TRUEchemie Anti-Streptolysin O (ASO) Test kit (Slide Agglutination)

for the qualitative and semi-quantitative determination o f ASO in serum

INTENDED USE

The TRUEchemie Anti-Streptolysin O (ASO) Test kit (Slide Agglutination) is used for the qualitative and semi-quantitative determination of Anti Streptolysin-O in serum.

INTRODUCTION

The group a beta-hemolytic Streptococci produce various exotoxins such as Streptolysin-O & Streptolysin-S which can act as antigens. The affected individuals produce specific antibodies-Antistreptolysin – O (ASO). Detection of ASO is very useful in the diagnosis of streptococcal infections. The elevated ASO titre may be associated with acute rheumatic fever and glomerulonephritis. An elevated ASO titre of more than 200 IU/ml indicates an acute streptococcal infection. Testing of successive serum sample for an interval of 10-12 days is diagnostically more important than a single sample.

PRINCIPLE

The latex Reagent is coated with Streptolysin-O. The specimen containing ASO, on mixing with Latex Reagent agglutinates, showing the positive test result. If ASO is absent there will be no agglutination, which is a negative test result.

PACK SIZE

Kit Size	25 T	50 T
Cat. No.	ADX801	ADX802
Kit Contents		
1) ASO Latex	1 x 1 ml	1 x 2 ml
2) ASO Positive Control	1 x 0.250 ml	1 x 0.250 ml
3) ASO Negative Control	1 x 0.250 ml	1 x 0.250 ml
Accessories Reusable Plastic Slides Disposable Plastic Droppers Disposable Plastic Sticks Rubber Teat		

REAGENT PREPARATION

Ready to use reagents.

WARNINGS AND PRECAUTIONS

1. Bring all the reagents and samples to Room tempratu re before use.
2. Do not freeze the Latex Reagent.
3. Do not use hemolysed or turbid specimen. The use of plasma instead of serum could lead to erroneous results. Drying of the mixture at the periphery of the circle could lead to erroneous results.
4. The ASO Latex Reagent should be shaken well prior to use, to ensure a homogeneous suspension of latex.
5. The source material used in the manufacturing of Positive & Negative Controls is tested for HBsAg & HIV antibodies and found to be negative. However, for better safety these controls should be handled with proper care.
6. **Do not read results beyond 2 minutes.**
7. While dispensing Latex Reagent, hold the glass dropper vertically to ensure uniform drop size.
8. The disposal of the residues has to be done as per local legal regulations.

REAGENT STORAGE & STABILITY

The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at 2-8°C. Do not use reagents over the expiration date.

SPECIMEN COLLECTION AND STORAGE

Only serum should be used for testing. In case of a delay in testing, store at 2-8°C

TEST PROCEDURE

(A) QUALITATIVE TEST:

1. Place one drop (40 µl) of each specimen, Positive Control & Negative Control in separate circles using separate plastic droppers for each.
2. Add one drop (35 µl) of Latex Reagent in e ach circl e of slide.
3. Mix well and spread the reaction mixture in the entire circle.
4. Rock the slide gently for 2 minutes and look for agglutination.

INTERPRETATION OF RESULTS:

Agglutination with positive control and no agglutination with Negative Control validates test results.
Agglutination within 2 minutes is a positive test and indicates presence of ASO in the test specimen. No agglutination up to 2 minutes is a negative test and indicates absence of ASO in the test specimen.

DO NOT OBSERVE RESULTS BEYOND 2 MINUTES

(B) SEMI QUANTITATIVE TEST:

1. Dilute the specimen serially 1:2, 1:4, 1:8, 1:16, using a normal saline.
2. Place one drop of each diluted serum sample using plastic droppers in each circle ofslide & proceed further as in Qualitative Test (A).

The highest dilution which shows clear cut agglutination within 2 minutes indicates the ASOtitre. The approximate ASO concentration can be obtained by multiplying titre by sensitivity of the test.
ASO in IU/ml = D x S
D= Highest dilution showing clear cut agglutination.
S= Sensitivity of the test is 200 IU/mL.

QUALITY CONTROLS

Positive & Negative Controls are used to validate the kit performance.

INTERFERENCES

Nonspecific positive reaction may occur if plasma is used or serum is highly lipemic or hemolysed.

NOTES

1. Positive & Negative Controls are ready to use & should not be diluted while using in test procedure.
2. Improper mixing and drying of reagents may lead to erroneous results.
3. Contaminated sera and a longer reaction time beyond 2 minutes may lead to false positive results.
4. As with all diagnostic tests, the final diagnosis should be based on correlation of test results with other clinical symptoms & findings.
5. For accuracy of results, the procedure has to be followed meticulously.

REFERENCES

1. Rantz, L.D., Dicaprio J.M. Randall, E., (1952); AM.J.Med.Sci.24
2. Kilen, G.C.(1976) ; Manual of Clinical Immunology ASM, 264.
3. ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

Index of symbols

Consult instructions for use	REF Catalogue number	Caution
IVD *In vitro* diagnostic medical device	LOT Batch code	Non-sterile
Temperature limit 2-8 °C	Do not re-use	Use-by date
Manufacturer	Date of manufacture	Keep dry
		Keep away from sunlight
Do not use if package is damaged	Contains sufficient for <n> tests	

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PI-ADX80 Rev. D
Effective date: 24.01.2024
English version