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Antistreptolysin O (Turbi-Latex)

Diagnostic reagent set for the in-vitro determination of antistreptolysin O antibodies present in infected human serum.

REF: BS.1/AST1.050.0050	50 tests	REF: BS.1/AST1.100.0100	100 tests

CLINICAL SIGNIFICANCE [1-2]

In infections caused by ß-hemolytic streptococci, Streptolysin O is liberated from the bacteria stimulating production of antistreptolysin O (ASO) antibodies. The extent and degree of the infection can be monitored by measuring the levels of these antibodies. Increase in ASO titre generally occurs one to four weeks after onset of infection with ß-hemolytic streptococci Group A. As the infection subsides, the titre declines and returns to normal levels within six months. If the titre does not decrease, a recurrent or chronic infection may exist.

METHOD PRINCIPLE [2]

BioScien ASOT turbidimetric immunoassay for the determination of ASO in human serum is based on the principle of agglutination reaction. The test sample is mixed with activation buffer (R1), latex reagent (R2) and allowed to react. Presence of ASO in the test sample results in the formation of an insoluble complex producing a turbidity, which is measured at 540 nm

REAGENT COMPOSITION

Reagents:	Composition
R1: Buffer Reagent	Tris buffer 20 mmol/l, PH 8.2, Sodium azide0.95 g/L
R2: Latex Reagent	Latex particles coated with streptolysin O, pH 10.0 Sodium azide 0.95 g/L.
Calibrator	equivalent to the stated amount of ASO on a IU/ml

PRECAUTIONS AND WARNINGS

Reagent to be handled by entitled and professionally educated person. Do not ingest or inhale as reagent (R) contains sodium azide which is classified as dangerous substance for environment.

Good Laboratories practices using appropriate precautions should be followed in:

- Wearing personnel protective equipment (overall, gloves, glasses,).
- Do not pipette by mouth.
- In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.
- Respect country requirement for waste disposal.
  S56: dispose of this material and its container at hazardous or special waste collection point.
  S57: use appropriate container to avoid environmental contamination.
  S61: avoid release in environment.

For further information, refer to the ASOT reagent material safety data sheet.

REAGENT PREPARATION, STORAGE AND STABILITY

BioScien ASOT reagent is stable until expiration date stated on label when properly stored in an upright position and refrigerated at 2-8°C (do not freeze).
Working reagent: Swirl the latex vial gently before use. Prepare the necessary amount as follows: 4 ml Buffer+ 1 ml Latex Reagent.
Calibrator: Reconstitute with 1 ml distilled water. Mix gently and incubate at room temperature for 10 minutes before use.
Stability: 1 month deep freezed

Deterioration
The ***BioScien*** ASOT reagent can be damaged due to Presence of particles and turbidity.

SPECIMEN COLLECTION AND PRESERVATION [2]

Clean and dry glassware free from detergents must be used for sample collection, freshly collected serum is preferable. Specimen should be free of turbidity and hemolysis. Fresh, uncontaminated serum samples may be stored at 2-8°C in case of delay in testing up to 72 hours.

SYSTEM PARAMETERS

Wavelength	540 nm (530 – 550 nm)
Optical path	1 cm
Assay type	Fixed time Turbidimetric
Temperature	37 °C

EQUIPMENT REQUIRED NOT PROVIDED

- Sterile Syringe
- Analytical tubes
- Centrifuge
- Stop watch
- Variable Micropipettes
- Automatic analyzer

ASSAY PROCEDURE

1. Bring the working reagents and the photometer (cuvette holder) to 37° C.
2. Adjust the instrument to zero with distilled water.
3. Pipette into a cuvette:

R1: Buffer Diluent	400 µl
R2: Latex Reagent	100 µl
Calibrator or Sample	5 µl

4. Mix and read the absorbance after immediately (A1) and after 2 minutes (A2) of the sample addition.

CALCULATION

$$\frac{(A2\text{-}A1)\ \text{sample}}{(A2\text{-}A1)\ \text{calibrator}} \times \text{Calibrator concentration} = \text{IU/ml ASO}$$

QUALITY CONTROL

Control sera are recommended to monitor the performance of manual and automated assay procedures.
Each laboratory should establish its own quality control scheme and corrective actions if controls do not meet the acceptable tolerances.
For more information please contact ***BioScien*** technical support.

PERFORMANCE CHARACTERISTICS

Precision	Within run (Repeatability)		Run to run (Reproducibility)	
	Normal level	High level	Normal level	High level
n	10	10	10	10
Mean IU/ml	103	351	135	322
SD.	3.8	4.3	6.1	5.3
CV. %	3.7	1.2	4.5	1.7

Analytical sensitivity: 20 IU/ml
Analytical linearity: up to 800 IU/ml
Specimens showing higher concentration should be diluted 1+2 using physiological saline and repeat the assay (result×3).

INTERFERING SUBSTANCES

Hemoglobin (10 g/L) , bilirubin (20 mg/dL) and lipemia (10 g/L) ,and rheumatoid factors (600 IU/ml) do not interfere. Other substances may interfere.

LIMITATIONS OF PROCEDURE

1. The results of this test ***should not*** be used as a single diagnostic tool to make a clinical diagnosis. Instead, the test results must be evaluated together with other clinical findings and observed symptoms to aid in the final diagnosis.
2. Temperature of the reagents and specimens is critical to test outcome.
3. Do not use damaged or leaking reagents.
4. TAB vaccinated patients may show a high titer of antibodies to each of the antigens. Similarly, an amnestic response to other vaccines and unrelated fevers in case of patients who have had prior infection or immunization may give a false result.
5. Agglutinins usually appear by the end of the first week of infection, blood sample taken earlier may give a negative result.

EXPECTED VALUES

Up to 200 IU/ml

Each laboratory should establish its own reference range.

REFERENCES

1. Tadzynsky LA, Ryan ME. Diagnostic of rheumatoid fever. A guide to criterial and manifestations. Postgrad Med 1986;79:295.
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3. Passing H, Bablok W. A new biometrical procedure for testing the equality of measurements from two analytical methods. Application of linear regression procedures for method comparison studies. Part I. J Clin Chem Clin Biochem 1983; 21:709-20.
4. Curtis GDW, Kraak WAG, Mitchell RG. Comparison of latex and hemolysis tests for determination of antiestreptolysin O (ASO) antibodies. J Clin Pathol 1988; 41: 1331.
5. Rantz LA, Randall E. A modification of the technic for determination of the antiestreptolysin titer. Proc Soc Exp Biol Med 1945; 59:22.
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SYMBOLS IN PRODUCT LABELLING

IVD	For in-vitro diagnostic use	Σ	Number of <n> test in the pack
LOT	Batch Code/Lot number	⚠	Caution
REF	Catalogue Number		Do not use if package is damaged
	Temperature Limitation		Consult Instruction for use
	Expiration Date		
	Manufactured by		

EC REP

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