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. 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. 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.

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 To Room Temperature Before Use
DO NOT FREEZE Any Reagent

KIT COMPONENTS
Test Latex Reagent
1 x 2.6mL
Control Latex Reagent
1 x 2.6mL
Positive Control Reagent
1 x 0.5mL
Negative Control Reagent
1 x 0.5mL
Disposable 8-Well Test Cards
40 each
Disposable Mixing Sticks
300 each
Test Instructions
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QUALITY CONTROL

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
- Columbia CNA Agar
- Mannitol Salt 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 emulsifying the colony in the latex reagent. Spread to cover the entire circle.
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:
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.
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.
PERFORMANCE CHARACTERISTICS

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

<table>
<thead>
<tr>
<th>Organism</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>S. aureus</td>
<td>133</td>
</tr>
<tr>
<td>S. epidermidis</td>
<td>6</td>
</tr>
<tr>
<td>S. saprophyticus</td>
<td>4</td>
</tr>
<tr>
<td>S. intermedius</td>
<td>1</td>
</tr>
</tbody>
</table>

Test Results with Sure-Vue® Color Staph ID:

- **True Positives** = 132
- **False Negatives** = 0
- **Specificity** = 100%
- **Sensitivity** = 99%

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**


**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.