AVIPATH® STAPH Ref OD044

Rapid Latex Agglutination Test for the presumptive identification of Staphylococcus aureus

Store at 2°C to 8°C. DO NOT FREEZE

For in-vitro diagnostic use only.

INTRODUCTION AND INTENDED USE

AVIPATH STAPH is a rapid latex agglutination test for the detection of Staphylococci which produce clumping factor and/or Protein A from those species of Staphylococci which do not.
For professional use only.

PRINCIPLE OF THE TEST

The latex particles are coated with human fibrinogen and IgG. The fibrinogen will bind with coagulase and the IgG will bind Protein A. Both factors are associated with **S. aureus.**

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OD044

LATEX
Suspension of Polystyrene particles (approximately 0.5%) coated with IgG and human fibrinogen. Working Strength.

SOLN	SALINE	2.5 ml

Saline solution with preservative. Working Strength.

STIRRERS	**100**
DISPOSABLE TEST SLIDES	**17**
INSTRUCTION LEAFLET	**1**

MATERIAL REQUIRED BUT NOT PROVIDED

Bacteriological loops.

PRECAUTIONS

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

AVIPATH STAPH Latex Reagents contain materials of human origin which have been tested and confirmed negative for HCV, HIV I and HIV II antibodies, and HBsAg by approved procedures at single donor level. Because no test can offer complete assurance that products derived from human source will not transmit infectious agents it is recommended that the reagents within this kit be handled with due care and attention during use and disposal. Do not ingest.

AVIPATH STAPH 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.

AVIPATH STAPH reagents contain 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. Do not ingest

Do not use damaged or contaminated kit components

STORAGE

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

Expiry date is the last day of the month on the bottle and the kit label. The kit will perform within specification until the stated expiry date as determined from date of product manufacture and stated on the kit and components. 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

Specimens should be fresh 18 to 24 hour cultures, and may be tested direct from the culture plate. If there is insufficient growth, sub culture to blood or nutrient agar and incubate overnight at 37°C. The morphology of the colonies should be checked so that they resemble **S. aureus.** Wherever possible, pure cultures should be used for the test procedure.

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

Some species of Staphylococcus other than **S. aureus**, notably **S. intermedius** and **S. hyicus** may give positive results in conventional coagulase test and may also agglutinate latex reagents. Occasionally rare species such as **S. lugdunensis** and **S. schleiferi** have been reported as clumping factor positive. Novobiocin-resistant strains may also give false positive results using latex based tests. Several species such as **E. coli** and **C. albicans** are capable of agglutinating latex particles non-specifically. Organisms that possess immunoglobulin binding factors may also agglutinate latex based reagents.

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.

Any colonies of bacteria tested positive by **AVIPATH STAPH** should be confirmed as **S. aureus** by biochemical tests.

ASSAY PROCEDURE

1. Allow the test reagents to reach room temperature.
2. Place one drop of the isotonic saline onto one of the test circles.
3. Using a sterile loop, pick 2-4 colonies of the suspected Staphylococcus bacteria and emulsify in the isotonic saline on the test circle.
4. If agglutination or clumping occurs at this point it is autoagglutination and the sample is unsuitable for the test.
5. Shake the latex reagent vigorously, then, using the dropper provided, add one drop of reagent to the test circle.
6. Mix the reagent and culture emulsion using a disposable stirrer ensuring coverage of the test circle with the mixture.
7. Gently and evenly, rock and rotate the test slide for one minute whilst examining the test slide for agglutination.

RESULTS

Examine the test slide under a strong light source after 1 minute. A positive result is indicated by the obvious agglutination pattern of the latex in a clear solution. A negative result is indicated by no change in the latex suspension on the test slide. Agglutination indicates the presence of either coagulase or protein A. No agglutination indicates the absence of these two components. A low or suspected positive result should be re-assessed. Diagnosis should not be made solely on the findings of one clinical assay.

QUALITY CONTROL

Test in the following way on each batch of tests to ensure the test is valid.

1. Check that the latex reagent agglutinates with a known **S. aureus** strain.
2. Check that the latex reagent does not autoagglutinate with isotonic saline solution.

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

Precision, repeatability and reproducibility is 100% +/- one double dilution.

	Positive	Negative	Total
Staph aureus	15	0	15
Non Staph aureus	0	129	129
	3	17	20 [1]
	1	9	10 [2]
	4	6	10 [3]
	3	7	10 [4]
	5	5	10 [5]
	1	9	10 [6]
	32	182	214

[1] Staph saprophyticus [a, b]
[2] Staph cohnii [a, b]
[a] Novobiocin resistant
[3] Staph lugdunensis [b]
[b] See Limitations of Use Section
[4] Staph scheiferi [b]
[5] Staph sciuri [a, b]
[6] Staph warneri

Sensitivity 15 / 15 = 100%
Specificity 138 / 139 = 99.28%

REFERENCES

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OMEGA DIAGNOSTICS LTD.
Omega House, Hillfoots Business Village
Alva FK12 5DQ, Scotland, United Kingdom
odl@omegadiagnostics.co.uk
www.omegadiagnostics.com

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