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

A. 510(k) Number:

k121679

B. Purpose for Submission:

New device – New glucose test strips with a modified GDH-PQQ methodology that has reduced reactivity to maltose

C. Measurand:

Venous, arterial, neonatal heelstick, and capillary whole blood glucose from the fingertip

D. Type of Test:

Quantitative amperometric assay, glucose dehydrogenase (mutant GDH- PQQ)

E. Applicant:

Roche Diagnostics Corporation

F. Proprietary and Established Names:

ACCU-CHEK Inform II Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:
   21 CFR 862.1345, Glucose test system
   21 CFR 862.1660, Quality control material

2. Classification:
   Class II
   Class I (reserved)

3. Product code:
   NBW, System, Test, Blood Glucose, Over the Counter
   LFR, Glucose Dehydrogenase, Glucose
   JJX, Single (specified) analyte controls

4. Panel:
   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
   See Indications for Use below.

2. Indications(s) for use:
   The ACCU-CHEK Inform II Test strip is for use with the ACCU-CHEK Inform II meter to quantitatively measure glucose (sugar) in venous whole blood, arterial whole blood, neonatal heelstick, or fresh capillary whole blood samples drawn from the fingertip as an aid in monitoring the effectiveness of glucose control. The system is not for use in diagnosis or screening of diabetes mellitus, nor for testing neonate cord blood samples.

   The ACCU-CHEK Inform II Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings. This system should only be used with single-use, auto-disabling lancing devices.

   The ACCU-CHEK Inform II Controls are intended for quality control performance checks on the ACCU-CHEK Inform II system with ACCU-CHEK Inform II test strips.

   The ACCU-CHEK Inform II Linearity Test Kit is intended for use for periodic verification of linearity of the ACCU-CHEK Inform II system using ACCU-CHEK Inform II test strips.

3. Special conditions for use statement(s):

   For in vitro diagnostic use only
   Not for testing neonate cord blood samples
   Do not use for diagnosis or screening of diabetes mellitus
   Inaccurate results may occur in "severe dehydration as a result of diabetic ketoacidosis or due to hyperglycemic hyperosmolar non-ketotic syndrome, hypotension, shock, decompensated heart failure NYHA Class IV, or peripheral arterial occlusive disease."
   The performance of this system has not been evaluated in the critically ill.
   For use with single-use, auto-disabling lancing devices

4. Special instrument requirements:

   ACCU-CHEK Inform II Blood Glucose Meter

I. Device Description:

The ACCU-CHEK Inform II Blood Glucose Monitoring System consists of a the ACCU-CHEK Inform II meter, ACCU-CHEK Inform II test strips (sold separately; code keys are provided in test strip vials), ACCU-CHEK Inform II control solutions (Levels 1 and 2; sold separately), ACCU-CHEK Inform II Linearity Test Kit (6 levels; sold separately), base unit with power supply, code key reader, quick reference guide, accessory box, and Operator's Manual.

The enzyme on the test strip is a mutant variant of quinoprotein glucose dehydrogenase (Mut. Q-GDH), from Acinetobacter calcoaceticus, recombinant in E. coli. Each test strip contains the following reagent compositions: Quinoprotein glucose dehydrogenase (15.27%); Pyrroloqauinoline quinine (0.14%); Nitrosoaniline Mediator (6.72%); and other non-reactive ingredients.

Each box of ACCU-CHEK Inform II control solutions contains one vial (2.5 mL) of each of the 2 buffered aqueous solutions containing D-glucose: Level 1 (e.g. 40-50 mg/dL), Level 2 (e.g. 120 to 150 mg/dL).

The ACCU-CHEK Inform II Linearity Test Kit contains 2.5 mL of each of the 6 buffered aqueous solutions containing D-glucose: (ACCU-CHEK Linearity 1 (28 mg/dL), 2 (45 mg/dL), 3 (118 mg/dL), 4 (307 mg/dL), 5 (511 mg/dL), and 6 (559 mg/dL).

