MR.GLUCOSE
DIAGNOSTIC KIT
FOR DETERMINATION OF
GLUCOSE CONCENTRATION

Kit name
Mr.GLUCOSE 500
Mr.GLUCOSE 1000
Kit size
5 x 100 ml
1 x 1000 ml
Cat. No.
GB16MR
GB17MR

INTRODUCTION
Glucose is a simple six-carbon sugar. Oxidative metabolism of glucose provides the energy for most cellular processes. Glucose level in the blood is tightly controlled by several hormones. Elevated glucose level is the classic sign of diabetes mellitus. Glucose level abnormalities (hyper- or hypoglycemia) might be caused also by pancreas tumors and diseases of liver, thyroid gland or adrenal Glands.

METHOD PRINCIPLE
Colorimetric, enzymatic method with glucose oxidase.

\[
glucose + H_2O + O_2 \rightarrow \text{gluconic acid} + H_2O_2
\]

\[
2 H_2O_2 + \text{phenol} + 4\text{-aminooantipyrine} \rightarrow 4\text{-}(p\text{-benzochinonomonoimino)}\text{-phenazone} + 4 H_2O
\]

The colour intensity is proportional to the glucose concentration.

REAGENTS
Package
Mr.GLUCOSE 500  Mr.GLUCOSE 1000
R1-GLUCOSE  5 x 100 ml  1 x 1000 ml
R2-STANDARD  1 vial  1 vial

R2-STANDARD is glucose standard solution: Refer standard value mentioned in the vial.

Working reagent preparation and stability
The reagent is ready to use.

Concentrations in the test
- glucose oxidase (GOD) \( \geq 20000 \text{ U/L} \)
- peroxidase (POD) \( \geq 2000 \text{ U/L} \)
- 4 - Hydroxybenzoic acid \( 10 \text{ mmol/L} \)
- Phosphate buffer \( 50 \text{ mmol/L} \)
- Mutarotase \( \geq 1500 \text{ U/L} \)

Warnings and notes
Product for in vitro diagnostic use only.
The reagents are usable when the absorbance of the working reagent is less than 0.300 (read against distilled water, wavelength \( \lambda=500 \text{ nm} \), cuvette l=1 cm, at temp. 25°C).

ADDITIONAL EQUIPMENT
- automatic analyzer or photometer able to read at 500 nm (Hg 546 nm);
- thermostat at 37°C;
- 5% trichloroacetic acid (TCA) for determination of glucose concentration in whole blood;
- General laboratory equipment;

SPECIMEN
Use fresh unhaemolysed serum. The stability of glucose in specimen is reduced by bacterial contamination and by glycolysis. Serum or plasma should be separated from the cells, as soon as possible, to prevent glycolysis. The addition of sodium fluoride is recommended to inhibit glycolysis. Other commonly used anticoagulants with concentration not causing interference are:
- Fluoride - 10 mg/ml blood
- Oxalate - 20 mg/ml blood
- EDTA - 10 mg/ml blood
- Citrate - 30 mg/ml blood
- Heparin - 2 mg/ml blood

PROCEDURE
These reagents may be used both for manual assay and in several automatic analysers. Applications for them are available on request.

Manual procedure - End Point Method
wavelength 500 nm (Hg 546 nm)
temperature 20-25°C / 37°C
cuvette 1 cm

Serum, plasma, cerebrospinal fluid
Pipette into the cuvettes:

<table>
<thead>
<tr>
<th>Standard (S)</th>
<th>Test (T)</th>
<th>Reagent blank (RB)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 µl</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>10 µl</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Mix well, incubate for 10 min. at 37°C or 15 min at 20-25°C. Read the absorbance of the test (T) and standard (S) against reagent blank (RB).

