The Creative Approach to Bioscience

**β2-MICROGLOBULIN**

Mono-Reagent Procedure

**Intended Use**

In vitro diagnostic reagents for the quantitative determination of β2-Microglobulin (β2-m) in serum by means of particle enhanced turbidimetric immunoassay.

**Background**

β2-microglobulin (β2-m), an 11,800 Da protein consisting of 100 aminoacid residues, first isolated from urine by Berggard and Beare. It is located on the surface of lymphocytes and other nucleated cells and was identified as the light chain of the class I major histocompability complex. The cell membrane turnover is the main source of β2-m in serum, where its level rises when its production rate increases. Free β2-m is filtered by the glomerulus and subsequently reabsorbed almost completely in the proximal tubular cells, where it is catabolized. Increased urinary excretion of β2-m is a sensitive indicator of renal tubular disorders and has been used to detected early nephotoxicity in patients treated with gentamicin and other nephrotoxic drugs. Besides renal insufficiency, serum level of β2-m was shown to be elevated in a variety of diseases including carcinomas and lymphoid tumours and inflammatory and autoimmune diseases such as Sjogren’s syndrome and rheumatoid arthritis.

Detection of elevated serum β2-m has also been reported as a useful marker of acquired immune deficiency syndrome and in myeloma patients. This test provides the advantage of being economical, rapid, precise, accurate and suitable for the analysis of large series of serum specimens.

**Test Principle**

This β2-m test is based upon the reactions between β2-m in the sample and latex-covalently bound goat antihuman β2-m antibodies. β2-m values are determined photometrically.

**Reagents**

- **Buffer**: TRIS buffer, pH: 7.2, containing detergents, polyethylene glycol and 0.09 % sodium azide as preservative.
- **Latex reagent**: suspension of latex microparticules covalently bound goat antihuman β2-m antibodies in a glycine buffer (0.1 M), containing NaCl (0.15 M) and bovine serum albumin (0.5%).
- **Preservative**: Sodium azide 0.075%.
- **Calibrator**: Human-based reference fluid. Preservative: sodium azide, 0.075%.

All raw materials of human origin used in the manufacture of this product passed the tests for HBSAg, anti-HIV-1/2 and HCV with commercially available test methods. However, this product should be handled as though capable of transmitting infectious diseases.

**Precautions and Warnings**

For in vitro diagnostic use only. Do not pipette by mouth. Reagents containing sodium azide must be handled with precaution. Sodium azide can form explosive azides with lead and copper plumbing. Since absence of infectious agents cannot be proven, all specimens and reagents obtained from human blood should always be handled with precaution using established good laboratory practices.

Disposal of all waste material should be in accordance with local guidelines.

For other diagnostic tests, results should be interpreted considering all other test results and the clinical situation of the patient.

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**SYMBOLS IN PRODUCT LABELLING**

- **Authorized Representative**: For in-vitro diagnostic use
- **Batch Code/Lot number**: Use by/Expiration Date
- **Catalogue Number**: CAUTION: Consult instructions for use
- **Manufactured by**: Manufactured by

**Storage and Stability**

Reagents in the original vial are stable to the expiration date on the vial label when capped and stored at (2 - 8 °C). Immediately following the completion of an assay run, the reagent vial should be capped until next use in order to maximize curve stability. Once opened the reagent can be used within 1 month if stored tightly closed at (2 - 8 °C) after use. Do not freeze reagents.

The β2-Microglobulin latex reagent should have a white, turbid appearance free of granular particulate. Visible agglutination or precipitation may be a sign of deterioration, and the reagent should be discarded.

The β2-Microglobulin buffer reagent should be clear and colourless. Any turbidity may be a sign of deterioration and reagent should be discarded.

**Specimen Collection and Preparation**

Serum specimens should be collected by venipuncture following good laboratory practices. Suitable assay specimens are human serum samples, as fresh as possible (stored up to 7 days at 2 - 8 °C) or deep-frozen. Any additional clotting or precipitation which occurs due to the freeze/thaw cycle should be removed by centrifugation prior to assay.

Lipemic specimens, or turbid frozen specimens after thawing, must be clarified before the assay by high-speed centrifugation (10 min at approx. 15,000 rpm). Heat-inactivation of the serum samples can lead to a loss of the antigenic properties of the β2-m and must therefore be avoided.

**Reagent Preparation**

Working Reagent is prepared with 1 part of Latex Reagent and 9 parts of Buffer Reagent. Prepare a fresh WR based on its workload. Shake gently the reagents before pipetting.

**Procedure**

- **Wavelength**: 600 nm
- **Temperature**: 37°C
- **Cuvette**: 1 cm light path
- **Measurement against distilled water blank**

Bring the reagents at 37°C and pipette:

<table>
<thead>
<tr>
<th>Calibration</th>
<th>Sample</th>
<th>Blank</th>
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</thead>
<tbody>
<tr>
<td>Calibrator</td>
<td>3.5 μl</td>
<td></td>
</tr>
<tr>
<td>Sample</td>
<td>–</td>
<td>3.5 μl</td>
</tr>
<tr>
<td>Distilled Water</td>
<td>–</td>
<td>3.5 μl</td>
</tr>
<tr>
<td>Work. Reagent</td>
<td>500 μl</td>
<td>500 μl</td>
</tr>
</tbody>
</table>

Mix and measure absorbance immediately (A1) incubate 5 min (37°C), after incubation read absorbance (A2).

**Calculation**

Plot the calibration curve and the sample concentration is obtained by interpolation the sample absorbance (A2) in the calibration curve.

If is an one point calculation:

\[
\frac{(A_2-A_1)\text{sample}}{(A_2-A_1)\text{blank}} = \text{Calibrator concentration}
\]

**Intended Use**

REF: 554 002  100 test (R1 buffer: 42.5 ml, R2:Latex: 8.5 ml)
Linearity

Up to 20 mg/L.

Calibration and Quality Control

| Calibrator 1 | 100 µl of Spectrum β2-m Calibrator* |
| Calibrator 2 | 100 µl of Calibrator 1 + 100 µl of Saline Solution |
| Calibrator 3 | 100 µl of Calibrator 2 + 100 µl of Saline Solution |
| Calibrator 4 | 100 µl of Calibrator 3 + 100 µl of Saline Solution |
| Calibrator 5 | 100 µl of Saline Solution |

* See values on the label or on the insert. Multiply by the appropriate factor.

For quality control use Spectrum Control or other suitable control material. The control intervals and limits must be adapted to the individual laboratory requirements. Values obtained should fall within established limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits. Control must be assayed and evaluated as for patient samples.

Expected Values

Values from 0.8 to 2.4 mg/L are within the normal range. Each laboratory should establish an expected range for the geographical area in which it is located.

References


ORDERING INFORMATION

<table>
<thead>
<tr>
<th>CATALOG NO.</th>
<th>QUANTITY</th>
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<tbody>
<tr>
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<td>100 test</td>
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