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

A. 510(k) Number:

k063852

B. Purpose for Submission:

New device

C. Measurand:

Cholesterol, HDL-cholesterol, Triglycerides, calculated LDL-cholesterol

D. Type of Test:

Quantitative, enzymatic

E. Applicant:

Home Access Health Corp.

F. Proprietary and Established Names:

accessa Cholesterol Panel (Capillary blood self-collection and transportation system for Total Cholesterol, HDL-Cholesterol, Triglycerides, and Calculated LDL-Cholesterol)

G. Regulatory Information:

1. Regulation section:

   21CFR 862.1675 (Blood specimen collection devices)

   21CFR 862.1175 (Total Cholesterol)

   21CFR 862.1475 (HDL Cholesterol)

   21CFR 862.1705 (Triglycerides)

2. Classification:

   Class II

3. Product code:

   JKA, CHH, LBS, JGY

4. Panel:

   75 (Chemistry)

H. Intended Use:

1. Intended use(s):

   See Indication for use below.

2. Indication(s) for use:

   The accessa Cholesterol Panel is intended for *in vitro*, quantitative determination of Total Cholesterol, HDL-Cholesterol, Triglycerides and calculated LDL-Cholesterol in dried micro-serum samples ("Cholesterol Panel"). Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis and various liver and renal diseases. The Cholesterol Panel is not intended for use on neonates. LDL-Cholesterol cannot be determined where the triglycerides value is greater than 400 mg/dL.

3. Special conditions for use statement(s):

   For prescription use and over-the-counter use; The labeling said "Do NOT use if you have any blood clotting disorder (hemophilia), or are taking prescription medications that thin your blood unless otherwise directed by your doctor."

4. Special instrument requirements:

   Roche Cobas Mira Plus analyzer in the clinical laboratory located at Home Access Health Corporation.

I. Device Description:

The accessa Cholesterol Panel incorporates the use of two separately regulated products, the Home Access Micro Serum Specimen (MSS) Collection Kit and the Home Access Health Corporation (HAHC) Clinical Chemistry Laboratory Lipid profile test methods.

The accessa Cholesterol Panel kit is comprised of the following:

- Blood collection/transportation cassette

- Sample Return Pouch with Desiccant
- 2 Safety lancets
- Gauze pad
- Adhesive bandage
- Instructions for use
- Brochure: "Things you need to know to keep your heart healthy"
- Prepaid US Mail return mailer
- Informed Consent Form

The testing services are done in the clinical laboratory located at Home Access Health Corporation using the Roche Cobas Mira Plus chemical analyzer. Once the dried serum sample is received in the laboratory, it is eluted with a diluent into a diluted serum sample and is assayed using the following predicate reagents. The lipid profile results will be calculated automatically by the analyzer.

- Amresco Cholesterol reagent
- Wako L-Type HDL-Cholesterol reagent
- Roche Triglycerides reagent

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Safe At Home Cholesterol Profile by BIOSAFE Laboratories, Inc.

   Predicate Test Methods for venous whole blood:

   • Total Cholesterol: Amresco Cholesterol Reagent Assay

   • HDL Cholesterol: Wako L-Type HDL-Cholesterol Reagent Assay

   • Triglycerides: Roche Triglycerides Assay

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

   k012221, k832780, k801834, k801298, respectively

3. Comparison with predicate:

Similarities and Differences Between Safe At Home Cholesterol Profile (predicate) and accessa Cholesterol Panel (candidate)		
Item	**Safe At Home Cholesterol Profile (Predicate-k012221)**	**accessa Cholesterol Panel (Candidate)**
Indications for use	The Safe At Home Cholesterol Profile Blood Collection and Transport System is intended for over-the-counter distribution, for the self-collection and transportation	The accessa Cholesterol Panel is intended for in vitro, quantitative determination of Total Cholesterol, HDL-Cholesterol,

