Size 137 X 218mm

CE

RHELAX-SLE®

SLIDE TEST FOR ANTI-DEOXYRIBONUCLEOPROTEIN

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.

RHELAX-SLE® is a latex agglutination slide test for the detection of antibodies to dsDNA and histones.

PRESENTATION

REF	REF	10440010	10440025
Latex		10 Tests	25 Tests
Control	+	0.4 ml	0.4 ml
Control	-	0.4 ml	0.4 ml
Six circle slide		1	1
Sample droppers		10	25
Mixing stick ladder		1	1
Rubber teat		1	1
Pack insert		1	1

REAGENTS

1. RHELAX-SLE® reagent is a uniform suspension of polystyrene latex particles coated with Deoxyribonucleoprotein (DNP).
2. Positive control, reactive with RHELAX-SLE® reagent.
3. Negative control, non-reactive with RHELAX-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^{0}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

1. In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
2. 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.
3. The reagents contain sodium azide 0.1 % as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.
4. 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.
5. Shake the latex reagent well before use to disperse the latex particles uniformly and to improve test readability.
6. Only a clean and dry slide must be used. Clean the slide with distilled water thoroughly and wipe dry.
7. Accessories provided with the kit only must be used for optimum results.
8. 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^{0}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.

Size 137 X 218mm

TEST PROCEDURE
Bring all reagents and samples to room temperature before use.

Qualitative Method
1. 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.
2. Place one drop of positive and negative control onto separate reaction circles of the slide.
3. Gently shake the RHELAX-SLE® latex reagent and add one drop to each sample and control taken on the slide.
4. Mix with separate mixing sticks, spreading the mixture uniformly over the entire reaction circle.
5. Immediately start a stopwatch. Rock the slide gently, back and forth, observing for agglutination macroscopically at **three minutes**.

Semi Quantitative Method.
1. Using isotonic saline prepare serial dilutions of the serum sample 1:2, 1:4, 1:8, 1:16,1:32 and so on.
2. Place each dilution of the serum sample onto separate reaction circles of the slide.
3. Add one drop of well mixed RHELAX-SLE® latex reagent to each dilution of the sample on the slide.
4. Mix with separate mixing sticks, spreading the mixture uniformly over the entire reaction circle.
5. 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
Markedly lipemic, haemolysed and contaminated serum samples could produce non-specific results.
Use of plasma rather than serum can lead to false positive results.
Anti-DNP may be found in diseases other than SLE. Low titres have been detected in rheumatoid arthritis, chronic hepatitis, periarteritis nodosa, dermatomyositis, scleroderma, atypical pneumonia, tuberculosis and lymphoma.

PERFORMANCE CHARACTERISTICS
- The performance characteristics of RHELAX-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	RHELAX-SLE®	
		+ VE	- VE
SLE + Ve samples	33	33	0
SLE - Ve samples	80	0	80
	113	33	80

- Sensitivity: 100%
- Specificity: 100%

- 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

1. Bennet R. M., et. al., Am. J. Clin. Path., 66:743-745 (1976).
2. Chapman J. C., Am. J. Med. Tech., 42:154-157 (1976).
3. Berrman H., Am. J. Med.Sci., 222, 473 (1961).
4. Dubois E., Drexler E., Arterberry J., JAMA 177, 141 (1961).
5. Alacon-Segouia D., et. al., Clin. Exp. Immuno., 6,557 (1970).
6. Data on file: Tulip Diagnostics (P) Ltd.

Size 137 X 218mm

SYMBOL KEYS

	Temperature limitation		Manufacturer		Contains sufficient for <n> tests
	Use by		Consult Instructions for use	CONTROL +	Positive control
	Date of Manufacture	REF	Catalogue Number	CONTROL -	Negative control
LOT	Batch Number/ Lot Number	IVD	*In vitro* Diagnostic Medical Device	REAGENT	Description of reagent
	This side up	EC REP	Authorised Representative in the European Community		

Size 137 X 218mm

TULIP DIAGNOSTICS (P) LTD.

REGD. OFFICE: GITANJALI, TULIP BLOCK, DR. ANTONIO DO REGO BAGH, ALTO SANTACRUZ, BAMBOLIM COMPLEX P.O., GOA-403 202, INDIA. Website: www.tulipgroup.com

PLOT NOS. 92/96, PHASE II C, VERNA IND. EST., VERNA, GOA-403 722, INDIA.

EC REP

CMC Medical Devices & Drugs S.L., C/ Horacio Lengo No. 18, CP 29006, Malaga, Spain

1121/VER-02