

SBio SLE

Slide Test for Anti-Deoxyribonucleoprotein

REF	90440025
Σ	25 T



Temperature Limitation	Manufacturer	This side up	EC REP Authorised Representative	Xn NaN, R22 S23-46-61
Use by (Last day of stated month)	Consult Instructions for use		CONTROL + Positive control	Harmful if swallowed. Do not breathe vapour. If swallowed, seek medical advice immediately and show this container or label. Avoid release to the environment. Refer to special instructions.
Date of Manufacture	REF Catalogue Number		CONTROL - Negative control	
LOT Batch Number	IVD In vitro Diagnostic Medical Device		REAGENT Description of reagent	
		Contains sufficient for <n> tests		

SUMMARY

The presence of autoantibodies to nuclear proteins is a common finding in Systemic Lupus Erythematosus (SLE) and other collagen diseases. Anti-DNP is present in high titres in the serum of majority of SLE patients with active disease but is present occasionally in remission states. Although Anti-DNP is found exclusively in SLE, only low titres may be detected in diseases such as chronic hepatitis, periarteritis nodosa, dermatomyositis, scleroderma and drug hypersensitivity. SBio SLE is a latex agglutination slide test for the detection of antibodies to dsDNA and histones.

REAGENTS

- SBio SLE reagent is a uniform suspension of polystyrene latex particles coated with Deoxyribonucleoprotein (DNP).
- Positive control, reactive with SBio SLE reagent.
- Negative control, non-reactive with SBio SLE reagent.

Each batch of reagents undergoes rigorous quality control at various stages of manufacture for its specificity, sensitivity and performance.

REAGENT STORAGE AND STABILITY

Store the reagent at 2-8°C. DO NOT FREEZE. The shelf life of the reagent is as per the expiry date mentioned on the reagent vial label. Do not use reagents after the expiry date

PRINCIPLE

Latex particles coated with DNP will agglutinate when mixed with serum containing Anti-DNP. No agglutination indicates absence of Anti-DNP in the serum.

NOTE

- In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
- The reagents that are derived from human source have been tested for HBsAg and Anti-HIV antibodies and are found to be non-reactive. However handle the material as if infectious.
- The reagents contain sodium azide 0.1 % as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.
- The reagent can be damaged due to microbial contamination or exposure to extreme temperatures. It is strongly recommended that the performance of the reagent be verified with the positive and negative controls provided with the kit.
- Shake the latex reagent well before use to disperse the latex particles uniformly and to improve test readability.
- Only a clean and dry slide must be used. Clean the slide with distilled water thoroughly and wipe dry.
- Accessories provided with the kit only must be used for optimum results.

- Do not use damaged or leaking reagents.

SAMPLE COLLECTION AND PREPARATION

No special preparation of the patient is required prior to sample collection by approved techniques. Use fresh clear serum samples. In case of delay in testing, store the serum samples at 2-8°C for upto 72 hours. For longer storage freeze the serum. However, repeated freezing and thawing of samples should be avoided.

ADDITIONAL MATERIAL REQUIRED

Test tube (10 x 75 mm), Pipettes, Isotonic saline, Stopwatch, Direct light source.

TEST PROCEDURE

Bring all reagents and samples to room temperature before use.

Qualitative Method

- Place one drop (40 µl) of sample to be tested onto one of the reaction circles of the slide using a sample dispensing pipette provided with the kit.
- Place one drop of positive and negative control onto separate reaction circles of the slide.
- Gently shake the SBio SLE latex reagent and add one drop to each sample and control taken on the slide.
- Mix with separate mixing sticks, spreading the mixture uniformly over the entire reaction circle.
- Immediately start a stopwatch. Rock the slide gently, back and forth, observing for agglutination macroscopically at **three minutes**.

Semi Quantitative Method.

- Using isotonic saline prepare serial dilutions of the serum sample 1:2, 1:4, 1:8, 1:16, 1:32 and so on.
- Place each dilution of the serum sample onto separate reaction circles of the slide.
- Add one drop of well mixed SBio SLE latex reagent to each dilution of the sample on the slide.
- Mix with separate mixing sticks, spreading the mixture uniformly over the entire reaction circle.
- Immediately start a stopwatch. Rock the slide gently back and forth, observing for agglutination macroscopically at **three minutes**.

INTERPRETATION OF RESULTS

Qualitative Method

Agglutination is a positive test result and indicates presence of Anti-DNP in the test specimen.

No agglutination is a negative test result and indicates absence of Anti-DNP in the test specimen.

Semi Quantitative Method

The titre of the serum is the reciprocal of the highest dilution, which gives agglutination.

REMARKS

1. Markedly lipemic, haemolysed and contaminated serum samples could produce non-specific results.
2. Use of plasma rather than serum can lead to false positive results.
3. Anti-DNP may be found in diseases other than SLE. Low titres have been detected in rheumatoid arthritis, chronic hepatitis, periarthritis nodosa, dermatomyositis, scleroderma, atypical pneumonia, tuberculosis and lymphoma.

PERFORMANCE CHARACTERISTICS

1. The performance characteristics of SBio SLE were evaluated using known positive and negative samples. The known samples were validated using other commercial manufacturers latex slide test reagent having similar performance characteristics.

	Total	SBio SLE	
		Positive	Negative
SLE +ve samples	33	33	0
SLE -ve samples	80	0	80
	113	33	80

Sensitivity: 100% Specificity: 100%

2. Repeatability and reproducibility (inter-assay and inter-lot) were evaluated on a number of SLE negative and SLE positive samples. No variations were found in the outcome of different tests.

WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

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EC REP

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