**Intended Use**

Enzymatic in vitro test for the quantitative determination of glucose in human serum, plasma, urine and CSF on automated clinical chemistry analyzers.

Please refer to your Package Insert or Operator's Manual for areas not completed.

**Summary**

Carbohydrates supply the body with glucose. Glucose is the most important monosaccharide in the blood; the postprandial concentration is 5 mmol of glucose per liter. Glucose substrate is an indispensable energy supplier which supports cellular function. Glucose degradation occurs in glycolysis. Glucose measurements are used in the diagnosis and monitoring of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia, and pancreatic islet cell carcinoma.

The hexokinase method, based on the work of Schmidt and Peterson and Young, is a recognized reference method.

**Principle**

UV test

- Sample and addition of R1 (buffer/ATP/NADP)
- Addition of R2 (HK/G-6-PDH) and start of reaction:

\[
\text{Glucose} + \text{ATP} \xrightarrow{\text{HK}} \text{G-6-P} + \text{ADP}
\]

Hexokinase catalyzes the phosphorylation of glucose to glucose-6-phosphate by ATP.

\[
\text{G-6-P} + \text{NADP}^+ \xrightarrow{\text{G-6-PDH}} \text{gluconate-6-P} + \text{NADPH} + \text{H}^+
\]

Glucose-6-phosphate dehydrogenase oxidizes glucose-6-phosphate in the presence of NADP to gluconate-6-phosphate. No other carbohydrate is oxidized. The rate of NADPH formation during the reaction is directly proportional to the glucose concentration and can be measured photometrically.

**Specimen Collection and Handling**

Universal Precautions apply.
Collect serum using standard sampling tubes
Heparin or EDTA plasma
Stability (no hemolysis): 8 hours at 15–25°C, 72 hours at 2–8°C.
Fluoride or iodacetate plasma
Stability: 24 hours at room temperature. Separate the sample from the cells (centrifuge) within 30 minutes of collection.

Urine
Fresh random urine: Perform the assay immediately. If the assay cannot be performed immediately, store the samples in a refrigerator. 24-hour urine: Collect the urine in a dark bottle and store on ice. CSF: Perform the assay immediately.

Centrifuge samples containing precipitate before performing the assay.

If testing cannot occur immediately, laboratory protocol is: Store at -70°C
Materials and Equipment Required

Test Instrument: Roche/Hitachi 911

Materials Provided:
Reagents as described in the package insert.

Additional Materials Required (but not provided):
- Calibrators and controls as indicated within the Calibration and Quality sections of this document.
- 0.9% NaCl
- General laboratory equipment

Reagents

R1  Buffer/ATP/NADP
   TRIS buffer: 100 mmol/l, pH 7.8; Mg\(^{2+}\): 4 mmol/l; ATP \(\geq 1.7\) mmol/l; NADP \(\geq 1.0\) mmol/l; preservative

R2  HK/G-6-PDH
   HEPES buffer: 30 mmol/l, pH 7.0; Mg\(^{2+}\): 4 mmol/l; HK \(\geq 8.3\) U/ml (yeast); G-6-PDH \(\geq 15\) U/ml (E.coli); preservative

Storage and Stability

Unopened kit components: Up to the expiration date at 2-8 °C
   R1: 28 days opened and refrigerated on the analyzer.
   R2: 28 days opened and refrigerated on the analyzer.

Supplier(s) for the above materials: Roche

Phone number of the supplier(s): 800-428-2336

Calibration

Standardization: The glucose HK method was standardized against the ID-MS method.
   S1: 0.9% NaCl
   S2: C.f.a.s. (Calibrator for automated systems), Cat. No. 759350

Calibration frequency: Two-point calibration is recommended:
   - after lot change
   - as required following quality control procedures

Calibration verification: Not necessary

Refer to the appropriate calibration section of your Operator's Manual and/or the Package Insert for specific calibration instructions.

Quality Control

For quality control, use Precinorm U, Precinorm U plus, Precipath U, Precipath U plus or other suitable control material.

The control intervals and limits must be adapted to the individual laboratory requirements. Values obtained should fall within established limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits.
If controls do not recover within the specified limits, take the following corrective action. See QC/QA SOP for details on corrective action.

Refer to the appropriate value sheets/Package Insert for additional information.

### Preparation of Working Solutions

R1: Ready for use  
R2: Ready for use

### Assay

Refer to the appropriate operator’s manual and/or the Instrument Settings section of the Package Insert and/or Application Sheet for analyzer-specific assay instructions. The performance of applications not validated by Roche is not warranted and must be defined by the user.

### Interpretation: Reporting Results

Refer to the Package Insert for expected values:

<table>
<thead>
<tr>
<th>Expected Values</th>
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<table>
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<tr>
<th>Critical Values</th>
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<td>( \geq 126 \text{ mg/dL} )</td>
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Protocol to follow if critical value result is obtained:  
Alert physician or study coordinator and document in “Alert Log”.

### Precautions and Warnings

For in vitro diagnostic use  
Exercise the normal precautions required for handling all laboratory reagents.  
Disposal of all waste material should be in accordance with local guidelines.

### Limitations — Interference

Criterion: Recovery within \( \pm 10\% \) of initial values.  
Icterus: No significant interference up to an I index of 60 (approximate conjugated and unconjugated bilirubin concentration:60 mg/dl).  
Hemolysis: No significant interference up to an H index of 1000 (approximate hemoglobin concentration 1000 mg/dl).
Lipemia (Intralipid): No significant interference up to an L index of 1000 (approximate triglycerides concentration 2000 mg/dl). There is poor correlation between turbidity and triglycerides concentration.

NOTE: Glucose values achieved on some proficiency testing materials, when evaluated against a glucose oxidase-oxygen electrode comparison method, demonstrate an approximate 3% positive bias on average.

**Performance Characteristics**

Refer to appropriate Package Insert.

**Contacts:**

**Technical Support:**
Roche Response Center® Customer Technical Support: 1.800.428.2336

**Service:**
Number to call for service: Above

**References**

Glucose HK Package Insert
Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46256
P/N 054400002
Effective Date

Effective date for this procedure: January 3, 2004

Author

Compiled by Roche Diagnostics Corporation

Revised by: Charlie Rhodes

Schedule for Review  (See QC/QA SOP for Signatures)

Last date revised:

Date Reviewed: Approved:

Date Reviewed: Approved:

Date Reviewed: Approved:

Date Reviewed: Approved:

Date Reviewed: Approved:

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