INSTRUCTIONS FOR USE

STAPH RAPID LATEX TEST

LATEX SLIDE AGGLUTINATION TEST FOR THE CONFIRMATORY IDENTIFICATION OF PRESUMPTIVE *STAPHYLOCOCCUS AUREUS* COLONIES

1 – INTRODUCTION

Staph Rapid Latex Test is a manual, 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, to be used for industrial diagnostics only and not for use in clinical testing.

2 - PRINCIPLE OF THE METHOD

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.

3 - MATERIALS PROVIDED – PACKAGING

Product	Type	REF	Pack
STAPH RAPID LATEX TEST	Latex agglutination test	**271060U** (100 tests)	1 glass bottle containing latex for Staphylococci (REAG TEST ST1). Latex particles coated with human fibrinogen and IgG. Preserved with 0.099% sodium azide. (1x5,0 mL = 100 tests – blue cap) 1 glass bottle containing Positive Control (CONTROL +): Inactivated preparation of *S. aureus* preserved with 0.099% sodium azide. (1.0 mL – black cap) Slide, 6 test areas: waterproof sheets for reaction (25 items) Sticks: plastic sticks for mixing (100 items) Secondary packaging: cardboard box.

4 - MATERIALS REQUIRED BUT NOT PROVIDED

Bacteriological loops.

5 - PRECAUTIONS AND WARNINGS

- STAPH RAPID LATEX TEST is for professional use only, to be used for industrial diagnostics only and not for use in clinical testing.
- The positive control has been inactivated during the manufacturing process. However, it should be handled as though potentially infectious.
- 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.
- Normal precautions exercised in handling laboratory reagents should be followed. Dispose of waste observing all local, state, provincial or national regulations. 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 sensitivity of the test may be reduced at low temperatures. Allow the reagents and samples to reach room temperature (15-30ºC/59-86ºF) before use.
- Do not use after expiration date or if the packaging is damaged. The quality of the reagent cannot be guaranteed beyond their shelf-life date or if the reagents are stored under inappropriate conditions.
- Do not dilute any of the kit reagents.
- Do not allow the latex reagent dropper to touch the positive control or bacterial samples.
- All operations linked to the use of the test must be performed in accordance with Good Laboratory Practices and according to the Instruction for use of the kit.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- Be careful only to record agglutination. Reactions that are “curdy” or “stringy” may not be true agglutination.
- The Certificates of Analysis and the Safety Data Sheet of the product are available on the website www.masciabrunelli.it.
- The information provided in this document has been defined to the best of our knowledge and ability and represents a guideline for the proper use of the product but without obligation or liability. In all cases existing local laws, regulations and standard procedures must be observed for the examination of samples collected from human and animal organic districts, for environmental samples and for products intended for human or animal consumption. Our information does not relieve our customers from their responsibility for checking the suitability of our product for the intended purpose.

6 - STORAGE CONDITIONS AND SHELF LIFE

All the kit components will remain stable until the expiration date printed on the label, when stored tightly closed at 2-8ºC and contaminations are prevented during their use. Do not freeze: frozen reagents could change the functionality of the test.

7 – SPECIMENS COLLECTION

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.

8 - TEST PROCEDURE

Allow the components of the kit to reach to room temperature (15-30ºC/59-86ºF) prior to testing.

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

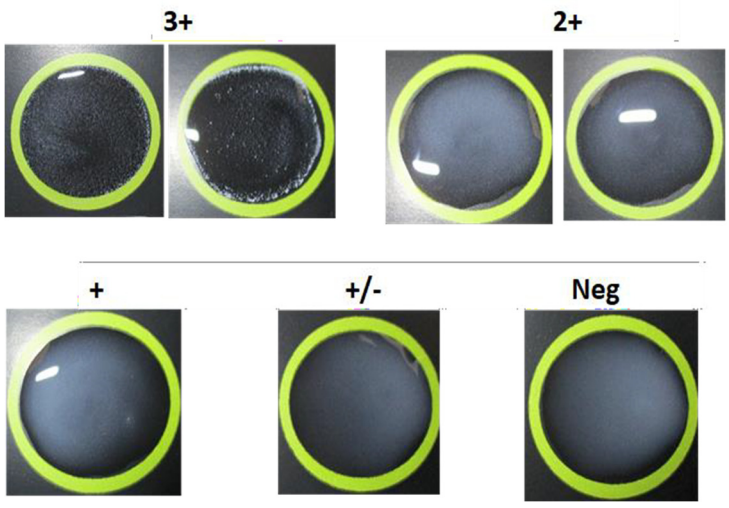
1. Mix the REAG TEST ST1 by gentle inversion and add 1 drop to a circle of a clean dry, test slide.
2. Using a sterile loop, pick one colony of the organism to be tested and emulsify in the drop of latex reagent on the slide. Spread over the area of the circle with a mixing stick.
3. Gently rock the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

9 – READING, 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.

Reaction grade	Description
3+	Large, agglutinated particles, which may form a ring of white precipitation. Background is clear.
2+	Visible agglutination, but background appears milky.
+	Fine agglutination where the particles are seen only when rocking. Background appears milky.
Trace (Tr +/-)	Very fine agglutination only seen when rocking with a milky background. A middle ground between + reaction and a negative reaction.
Negative (-)	No agglutination appears as a milky liquid.

Figure 1 – Reaction grade pattern examples



10 – LIMITATIONS OF THE METHOD

- The results should be interpreted in the context of all available laboratory information.
- Test only pure, single colonies since mixed colonies may give erroneous results.
- Cultures older than 30 hours may auto-agglutinate.
- Media with a high salt content, such as Mannitol Salt Agar, inhibit Protein A production and this may lead to false negative results.

- Rough strains of S*taphylococcus* 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.
- Stringy reactions on the slide may not be true positive reactions and further biochemical tests are required.
- Some yeasts may cause false positive results.
- All coagulase positive strains of *Staphylococcus* will react with Staph Rapid Latex Test 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.
- Staph Rapid Latex Test is intended for the identification of presumptive *S. aureus*. Colonies giving positive results should be confirmed as S. aureus by biochemical tests.
- The components of this product were always tested together without compatibility with components from other manufacturers. While not excluding the possibility that these components can be used with components of the same formulation but produced by other companies, there is no experimental evidence of such compatibility.

TABLE OF APPLICABLE SYMBOLS

	Temperature limitation		Batch code (DXXX)		Keep away from heat		Manufacturer		Keep dry
	Consult Instructions for use		Use by (year/month)		Catalogue number		Do not reuse		Fragile, handle with care

REVISION HISTORY

Version	Description of changes	Date

Note: minor typographical, grammatical, and formatting changes are not included in the revision history.