AVITEX ASO ® Ref OD083/OD033/OD033/E

Latex serology test for detection of Streptococcal Antibodies
Store at 2°C to 8°C. DO NOT FREEZE.
For in-vitro diagnostic use only.

INTRODUCTION AND INTENDED USE

AVITEX ASO is a rapid latex agglutination test kit for the detection of anti-streptolysin-O (ASO) antibodies in human serum.

ASO antibodies are found in sera of patients in response to infection with haemolytic streptococci of groups A, C or G. Streptolysin-O is highly antigenic therefore patients with these infections produce specific antibodies detectable by the **AVITEX ASO** reagent.
For professional use only.

PRINCIPLE OF THE TEST

AVITEX ASO latex particles are coated with purified and stabilised streptolysin-O. When the latex suspension is mixed with serum containing elevated levels of ASO antibodies on a slide, clear agglutination is seen within 2 minutes.

This test has been calibrated to WHO ASO First International Standard Preparation 97/662.

CONTENTS

	Ref OD083	Ref OD033	Ref OD033/E
Latex			

Suspension of polystyrene latex particles (approximatly 1.5%) coated with streptolysin O. Working Strength.

CONTROL	**+**	**0.5ml**	**0.5ml**	**N/A**

Positive Control. Serum containing anti-streptolysin-O antibodies. Working Strength.

CONTROL	**–**	**0.5ml**	**0.5ml**	**N/A**

Negative Control. Serum free of anti-streptolysin-O antibodies. Working Strength.

STIRRERS	**50**	**100**	**N/A**
DISPOSABLE TEST SLIDE	**1**	**1**	**N/A**
INSTRUCTION LEAFLET	**1**	**1**	**1**

MATERIAL REQUIRED BUT NOT PROVIDED

Micropipettes (50 µl)
Isotonic saline (0.9% NaCI)

PRECAUTIONS

AVITEX ASO reagents contain materials of human origin which have been tested and confirmed negative for HCV, HIV I and HIV II antibodies, and HBsAg by FDA 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. All reagents should, however, be treated as potential biohazards in use and for disposal. Do not ingest.

AVITEX ASO 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 disposal. Final disposal must be in accordance with local legislation.

AVITEX 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.

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

Obtain a sample of venous blood from the patient and allow a clot to form and retract. Centrifuge clotted blood sample and collect clear serum. Fresh serum samples are required.

Do not use haemolysed, contaminated or lipaemic serum for testing as this will adversly affect the results.

Serum may be stored at 2°C to 8°C for up to 48 hours prior to testing. If longer storage is required, store at –20°C for up to 6 weeks. Thawed samples must be mixed prior to testing.

Do not repeatedly freeze-thaw the specimens as this will cause false results.

DO NOT DILUTE THE TEST SERA PRIOR TO USE IN THE QUALITATIVE TEST.

REAGENT PREPARATION

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

The test slide should be thoroughly cleaned before use as traces of detergent or prior specimen may affect the result.
Recommended Cleaning procedure:

1. Used cards must be immediately immersed in a disinfectant solution. Follow disinfectant manufactures guidelines.
2. The reaction circles must be physically rubbed with non-abrasive material to ensure removal of possible adhering particles.
3. Thoroughly rinse in purified water.
4. Allow reaction card to dry.
5. Spray cards with a 70% alcohol solution.
6. Allow the alcohol to evaporate prior to re-use.

LIMITATIONS OF USE

The use of samples other than serum has not been validated in this test.

There is no reuse protocol for this product.

Diagnosis should not be made solely on the findings of one clinical assay. When making an interpretation of the test it is strongly advised to take all clinical data into consideration.

Positive reactions can occur with patients suffering from clinical conditions such as rheumatoid arthritis, tonsillitis and various other infections where elevated levels of ASO have been found.

ASSAY PROCEDURE

Qualitative Method

1. Allow test reagents and sera to come to room temperature.
2. Transfer one drop of patient's serum (50µl) to the test circle on the slide.
3. Shake the latex reagent, then, using the dropper provided, add one drop of suspension to the test circle.
4. Mix the drops using a disposable stirrer ensuring coverage of the test circle with the mixture.
5. Gently and evenly, rock and rotate the test slide for 2 minutes whilst examining the test slide for agglutination.

Semi Quantitative Method

1. Using isotonic saline prepare serial dilutions of the patients serum (1/2, 1/4, 1/8, 1/16, 1/32, 1/64 and so on)
2. Transfer one drop of each serum dilution (50µl) to the test circle on the slide.
3. Shake the latex reagent, then, using the dropper provided, add one drop of suspension to the test circle.
4. Mix the drops using a disposable stirrer ensuring coverage of the test circle with the mixture.
5. Gently and evenly, rock and rotate the test slide for 2 minutes whilst examining the test slide for agglutination.

RESULTS AND INTERPRETATION

Examine the test slide under a strong light source after 2 minutes.

Kit controls or known level value samples should be tested with each test run. The kit negative control should give a negative result after 2 minutes. The kit positive control should give a positive result at a titre of 1/4 +/- one double dilution after 2 minutes. If levels of controls or users known samples do not give expected results, test results must be considered invalid. A low or suspected positive result should be re-assessed.

QUALITATIVE METHOD

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.

Positive results will be obtained at a ASO serum concentration of 200IU/ml or more and negative results will be obtained at a ASO concentration below 200 IU/ml.

SEMI-QUANTITATIVE METHOD

The serum ASO concentration can then be calculated approximately by multiplying the dilution factor (i.e 2, 4, 8 or 16) by the detection limit, i.e. 200, to give the number of IU/ml concentration e.g. if the agglutination titre appears at 1/4 the approximate serum ASO concentration is 4 x 200 = 800 IU/ml.
Titres of 1026 IU/ml have been detected with Avitex ASO with no prozone (Hook) effect.

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^{o}C to 25^{o}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

Reproducability of AVITEX ASO is 100% (+/- one double dilution).

	Avitex ASO		Totals
	+	-	
ASO +	48	1	49
ASO -	2	67	69
	50	68	118

Sensitivity 48/49 = 97.96%
Specificty 115/118 = 97.46%

REFERENCES

1. Todd E. W., (1934), J Path and Bact., 39, 299-320.
2. Klein, G.C., (1980), Manual of Clin.Immunol., 7th Ed., 431.
3. Spaun J., Bentzon M.W., Larsen S.O., et.al., (1961), Bull. WHO, 24, 271-279.
4. Klein, G.C., et al., (1971),Appl. Microbiol., 21, 999.

8009A Issue 3 Revised April 2003.

OMEGA DIAGNOSTICS LTD.
Omega House, Hillfoots Business Village
Alva FK12 5DQ, Scotland, United Kingdom
odl@omegadiagnostics.co.uk
www.omegadiagnostics.co.uk
AN ISO 9001:2000 CERTIFIED COMPANY