Staphylo Rapid Test

IVD CE

Rapid latex test for the detection and identification of coagulase and/or protein A positive strains of Staphylococci (*S. aureus*) from primary cultures

Technical Sheet

INFORMAZIONI PER L'ORDINE

Format	Code	Contents
Kit 2 x 50 det.	REF CSI087245	2 vials x 1.5 ml

INTENDED USE

In vitro diagnostic medical device for the execution of the rapid latex agglutination test for the detection and identification of coagulase and/or protein A positive strains of Staphylococci (S. aureus) from primary cultures obtained from samples of human origin. Test results should always be interpreted in relation to the clinical context. For professional use only.

CLINICAL SIGNIFICANCE

Staphylococci are commonly present on skin or mucous membranes as saprophytic flora but they may be often implicated in opportunistic infections. *S. aureus*, in particular, is the etiological agent of many septic diseases. Some strains of staphylococci producing enterotoxins are the cause of food poisoning and, recently, an exotoxin of *S. aureus* has been associated to the "toxic shock syndrome". Thus, the importance of a fast system for an early identification of *S. aureus*. The more common methods for the identification of presumed pathological strains are based on the detection of coagulase (tube test for free coagulase or slide test for bound coagulase) or observation of bacterial growth as mannitol fermentation, DNase production etc. This traditional methodology requires an incubation period of 1 or more days. Latex identification tests have been recently developed by which the presence of clumping factor and protein A can be demonstrated. The Sclavo Staphylo Rapid test is a complete set for identifying the presence of bound coagulase and/or protein A on the cell surface of the tested strain directly from primary culture within a few minutes without the need for any other material or instrument.

PRINCIPLE

The specimen is spread on a circle of the test slide in which the latex sensitized with human fibrinogen and IgG is previously distributed. If the clumping factor and/or protein A should be present in the specimen, it will cause a visible agglutination (clumping).

The Sclavo kit is composed of latex polystyrene particles coated with fibrinogen (for binding to coagulase) and human IgG (for binding to protein A) and a non-sensitized control latex (for the detection of any non-specific reactions). When colonies of *Staphylococcus aureus* are mixed, in two adjacent reaction cells, with the sensitized latex reagent and with the control latex, with the first, a rapid and intense visible agglutination will develop, while, with the second, no evident reaction will develop (confirming the specificity of the reaction).

Storage and stability

= Storage temperature 2-8 °C

If stored closed at 2-8°C, avoiding direct light, the reagents are stable until the expiration date printed on the label. Avoid freezing and bacterial contamination.
Stability tests repeated on three different batches confirmed a total validity of 24 months if stored 2-8° C. Slight variations of composition from batch to batch do not affect test result.

COMPONENTS

Reagent L - 1 x 1,5 mL
Lattice sensitized with human fibrinogen and IgG. Ready to use suspension.
Contains sodium azide 0.9 g/L as preservative.
Control Latex - 1 x 1,5 mL
Unsensitized latex. Ready to use suspension.
Contains sodium azide 0.9 g/L as preservative.
Plastic Sticks number: 50.
Disposable test slides black background number 10.
Reagent contains sodium azide which may react with lead and copper in plumbing to form explosive metal azides. On disposal flush with large volumes of water to prevent azide build up.

PRECAUTIONS AND WARNINGS

1. This kit contains components of human origin. These were tested for hepatitis B virus surface antigen and anti-HCV and anti-HIV-1/HIV-2 antibodies and were negative. However, it is recommended to handle the reagents according to good laboratory practice.
2. Test samples may contain pathogenic organisms and should therefore always be treated with due precautions.
3. Reagents and waste materials must be disposed of in accordance with Community waste regulations or applicable national or regional provisions.
4. In addition to any risk statements relating to active components, reagents may contain non-active components such as preservatives and detergents. The total concentration of these components is below the limits set out in Regulation 1272/2008 EC and subsequent amendments and additions.
5. It is recommended to handle the reagents according to good laboratory practice and to use appropriate personal protective equipment.
6. The kit should only be used by qualified and properly trained technical personnel.
7. Diagnoses are carried out exclusively by authorized and qualified personnel.
8. It is recommended to handle the reagent according to good laboratory practice
9. Comply with national directives on occupational safety and quality assurance.
10. Use equipment that complies with current regulations.
11. Laboratory standards for protection against infection should be used

Reporting serious incidents

Please inform the manufacturer (through your distributor) and the competent authority of the member state of the European Union in which the user and/or patient is established, of cases of serious incident that has occurred in relation to the device. For other jurisdictions, reports of serious incidents must be made in accordance with the regulatory requirements of the home Member State. By reporting serious incidents, you help provide more information about the safety of your in vitro medical diagnostic device.

