1. INTENDED USE
The kit has been designed for the quantitative determination of Human Insulin Autoantibodies (IAA) in human serum.

The method can be used for samples over the range of 0-175 IU/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
Type 1 diabetes, commonly referred to as insulin-dependent diabetes (IDDM), is caused by pancreatic beta-cell destruction that leads to an absolute insulin deficiency. The clinical onset of diabetes does not occur until 80% to 90% of these cells have been destroyed. Prior to clinical onset, type 1 diabetes is often characterized by circulating autoantibodies against a variety of islet cell antigens, including glutamic acid decarboxylase (GAD), tyrosine phosphatase (IA2), and insulin. The autoimmune destruction of the insulin-producing pancreatic beta cells is thought to be the primary cause of type 1 diabetes.

The presence of these autoantibodies provides early evidence of autoimmune disease activity, and their measurement can be useful in assisting the physician with the prediction, diagnosis, and management of patients with diabetes. Insulin is the only beta-cell specific autoantigen thus far identified.

Antibodies to insulin are found predominantly, though not exclusively, in young children developing type 1 diabetes. In insulin-naïve (untreated) patients, the prevalence of antibodies to insulin is almost 100% in very young individuals and almost absent in adult onset of type 1 diabetes. Because the risk of diabetes is increased with the presence of each additional autoantibody marker, the positive predictive value of insulin antibody measurement is increased when measured in conjunction with antibodies to GAD and IA-2.

3. PRINCIPLE OF THE TEST
Sandwich immunoluminometric assay;
Use purified INSULIN antigen to label FITC, and use mouse anti-human IgG to label ABEI. Sample, Calibrator, Control, FITC label and magnetic microbeads coated with purified INSULIN antigen are mixed thoroughly and incubated at 37 °C and cycle washing for 1 time. Then add ABEI Label, incubation and form a sandwich, then washing for the 2nd 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 IAA present in controls or samples.

4. KIT COMPONENTS
4.1 Material supplies

<table>
<thead>
<tr>
<th>Contents of kit</th>
<th>Volume (ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nano magnetic microbeads: TRIS buffer, 1.2%(W/V), 0.2%NaNO₃, coated with purified INSULIN antigen</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: mouse anti-human IgG labeled ABEI, contains BSA, 0.2%NaNO₃</td>
<td>22.5ml</td>
</tr>
<tr>
<td>FITC Label: purified insulin antigen labeled FITC, contains BSA, 0.2%NaNO₃</td>
<td>12.5ml</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.

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.
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 be <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 be <15%.

13.3 Sensitivity

The sensitivity is defined as the concentration of IAA 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 2 IU/ml.

13.4 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

