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

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

k070585

**B. Purpose for Submission:**

Modification to previously cleared device

**C. Measurand:**

Glucose

**D. Type of Test:**

Quantitative (Glucose Dehydrogenase)

**E. Applicant:**

Roche Diagnostics Corporation

**F. Proprietary and Established Names:**

ACCU-CHEK Performa Blood Glucose Meter

**G. Regulatory Information:**

1. Regulation section:
   21 CFR §862.1345, Glucose Test System

2. Classification:
   Class II

3. Product code:
   LFR, NBW

4. Panel:
   Clinical Chemistry (75)

**H. Intended Use:**

1. Intended use / Indication(s) for use:

   The ACCU-CHEK Performa system is designed to quantitatively measure the concentration of glucose for monitoring glucose in the home or in health care facilities. Testing sites include traditional fingertip site along with palm, forearm, upper arm, thigh, and calf.

   Professionals may use the test strips to test capillary, venous, arterial, and neonatal blood; home use is limited to capillary whole blood testing.

2. Special conditions for use statement(s):

   This device is intended for use with whole blood but produces plasma equivalent glucose results.

3. Special instrument requirements:

   ACCU-CHECK Performa Blood Glucose Meter

**I. Device Description:**

The ACCU-CHEK Performa system starter kit includes the glucose meter with battery, test strips with a code key, and the lancing device with lancets. Control solutions are available but will be sold separately. The test strips, lancing device, and lancets may also be sold separately.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

   Roche Diagnostics Corporation ACCU-CHEK Aviva Blood Glucose Meter

2. Predicate 510(k) number(s) and device history:

   The Roche Aviva glucose meter was initially cleared under k043474 for consumer (OTC) and professional use. Cleared matrices were venous or capillary whole blood with consumer use limited to fingerstick capillary blood. The meter was also cleared for alternate site testing from the palm, forearm, upper arm, thigh, and calf.

   The Aviva meter was submitted again under k060620 for the addition of arterial, neonatal capillary, and neonatal cord blood as acceptable matrices. The hematocrit range of the meter to was also extended to 10 – 70%.

The current device is a modification of the Aviva meter as outlined in the comparison chart below.

3. Comparison with predicate:

| Similarities | | |
|---|---|---|
| Item | Device | Predicate |
| Detection Method | Same | Amperometry |
| Enzyme | Same | Glucose dehydrogenase with nitrosoaniline mediator |
| Reportable Range | Same | 10 – 600 mg/dL |
| Time to Result | Same | 5 seconds |
| Sample Volume | Same | 0.6 µL |
| Hematocrit Range | Same | 10 – 70% |
| Stored Results | Same | 500 glucose results with time and date |

| Differences | | |
|---|---|---|
| Item | Device | Predicate |
| Quality Control | Provided separately | Included |
| Number of electrodes on strip | 6 | 8 |
| Strip width | 7 mm | 8 mm |
| Physical dimensions | 93 x 52 x 22 mm (LWH) 62 g with battery | 94 x 53 x 22 mm (LWH) 60 g with battery |

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

ISO 15197 (2003): *In vitro* diagnostic test systems —Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus

FDA Guidance Document: Review Criteria for Assessment of Portable Blood Glucose In Vitro Diagnostic Devices Using Glucose Oxidase, Dehydrogenase, or Hexokinase Methodology (1997)

**L. Test Principle:**

The ACCU-CHEK Performa System utilizes Glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) technology. The enzyme glucose dehydrogenase converts the glucose in a blood sample to gluconolactone. This

reaction liberates an electron that reacts with a coenzyme electron acceptor, the oxidized form of the mediator hexacyanoferrate (III), forming the reduced form of the mediator hexacyanoferrate (III). The test strip employs the electrochemical principle of biamperometry. The meter applies a voltage between two identical electrodes, which causes the reduced mediator formed during the incubation period to be reconverted to an oxidized mediator. This generates a small current that is read by the meter and reported as the glucose result.

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

Performance testing studies were done to evaluate the modifications to the meter. Some performance parameters were reviewed in the predicate device submissions. See k043474 and k060620 for additional information on device performance evaluations.

1. Analytical performance:

   a. *Precision/Reproducibility:*

   The sponsor evaluated the between-lot and between-day imprecision of the device using replicate measurements of glucose linearity solutions. Data was collected over 10 days using 10 meters and 3 strip lots. For glucose values ≤ 75 mg/dL, the sponsor calculated the standard deviation and for values > 75 mg/dL the coefficient of variation was calculated:

   | Linearity Sample | Mean (mg/dL) | Pooled Standard Deviation | Pooled Coefficient of Variation |
   |---|---|---|---|
   | Low | 50.7 | 1.8 | -- |
   | Medium | 121.3 | -- | 2.3 |
   | High | 301.4 | -- | 1.9 |

   The sponsor also evaluated the within-run imprecision of the device using control solutions and venous blood. Results were as follows:

   | Control Sample | Mean (mg/dL) | Pooled Standard Deviation | Pooled Coefficient of Variation |
   |---|---|---|---|
   | Low | 48.1 | 1.52 | -- |
   | Medium | 121.6 | -- | 2.02 |
   | High | 299.3 | -- | 2.05 |

   | Venous Sample | Mean (mg/dL) | Pooled Standard Deviation | Pooled Coefficient of Variation |
   |---|---|---|---|
   | L1 | 38.8 | 1.8 | -- |

| | | | |
|---|---|---|---|
| L2 | 81.9 | -- | 3.4 |
| L3 | 140.9 | -- | 3.4 |
| L4 | 194.8 | -- | 3.2 |
| L5 | 323.3 | -- | 2.4 |

b. *Linearity/assay reportable range:*

Linearity was established under k043474. The reportable range of the meter is 10 – 600 mg/dL.

