

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
ASSAY AND INSTRUMENT COMBINATION TEMPLATE**

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

k062058

**B. Purpose for Submission:**

Change in read time, addition of correcting algorithms

**C. Measurand:**

Glucose

**D. Type of Test:**

Whole Blood Glucose Concentration through a Quantitative Amperometric Assay (Glucose Oxidase)

**E. Applicant:**

Bayer HealthCare, LLC.

**F. Proprietary and Established Names:**

Ascensia® CONTOUR ® Blood Glucose Monitoring System

**G. Regulatory Information:**

1. Regulation section:

21 CFR § 862.1345, Glucose Test System

2. Classification:

Class II

3. Product code:

NBW, LFR

4. Panel:

75 (Clinical Chemistry)

**H. Intended Use:**

1. Intended use(s):

See indications for use 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 and neonatal blood samples. Capillary samples may be drawn from the fingertip, palm, forearm, and in the case of neonates, the heel. 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 use and by healthcare professionals
4. Special instrument requirements:  
Ascensia® CONTOUR ® Blood Glucose Monitoring System

**I. Device Description:**

The Ascensia® CONTOUR ® Blood Glucose Monitoring System is used for the measurement of glucose in whole blood. The system contains a blood glucose meter, a bottle of strips, a bottle of normal control solution, a lancing device and lancets, and instructions for use.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):  
Ascensia® CONTOUR ® Diabetes Care System
2. Predicate 510(k) number(s):  
k023657, k060470
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Detection Method	Amperometry	Amperometry
Enzyme	Glucose Dehydrogenase (FAD)	Glucose Dehydrogenase (FAD)
Sample Volume	0.6 µL	0.6 µL
Test Range	10 – 600 mg/dL	10 – 600 mg/dL

Differences		
Item	Device	Predicate
Test Time	5 seconds	15 seconds
Tests Stored in Memory	480	240
Correction factors	Added correcting algorithms	None.

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

ISO 15197: In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.

**L. Test Principle:**

Once a whole blood sample is applied to the sample chamber of the test strip, glucose measurement commences. Glucose measurement is based on electrical potential caused by the reaction of glucose with the reagents contained on the strip's electrodes. The current resulting from this enzymatic reaction is measured and converted to glucose concentration by the meter.

**M. Performance Characteristics (if/when applicable):**1. Analytical performance:a. *Precision/Reproducibility:*

## With-in Run Precision:

Human whole blood samples with hematocrit of 35%-50% were collected in tubes with sodium heparin anticoagulant. Using a 10% aqueous glucose solution, blood samples were prepared within the following ranges prescribed in ISO 15197 section 7.2.2.2:

30-50 mg/dL (*actual value = 41.3 mg/dL*)  
51-110 mg/dL (*actual value = 99.2 mg/dL*)  
111-150 mg/dL (*actual value = 119.5 mg/dL*)  
151-250 mg/dL (*actual value = 200.0 mg/dL*)  
251-400 mg/dL (*actual value = 325.5 mg/dL*)

A total of ten blood glucose meters were used to test one test sensor lot with the above blood samples. One bottle of test sensors was assigned to each instrument at the start of the study. One operator performed all the testing. Ten tests were performed with each blood sample on each instrument. Results are summarized below.

Pooled Statistics for the Shogun System

Level (mg/dL)	Grand Mean (mg/dL)	Pooled Variance	Pooled %CV
40*	38	3.7	4.8
100	101	26.8	5.1
120	118	19.4	3.7
200	205	48.1	3.3
325	326	139.7	3.6

\*Pooled SD=1.9

## Day-to-Day Precision:

One bottle of Ascensia Contour test sensors was assigned to each of ten Ascensia Contour instruments. On each day of ten consecutive working days (no testing on weekends), one test sensor was tested on each instrument with each level of Low, Normal and High Ascensia Microfill control solution. One operator performed all of the testing.