I. Substantial Equivalence Information:

1. Predicate device name(s):

   ACCU-CHEK Inform System; k003846
   ACCU-CHEK Aviva Control Solutions; k043474
   Nova StatStrip Glucose Linearity Kit; k060345

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

   k003846
   k043474
   k060345

3. Comparison with predicate:

Similarities and Differences		
Item	Device	Predicate (k003846)
Brand Name	**ACCU-CHEK Inform II**	**ACCU-CHECK Inform**
Indications for Use/Intended Use	The ACCU-CHEK Inform II test strips are for use with the ACCU-CHEK Inform II meter to quantitatively measure glucose (sugar) in venous whole blood, arterial whole blood, neonatal	Same

Similarities and Differences		
Item	Device	Predicate (k003846)
	heelstick, and capillary whole blood samples drawn from the fingertips as an aid in monitoring the effectiveness of glucose control. The systems are not for use in diagnosis or screening of diabetes mellitus, nor for testing neonate cord blood samples.	
Enzyme	Glucose Dehydrogenase – PQQ modified by site-directed mutagenesis	Glucose Dehydrogenase - PQQ
Detection Method	Electrochemical Biosensor	Same
Measurement range	10-600 mg/dL	Same
Measuring time	5 sec	Same
Sample volume	0.6 μL	Same
Sample Site	Capillary, venous, arterial, and neonate (capillary/heelstick)	Whole blood samples
Hematocrit range	10-65%	20-65% for glucose <200 mg/dL 20-55% for glucose>200 mg/dL

Similarities and Differences		
Item	Device	Predicate (k043474)
Brand Name	**ACCU-CHEK Inform II Control Solutions**	**Aviva Control Solutions**
Intended Use	For performance checks on the ACCU-CHEK Inform II system with ACCU-CHEK Inform II test strips	Same
Analyte	Glucose	Same
Number of Levels	2 Levels	Same

Similarities and Differences		
Item	Device	Predicate (k060345)
Brand Name	**ACCU-CHEK Inform II Linearity Kit**	**Nova StatStrip Glucose Linearity Kit;**
Intended Use	For periodic verification of linearity of the ACCU-CHEK Inform II system using	Same

Similarities and Differences		
	ACCU-CHEK Inform II test strips.	
Analyte	Glucose	Same
Number of levels	6 Levels	5 Levels

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.
- CLSI EP5-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline.
- CLSI EP7-A2, Interference Testing in Clinical Chemistry; Approved Guideline.

L. Test Principle:

The test is based on electrochemical biosensor technology and the principle of capillary action. The electrical current generated by the reaction of glucose with the reagent of the strip is measured by the meter and is displayed as the corresponding blood glucose level. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. Precision/Reproducibility:

Repeatability studies were performed with venous whole blood samples at five glucose concentration ranges. A total of 50 strip vials/lot were used. Ten runs were performed on each sample with 5 replicates per vial/strip lot resulting in a total of 100 replicates collected for test strip lot and each glucose level tested. Results are summarized below:

Glucose Level	30-50 (mg/dL)			50-110 (mg/dL)			110-150 (mg/dL)		
Test Strip Lot	1	2	3	1	2	3	1	2	3
Mean (mg/dL)	35.9	36.1	37.2	77.4	76.9	80.0	124.8	123.4	126.3
SD	1.1	1.2	1.4	2.7	2.7	4.4	4.4	4.2	3.7
CV%	3.2	3.3	3.6	3.4	3.5	3.3	3.5	3.4	3.0
N	100	100	100	100	100	100	100	100	100

Glucose Level	150-250 (mg/dL)			250-400 (mg/dL)		
Test Strip Lot	1	2	3	1	2	3
Mean (mg/dL)	194.1	191.8	197.5	319.8	316.6	325.4
SD	6.9	5.8	6.4	9.6	9.5	9.5
CV%	3.5	3.0	3.2	3.0	3.0	2.9
n	100	100	100	100	100	100

Intermediate precision was evaluated using three glucose linearity solutions, Level 2, Level 3, and Level 4. Each sample was measured in duplicate with three test strip lots and 10 Rightest GM700 meters. From each of 10 test strip vials (3 test strip lots) a test was performed on each of the 3 linearity level solutions for 10 days. A total of 10 replicates were collected per vial, strip lot, and glucose level tested for a total of 300 measurements per glucose level. Results are summarized below:

Glucose Level	Level 2			Level 3			Level 4		
Test Strip Lot	1	2	3	1	2	3	1	2	3
Mean (mg/dL)	44.6	45.1	45.2	117.6	117.6	118.6	305.6	305.6	307.9
SD	1.2	1.1	1.2	2.2	1.9	2.1	4.6	4.3	5.9
CV%	2.6	2.4	2.7	1.9	1.6	1.7	1.5	1.4	1.9
n	100	100	100	100	100	100	100	100	100

b. Linearity/assay reportable range:

Linearity was evaluated using 9 venous blood samples ranging in glucose concentrations from 2.0 to 629.7 mg/dL (2.0, 14.5, 36.5, 57.8, 79.8, 151.9, 307.0, 474.2, 629.7 mg/dL) as measured by the reference method. Each sample was tested in replicates of 4 on each of 8 strip lots resulting in a total of 32 replicates for each strip lot and glucose level. The values from the Inform II meter were compared with those obtained from the reference method. The results from regression analysis are summarized below:

Lot #1: $y=0.9593x+2.92$; $R^2 = 0.999$
Lot #2: $y=0.9884x+3.447$; $R^2 = 0.998$
Lot #3: $y=0.9946x+3.80$; $R^2 = 0.998$

The results of the study support the sponsor's claimed glucose measurement range of 10 to 600 mg/dL.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
According to the sponsor, the ACCU-CHEK Inform II system is traceable to the NIST SRM 917 glucose reference material. A method comparison was performed using the candidate device and a hexokinase method (Hitachi 917) as the reference method (see Section 2.a.)

The ACCU-CHEK Inform II control solutions used with the ACCU-CHEK Inform II Blood Glucose Monitoring System were previously cleared under k043474.

Value Assignment and Stability Testing: Two ACCU-CHEK Inform II control solutions (Levels 1 and 2) and 6 levels in the ACCU-CHEK Inform II Linearity Test Kit (Levels 1 to 6) are available for use with the ACCU-CHEK Inform II test system. The Linearity Solutions levels 2 and 4 are the same as the Control solution levels 1 and 2, respectively. Value assignment for the control solutions and linearity set is based on the mean of repeated measurements compared to the established target values for each level. The target values for the linearity levels are provided in the linearity kit package insert and the control solution ranges are printed on the test strip vial label.

Open vial and closed vial (shelf-life) stability is assessed using real-time testing for the control solutions and linearity set solutions. Protocols and acceptance criteria were reviewed and found to be acceptable to support the shelf life stability claim of 24 months and an open-vial stability claim of 3 months when stored at the recommended storage temperatures of 39°F to 86°F (4°C to 30°C). Labeling instructs the user not to freeze the solutions.

The sponsor provided a protocol and acceptance criteria to verify the closed-vial stability (shelf life) and open vial stability of the test strips. The stability protocols and acceptance criteria were reviewed and found to be acceptable. The sponsor claims a closed-vial (shelf life) and open-vial stability of 18 months when stored at 36-86°F. The labeling instructs the users not to freeze the test strips.

c. *Detection limit:*
The reportable range for the ACCU-CHEK Inform II Blood Glucose Monitoring System is 10 to 600 mg/dL. This range was verified by the linearity study (M.1.b).

d. *Analytical specificity:*
To assess potential interference the sponsor used venous whole blood samples adjusted to 5 different glucose levels of approximately 25, 55, 120, 350 and 500 mg/dL (concentrations of 10, 15, 20, 40, 60, 80, 100, 200 and 300 mg/dL glucose were used in testing galactose) and split into a control sample and a test sample. Various endogenous and exogenous substances were then added to the test sample only. Concentrations tested were at least three times the upper therapeutic level (for drugs) or three times the highest expected concentration (for endogenous substances).

Each sample was analyzed in duplicate per meter per test strip lot for a total of 32 measurements per sample. The % difference between the test sample and the control sample was calculated and concentration at which no significant interference was observed is presented in the table below:

Potential Interfering Substance	**Concentration at which no significant interference is observed (mg/dL)**		**Potential Interfering Substance**	**Concentration at which no significant interference is observed (mg/dL)**
Amoxicillin	600		L-Cystine	50
Captopril	0.5		L-Glutathione, oxidized	183.9
Chlorpropamide	80		L-Glutathione, reduce	12.3
Cholesterol	500		Maltose	500
Cimetidine	10		Maltotriose	500
Citric Acid	30		Maltotetraose	500
Conjugated Bilirubin	15		Maltopentaose	500
Unconjugated Bilirubin	40		Naproxen	100
Diltiazem	20		Oxalic Acid	20
Ethanol	350		Potassium Chloride	50
Furosemide	6		Probenecid	60
Gamma Globulins	3000		Sodium Bicarbonate	336
Gentistic acid	50			
Glucosamine	450		Tolbutamide	100
Hemoglobin	500		Tolazamide	200
Ibuprofen	40		Xylose	100
L-Cysteine	5			