Similarities and Differences Between Safe At Home Cholesterol Profile (predicate) and accessa Cholesterol Panel (candidate)		
Item	**Safe At Home Cholesterol Profile (Predicate-k012221)**	**accessa Cholesterol Panel (Candidate)**
	of dried capillary blood for in vitro diagnostic quantitative determination of Total Cholesterol, HDL-Cholesterol, Triglycerides and Calculated LDL-Cholesterol in dried blood spots. This kit is not intended for use on neonates. LDL cannot be determined where the triglycerides value is greater than 400 mg/dL	Triglycerides and calculated LDL-Cholesterol in dried micro-serum samples ("Cholesterol Panel"). Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis and various liver and renal diseases. The Cholesterol Panel is not intended for use on neonates. LDL-Cholesterol cannot be determined where the triglycerides value is greater than 400 mg/dL.
Location of collection	Home	Same
Location of analysis	Laboratory	Same
Distribution	Over-the-counter	Same, plus prescription use
Analysis	Mail in to laboratory	Same
Report	Mailed to user	Same
LDL	Calculated	Same
Fasting required	Yes	Same

Similarities and Differences for Cholesterol		
Item	Predicate	Candidate
	Amresco Cholesterol Reagent (Predicate-k832780)	**accessa Cholesterol Panel (Candidate)**
Intended Use	*In vitro* quantitative determination of total cholesterol in serum	Same
Clinical Chemistry Analyzer	Roche Cobas Mira Plus analyzer	Same
Linearity	Up to 500 mg/dL	82-500 mg/dL
Specimen Collection/Collection Device	Venipuncture blood sample from fasted individuals, collected in vacutainer containing 4 to 10 mL blood.	Dried micro serum capillary blood specimens from fasted individuals, self-collected into a glass fiber strip. Volume of capillary blood required is less than 0.1 mL.
Specimen stability	Samples are stable for up to 7 days at room temperature and up to 6 months at -20^{o}C.	Samples stable up to 21 days at room temperature.
Reported values for analytes	Unchanged from the analyzer	Calculated using data from the analyzer.

Similarities and Differences for HDL Cholesterol		
Item	Predicate	Candidate
	Wako L-type HDL-C Reagent (Predicate-k801834)	**accessa Cholesterol Panel (Candidate)**
Intended Use	*In vitro* quantitative determination of high density lipoprotein cholesterol (HDL) in serum	Same
Clinical Chemistry Analyzer	Roche Cobas Mira Plus analyzer	Same
Linearity	Up to 180 mg/dL	23-151 mg/dL
Specimen Collection/Collection Device	Venipuncture blood sample from fasted individuals, collected in vacutainer containing 4 to 10 mL blood.	Dried micro serum capillary blood specimens from fasted individuals, self-collected into a glass fiber strip. Volume of capillary blood required is less than 0.1 mL.
Specimen stability	Samples are stable for up to 4 days at 4-6 ^{o}C.	Samples stable up to 21 days at room temperature.
Reported values for analytes	From the analyzer	Calculated using data from the analyzer.

Similarities and Differences for Triglycerides		
Item	Predicate	Candidate
	Roche Triglycerides Reagent (Predicate-k801298)	**accessa Cholesterol Panel (Candidate)**
Intended Use	*In vitro* quantitative determination of triglycerides in serum	Same
Clinical Chemistry Analyzer	Roche Cobas Mira Plus analyzer	Same
Linearity	Up to 900 mg/dL	16-900 mg/dL
Specimen Collection/Collection Device	Venipuncture blood sample from fasted individuals, collected in vacutainer containing 4 to 10 mL blood.	Dried micro serum capillary blood specimens from fasted individuals, self-collected into a glass fiber strip. Volume of capillary blood required is less than 0.1 mL.
Specimen stability	Samples are stable for 5 to 7 days when stored in the refrigerator and up to 3 months at -20^{o}C.	Samples stable up to 21 days at room temperature.
Reported values for analytes	From the analyzer	Calculated using data from the analyzer.

