**MAGLUMI IgG (CLIA)**

1. **INTENDED USE**
   The kit has been designed for the quantitative determination of Immunoglobulin G (IgG) in human serum. The method can be used for samples over the range of 0-40000 μg/ml. The test has to be performed on the Maglumi fully auto analyzer (Including Maglumi 1000, Maglumi 2000, Maglumi 2000 plus).

2. **SUMMARY AND EXPLANATION OF THE TEST**
   IgG is the major antibody containing protein fraction of blood. With significant decreases in IgG level, on either a congenital or acquired basis, there is an increased susceptibility to infectious processes ordinarily dealt with by humoral antibody (ie, bacterial infection). Thus, patients with repeated infection should have their immunoglobulins, and specifically IgG, measured. Therapy with exogenous gamma globulins may be efficacious in such patients. Conversely, IgG levels will be increased in immunocompetent individuals responding to a wide variety of infections or inflammatory insults (indeed, this represents the basis of the serologic diagnosis of infectious diseases). IgG specific antibody can now be demonstrated for numerous organisms, and when coupled with IgM specific antibody, can give an accurate diagnosis of acute or chronic infection. Today, a major cause for a polyclonal increase in IgG is the acquired immunodeficiency syndrome. Monoclonal IgG can be demonstrated in many cases of multiple myeloma. 3 g/dl of monoclonal IgG is a major diagnostic criterion for myeloma. Oligoclonal IgG can be seen in multiple sclerosis and some chronic hepatitides.

   A monoclonal gammapathy may be present when the total IgG value is in the normal range. While many of these patients do not have multiple myeloma, evaluation of these patients for evaluation of the gammapathy and the presence of Bence Jones protein in urine is important.

3. **PRINCIPLE OF THE TEST**
   Competitive immunoluminometric assay: Use an anti-IgG polyclonal antibody to label ABEI, and use purified IgG antigen to label FITC. Sample, Calibrator, or Control, ABEI Label, FITC Label and magnetic microbeads coated with anti-FITC are mixed thoroughly and incubated at 37°C, forming antibody-antigen complexes; after sediment in a magnetic field, decant the supernatant, then cycle washing for 1 time. Subsequently, the starter reagents are added and a flash chemiluminescent reaction is initiated. The light signal is measured by a photomultiplier as RLU within 3 seconds and is proportional to the concentration of IgG present in controls or samples.

4. **KIT COMPONENTS**
   4.1 Material supplies
   **Reagent Integral for 100 determinations**

<table>
<thead>
<tr>
<th>Component</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nano magnetic microbeads: TRIS buffer, 1.2%(W/V)</td>
<td>12.5ml</td>
</tr>
<tr>
<td>0.2%NaN₃ coated with sheep anti- FITC polyclonal antibody.</td>
<td>2.5ml</td>
</tr>
<tr>
<td>Calibrator low</td>
<td>2.5ml</td>
</tr>
<tr>
<td>Calibrator high</td>
<td>2.5ml</td>
</tr>
<tr>
<td>ABEI Label: anti-IgG monoclonal antibody labeled ABEI, contains BSA, 0.2%NaN₃.</td>
<td>6.5ml</td>
</tr>
<tr>
<td>FITC Label: anti-IgG monoclonal antibody labeled FITC, contains BSA, 0.2%NaN₃.</td>
<td>6.5ml</td>
</tr>
<tr>
<td>Diluent</td>
<td>25ml</td>
</tr>
</tbody>
</table>

   All reagents are provided ready-to-use.

   *Please prepare 0.9% sodium chloride solution in case of insufficient diluents.

   **Accessories required but not provided**

   - Maglumi Reaction module
   - Maglumi Starter kit 1+2
   - Maglumi Light check
   - Maglumi Wash/System Liquid

4.2 Preparation of the Reagent Integral
   Before the sealing is removed, gentle and careful horizontal shaking of the Reagent Integral is essential (avoid foam formation)! Remove the sealing and turn the small wheel of the magnetic microbeads compartment to and fro until the colour of the suspension has changed into brown. Place the Integral into the reagent area and let it stand there for 30 mins. During this time, the magnetic microbeads are automatically agitated and completely resuspended.

   **Do not interchange Nano Magnetic Microbeads from different reagents!**

4.3 Storage of the Reagents Integral
   - Sealed: Stored at 2-8°C until the expiry date.
   - Opened: Stable for 4 weeks. After this period, it is still possible to

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**FOR PROFESSIONAL USE ONLY**

Store at 2...8 °C

**COMPLETELY READ THE INSTRUCTIONS BEFORE PROCEEDING**

**SYMBOLS USED ON LABELS**

- **EC**
  - Authorized Representative in Europe

- **REP**
  - Manufacturer

- **CONT**
  - Attention. See Instructions For Use

- **IVD**
  - In vitro diagnostic medical device

- **LOT**
  - (In vitro diagnostic use)

- **REF**
  - Lot number

- **CL**
  - Catalogue Code

- **z**
  - Expiry date (Use by…)

- **℃**
  - Temperature limitation
    - ( store at 2...8 °C)

- **Σ**
  - Number of tests

- **σ**
  - Keep away from sunlight

- **microbeads:**
  - Biological risks

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keep on using the Reagent Integral provided that the controls are found within the expected ranges.
  - Keep upright for storage.
  - Keep away from direct sunlight.

5. Origin of Calibrators.
Calibrators in the Reagent Kit are from Biodesign. Biological root: extracted from human placenta’s blood, processed by SDS PAGE purification with a purity ≥95%, No HbsAg, anti-HCV, and anti-HIV is found.

