Fisher HealthCare

KIT 150 TESTS, CAT. NO. 23 038056
KIT 300 TESTS, CAT. NO. 23 046870

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Sure-Vue® SELECT Staph ID

SCREENING / IDENTIFICATION SYSTEM

Latex Slide Agglutination Test Kit

INTENDED USE

The **Sure-Vue® SELECT Staph ID** latex slide agglutination test is a rapid test for the detection of both clumping factor and protein A which are used in the identification of *Staphylococcus aureus*.

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]

PRINCIPLE

The **Sure-Vue® SELECT 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 usually within 5-20 seconds, producing a red agglutination with clearing of the opaque 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 COMPONENT	150 tests	300 tests
Test Latex Reagent Protein-coated latex particles suspended in buffer and 0.02% sodium azide.	2 x 3.4mL	3 x 4.6mL
Disposable 6- Well Test Cards	25 each	50 each
Disposable Mixing Sticks	150 each	300 each
Test Instructions	1	1

MATERIALS REQUIRED BUT NOT SUPPLIED

- A timing device

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

PRECAUTIONS

This product is FOR *IN VITRO* DIAGNOSTIC USE and should be used by properly trained individuals. Appropriate precautions should be taken against microbial hazards. The toxicity of these reagents has not been determined. Do not pipet by mouth; do not ingest.

STORAGE

This reagent should be stored at 2 - 8ºC. Under these conditions, the shelf life given on the label will be maintained. Return to refrigerated storage after use.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Overnight culture of a primary plate will provide fresh, sufficient sized colonies. Sample 2 colonies 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

Use only fresh (18 - 24 hour) control and test organisms.

1. Prior to each use, resuspend the **Sure-Vue® SELECT Staph ID** reagent by gentle inversion for a few seconds. Place a drop (~40µl) in each circle of the slide. One drop is necessary for each specimen to be tested.

2. Using a separate applicator stick for each test well, pick up **two** fresh colonies of identical morphology. Deposit and spread the colony material onto a dry portion of the well, next to the droplet of reagent. Then, mix the bacteria into the reagent droplet to obtain a homogeneous suspension covering the entire well.

3. Rotate the slide for 25 seconds observing for red clumps. Positive reactions (refer to Results section) usually take 5 to 20 seconds.

RESULTS

The test is considered positive when red clumps of agglutination, accompanied by clearing of the opaque background are visible to the unaided eye. The test is considered negative when no agglutination occurs.

Rough or stringy reactions appear as red specks or stringy aggregates and should be interpreted as positive when accompanied by a clearing of the background or negative when accompanied by an opaque pink (no clearing) background.

NOTE: Auto-agglutination is indicative of contamination or deterioration. The test is considered invalid if either stock control gives an unexpected result or the expiration date of the reagent has been exceeded.

QUALITY CONTROL

Evaluate the latex reagents each time they are used to verify the absence of any aggregation or autoagglutination. Do not use if auto-agglutination is evident or if the expiration date has been exceeded. Contact Sure-Vue® Technical Services (1-877-500-2049) if auto-agglutination is observed.

- Add one drop of reagent to a slide to check for auto-agglutination. No agglutination should occur.
- Use a known *S. aureus* control organism and treat as in PROCEDURE, steps 1-3. This is the positve control and should agglutinate.
- Use a known *S. epiderimidis* control organism and treat it as in PROCEDURE, steps 1-3. This is the negative control and should not agglutinate.

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.

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® SELECT Staph ID** latex reagents should appear as a red 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.

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.

PERFORMANCE CHARACTERISTICS

The **Sure-Vue® SELECT Staph ID** latex was evaluated on 243 isolates.

S. aureus	**N =156**		
MRSA	N = 61		
Non- S. aureus	**N = 87**		
S. epidermidis	N = 48	S. hominis	N = 11
S. saprophyticus	N = 6	S. capitis	N = 7
S. intermedius	N = 2	S. caprae	N = 2
S. lugdunesis	N = 2	S. auriculans	N = 1
S. haemolyticus	N = 4	S. warneri	N = 4

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

True Positives =156
False Negatives =0
Sensitivity =100%

True Negatives =87
False Positives =3
Specificity =97%

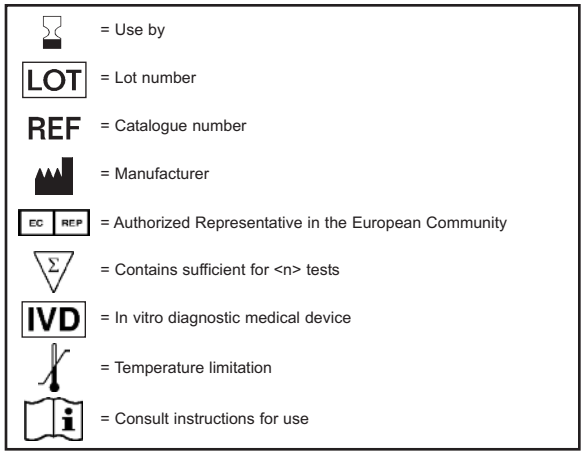
MRSA True Positives =61
False Negatives =0
Sensitivity =100%

Although there is no label claim as to the detection level of MRSA, this study included 61 cultures as determined by growth on an Oxacillin plate or analyzer. These test reagents and format detected all 61 organisms.

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.



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