Liquid Reagent – ready to use

**GLUCOSE**

**GOD-PAP**

Single Reagent

Diagnostic reagent for quantitative in vitro determination of glucose in human serum or plasma on photometric systems

**TEST PRINCIPLE**

In the presence of glucose oxidase, glucose is oxidized to gluconic acid and hydrogen peroxide. Hydrogen peroxide reacts, in the presence of peroxidase, with phenol and 4-aminobipyrine to form a quinoneimine dye (Trinder’s reaction) [3].

\[
\text{Glucose} + O_2 \xrightarrow{\text{GOD}} \text{Gluconic acid} + H_2O_2 \\
2H_2O_2 + \text{Phenol} + 4 \text{Aminoantipyrine} \xrightarrow{\text{POD}} \text{Quinimine} + 4H_2O
\]

The intensity of the pink colour formed is proportional to the glucose concentration.

**TEST PARAMETERS**

Method: Colorimetric, enzymatic, GOD-PAP, endpoint, increasing reaction

Wavelength: 500 nm, Hg 546 nm

Temperature: 20 – 25 °C or 37 °C

Sample: Serum, heparinized or EDTA-plasma,

Linearity: up to 100 mg/dL (5.55 mmol/L)

Sensitivity: The lower limit of detection is 1 mg/dL (0.06 mmol/L).

**REFERENCE RANGE**

Newborns: 36 – 99 mg/dL (2.0 – 5.5 mmol/L)

1 h: 36 – 99 mg/dL (2.0 – 5.5 mmol/L)

2 h: 36 – 89 mg/dL (2.2 – 4.9 mmol/L)

5 – 14 h: 34 – 77 mg/dL (1.9 – 4.3 mmol/L)

10 – 28 h: 46 – 81 mg/dL (2.6 – 4.5 mmol/L)

44 – 52 h: 48 – 79 mg/dL (2.7 – 4.4 mmol/L)

**UNIT CONVERSION**

\[
\text{mmol/L} = \frac{\Delta A \text{Sample}}{\Delta A \text{Std/Cal}} \times \text{Conc. Std/Cal [mg/dL]}
\]

**CALCULATION**

Glucose [mg/dL] = \frac{\Delta A \text{Sample}}{\Delta A \text{Std/Cal}} \times \text{Conc. Std/Cal [mg/dL]}

**STANDARD**

(Not included in the kit – has to be ordered separately)

Concentration: 100 mg/dL (5.55 mmol/L)

Storage: 2 – 25 °C

Stability: up to the expiration date

Close immediately after use! Avoid contamination!

**MANUAL TEST PROCEDURE**

Bring reagents and samples to room temperature.

Pipette into test tubes Blank Std./Cal. Sample

Reagent 1000 µL 1000 µL 1000 µL

Sample - - 10 µL

Standard/Calibrator - 10 µL -

Dist water - 10 µL -

Mix. Incubate 10 minutes at 37 °C or 20 minutes at 20 – 25 °C. Read absorbance of sample and Std./Cal. within 60 minutes against reagent blank.

**SUMMARY**

Measurement of glucose concentration in serum or plasma is mainly used in diagnosis and monitoring of treatment in diabetes mellitus. Other applications are the detection of neonatal hypoglycaemia, the exclusion of pancreatic islet cell carcinoma as well as the evaluation of carbohydrate metabolism in various diseases.

**REAGENT STABILITY AND STORAGE**

The reagent is ready to use.

