ANTI-STREPTOLYSIN-O 2 (ASO 2)

LATEX-ENHANCED IMMUNOTURBIDIMETRIC ASSAY
RX DAYTONA PLUS

INTENDED USE

An ASO test system is a device intended for the quantitative *in vitro* determination of Anti-Streptolysin-O (ASO) concentration in serum. This product is suitable for use on the RX **daytona plus** and RX **series** analyser.

FOR PRESCRIPTION USE ONLY

Cat. No.		
LO 8305	R1. ASO Assay Buffer	1 x 7.7 ml
	R2. ASO Latex Reagent	1 x 11.2 ml

GTIN: 05055273209181

CLINICAL SIGNIFICANCE

Streptolysin O (SLO) is a lethal, exocellular protein produced by Group A streptococci bacteria. It is so named because it is reversibly inactivated by atmospheric oxygen.

The binding of active SLO to the surface of erythrocytes causes disruption of the cytoplasmic membrane resulting in cell lysis. Anti-streptolysin O antibodies (ASO) are produced by the host to neutralise the haemolytic action of the SLO.

Measurement of ASO in serum is used for the diagnosis of streptococcol infections such as rheumatic fever and glomerulonephritis. The ASO level can be used as a measure of the extent and degree of infection. Elevated ASO levels may also be present in other conditions such as scarlet fever, acute rheumatoid arthritis, tonsillitis and various other streptococcal infections and in healthy carriers.

PRINCIPLE

In those infections promoted by acute streptococcal infection, antibodies to the exotoxin of streptococcus are usually produced. By reacting suspended uniform polystyrene particles coated with Streptolysin O together with serum containing antibodies, an increase in turbidity occurs. By comparing with a standard, a quantitative value for the concentration of Anti-Streptolysin O (ASO) present in serum can be obtained.

SAMPLE COLLECTION AND PREPARATION

Fresh or deep frozen serum is recommended. The serum may be stored between +2 and +8°C up to 48 hours after collection. The sample can be frozen (-20°C) for longer periods. Do not use plasma.

REAGENT COMPOSITION

Contents	
R1. ASO Assay Buffer	
Glycine buffer	
Sodium Azide	0.09% w/v
R2. ASO Latex Reagent	
Particle suspension containing latex coated with streptolysin-O antigen	
Sodium Azide	0.09% w/v

SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

Solutions R1 and R2 contain Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water for 10 minutes. In case of contact with eyes or if ingested, seek immediate medical attention.
Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents, flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.

Safety data sheets are available on request.

Please dispose of all biological and chemical materials according to local guidelines.

The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.

STABILITY AND PREPARATION OF REAGENTS

R1. ASO Assay Buffer
Supplied ready for use. Stable up to expiry date when stored at +2 to +8°C, protected from light.

R2. ASO Latex Reagent
Supplied ready for use. Stable up to expiry date when stored at +2 to +8°C, protected from light. Invert several times before use, avoiding the formation of foam.

R1 = ASO Assay Buffer
R2 = ASO Latex Reagent

MATERIALS PROVIDED

ASO Assay Buffer
ASO Latex Reagent

MATERIALS REQUIRED BUT NOT PROVIDED

Randox Liquid Specific Protein Calibrator, Cat. No. IT2691 (Level 5)
Randox Liquid Assayed Specific Protein Controls:

Level 1	Cat. No. PS 2682
Level 2	Cat. No. PS 2683
Level 3	Cat. No. PS 2684

RX **series** Saline (Cat. No. SA 8396)

PROCEDURE NOTES

The Chemistry parameters for Randox Dedicated RX **series** Assays are predefined on the hard drive of the analyser PC. The required programs should be downloaded to the analyser software. Please note that the predefined chemistry parameters use SI units. If alternative units are required, these can be edited by the user. In this case, the technical range should be edited in accordance with the users selected units. All necessary instructions are encoded on the bar code. If the barcode cannot be read by the analyser, enter manually the series of numbers given beneath the barcode. If problems continue, contact Randox Laboratories Technical Services, Northern Ireland +44 (0) 28 9445 1070.

RX DAYTONA PLUS CALIBRATION

0.9% NaCl as zero calibrator and Randox Liquid Specific Protein Calibrator are recommended for calibration.

TRACEABILITY

Randox ASO Assay is traceable to NIBSC Q4578.

