### Intended Use

This reagent is intended for the in vitro diagnostic use in the quantitative determination of glucose in human serum, plasma or urine.

### Clinical Significance

The accurate estimation of glucose is important in the diagnosis and management of hyperglycaemia and hypoglycaemia. Hyperglycaemia may occur as a result of diabetes mellitus, in patients receiving glucose containing fluids intravenously, during severe stress or cerebrovascular accidents. Hypoglycaemia may be the result of an insulinoma, insulin administration, inborn errors of carbohydrate metabolism or fasting. Often in the investigation of these disorders glucose determinations are performed in conjunction with various tolerance tests or stimulation tests. For a more detailed discussion of glucose metabolism the user should refer to a standard text book such as Kaplan.

### Methodology

The glucose oxidase reaction in conjunction with an auxiliary reaction has been widely used for the determination of glucose in biological fluids. Many different auxiliary reactions have been developed in order to improve the overall specificity of the reaction system or retain the inherent specificity of glucose oxidase.

The method utilised in this reagent is based on the hydrogen peroxide indicator reaction which couples 4-aminoantipyrine to a phenolic compound as first proposed by Trinder. This method has been validated in an extensive study by Penneck et al. Pennoch compared Trinder's method with six other common methods and found it highly reliable with respect to both accuracy and precision. The method was further shown by Penneck and Sharp and Szasz et al to be resistant to well known interfering compounds such as uric acid, glutathione and creatinine.

1. Glucose + O₂ + H₂O → Gluconic Acid + H₂O₂
2. H₂O₂ + HBA + 4-AAP → Quinonimine dye + H₂O

### REAGENT COMPOSITION

**Active Ingredients**

| Glucose oxidase | >15 000 U/L |
| Peroxidase | >100 U/L |
| 4-aminoantipyrine | 0.5 mmol/L |
| 4-hydroxybenzoic acid | 10 mmol/L |
| Phosphate buffer | 119 mmol/L |

Also contains non-reactive fillers and stabilizers.

### pH Warning

pH 7.5 ± 0.10 at 20°C

### Stability and Storage

Prior to use:

When stored refrigerated at 2-8°C the reagent is stable until the expiry date stated on the bottle and kit box label.

### Calculation

Results are calculated, usually automatically by the instrument, as follows:

\[
\text{Glucose (mg/dL)} = \frac{\text{Absorbance of Unknown}}{\text{Calibrator Value}} \times \text{Calibrator Value}
\]

**Example:**

Absorbance of calibrator = 0.46
Absorbance of unknown = 0.10
Value of calibrator = 13.2 mmol/L (238 mg/dL)

\[
\text{Glucose} = \frac{0.10}{0.46} \times 13.2 = 2.76 \text{ mmol/L}
\]

\[
\text{Glucose} = \frac{0.10}{0.46} \times 238 = 51 \text{ mg/dL}
\]
For urine specimens the results must be multiplied by the dilution factor and 24 hour collections by the volume in liters.

**Urinary Glucose**

= Glucose Result × Dilution × Volume (L)

(mmol/24 hours) (mmol/L) Factor

**Example:**

Glucose result = 0.7 mmol/L (12.6 mg/dL)

Dilution of Urine = Neat

24 Hour volume of urine = 0.35 Liters

Urine Glucose = 0.7 x 1 x 0.95 = 0.67 mmol/24 hours

Urine Glucose = 12.6 x 1 x 0.95 = 11.97 mg/24 hours

**Notes:**

1. The reagent and sample volumes may be altered proportionally to accommodate different spectrophotometer requirements.
2. Specimens with glucose values above 35 mmol/L (630 mg/dL) should be diluted with isotonic saline and reassayed. Multiply results by the dilution factor.
3. Unit conversion: mmol/L x 18 = mg/dL.
4. Avoid direct sunlight.

**Calibration**

Calibration is required. An aqueous standard or serum based calibrator, with an assigned value traceable to a primary standard (eg NIST or IFCC) is recommended. For calibration frequency on automated instruments, refer to the instrument manufacturers specifications.

