# TRUEchemie Anti-Streptolysin O (ASO) Test kit (Immunoturbidimetry)

**for the direct quantitative determination of ASO by turbidimetric test in human serum or plasma**



## INTENDED USE

The TRUEchemie Anti-Streptolysin O (ASO) Test kit (Immunoturbidimetry) is a quantitative turbidimetric test for the measurement of ASO in human serum or plasma.

## PRINCIPLE

Latex particles coated with streptolysin O (SLO) are agglutinated when mixed with samples containing ASO. The agglutination causes an absorbance change, depending upon the ASO contents of the patient sample that can be quantified by comparison with a calibrator of known ASO concentration.

## INTRODUCTION

Streptolysin O (SLO) is a lethal, exocellular protein released by Group A Streptococcal bacterium. The release of SLO stimulates the production of anti-streptolysin O (ASO) antibodies to neutralize its hemolytic effect. The ASO test is used to determine recent streptococcal infection and post streptococcal complications including rheumatic fever and glomerulonephritis. The presence and level of ASO antibodies in human serum directly reflects the extent and degree of infection. Elevated levels of ASO may also be present in other conditions including scarlet fever, acute rheumatoid arthritis, tonsillitis and various other streptococcal infections as well as in health carriers.

## PACK SIZE

| Kit Size | 25 mL | 50 mL |
|---|---|---|
| Cat No. | ADX901 | ADX902 |
| **Kit contents** | | |
| ASO Diluent (R1) | 1 x 20 mL | 1 x 40 mL |
| ASO Latex (R2) | 1 x 5 mL | 1 x 10 mL |
| ASO Calibrator | 1 x 0.5 mL | 1 x 0.5 mL |

## REAGENTS COMPOSITION

| | |
|---|---|
| ASO Diluent (R1) | Tris buffer 20 mmol/L, pH 8.2. Sodium azide 0.95 g/L. |
| ASO Latex (R2) | Latex particles coated with streptolysin O, pH 10.0. Sodium azide 0.95 g/L. |
| ASO Calibrator | Human serum. ASO concentration is stated on the vial label |

## REAGENT PREPARATION

Ready to use reagents.

TRUEchemie ASO calibrator – Ready to use.

## WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use.
2. Components from human origin have been tested and found to be negative for the
3. presence of HBsAg, HCV, and antibody to HIV (1/2). However, handle cautiously as
4. potentially infectious.
5. Avoid ingestion. DO NOT PIPETTE BY MOUTH.
6. The disposal of the residues has to be done as per local legal regulations.

## CALIBRATION

Use Truechmie ASO calibrator which are ready to Use
The sensitivity of the assay and the target value of the calibrator have been standardized against the ASO International Calibrator (WHO). Recalibrate when control results are out of specified tolerances, when using different lot of reagent and when the instrument is adjusted.

## 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.
**Reagent deterioration:** Do not freeze the reagents, frozen Latex or Diluent could change the functionality of the test.
**Calibrator:** Calibrator should be stored at 2-8°C and they are stable till the expiry date mentioned on the label.

## SPECIMEN COLLECTION AND STORAGE

Fresh serum. Stable 7 days at 2 - 8ºC or 3 months at - 20ºC.
Samples with presence of fibrin should be centrifuged before testing.
Do not use highly haemolyzed or lipemic samples.

## MATERIALS REQUIRED BUT NOT PROVIDED

1. Pipettes to accurately measure required volumes.
2. Test tubes/rack
3. Timer
4. 37°C heating block or water bath
5. Photometer capable of accurately measuring absorbance at 540 nm

## TEST PROCEDURE

Wavelength : 540 nm
Temperature : 37 °C
Prewarm the Reagent to reaction temperature.

| | Blank (µL) | Calibrator (µL) | Sample (µL) |
|---|---|---|---|
| Distilled water | 1000 | - | - |
| ASO Diluent (R1) | - | 800 | 800 |
| ASO Latex (R2) | - | 200 | 200 |
| Calibrator | - | 10 | - |
| Sample | - | - | 10 |

