

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

A. 510(k) Number:

k060470

B. Purpose for Submission:

Change in technology for test strip

C. Measurand:

Glucose

D. Type of Test:

Quantitative, Glucose Dehydrogenase (FAD-GDH)

E. Applicant:

Bayer HealthCare

F. Proprietary and Established Names:

Ascensia® CONTOUR® Blood Glucose Monitoring System (modified test strip)

G. Regulatory Information:

1. Regulation section:

21 CFR §862.1345, Glucose test system

2. Classification:

Class II

3. Product code:

LFR, NBW

4. Panel:

75, Clinical Chemistry

H. Intended Use:

1. Intended use(s):

See indication for Use section below.

2. Indication(s) for use:

The Ascensia® CONTOUR® Blood Glucose Monitoring System is used for the measurement of glucose in whole blood. The Ascensia® CONTOUR® Blood Glucose Monitoring System is an over-the-counter (OTC) device used by persons with diabetes and by healthcare professionals in home settings and in healthcare facilities.

The Ascensia® CONTOUR® Blood Glucose Monitoring System is indicated for use with capillary, venous and arterial whole blood samples. Capillary samples may be drawn from the fingertip, palm, forearm, abdomen and thigh.

The frequent monitoring of blood glucose is an adjunct to the care of persons with diabetes.

3. Special conditions for use statement(s):

For over the counter and prescription use.

Contraindication: Capillary blood glucose testing may not be clinically appropriate for persons with reduced peripheral blood flow. Shock, severe hypotension, hyperosmolar hyperglycemia and severe dehydration are examples of clinical conditions that may adversely affect the measurement of glucose in peripheral blood.

4. Special instrument requirements:

Ascensia CONTOUR Blood Glucose Meter (k023657)

I. Device Description:

The Ascensia® CONTOUR® Blood Glucose Monitoring System consists of the Ascensia CONTOUR Blood Glucose Meter, Ascensia CONTOUR or MICROFILL blood glucose test strips, lancet device, control solutions and instructions for use manual.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Bayer Ascensia Contour Diabetes Care System

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

k023657

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended use	Measures glucose in whole blood by people with diabetes or healthcare professionals	Measures glucose in whole blood by people with diabetes or healthcare professionals
Specimens Types	Capillary, venous or arterial blood	Capillary, venous or arterial blood
Anatomical Sites	Capillary samples from the fingertip, palm, forearm, abdomen and thigh	Capillary samples from the fingertip, palm, forearm, abdomen and thigh
Measuring range	10-600 mg/dL	10-600 mg/dL
Test time	15 seconds	15 seconds
Limitation	Do not use during Xylose absorption testing	Do not use during Xylose absorption testing

Differences		
Item	Device	Predicate
Enzyme Used	FAD-GDH	PQQ-GDH
Limitation	Test strip does not have interference with maltose or icodextrin peritoneal dialysis solution	Test strip has interference problems with maltose and icodextrin peritoneal dialysis solution

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

ISO International Standard 15197

L. Test Principle:

The Ascensia CONTOUR Blood glucose meter measures the electrical current generated from the reaction of glucose with reagents on the electrode of the test strip. Glucose in the blood sample reacts with FAD glucose dehydrogenase and potassium ferricyanide in the test strip, generating electrons that produce a current that is proportional to the glucose in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

The intra assay precision of the device was evaluated by assaying 5 whole blood specimens at different concentrations (50-325 mg/dL) within one run using 10 meters. The results are presented in the table below:

	Level 1	Level 2	Level 3	Level 4	Level 5
N	100	100	100	100	100
Grand Mean (mg/dL)	48	102	126	202	338
Pooled SD	1.4	1.5	1.7	3.0	5.4
Pooled %CV	3.0	1.4	1.3	1.5	1.6
Range %CV	2.5 - 3.5	1.1 – 1.8	0.4 – 2.7	1.1 – 1.9	0.8 – 2.2

Inter assay precision was evaluated by assaying 3 control solutions of different concentrations (30-350 mg/dL) once a day for 10 days using 10 meters. The results are presented in the table below:

	Level 1	Level 2	Level 3
N	100	100	100
Grand Mean (mg/dL)	39	116	356
Pooled SD	0.8	1.5	5.4
Pooled %CV	2.0	1.3	1.5
Range %CV	1.2 – 3.0	0.9 – 1.6	1.0 – 2.0

b. *Linearity/assay reportable range:*

The linearity of the glucose measurements was demonstrated by comparing 92 prepared blood samples on the Ascensia Contour meter and the YSI method. The concentration range of the samples was 10-609 mg/dL. Linear regression of comparison data yielded the following relationship:

$$y = 0.986(x) - 2.0, r^2 = .997$$

The reportable range is 10-600 mg/dL

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

Traceability is referenced to the NIST SRM 917a (dry D-glucose).

d. Detection limit:

The detection limit is 10 mg/dL. See the linearity study in b. above.

