STAPH RAPID LATEX TEST KIT

For professional *in Vitro* **diagnostic use only**

Latex slide agglutination test for the confirmatory identification of presumptive *Staphylococcus aureus* colonies

INTENDED USE
Staph Rapid Latex Test Kit is a rapid latex slide agglutination test for the confirmatory identification of presumptive Staphylococcus aureus colonies from primary plate culture. The kit is intended for professional use only.

PRINCIPLE OF THE TEST
Latex particles are coated with fibrinogen (to which coagulase binds) and IgG (which binds with Protein A). When mixed with a suspension of S. aureus, the latex particles rapidly agglutinate to form visible clumps. No obvious agglutination occurs in the absence of coagulase/Protein A-positive Staphylococci.

REAGENTS AND MATERIALS PROVIDED
REAG TEST ST1: 2 x 2,5mL- Latex particles coated with human fibrinogen and IgG.Preserved with 0.099% sodium azide (Black cap)
CONTROL +: 1 x 1mL. Inactivated preparation of S. aureus preserved with 0.099% sodium azide. (White cap)
17 CARD (SLIDE): Disposable agglutination slides (6 areas test)
100 STICKS: Disposable mixing sticks 4 x 25 items
INSTRUCTION FOR USE

MATERIALS REQUIRED BUT NOT SUPPLIED
Bacteriological loops; Timer

WARNINGS AND PRECAUTIONS
Safety:
- The reagents supplied in this kit are for in vitro diagnostic use only
- The kit is intended for professional use only.
- Sodium azide, which is used as a preservative in the kit reagents can react with lead or copper plumbing to form potentially explosive metal azides. Dispose by flushing with a large volume of water to prevent azide build-up.
- The IgG and fibrinogen used to sensitise the latex reagent are derived from human plasma which has been tested and found negative for the presence of antibodies to HIV-1, HIV-2 and HCV, and HbsAg. It should nevertheless be handled as though potentially infectious.
- Appropriate precautions should be taken when handling or disposing of potential pathogens. Decontamination of infectious material can be achieved with sodium hypochlorite at a final concentration of 3% for 30minutes. Liquid waste containing acid must be neutralised before treatment.
- The positive control has been inactivated during the manufacturing process. However, it should be handled as though potentially infectious.

Procedural:
- Staph Rapid Latex Test Kit should be used according to the kit instructions.
- Allow all reagents to reach room temperature before use.
- Do not dilute any of the kit reagents
- Do not intermix reagents from different batches of kits.
- Do not freeze any of the kit reagents
- Do not allow the latex reagent dropper to touch the positive control or bacterial samples.
- Be careful only to record agglutination. Reactions that are “curdy” or “stringy” may not be true agglutination.
- Ensure the slide is clean and dry prior to use.

STORAGE AND SHELF LIFE
Staph Rapid Latex Test Kit should be stored at 2-8°C when not in use. The kit should not be used after the expiry date printed on the label.

SPECIMENS
Select 1-2 isolated colonies grown for 18-24 hours at 35-37°C on primary isolation medium such as 5% blood agar. The morphology of the colonies tested should resemble that of S. aureus. Pure single colonies should be tested to minimise the possibility of erroneous results. If necessary, isolate by streaking on to a new agar plate. Colonies with atypical morphologies can be tested for Gram-positive staining to maximise the probability that Staphylococci have been selected for testing.

PROCEDURE
Quality Control:
The following controls should be performed each time the kit is used.
1. **Positive Control:** Add one drop of Positive Control to one circle on the test slide. Mix the REAG TEST ST1 by gentle inversion and add 1 drop to the same circle and mix with a mixing stick. Do not allow the dropper to touch the positive control. Rock the slide gently. Within 2 minutes, agglutination, indicating a positive result, should be visible. If no agglutination is seen, a fresh kit should be used.
2. **Negative Control:** Mix the REAG TEST ST1 by gentle inversion and add 1 drop to a circle on the test slide. Using a known coagulase/Protein A-negative Staphylococcus, e.g. *S. epidermidis*, take one fresh colony of 18-24 hour growth and emulsify in the drop of latex reagent on the slide. Gently rock the slide for 2 minutes. No agglutination should occur.