The following summarizes the specific materials used in the study:

Control		
<u>Level</u>	<u>Lot #</u>	<u>Control Ranges</u>
Low	1197	32 – 44 mg/dL
Normal	V99216	99 – 136 mg/dL
High	V99207	288 – 398 mg/dL

Results from the precision evaluation are summarized in the table below.

**Pooled Statistics for the Shogun System**

<b>Control Solution</b>	<b>N</b>	<b>Grand Mean</b>	<b>Pooled Variance</b>	<b>Pooled %CV</b>
Low*	100	40	0.5	1.7
Normal	100	124	2.7	1.3
High	100	368	14.9	1.0

\*Pooled SD=0.7

*b. Linearity/assay reportable range:*

To establish the linearity of the Contour system throughout the entire reportable range of 10 to 600 mg/dL, data from three studies were combined. In one study, blood with 40% hematocrit was adjusted to plasma glucose concentrations of 10, 20, 30, 40, 50, and 60 mg/dL and tested with four Contour lots, n=16 per lot. In a second study, 12 Contour lots were tested with blood adjusted to 50, 120, and 300 mg/dL glucose, n = 24 per lot. In a third study, 10 Contour lots were tested with blood adjusted to 43, 62, 127, 331, and 609 mg/dL, n = 20 per lot. Regression analysis (using the proportionally weighted least-squares model) conducted with the combined lot means from all three studies (N = 110) yields the following statistics:

N	110
Slope	0.987
Intercept	-0.7
r <sup>2</sup>	0.996

*c. Traceability, Stability, Expected values (controls, calibrators, or methods):*  
Traceability is referenced to the NIST SRM 917a (dry D-glucose).

*d. Detection limit:*

10 mg/dL. This level was determined to be detectable by the linearity study (above) and by the hematocrit sensitivity study (see Analytical Specificity below).

*e. Analytical specificity:*

The interference effect of oxidizable substances (acetaminophen, uric acid, ascorbic acid) were tested at the following levels and were found to meet the sponsors acceptance criteria that the bias at the following limiting plasma concentrations be

less than 15%:

Bilirubin: 20 mg/dL

Acetaminophen: 20 mg/dL

Uric Acid: 15 mg/dL

Ascorbic Acid: 5 mg/dL

To verify that the Contour system provides accurate results at the lower end of the reportable range (where actual clinical specimens are rare and clinical trials cannot be expected to provide extensive data), a dose response study was conducted with blood at three hematocrit levels (40%, 55%, and 70%) adjusted to plasma glucose concentrations of 10, 20, 30, 40, 50, and 60 mg/dL. Four Contour lots (SN05M26A, SN06A06C, 6EC3C01 and 6EC3C02) were each tested with eight Contour meters, two replicates per meter, for a total of 16 replicates per lot per sample. Readings were compared to YSI plasma glucose. The sponsor's acceptance criterion was 95% of results within  $\pm 15$  mg/dL of the YSI mean which 100% of the samples met.

Regression statistics are summarized below.

	40% Hematocrit	55% Hematocrit	70% Hematocrit
N	384	384	384
Regression equation	$y = 0.880(x) + 1.1$	$y = 0.788(x) + 10.1$	$y = 0.892(x) + 7.3$
$r^2$	0.985	0.956	0.975

To test the accuracy of the hematocrit correction algorithm, three lots, n = 20 per lot, with blood adjusted to hematocrit levels of 0% (pure plasma), 20%, 35%, 45%, 55%, and 70% at glucose concentrations of 80 and 350 mg/dL were tested. The sponsor's acceptance criteria were a difference between mean at 45% hematocrit (normal) and means at 0% and 70% hematocrit  $< 10\%$  or 7.5 mg/dL. Results are summarized below.

