LORNE LABORATORIES LTD.

GREAT BRITAIN

TURBILATEX KIT

DIRECTIONS FOR USE

β-2-microglobulin Turbi-Kit: For Detection Of β-2-Microglobulin.

SUMMARY

β_2-microglobulin is a cell membrane associated 100 amino acid peptide. It is increased non-specifically in inflammatory reactions and in active chronic lymphocytic leukaemia in which there is increased lymphocyte turnover. It is a prognostic marker in multiple myeloma and may be a useful indicator of glomerular and tubular dysfunction. β_2-microglobulin is increased in AIDS patients with progressive disease.

PRINCIPLE

The β_2-microglobulin-Turbilatex is a quantitative turbidimetric test for the measurement of β_2-microglobulin in serum, plasma and urine.
Latex particles coated with anti-human β_2-microglobulin are agglutinated (clump) when mixed with samples containing β_2-microglobulin. The agglutination causes a change in absorbance, dependent on the β_2-microglobulin concentration in the patient sample. The β_2-microglobulin concentration can be quantified by comparing the absorbance change against the absorbance change of a calibrator of known β_2-microglobulin concentration (see **Limitations**).

KIT DESCRIPTION

Lorne β_2-microglobulin-Turbilatex Kit is for the detection of β_2-microglobulin. 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

Fresh serum can be stored at 2-8ºC for 7 days or for up to 3 months at or below –20ºC.
Fresh urine samples have to be adjusted to pH 7-8 by addition of K_2HPO_4. The urine is then stable for 2 days at 2-8ºC or for up to 3 months at or below –20ºC.
Do not use haemolysed or lipaemic samples.

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 β_2-microglobulin Control (catalogue number 1107034) 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) β_2-m Diluent (R1): Tris buffer 20 mmol/l, pH 8.2, Sodium azide 0.95 g/L.
2) β_2-m Latex (R2): Latex particles coated with goat IgG Anti-human β_2-microglobulin, pH 7.5, Sodium azide 0.95 g/L.
3) β_2-m CAL: Calibrator. β_2-microglobulin concentration is stated on the vial label.

4) Optional: Ref: 1107034 β_2-microglobulin Control serum.

MATERIALS AND EQUIPMENT REQUIRED

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

MINDRAY BS-120 / BS-200 APPLICATION

Test	β2-m	R1	240
Nº	**	R2	60
Full name	β2-m	Sample volume	3
Standard nº	1	R1 Blank	
Reac.type	Fixed time	Mixed Rgt Blank	
Pri. wavelength	546 nm	Linearity Range	*
Sec. wavelength		Linearity Limit	18 mg/L
Direction	Increase	Substrate Limit	*
Reac. time	1 7	Factor	
Incub. time		Pro-zone check	*
Units	mg/L	q1	q2
Precision	0.01	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 18 days. After this period, the Blank parameter must be performed again in order to validate the calibration.

CALIBRATION

1. Use β_2-microglobulin calibrator reference 1107032.
   Serum method: Reconstitute with 1.0 ml of distilled water. Mix gently and incubate at room temperature for 10 minutes before use.
   Urine method: Dilute reconstituted calibrator 1/6 with NaCl 9 g/L (50 µl calibrator + 250 µl NaCl 9 g/L).
2. The sensitivity of the assay and the target value have been standardized against the 1st international β_2-microglobulin standard from the World Health Organisation (WHO).
3. Recalibrate the assay when control results are out of specified tolerances, when using a different lot of reagents or when the instrument has been adjusted.

LIMITATIONS

1. Serum method: Hemoglobin (≤ 10 g/L), bilirubin (≤ 20 mg/dL), and lipaemia (≤ 10 g/L) do not interfere. Rheumatoid Factors (≥ 150 IU/mL) interfere.

Urine method: Urea (≤ 50 g/L), Uric acid (≤ 20 g/L) and Glucose (≤ 100 g/L) do not interfere.
Other substances may interfere[7].

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. Normal values in serum are from 1.0–3.0 mg/L.
   Normal values in urine are from 0.1–0.3 mg/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 **MINDRAY BS-120 / BS-200 APPLICATION**.
2. Any deviations should be validated prior to use using established laboratory procedures.

BIBLIOGRAPHY

1. Bhalla R.B et al. Clin Chem 1983; 29: 1560.
2. Malaguarnera M et al. Digestive Diseases and Sciences 1997; 42: 762-766.
3. Chironna et al. Int J Clin Lab Rws 1994; 24: 90-93.
4. Wibell L et al. Nephron 1973; 10: 320-331.
5. Berggard B et al. Scand J Clin Lab Invest 1980; 40: 13-25.
6. Davey P G et al. Clin Chem 1982; 28/6: 1330-1333.
7. 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	154150A

For the availability of other sizes, please contact:

Lorne Laboratories Limited
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Danehill
Lower Earley
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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		