ELITex Staph

Latex slide agglutination test for the identification of *Staphylococcus aureus*

60 tests **Ref. 22711**

160 tests **Ref. 22712**

8000010-EN-2025-01

For *in vitro* diagnostic use only, for professional use only.
Single use test.

CE

1 - AIM

ELITex Staph is a slide agglutination test for the rapid identification of methicillin-resistant or susceptible *Staphylococcus aureus* strains, from primary plate cultures.
Each kit allows 60 or 160 tests to be carried out.

2 - INTRODUCTION

Staphylococci are a serious problem in hospital epidemiology. *Staphylococcus aureus* is the main pathogenic species and is responsible for septicaemia and nosocomial infections. Coagulase-Negative Staphylococci (CNS) are most frequently considered to be opportunistic pathogens.
Multi-drug resistance poses considerable therapeutic problems, particularly with respect to methicillin resistant staphylococci. The ability to rapidly differentiate *Staphylococcus aureus* from other staphylococci species is therefore a necessity in microbiological diagnosis.

3 - PRINCIPE

Red latex particles are sensitized with 3 proteins:

1. Fibrinogen which reacts with the fibrinogen affinity factor or the Clumping Factor;
2. The Fc fragment of human IgG which reacts with *Staphylococcus aureus* protein A;
3. Polyclonal antibodies that consist of IgG anti-*Staphylococcus aureus* capsular polysaccharides, expressing neither protein A nor Clumping Factor (1, 2, 3).

The presence of *Staphylococcus aureus* is revealed by a strong agglutination reaction, visible to the naked eye. In the absence of *Staphylococcus aureus*, there is no agglutination.
The test procedure is straight forward and rapid. The results are obtained within 1 minute.

4 – REAGENTS AND MATERIAL

Description – 60 tests (Ref. 22711)	**Quantity**
TEST LATEX: Dispenser vial containing 1.8 mL of sensitized latex	**1**
CONTROL LATEX: Dispenser vial containing 1.8 mL of unsensitized latex	**1**
TEST CARD: Disposable reaction cards	**15**
STICK: Disposable stirrers	**120**

Description – 160 tests (Ref. 22712)	**Quantity**
TEST LATEX: Dispenser vial containing 2.4 mL of sensitized latex	**2**
CONTROL LATEX: Dispenser vial containing 2.4 mL of unsensitized latex	**2**
TEST CARD: Disposable reaction cards	**40**
STICK: Disposable stirrers	**320**

5 - PRECAUTIONS

- The reagents are intended solely for *in vitro* use and must be handled by authorised personnel.
- Tests are for single use only.
- All the reagents contain raw materials of animal origin and must be handled with caution.
- The patient samples and inoculated reagents are potentially infectious; they must be handled with caution, in observance of hygiene rules and the current regulations for this type of product in the country of use.
- The **TEST LATEX** contains raw materials of human origin which has been screened for and found not to contain anti-HIV antibodies, anti-HCV antibodies and HBsAg. Nonetheless it must be handled as a potentially infectious product.
- The reagents contain sodium azide (< 0.1%).
- Do not use reagents after the expiry date.
- Do not use reagents from different batch numbers.
- Allow the reagents to reach room temperature.
- Carefully shake the latex suspensions before use.
- When dispensing the latex suspensions, make sure that the dispenser vial is perfectly vertical. Check for the absence of air bubbles in the drops to ensure constant delivery volumes. As a precaution measure, wipe the dispenser vial tip after use.

6 – SAMPLE COLLECTION

Use freshly isolated colonies of Gram positive cocci grouped in clumps and of identical appearance grown (18-24h at 37°C) in either trypticase soy agar with or without the addition of 5% sheep blood or alternatively, Columbia agar. Sample collection must be carried out **from a pure culture**, in compliance with good laboratory practice.

7 – CONSERVATION AND PREPARATION OF REAGENTS

Reagents are ready-to-use.
Reagents conserved at 2-8°C, in their original state, are stable up to the expiry date indicated on the box. They must not be frozen.

