LORNE LABORATORIES LTD.

GREAT BRITAIN

TURBILATEX KIT

DIRECTIONS FOR USE

RF Turbi-Kit: For Detection Of Rheumatoid Factors (RF).

SUMMARY

Rheumatoid factors are a group of antibodies directed to determinants in the Fc portion of the IgG molecule. Although rheumatoid factors are found in a number of rheumatoid disorders, such as systemic lupus erythematosis (sLE) and Sjögren's syndrome, as well as in non-rheumatoid conditions, it's central role lies in aiding in the diagnosis of rheumatoid arthritis (RA). A study of the "American College of Rheumatology" shows that 80.4% of RA patients were RF positive.

PRINCIPLE

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

KIT DESCRIPTION

Lorne RF Latex Test Kit is for the detection of RF. Test reagent consists of latex particles coated with human γ-globulin. 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 sera are used to monitor the performance of manual and automated assay procedures. It is recommended that ASO/RF/RF Level L (catalogue number 1102114) and ASO/RF/RF Level H (catalogue number 1102115) is used. Tests must be considered invalid if controls do not show expected results.
2. Use RF calibrator reference 1107007. Reconstitute with 2.0 ml of distilled water. Mix gently and incubate at room temperature for 10 minutes before use. The reconstituted calibrator is stable for 1 month at 2-8ºC or for up to 3 months at or below –20ºC.
3. All the reagents must be allowed to reach 18-25ºC before use.
4. Shake the reagents well before use to ensure homogeneity.
5. Do not interchange components between different kits.
6. 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 human γ-globulin, pH 7.4, Sodium azide 0.95 g/L.
3) RF-Cal: Calibrator. RF concentration is stated on the label.

4) Optional: Ref: 1102114 Control serum ASO/RF/RF level L(ow).
5) Optional: Ref: 1102115 Control serum ASO/RF/RF level H(igh).

MATERIALS AND EQUIPMENT REQUIRED

- SPINLAB 180 autoanalyser.
- Laboratory equipment.

SPINLAB 180 APPLICATION

Name	RF	Ref. male low	*
Abbr. Name	RF	Ref. male high	*
Mode	Twopoints	Ref. female low	*
Wavelength	620 nm	Ref. female high	*
Units	IU/L	Ref. Ped. low	*
Decimals	2	Ref. Ped. high	*
Low Conc.	6 IU/L	Panic value low	*
High Conc.	160 IU/L	Panic value high	*
Calibrator Name**	CAL RF**	Control 1	*
Prozone check	No	Control 2	*
		Control 3	*
		Correlat. Factor	1.000
		Correlat. offset	0.000

Dual Mode

Sample blank	No
R1 bottle (ml)	25 ml
normal volume	240 µl
Rerun volume	240 µl
Sample	
normal volume	3.0 µl
Rerun volume	3.0 µl
R2 bottle (ml)	5 ml
normal volume	60 µl
Rerun volume	60 µl
Predilution	No
Slope blank	No
Point one, two	-3,130 sec.

Reagent blank	Yes
Low absorbance	-0.100 Abs
High absorbance	3.000 Abs
R. Abs. L. Limit	-0.100 Abs
R. Abs. H. Limit	3.000 Abs
Substrate Depletion	3.000 Abs

**Adjust maximum inaccuracy calibration % until the calibration curve covers the whole range of absorbances.

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	6
Calibrator RF (µl)	-	25	50	100	200	400
NaCl 9 g/L (µl)	400	375	350	300	200	-
Factor	0	0.0625	0.125	0.25	0.5	1.0

LIMITATIONS

1. Hemoglobin (≤ 10 g/L), bilirubin (≤ 20 mg/dL) and lipemia (≤ 10 g/L) do not interfere. Other substances may interfere[6].
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. The sensitivity of the assay and the target value of the calibrator have been standardised against the World Health Organisation International Reference NIBSC 64/2 (Rheumatoid Arthritis Serum). 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.
3. Normal values are up to 20 IU/L. 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 **SPINLAB 180 APPLICATION**.
2. Any deviations should be validated prior to use using established laboratory procedures.

BIBLIOGRAPHY

1. Frederick Wolfe et al. Arthritis and Rheumatism 1991; 34: 951-960.
2. Robert W.Dorner et al. Clinica Chimica Acta 1987; 167:1-21.
3. Robert H Shmerling et al. The American Journal of Medicine 1991; 91: 528-534.
4. Vladimir Muié et al. Scand J Rheumatology 1972; 1: 181-187.
5. Paul R et al. Clin Chem 1979; 25/11: 1909-1914.
6. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995

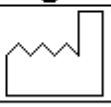
AVAILABLE KIT SIZES

Kit Size	Catalogue Number
150 Tests Per Kit	152150A

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
Fax: +44 (0) 118 986 4518
E-mail: info@lornelabs.com

TABLE OF SYMBOLS

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