Instructions For Use
ENGLISH

# Staph Latex Kit

For the confirmatory identification of *Staphylococcus aureus*.

## INTENDED PURPOSE

Latex slide agglutination test for the identification of *Staphylococcus aureus* from selective and/or enrichment cultures. This kit is not intended for use in the diagnosis of disease or other conditions in humans.

## DESCRIPTION

This agglutination kit rapidly detects and presumptively identify *S. aureus* from culture by latex agglutination. It is particularly suited to screening samples when prompt results are needed as it allows laboratories to eliminate staphylococci-negative samples from further testing, reducing the number of samples requiring confirmatory testing.

## KIT CONTENTS

- Staph Latex Reagent (1 x 5 ml)
- Positive Control (1 x 1 ml)
- Disposable agglutination slides (25 pcs), with 6 test areas each
- Disposable mixing sticks (100 pcs)

## METHOD PRINCIPLE

Latex particles are coated with fibrinogen for detection of bound coagulase (or clumping factor) and specific IgG for detection of 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.

## MATERIALS REQUIRED BUT NOT PROVIDED

- Inoculating loops, pipettes, timer or clock
- Coagulase/Protein A-negative staphylococci, e.g. *S. epidermidis* – OPTIONAL: Required for negative control (see USER QUALITY CONTROL)
- 0.85% saline (physiological solution) – OPTIONAL: Might be used for troubleshooting (see point 5 under LIMITATIONS)

## REAGENTS

- Staph Latex Reagent (blue cap): Latex particles coated with human fibrinogen and IgG, preserved with 0.099% sodium azide.
- Positive Control (black cap): Inactivated preparation of *S. aureus*, preserved with 0.099% sodium azide.

## TEST PROCEDURE

Depending on the test culture either procedure A or B can be used as follows:

- **Procedure A** for identification from solid media
- **Procedure B** for identification from liquid media

| | | | |
|---|---|---|---|
| 1 | A | B | Allow the reagents to reach room temperature before use. Always invert gently to obtain an even suspension immediately prior to use. |
| 2 | A | B | Dispense one drop of Staph latex reagent into a circle of an agglutination slide. |
| 3 | A | | Using an inoculating loop, pick a colony from the agar plate and emulsify the colony in the drop of latex reagent on the slide. Suspensions should only be made from colonies with morphologies resembling S. *aureus*. |
| | | B | Using a Pasteur pipette, transfer one drop of the broth culture into a circle of an agglutination slide. |
| 4 | A | B | Rock the slide gently for up to 2 minutes and observe for autoagglutination or clumping. |
| 5 | A | B | After reading, discard the used mixing sticks and slides. Dispose of hazardous or biologically contaminated materials according to the practices of your institution. |

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## INTERPRETING RESULTS

A positive test will display agglutination, which means clumping or aggregation of the latex particles, whereas a negative result will show no clumping.

Agglutination within 2 minutes is a positive result indicating the presence of *S. aureus* in the sample.

Absence of agglutination indicates there is no *S. aureus* and other coagulase/Protein A-positive strains of *Staphylococcus* in the test culture.

## STORAGE

Store at 2-8°C in its original packaging. Keep away from sources of heat and avoid excessive changes of temperature. Use until the expiry date indicated on the label. Eliminate without using if there are signs of deterioration. **Do not freeze any of the kit reagents.**

## USER QUALITY CONTROL

Quality control testing should be run with each shipment and new kit lot number received. It is responsibility of the individual laboratory to choose frequency and modality of QC according to internal standard operating procedures (SOPs) based on national/international guidelines.

To check the activity of the latex reagent the following controls can be performed:

**1. Positive Control:** Dispense one drop of Positive control (each kit contains sufficient reagent for 20 tests) into one circle on the agglutination slide. Add one drop of Staph latex reagent to the same circle and mix with a mixing stick. **Do not allow the dropper tip to touch the drop of positive control on the slide**. Rock the slide gently. Within 2 minutes, agglutination, indicating a positive result, should be visible. If no agglutination is seen, reagents should be discarded, and a fresh kit should be used.

**2. Negative Control:** Dispense one drop of Staph latex reagent into one circle on the agglutination slide. Take a a known coagulase/Protein A-negative *Staphylococcus* strain, e.g. *S. epidermidis,* from a fresh (18-24 h) culture. Using an inoculating loop, pick a colony and emulsify onto the drop of latex reagent on the slide. Rock the slide gently for 2 minutes and observe for agglutination. If any agglutination is seen, the latex reagent should be discarded.

## LIMITATIONS

1. Results should be interpreted in the context of all available laboratory information.
2. Only pure, single colonies should be tested since mixed colonies may give erroneous results.
3. Cultures older than 30 hours may auto-agglutinate.
4. Culture media with a high salt content, such as Mannitol Salt Agar, inhibit Protein A production and this may lead to false negative results.
5. 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.
6. Some yeasts may cause false positive results.
7. This kit does not allow to distinguish *S. aureus* from other coagulase positive strains, such as *S. intermedius*.
8. Identification with this product is presumptive and all positive results should be confirmed by further identification tests and serotyping of pure cultures.

## WARNING AND PRECAUTIONS

**For professional use only**. **This kit and its reagents should not be used for clinical testing.** Operators must be trained and have certain experience. Please read the instructions carefully before using this product. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this document.

Consult the Safety Data Sheet (SDS) for information regarding hazards and safe handling practices.

Do not dilute any of the kit reagents. Do not intermix reagents from different batches of kits. Ensure the slide is clean and dry prior to use. Be careful only to record agglutination as for example reactions that are “curdy” or “stringy” may not be true agglutination.

## DISPOSAL OF WASTE

Disposal of waste must be carried out according to national and local regulations in force.

## BIBLIOGRAPHY

See the references at the end of this document.

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## TABLE OF SYMBOLS

See the table of symbols at the end of this document.

## ORDER INFORMATION

| Product | Packaging | Ref. |
|---|---|---|
| Staph Latex Kit | 100 tests | 96163 |

### Revision History

| Revision | Release Date | Change Summary |
|---|---|---|
| 0 | 2024-10-14 | Document creation |
| 1 | 2025-01-20 | Removed SHELF LIFE as it may vary from lot to lot based on individual kit components |

This IFU document and the SDS are available from the online Support Center:

**liofilchem.com/ifu-sds**

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## References

1. Public Health England (2018 Coagulase test. UK Standards for Microbiology Investigations. TP 10 Issue 6.
2. Katz DS (2011) Bacterial Agglutination Protocol. American Society for Microbiology (ASM).

## Table of Symbols

| | |
|---|---|
| LOT | Batch code |
| REF | Catalogue number |
|  | Manufacturer |
|  | Use by |
|  | Fragile, handle with care |
|  | Temperature limitation |
|  | Contains sufficient for <n> tests |
|  | Consult instructions for use |
|  | Do not reuse |
|  | Keep away from sunlight |

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