**REAGENT COMPOSITION**

**COMPONENTS**

**CONCENTRATIONS**

Phosphate Buffer, pH 7.5 250 mmol/L

Phenol 5 mmol/L

4-Aminoantipyrine 0.5 mmol/L

Glucose Oxidase (GOD) ≥ 10 KU/L

Peroxidase (POD) ≥ 1 KU/L

**REFERENCE RANGE**

[1] *
**Children (fasting):**

<table>
<thead>
<tr>
<th>Age</th>
<th>mg/dL</th>
<th>mmol/L</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 – 6 years</td>
<td>74 – 127</td>
<td>4.1 – 7.0</td>
</tr>
<tr>
<td>7 – 19 years</td>
<td>70 – 106</td>
<td>3.9 – 5.9</td>
</tr>
</tbody>
</table>

**Adults (fasting):**

<table>
<thead>
<tr>
<th>Sample</th>
<th>mg/dL</th>
<th>mmol/L</th>
</tr>
</thead>
<tbody>
<tr>
<td>serum / plasma</td>
<td>70 – 115</td>
<td>3.9 – 6.4</td>
</tr>
</tbody>
</table>

*Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.*

**PERFORMANCE CHARACTERISTICS**

**LINEARITY, MEASURING RANGE**

The test has been developed to determine glucose concentrations within a measuring range from 1 – 400 mg/dL (0.06 – 22.2 mmol/L). If values exceed this range, samples should be diluted 1+4 with NaCl solution (9 g/L) and the result multiplied by 5.

**SENSITIVITY/LIMIT OF DETECTION**

The lower limit of detection is 1 mg/dL (0.06 mmol/L).

**PRECISION (at 37°C)**

<table>
<thead>
<tr>
<th>Intra-assay n = 20</th>
<th>Mean [mg/dL]</th>
<th>SD [mg/dL]</th>
<th>CV [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>64.2</td>
<td>1.12</td>
<td>1.74</td>
</tr>
<tr>
<td>Sample 2</td>
<td>122</td>
<td>1.57</td>
<td>1.28</td>
</tr>
<tr>
<td>Sample 3</td>
<td>296</td>
<td>4.41</td>
<td>1.49</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>from day to day n = 20</th>
<th>Mean [mg/dL]</th>
<th>SD [mg/dL]</th>
<th>CV [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>92.5</td>
<td>1.10</td>
<td>1.19</td>
</tr>
<tr>
<td>Sample 2</td>
<td>121</td>
<td>1.02</td>
<td>2.01</td>
</tr>
<tr>
<td>Sample 3</td>
<td>292</td>
<td>2.01</td>
<td>0.69</td>
</tr>
</tbody>
</table>

**SPECIFICITY/INTERFERENCES**

No interference up to:

- ascorbic acid 15 mg/dL
- bilirubin 40 mg/dL
- hemoglobin 200 mg/dL
- triglycerides 2000 mg/dL

For further information on interfering substances refer to Young DS [6].

**METHOD COMPARISON**

A comparison between Dialab Glucose (y) and a commercially available test (x) using 78 samples gave following results: y = 1.00 x + 1.00 mg/dL; r = 0.996.

**CALIBRATION**

The assay requires the use of a Glucose Standard or a Calibrator.

We recommend the Dialab Glucose Standard and the Dialab multi calibration serum Diacal Auto.

The assigned values of the calibrator have been made traceable to the reference method gas chromatography – isotope dilution mass spectrometry (CG-IDMS).

**QUALITY CONTROL**

All control sera with Glucose values determined by this method can be used. We recommend the Dialab serum controls Diacon N (control serum with values in the normal range) and Diacon P (control serum with values in the abnormal range). Each laboratory should establish corrective action in case of deviations in control recovery.

**AUTOMATION**

Special applications for automated analysers can be made on request.

**WARNINGS AND PRECAUTIONS**

1. The reagent contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.

2. In very rare cases, samples of patients with gammopathy might give falsified results [7].

3. N-acetylcysteine (NAC), acetaminophen and metamizole medication leads to falsely low results in patient samples.

4. Please refer to the safety data sheet and take the necessary precautions for the use of laboratory reagents.

5. For diagnostic purposes, the results should always be assessed with the patient’s medical history, clinical examinations and other findings.

6. For professional use only!

**WASTE MANAGEMENT**

Please refer to local legal requirements.

**REFERENCES**