Test Procedure:
1. Mix the REAG TEST ST1 by gentle inversion and add 1 drop to a circle of a clean dry, test slide.
2. Using a sterile loop, pick one colony of the organism to be tested and emulsify in the drop of latex reagent on the slide. Spread over the area of the circle with a mixing stick.
3. Gently rock the slide for up to 2 minutes and observe for agglutination.
4. After reading, discard used slides and mixing sticks into suitable disinfectant

INTERPRETATION
Agglutination within 2 minutes is a positive result and indicates the presence of S. aureus. No agglutination indicates the absence of S. aureus and of other coagulase/Protein A-positive strains of Staphylococcus

LIMITATIONS OF USE
1. Results should be interpreted in the context of all available clinical and laboratory information.
2. Test only pure, single colonies since mixed colonies may give erroneous results.
3. Cultures older than 30 hours may auto-agglutinate.
4. Media with a high salt content, such as Mannitol Salt Agar, inhibit Protein A production and this may lead to false negative results.
5. Rough strains of Staphylococcus may cause false positive reactions. These strains are rare and distinguishable from smooth strains by their colonial morphology. If suspected, these can be confirmed by emulsifying in a drop of saline and examining carefully for a smooth suspension.
6. Stringy reactions on the slide may not be true positive reactions and further biochemical tests are required.
7. Some yeasts may cause false positive results.
8. All coagulase positive strains of Staphylococcus will react with Staph Rapid Latex Test Kit and *S. aureus* will therefore not be distinguishable from *S. intermedius* and *S. hyicus*. However, the latter two strains are infrequently isolated from human sources and are more commonly found in animals or as saprophytes.
9. Staph Rapid Latex Test Kit is intended for the identification of presumptive *S. aureus*. Colonies giving positive results should be confirmed as S. aureus by biochemical tests.

PERFORMANCE CHARACTERISTICS
Staph Rapid Latex Test Kit has been evaluated in comparison with a well-established commercially available latex agglutination test for S. aureus. 121 isolates of S. aureus and other closely related strains of Staphylococcus and a range of 56 potentially cross-reacting bacteria were tested in both products.

		Staph Rapid Latex Test Kit		
		+ve	-ve	Total
Commercial Latex Test	+ve	63*	0	63
	-ve	0	114	114
Total		63	114	177

Sensitivity: 63/63 = 100%
Specificity: 114/114 = 100%
Concordance: 177/177 = 100%

*Of the 63 isolates in this group, 9 were cross reactants in both tests. These were isolates of *C. diversus* (1), *A. baimannii* (2), *P. stuartii* (1), *B. cereus* (2), *K. oxytoa* (1), *Strep spp* (2)
However, all of the above either do not grow, or show very atypical morphologies, when cultured on Staphylococcus-selective media. In the case of *B. cereus,* agglutination was atypical (stringy)

REPRODUCIBILITY
Intra-batch reproducibility was established by testing sensitivity and specificity of 1 batch of product against serial dilutions of reference and kit control antigens and a panel of bacterial samples. Different operators carried out tests on 3 separate occasions. End-point titres obtained with reference/control antigens and qualitative results with the panel were identical in the three assays.

Inter-batch reproducibility was examined by testing sensitivity and specificity of 3 batches of product against serial dilutions of reference and kit control antigens, and a panel of bacterial samples. Between the 3 batches, no variation in end-point titres was seen and qualitative results with the panel correlated 100%.

IVD	In Vitro Diagnostic Medical Device		Temperature limitation	LOT	Batch code (EXXX)		Manufacturer		Keep dry	NON STERILE	Non-sterile
	Consult Instructions for use		Use by (year/month)	REF	Catalogue number		Do not reuse		Fragile, handle with care		Keep away from heat

CONTENT (100 tests) **REF 271060**

REAG TEST ST1 (STAPH LATEX)	2 x 2.5 mL (dropper black cap)
CONTROL +	1 mL (dropper white cap)
DISPOSABLE AGGL. CARDS (SLIDE)	17 cards with 6 wells each
MIXING STICKS	4 x 25 disposable mixing sticks
INSTRUCTIONS FOR USE	1 item

EDMA CODE 14 02 02 04 00 CE IVD

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