

SBio ASO

Slide Test for Anti-Streptolysin O

REF	90430050	90430100
Σ	50 T	100 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

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

- those which produce soluble hemolysin and
- 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.

SBio ASO is a latex agglutination slide test for the detection of anti-streptolysin O.

REAGENTS

- SBio ASO reagent: A uniform suspension of polystyrene latex particles coated with streptolysin O. The SBio 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 SBio ASO is traceable to the International Standard for Antistreptolysin 'O' (97/662).
- Positive control, reactive with the SBio ASO reagent.
- Negative control, non-reactive with the SBio 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

Store the reagents 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

SBio ASO slide test for detection of antibodies to streptolysin O is based on the principle of agglutination. The test specimen (serum) is mixed with SBio 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

- 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. Reagent contains 0.1% Sodium Azide 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 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.
- Shake the SBio ASO latex reagent well before use to disperse the latex particles uniformly and improve test readability.
- Only a clean and dry slide must be used. Clean the slide with distilled water and wipe dry.
- Accessories provided with the kit only must be used for optimum results.
- 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.

ADDITIONAL MATERIAL REQUIRED

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

TEST PROCEDURE

Bring reagent and samples to room temperature before testing.

Qualitative Method

- Pipette one drop (40 μ l) of test sample onto the slide using a disposable pipette provided with the kit.
- Add one drop of SBio ASO latex reagent to the drop of test sample on the slide.
- Using a mixing stick, mix the serum and the SBio ASO latex reagent uniformly over the entire circle. Do not let the dropper tip touch the liquid on the slide.
- Immediately start a stopwatch. Rock the slide gently back and forth observing for agglutination macroscopically at **two minutes**.

Semi Quantitative method

- Using isotonic saline prepare serial dilutions of the serum sample positive in the qualitative method 1:2, 1:4, 1:8, 1:16 and so on.

- Pipette one drop (40 µl) each of the diluted specimens on the slide. Start with the 1:2 diluted test specimen.
- Add one drop of SBio ASO reagent to it and mix well. Spread the mixture uniformly over the entire circle.
- 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. No agglutination is a negative test result and indicates the absence of detectable levels of Anti-streptolysin O in the test specimen.

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:

$$\text{ASO (IU/ml)} = S \times D$$

Where S = sensitivity of the reagent i.e. 200 IU/ml.

D = Highest dilution of serum showing agglutination.

REMARKS

- Markedly lipemic, hemolysed and contaminated serum samples could produce nonspecific results.
- Serum samples having markedly higher protein content may produce non specific reagent aggregation.
- Use of plasma rather than serum can lead to false positive results.
- Do not read results beyond two minutes.
- It is recommended that all positive test results should be further tested with methods enabling quantitation of ASO titres.

- It is recommended that results of the tests should be correlated with clinical findings to arrive at the final diagnosis.

PERFORMANCE CHARACTERISTICS

- The performance characteristics of SBio ASO 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	SBioASO	
		Positive	Negative
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 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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- Klein G.C., (1980) Manual of Clin. Immunol., 7th Ed., 431.
- Spaun J., Bentzon M.W., Larsen S.O. et al., (1961) Bull. WHO, 24, 271-279.
- Klein G.C. et al., (1971) Appl. Microbiol., 21, 999.

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EC REP

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