

This diagnostic kit is for qualitative & semiquantitative estimation of ASO in the serum.

#### PRINCIPLE:

The Latex Reagent consists of Latex particles coated with streptolysin -O. When specimen is mixed with Latex reagent, in presence of ASO agglutination is observed which confirms positive test result. No agglutination shows negative test result & absence of ASO in specimen.

#### CLINICAL SIGNIFICANCE:

Streptococci infected individuals produce specific antibodies - Antistreptolysin - O (ASO) against antigen such as streptolysin-0 streptolysin-S. These antigen are produced as exotoxins by the group A beta-hemolytic Streptococci. Streptococcal infection results in increased ASO levels, so ASO titre serve as important factor in detection of streptococcal infection. The elevated ASO titre also seen in case of glomerulonephritis & acute rheumatic fever. Acute streptococcal infection is confirmed if ASO titre is more than 200 IU/ml.

#### SAMPLE COLLECTION & STORAGE:

- Only Serum sample must be used.
- Store at 2-8°C

#### PRECAUTION:

- Do not freeze Latex Reagent.
- All the reagents & samples should be at room temperature prior to use.
- Shake well the Latex Reagent to get the homogenous suspension & uniform drop size of Latex Reagent.
- Avoid the use of hemolysed or turbid specimen. Drying of the mixture at the periphery of the circle & use of plasma could lead to erroneous results.
- Do not read results beyond 2 minutes.
- Handle the controls with great care for better safety measures although source materials used in manufacturing of positive & negative controls is tested for HBsAg & HIV antibodies & found to be negative.

#### KIT CONTENTS:

- a) **Reagents**
- |           |                  |
|-----------|------------------|
| Reagent 1 | ASO Antigen      |
| Reagent 2 | Positive Control |
| Reagent 3 | Negative Control |
- b) **Accessories**
- Glass slides
  - Plastic dropper
  - Disposable Mixing sticks

#### PROCEDURE:

##### QUALITATIVE DETECTION:

- Place one drop each of specimen, positive control and negative control in separate circles of test slide using separate droppers.
- Add one drop of Latex Reagent in each of above circle of test slide.
- Mix well with disposable applicator stick.
- Rock the slide gently for 2 minute and observe the agglutination reaction.

##### RESULT INTERPRETATION:

- **Positive test results:** confirmed by agglutination within 2 minutes and indicates presence of ASO in the specimen.
- **Negative test results:** indicated by no agglutination & thereby shows absence of ASO in specimen.

##### SEMIQUANTITATIVE TEST:

- Dilute the specimen serially 1:2, 1:4, 1:8, 1:16 using normal saline.
- Place one drop on each of diluted specimen in the separate circles.
- Add one drop of Latex Reagent to each of above circle.
- Mix well with disposable applicator stick.
- Rock the slide for 2 minutes and observe the agglutination reaction.

##### RESULT INTERPRETATION:

- Agglutination in the highest specimen dilution within 2 minutes corresponds to ASO titre in the specimen.
- The concentration of ASO can be calculated as follows.
- ASO in IU/ml = D X S.
- D = Highest dilution showing clear cut agglutination.
- S = Sensitivity of the test 200 IU/ml.

##### LIMITATIONS:

- 1) As with all diagnostic test, the final diagnosis should be based on correlation of test result with other, clinical symptoms & findings.
- 2) Erroneous results could be because of improper mixing and drying of reagents or use of highly lipaemic or hemolysed or contaminated sera.
- 3) Positive and Negative controls should be handle with care and should not to be diluted.











##### BIBLIOGRAPHY:

- Kilen, G. C. (1976): Manual of Clinical immunology ASM, 264
- Rantz, L.D., Di Caprio, J.M., Randall, E., (1952); Am. J. Med. Sci. 24

#### REAGENT STORAGE AND STABILITY

All the reagents are to be stored at 2-8°C and are stable till expiry date mentioned on the label.

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|   |                                     |   |                              |
|---|-------------------------------------|---|------------------------------|
|  | Attention, see instructions for use |  | Consult Instructions For Use |
|  | For in vitro diagnostic use only    |  | Catalog #                    |
|  | Store between 2-8°C                 |  | Lot Number                   |
|  | Do not use if package is damaged    |  | Date of Manufacturing        |
|  | Manufacturer                        |  | Use by                       |