LORNE LABORATORIES LTD.

GREAT BRITAIN

TURBILATEX KIT

DIRECTIONS FOR USE

Lp(a) Turbi-Kit: For Detection Of Lipoprotein a (Lp(a)).

SUMMARY

Lp(a) is a plasma lipoprotein with a lipid composition very similar to low density lipoprotein (LDL). The apolipoprotein, however, is composed of two proteins linked by disulphide bonds. The plasma level of Lp(a) is positively correlated the occurance of coronary heart disease and cerebrovascular disease particularly in hypercholesterolemic subjects.

PRINCIPLE

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

KIT DESCRIPTION

Lorne Lp(a)-Turbilatex Kit is for the detection of Lp(a). 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 2-8ºC for 7 days or for up to 3 months at or below –20ºC. 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 serum is used to monitor the performance of manual and automated assay procedures. It is recommended that Lp(a) Control (catalogue number 1107024) is used. Tests must be considered invalid if the control does not show expected results.
2. All the reagents must be allowed to reach 18-25ºC 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): Glycine buffer 50 mmol/l, pH 9.0, Sodium azide 0.95 g/L.
2) Latex (R2): Latex particles coated with mouse monoclonal Anti-human Lp(a), pH 8.2, Sodium azide 0.95 g/L.

3) Optional: Ref: 1107022 Lp(a) Calibrator.
4) Optional: Ref: 1107024 Lp(a) Control serum.

MATERIALS AND EQUIPMENT REQUIRED

a) MINDRAY BS-120 / BS-200 autoanalyser.
b) Laboratory equipment.

MINDRAY BS-120 / BS-200 APPLICATION

Test	Lp(a)		R1	240
Nº	**		R2	60
Full name	Lp(a)		Sample volume	5
Standard nº	5		R1 Blank	
Reac.type	Fixed time		Mixed Rgt Blank	
Pri. wavelength	578 nm		Linearity Range	3-80 mg/dL
Sec. wavelength			Linearity Limit	*
Direction	Increase		Substrate Limit	*
Reac. time	1	13	Factor	
Incub. time			Pro-zone check	*
Units	mg/dL		q1	q2
Precision	0.1		q3	q4
			PC	Abs

Calibration (Cal + Reagent BLK)

Rule	Spline
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 8 days. After this period, the Blank parameter must be performed again in order to validate the calibration.

CALIBRATION CURVE

Prepare the following RF calibrator dilutions in NaCl 9 g/L. Multiply the concentration of the RF calibrator by the corresponding factor stated in the table below to obtain the RF concentration of each dilution.

Calibrator dilution	1	2	3	4	5
Calibrator RF (µl)	-	25	50	75	100
NaCl 9 g/L (µl)	100	75	50	25	-
Factor	0	0.25	0.50	0.75	1.00

LIMITATIONS

1. Hemoglobin (≤ 5 g/L), bilirubin (up to 20 mg/dL) and lipemia (≤ 20 g/L), Plasminogen (≤ 680 mg/dL), ascorbic acid (≤ 200 mg/dL) and Rheumatoid Factors (≤ 100 IU/mL) do not interfere. Other substances may interfere[5].
2. False positive or false negative results may also occur due to:
   - Contamination of test materials
   - Improper storage of test materials or omission of reagents
   - Deviation from the recommended techniques

SPECIFIC PERFORMANCE CHARACTERISTICS

1. The kit has been characterised by all the procedures mentioned in the **Recommended Techniques**.
2. The sensitivity of the assay and the target value of the calibrator have been standardised against an internal reference material. It is not recommended to use another commercially available Lp(a) calibrator.
3. Normal values are up to 30 mg/dL. Each laboratory should establish its own reference range.

DISCLAIMER

1. 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**.
2. Any deviations should be validated prior to use using established laboratory procedures.

BIBLIOGRAPHY

1. Gaubatz JW et al. J Biol Chem 1983; 258:4528-4589.
2. Berg KA et al. Acta Pathol Microbiol Scand 1963; 59: 369-382.
3. Scanu AM et al. J Clin Invest 1990; 85: 1709-1715.
4. Frank S et al. Eur J Clin Invest 1996; 26: 209-114.
5. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995

AVAILABLE KIT SIZES

Kit Size	Catalogue Number
100 Tests Per Kit	153100A

For the availability of other sizes, please contact:

Lorne Laboratories Limited
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Danehill
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England
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TABLE OF SYMBOLS

LOT	Batch Number	IVD	*In-vitro* Diagnostic
REF	Catalogue Reference		Store At
	Expiry Date		Manufacturer
	Read Pack Insert		