



TURBILATEX KIT
DIRECTIONS FOR USE

ASO Turbi-Kit: For Detection Of Anti-Streptolysin O (ASO) In Serum.

SUMMARY

In acute streptococcal infections, the toxic immunogenic exoenzyme streptolysin O (ASO) is produced in response to streptolysin O antigens liberated by haemolytic streptococci of groups A, C and G. Information on extent and degree of infection can be obtained by measuring serum ASO levels. Elevated ASO levels have also been found in patients suffering from scarlet fever, acute rheumatoid arthritis, tonsillitis, and other streptococcal infections as well as in healthy carriers.

PRINCIPLE

The ASO-Turbilatex is a quantitative turbidimetric test for the measurement of ASO in serum or plasma. Latex particles coated with Streptolysin O are agglutinated (clump) when mixed with samples containing ASO. The agglutination causes a change in absorbance, dependent on the ASO concentration in the patient sample. The ASO concentration can be quantified by comparing the absorbance change against the absorbance change of a calibrator of known ASO concentration (see **Limitations**).

KIT DESCRIPTION

Lorne ASO-Turbilatex Kit is for the detection of ASO. All the latex reagents are supplied at optimal dilution for use with all recommended techniques without need for further dilution or addition. For lot reference number and expiry date see **Vial Labels**.

STORAGE

Do not freeze. Each kit component is stable until the expiry date on the individual vial labels when stored at the temperature indicated on the individual vial labels. Prolonged storage at temperatures outside this range may result in accelerated loss of reagent reactivity.

SPECIMEN COLLECTION

Specimens should be drawn with or without anticoagulant using an aseptic phlebotomy technique. If testing is delayed specimens can be stored at 2-8°C for 7 days or for up to 3 months at or below -20°C. Specimens must be free from bacterial contamination, fibrin, gross lipaemia and gross haemolysis.

PRECAUTIONS

1. The kit is for *in vitro* diagnostic use only.
2. Do not use kit past expiration date (see **Vial and Box Label**).
3. Protective clothing should be worn when handling the reagents, such as disposable gloves and a laboratory coat.
4. Materials used to produce the kit were tested at source and found to be negative for HIV 1+2, HCV and HBsAg using approved microbiological tests. However, no known tests can guarantee that products derived from human or animal sources are free from infectious agents. Care must be taken in the use and disposal of each vial and its contents.

DISPOSAL OF KIT REAGENT AND DEALING WITH SPILLAGES

For information on disposal of kit reagent and decontamination of a spillage site see **Material Safety Data Sheets**, available on request.

CONTROLS AND ADVICE

1. It is recommended that control sera are used to monitor the performance of manual and automated assay procedures. It is recommended that ASO/ASO/RF Level L (catalogue number 1102114) and ASO/ASO/RF Level H (catalogue number 1102115) is used. Tests must be considered invalid if controls do not show expected results.
2. All the reagents must be allowed to reach 18-25°C before use.
3. Shake the reagents well before use to ensure homogeneity.
4. Do not interchange components between different kits.
5. Use of kit and interpretation of results must be carried out by properly trained and qualified personnel in accordance with the

requirements of country where kit is in use. The user must determine the suitability of the kit for use in other techniques.

KIT COMPONENTS SUPPLIED

- 1) Diluent (R1): Tris buffer 20 mmol/l, pH 8.2, Sodium azide 0.95 g/L.
- 2) Latex (R2): Latex particles coated with Streptolysin O, pH 10.0, Sodium azide 0.95 g/L.
- 3) ASO-Cal: Calibrator. ASO concentration is stated on the label.
- 4) Optional: Ref: 1102114 Control serum ASO/ASO/RF level L(ow).
- 5) Optional: Ref: 1102115 Control serum ASO/ASO/RF level H(igh).

MATERIALS AND EQUIPMENT REQUIRED

- MINDRAY BS-120 / BS-200 autoanalyser.
- Laboratory equipment.

MINDRAY BS-120 / BS-200 APPLICATION

Test	ASO	R1	240
N ^o	**	R2	60
Full name	ASO	Sample volume	3
Standard n ^o	1	R1 Blank	
Reac.type	Fixed time	Mixed Rgt Blank	
Pri. wavelength	546 nm	Linearity Range	*
Sec. wavelength		Linearity Limit	800 UI/ml
Direction	Increase	Substrate Limit	*
Reac. time	1 7	Factor	*
Incub. time		Pro-zone check	*
Units	UI/mL	q1	q2
Precision	0.1	q3	q4
		PC	Abs

Calibration (Cal + Reagent BLK)

Rule	One-point Linear
Sensitivity	1
Replicates	2
Interval (days)	0
Difference limit	
SD	
Blank Response	
Error Limit	
Correlation coefficient	1

The Blank parameter must be performed in order to get accurate test results in CALIB screen on the main menu. The Blank calibration is stable for 38 days. After this period, the Blank parameter must be performed again in order to validate the calibration.

LIMITATIONS

1. 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 interfere⁷.
2. False positive or false negative results may also occur due to:
 - a) Contamination of test materials
 - b) Improper storage of test materials or omission of reagents
 - c) Deviation from the recommended techniques

SPECIFIC PERFORMANCE CHARACTERISTICS

1. The kit has been characterised by all the procedures mentioned in the **Recommended Techniques**.
2. Use ASO calibrator reference 1107012. The calibrator is reconstituted with 1.0 mL of distilled water. Mix gently and incubate at room temperature for 10 minutes before use.
3. The sensitivity of the assay and the target value of the calibrator have been standardised against the ASO International Calibrator (WHO). Recalibrate the assay when the control sera results are

out of specified tolerances, when using different lot numbers of reagent or when the instrument is adjusted.

- Normal values are up to 200 IU/mL (adults) and 100 IU/mL (children < 5 years old). Each laboratory should establish its own reference range.

DISCLAIMER

- The user is responsible for the performance of the kit by any method other than those mentioned in the **MINDRAY BS-120 / BS-200 APPLICATION**.
- Any deviations should be validated prior to use using established laboratory procedures.

BIBLIOGRAPHY

- Haffejee I, Quarterly Journal of Medicine 1992, New series 84; 305:641-658.
- Alouf Jodeph E. Pharma Ther 1980; 11:661-717.
- M.Fasani et al. Eur J Lab Med 1994; vol2. N° 1:67.
- Todd E W. J Exp Med 1932; 55:267-280.
- Klein, GC. Applied Microbiology 1970; 19: 60-61.
- Klein, GC. Applied Microbiology 1971; 21: 999-1001.
- Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995








AVAILABLE KIT SIZES

Kit Size	Catalogue Number
150 Tests Per Kit	150150A

For the availability of other sizes, please contact:

Lorne Laboratories Limited
 Unit 1 Cutbush Park Industrial Estate
 Danehill
 Lower Earley
 Berkshire RG6 4UT
 England
 Tel: +44 (0) 118 921 2264
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 E-mail: info@lornelabs.com

TABLE OF SYMBOLS

	Batch Number		<i>in-vitro</i> Diagnostic
	Catalogue Reference		Store At
	Expiry Date		Manufacturer
	Read Pack Insert		