

AVIPATH® STREP Ref OD014/L

Latex agglutination test for grouping Streptococcal cultures.

Identifies Group A, B, C, D, F and G

Store at 2°C to 8°C. DO NOT FREEZE

For in-vitro diagnostic use only.

INTRODUCTION

Conventional Lancefield grouping of streptococcal isolates is laborious and time consuming. Latex agglutination technology combined with a rapid efficient extraction method allows grouping to be carried out directly from solid phase media as well as from liquid culture. OMEGA's AVIPATH STREP provides both of these advantages for all the groups of streptococci commonly found in human infection.

INTENDED USE

This product is intended to be used as an in-vitro diagnostic aid for the identification of laboratory isolates of Lancefield's groups A, B, C, D, F and G Streptococci.

For professional use only.

PRINCIPLE OF THE TEST

Streptococci possess specific polysaccharide cell wall antigens which allow the bacteria to be classified into groups. The antigen is extracted into solution by the action of an enzyme. Solubilised antigen is then added to a suspension of latex particles coated with specially purified rabbit antibodies to the group antigens. If a group antigen is present, that group of latex will agglutinate. If no group antigen is present, the latex stays in smooth suspension.

CONTENTS

Sufficient reagents are provided to identify 50 isolates.



Latex A

Suspension of latex particles coated with anti-body to Group A streptococcal antigens 0.2%. Working Strength.

Latex B

Suspension of latex particles coated with anti-body to Group B streptococcal antigens 0.2%. Working Strength.

Latex C

Suspension of latex particles coated with anti-body to Group C streptococcal antigens 0.2%. Working Strength.

Latex D

Suspension of latex particles coated with anti-body to Group D streptococcal antigens 0.2%. Working Strength.

Latex F

Suspension of latex particles coated with anti-body to Group F streptococcal antigens 0.2%. Working Strength.

Latex G

Suspension of latex particles coated with anti-body to Group G streptococcal antigens 0.2%. Working Strength.

Control +

0.5 ml

Positive Control. Clear solution of culture medium containing extracted and inactivated streptococcal Group A, B, C, D, F & G antigens. Working Strength.

ENZ Ext

20 ml

Extraction Enzyme. Solution of enzymatic reagents (approximately 0.05%). Working Strength.

STIRRERS

300

PLASTIC SLIDE

50

INSTRUCTION LEAFLET

1

MATERIAL REQUIRED BUT NOT PROVIDED

Water Bath (37°C).
Disinfectant container.
Micropipettes capable of dispensing 50, 100 and 400µl
Test tubes

PRECAUTIONS

AVIPATH STREP Latex reagents do not contain dangerous substances as defined by current UK Chemicals (Hazardous Information and Packaging for Supply) regulations. All reagents should, however, be treated as potential biohazards in use and for disposal. Final disposal must be in accordance with local legislation. Do not ingest.

AVIPATH STREP reagents contains 0.095% sodium azide as a preservative which may be toxic if ingested. Sodium azide may react with lead and copper plumbing to form highly explosive salts. On disposal, flush with large quantities of water.

Handle all organism suspensions, antigen extracts and used test cards as potentially infectious. The enzyme extraction method may not kill all the bacteria present. Dispose of contaminated items safely.

STORAGE

Reagents must be stored at temperatures between 2°C to 8°C.

The kit will perform within specification until the stated expiry date as determined from date of product manufacture and stated on kit and components. Expiry date is the last day of the month on the bottle and the kit label. Do not use reagents after the expiry date.

Exposure of reagents to excessive temperatures should be avoided. Do not expose to direct sunlight.

DO NOT FREEZE ANY OF THE REAGENTS as this will cause irreversible damage.

SPECIMEN COLLECTION AND PREPARATION

Isolation and subculture of the organism may be done using conventional media. Bacteria from primary plate cultures or pure subcultures on solid or in liquid media may be used. Primary cultures in liquid media should not be tested. If the growth of the presumptive streptococcus is in low density on the plate or overgrown by other bacteria, isolate before testing.