The sponsor has the following limitations in their labeling:

- Lipemic samples (triglycerides) in excess of 1800 mg/dL may produce elevated results.
- Intravenous administration of ascorbic acid which results in blood concentrations of ascorbic acid > 3 mg/dL will cause overestimation of glucose results.
- Blood concentrations of galactose >15 mg/dL will cause overestimation of blood glucose results.

Sodium:
A separate study was conducted using over 4000 hospitalized venous and arterial patient samples with sodium concentration bins of <125 mmol/L, 125-134 mmol/L, 135-144 mmol/L, 145-150 mmol/L and >150 mmol/L with glucose concentrations that reasonably spanned the glucose measuring range of the system. Samples were adjusted to achieve glucose concentrations to reasonably span the glucose measuring range in each of the sodium bins. Overall glucose concentrations ranged from 11.4 mg/dL to 583.8 mg/dL. Results obtained using the ACCU-CHEK Inform II Blood Glucose Monitoring System were compared to those obtained with the reference method (Hitachi 917) and demonstrated no significant bias with samples containing extreme sodium concentrations.

e. Assay cut-off:
Not Applicable.

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

To assess system accuracy, results from the ACCU-CHEK Inform II Blood Glucose Monitoring System were compared to a reference method, PCA-HK (Hitachi 917). Capillary samples from 100 participants with glucose with concentrations ranging from 21-547 mg/dL glucose obtained using PCA-HK. To obtain blood glucose concentrations <50 mg/dL and > 400 mg/dL, samples were allowed to glycolize or were spiked to achieve the desired glucose concentration. The results relative to reference are summarized in the tables below:

Inform II Fingerstick vs. Reference

For glucose concentrations <75 mg/dL

within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
11/16 (68.8%)	16/16 (100%)	16/16 (100%)

For glucose concentrations ≥ 75 mg/dL

within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
57/84 (67.9%)	74/84 (88.1%)	83/84 (98.8%)	84/84 (100%)

Results from regression analysis for Inform II fingerstick results vs. Reference:
$y = 1.012x – 2.7$; $r = 0.993$

User Performance Study:
To assess the performance of the ACCU-CHEK Inform II Blood Glucose Monitoring System in the hands of the intended users the sponsor performed a study with 174 lay user participants. Results were analyzed by comparing blood glucose results from the ACCU-CHEK Inform II meter obtained by the lay user against the reference value (Hitachi 917). The samples ranged from 56 to 579 mg/dL as measured by the reference method. The results are summarized in the tables below:

Lay-user Inform II vs. PCA-HK reference:

For glucose concentrations <75 mg/dL

within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
3/4 (75%)	4/4 (100%)	4/4 (100%)

For glucose concentrations ≥ 75 mg/dL

within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
87/170 (51.2%)	146/170 (85.9%)	166/170 (97.60%)	168/170 (98.8%)

Regression Analysis lay-user Inform II vs. Ref: $y = 0.933x+6.6$; $r = 0.99$

Neonatal Study:

To assess the performance of the ACCU-CHEK Inform II Blood Glucose Monitoring with neonatal capillary samples (heel stick) 191 samples ranging from 18 to 153 mg/dL **(**as measured by the reference method) ACCU-CHEK Inform II Blood Glucose Monitoring System were tested by a technician using 3 lots of test strips. The results relative to reference are summarized below for each test strip lot:

For glucose concentrations <75 mg/dL

Lot	within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
#1	87/105 (82.9%)	101/105 (96.2%)	105/105 (100%)
#2	83/105 (79.0%)	99/105 (94.3%)	105/105 (100%)
#3	83/105 (79.0%)	99/105 (94.3%)	104/105 (99.0%)

For glucose concentrations ≥ 75 mg/dL

lot	within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
#1	56/86 (65.1%)	76/86 (88.4%)	84/86 (97.7%)	86/86 (100%)
#2	52/86 (60.5%)	76/86 (88.4%)	84/86 (97.7%)	85/86 (98.8%)
#3	53/86 (61.6%)	73/86 (84.9%)	84/86 (97.7%)	85/86 (98.8%)

