CORMAY ASO 500

DIAGNOSTIC KIT FOR DETERMINATION OF ANTI-STREPTOLYSIN O LEVELS

Kit name	Kit size	Cat. No
CORMAY ASO 500	1 x 795 ml	6-329

INTRODUCTION
Most people infected with hemolytic streptococcus produce anti-streptolysin O (ASO), antibodies against streptolysin O (SLO), an exotoxin of Streptococcus. Measuring the level of ASO is effective for diagnosing, judging the progress of medical treatment, and assessing recovery from diseases caused by hemolytic streptococcus such as rheumatic fever, acute glomerulonephritis, scarlatina and tonsillitis.

METHOD PRINCIPLE
When an antigen-antibody reaction occurs between ASO in a sample and SLO which has been sensitized to latex particles, agglutination results. This agglutination is detected as an absorbance change (572 nm), with the magnitude of the change being proportional to the quantity of ASO in the sample. The actual concentration is then determined by interpolation from a calibration curve prepared from calibrators of know concentration.

REAGENTS
Package

1-Reagent	1 x 295 ml
2-Reagent	1 x 500 ml

Reagent preparation and stability
The reagents are ready to use.
The reagents are stable up to the kit expiry date printed on the package when stored at 2-10°C. On board stability of the reagents depends on type of analyser used for analysis. Protect from light and avoid contamination!

Concentrations in the test

suspension of latex particles sensitized with SLO (pH 8.2)	0.17 w/v%
glycine buffer solution (pH 8.3)	

Warnings and notes
- Product for in vitro diagnostic use only.
- Reagent bottles should be shaken before use by gently inverting several times.
- After measurements are taken, reagent bottles should capped and kept at 2-10°C. Care should be taken not to interchange the caps of reagent bottles.
- Reagents with different lot numbers should not be interchanged or mixed.
- The reagents contain sodium azide (< 0.1%) as a preservative. Avoid contact with skin and mucous membranes.

ADDITIONAL EQUIPMENT
- automated clinical chemistry analyser capable of accommodating two-reagent assays;
- general laboratory equipment;

SPECIMEN
Serum or plasma (Na-EDTA, K-EDTA, Na-Heparin, Li-Heparin, citric acid). After blood has clotted thoroughly, the sample is centrifuged and the serum is separated from blood cells and fibrins.
If the test cannot be done immediately, the sample should be placed in a tightly sealable container and stored at -20°C. Repeated freezing and thawing should be avoided.
Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE

wavelength	572 nm
temperature	37°C

These reagents may be used in automatic analysers according to their service manual. Applications for analysers are available on request.

REFERENCE VALUES [3]

serum, plasma	< 160 IU/ml

It is recommended for each laboratory to establish its own reference ranges for local population. Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration.

QUALITY CONTROL
For internal quality control it is recommended to use the CORMAY IMMUNO-CONTROL I (Cat. No 4-288) with each batch of samples.
For the calibration of automatic analysers systems the CORMAY ASO CALIBRATOR kit (Cat. No 4-278) is recommended.
Calibration stability depends on type of analyser used for analysis. The calibration curve should be prepared with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS
These metrological characteristics have been obtained using an automatic analyser Biolis 24i Premium and Hitachi 917. Results may vary if a different instrument is used.

- **Sensitivity:** 38 IU/ml.

- **Linearity:** up to 1100 IU/ml.
  For higher concentrations dilute the sample with 0.9% NaCl and repeat the assay. Multiply the result by dilution factor.

- **Specificity / Interferences**
  Haemoglobin up to 0.5 g/dl, bilirubin up to 20 mg/dl and triglycerides up to 500 mg/dl do not interfere with the test.

- **Precision**

Repeatability (run to run) n = 20	Mean [IU/ml]	SD [IU/ml]	CV [%]
level 1	46.8	1.07	2.29
level 2	80.2	1.31	1.63
level 3	221.7	2.62	1.18

Reproducibility (day to day) n = 12	Mean [IU/ml]	SD [IU/ml]	CV [%]
level 1	48.8	2.83	5.81
level 2	78.8	2.60	3.30
level 3	219.8	5.24	2.38

- **Method comparison**

A comparison between CORMAY reagent (y) and another commercially available assay (x) using 50 samples gave following results:
y = 1.11 x - 44 IU/ml;
R = 0.945 (R – correlation coefficient)

WASTE MANAGEMENT
Please refer to local legal requirements.

LITERATURE

1. Galvin J. P. et al.: Particle enhanced photometric immunoassay systems., Clin. Lab. Assays (Pap. Annu. Clin. Lab. Assays Conf.), 4th, 73, (1983).

2. Singer J. M. et al.: The latex fixation test. I. Application to the serologic diagnosis of rheumatoid arthritis, Amer. J. Med., 21, 888, (1956).
3. Shojiro Kano: antistreptolysin O (ASO), Nippon Rinsho, 57, 108 (1999).

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