6. Calibration
6.1 2 point recalibration
Via the measurement of calibrators, the predefined master curve is adjusted (recalibrated) to a new, instrument-specific measurement level with each calibration.

6.2 Frequency of Recalibration
  - After each exchange of lot (Reagent Integral or Starter Reagents).
  - Every week and/or each time a new Integral is used (recommendation).
  - After each servicing of the Maglumi Fully Auto analyzer.
  - If controls are beyond the expected range.

7. Sample Collection, Material and Storage
Collect samples using standard procedures.
Sample material: serum.
Store at 2-8°C: 24 hours.
For longer storage periods: freeze to below -20°C.
Avoid repeated freezing and thawing cycles.
Stored samples should be thoroughly mixed prior to use (Vortex mixer).

8. WARNING AND PRECAUTIONS FOR USERS
  - For use in IN-VITRO diagnostic procedures only.
  - Do not interchange reagents from different lots. Do not use kit components beyond their labelled expiry date.
  - All samples, biological reagents and materials used in the assay must be considered potentially able to transmit infectious agents. They should therefore be disposed of in accordance with the prevailing regulations and guidelines of the agencies holding jurisdiction over the laboratory, and the regulations of each country. Disposable materials must be incinerated; liquid waste must be decontaminated with sodium hypochlorite at a final concentration of 5% for at least half an hour. Any materials to be reused must be autoclaved using an overkill approach (USP 24,2000,p.2143). A minimum of one hour at 121°C is usually considered adequate, though the users must check the effectiveness of their decontamination cycle by initially validating it and routinely using biological indicators.
  - The calibrators in this kit are prepared from bovine serum products. However, because no test method can offer complete assurance that HIV, Hepatitis B Virus or other infectious agents are absent, these reagents should be considered a potential biohazard and handled with the same precautions as applied to any serum or plasma specimen.

9. Test Procedure
To ensure proper test performance, strictly adhere to the operating instructions of the Maglumi Fully Auto Analyzer. Each test parameter is indentified via a barcode on the Reagent Integral. For further information please refer to the Maglumi Fully Auto Operator’s Manual.

10. Quality Control
  - Observe quality control guidelines for medical laboratories.
  - Use suitable controls for in-house quality control.

11. Results
11.1 Calculation of Results
  - The analyzer automatically calculates the IgG concentration in each sample by means of a calibration curve which is generated by a 2-point calibration master curve procedure. The results are expressed in μg/mL. For further information please refer to the Maglumi Fully Auto Operator’s Manual.

11.2 Interpretation of Results
  - Reference values: serum: 5000-17000 μg/mL.
  - Results may differ between laboratories due to variations in population and test method. Each laboratory should establish its own reference range.

12. Limitations of the procedure
12.1 Patients with malignancies may exhibit IgG values within the normal range. IgG concentrations may be elevated in case of liver cirrhosis, hepatitis or tyrosinaemia. Thus, IgG determination is more suitable for therapeutic monitoring and follow-up as well as for a comparison with histological results. IgG serum levels may only be interpreted in context with the clinical picture and other diagnostic procedures. The IgG assay should not be used as the only criterion for cancer screening.

12.2 Precision
Intra-assay coefficient of variation was evaluated on Calibrator High repeatedly measured 10 times in the same assay, calculating their coefficient of variation, the results should <10%.
Inter-assay coefficient of variation was evaluated on three batches of kit, repeatedly measured 10 times of Calibrator High, calculating three batches of kit for Calibrator High between the measured values of the coefficients of variation, the results should <15%.

13. Performance Characteristics
13.1 Accuracy
Consider calibrator high of known concentration as a sample, dilute it by 1:2 ratio with diluent, and measure its diluted concentration for 10 times. Then calculate the recovery of measured concentration and expected concentration. The recovery should be within 90%-110%.

13.2 Precision
Intra-assay coefficient of variation was evaluated on Calibrator High repeatedly measured 10 times in the same assay, calculating their coefficient of variation, the results should <10%.
Inter-assay coefficient of variation was evaluated on three batches of kit, repeatedly measured 10 times of Calibrator High, calculating three batches of kit for Calibrator High between the measured values of the coefficients of variation, the results should <15%.

13.3 Sensitivity
The sensitivity is defined as the concentration of IgG equivalent to the mean RLU of 20 replicates of the zero standard plus two standard deviations corresponding to the concentration from the standard curve. The sensitivity is typically less than 0.3 μg/mL.

13.4 Specificity
The specificity of the IgG assay system was assessed by measuring the apparent response of the assay to various potentially cross reactive analytes. When IgE=320 IU/ml, the detection result of IgG <3 μg/mL; When IgA=40μg/mL, the detection result of IgG <0.4μg/mL; When IgM=40μg/mL, the detection result of IgG <0.4μg/mL.

13.5 Linearity
Conduct a logarithmic transform to the RLU value and concentration value of each standard. After a double logarithmic fitting, the absolute value of its linearity should exceed 0.9800.

14. References
1. Anti-Helicobacter pylori immunoglobulin G (IgG) and IgA antibody responses and the value of clinical presentations in diagnosis of H. Pylori infection in patients with precancerous lesions World Journal of Gastroenterology
2. Detection of H pylori infection by ELISA and Western blot techniques and evaluation of anti CaAga seropositivity in adult Turkish dyspeptic patients World Journal of Gastroenterology