**Reading & Calculations**
Blank the Photometer with Distilled water.
Mix well and read absorbance of sample and test against distilled water at 540 nm as follows:
Initial absorbance $A_0$ – Exactly after 5 sec.
Final absorbance A1 – Exactly after 120 sec. after $A_0$
Determine Δ A for Calibrator (C) and Test (T)
$\Delta AC = \Delta AC_1 - \Delta AC_0$
$\Delta AT = \Delta AT_1 - \Delta AT_0$

**Calculations:**

$$\text{Serum/plasma ASO (U/mL)} = \frac{\Delta AT}{\Delta AC} \times \text{Calibrator concentration (U/mL)}$$

## QUALITY CONTROL

Quality Controls are recommended to monitor the performance of automated assay procedures. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

## EXPECTED VALUE

Normal values up to 200 IU/mL (adults) and 100 IU/mL (children < 5 years old).
Each laboratory should establish its own reference range. It is recommended that results of the test should be correlated with clinical findings to arrive at the final diagnosis.

## PERFORMANCE CHARACTERISTICS

**1.Sensitivity**: 20 IU/mL
**2.Linearity limit:** Up to 800 IU/mL, under the described assay conditions. Samples with higher concentrations, should be diluted 1/3 in NaCl 9 g/L and retested again. The linearity limit depends on the sample-reagent ratio, as well the analyzer used. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.
**3. Detection limit:** Values less than 20 IU/mL give non-reproducible results.
**4. Prozone effect:** No prozone effect was detected up to 3000 IU/mL.

**PRECISION:**

| Intra-assay precision within run (n=10) | Mean (IU/mL) | SD (IU/mL) | CV (%) |
|---|---|---|---|
| Low | 84.8 | 0.7 | 0.8 |
| High | 224.4 | 1.3 | 0.6 |

| Inter-assay precision run to run (n=10) | Mean (IU/mL) | SD (IU/mL) | CV (%) |
|---|---|---|---|
| Low | 84.8 | 1.1 | 1.3 |
| High | 225.8 | 1.0 | 0.5 |

The reagent was tested for 10 days, using two different ASO concentrations. The coefficient of variation was <5%.

## AUTOMATED PROCEDURE

Appropriate program sheet is available for different analyzers upon request.

## METHOD COMPARISON

Results obtained using TRUEchemie ASO reagent (y) did not show systematic differences when compared with another commercial reagent (x) with similar characteristics. The results obtained is below: The correlation coefficient ($r^2$) was 0.998 and the regression equation is y=0.985x+1.627. The results of the performance characteristics depend on the analyzer used.

## INTERFERENCES

Bilirubin (20 mg/dL), hemoglobin (10 g/L), lipemia (10 g/L) and rheumatoid factors (600 IU/mL), do not interfere. Other substances may interfere.

## WASTE MANAGEMENT

Please refer to local regulation requirements.

## SYSTEMS PARAMETERS

| | |
|---|---|
| Mode | : Fixed kinetic |
| Calibrator concentration | : Stated on vial |
| Wave length | : 540 nm |
| Units | : IU/mL |
| Flow cell Temp | : 37°C |
| Blank | : Distilled Water |
| Reagent volume | : 1000 µL (R1: 800 µL + R2: 200 µL) |
| Sample volume | : 10 µL |
| Lag time | : 5 sec |
| Read time | : 120 sec. (2 min.) |
| Normal Values | : up to 200 IU/mL (adults),100 IU/mL (children < 5 years old). |
| Sensitivity | : 20 |
| Linearity | : 800 |
| Reaction Slope | : Increasing |

## REFERENCES


1. Haffejee I, Quarterly Journal of Medicine 1992, New series 84; 305: 641 – 658.
2. Alouf Jodeph E. Pharma Ther 1980; 11: 661-717.
3. M Fasani et al. Eur J Lab Med 1994; vol2.n1: 67.
4. Todd E W. J Exp Med 1932; 55: 267 - 280.
5. Klein, GC. Applied Microbiology 1970; 19:60-61.6Klein GC. Applied Microbiology 1971; 21: 999-1001.
6. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.
7. 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 |
| 2°C 8°C Temperature limit 2-8°C | Do not re-use | Use-by date |
| Manufacturer | Date of manufacture | Keep dry |
| Do not use if package is damaged | Keep away from sunlight | |


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