QUALITY CONTROL

Randox Liquid Assayed Specific Protein Control is recommended for Quality Control. Two levels of controls should be assayed at least once a day. Values obtained should fall within a specified range. If these values fall outside the range and repetition excludes error, the following steps should be taken:

1. Check instrument settings and light source.
2. Check cleanliness of all equipment in use.
3. Check water, contaminants i.e. bacterial growth may contribute to inaccurate results.
4. Check reaction temperature.
5. Check expiry date of kit and contents.
6. Contact Randox Laboratories Technical Services, Northern Ireland +44 (0) 28 9445 1070.

Quality control requirements should be determined in conformance with government regulations or accreditation requirements.

NORMAL RANGES

≤ 100 IU/ml for Children, Preschool.[3]
≤ 250 IU/ml for Children, School age.[3]
≤ 200 IU/ml for Adults. [4]

Ideally, each laboratory should establish an expected range for the relevant geographical location.

SPECIFIC PERFORMANCE CHARACTERISTICS

The following performance data was obtained using a RX **daytona plus** analyser at +37°C.

SPECIFICITY/INTERFERENCE

The antiserum is monospecific for human ASO and has not been shown to cross-react with other serum proteins under the conditions of the assay.

The analytes below were tested up to the following levels at ASO concentrations of 80.0 IU/ml and 530 IU/ml and were found not to interfere:

	80.0 IU/ml	**530 IU/ml**
Haemoglobin	1000 mg/dl	1000 mg/dl
Free Bilirubin	60 mg/dl	60 mg/dl
Conjugate Bilirubin	60 mg/dl	60 mg/dl
Triglycerides	2000 mg/dl	2000 mg/dl
Intralipid®	1000 mg/dl	2000 mg/dl

Physiological changes in serum or plasma analyte concentrations can be caused by a number of substances. Comprehensive discussion of possible interfering substances, their serum or plasma concentrations, and their possible physiological involvements is beyond the scope of this document. The listed reference contains specific details on known potential interfering substances[5]. The user must remain vigilant to the possible effect on results of unknown interferences from medications or endogenous substances. All patient results must be evaluated in light of the total clinical status of the patient.

PROZONE

Antigen excess effects are not noted until levels approach 9000 IU/ml.

REPORTABLE RANGE

Linearity data demonstrates that the reportable range for ASO on the RX **daytona plus** is 12 to 931 IU/ml**.**

SENSITIVITY

The limit of Quantitation (LoQ), the limit of Detection (LoD) and the limit of Blank (LoB) were determined consistent with CLSI guidelines EP17-A. LoQ is the lowest concentration that can be detected with ≤20% bias and ≤20% imprecision. LoD is the lowest concentration that can be detected to determine the presence or absence of ASO. LoB is the highest concentration.

RX daytona plus

Limit of Blank (IU/ml)	0.00
Limit of Detection (IU/ml)	2.46
Limit of Quantitation (IU/ml)	12

PRECISION

Within Run Precision

	Level 1	Level 2	Level 3
Mean (IU/ml)	147	312	485
SD	3.06	6.16	8.46
CV(%)	2.08	1.98	1.74
n	80	80	80

Total Precision

	Level 1	Level 2	Level 3
Mean (IU/ml)	147	312	485
SD	6.53	12.6	14.9
CV(%)	4.45	4.03	3.07
n	80	80	80

CORRELATION

This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:

Y = 0.91X + 15.29
and a correlation coefficient of r = 1.00

40 patient samples were analyzed spanning the range 25.08 to 1444.365 IU/ml.

REFERENCES

1. Spaun, J., Bentzon, M.W., Larson, S.O., Hewitt, L.F., Bull. Wld. Hlth. Org. **24:** 271-279 (1961).
2. Galvin, J.P. *et al*., Clin. Lab. Assays **4:** 73-95 (1983).
3. Klein G.C., Baker C.N., Jones W.L., Upper limits of normal Antistreptolysin-O and Antideoxyribonuclease B titres. Applied Microbiology. 1971; 21: 999-1001.
4. Thomas L. ed., Clinical Laboratory Diagnosis. Streptococcus pyrogenes Infection. In: Thomas L. ed., Clinical Laboratory Diagnosis. Use and assessment of Clinical Laboratory results. 1st Edition (1998). TH-Books, Frankfurt/Main – Germany.
5. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Washington, DC: AACC Press; 2000.

The presence of a vertical bar in the margin indicates a technical update from the previous revision.

EC REP

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Revised 09 Jan 24 ld