Glucose GOD FS*

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

Order Information
Cat. No. Kit size
1 2550 99 10 021 R 5 x 25 mL + 1 x 3 mL Standard
1 2550 99 10 026 R 6 x 100 mL
1 2550 99 10 023 R 1 x 1000 mL
1 2500 99 10 030  6 x 3 mL Standard

Summary [1,2]
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 hypoglycemia, the exclusion of pancreatic islet cell carcinoma as well as the evaluation of carbohydrate metabolism in various diseases.

Method
“GOD-PAP”: enzymatic photometric test

Principle
Determination of glucose after enzymatic oxidation by glucose oxidase. The colorimetric indicator is quinoneimine, which is generated from 4-aminoantipyrine and phenol by hydrogen peroxide under the catalytic action of peroxidase (Trinder’s reaction) [3].

Glucose + O₂ → Gluconic acid + H₂O₂
2 H₂O₂ + 4-Aminoantipyrine + Phenol → Quinoneimine + 4 H₂O

Reagents
Components and Concentrations
Reagent: Phosphate buffer pH 7.5 250 mmol/L
Phenol 5 mmol/L
4-Aminoantipyrine 0.5 mmol/L
Glucose oxidase (GOD) ≥ 15 kU/L
Peroxidase (POD) ≥ 1 kU/L
Standard: 100 mg/dL (5.55 mmol/L)

Storage Instructions and Reagent Stability
Reagent and standard are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C, protected from light and contamination is avoided. Do not freeze the reagents!

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 sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient’s medical history, clinical examinations and other findings.
5. For professional use only!

Waste Management
Please refer to local legal requirements.

Reagent Preparation
Reagent and standard are ready to use.

Materials required but not provided
NaCl solution 9 g/L
General laboratory equipment

Specimen
Serum, heparin, plasma or EDTA plasma
Separate at the latest 1h after blood collection from cellular contents.
Stability in plasma after addition of a glycolytic inhibitor (Fluoride, monoiadacetate, mannose) [4]:
2 days at 20 – 25°C
7 days at 4 – 8°C
1 day at -20°C
Stability in serum (separated from cellular contents, hemolysis free) without adding a glycolytic inhibitor [2,5]:
8 h at 25°C
72 h at 4°C
Only freeze once! Discard contaminated specimens.

Assay Procedure
Application sheets for automated systems are available on request.

Wavelength 500 nm, Hg 546 nm
Optical path 1 cm
Temperature 20 – 25°C/37°C
Measurement Against reagent blank

Calculation
With standard or calibrator

Glucose [mg/dL] x 0.05551 = Glucose [mmol/L]

Calibrators and Controls
For calibration of automated photometric systems, DiaSys TruCal U calibrator is recommended. The assigned values of this calibrator have been made traceable to the reference method gas chromatography – isotope dilution mass spectrometry (GC-IDMS). DiaSys TruLab N and P controls should be assayed for internal quality control. Each laboratory should establish corrective action in case of deviations in control recovery.
Performance Characteristics

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). When values exceed this range samples should be diluted 1 + 4 with NaCl solution (9 g/L) and the result multiplied by 5.

Specificity/Interferences
No interference was observed by ascorbic acid up to 15 mg/dL, bilirubin up to 40 mg/dL, hemoglobin up to 200 mg/dL and lipemia up to 2000 mg/dL triglycerides. For further information on interfering substances refer to Young DS [6].

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 precision</th>
<th>Mean [mg/dL]</th>
<th>SD [mg/dL]</th>
<th>CV [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>43.9</td>
<td>0.30</td>
<td>0.67</td>
</tr>
<tr>
<td>Sample 2</td>
<td>89.5</td>
<td>0.72</td>
<td>0.81</td>
</tr>
<tr>
<td>Sample 3</td>
<td>297</td>
<td>2.45</td>
<td>0.82</td>
</tr>
</tbody>
</table>

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<th>SD [mg/dL]</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>45.7</td>
<td>0.40</td>
<td>0.87</td>
</tr>
<tr>
<td>Sample 2</td>
<td>92.3</td>
<td>0.79</td>
<td>0.85</td>
</tr>
<tr>
<td>Sample 3</td>
<td>301</td>
<td>2.09</td>
<td>0.70</td>
</tr>
</tbody>
</table>

Method Comparison
A comparison of DiaSys Glucose FS (y) with a commercially available test (x) using 78 samples gave following results:
\[ y = 1.00 \times x + 1.00 \text{ mg/dL}; r = 0.996 \]

Reference Range [1]

<table>
<thead>
<tr>
<th>Newborns:</th>
<th>[mg/dL]</th>
<th>[mmol/L]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cord blood</td>
<td>63 – 158</td>
<td>3.5 – 8.8</td>
</tr>
<tr>
<td>1 h</td>
<td>36 – 99</td>
<td>2.0 – 5.5</td>
</tr>
<tr>
<td>2 h</td>
<td>36 – 89</td>
<td>2.2 – 4.9</td>
</tr>
<tr>
<td>5 – 14 h</td>
<td>34 – 77</td>
<td>1.9 – 4.3</td>
</tr>
<tr>
<td>10 – 28 h</td>
<td>46 – 81</td>
<td>2.6 – 4.5</td>
</tr>
<tr>
<td>44 – 52 h</td>
<td>48 – 79</td>
<td>2.7 – 4.4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Children (fasting):</th>
<th></th>
<th></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>

<table>
<thead>
<tr>
<th>Adults (fasting):</th>
<th></th>
<th></th>
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</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.

Literature

Manufacturer
DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65559 Holzheim Germany