			Hematocrit Effect					
			0% Hct	20% Hct	35% Hct	45% Hct	55% Hct	70% Hct
Percent Deviation from 45% Hct	80 mg/dL	SN05L10C	-1.8%	2.3%	2.2%	0.0%	-1.4%	-2.8%
		SN05L10D	-0.5%	4.1%	4.7%	0.0%	-3.1%	-9.5%
		SN05L15	1.8%	5.4%	6.3%	0.0%	-2.7%	-8.3%
		Mean	-0.2%	3.9%	4.4%	0.0%	-2.4%	-6.8%
	350 mg/dL	SN05L10C	-1.9%	-4.2%	-0.4%	0.0%	0.5%	-4.4%
	SN05L10D	-1.4%	-3.4%	1.0%	0.0%	0.9%	-3.8%	
	SN05L15	0.1%	-2.8%	0.9%	0.0%	1.8%	-3.3%	
	Mean	-1.1%	-3.5%	0.5%	0.0%	1.1%	-3.8%	

To test the accuracy of the hematocrit correction algorithm at higher levels closer to the claimed range, three lots, n = 5 per lot, with blood adjusted to hematocrit levels of 0% (pure plasma), 20%, 45%, 60%, and 70% at glucose concentrations of 450 and

550 mg/dL were tested. The sponsor's acceptance criteria were was a difference between mean at 45% hematocrit (normal) and means at 0% and 70% hematocrit <10% or 7.5 mg/dL. Results are summarized below.

			0% Hct	20% Hct	45% Hct	60% Hct	70% Hct
Percent Deviation from 45% Hct	450 mg/dL	6JC3C07	5.2	2.2	0.0	3.7	2.5
		6JC3C05	2.9	3.9	0.0	2.0	0.3
		6HC3C09	0.9	3.4	0.0	3.2	0.5
		Mean	<b>3.0</b>	<b>3.2</b>	<b>0.0</b>	<b>3.0</b>	<b>1.1</b>
	550 mg/dL	6JC3C07	1.0	-2.8	0.0	3.4	1.3
		6JC3C05	4.8	-0.3	0.0	2.8	-0.3
		6HC3C09	0.1	-1.2	0.0	3.0	-1.1
		Mean	<b>2.0</b>	<b>-1.4</b>	<b>0.0</b>	<b>3.1</b>	<b>-0.1</b>

In addition to testing compounds that are known to interfere with electrochemical glucose monitoring systems (above), testing was also conducted with a variety of common compounds found in medications or food or occurring naturally in the blood. The following substances were tested and found to either have no effect trend at any concentration or to have a limiting concentration (interpolated or extrapolated concentration creating a bias of 15% at either 80 or 300 mg/dL glucose) that was significantly higher than the upper limit of the therapeutic or reference range.

Compound	High Normal / Therapeutic Concentration	Test Levels	Limiting Concentration
Acetone	2 mg/dL	17, 34, 67	N.S.
Acetylsalicylic Acid	2 – 10 mg/dL	8, 17, 34, 67	74 mg/dL
Albumin	3.4 – 5.4 g/L	17, 32, 56 g/L	N.S.
$\beta$ -hydroxybutyric Acid	32 mg/dL	14, 28, 56	N.S.
Caffeine	1.5 mg/dL	1.7, 3.4, 6.7	N.S.
Creatinine	1.5 mg/dL	8, 17, 34	N.S.
Dobutamine	0.07 mg/dL	9, 17, 34	16 mg/dL
Dopamine	0.03 mg/dL	1.1, 2.2, 4.5, 9.0	3.7 mg/dL
Ethanol	300 mg/dL	98, 196, 392	N.S.
Fructose	7 mg/dL	84, 168, 336	N.S.
Gentisic Acid	5.0 mg/dL	28, 56, 112	15 mg/dL
Glipizide	0.8 mg/dL	0.8, 1.7, 3.4	8.4 mg/dL
Glucosamine	30 mg/dL	56, 112, 224	N.S.
Glutathione	68.5 ± 10.7 mg/dL in RBC	35, 70, 140, 280	28.8 mg/dL in plasma
Glyburide	0.4 mg/dL	0.6, 1.1, 2.2	N.S.
Heparin	4000 units/dL	3808, 6048, 10528	N.S.
Ibuprofen	4.2 mg/dL	11, 22, 45	N.S.
L-Dopa	0.3 mg/dL	0.3, 0.7, 1.3	1.9 mg/dL
Metformin	4.0 mg/dL	1.1, 2.2, 4.5	N.S.
Methyldopa	0.75 mg/dL	0.8, 1.7, 3.4	3.6 mg/dL
Naproxen	12 mg/dL	28, 56, 112	208 mg/dL
Precose	6 mg/dL	5.6, 11.2, 22.4	N.S.
Sodium lactate	20 mg/dL	7, 14, 56, 112	N.S.
Sodium salicylate	30 mg/dL	28, 56, 112	41 mg/dL
Sucrose	2.7 mg/dL	5.6, 11.2, 22.4	N.S.
Tetracycline	0.4 mg/dL	1.1, 2.2, 4.5	N.S.
Triglycerides	190 mg/dL	2580, 5160	5070 mg/dL