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

1. CLSI EP5-A, *Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline.*
2. CLSI EP6-A, *Evaluation of the Linearity of Quantitative Analytical Methods; Proposed Guideline.*
3. CLSI EP7-A, *Interference Testing in Clinical Chemistry; Proposed Guideline*
4. CLSI EP9-A2, *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline Second edition*
5. CLSI EP17-A, *Protocols for Demonstration, Verification, and Evaluation of Limits of*

Detection and Quantitation: Approve Guideline-2004

6. FDA guidance document, *Guidance for 510(k)s on Cholesterol Tests for Clinical Laboratory, Physicians' Office Laboratory and Home Use-1995*
7. *American Society for Testing and Materials methodology for accelerated aging of medical devices (ASTM F1980)*
8. *The National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III),* NIH, May 2001

L. Test Principle:

The lay user follows the directions to self-collect a capillary blood sample (approximately 100 micro liters), package and mail the sample to the Home Access Health Corporation. Once the dried sample is received in the laboratory, it is eluted into a usable serum sample. Once eluted, the sample can be assayed as a diluted serum sample using FDA-cleared reagents. All testing is done using the Roche Cobas Mira Plus analyzer for total cholesterol, HDL-cholesterol, and triglycerides. The LDL-cholesterol was calculated using the Friedewald formula.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

Cholesterol was certified by the Cholesterol Reference Method Laboratory Network (CRMLN) as meeting the National Cholesterol Program's (NCEP) performance criteria for accuracy and precision.

a. Precision/Reproducibility:

A precision study was performed based on the CLSI EP5-A guideline and NCEP guidelines for accuracy. Two volunteers were chosen as a sample source as their lipoprotein levels were closed to "high" and "low" medical decision levels. Their blood was drawn and spotted onto the 240 blood collection cassettes (micro serum samples, MSS). These MSS samples are allowed to dry, then eluted, and measured on the Roche Cobas Mira analyzer for total cholesterol, HDL-cholesterol, and Triglycerides. All samples were tested twice a day in duplicate for 20 days (N=80). The precision results are shown below:

Analyte	Concentration	MSS Within run		MSS Total	
	Mean [ng/dL]	SD [ng/dL]	CV [%]	SD [ng/dL]	CV [%]
CHO	206	4.75	2.31	6.18	3.00
CHO	240	5.69	2.37	6.55	2.73
HDL	40	1.26	3.15	1.57	3.92
HDL	73	1.55	2.13	2.49	3.41
TG	150	5.37	3.58	7.2	4.80
TG	305	8.97	2.94	13.39	4.39

For accuracy based on the NCEP guideline's allowable precision, bias, and total % error, the results of the micro serum samples (MSS) are shown in the table below:

Analyte	Expected value	MSS Total CV%	MSS Bias %	MSS Total Error%	NCEP total Error%
Cholesterol	206	3.00	-1.12	7.36	<8.9
Cholesterol	240	2.73	-1.3	6.65	<8.9
HDL Cholesterol	40	3.92	-2.89	10.63	<12.8
HDL Cholesterol	73	3.41	-0.46	7.15	<12.8
Triglycerides	150	4.80	3.2	12.26	<14.8
Triglycerides	305	4.39	-1.47	9.94	<14.8

b. Linearity/assay reportable range:

A linearity study was performed to validate a linear range of lipid profile testing in micro serum samples (MSS) according to the CLSI EP6-A guideline. Lipid profile testing includes testing of three analytes: Total Cholesterol, HDL Cholesterol, and Triglycerides. A pair of blood specimens was chosen for each analyte based on high and low levels of each lipoprotein. These specimens were then mixed in different proportions and spotted onto blood collection /transportation cassettes (MSS samples). These MSS samples were then eluted and measured, and their MSS results calculated and compared to the expected plasma values (blood drawn by venipuncture). A total of 11 sets of MSS with different levels were tested in replicates of 4. MSS values were plotted against the expected values and an appropriate line fitted by standard linear regression yielded the following:

For Total Cholesterol: $Y= 0.9648 + 11.26$, $r^2=0.9943$, sample ranges tested was 82-564 mg/dL.

For HDL Cholesterol: $Y= 0.987 + 1.088$, $r^2=0.9982$, sample ranges tested was 10-151 mg/dL.

For Triglyceride: $Y= 0.9860 – 1.03$, $r^2=0.9986$, sample ranges tested was 16-1015 mg/dL.

The sponsor chose the following as their device's linearity ranges: 82-500 mg/dL for total cholesterol, 23-151 mg/dL for HDL-cholesterol and 16-900 mg/dL for Triglycerides.