PROCEDURE

Quality Control

Perform a quality control every time it is used a new batch of product, using the same procedure used for samples. For Quality Control use the following bacterial strains:
Eseguire il controllo qualità ogni volta che si usa un nuovo lotto di kit utilizzando la stessa procedura utilizzata per i campioni. Per il Controllo qualità utilizzare i seguenti ceppi batterici:
Positive Control MSSA: *S. aureus* ATCC 25923
Positive Control MRSA: *S. aureus* ATCC 43300
Negative Control: *S. epidermidis* ATCC 12228
If latex is grainy or self-agglutinated at the time of use, IT SHOULD NOT BE USED.

REAGENT PREPARATION

Latex reagents are ready to use. Bring to room temperature. Bring to room temperature and mix slowly the latex reagents to obtain a homogenous suspension. After opening, the reagent is stable until the expiry date, if maintained in conditions reported in the "Preservation and Stability" paragraph. Avoid exposure to significant temperature variations.

SPECIMEN COLLECTION AND PRESERVATION

From primary or secondary isolation culture, select well isolated colonies. These should appear to be circular (diameter of 2-4 mm), smooth and slightly convex. A Gram staining is suggested to check the purity of the specimen. The test is unadvised for colonies growth on selective agar with high salt concentration due to difficulties in a correct sampling and in possible false agglutination. A fresh overnight culture should be used, preferably from enriched media such as blood agar or nutrient agar.

For more information on the collection and treatment of samples, refer to what is reported on the specialized bibliography. For the execution of the test select colonies well isolated from primary or secondary isolation cultures. These should be circular in appearance (diameter 2-4 mm), smooth and slightly convex. A Gram stain is suggested to check the purity and morphology of the sample. It is not recommended to perform the test on colonies developed on selective agar with a high salt concentration due to the difficulty of correct sampling and the possibility of false agglutination. *IT IS RECOMMENDED TO USE FRESH CULTURES* (max 18-24 hours), preferably developed on enrichment media such as blood agar or nutrient agar.

PROCEDURE

Technique

1. For each sample add into two separate circles 1 free-falling drop of Reagent **L** and 1 free-falling drop of **Control Latex** (holding the dropper vertically).
2. Collect the specimen (3-4 colonies) using a plastic stick and emulsify it thoroughly with the drop of the Reagent L (do not rub too vigorously so as not to damage the surface of the cardboard)
   Warning: do not collect part of the culture media, it could interfere with the reading of the reaction.
3. Repeat step 2 also with Control latex
4. Using a clean stick for each circle, mix and spread the reaction mixture carefully. Discard used sticks.
5. Tilt and rotate the slide. Observe each circle for evidence of agglutination (clumping) (specific agglutinations appear within 60 seconds).

INTERPRETATION OF RESULTS

Positive: Positive reaction is characterized by agglutination, in absence of milky background, in the circle with Reagent L and absence of agglutination in the circle with Control Latex. Generally, the reaction is immediate. Later agglutinations, after 60 seconds, are to be ignored. The positive reaction indicates the presence of coagulase and/or protein A in the strain examined
Negative: Negative reaction is characterized by absence of agglutination both with Reagent L and Control Latex. In the event that there has not been a complete emulsion, traces of graininess can be highlighted.

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When an incomplete emulsion of the specimen is obtained, traces of granules can be observed.

N.B. *Some strains of Staphylococcus may be difficult to emulsify; This should be kept in mind when reading the results because latex may be grainy or fibrous even in the absence of an agglutination reaction.*

Note: discard all used materials following infectious disposal procedure

LIMITATIONS OF THE PROCEDURE

- Only well-isolated pure colonies should be tested (mixed colonies may result in falsely positive or negative results)
- Colonies older than 30 hours can give rise to self-agglutination phenomena
- The presence of filamentous reactions is not always an indication of a positive reaction, in doubtful cases carry out confirmatory biochemical tests
- All positive staphylococcus coagulase strains react with the Staphylorapid test: for this reason, it is not possible to distinguish between S. aureus and *S. intermedius* and S. hyicus (which are rare from human samples).
- Some streptococci, other microorganisms that possess immunoglobulin-binding factors and some strains of Escherichia coli may cause nonspecific agglutination. For this reason, it is recommended to use colonies for the test that from the morphology on culture medium and microscopic analysis, have already been identified as staphylococci.

Analytical performances

Sclavo Staphylo Rapid test was performed on 227 strains (identified both with molecular and biochemical techniques) isolated from blood agar culture. The following results were obtained:

SENSIBILITY		
MSSA	139/139	100%
MRSA	72/75	98%
SPECIFICITY		
STAPH (NON AUREUS)	0/13	100%

Bibliography

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Symbols used for IFU and Packaging	
IVD In vitro diagnostics medical device	Manufacturer
REF Catalog number	Instruction for Use
LOT Lot Number	Storage Temperature
Expiration Date	Biological Risk

REVISION	DATE	CHANGES
D	10-2022	Modified for IVDR Compliance

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