and/or Protein-A associated with *S. aureus*, is not present at detectable levels indicating a negative result.

PERFORMANCE CHARACTERISTICS

The **Sure-Vue® Color Staph ID** latex was evaluated on 144 isolates.

S. aureus	N=133
S. epidermidis	N=6
S. saprophyticus	N=4
S. intermedius	N=1

Test Results with **Sure-Vue® Color Staph ID:**

True Positives =132
False Negatives =1
Sensitivity =99%

True Negatives =11
False Positives =0
Specificity =100%

MRSA

True Positives =36
False Negatives =0
Sensitivity =100%

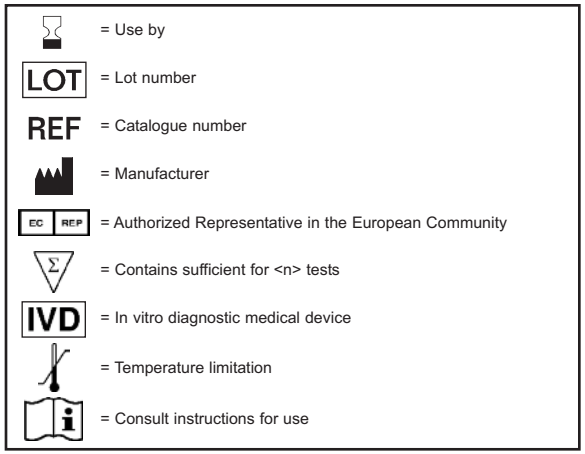
Although there is no label claim as to the detection level of MRSA, this study included 36 cultures as determined by growth on an Oxacillin plate. These test reagents and format detected all 36 organisms.

S. saprophyticus has been reported to cause false positive results in latex test systems. Several ATCC traceable strains of *S. saprophyticus* were tested in this and in several other commercial kits. One of these traceable organisms falsely agglutinated all commercial kits tested. **Because this organism also agglutinated the Control Latex Reagent, it was properly identified as Non-interpretable.** When such is suspected, further identification of isolates may be conducted using biochemical tests and novobiocin sensitivity (*S. saprophyticus* is resistant to novobiocin).

BIBLIOGRAPHY

1. Kloos WE and Smith PB: Manual of Clinical Microbiology, 3rd ed., Lennett EH, Balows A, Hausler WJ, Jr and Truant JP (ed); American Society for Microbiology, Washington, D.C.
2. Essers L and Radebold K: J Clin Microbiol 1980; 12:641 - 643.
3. Philips, WE and Kloos WE: Identification of coagulase-positive *Staphylococcus intermedius* and *Staphylococcus hyicus subsp. hyicus* isolates from veterinary clinical specimens: J Clin Microbiol 1981;14:671-673.

NOTE: Adulteration of these reagents, or otherwise failing to follow the instructions exactly as set forth in this labeling can adversely affect performance characteristics and any stated or implied claim.



Integrated Science Systems
1215 George C Wilson Dr. #A4
Augusta, GA30909, U.S.A.

Manufactured for: biokit/INOVA Diagnostics, Inc.
San Diego, CA 92131, U.S.A.
1-800-926-3353

Distributed by: Fisher HealthCare, Inc.
Houston, TX 77038, U.S.A.
To Order: 1-800-640-0640

EC REP MT Promedt Consulting GmbH
Altenhofstrasse 80
66386 St. Ingbert, Germany
Tel.: +49 6894 - 581020
Fax: +49 6894 - 581021

SVCS(1213).Rev07