Strep-Check Kit

For the confirmatory identification of Lancefield group streptococci.

INTENDED PURPOSE

Latex slide agglutination test for the identification of streptococci of Lancefield group A, B, C, D, F and G 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 the Lancefield groups A, B, C, D, F and G of streptococci from culture by latex agglutination.

Lancefield grouping is a serological method for classifying streptococci into one of 20 groups, named Lancefield groups A to V (excluding I and J), based on the presence of polysaccharide and teichoic acid antigens in the bacterial cell wall. Those that are clinically significant are A, B, C, D, F and G (all beta-haemolytic streptococci, except group D which is composed of alpha-haemolytic organisms).

KIT CONTENTS

- Strepto A Latex Reagent (1 x 2.5 ml)
- Strepto B Latex Reagent (1 x 2.5 ml)
- Strepto C Latex Reagent (1 x 2.5 ml)
- Strepto D Latex Reagent (1 x 2.5 ml)
- Strepto F Latex Reagent (1 x 2.5 ml)
- Strepto G Latex Reagent (1 x 2.5 ml)
- Extraction Enzyme (2 x 10 ml after reconstitution)
- Positive Control (1 x 1 ml)
- Disposable agglutination slides (60 pcs), with 6 test areas each
- Disposable mixing sticks (12 x 25 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

- Sterile distilled water, inoculating loops, pipettes, test tube, water bath, timer or clock
- Physiological solution (0.85% saline) – OPTIONAL: Required for negative control (See USER QUALITY CONTROL)

REAGENTS

- Strep A Latex Reagent (red cap): Latex particles coated with Lancefield group A antiserum, preserved with 0.099% sodium azide.
- Strep B Latex Reagent (yellow cap): Latex particles coated with Lancefield group B antiserum, preserved with 0.099% sodium azide.
- Strep C Latex Reagent (white cap): Latex particles coated with Lancefield group C antiserum, preserved with 0.099% sodium azide.
- Strep D Latex Reagent (green cap): Latex particles coated with Lancefield group D antiserum, preserved with 0.099% sodium azide.
- Strep F Latex Reagent (blue cap): Latex particles coated with Lancefield group F antiserum, preserved with 0.099% sodium azide.
- Strep G Latex Reagent (gray cap): Latex particles coated with Lancefield group G antiserum, preserved with 0.099% sodium azide.

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- Extraction Enzyme. A bottle of the freeze-dried extraction enzyme must be reconstituted with 10 ml of sterile distilled water.
- Positive Control (black cap): Inactivated preparation of Lancefield group A, B, C, D, F and G antigens, 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 0.4 ml Extraction Enzyme into a test tube.
3	A		Using an inoculating loop, pick 2-6 colonies from the agar plate and emulsify them in the extraction enzyme in the tube. Suspensions should only be made from colonies with morphologies resembling streptococci.
		B	Pipette 0.1 ml of an overnight broth culture into the tube containing the extraction enzyme.
4	A	B	Incubate the tube containing the mixture in a water bath at 37 ± 1°C for 10 minutes. Shake tube vigorously after 5 minutes incubation.
5	A	B	Dispense one drop of each latex reagent into one circle of the agglutination slide properly labelled.
6	A	B	Using a Pasteur pipette, add one drop of the extract to each drop of latex reagent. Mix the contents of each circle with a separate mixing stick to avoid cross contamination.
7	A	B	Rock the slide gently for up to 1 minute and observe for autoagglutination or clumping.
8	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.

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 with one grouping reagent within 1 minutes is a positive result indicating the presence of tested Lancefield group (A, B, C, D, F or G) in the sample. The test should also be considered positive if one grouping reagent gives a substantially stronger reaction than the other five.

Absence of agglutination indicates that the tested Lancefield group is not present in the test culture.

Note: If agglutination occurs in all groups, either the enzyme has been over-inoculated in which case repeat the test using a lighter inoculum, or a mixed culture was tested, in which case subculture and retest.

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 latex reagents and positive control.**

Once reconstituted as indicated in the REAGENTS section above, the **Extraction Enzyme** will retain its activity for at up to 3 months. Alternatively, it may be stored in aliquots of 0.4 ml frozen at -20°C for at up to 6 months. In addtion, always check the expiry date indicated on the label. **Do not freeze and thaw the extraction enzyme more than once**.

SHELF LIFE

2 years.

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 40 tests) into one circle on the agglutination slide. Add one drop of latex reagent to the same circle and mix with a mixing

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stick. **Do not allow the dropper tip to touch the drop of positive control on the slide**. Rock the slide gently. Within 1 minute, agglutination, indicating a positive result, should be visible. If no agglutination is seen, reagents should be discarded, and a fresh kit should be used. **NOTE:** The Positive control requires no extraction or dilution.

2. Negative Control: The latex reagents do not auto agglutinate in normal saline solution.

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. False negative results can occur if an insufficient amount of culture is used for the extraction.
4. False positive reactions can occur, however that organisms are likely to non-specifically agglutinate all latex reagents.
5. Some strains of Group D streptococci have been found to also possess group G antigen.
6. Lancefield serotyping is useful in identification of *Streptococcus* spp., however, it should be used in conjunction with other tests to get accurate identification.
7. 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.

TABLE OF SYMBOLS

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

ORDER INFORMATION

Product	Packaging	Ref.
Strep-Check Kit	50 tests	96160

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Revision History

Revision	Release Date	Change Summary
0	2024-10-14	Document creation

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

liofilchem.com/ifu-sds

References

1. Public Health England (2021) Identification of *Streptococcus* species, *Enterococcus* species and morphologically similar organisms. UK Standards for Microbiology Investigations. ID 4 Issue 4.
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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