It was found that the anticoagulant EDTA, especially when occurring at concentrations higher than normal due to under-filling an EDTA tube, is electrochemically active enough to produce a significant negative bias. For this reason, EDTA tubes will be restricted in the Limitations section of the labeling.

To investigate the effect of altitude on the system, three lots of reagent were tested across eight (8) meters both inside and outside a hypoxic chamber simulating an altitude of 12,095 feet. A maximum of three (3) repetitions on each meter were performed (n=24). Time limitations in some cases allowed for only two (2) repetitions on each meter (n=16). Whole blood samples with plasma glucose values of 50, 100, and 400 mg/dL were tested in the above manner, at both 40% and 60% hematocrits. The acceptance criteria defined by the sponsor was <10% difference between means in the low oxygen chamber and means outside the chamber. No systematic response to altitude is seen at either Hematocrit level, and percent bias at all levels was found to be less than 10%. Therefore the system is not significantly affected by lack of atmospheric oxygen up to 12,000 feet above sea level.

- f. *Assay cut-off:*  
Not Applicable.

2. Comparison studies:

a. *Method comparison with predicate device:*

Fingerstick testing was conducted in two four-day studies. Data collected in four separate studies with contrived blood specimens were also used in order to bring the distribution of samples into compliance with the protocol:

Distribution of Plasma Glucose Values							
Glucose Range (mg/dL)	<50	50 - 80	81 - 120	121 - 200	201 - 300	301 - 400	>400
% of Samples	5%	15%	20%	30%	15%	10%	5%

Each specimen was tested with three Contour lots, n = 2 per lot for a total of six readings per specimen. After filling each bin in the ISO distribution, no additional specimens falling in that bin were included in the analysis. A total of 105 diabetic volunteers participated in the two fingerstick studies after giving informed consent, and of these donors, 74 met the distribution requirements. Since no diabetic subjects presented with extremely low or high blood glucose concentrations in either of the two fingerstick studies, readings from contrived samples were used to fill the extreme bins. Low glucose specimens were obtained from a dose response study designed to simulate neonatal specimens. In this study, blood was adjusted to glucose concentrations between 10 and 60 mg/dL. To fill the lowest bin, the five lower levels (11.4, 20.5, 30.7, 40.6, and 49.8) were used (taking the two replicates generated with the first meter used with each lot). To help fill the second lowest bin, three samples at the 60 mg/dL level, each with a different hematocrit (40%, 55%, and 70%) were used. Data from a second study was used to obtain two samples at 63 mg/dL (two testers), four samples at 301 mg/dL (two testers, two meters per tester), two samples at 405 mg/dL (two testers), and one sample at 503 mg/dL. Data from a third study was used to obtain two samples at 51 mg/dL (two meters), two samples at 79 mg/dL (two meters), and one sample at 201, 301, 404, and 554 mg/dL. A fourth study was used to obtain one sample at 300 mg/dL.

A total of 13 lots were represented in the studies. The following table summarizes the distribution of specimens and lots in each study.

