

# Bioway Chemistry Reagent Series

## Anti-streptolysin O Test Kit

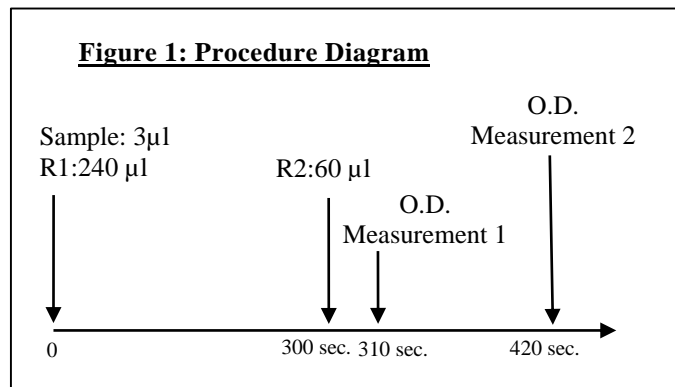
Detection of Anti-streptolysin O in Human Serum on Chemistry Analyzers



Cat. No. R011K11

Anti-streptolysin O Test Kit

### SUMMARY OF TEST PROCEDURE



**Table 1: Instrument Parameters\***

Calibration method	6 point non-linear	Slope of reaction	increase
Wavelength	Pr: 570nm Se: 700nm	Sample volume	3 µl
Test method	2 point end	R1 volume	240 µl
Reaction temperature	37°C	R2 volume	60 µl

\*Refer to Figure 1 and the package insert for detail

### INTENDED USE

**Bioway Chemistry Reagent Series Anti-streptolysin O Reagent Kit** (the Kit) is a latex-enhanced immunoturbidimetric assay intended for *in vitro* quantitative detection of Anti-streptolysin O in human serum on automated clinical chemistry analyzers.

### SUMMARY AND EXPLANATION

Anti-streptolysin O (ASO) is the antibody produced in response to streptolysin O, an antigen produced by Lancefield group A streptococci. The World Health Organisation recommends the use of ASO to aid the diagnosis of streptococcal infections. ASO titers are elevated in the sera 80 to 85% of patients with rheumatic fever and in 95% of patients with acute glomerulonephritis. Raised ASO levels can also occur in other conditions such as scarlet fever, acute rheumatic arthritis, tonsillitis and various other streptococcal infections.

### TEST PRINCIPLES

The Kit utilizes latex-enhanced immunoturbidimetry to measure the ASO level in human serum or plasma. During the test, ASO in the sample binds with the Streptolysin O that is coated on latex particles to cause agglutination. The turbidity caused by agglutination is detected optically by chemistry analyzer. The change in absorbance is proportional to the level of ASO in the sample. The actual concentration is obtained by comparing with a calibration curve with known concentrations.

### MATERIALS PROVIDED

#### Reagents:

<b>R1</b>	Buffer solution, sodium azide < 0.1%
<b>R2</b>	latex particles coated with anti-ASO, sodium azide < 0.1%

### MATERIALS NEEDED BUT NOT PROVIDED

- Automated chemistry analyzer.
- ASO calibrator set (available for purchase) and control set (commercially available).

### INSTRUMENT

The Kit is applicable on most automated chemistry analyzers. Refer to specific instrument application for suggested settings.

### STORAGE AND STABILITY

Store the reagents at 2-8°C. Avoid direct sunlight. The Kit is stable through the expiration date when stored properly. R1 and R2 reagents are stable for 1 month at 2-8°C after opening.

### PRECAUTIONS

- The Kit is for *in vitro* diagnostic use only. Not for use in humans or animals.
- The instructions must be followed to obtain accurate results.
- Do not use the reagents beyond the expiration date.
- Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.
- Reagents contain less than 0.1% sodium azide as preservative; avoid contact with skin and eyes, flush with copious amounts of water when disposing.

### SPECIMEN COLLECTION AND HANDLING

Follow standard laboratory procedures to collect serum samples. It is recommended to perform test immediately after sample collection. If the test cannot be done immediately, store sample at 2- 4° C for up to 3 days or at -20° C for up to 1 months. Avoid repeated freezing and thawing.

### TEST PROCEDURE (see Figure 1)

No pretreatment required for reagents and samples.

**Calibration:** 6 level calibrator set available for purchase. Recommend using Bioway calibrators for optimal results. Use multi-point non-linear calibration method.

**Test procedure:** see Figure 1 and Table 1 for instrument parameter setup. Refer to specific instrument application for suggested setting.

- Add 3 µl of sample and 240 µl of R1; mix well and incubate at 37°C for 300 seconds.
- Add 60 µl of R2, mix well and incubate at 37°C for 10 seconds.
- Take optical density measurement OD 1.
- Take optical density measurement OD 2 at 420 seconds.
- Calculate  $\Delta OD = OD 2 - OD 1$

### RESULT

The ASO value can be obtained by using the calculated  $\Delta OD$  to find the corresponding value on a calibration curve prepared with known values.

### EXPECTED VALUES

<200 IU/mL, for adults  
<240 IU/mL, for children

It is recommended for each laboratory to establish its own expected values. ASO levels can be influenced by hereditary factors and vary with geographical location and ethnic population.

### QUALITY CONTROL

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Using commercially available controls with known concentration is recommended before each batch of tests to ensure the test is properly performed and all reagents and the instrument are functional as specified.

### LIMITATIONS

1. The Kit is for *in vitro* use on automated chemistry analyzers only.
2. Hemolysis samples may cause inconsistent results.
3. The test result from the Kit should not be used as the only basis for definite diagnosis.

### PERFORMANCE CHARACTERISTICS

**Linearity:** 20 – 800 IU/mL ( $R \geq 0.990$ )

**Precision:** Within Run:  $CV \leq 6\%$ ;  
Run-to-Run:  $CV \leq 10\%$

**Interference:** no interference detected for: Bilirubin (60 mg/dL), triglyceride (1000 mg/dL), and hemoglobin (1000 mg/dL).

**Reagent Blank Absorbance:** at 570nm wavelength and 10 mm optical diameter, O.D.  $\leq 1.50$ .

### REFERENCES

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4. Kaplan, EL, Rothermel, CD, Johnson, DR. Antistreptolysin O and Anti-Deoxyribonuclease B titers: Normal values for children ages 2 to 12 in the United States. Pediatrics; 101: 86-88, 1998.
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Not Intended for Sale in the United States.

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