274 mm x 218mm

Insight | ASO

Rapid Immunochromatographic assay for the detection of Anti - Streptolysin O in human serum

DEVICE

INTENDED USE

INSIGHT-ASO is a rapid, self-performing, immunochromatograhic assay for the detection of Anti - Streptolysin O in human serum.

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 240 IU/ml may indicate an acute streptococcal infection.
INSIGHT-ASO detects the presence of Anti - Streptolysin O in human serum, qualitatively, at concentrations as low as 240 IU/ml.

PRINCIPLE

INSIGHT-ASO is based on the principle of agglutination of antibodies/antisera with respective antigen in immunochromatography format along with use of nano gold particles as agglutination revealing agent. The conjugate pad is impregnated with two components - SLO (Streptolysin 'O') antigen conjugated to colloidal gold and streptavidin conjugated to colloidal gold. As the test specimen flows through the membrane assembly of the device, the SLO colloidal gold conjugate complexes with the Anti - SLO in the test specimen and travels on the membrane due to capillary action along with the streptavidin colloidal gold conjugate. This complex moves further on the membrane to the test region where it is immobilized by agglutinating sera for human IgG coated on the membrane, leading to formation of pink/purple colored band. The absence of this band in the test region indicates a negative result. The streptavidin colloidal gold conjugate and unbound complex if any move further on the membrane and are subsequently immobilized by the biotinylated BSA coated on the membrane at the control region (C) forming a pink / purple colored band. This control band acts as a procedural control and serves to validate the results.

REAGENTS AND MATERIALS SUPPLIED

A. Each INSIGHT-ASO kit contains individual pouches each containing a
   1. Membrane test assembly impregnated with colloidal gold conjugated to SLO antigen and the streptavidin, Agglutinating sera for human IgG and biotinylated BSA at the respective regions.
   2. Desiccant pouch.
   3. Sample applicator.
B. Sample running buffer.
C. Package insert.

OPTIONAL MATERIAL REQUIRED

Stopwatch, Micro pipette.

STORAGE AND STABILITY

The sealed pouches in the test kit and the kit components may be stored between 4-30° C till the duration of the shelf life as indicated on the pouch/carton. DO NOT FREEZE.

NOTE

1. For in vitro diagnostic and professional use only. NOT FOR MEDICINAL USE.
2. Do not use beyond expiry date.
3. Read the instructions carefully before performing the test.
4. Handle all specimens as if potentially infectious.
5. Follow standard biosafety guidelines for handling and disposal of potentially infectious material.
6. If desiccant colour at the point of opening the pouch has turned from blue to pink or colourless, another test device must be run.
7. Contact with the contents of desiccant pouch containing, among other substances, cobalt chloride (CAS# 7646-79- 9) should be kept to a minimum. Inhalation / swallowing may cause harm.

SPECIMEN COLLECTION AND PREPARATION

1. INSIGHT-ASO uses human serum as specimen.
2. No special preparation of the patient is necessary prior to specimen collection by approved techniques.
3. Though fresh specimen is preferable, in case of delay in testing, it may be stored at 2-8°C for maximum up to 1 week.
4. Refrigerated specimens must be brought to room temperature prior to testing.
5. Repeated freezing and thawing of the specimen should be avoided.
6. Do not use viscous/turbid, lipaemic, hemolysed, clotted and contaminated serum specimens.
8. Specimen containing precipitates or particulate matter must be centrifuged and the clear supernatant only used for testing.

TESTING PROCEDURE

1. Bring the kit components of INSIGHT-ASO to room temperature before testing.
2. Open a foil pouch by tearing along the "notch".
3. Remove the testing device and the sample applicator.
4. Check the colour of the desiccant pouch. It should be blue. If the desiccant has turned colourless or pink, discard the test device and use another device. Once opened, the device must be used immediately.
5. Label the device with specimen identity.
6. Place the testing device on a flat horizontal surface.
7. Using calibrated pipette, pipette out 500µl of sample running buffer and dispense into a test tube. Then pipette out 5µl of specimen and dispense into test tube (1:100 dilution), mix well. This is test specimen.
8. Dispense 2 drops of the test specimen into the specimen port (S).
9. Start the stopwatch. Read the results within 5 minutes. Do not interpret the results beyond 8 minutes.

INTERPRETATION OF RESULTS

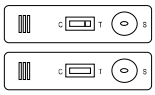
Negative Result:

The appearance of one pink/ purple coloured band at the Control Region (C) indicates absence of ASO in the specimen.

Positive Result:

The appearance of two pink/purple coloured bands at the Control Region (C) and Test Region (T) indicates that the specimen contains detectable levels of ASO.

Invalid Result:



The test result is invalid if no band appears on the device. The test should be considered invalid if only the test band appears and no control band appears. In such cases, verify the test procedure and repeat the test with a new INSIGHT ASO device.

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 8 minutes.
5. It is recommended that all positive test results should be further tested with methods enabling quantitation of ASO titres.
6. It is recommended that results of the tests should be correlated with clinical findings to arrive at the final diagnosis.

PERFORMANCE CHARACTERISTICS

The sensitivity of INSIGHT ASO is 240 IU/ml.

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. Todd W.W., (1934), J. Path and Bact., 39, 299-320.
2. Klein G.C., (1980), Manual of Clin. Immunol.., 7th Ed., 431.
3. Spaun J., Bentzon M. W., Larsen S.O., et. al., (1961), Bull. WHO, 24, 271-279.
4. Klein G. C., et. al., (1971), Appl. Microbiol., 21, 999.
5. Clinical Laboratory Diagnostics, Edited by Lothar Thomas, M.D., 1st Ed., 1998, TH-Books Verlagsgesellschaft mbH, Frankfurt, Germany.
6. Data on file: Tulip Diagnostics (P) Ltd.

Manufactured by:

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