CE

RHELAX-ASO®

SLIDE TEST FOR ANTI-STREPTOLYSIN O

SUMMARY

Streptococcus belongs to the family of lactobacillacae and the majority is facultative anaerobes. The facultative anaerobic streptococci are divided into two categories:

1. those which produce soluble hemolysin and
2. those which do not produce soluble hemolysin

The first group of streptococci are called β-hemolytic streptococci, which can be further subdivided into group (a), group (b), group (c) and group (d). It includes most of the species associated with primary streptococcal infections in humans.

The group (a) β-hemolytic streptococci produce various exotoxins such as streptolysin O and streptolysin S that can act as antigens. The affected individuals produce specific antibodies against streptolysin O, namely Anti-streptolysin O.

Determination of these antibodies is very useful for the diagnosis of streptococcal infections and their relative effects such as rheumatic fever and acute glomerulonephritis. An elevated ASO titre of more than 200 IU/ml may indicate an acute streptococcal infection.

PRESENTATION

REF		10430005	10430025	104300035	10430050	104300070	10430100
Latex/ Tests		5 ml	25 Tests	35 Tests	50 Tests	70 Tests	100 Tests
Control	+	-	0.4 ml	0.4 ml	0.4 ml	0.4 ml	0.4 ml
Control	-	-	0.4 ml	0.4 ml	0.4 ml	0.4 ml	0.4 ml
Six circle black plastic slide		-	1	1	1	1	1
Sample droppers		-	25	35	50	70	100
Mixing stick ladder		-	1	2	2	3	4
Rubber teat		-	1	1	1	2	2
Pack insert		1	1	1	1	1	1

REAGENTS

1. RHELAX®-ASO reagent: A uniform suspension of polystyrene latex particles coated with streptolysin O. The RHELAX®-ASO reagent is standardized to detect antibodies to streptolysin O in concentrations ranging from 200 IU/ml or more. The standardization of detection limit of RHELAX®-ASO is traceable to the International Standard for Antistreptolysin 'O' (97/662).
2. Positive control, reactive with the RHELAX®-ASO reagent.
3. Negative control, non-reactive with the RHELAX®-ASO reagent.

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

REAGENT STORAGE AND STABILITY

1. Store the reagents at 2-8°C. DO NOT FREEZE.
2. 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

RHELAX®-ASO slide test for detection of antibodies to streptolysin O is based on the principle of agglutination. The test specimen (serum) is mixed with Rhelax®-ASO latex reagent and allowed to react. If antibodies to streptolysin O are present in concentrations more than 200 IU/ml then a visible agglutination is observed. If antibodies to streptolysin O are not present or are in concentrations less than 200 IU/ml then no agglutination will be observed.

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. Reagent contains 0.1% Sodium Azide 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 on exposure to extreme temperatures. It is recommended that the performance of the reagent be verified with the positive and negative controls provided with the kit.

5. Shake the RHELAX®-ASO latex reagent well before use to disperse the latex particles uniformly and improve test readability.
6. Only a clean and dry slide must be used. Clean the slide with distilled water and wipe dry.
7. Accessories provided with the kit only must be used for optimum results.
8. Do not use damaged or leaking reagents.

SPECIMEN COLLECTION AND PREPARATION

No special preparation of the patient is required prior to specimen collection by approved techniques.
Only serum should be used for testing. Should a delay in testing occur, store the samples at 2-8°C. Samples can be stored for upto a week. Do not use hemolysed serum.

MATERIAL PROVIDED WITH THE KIT

Reagent

RHELAX®-ASO latex reagent, Positive control, Negative control.

Accessories

Slide with six reaction circles, Sample dispensing pipettes, Mixing sticks, Rubber teat.

ADDITIONAL MATERIAL REQUIRED

Stop watch, Test tubes, A high intensity direct light source, Isotonic saline.

TEST PROCEDURE

1. Bring reagent and test specimen (serum) to room temperature before use.
2. Tighten the cap of each; Latex reagent bottle, positive control and negative control bottles respectively in the clockwise direction to pierce the bottle nozzle.

Qualitative Method

1. Pipette one drop of test specimen (serum) onto the slide using a disposable pipette provided with the kit.
2. Add one drop of RHELAX®-ASO latex reagent to the drop of test specimen (serum) on the slide by holding the latex reagent vial vertically. Do not let the dropper tip touch the liquid on the slide.
3. Using a mixing stick, mix the test specimen (serum) and the RHELAX®-ASO latex reagent uniformly over the entire circle. Do not let the dropper tip touch the liquid on the slide.
4. Immediately start a stopwatch. Rock the slide gently back and forth observing for agglutination macroscopically at **two minutes**.

Semi Quantitative method

1. Using isotonic saline prepare serial dilutions of the test specimen (serum) sample positive in the qualitative method 1:2, 1:4, 1:8, 1:16 and so on.
2. Pipette the diluted test specimen (serum) on the slide. Start with the 1:2 diluted test specimen.
3. Add one drop of RHELAX®-ASO reagent to it and mix well. Spread the mixture uniformly over the entire circle.
4. Immediately start a stopwatch. Rock the slide gently, back and forth, observing for agglutination macroscopically at **two minutes**. Proceed similarly with each dilution as test specimen.

INTERPRETATION OF TEST RESULTS

Qualitative Method

Agglutination is a positive test result and indicates the presence of detectable levels of Anti-streptolysin O in the test specimen (serum).
No agglutination is a negative test result and indicates the absence of detectable levels of Anti-streptolysin O in the test specimen (serum).

Semi Quantitative Method

Agglutination in the highest serum dilution corresponds to the amount of ASO in IU/ml present in the test specimen.
The concentration of ASO can be calculated as follows:
ASO (IU/ml) = S x D
Where S = sensitivity of the reagent i.e. 200 IU/ml.
D = Highest dilution of serum showing agglutination.

REMARKS

1. Markedly lipemic, hemolysed and contaminated serum samples could produce non-specific results.
2. Serum samples having markedly higher protein content may produce non-specific reagent aggregation.
3. Use of plasma rather than serum can lead to false positive results.
4. Do not read results beyond two minutes.
5. It is recommended that all positive test results should be further tested with methods enabling quantitation of ASO titres.
6. The RHELAX®-ASO reagent is free from prozone effect at ASO level between 200 IU/ml to 4000 IU/ml of ASO concentration.

7. It is recommended that results of the tests should be correlated with clinical findings to arrive at the final diagnosis.
8. Cap the reagent vial tightly after use to avoid spilling of reagent inside the cap.
9. Always keep the reagent vial in upright position during storage.

PERFORMANCE CHARACTERISTICS

The performance characteristics of RHELAX®-ASO were evaluated using known positive and negative serum samples. The known serum samples were validated using other commercial manufacturers latex slide test reagent having similar performance characteristics.

	Total	RHELAX®-ASO	
		+ VE	- VE
ASO + Ve samples	25	25	0
ASO - Ve samples	75	0	75
	100	25	75

Sensitivity: 100% Specificity: 100%

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

WARRANTY

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

BIBLIOGRAPHY

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2. Klein G.C., et.al. (1971), Upper Limits of Normal Antistreptolysin O and Antideoxyribonuclease B Titres, Applied Microbiology, 21, 999-1001.
3. Clinical Laboratory by Lothar Thomas , M.D., 1st edition, 1988, TH-Books, Verlagsgesellschaft mbH, Frankfurt, Germany, pgs 1202-1203.
4. Data on file: Tulip Diagnostics (P) Ltd.

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	

TULIP DIAGNOSTICS (P) LTD.

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