Linear regression results Inform II neonate capillary vs. whole blood PCA-HK reference (N=191):

Lot#1: y = 0.994x - 3.5; r = 0.979
Lot#2: y = 1.011x + 1.5; r = 0.976
Lot#3: y = 1.003x - 2.1; r = 0.980

Venous Study:
To assess the performance of the ACCU-CHEK Inform II Blood Glucose Monitoring System using venous blood, 450 venous (lithium heparin) samples were used containing glucose concentrations of 19 to 546 mg/dL (as measured by the reference method). The results obtained from the Inform II system were compared to results obtained using the reference method (Hitachi 917) and are summarized below:

For glucose concentrations <75 mg/dL

within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
67/77 (87.0%)	76/77 (98.7%)	76/77 (98.7%)

For glucose concentrations ≥ 75 mg/dL

within ± 5 %	Within ± 10 %	within ± 15 %	within ± 20 %
277/373 (74.3%)	357/373 (95.7%)	371/373 (99.5%)	372/373 (99.7%)

Linear regression results Inform II venous vs. whole blood PCA-HK reference (N=450): y = 1.009x – 1.9; r =0.995

Arterial Study:
To assess the performance of the ACCU-CHEK Inform II Blood Glucose Monitoring with 214 arterial (lithium heparin) samples ranging from 58 to 322 mg/dL according to the reference method were tested by a technician using 3 lots of test strips. Results from the Inform II meter were compared to those obtained from the reference (Hitachi 917). The results relative to reference are summarized below:

For glucose concentrations <75 mg/dL

Lot	within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
#1	4/4 (100%)4	4/4 (100%)	4/4 (100%)
#2	4/4 (100%)4	4/4 (100%)	4/4 (100%)
#3	4/4 (100%)4	4/4 (100%)	4/4 (100%)

For glucose concentrations ≥ 75 mg/dL

lot	within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
#1	154/210 (73.3%)	205/210 (97.6%)	210/210 (100%)	210/210 (100%)
#2	147/210 (70.0%)	201/210 (95.7%)	210/210 (100%)	210/210 (100%)
#3	146/210 (69.5%)	203/210 (96.7%)	208/210 (99.0%)	210/210 (100%)

Linear regression results Inform II arterial vs. whole blood PCA-HK reference (N=214):

Lot#1: y=1.038x -3.5; r = 0.992
Lot#2: y=1.038x -3.5; r = 0.990
Lot#3: y=1.029x -1.5; r = 0.990

b. Matrix comparison:

Anticoagulant study:
Venous blood was drawn from ten donors having glucose levels in 5 different glucose bins: <70, 71-110, 111-150, 151-250, >251 mg/dL. The donor blood was collected into each of 4 vacutainer tubes (lithium heparin, sodium heparin, EDTA, and sodium fluoride/potassium oxalate) and into vacutainer tubes containing no anticoagulant. Each anticoagulant was tested in replicates of sixteen. Results of the study demonstrate no significant bias when results from samples containing EDTA, lithium heparin, or sodium heparin were compared to results from samples containing no anticoagulant and support the use with the ACCU-CHEK Inform II system.

The sponsor includes the following limitation in the labeling: Iodoacetate or fluoride-containing anticoagulants are not recommended.

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):

4. Clinical cut-off:
   Not Applicable

5. Expected values/Reference range:

Time of day	People without diabetes
Fasting and before meals	<100 mg/dL
2 hours after meals	<140 mg/dL

(1) American Diabetes Association: Diagnosis and Classification of Diabetes Mellitus (Position Statement). *Diabetes Care* 34 (Supp. 1) S66, 2011.

(2) *Tietz Fundamentals of Clinical Chemistry, 6th Edition*, Edited by Burtis CA and Ashwood ED, W. B. Saunders Co., Philadelphia, PA, 2008, p. 849.

N. Instrument Name:

ACCU-CHEK Inform II Blood Glucose Meter

O. System Description:

1. Modes of Operation:

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

Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?:

Yes __X__ or No _____.

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?:

Yes __X__ or No _____.

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes __X__ or No _____.