e. Analytical specificity:

Interference of the assay was assessed by spiking various endogenous and exogenous compounds into prepared whole blood samples. The sponsor prepared a low whole blood sample at approximately 80 mg/dL and a high whole blood sample at approximately 350 mg/dL. The sponsor then added the interfering substance and ran each sample on the Ascensia Contour meter. The results are presented in the table below:

Substance	Concentration	Sponsor's Allowable Bias
Bilirubin	20 mg/dL	15%
Acetaminophen	20 mg/dL	20%
Uric Acid	15 mg/dL	20%
Ascorbic Acid	5 mg/dL	15%
Maltose	200 mg/dL	7%
Galactose	200 mg/dL	7%

The sponsor presented data that supported using the test system between 10°C to 40°C.

Hematocrit Effect:

The effect of sample hematocrit variation on the Ascensia Contour test system was tested by comparing the glucose result to the hematocrit value obtained both during the laboratory and the clinical study. A laboratory study was conducted to show performance at lower glucose concentrations with different hematocrits. Six blood samples at glucose concentrations between 10-60 mg/dL were adjusted to the following hematocrit levels 40%, 55% and 70% and tested in 72 replicates. The results met the sponsor's acceptance criterion of >95% of readings within ± 15 mg/dL of the reference method. The comparison to the YSI plasma (x) values resulted in the following regression equations:

$$40\% \text{ hematocrit } Y = 0.918(x) - 1.272, r^2 = 0.995$$

$$55\% \text{ hematocrit } Y = 0.875(x) + 0.632, r^2 = 0.994$$

$$70\% \text{ hematocrit } Y = 0.781(x) + 8.665, r^2 = 0.984$$

In another laboratory study, the effect of hematocrit was assessed using three lots of test strips with whole blood at four plasma glucose concentrations of 50, 100, 200 and 400 mg/dL adjusted to three hematocrit levels of 20% 40%

and 60%. The normalized bias from YSI at 40% hematocrit levels is as follows:

20% Hematocrit			60% Hematocrit	
YSI glucose	Modified strip	Bias	Modified strip	Bias
50	55	10%	53	6%
100	110.1	10%	91.2	- 8.8%
200	242.3	21%	165.7	- 17.1%
400	473.3	18%	291.8	- 27.1%

In the lay user study, samples were assayed using the Ascensia Contour modified test strip and compared to the YSI reference method. The glucose concentrations ranged from 53 mg/dL to 489 mg/dL and the hematocrits ranged from 29% to 59%. The data showed that 96.1% of the results were within ± 15 mg/dL or 20% of the laboratory glucose method.

The claimed range for Hematocrit is 20~60%. A limitation is included in the labeling: "At glucose ranges above 200 mg/dL, hematocrit levels above 55% will cause lowered results."

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

Accuracy was based on the ISO International Standard 15197. Acceptable accuracy for results shall be: 95% of the individual results shall fall within ± 15 mg/dL at glucose concentration < 75 mg/dL and within 20% at glucose concentration ≥ 75 mg/dL. One hundred and six (106) capillary blood samples were collected and run on the Ascensia Contour meter and then run on a reference method. Three lots of test strips were tested with each participant; two replicates per lot for a total of 636 fingerstick readings. The sample range was from 58 to 485 mg/dL. Results are shown in the tables below:

Accuracy results for glucose concentration < 75 mg/dL (4.2 mmol/L)

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
11/12 (91.7%)	12/12 (100%)	12/12 (100%)

Accuracy results for glucose concentration ≥ 75 mg/dL (4.2 mmol/L)

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
304/624 (48.7%)	517/624 (82.9%)	609/624 (97.6%)	624/624 (100%)

A linear regression was also performed and has the following results,
 $y = 0.98x - 1.7$, $n=106$.

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):

The consumer study was performed at two POC sites with a total of 205 lay-users. The lay-users ranged in age, education and were equally divided between males and females. Each participant performed their own fingerstick and tested three different lots of the modified test strip. The Healthcare Provider performed testing also on all three test strips. A fingerstick blood sample was collected and measured on an YSI analyzer.

Site	Number of samples	Ascensia vs. YSI	r value	Sample Range (mg/dL)
Combined Lay-User and HCP Results				
1	582	$y = 0.92x + 1.00$	0.954	53 – 460
2	612	$y = 1.00x - 5.55$	0.949	53 - 489

The Parks Error Grid for the combined results is:

	Zone A	Zone B
Lay-User	92.8%	7%
HCP	93.3%	7%

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The labeling provides the following statement: “Standard medical practice goals for a typical non-pregnant individual with diabetes are: fasting glucose 90 -130 mg/dL and post-prandial (2 hours after meals) less than 180 mg/dL.”¹

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.

¹ American Diabetes Association: Standards of Medical Care for Patients with Diabetes Mellitus (position statement). Diabetes Care 2001; 24(7): 1303-04