

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

A. 510(k) Number:

k052163

B. Purpose for Submission:

Addition of cerebrospinal fluid as a new matrix

C. Measurand:

Glucose

D. Type of Test:

Quantitative

E. Applicant:

Bayer HealthCare LLC

F. Proprietary and Established Names:

ADVIA IMS® Glucose Assay

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1345 – Glucose test system

2. Classification:

Class II

3. Product code:

CFR – Hexokinase, glucose

4. Panel:

Chemistry (75)

H. Intended Use:

1. Intended use(s):

The Bayer ADVIA IMS® Glucose (GLU) method is for *in vitro* diagnostic use to measure glucose in human serum, plasma, urine, or cerebrospinal fluid. Such measurements are used as an aid in the diagnosis, monitoring and treatment of carbohydrate metabolism disorders, including diabetes mellitus and neonatal hypoglycemia.

2. Indication(s) for use:

The Bayer ADVIA IMS® Glucose method is for *in vitro* diagnostic device for use to measure glucose in human serum, plasma (lithium heparin), urine and cerebrospinal fluid (CSF) on the ADVIA IMS® system. Such measurements are used as an aid in the diagnosis, monitoring and treatment of carbohydrate metabolism disorders including diabetes mellitus and neonatal hypoglycemia.

3. Special conditions for use statement(s):

This device is for prescription use.

4. Special instrument requirements:

ADVIA IMS® system

I. Device Description:

The ADVIA IMS® Glucose Assay is the same as that cleared under K000921. The only change was to allow use of cerebrospinal fluid as a matrix.

The ADVIA IMS Glucose method reagent pack is sufficient for 1250 tests. The reagent pack consists of R1, R2, and DIL 2. R1 is 20.5 mL solution containing adenosine triphosphate and surfactant. R2 contains hexokinase (yeast), glucose-6-phosphate dehydrogenase (*L. mesenteroides*), and nicotinamide adenine dinucleotide, supplied lyophilized. DIL 2 is 21.0 mL of surfactant.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Bayer ADVIA® 1650 Glucose Hexokinase II

2. Predicate 510(k) number(s):

k042015

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Indications for Use	Aid in the diagnosis, monitoring and treatment of carbohydrate metabolism disorders including diabetes mellitus and neonatal hypoglycemia	Same
Specimen	Serum, plasma, urine, and cerebrospinal fluid	Same
Assay Principle	Colorimetric endpoint chemistry utilizing hexokinase and glucose-6-phosphate dehydrogenase	Same

Differences		
Item	Device	Predicate
Instrumentation	ADVIA IMS system	ADVIA 1650 Chemistry system
Assay Range	1-600 mg/dL (0.1-33.3 mmol/L)	0-700 mg/dL (0-38.5 mmol/L)

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

CLSI document EP5- A - Evaluation of Precision Performance of Clinical Chemistry Devices

CLSI document EP9-A – Method Comparison and Bias Estimation Using Patient Samples

L. Test Principle:

The ADVIA IMS Glucose method is a colorimetric endpoint chemistry. The method is based on the combination of hexokinase (HK) and glucose-6-phosphate dehydrogenase (G6PD) for the specific measurement of glucose. HK catalyzes the phosphorylation of glucose using adenosine-5'-triphosphate (ATP). G6PD catalyzes the nicotinamide adenine dinucleotide (NAD)-mediated oxidation of glucose-6-phosphate (G-6-P) to 6-phosphoglucono-δ-lactone (6-PG) with the concomitant production of NADH. The amount of NADH produced is in direct proportion to the

concentration of glucose in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Imprecision was evaluated at specific analyte levels using control materials in a protocol similar to that recommended in CLSI document EP5-A. The controls were tested over 11 days and included 17 runs. The results were as follows:

	N	Mean (mg/dL)	Within Run		Total	
			SD	%CV	SD	%CV
Control 1	64	35.6	0.74	2.1	0.82	2.3
Control 2	65	60.2	1.28	2.1	1.35	2.2

b. *Linearity/assay reportable range:*

The assay range is 1 to 600 mg/dL (0.1 to 33.3 mmol/L). Five samples from individual donors were pooled and divided into two aliquots. One aliquot was spiked with pure glucose to achieve a final concentration of approximately 500 mg/dL. The two aliquots were then codiluted to produce three additional, equally spaced levels. The five samples were then tested in duplicate on the ADVIA IMS. A least squares fit was generated for the first three points. The percent difference between the theoretical line and the actual recovery for the five samples was then determined. The results showed -3.6% to 1.2% deviation from the predicted value for all five samples (observed values: 65-532 mg/dL).

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

The ADVIA IMS Glucose method is traceable to the CDC Reference Method using reference materials from the National Institute of Standards and Technology via patient sample correlation.

Assigned values for calibrators and ranges of Assayed Chemistry Controls are traceable to this standardization.

d. *Detection limit:*

The minimum detectable concentration (sensitivity) is 0.1 mmol/L (1 mg/dL). This is based on 2 times the within-run standard deviation from at least 20 replicates of a sample containing no glucose.

e. Analytical specificity:

Analytical specificity was established in predicate submissions. Also, the sponsor noted that interfering substances are not expected in cerebrospinal fluid samples.

f. Assay cut-off:

See “Detection limit” above.

2. Comparison studies:

a. Method comparison with predicate device:

Correlation was evaluated with human CSF samples in a protocol similar to that recommended in CLSI document EP9-A. A total of 64 samples, with glucose concentrations ranging from 31 to 132 mg/dL (1.7 to 7.3 mmol/L), were tested on both platforms. The regression equation was as follows:

$$y = 0.92 + 2.3 \text{ mg/dL}, r = 0.997, (y = 0.92x + 0.13 \text{ mmol/L}, r = 0.997)$$

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

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

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The expected values/reference range for CSF was determined in the literature: 60

to 80 mg/dL (3.3 to 4.4 mmol/L). The expected values/reference range for serum or plasma is 60 to 121 mg/dL (3.3 to 6.7 mmol/L). The expected values/reference range for urine is < 0.5 g/day (< 2.78 mmol/day).

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.