**Intended Use**
System reagent for the quantitative determination of IgG immunoglobulins in human serum, plasma and cerebrospinal fluid on Beckman Coulter AU analyzers.

**Summary**
The measurement of IgG aids in the diagnosis of abnormal protein metabolism and the body’s lack of ability to resist infectious agents.

**Methodology**
Immune complexes formed in solution scatter light in proportion to their size, shape and concentration. Turbidimeters measure the reduction of incidence light due to reflection, absorption or scatter.
In the procedure, the decrease in intensity of light transmitted (increase in absorbance) through particles suspended in solution is the result of complexes formed during the antigen-antibody reaction.

**System Information**
For AU400/400/480, AU600/640/640 and AU2700/5400 Beckman Coulter Analyzers.

**Reagents**
Final concentration of reactive ingredients:

- **For Serum/Plasma Application**
  - Tris buffer pH 7.2: 48 mmol/L
  - Polyethylene glycol 6000: 3.1%
  - Goat anti-IgG antiserum: Dependent on titre
  - Also contains preservatives.

- **For CSF Application**
  - Tris buffer pH 7.2: 63 mmol/L
  - Polyethylene glycol 6000: 4.9%
  - Goat anti-IgG antiserum: Dependent on titre
  - 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 IgG 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 or precipitate, or any change in reagent color may indicate degradation and warrant discontinuance of use.

**Specimen Collection and Preparation**
Serum, EDTA and Lithium heparin plasma and CSF may be used.
Fasting serum specimen, free from hemolysis, is the recommended specimen. Avoid highly lipemic samples, which may produce excessively high scatter signals.1

**Sample Storage and Stability**
Serum & plasma specimens are stable at 2 – 8°C for up to 3 days or at ≤ -20°C for longer periods of time.1 CSF:2 Stable for 72 hours when stored at 4°C. Stable for 6 months when stored frozen at -20°C.

**Interfering Substances**
Results of studies3 show that the following substances interfere with this IgG procedure.

**Serum Plasma Application**
The criteria for no significant interference is recovery within 10% of the initial value.
- Bilirubin: No significant interference up to 40 mg/dL Bilirubin
- Hemolysis: No significant interference up to 500 mg/dL Hemolysate
- Lipemia: No significant interference up to 1000 mg/dL Intralipid*
- RF: No significant interference up to 1200 IU/mL Rheumatoid Factor

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

CSF Application
The criteria for no significant interference is recovery within 10% of the initial value.
Bilirubin: No significant interference up to 36 mg/dL Bilirubin
Hemolysis: No significant interference up to 500 mg/dL Hemolysate

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.

Procedure
A complete list of test parameters and operational procedure can be found in the User’s Guide appropriate to the analyzer.

Please note that there is a requirement to dedicate a separate test channel specifically for CSF sample settings when assigning this IgG application on Beckman Coulter AU analyzers.

Materials Provided
IgG Reagent

Materials Required But Not Provided
Serum Protein Multi-Calibrator (Cat # ODR3021)

Stability of Final Reaction Mixture
The Beckman Coulter AU analyzer automatically computes every determination at the same time interval.

Calibration
The frequency of calibration for the Serum and Plasma IgG procedure is every 90 days. Calibration of this IgG procedure is accomplished by use of the Serum Protein Multi-Calibrator (Cat # ODR3021), which is traceable to the International Reference Preparation ERM – DA470 (US designation RPPHS lot 91/0619) standard.

The frequency of calibration for the CSF IgG procedure is every 2 days. Calibration of this IgG procedure is accomplished by use of dilutions of level 4 of the Serum Protein Multi-Calibrator (Cat # ODR3021), which is traceable to the International Reference Preparation ERM – DA470 (US designation RPPHS lot 91/0619) standard.

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, 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
Results are automatically printed out for each sample in mg/dL. For S.I. units (g/L) the results must be multiplied by 0.01.

Dynamic Range
The Serum/Plasma IgG procedure is linear from 75 mg/dL to 3000 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.

The CSF IgG procedure is linear from 2 mg/dL to 50 mg/dL. Certain abnormal samples, such as those from myeloma patients, may give abnormally low or normal results due to the slow reaction of the abnormal protein with the antibody. Specimens suspected as such should be diluted with physiological saline and retested.

For CSF samples a prozone or hook effect may occur with highly elevated IgG samples (> 6,000 mg/dL polyclonal).

Expected Values

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum:</td>
<td>635 - 1741 mg/dL</td>
</tr>
<tr>
<td>CSF:</td>
<td>15 – 20 y</td>
</tr>
<tr>
<td></td>
<td>21 – 40 y</td>
</tr>
<tr>
<td></td>
<td>41 – 60 y</td>
</tr>
</tbody>
</table>

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 IgG reagent on Beckman Coulter AU analyzers according to established procedures. Results obtained in individual laboratories may differ.

Serum Plasma Application

Limit of Quantitation
The Limit of Quantitation (LoQ) for the IgG assay was determined to be less than 75 mg/dL using a within laboratory CV of 20%. This was determined using a method based on the CLSI protocol EP17A.

Precision Estimates of precision, based on CLSI recommendations are consistent with typical performance. The repeatability (within run precision) is less than or equal to 3.5% CV and the within laboratory (total) precision is less than 6% CV. Assays of serum pools and control sera were performed and the data reduced following CLSI guidelines above.
**Method Comparison**

Patient samples were used to compare this IgG Reagent. The table below demonstrates representative performance on AU analyzers.

<table>
<thead>
<tr>
<th>N = 80</th>
<th>Repeatability (Within Run)</th>
<th>Within Laboratory (Total)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean, mg/dL</td>
<td>SD</td>
<td>CV%</td>
</tr>
<tr>
<td>431</td>
<td>5</td>
<td>1.14</td>
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<tr>
<td>1088</td>
<td>16</td>
<td>1.45</td>
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<tr>
<td>2173</td>
<td>49</td>
<td>2.24</td>
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</table>

**CSF Application**

**Limit of Quantitation**

The Limit of Quantitation (LOQ) for the CSF IgG assay was determined to be less than 2 mg/dL using a within laboratory CV of 20%. This was determined using a method based on the CLSI protocol EP17A.

**Precision**

Estimates of precision, based on CLSI recommendations, are consistent with typical performance. The repeatability (within run precision) is less than or equal to 6% CV or 0.4 mg/dL and the within laboratory (total) precision is less than 7.5% CV or 0.5 mg/dL. Assays of serum pools and control sera were performed and the data reduced following CLSI guidelines above.

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<th>Within Laboratory (Total)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean, mg/dL</td>
<td>SD</td>
<td>CV%</td>
</tr>
<tr>
<td>3.5</td>
<td>0.1</td>
<td>2.68</td>
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<tr>
<td>10.1</td>
<td>0.1</td>
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<tr>
<td>35.6</td>
<td>0.3</td>
<td>0.93</td>
</tr>
</tbody>
</table>

**References**

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

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

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The table below demonstrates representative performance on AU analyzers.

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<tbody>
<tr>
<td>Y Method</td>
</tr>
<tr>
<td>X Method</td>
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<tr>
<td>Slope</td>
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<tr>
<td>Intercept</td>
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<tr>
<td>Correlation Coeff. (r)</td>
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<tr>
<td>No. of Samples (n)</td>
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<tr>
<td>Range (mg/dL)</td>
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