Coagulase test

For the detection of Staphylococcal coagulase

IVD CE

Istruzioni per l'Uso (IFU)

ORDERING INFORMATIONS

Format	Code	Composition
Kit 20 test	REF CSI051527	n° 5 vial x 2 ml (freeze dried)

INTENDED PURPOSE

In vitro diagnostic medical device for screening for staphylococcal coagulase. Test results should always be interpreted in relation to the clinical context. For professional use only.

CLINICAL SIGNIFICANCE

The coagulase test helps to identify *Staphylococcus aureus* which produces the enzyme coagulase (coagulates) plasma from coagulase-negative staphylococci (CONS).

PRINCIPLE OF THE METHOD

The coagulase test is used to differentiate Staphylococcus aureus (positive) from coagulase-negative staphylococcus (CONS). Coagulase is an enzyme produced by *S. aureus* that converts fibrinogen (soluble) in plasma to fibrin (insoluble). *Staphylococcus aureus* produces two forms of coagulase, bound and free.
Bound coagulase (aggregation factor) is bound to the bacterial cell wall and reacts directly with fibrinogen. This causes fibrinogen to alternate so that it precipitates onto the staphylococcal cell, causing cells to clump together when a bacterial suspension (containing Staphylococcus aureus) is mixed with plasma.

Storage and Stability

= Storage Temperature 2-8 °C

If stored at 2-8°C, avoiding direct light, the reagent is stable until the expiry date stated on the label. Do not freeze. Avoid microbial contamination.

KIT COMPOSITION

Lyophilized rabbit citrate plasma

PRECAUTIONS AND WARNINGS

1. Reagents and waste materials must be disposed of in accordance with EU waste regulations or applicable national or regional regulations
2. In addition to any risk statements relating to active components, the 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 as amended.
3. It is recommended to handle the reagents according to the standards of good laboratory practice and to use appropriate personal protective equipment.
4. The kit should only be used by qualified and properly trained technical personnel.
5. Diagnostics are carried out only by authorized and qualified personnel.
6. It is recommended that the reagent be handled according to the rules of good laboratory practice
7. Comply with national directives on occupational safety and quality assurance.
8. Use equipment that complies with current standards.
9. **The test should be performed with sterile glassware and distilled water.**

Reporting of 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

For quality control, use the following bacterial strains:

Organism		Expected result
S. aureus	ATCC 25923	Clot formation
S. epidermidis	ATCC 12228	Absence of clot

REAGENT PREPARATION

The reagent is lyophilized. Whan needed, dissolve the contents of one bottle (sufficient for 4 reactions) with 2 mL of sterile distilled water. The reconstituted product can be stored for 3 days at 2-8°C or aliquoted and stored at -20°C for one month (the product can be frozen only once).

SAMPLE PREPARATION AND STORAGE

Not applicable. The test is not performed directly on a human specimen; for the test well isolated colonies, already identified as Staphylococcus spp, are to be used.

PROCEDURE

Sample: Approximately 18 h aged, broth culture of a strain previously identified as *S. aureus* with other tests (colony morphology, Gram staining, seeding on Mannitol Salt Agar, catalase test, DNase test). As an alternative to broth culture, 4-5 well-isolated colonies taken from blood agar plates and resuspended in 0.5ml of sterile medium can be used directly for the test.

Steril tube (10x100 mm)		
- Rabbit Plasma	mL	0,5
- 18-hour broth culture (or plate colonies)	mL	0,5

Shake and place on the thermostat at 37°C. **Check every 30 min. Possible formation of the clot.**

Reading

The test must be considered positive if coagulation, even partial, of the plasma occurs no later than 3 h at 37°C. The test is considered more positive the shorter the clotting time.

Limitations of the procedure

Some microorganisms that use citrate in their metabolism can give rise to false positives. Normally this should not be a problem because bacteria that have already been identified as staphylococci should be used for the test. However, it is possible that other bacterial species have contaminated the sample to be analyzed. The use of coagulase in EDTA (REF. CSI051530) can eliminate this risk.
Some species of coagulase-negative staphylococcus may be positive. In addition, some species possess an enzyme that can cause the clot to dissolve after prolonged incubation.

ANALITYCAL PERFORMANCES

Specificity

Tests performed with three different lots of rabbit plasma in presence of:
Staphylococcus epidermidis ATCC 12228 (coagulase negative) had repeatedly shown negative results.
Staphylococcus aureus ATCC 25923 (coagulase positive) had repeatedly shown positive results.
Staphylococcus aureus ATCC 43300 (coagulase positive) had repeatedly shown positive results.

Precision

Repetitivity tests (in the run) and Reproducible tests (between run) performed with three different lots of Rabbit plasma in presence of known concentrations of Staphylococcus aureus ATCC 43300, had shown the expected results

Bacterial Strain		1h	2h	3h
S. epidermidis	ATCC 12228	-	-	-
S. aureus	ATCC 43300 10^2	-	-	+
S. aureus	ATCC 43300 10^3	-	+	++
S. aureus	ATCC 43300 10^4	++	+++	++++

References

MacFaddin JF, edit. Biochemical Tests for Identification of Medical Bacteria. 3rd ed. Philadelphia: Lippincott Williams & Wilkins; 2000. p. 105-19

Williams REO HG. Determination of Coagulase and Alpha-Haemolysin Production by Staphylococci. Br J Exp Pathol 1946;27:72-81.

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
C	12/2022	New issue for IVDR Regulation (EU) 2017/746 compliance

Sclavo Diagnostics International
Loc. Pian dei Mori, via Po n° 26-28 • 53018 (SI) (Italy)
Phone +39 0577 390 41 • Fax +39 0577 390 444
www.sclavodiagnostics.com