However, calibration stability is contingent upon optimum instrument performance and the use of reagents which have been stored as recommended in the stability and storage section of this package insert. Recalibration is recommended at anytime if one of the following events occurs:-

- The lot number of reagent changes.
- Preventative maintenance is performed or a critical component is replaced.
- Control values have shifted or are out of range and a new vial of control does not rectify the problem.

**Quality Control**

To ensure adequate quality control, normal and abnormal control with assayed values for this methodology should be run as unknown samples:-

- At least once per day or as established by the laboratory.
- When a new bottle of reagent is used.
- After preventative maintenance is performed or a critical component is replaced.
- With every calibration.

Control results falling outside the upper or lower limits of the established ranges indicate:

- Repeat the test.
- If repeated control results are outside the limits, prepare fresh control serum and repeat the test.
- If results are still out of control, recalibrate with fresh calibrator, then repeat the test.
- If results are still out of control, perform a calibration with fresh reagent, then repeat the test.
- If results are still out of control, contact Technical Services or your local distributor.

**Limitations**

1. Studies to determine the level of interference from haemoglobin, bilirubin and lipaemia were carried out. The following results were obtained:

- Haemoglobin: No interference from haemoglobin up to 750 mg/dL.
- Bilirubin: No interference from bilirubin up to 770 mmol/L (45 mg/dL).
- Lipaemia: No interference from lipaemia, measured as triglycerides up to 23 mmol/L (2000 mg/dL).

2. For a more comprehensive review of factors affecting glucose assays refer to the publication by Young.12

**Expected Values**

- Fasting serum: 13 4.11 - 5.56 mmol/L (74 - 100 mg/dL)
- Urine: 14 0.06 - 0.83 mmol/L (1 - 15 mg/dL)

For the diagnosis of diabetes, Impaired Fasting Glucose (IFG) or Impaired Glucose Tolerance (IGT) the W.H.O. recommend the following criteria:14

<table>
<thead>
<tr>
<th></th>
<th>Fasting plasma glucose</th>
<th>2 hrs after glucose load</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>IFG</strong></td>
<td>≥7.0 mmol/L (&gt;126 mg/dL)</td>
<td>≥11.1 mmol/L (≥200 mg/dL)</td>
</tr>
<tr>
<td><strong>IGT</strong></td>
<td>≤7.0 mmol/L (&lt;126 mg/dL)</td>
<td></td>
</tr>
</tbody>
</table>

**Performance Data**

The following data was obtained using the Infinity Glucose Oxidase Liquid Stable Reagent on a well maintained automated clinical chemistry analyser. Users should establish product performance on their specific analyser used.

**Imprecision**

Imprecision was evaluated over a period of 20 days using two levels of commercial control and following the NCCLS EP5-T procedure.15

<table>
<thead>
<tr>
<th></th>
<th>LEVEL I</th>
<th>LEVEL II</th>
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</thead>
<tbody>
<tr>
<td>Number of data points</td>
<td>80</td>
<td>80</td>
</tr>
<tr>
<td>Mean (mmol/L / mg/dL)</td>
<td>4.99 / 90</td>
<td>17.31 / 312</td>
</tr>
<tr>
<td>CV (%)</td>
<td>2.4</td>
<td>1.0</td>
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<tr>
<td>Total:</td>
<td>LEVEL I</td>
<td>LEVEL II</td>
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<td>80</td>
</tr>
<tr>
<td>Mean (mmol/L / mg/dL)</td>
<td>4.99 / 90</td>
<td>17.31 / 312</td>
</tr>
<tr>
<td>SD (mmol/L / mg/dL)</td>
<td>0.26 / 4.7</td>
<td>1.01 / 18.2</td>
</tr>
<tr>
<td>CV (%)</td>
<td>5.2</td>
<td>5.8</td>
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</tbody>
</table>

**Linearity**

When run as recommended the assay is linear between 0 and 35 mmol/L (0 - 630 mg/dL).

Linearity on automated instruments may vary from the quoted value. It is recommended that the user refer to the appropriate Themero instrument application for the instrument specific linearity claim.

**Analytical Sensitivity**

When run as recommended the sensitivity of this assay is 0.035 ΔAbs per mmol/L or 0.002 ΔAbs per mg/dL (1 cm light path, 500 nm).

**References**


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**Reorder Information**

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