Calculation
\[
\text{glucose concentration} = \frac{A(T)}{A(S)} \times \text{standard concentration}
\]

Manual procedure - Fixed Time Kinetic Method
wavelength 500 nm (Hg 546 nm)
temperature 20-25°C / 37°C
cuvette 1 cm

<table>
<thead>
<tr>
<th>Standard (S)</th>
<th>Test (T)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1000 µl</td>
<td>1000 µl</td>
</tr>
</tbody>
</table>

Mix well and after exactly 60 sec read absorbance A1 of the test (T) and standard (S) against air. After next 60 sec repeat absorbance reading (A2) and calculate \( \Delta A \) for the test and standard.

Calculation
\[
\text{glucose concentration} = \frac{\Delta A}{\Delta A} \times \text{standard concentration}
\]

Mr.GLUCOSE page 1
REFERENCE VALUES

<table>
<thead>
<tr>
<th></th>
<th>mg/dl</th>
<th>mmol/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>serum, plasma</td>
<td>65–110</td>
<td>3.6–6.1</td>
</tr>
<tr>
<td>Cerebrospinal fluid</td>
<td>40–70</td>
<td>2.2–3.9</td>
</tr>
</tbody>
</table>

It is recommended for each laboratory to establish its own reference ranges for local population.

QUALITY CONTROL
To ensure adequate quality control, each run should include assayed normal and abnormal controls. If commercial controls are not available, it is recommended that known value samples be aliquoted, frozen and used as controls.

For Fully Automated analyzers by using multicalibrators or albumin standard, the calibration curve can be plotted and the same should be prepared every 8 weeks or with change of reagent lot number.

PERFORMANCE CHARACTERISTICS

• Sensitivity / Limit of Quantitation: 0.5 mg/dl (0.03 mmol/l).

• Linearity: up to 500 mg/dl (27.5 mmol/l) using automatic analyzers; up to 400 mg/dl (22 mmol/l) for manual procedure. If glucose concentration exceeds the range of linearity, dilute sample with 0.9% NaCl and repeat the assay. Multiply the result by the dilution factor.

• Specificity / Interferences
  Haemoglobin up to 2.5 g/dl, ascorbate up to 62 mg/l, bilirubin up to 20 mg/dl and triglycerides up to 500 mg/dl do not interfere with the test.

WASTE MANAGEMENT
Please refer to local legal requirements.

LITERATURE

SYSTEM PARAMETERS

<table>
<thead>
<tr>
<th>Method</th>
<th>Endpoint</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wavelength</td>
<td>505 nm</td>
</tr>
<tr>
<td>Zero Setting</td>
<td>Reagent Blank</td>
</tr>
<tr>
<td>Temperature Setting</td>
<td>37°C</td>
</tr>
<tr>
<td>Incubation Temperature</td>
<td>37°C</td>
</tr>
<tr>
<td>Incubation Time</td>
<td>10 mins</td>
</tr>
<tr>
<td>Delay time</td>
<td>----</td>
</tr>
<tr>
<td>Read time</td>
<td>----</td>
</tr>
<tr>
<td>No. of Reading</td>
<td>----</td>
</tr>
<tr>
<td>Interval time</td>
<td>----</td>
</tr>
<tr>
<td>Sample Volume</td>
<td>0.01 ml (10 ul)</td>
</tr>
<tr>
<td>Reagent Volume</td>
<td>1.0 ml (1000 ul)</td>
</tr>
<tr>
<td>Standard Concentration</td>
<td>Refer Standard vial</td>
</tr>
<tr>
<td>Units</td>
<td>mg/dl</td>
</tr>
<tr>
<td>Factor</td>
<td>----</td>
</tr>
<tr>
<td>Reaction slope</td>
<td>Increasing</td>
</tr>
<tr>
<td>Linearity</td>
<td>500 mg/dl</td>
</tr>
</tbody>
</table>

Genuine Biosystem
A Genuine Service For better Tommorrow

Corporate Office :
No13, Dhandapani Street, Radha Nagar, Chrompet Chennai - 600 044.
Ph:044 - 4557 4989,

Works : No.87, Gandhi Salai, Alapakkam, Chennai - 600 063.
e-mail: genuinebiosystem@gmail.com
website:www.genuinebiosystem.com