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

**SUMMARY**

β₂-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. β₂-microglobulin is increased in AIDS patients with progressive disease.

**PRINCIPLE**

The β₂-microglobulin-Turbilatex is a quantitative turbidimetric test for the measurement of β₂-microglobulin in serum, plasma and urine. Latex particles coated with anti-human β₂-microglobulin are agglutinated (clump) when mixed with samples containing β₂-microglobulin. The agglutination causes a change in absorbance, dependent on the β₂-microglobulin concentration in the patient sample. The β₂-microglobulin concentration can be quantified by comparing the absorbance change against the absorbance change of a calibrator of known β₂-microglobulin concentration (see Limitations).

**KIT DESCRIPITON**

Lorne β₂-microglobulin-Turbilatex Kit is for the detection of β₂-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 2-8°C for 7 days or for up to 3 months at or below -20°C. Fresh urine samples have to be adjusted to pH 7-8 by addition of K₂HPO₄. The urine is then stable for 2 days at 2-8°C or for up to 3 months at or below -20°C. 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 β₂-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 18-25°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) β₂-m Diluent (R1): Tris buffer 20 mmol/l, pH 8.2, Sodium azide 0.95 g/L.
2) β₂-m Latex (R2): Latex particles coated with goat IgG Anti-human β₂-microglobulin, pH 7.5, Sodium azide 0.95 g/L.
3) β₂-m CAL: Calibrator. β₂-microglobulin concentration is stated on the vial label.
4) Optional: Ref: 1107034 β₂-microglobulin Control serum.

**MATERIALS AND EQUIPMENT REQUIRED**

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

**MINDRAY BS-120 / BS-200 APPLICATION**

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<th>R1</th>
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<td>**</td>
<td>R2</td>
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Calibration (Cal + Reagent BLK)

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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 β₂-microglobulin calibration 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 β₂-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.

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

AVAILABLE KIT SIZES

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<tr>
<td>150 Tests Per Kit</td>
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For the availability of other sizes, please contact:

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

TABLE OF SYMBOLS

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