The applicant has provided documentation that indicates the device was designed and developed under good software life-cycle processes.

3. Specimen Identification:

The ACCU-CHEK Inform II meter will store 2,000 patient results, 5,000 Operator IDs, and 4,000 Patient IDs.

4. Specimen Sampling and Handling:

   This device is intended to be used with capillary whole blood from the fingertip, capillary heel stick samples from neonates, venous, and arterial whole blood. After an operator ID is entered and the login is completed a patient sample can be run by first entering the patient ID either manually or by using the barcode scanner; the test strip lot is compared to the test strips in use; the test strip is inserted and the blood sample is applied.

5. Calibration:
   The system contains a code key reader that is separate from the meter. Each test strip vial contains a code key that contains the test strip code information specific to that test strip lot number. The code key is inserted into and read by the code key reader. The coding information that includes lot specific test strip properties is sent via infrared transmission to the meter where it (the code file) is stored.

6. Quality Control:

   The ACCU-CHEK Inform II Control Solutions are used as a quality control checks to make sure that the ACCU-CHEK Inform II system and ACCU-CHEK Inform II test strips are working correctly. The labeling provides instructions on when quality control testing should be performed.

   The ACCU-CHEK Inform II Linearity Test Kit is intended for use for periodic verification of linearity of the ACCU-CHEK Inform II system using ACCU-CHEK Inform II test strips. Linearity tests can help you to check the function and accuracy of the entire system over the full range of specified values. Linearity samples should be treated in exactly the same manner as described in the labeling for control solution testing. The labeling contains instructions on how to perform linearity testing with the linearity solutions and, using the target values provided, how to plot the results of the 6 levels of linearity test kit solutions. The labeling includes recommendations for when the linearity of the system should be checked.

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

1) Hematocrit study:
   The effect of different hematocrit levels was evaluated using venous whole blood samples with hematocrit levels of 10 – 65% (10,15, 20, 25, 30, 43, 50, 55, 60, 65 and 70%) spiked with glucose to achieve target concentrations of 25, 55, 120, 350, and 500 mg/dL. Three strip lots were evaluated, and there were 30 measurements for each combination of strip lot, glucose concentration, and hematocrit level tested. The results demonstrated that the ACCU CHEK Inform II Blood Glucose Monitoring System produces results within an acceptable bias over the claimed hematocrit range of 10 – 65%.

2) Altitude study:
To evaluate the effects of altitude on the Inform II system results, altered (spiked and glycolysed) venous blood samples from three donors were spiked to 5 glucose concentrations that reasonably spanned the measuring range of the system. The blood samples were tested at 10,150 feet above sea level and the results compared those obtained with the reference method (PCA-HK; Hitachi 917). The results demonstrate acceptable bias to the reference to support the claims in the labeling that altitudes up to 10,000 feet have no significant effect on blood glucose measurements from the ACCU CHEK Inform II Blood Glucose Monitoring System.

3) Temperature and humidity studies:
The sponsor performed temperature and humidity studies using venous blood samples at target glucose concentrations of 70, 120, and 250 mg/dL to evaluate temperatures ranging from 61-95°F (16-35°C) and relative humidity from 10-80%. Combinations of the claimed temperature and humidity operating conditions were evaluated meter results compared to a reference method. The results support the claimed range of operating conditions: 61-95°F and 10-80% relative humidity.

4) Sample volume study:
The sponsor performed a sample volume study to support the claimed minimum sample volume requirement for the ACCU-CHEK Inform II system (0.6 μL) using blood samples at three glucose concentrations (45, 120, 450 mg/dL). The system displays an error code when insufficient sample is detected. Results support the claimed sample volume of 0.6 μL.

5) Infection Control Studies: The device is intended for multiple-patient use. Clorox Germicidal wipes (EPA registration #67619-2) were validated demonstrating complete inactivation of live virus for use with the meter. The sponsor also demonstrated that there was no change in performance or in the external materials of the meter after 12,045 cleaning and disinfection cycles (one cycle includes one cleaning wipe plus one disinfecting wipe) to simulate 3 years of device use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

6) Electromagnetic Compatibility (EMC) testing was performed and found to be adequate for the Accu-Chek Inform II system.

7) ACCU-CHEK Customer Care Service Center is available 24 hours a day, 365 day a year by calling 1-800-440-3638.

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.