<b>Study</b>	<b>Lots*</b>	<50	50 – 80	81 – 120	121 – 200	201 – 300	301 – 400	>400
Fingerstick Study 1	A, B, C	0	3	11	29	7	4	0
Fingerstick Study 2	A, D, E	0	3	9	1	6	1	0
Contrived Blood Study 1	A, F, G	5	3	0	0	0	0	0
Contrived Blood Study 2	A, D, E	0	2	0	0	0	4	3
Contrived Blood Study 3	H, I, J	0	4	0	0	1	1	2
Contrived Blood Study 4	K, L, M	0	0	0	0	1	0	0
	<b>Total</b>	5	15	20	30	15	10	5

\* A: SN05M26A; B: SN05M26B; C: SN06A30A; D: 6FC3B01; E: 6FC3B02; F: 6EC3C01; G: 6EC3C02; H: SN06A17D; I: SN06A17E; J: SN06A17F; K: SN06A06C; L: SN06A06D; M: SN0617A

Contrived specimens were prepared with heparinized venous blood that was allowed to glycolyze to produce low glucose levels or that were supplemented with 20% glucose stock solution to produce high glucose levels. For fingerstick comparison readings, approximately 200 µL of fingerstick blood was collected into a heparinized micro-collection tube. To obtain comparison glucose values, all specimens were centrifuged to separate the plasma from the blood cells, and the plasma portion was tested on the YSI STAT Plus Glucose Analyzer. Plasma glucose levels ranged from 11 to 554 mg/dL. Hematocrit levels ranged from 26% to 70%. The tables below include the proportionally weighted regression statistics and the percentage of readings within several error limits around the YSI plasma glucose comparison values ( $\pm 5$ , 10, 15, and 20 mg/dL for samples  $< 75$  mg/dL,  $\pm 5\%$ , 10%, 15%, and 20% for samples  $\geq 75$  mg/dL).

Contour vs. YSI Plasma  
*Regression Equations*  
*(Proportionally Weighted Least Squares Model)*

Regression	$y = 1.002(x) - 1.1$
95% CI of Slope	0.994 to 1.010
95% CI of Intercept	-1.48 to -0.72
$S_{yx}$ (proportional to YSI)	7.25%

*Bias at Key Glucose Levels*

Plasma Glucose	60 mg/dL	126 mg/dL	200 mg/dL	400 mg/dL
%Bias	-1.6%	-0.7%	-0.3%	-0.1%

Contour Accuracy Assessment (ISO 15197 Section 7.4)  
Contour vs. YSI Plasma

*Accuracy Results for Glucose Concentration < 75 mg/dL*

N	Within $\pm 5$ mg/dL	Within $\pm 10$ mg/dL	Within $\pm 15$ mg/dL	Within $\pm 20$ mg/dL
108	87 (80.6%)	108 (100%)	108 (100%)	108 (100%)

*Accuracy Results for Glucose Concentrations  $\geq 75$  mg/dL*

N	Within $\pm 5$ %	Within $\pm 10$ %	Within $\pm 15$ %	Within $\pm 20$ %
492	261 (53.0%)	413 (83.9%)	467 (94.9%)	488 (99.2%)

*Summary Assessment of Accuracy*

Readings within ISO Minimum Acceptable Performance Criterion  
 $(\pm 15 \text{ mg/dL if } < 75 \text{ mg/dL, } \pm 20\% \text{ if } \geq 75 \text{ mg/dL})$

596 of 600 (99.3%)

The ISO 15197 standard specifies that at least 95% of readings should fall within  $\pm 20\%$  of the standing comparison method for levels  $\geq 75$  mg/dL and within  $\pm 15$  mg/dL for levels  $< 75$  mg/dL, and this limit is highlighted in all plots. The system meets the ISO 15197 criterion of at least 95% of readings falling within  $\pm 20\%$  (or  $\pm 15$  mg/dL at levels below 75 mg/dL) of the sponsor's comparative method, the YSI Stat Plus Glucose Analyzer.