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

Controls were previously cleared under k043474

d. *Detection limit:*

The detection limit was established under k043474

e. *Analytical specificity:*

Studies to establish the analytical specificity were conducted under k043474 and k060620. The sponsor also retested a subset of compounds for potential interference with the Performa system.

The following list will be included in the package insert as limitations for their potential to cause falsely elevated glucose results:

- Icodextrin (found in peritoneal dialysis solutions)
- Galactose
- Maltose
- Xylose
- Triglycerides (lipidemia)

f. *Assay cutoff:*

Not applicable.

2. <u>Comparison studies:</u>

a. *Method comparison with predicate device:*

For **capillary** blood samples, the sponsor performed two method comparison studies, one with consumers using the device and the other with lab professionals using the device. Only fingertip capillary samples were tested. For device performance with capillary samples from alternate sites, see

k043474.  For all other matrices, please see section b. *matrix comparison* below.

Professional study.  The professional study included paired whole blood and plasma samples from 220 individuals and included glucose concentrations from 36 - 569 mg/dL. Each of the whole blood samples was analyzed with three lots of test strips (n = 660) and on a laboratory instrument. Linear regression of the data from the three strip lots produced the following results:

| Lot | n | Range (mg/dL) | Slope | Intercept | r |
|-----|-----|-----------|-------|-----------|-------|
| 1 | 220 | 36 – 569 | 1.014 | 5.1 | 0.997 |
| 2 | 220 | 36 – 569 | 1.045 | 1.3 | 0.997 |
| 3 | 220 | 36 – 569 | 1.057 | 1.4 | 0.996 |

Data from lot 2 is presented in the labeling method comparison section as representative performance of all three lots.

Consumer study.  The sponsor also compared results obtained by consumers (total n = 241) with results obtained by a laboratory analyzer.  The data was collected using three strip lots with the following results:

| Lot | n | Range (mg/dL) | Slope | Intercept | r |
|-----|-----|-----------|-------|-----------|-------|
| 1 | 87 | 72 – 419 | 1.001 | 9.9 | 0.992 |
| 2 | 76 | 62 – 395 | 0.998 | 9.0 | 0.992 |
| 3 | 78 | 83 - 446 | 1.003 | 7.7 | 0.990 |

Data from lot 2 is presented in the labeling method comparison section as representative performance of all three lots.

b. *Matrix comparison:*

For **venous** blood samples, the sponsor collected data from two external facilities and three strip lots, comparing the Performa meter with a laboratory analyzer, with the following results:

| Lot | n | Range (mg/dL) | Slope | Intercept | r |
|-----|-----|-----------|-------|-----------|-------|
| 1 | 190 | 34 – 481 | 1.022 | 1.8 | 0.991 |
| 2 | 191 | 34 – 481 | 1.032 | -0.5 | 0.992 |
| 3 | 191 | 34 – 481 | 1.023 | 1.9 | 0.991 |

Data from lot 3 is presented in the labeling method comparison section as representative performance of all three lots.

For **arterial** blood samples, the sponsor collected data from two external facilities and three strip lots, comparing the Performa meter with a laboratory analyzer, with the following results:

| Lot | n | Range (mg/dL) | Slope | Intercept | r |
|-----|-----|---------------|-------|-----------|-------|
| 1 | 202 | 57 – 344 | 1.036 | 0.3 | 0.985 |
| 2 | 202 | 57 – 344 | 1.005 | 2.8 | 0.984 |
| 3 | 202 | 57 – 344 | 1.052 | 0.0 | 0.973 |

Data from lot 1 is presented in the labeling method comparison section as representative performance of all three lots.

For **neonatal** blood samples, the sponsor collected data from one external facility and three strip lots, comparing the Performa meter with a laboratory analyzer. The hematocrit range tested was 29 – 66%. The following results were observed:

| Lot | n | Range (mg/dL) | Slope | Intercept | r |
|-----|-----|---------------|-------|-----------|-------|
| 1 | 94 | 22 – 198 | 1.069 | -0.4 | 0.983 |
| 2 | 94 | 22 – 198 | 1.073 | -0.8 | 0.983 |
| 3 | 94 | 22 – 198 | 1.118 | -4.4 | 0.986 |

Ddata from lot 2 is presented in the labeling method comparison section.

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:

The sponsor included the following glucose values in their labeling for adults who do not have diabetes:

Fasting:  74 – 106 mg/dL
Two hours after a meal:  <140 mg/dL

This information is taken from Stedman, TL, *Stedman's Medical Dictionary*, 27th Edition, 1999, pg. 2082.

**N. Instrument Name:**

Roche Diagnostics Corporation ACCU-CHEK Performa Blood Glucose Meter

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

Yes ____X____ or No _____

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:

For consumers, this device is intended to be used with capillary whole blood from the finger, palm, forearm, upper arm, thigh, and calf. Professionals may use the test strips to test capillary, venous, arterial, and neonatal blood. When venous or arterial blood is tested, samples must be anticoagulated with heparin or EDTA and analyzed within 30 minutes.

5. Calibration:

A Code Key is provided with each box of test strips to calibrate the meter for that strip lot. No further calibrations are required of the user.

6. <u>Quality Control</u>:

High and low glucose control solutions are provided separately and were cleared under k043474.   After the user marks the control sample as Low or High, the meter checks the value automatically based on the lot number of the strips.  If the control result is out of range, an "Err" error message is displayed.  Should this occur, the user is referred to the Troubleshooting Checks section of the User's Manual. The user can also compare the result to the control range printed on the strip vial.

**P. Other Supportive Instrument Performance Characteristics:**

**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.