AVITEX® SLE Ref OD093/ OD043

Latex serology test for the detection of antibodies to anti-deoxyribonucleoprotein (anti-DNP) in human serum

Store at 2ºC to 8ºC. DO NOT FREEZE.

For in-vitro diagnostic use only.

INTRODUCTION AND INTENDED USE

Systemic Lupus Erythematosus (SLE) has been defined as a prototypic autoimmune disease.
The antibodies most associated with SLE are those directed against deoxyribonucleoprotein (DNP). These antibodies are believed to cause the formation of the LE cell, occurring in 60 to 80% of patients diagnosed as having SLE.

This disease effects 50 out of 100,000 people with a rate of incidence of 9:1 between women and men. The prevalent age group is young women between the ages of 25 and 35 years of age.

AVITEX SLE is a rapid latex agglutination test kit for the presumptive detection of the Systemic Lupus Erythematosus (SLE) in human serum by the detection and quantitation of antibodies in serum to deoxyribonucleoprotein (DNP).
For professional use only.

PRINCIPLE OF THE TEST

The **AVITEX SLE** latex particles are coated with deoxyribonucleoprotein (DNP). When the latex suspension is mixed with serum containing anti DNP antibodies, a clear agglutination is seen within 1 minute.

This test has been calibrated against in house standards. There is no International standard for this test.

CONTENTS

	Ref OD093	Ref OD043
	50	100
LATEX	Solution of Polystyrene particles (approx 0.7 %) coated with DNP in stabilising buffer. Working Strength.	
CONTROL +	**0.5ml** Serum containing antibodies to DNP. Working Strength.	**0.5ml**
CONTROL -	**0.5ml** Serum free of antibodies to DNP. Working Strength.	**0.5ml**
STIRRERS	**50**	**100**
PLASTIC TEST SLIDE	**1**	**1**
INSTRUCTION LEAFLET	**1**	**1**

MATERIAL REQUIRED BUT NOT PROVIDED

Micro-pipettes (50 µl)
Isotonic saline (0.9% NaCl)

PRECAUTIONS

AVITEX reagents contain materials of human origin which have been tested and confirmed negative for HIV I and II antibodies, HCV and HBsAg by FDA approved procedures. 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.

AVITEX 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 2ºC to 8ºC.

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 2ºC to 8ºC for up to 48 hours prior to testing. If longer storage is required, store at ï 20ºC 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 (20ºC to 25ºC) 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.

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.

20-25% of SLE patients do not exhibit the formation of LE cells.

Positive reactions can occur with patients suffering from clinical conditions such as chronic hepatitis, periarteritis nodosa, dermatomyositis, rheumatoid arthritis and scleroderma.

ASSAY PROCEDURE

Qualitative Method

Allow test reagents and sera to reach room temperature.

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

RESULTS AND INTERPRETATION

Examine the test slide under a strong light source after 1 minute.

Kit controls or known level value samples should be tested with each test run. The kit negative control should give a negative result after 1 minute. The kit positive control should give a positive result at a titre of 1/64 +/- one double dilution after 1 minute. 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.

SLE tests are important in the detection and identification of various autoimmune and other inflammatory diseases. It should be noted that positive tests for antibodies DNP are not given by every test in every case of clinically diagnosed SLE.
Antibodies are produced against DNP which has been released during the progression of the disease from dying cells. These antibodies are present in increased numbers and are highly specific to SLE. 60% to 80% of patients with active SLE have a positive anti-DNP test.

It has also been reported that many widely used drugs such as hydralazine, isoniazid, procainamide and a number of anti-convulsant drugs can induce a systemic lupus erythematosus (SLE) syndrome. Anti DNP is not found with drug ï induced Lupus but correlates well with disease activity and with occurrence of glomerulonephritis.

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 (20ºC to 25ºC). 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 Avitex SLE is 100% (+/- one double dilution).

In a comparison with alternative techniques the following results were obtained.

	AVITEX SLE	LE Cell Assay	Fluorescent ANA assay.	Total
Active SLE	24 (83%)	25 (86%)	24 (83%)	29
Inactive SLE	4 (17%)	4 (17%)	16 (70%)	23
Connective Tissue Disease	0 (0%)	1 (12.5%)	4 (50%)	8
SLE Negative	94 (99%)	94 (99%)	89 (94%)	95

REFERENCES

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