*b. Matrix comparison:*

See Method Comparison section above.

*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):*

Capillary Blood

Performance of the blood glucose monitoring system with capillary blood specimens and an assessment of the User Guide and Quick Reference Guide to show how well untrained subjects could perform a fingerstick, obtain an accurate blood glucose measurement, and perform control solution assays was examined at one site by 109

subjects with diabetes. Health care professionals (HCP) tested in parallel. Meters referenced to whole blood and plasma laboratory glucose and three test strip lots were used. The blood glucose results obtained with the system by the subjects and health care professionals were compared to laboratory glucose results using linear regression and are summarized below.

Capillary Fingerstick vs. YSI		
	glucose range 75-397 mg/dL hematocrit: 31-59%	
	Lay User	HCP
N	108	108
Slope	0.9585	0.9479
y-intercept	3.7876	6.4176
r <sup>2</sup>	0.9661	0.9674

### Alternate Site Testing

For alternate site testing, the average of two fingertip test results with the system was used as the comparative method for all alternative site lancing results. A hematocrit determination for each subject was performed from fingertip blood. Results using linear regression are summarized below:

AST vs. Fingerstick		
	Palm	Forearm
glucose range:	41-374 mg/dL	39-394 mg/dL
hematocrit:	31-53%	31-53%
N	50	47
Slope	0.9993	1.0126
y-intercept	2.5104	-7.8537
r <sup>2</sup>	0.9721	0.9497

### Neonatal Blood

Performance of the system with neonatal blood specimens was examined by health care professionals (HCP) at 2 sites using blood samples from 124 subjects (for the regression calculation 2 samples were removed as outliers meeting the NCCLS guideline for outliers: Method Comparison and Bias Estimation Using Patient Samples (EP9-A)). Three test strip lots were used. The blood glucose results obtained with the system were compared to laboratory glucose results. Results using linear regression are summarized below:

Neonatal vs. YSI	
glucose range: 27-131 mg/dL	
hematocrit: 27-70%	
N	122
Slope	1.0065
y-intercept	-0.0522
r <sup>2</sup>	0.8952

The sponsor also demonstrated that these results met the ISO accuracy criteria of 95% of the meter results for all lots falling within  $\pm 15$  mg/dL for samples < 75 mg/dL and within  $\pm 20\%$  for specimens > 75 mg/dL of a laboratory reference method. Results are summarized in the tables below.

#### AGREEMENT OF NURSERY SAMPLES TO THE SITE LABORATORY GLUCOSE METHODS

Test Strip Lot	Meter Reference	Results Within Given Limits of the Laboratory Glucose Method		
		$\pm 7.5 \text{ mg/dL}$ or 10%	$\pm 15 \text{ mg/dL}$ or 20%	$\pm 22.5 \text{ mg/dL}$ or 30%
05M26A	Plasma	79.5% (35/44)	97.7% (43/44)	97.7% (43/44)
05M26B	Plasma	73.8% (31/42)	97.6% (41/42)	97.6% (41/42)
06A30A	Plasma	71.1% (27/38)	89.5% (34/38)	100% (38/38)
Combined	Plasma	75.0% (93/124)	97.6% (121/124)	98.4% (122/124)

Thirty-two samples were obtained (based on the average of the laboratory analyzer results) ranging from 10-50 mg/dL. The table below shows that the Contour system's accuracy is adequate for samples ranging from 10-50 mg/dL, meeting ISO accuracy criteria of 95% of the meter results for all lots falling within  $\pm 15$  mg/dL for samples < 75 mg/dL and within  $\pm 20\%$  for specimens > 75 mg/dL of a laboratory reference method.

