

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
DEVICE ONLY TEMPLATE**

**A. 510(k) Number:**

k041052

**B. Purpose for Submission:**

Modification of previous product (see predicate)

**C. Analyte:**

Glucose

**D. Type of Test:**

Quantitative enzymatic assay

**E. Applicant:**

Hemagen Diagnostics Inc.

**F. Proprietary and Established Names:**

Raichem Glucose UV (liquid)

**G. Regulatory Information:**

1. Regulation section:  
21 CFR §862.1345, Glucose test system
2. Classification:  
Class II
3. Product Code:  
CFR
4. Panel:  
Chemistry (75)

**H. Intended Use:**

1. Indication(s) for use:  
“This reagent is intended for the quantitative enzymatic determination of glucose in serum or plasma. For in vitro diagnostic use only.

This glucose test system is a device intended to measure glucose quantitatively in serum or plasma. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell tumors. The intended patient population may be adult, pediatric, and neonatal..”

2. Special condition for use statement(s):  
This product is for prescription use only.
3. Special instrument Requirements:  
Roche COBAS Mira Chemistry System

**I. Device Description:**

The device consists of two liquid reagents. Reagent 1 contains magnesium, NAD, ATP, buffers, stabilizers, and fillers while Reagent 2 contains glucose-6-phosphate dehydrogenase, hexokinase, buffers, stabilizers, and fillers. The reagents are ready for use.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):  
Roche Reagent for Glucose
2. Predicate K number(s):  
k953847
3. Comparison with predicate:  
The predicate and the proposed assay have in common: the same intended use, the same reaction methodology and test principle, the same matrices (serum or plasma), both are provided in two vials of liquid and ready-to-use, and are used by the same instrument family.

**K. Standard/Guidance Document Referenced (if applicable):**

Area of Study	Reference Procedure	Procedure Title
Method Comparison/ Anticoagulant Studies	NCCLS EP9-A	User Comparison of Quantitative Clinical Laboratory Methods Using Patient Samples
Precision	NCCLS EP5-A	User Evaluation of Precision Performance of Clinical Chemistry Devices
Linearity	NCCLS EP6-A	Evaluation of the Linearity of Quantitative Methods
Interferences/ Cross-Reactivity	NCCLS EP7-A	Interference Testing in Clinical Chemistry
Guidance	FDA (Draft)	"Data for commercialization of original equipment manufacturer, secondary, and generic reagents for automated analyzers, 10 June 1996"

**L. Test Principle:**

Glucose is phosphorylated by hexokinase in the presence of ATP and magnesium to yield glucose-6-phosphate (G-6-P) and adenosine diphosphate (ADP). Glucose-6-

phosphate dehydrogenase oxides G-6-P to 6-Phosphogluconate, with the concurrent reduction of NAD to NADH. NADH absorbs light at 340 nm; thus, the level of glucose is directly proportional to an increase in absorbance at 340 nm.

#### M. Performance Characteristics (if/when applicable):

##### 1. Analytical performance:

###### a. Precision/Reproducibility:

Precision studies were performed according to NCCLS EP5-A guidelines; over 20 days, two runs per day, with two levels of Raichem quality controls tested in duplicate. The sponsor set acceptance criteria as  $\leq 3.3\%$ .

#### Precision of Raichem Glucose Liquid Reagent

Level	Assay Values		Mean (mg/dL)	Within Run		Total Imprecision	
	Min	Max		Std Dev	% CV	Std Dev	% CV
<b>Normal</b>	82	92	87	1.4	1.6	2.0	2.3
<b>Abnormal</b>	294	316	303	3.3	1.1	5.0	1.7

The sponsor tested recovery by assaying two levels of control material in duplicate. Acceptance criteria were based on whether the results were within the specified range of the controls.

#### Control Recovery (mg/dL) by Raichem Glucose Reagent

	Range	Mean Results
Assayed Serum Control 1	76 - 94	84
Assayed Serum Control 2	275 - 336	302

###### b. Linearity/assay reportable range:

NCCLS EP6-A guidelines were used to design this study. A glucose-spiked sample was diluted to span the linear range. All seven dilutions and the zero level (water) were read three times. Recovery was calculated from the assay mean; all recoveries were within the manufacturer's specification of 92.5% to 107.5% of the assigned value of the diluted sample. The data supports the claim of linearity to 800 mg/dL (1200 mg/dL with auto-dilute feature on).

###### c. Traceability (controls, calibrators, or method):

No traceability was provided.

The manufacturer claims that the on-board stability of the assay reagents are 9 days when the rack is used in an uncooled reagent position, and 11 days when the reagents are in the cooled (4°C) compartment. Unopened, refrigerated assay reagents are stable for 18 months.

*d. Detection limit:*

Water was assayed twenty times in a single analytical run. The detection limit is calculated as the mean (or zero if the mean is less than zero) plus two standard deviations of the results. The observed mean and standard deviation was -0.17 and 0.21 mg/dL respectively. Therefore, the detection limit of the assay is 0.42 mg/dL glucose.

*e. Analytical specificity:*

Interference of <10% has been demonstrated from 60 mg/dL bilirubin (conjugated and unconjugated), 1000 mg/dL hemoglobin, or 700 mg/dL triglycerides (as intralipid). Less than 6% difference was observed between normal serum and plasma treated with sodium heparin or EDTA.

*f. Assay cut-off:*

Not applicable.

2. Comparison studies:*a. Method comparison with predicate device:*

Values were obtained from 131 serum samples tested in duplicate on a Cobas MIRA analyzer using the predicate reagent and the Raichem reagent. Samples >800 mg/dL were automatically diluted and re-read. All regression statistics are within the manufacturer's specifications.

**Regression Statistics: Comparison of Raichem and Predicate**

<b>Value</b>	<b>Serum</b>
<b>Intercept</b>	2.89
<b>Slope</b>	1.01
<b>R<sup>2</sup> value</b>	0.997
<b>N</b>	131
<b>Range</b>	9 to 718 mg/dL

*b. Matrix comparison:*

N/A

3. Clinical studies:*a. Clinical sensitivity:*

N/A

*b. Clinical specificity:*

N/A

*c. Other clinical supportive data (when a and b are not applicable):*

N/A

4. Clinical cut-off:  
N/A
5. Expected values/Reference range:  
The conventional fasting reference range for glucose is 74 – 106 mg/dL according to Tietz Textbook of Clinical Chemistry, 5<sup>th</sup> edition 2001:447.

**N. Conclusion:**

The submitted information in this pre-market notification is complete and supports a substantial equivalence decision.