8 – MATERIAL REQUIRED BUT NOT SUPPLIED

- Calibrated incubator at 37°C
- Contaminated waste container

9 - METHOD

Allow the reagents to reach room temperature before use.

- Carefully shake the latex suspensions.
- Place one drop of **TEST LATEX** on the slide.
- Using a Pasteur pipette or a loop or a stirrer, take 2 to 5 colonies for testing and with a rotating movement, vigorously emulsify them with the **TEST LATEX**.
- Manually apply a rotating movement to the card and within one minute observe the possible appearance of a strong agglutination reaction (do not continue the test for longer than 1 minute).
- Repeat the operation, described below, by replacing the **TEST LATEX** by the **CONTROL LATEX**.

10 - READING

Negative reaction: Absence of agglutination.
Positive reaction: Strong agglutination, visible to the naked eye, within one minute.

11 – INTERPRETATION OF RESULTS

TEST LATEX	CONTROL LATEX	INTERPRETATION
-	-	**NEGATIVE REACTION** The tested strain is not *Staphylococcus aureus*
-	+	
+	-	**POSITIVE REACTION** The tested strain is *Staphylococcus aureus*
+	+	**UNINTERPRETABLE REACTION**

12 – CAUSES OF ERROR AND TEST LIMITS

- The majority of *Staphylococcus aureus* strains sensitive or resistant to methicillin react in less than 20 seconds with the appearance of a strong agglutination reaction. Certain strains with weak “Clumping Factor” and/or protein A production can demonstrate clear agglutination at around one minute.
- The presence of antibiotics can alter bacterial structures. The testing of colonies taken from the medium used in an antibiogram must be avoided.
- Certain strains such as *Staphylococcus lugdunensis* and *Staphylococcus schleiferi* that produce fibrinogen affinity factor can interfere with the test.
- Negative results can be observed if the isolated *Staphylococcus* strain produces neither “Clumping Factor”, nor protein A and possesses capsular polysaccharides that do not correspond to the polyclonal antibodies used in the prepation of the reagent.
- During primary isolation on certain selective culture media (Columbia agar with nalidixic acid etc…), certain strains will not agglutinate. It would therefore be necessary to carry out one or more subcultures on non-selective media. In this case, the results will need to be associated with the reference tests used in the identification of the staphylococci.
- In all cases, it is necessary that the clinical, epidemiologic and biological data are taken fully into consideration before establishing the final diagnosis.

13 - PERFORMANCE

During evaluation, **ELITex Staph** demonstrated good sensitivity with methicillin resistant strains of *Staphylococcus aureus* (MRSA), producing little protein A and/or fibrinogen affinity factor. The presence of polyclonal antibodies makes it possible to detect certain strains of MRSA not revealed by 1st generation tests. Thus, with a total of 102 *S. aureus* strains, the sensitivity was 99.02% and with a total of 108 Staphylococci strains other than *S.aureus*, a specificity of 99.07% was obtained.

14 – WASTE ELIMINATION

Waste should be disposed of in accordance with the hygiene rules and current regulations for this kind of product in the country of use. In the event of accidental spillage of latex, or contamination of the work area by colonies, clean using absorbent paper and bleach.

15 - BIBLIOGRAPHY

1. G. CARRET, R. BISMUTH, J.-P. FLANDROIS, M. SAULNIER - Relative value of coagulase and fibrinogen affinity for the identification of *S. aureus* - *J. Appl. Bacteriol.*, 1982, 53, 351-354.
2. J.M.FOURNIER, A.BOUTONNIER, A.BOUVET - *Staphylococcus aureus* strains which are not identified by rapid agglutination methods are of capsular serotype 5 - *Journal of Clinical Microbiology*, juni 1989, 1372-1374.
3. W.-E. KLOOS, D.-W. LAMBE - Staphylococcus - *Manual of Clinical Microbiology*, 5e ed. Am. Soc. Mie., Washington D.C., 1991.

The changes from the previous version are highlighted in grey.

ELITech MICROBIO
Parc d’activités du Plateau
Allée d’Athènes
83870 SIGNES
FRANCE
☎: 33 (0)4 94 88 55 00
http://www.elitechgroup.com