The glucose level in blood is maintained within a fairly narrow range under diverse conditions (feeding, fasting, or severe exercise) by regulatory hormones such as insulin, glucagon, or epinephrin. Measurement of glucose is one of the most frequently performed procedures in clinical chemistry laboratories in conjunction with other tolerance testing (Glucose tolerance test, Glucose 2h post-prandial...). The most frequently encountered disorder of carbohydrate metabolism in blood is hyperglycemia due to diabetes mellitus. Hyperglycemia higher than 300 mg/dL (16.5 mmol/L) may induce ketoacidosis and hyperosmolar coma.

In prolonged hypoglycemia, lower than 30 mg/dL (1.7 mmol/L), severe irreversible encephalopathic damage may occurs.

### Principle

Trinder Method. Glucose is oxidised by GOD to gluconic acid and hydrogen peroxide which in conjunction with POD, reacts with chloro-4-phenol and PAP to form a red quinoneimine. The absorbance of the coloured complexe, proportional to the concentration of glucose in the specimen is measured at 500 nm.

### Reagents Composition

- **Vial R1**: Phosphate Buffer 150 mmol/L, Glucose oxidase (GOD) > 20 000 UI/L, Peroxidase (POD) > 1000 UI/L, 4-Amino-antipyrine (PAP) 0.8 mmol/L

- **Vial R2**: Chloro-4-phenol 2 mmol/L

- **Vial R3**: Glucose 100 mg/dL (5.55 mmol/L)

### Safety Cautions

- Verify the integrity of the contents before use
- Use adequate protections (overall, gloves, glasses).
- Do not pipette by mouth.
- In case of contact with skin or eyes, thoroughly wash affected areas with plenty of water and seek medical advice.
- Material Safety Data Sheet is available upon request.
- Waste disposal: Respect legislation in force in the country.

All specimens should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions. Respect legislation in force in the country.

### Interferences

- Ascorbic acid: No interference up to 10 mg/dL.
- Total bilirubin: Negative interference above 20 mg/dL.
- Direct bilirubin: No interference.
- Hemolysis: No interference.
- Lipemia: Positive interference above 626 mg/dL of triglycerides.

For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S.

### Material Required but Not Provided

1. Basic medical analysis laboratory equipment.
2. Normal and pathological control sera.

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**Technical Support and Orders**

Tel : (33) 03 23 25 15 50
Fax : (33) 03 23 25 62 56

**CE Marked**

**VIT IN VITRO DIAGNOSTIC USE**

**Made in France**

**Latest revision : www.biolabo.fr**

**Revision : 26/07/2011**
**CALIBRATION**

- Standard enclosed in the Kit (vial R3) or BIOLABO-Multicalibrator REF 95015 traceable to SRM 965a.
- Or any calibrator traceable to a reference method or material. The calibration frequency depends on proper instrument functions and on the preservation of the reagent.

It is recommended to calibrate in the following cases:
1. When changing batch of reagent.
2. After maintenance operations on the instrument.
3. If control values are out of range, even after using a new vial of fresh control.

**QUALITY CONTROL**

- BIOLABO EXATROL-N (level I) REF 95010.
- BIOLABO EXATROL-P (level II) REF 95011.
- Assayed control referring to the same method.
- External quality control program.

It is recommended to control in the following cases:
- At least once a run.
- At least once within 24 hours.
- When changing vial of reagent.
- After maintenance operations on the instrument.

If control is out of range, apply following actions:
1. Repeat the test with the same control.
2. If control is still out of range, prepare a fresh control and repeat the test.
3. If control is still out of range, use a new vial of calibrator or a fresh calibrator and repeat the test.
4. If control is still out of range, use a new vial of reagent.
5. If control is still out of range, please contact BIOLABO technical support or your local Agent.

**EXPECTED VALUES** (2)

<table>
<thead>
<tr>
<th>In serum or plasma</th>
<th>mg/dL</th>
<th>[mmol/L]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Newborn, 1 day</td>
<td>40-60</td>
<td>[2.2-3.3]</td>
</tr>
<tr>
<td>Newborn &gt; 1 day</td>
<td>50-80</td>
<td>[2.8-4.4]</td>
</tr>
<tr>
<td>Children</td>
<td>60-100</td>
<td>[3.3-5.6]</td>
</tr>
<tr>
<td>Adult</td>
<td>74-106</td>
<td>[4.1-5.9]</td>
</tr>
<tr>
<td>60-90 years</td>
<td>82-115</td>
<td>[4.6-6.4]</td>
</tr>
<tr>
<td>&gt; 90 years</td>
<td>75-121</td>
<td>[4.2-6.7]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>In CSF</th>
<th>mg/dL</th>
<th>[mmol/L]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infant, Child</td>
<td>60-80</td>
<td>[3.3-4.4]</td>
</tr>
<tr>
<td>Adult</td>
<td>40-70</td>
<td>[2.2-3.9]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>In 24 h urines</th>
<th>mg/dL</th>
<th>[mmol/L]</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-15 mg/dL, 0.1-0.8 mmol/L</td>
<td>&lt; 0.5 g/24 hours</td>
<td>&lt;2.78 mmol/24 hours</td>
</tr>
</tbody>
</table>

Each laboratory should establish its own normal ranges for the population that it serves.

**PERFORMANCES**

<table>
<thead>
<tr>
<th></th>
<th>Normal level</th>
<th>High level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean mg/dL</td>
<td>81</td>
<td>269</td>
</tr>
<tr>
<td>S.D. mg/dL</td>
<td>1.05</td>
<td>1.80</td>
</tr>
<tr>
<td>C.V. %</td>
<td>1.3</td>
<td>0.67</td>
</tr>
</tbody>
</table>

Detection limit: approximately 10 mg/dL.

Sensitivity for 100 mg/dL: approximately 0.420 Abs at 500 nm.

Comparison with a commercially available reagent:

\[ y = 0.969 \times x + 1.33 \]

\[ r = 0.9964 \]

**LINEARITY**

The reaction is linear up to at least 500 mg/dL (28 mmol/L).

Above, dilute the specimen with saline solution and re-assay taking into account dilution factor to calculate the result. Linearity limit depends on specimen/reagent ratio.

**MANUAL PROCEDURE**

Let stand reagents and specimens at room temperature.

<table>
<thead>
<tr>
<th>Pipette into well identified test tubes :</th>
<th>Blank</th>
<th>Standard</th>
<th>Assay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reagent</td>
<td>1 mL</td>
<td>1 mL</td>
<td>1 mL</td>
</tr>
<tr>
<td>Demineralised water</td>
<td>10 µL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standard</td>
<td></td>
<td>10 µL</td>
<td></td>
</tr>
<tr>
<td>Specimen</td>
<td></td>
<td>10 µL</td>
<td></td>
</tr>
</tbody>
</table>

Mix. Let stand for 10 minutes at 37°C or 20 minutes at room temperature. Read absorbance at 500 nm (460-560) against reagent blank.

Coloration is stable for 15-20 minutes at 37°C, and then slowly decreases.

Note: Specific procedures are available upon request for automated instruments. Please contact BIOLABO technical support.

**CALCULATION**

Calculate the result as follows:

\[ \text{Result} = \frac{\text{Abs (Assay)}}{\text{Abs (Standard)}} \times \text{Standard concentration} \]

**REFERENCES**

(7) SRM : Standard Reference Material ®