INSTRUCTIONS FOR USE

STAPH RAPID LATEX TEST KIT

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

1 – CLINICAL SIGNIFICANCE AND INTENDED USE

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

Staphylococcus spp. occur as commensal organisms on the mucous membranes and skin of humans. However, *Staphylococcus aureus* can be responsible for a wide range of pyogenic infections including superficial suppurative lesions, food poisoning and toxic shock, as well as a variety of other conditions. It is therefore one of the most important pathogens regularly encountered in the laboratory. Due to the frequency and importance of Staphylococcal infection a rapid and accurate diagnosis is needed for correct patient management, especially as resistance to numerous common antibiotics has been shown.

Two of the traditional diagnostic tests for *S. aureus*, the tube and slide coagulase tests, only detect the activity of a characteristic coagulase enzyme. However, these tests can be difficult to interpret and are liable to suffer from false positive results associated with non-specific factors frequently found in plasma. Non-specific coagulation due to other bacterial enzymes may also occur. However, 99% of *S. aureus* isolates also produce detectable levels of protein A on their surface, a characteristic which can be used to differentiate *S. aureus* from other species of Staphylococci in which this protein is rare. Staph Rapid Latex Test Kit is a sensitive and specific latex agglutination for the identification of *S. aureus* which overcomes the problems associated with the traditional tests by detecting both coagulase and protein A, offering rapid and accurate identification of S. aureus in 2 minutes. Staph Rapid Latex Test Kit contains all ancillary reagents needed to complete the test and is suitable for clinical, food and environmental laboratories.

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

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 KIT CND: W0104080303 EDMA: 14.02.03.03; RDM: 1555758/R	Latex agglutination test	**271060** (100 tests)	2 glass bottles containing latex for Staphylococci (REAG TEST ST1). Latex particles coated with human fibrinogen and IgG. Preserved with 0.099% sodium azide. (2x2,5 mL = 100 tests) 1 glass bottle containing Positive Control (CONTROL +): Inactivated preparation of *S. aureus* preserved with 0.099% sodium azide. (1.0 mL) Slide, 6 test areas: plastic waterproof sheets for reaction (17 items) Sticks (1x25): plastic sticks for mixing (4 items) Secondary packaging: cardboard box.

4 - MATERIALS REQUIRED BUT NOT PROVIDED

Bacteriological loops. Timer or clock.

5 - PRECAUTIONS AND WARNINGS

- STAPH RAPID LATEX TEST KIT is for *in vitro* diagnostic, for professional use only; it is to be used by adequately trained and qualified laboratory personnel.
- Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and antibody to HIV (1/2). However handle cautiously as potentially infectious.
- The positive control has been inactivated during the manufacturing process. However, it should be handled as though potentially infectious.
- 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.
- The slides are made of plastic, washed with distilled water. If the test area of the slide becomes water resistant, clean it with alcohol.
- 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.
- 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.
- 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.
- Notify Mascia Brunelli Spa and the Relevant Authorities of any serious incidents occurring in connection with the in vitro diagnostic device. complaint@masciabrunelli.it

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.

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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.

10 – 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
Latex test on the market	+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%.

11 – LIMITATIONS OF THE METHOD

- As with all diagnostic tests, a final diagnosis cannot rely on the outcome of a single test but the results should be interpreted in the context of all available clinical and 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 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.
- 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 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.
- 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.
- The components of this I.v.D. 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

IVD	In Vitro Diagnostic Medical Device		Temperature limitation	LOT	Batch code (DXXX)		Manufacturer		Keep dry	UDI	Unique device identifier
	Consult Instructions for use		Use by (year/month)	REF	Catalogue number		Do not reuse		Fragile, handle with care		Keep away from heat

REVISION HISTORY

Version	Description of changes	Date
Instructions for Use (IFU) - Revision 2	Updated layout and content	2022/09

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

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