#### AGREEMENT OF NURSERY SAMPLES TO THE SITE LABORATORY GLUCOSE METHODS - Specimens 10 to 50 mg/dL

Test Strip Lot	Meter Reference	Results Within Given Limits of the Comparative Glucose Method		
		$\pm 7.5 \text{ mg/dL}$ or 10% <sup>a</sup>	$\pm 15 \text{ mg/dL}$ or 20% <sup>b</sup>	$\pm 22.5 \text{ mg/dL}$ or 30% <sup>c</sup>
Combined	Plasma	68.8% (22/32)	96.9% (31/32)	96.9% (31/32)

The Contour's meter bias was compared to the hematocrit level for each blood specimen. Correlation coefficients were determined using linear regression shown in the table below.

### ASSOCIATION RESULTS FOR METER BIAS VS. SPECIMEN HEMATOCRIT LEVEL

<u>Plasma or WB</u>	<u>Strip Lot</u>	<u>Site</u>	<u>N</u>	<u>Slope</u>	<u>Slope 95% C.I.</u>	<u>Intercept (mg/dL)</u>	<u>Intercept 95% C.I.</u>	<u>Sy.x</u>	<u>Correlation Coefficient</u>
Plasma	All lots	1&2	122	0.44	0.14 to 0.73	-21.76	-37.4 to -6.12	11.47	0.255

Since the sponsor's neonatal clinical samples did not cover the claimed range of the meter, contrived samples were used to test the low and high ranges at high levels of Hematocrit. These studies are found in the above in the Analytical Specificity section.

#### Venous Blood

Performance of the system with venous blood specimens was examined at one site by a medical technologist who measured the glucose in 169 samples. Venous blood samples were collected into tubes containing heparin. The material assayed in this study consisted of excess volume that remained after routine laboratory blood work had been completed. Plasma and whole blood referenced meters and three test strip lots were used. The glucose concentration in the samples was adjusted, as necessary, to span the operating range of the system. Results were compared to glucose results obtained at the site with a laboratory analyzer. Results using linear regression are summarized below:

Venous Blood vs. YSI	
glucose range: 12-609 mg/dL	
hematocrit: 15-53%	
N	169
Slope	0.8927
y-intercept	3.614
r <sup>2</sup>	0.9884

The bias of results is within the ISO accuracy limits of  $\pm 15$  mg/dL or 20% of the laboratory glucose method. The results are shown below.

Median Differences From The Laboratory Method		
Lot	<75 mg/dL (n=26)	$\geq 75$ mg/dL (n=143)
05M26A	-2.0 mg/dL	-7.4%
05M26B	-2.0 mg/dL	-8.3%
06A30A	-3.0 mg/dL	-11.0%

4. Clinical cut-off:  
Not Applicable.

5. Expected values/Reference range:

The sponsor included the following Expected Values for normal glucose levels in their meter's user manual:

Status	Range (mg/dL)
Before meals	90-130
2 hours after meals	<180

American Diabetes Association: Standards of Medical Care in Diabetes (Position Statement). Diabetes Care 29 (Suppl. 1):S10, 2006.

**N. Instrument Name:**

Ascensia® CONTOUR ® Blood Glucose Monitoring System

**O. System Descriptions:**

1. Modes of Operation:

Each test strip is single use and must be replaced with a new strip for additional readings.

2. Software:

FDA reviewed applicant's Hazard Analysis and software development processes for this line of product types in k023657 and updated functions in this submission.

3. Specimen Identification:

There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

4. Specimen Sampling and Handling:

This device is intended to be used with capillary whole blood from the finger, the palm, or the forearm only. Since the whole blood sample is applied directly to the test strip there are no special handling or storage issues.

5. Calibration:

Calibration of the meter occurs by insertion of the test strip and the meter's recognition of the strip configuration.

6. Quality Control:

The sponsor provides a glucose control solution with the test strips. The meter recognizes the sample as a control solution which prevents control results from being stored in the internal memory. An acceptable range for each control level is printed on the test strip vial label and box. The user is referred to the troubleshooting section of the owner's manual if control results fall outside these ranges.

**P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:**

None.

**Q. Proposed Labeling:**

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

**R. Conclusion:**

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