REAGENT PREPARATION

All reagents should be brought to room temperature (20°C to 25°C) and mixed gently prior to use. Do not induce foaming.

LIMITATIONS OF USE

Care should be taken when testing organisms directly from selective media. High salt concentrations are known to destabilise latex solutions producing variable results.

When making an interpretation of the test it is strongly advised to take all clinical data into consideration.

There is no reuse protocol for this product.

ASSAY PROCEDURE

For Agar Plate Isolates

1. (a) Pipette 400 μ L of Extraction Enzyme into a clean test tube.
(b) Pick 2-3 colonies from the medium using a sterile loop.
Emulsify the colonies in the Extraction Enzyme.

For Liquid Cultures /isolates

1. Pipette 100 μ L of an overnight culture (pure) into a tube containing 400 μ L extraction enzyme.
2. Incubate the bacteria/enzyme suspension in a water bath at 37°C for 10 minutes shaking after 5 minutes.
3. Add 50 μ L of extract to each of the circles on the test card.
4. Shake each of the latex reagents to suspend the particles and then add one drop of each to the corresponding circle of the test card.
5. Mix and spread the fluid over the whole area of each circle, using a clean mixing stick each time.
6. Rotate and rock the card gently for up to 1 minute. One of the groups should show strong agglutination by this time. The remaining 5 should show no agglutination. Note the result and dispose of the test card safely.

RESULTS AND INTERPRETATION

Strong agglutination of one latex reagent and no agglutination of the other 5 reagents is a positive identification of the group. If any other pattern occurs, further tests are necessary. Refer to the diagram for a suitable scheme to follow.

The positive control should produce a positive result with each Group Latex within one minute.

A negative result can be simulated by substituting uninoculated extraction enzyme for inoculated extraction enzyme in the testing procedure.

A negative result should be produced within one minute.

If controls or users own samples do not give expected results, test results must be considered invalid.

Notes on Streptococcal identification scheme.

1. *Streptococcus pneumoniae* is haemolytic, optochin sensitive and bile soluble. On normal blood agar it produces typical 'draughtsman' type colonies.
2. Streptococci and Listeria monocytogenes are haemolytic and catalase positive. Their cell morphology also distinguishes them from streptococci.
3. Enterococci are typically seen as diplococci or short chains of organisms. Aerococci occur as single cells or in tetrads, are non haemolytic, grow in 6.5% NaCl broth and have variable bile-aesculin reactions.

TROUBLESHOOTING

Use a separate disposable tip for each sample to prevent cross contamination.

Replace caps on all reagents immediately after use.

Prior to the start of the assay bring all reagents to room temperature (20°C to 25°C). Gently mix all reagents by gentle inversion or swirling.

For use by operatives with at least a minimum of basic laboratory training.

Do not use damaged or contaminated kit components.

EVALUATION DATA

Reproducibility of AVIPATH STREP is 100% (+/- one double dilution).

In an evaluation against two major competitors the Specificity of AVIPATH STREP was found to be 100% and the Sensitivity of AVIPATH STREP was found to be 100%.

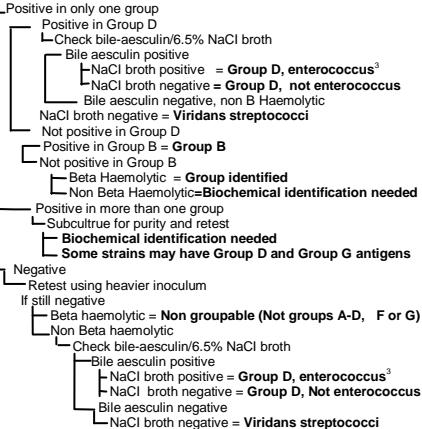
Calibrated against major competitors and in house standards.

STREPTOCOCCAL IDENTIFICATION SCHEME

Isolation of presumptive "Streptococcus" species.

If Alpha haemolysis present, exclude *Streptococcus pneumoniae* (1)
If Beta haemolysis present, exclude *Staphylococcus* and *Listeria* (2)
Note cell morphology (2,3)

Carry out AVIPATH STREP grouping



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8023A ISSUE 4A Revised May 2015

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