**Intended Use**
System reagent for the quantitative determination of β-2-Microglobulin (β2M) in human serum on Beckman Coulter AU analyzers.

**Summary**
β-2-Microglobulin occurs in serum, urine, cerebrospinal and other body fluids in low concentrations. Increased concentrations of β2M in serum are found in patients with malignancies, renal diseases (due to reduced glomerular filtration) and infectious conditions including human immunodeficiency virus (HIV) infection. β-2-Microglobulin has been found to be the most powerful prognostic indicator of Multiple Myeloma.1,2

**Methodology**
Immune complexes formed in solution scatter light in proportion to their size, shape and concentration. Turbidimeters measure the reduction of incident light due to reflection, absorption, or scatter.

In the procedure, the measurement of the decrease in light transmitted (increase in absorbance) through particles suspended in solution as a result of complexes formed during the antigen-antibody reaction, is the basis of this assay.

**System Information**
For AU400/4000/480, AU600/640/640e/680 and AU2700/5400 Beckman Coulter Analyzers.

**Reagents**
Final concentration of reactive ingredients:
- Phosphate buffer: 22 mmol/L
- Latex particles coated with rabbit IgG anti-β-2-Microglobulin antibodies
- Polyethylene Glycol
- Also contains preservatives.

**Precautions**
1. For in vitro diagnostic use.
2. Do not ingest. Harmful if swallowed.
3. Contains sodium azide as a preservative which may react with lead joints in copper plumbing to form explosive compounds. Even though the reagent contains minute quantities of sodium azide, drains should be well flushed with water when discarding the reagent.

**Preparation of reagents**
The β-2-Microglobulin reagent is ready for use. No preparation is required.

**Storage and stability**
1. The unopened reagents are stable until the expiration date printed on the label when stored at 2 – 8°C.
2. Opened bottles of reagent are stable for 90 days when stored in the refrigerated compartment of the analyzer.

**Indications of Deterioration**
Visible signs of microbial growth, turbidity, precipitate, or change in color in the β-2-Microglobulin reagents may indicate degradation and warrant discontinuation of use.

**Specimen Collection and Preparation**
A fasting serum specimen, free from hemolysis, is the recommended specimen. Avoid highly lipemic samples, which may produce excessively high scatter signals.3

**Sample Storage and Stability**
Samples can be stored for 1 week at 2 – 8°C or for up to one year at ≤ -20°C.2

**Interfering Substances**
Results of studies4 show that the following substances may interfere with this β-2-Microglobulin procedure:

- Ascorbate: No significant interference to 20 mg/dL Ascorbate
- Bilirubin: No significant interference to 40 mg/dL Bilirubin
- Hemolysis: No significant interference to 500 mg/dL Hemolysate
- Lipemia: No significant interference to 1000 mg/dL Intralipid*

* Intralipid, manufactured by KabiVitrum Inc., is 20% IV fat emulsion used to emulate extremely turbid samples.

The information presented is based on results from Beckman Coulter studies and is current at the date of publication. Beckman Coulter Inc. makes no representation about the completeness or accuracy of results generated by future studies. For further information on interfering substances, refer to Young for a compilation of reported interferences with this test.5

**Procedure**
A complete list of test parameters and operational procedure can be found in the User’s Guide appropriate to the analyzer.
\( \beta \)-2-Microglobulin

**Materials Provided**

- \( \beta \)-2-Microglobulin Reagent

**Materials required but not provided**

- Serum Protein Multi-Calibrator 2 (Cat # ODR3023)

**Stability of Final Reaction Mixture**

The Beckman Coulter AU analyzers automatically compute every determination at the same time interval.

**Calibration**

The frequency of calibration for the \( \beta \)-2-Microglobulin turbidimetric procedure is every 90 days. Calibration of this \( \beta \)-2-Microglobulin procedure is accomplished by use of the Serum Protein Multi-Calibrator 2 (ODR3023), which is traceable to IFCC International Reference Preparation CRM470 (RPPHS).

Recalibration of this test is required when any of these conditions exist:

1. A reagent lot number has changed or there is an observed shift in control values.
2. Major preventative maintenance was performed on the analyzer.
3. A critical part was replaced.

**Quality Control**

During operation of the Beckman Coulter AU analyzer at least two levels of an appropriate quality control material should be tested a minimum of once a day. In addition, these controls should be performed after calibration, with each new lot of reagent, and after specific maintenance or troubleshooting steps described in the appropriate User’s Guide. Quality control testing should be performed in accordance with regulatory requirements and each laboratory’s standard procedure.

**Results**

Automatically printed out for each sample in mg/dL at 37°C.

**Dynamic Range**

The \( \beta2M \) turbidimetric procedure is linear from 0.05 - 1.6 mg/dL. Samples exceeding the upper limit of linearity should be diluted and repeated. The sample may be diluted, repeated and multiplied by the dilution factor automatically utilizing the AUTO REPEAT RUN.

Prozone or hook effect may occur with highly elevated \( \beta \)-2-Microglobulin samples (>200 mg/dL).

**Note:** Samples from patients with paraproteinemia may occasionally give spuriously elevated results, such samples should be diluted prior to analysis.

**Expected Values**

Adults: 0.097 - 0.184 mg/dL

Expected values may vary with age, sex, diet and geographical location. Each laboratory should determine its own expected values as dictated by good laboratory practice.

**Specific Performance Characteristics**

The following data was obtained using the \( \beta \)-2-Microglobulin reagent on Beckman Coulter AU analyzers according to established procedures. Results obtained in individual laboratories may differ.

**Precision**

Estimates of precision, based on CLSI recommendations, are consistent with typical performance. The within run precision is less than 5% CV and total precision is less than 10% CV. Assays of serum pools and control sera were performed and the data reduced following CLSI guidelines above.

<table>
<thead>
<tr>
<th>N = 100</th>
<th>Mean, mg/dL</th>
<th>SD</th>
<th>CV%</th>
<th>SD</th>
<th>CV%</th>
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<tr>
<td>0.07</td>
<td>0.001</td>
<td>1.7</td>
<td></td>
<td>0.001</td>
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<tr>
<td>0.18</td>
<td>0.001</td>
<td>0.8</td>
<td></td>
<td>0.002</td>
<td>0.9</td>
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<tr>
<td>0.30</td>
<td>0.001</td>
<td>0.5</td>
<td></td>
<td>0.002</td>
<td>0.7</td>
</tr>
</tbody>
</table>

**Method Comparison**

Serum

Patient samples were used to compare this \( \beta \)-2-Microglobulin Reagent. The table below demonstrates representative performance on AU analyzers.

<table>
<thead>
<tr>
<th>Y Method</th>
<th>AU640</th>
</tr>
</thead>
<tbody>
<tr>
<td>X Method</td>
<td>AU600</td>
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<tr>
<td>Slope</td>
<td>0.976</td>
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<tr>
<td>Intercept</td>
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<tr>
<td>Correlation Coeff. (r)</td>
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</tr>
<tr>
<td>No. of Samples (n)</td>
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</tr>
<tr>
<td>Range (mg/dL)</td>
<td>0.051-0.450</td>
</tr>
</tbody>
</table>

**References**

6. Beckman Coulter Inc., data on samples collected from 200 blood donors in North Texas.
8. Data is on file for specific AU analyzers.

Manufactured by: Beckman Coulter, Inc., 250 S. Kraemer Blvd. Brea, CA 92821, USA