



DIAGNOSTIC KIT FOR DETERMINATION OF ANTI-STREPTOLYSIN O LEVELS

INTRODUCTION

Most people infected with hemolytic streptococcus produce antistreptolysin 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

| 8 | Cat. No 4-270 (24-TRAY) | Cat. No 4-489 (36-TRAY) |
|-----------|----------------------------|----------------------------|
| 1-Reagent | 2 x 14 ml | 3 x 10 ml |
| 2-Reagent | 2 x 20 ml | 3 x 13 ml |

The reagents when stored at 2-10°C are stable up to expiry date printed on the package. Stability on board of the analyser at 2-10°C: Prestige 24i - 12 weeks, Biolis 24i Premium – 12 weeks. Protect from light and avoid contamination!

Concentrations in the test

| suspension of latex particles sensitized with | 0.17 w/v% |
|---|-----------|
| SLO (pH 8.2) | |
| 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.

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

These reagents may be used in automatic analysers Prestige 24i, Biolis 24i, Sapphire 400 and Prestige 24i Premium, Biolis 24i Premium, Sapphire 400 Premium.

- 1-Reagent and 2-Reagent are ready to use.
- 1-Reagent put on basic position in reagent tray.

2-Reagent put on start position in reagent tray.

For reagent blank 0.9% NaCl is recommended.

REFERENCE VALUES³

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.

The calibration curve should be prepared every 12 weeks (Prestige 24i, Biolis 24i Premium), 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 the automatic analysers 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)

| Repeatability (run to run) | Mean | SD | CV |
|----------------------------|---------|---------|------|
| n = 20 | [IU/ml] | [IU/ml] | [%] |
| 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

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

APPLICATION for Prestige 24i, Biolis 24i and Sapphire 400

| Item name 51 | ASO | | | | | |
|------------------|----------|-----------|-------|------|-----|------|
| Data information | 1 1 | Calibrati | - | | | |
| Units | IU/ml | Туре | Li | near | | |
| Decimals | 0 | Standard | | | | |
| | | #1 | * | #4 | | |
| Analysis | | #2 | | #5 | | |
| Туре | END | #3 | | #6 | | |
| Main W.Length1 | 570 | | | | | |
| Sub W.Length2 | 800 | Normal F | lange | | | |
| Method | Immuno | | M | ale | Fer | nale |
| | | | Low | High | Low | High |
| Corr | | Serum | 0 | 160 | 0 | 160 |
| Slope | Inter | Urine | | | | |
| Y= 1.000 | X+ 0.000 | Plasma | 0 | 160 | 0 | 160 |
| | | CSF | | | | |
| | | Dialysis | | | | |
| | | Other | | | | |

| Aspiration Kind | | Double | | Data P Read | 100033 | | Abcor | bance Li | mit |
|--------------------|-----|---------|-------|----------------|--------------|------------|------------|-------------|-------|
| KIIIU | 11 | Jouble | | Keau | C 1 1 | F 1 | | | |
| | | | 1 | | Start | End | Low | | 000 |
| | | lume | | Main | 52 | 54 | High | ı 3. |)00 |
| Sample | 3 | | | Sub | 37 | 38 | | | |
| Reagent1 | 100 |) | μl | | | | | | |
| Reagent2 | 170 |) | | Factor | | | Endpoint I | Limit | 2.000 |
| | | | | Blank co | prrection | | Linear Che | eck (%) | 0 |
| | | | | | | | | | |
| Third Mix | . (| DN | | Dilutio | n | | | | |
| R1 Blank | V | Vater-l | Blank | Diluent | t | 99:Di | 11 | | |
| Monitor | | | | Prozor | ne Check | | | | |
| 0 Level Po | int | 1 | | | | Start | End | Limit | (%) |
| Span | | 3.00 |) | First | | | | | |
| | | | | Second | l | | | | Low |
| | | | | Third | | | | | Low |
| | | | | | | | | | |

| Auto Rer | un SW | | Auto Rerun | Condition (A | bsorbance) |
|----------|-------------|---------|--------------|--------------|------------|
| OFF | | | Absorbance F | Range | |
| | | | | Lower | OFF |
| Auto Rer | un Range (H | Result) | | Higher | OFF |
| | OFF | OFF | | | |
| | Lower | Higher | Prozone Rang | ge | OFF |
| Serum | | | | | |
| Urine | | | | | |
| Plasma | | | | | |
| CSF | | | | | |
| Dialysis | | | | | |
| Other | | | | | |

APPLICATION for Prestige 24i Premium, Biolis 24i Premium and Sapphire 400 Premium

| | <u> </u> | _ | | | | | | | | | - | |
|---|---|---|--------------------------|---------------------------|--------------|--|---------------------|----------|---|--|---|--|
| Item No | . 51 | Item | Name | ASC |) | | | | | L | Ol | otical |
| | | | | | | | | | | | | |
| Data in | formati | on | | | | Calib | ratio | n | | | | |
| Units | | | IU/ml | | | Type | | | Li | inear | 1 | |
| Decimal | le. | | 0 | | | Std sa | mnla | | | | - | |
| Deema | 15 | | 0 | | | | | | | * | μ | |
| | | | | | | Blank | l |) | #1 | * | #2 | |
| Analysi | S | | | | | #3 | | | #4 | | #5 | 5 |
| Type | | | END m | ethod | | #6 | | | | | | |
| Main W | ave Ler | noth | 570 nm | | | | | | | | | |
| | | | | | | | | | | | | |
| Sub Wa | ve Leng | gth | 800 nm | | | | | | | | | |
| Method | | | Immun | 0 | | | | | | | | |
| | | | | | | | | | | | | |
| | | | | | | | | | | | | |
| Correla | tion | | | | | | | | | | | |
| | Slope | | Inte | ercept | | | | | | | | |
| Y= | 1 | X | | | | | | | | | | |
| 1- | 1 | Λ | τU | | | | | | | | | |
| | | | | | | | | | | | | |
| Item No | . 51 | Item | Name | ASC |) | | | | | | Or | otical |
| | | | | | | • | | | | L | | |
| Aspirat | ion | | | | | Do | ta Di | roces | | | | |
| | | nh!- | | | | | | 10000 | | 0 | tout | Ec.4 |
| Kind | Do | uble | | | | Re | ađ | | | - | tart | End |
| Vol. | | | | | | | |] | Main | | 50 | 52 |
| | Kind | Vo | l. Ac | id 1 | Units | | | | Sub | 3 | 37 | 38 |
| Sam | | 3 | | | μl | | | <u> </u> | | | | |
| | | - | | | | A 1- | о Т - | nit | Low | , | | High |
| | gent 1 | 16 | | | μl | AU | s.LII | m | | / | | High |
| Rea | gent 2 | 11 | 0 1 | 0 | μl | | | | -3 | | ~ | 3 |
| | | | | | | | | | | | | |
| Blank v | alue | | | | | Co | rrec | tion | value | | | |
| Water I | | | | | | | | orrec | | | 1 | |
| water | Jiank | | | | | | | | | | | |
| | | | | | | | | int Li | | | 2 | |
| Reaction | n Moni | tor | | | | Lir | near (| Chec | k (%) | | | |
| 0 Level | Point | 1 | l | | | _ | | | | | | |
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| Span Third n ON Item No Normal | nixing 51 Range M Low | Item ale High | Name Fe | emale Hig | ţh | Fir Sec Panic | st cond | nge | tart Male | End | Op | Low otical |
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