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

Home Access Health Corp. has documented traceability to the NCEP's recommended accuracy base for Total Cholesterol by performing a direct comparison with a

Cholesterol Reference Method Laboratory Network laboratory using fresh human specimens which cover the NCEP medical decision points.

Shelf-life of the blood collection cassette was determined by an accelerated aging study according to the ASTM F1980 document. The sponsor concluded that the blood collection cassette has a shelf-life of 36 months. Sample stability study was conducted by collecting capillary whole blood samples on the collection cassettes and stored at room temperature for 21 days. The acceptance criteria are: the % bias between the control condition and the tested conditions must meet the NCEP acceptance criteria of bias of <3% for cholesterol, <5% for HDL and <5% for triglyceride. Results indicated that the micro serum samples are stable up to 21 days at room temperature.

In addition, a shipping study consisting of spotted dry samples shipped in presumably worst-case real-time shipping conditions, during the hottest month of the year, August, from south (Florida) and southwest (California) locations of the continental USA was conducted and the results showed acceptable stability according to the NCEP acceptance criteria for bias.

Furthermore, a sample stability study that challenge between the extreme temperatures (45 ^{o}C and -20^{o}C) was conducted to simulate the worst case scenario, consists of samples stressed at 45^{o}C, then thawed and frozen at -20^{o}C for two and half days was performed. The results also showed acceptable stability according to the NCEP acceptance criteria for bias.

d. Detection limit:

A detection limit study was performed to assess the detection limits of the micro serum samples for total cholesterol, HDL-cholesterol, and triglycerides based on CLSI EP-17A guideline. Limit of Blank (LoB) is determined by using the simulated blood samples: washed red blood cells from 4 different donors mixed with an osmotically balanced salt solution. Limit of Detection (LoD) was conducted by running a sample with concentration up to 4 times the LoB. Testing was done 10 times a day for 3 days on two analyzers (N=60). The calculated limit of detection for total cholesterol is 29 mg/dL, HDL-cholesterol is 11 mg/dL, and triglycerides is 4 mg/dL.

e. Analytical specificity:

An interference study was conducted to determine the effect of common interference substances based on the CLSI EP7-A guidelines. Two levels (around medical decisions points) of total cholesterol, HDL, and triglycerides were tested. Blood samples were draw from volunteers and split into two pools: one pool was used as the control blood and the other pool was used to spike with different levels of interferents. The following interference substances were tested: bilirubin, hemoglobin, ascorbic acid, and triglycerides. Stock solutions of the above chemicals were prepared and spiked into the tested pool sample with different concentrations.

The % bias was calculated based on the differences between the spiked sample and the control sample. Results of the interference studies of various potential interferents were shown as follows:

For the total cholesterol assay:

Bilirubin: Interference ≤ 3% for up to 17.4 mg/dL bilirubin
Hemolysis: Interference ≤ 3% for up to 500 mg/L hemoglobin (The sponsor states that the lab will visually inspect all specimens and reject any that are hemolyzed.)
Ascorbic acid: Interference ≤ 7% for up to 6 g/L ascorbic acid

For the HDL-cholesterol assay:

Bilirubin: Interference ≤ 5% for up to 42.3 mg/dL bilirubin
Hemolysis: Interference ≤ 5% for up to 500 mg/L hemoglobin
Triglyceride: Interference ≤ 5% for up to 625 mg/L Triglycerides
Ascorbic acid: Interference ≤ 5% for up to 6 g/L ascorbic acid

For the Triglycerides assay:

Bilirubin: Interference ≤ 5% for up to 17.4 mg/dL bilirubin
Hemolysis: Interference ≤ 5% for up to 500 mg/L hemoglobin
Ascorbic acid: Interference ≤ 10% for up to 6 g/L ascorbic acid

A hematocrit study was conducted based on the CLSI EP7-A guideline. For each analyte, total cholesterol, HDL-cholesterol, and triglycerides, two volunteer donors were drawn. The venous blood was drawn and spun down to separate red blood cells and plasma. Then the blood cells were mixed back with plasma to reach 35% (low), 45% (control) and 55% (high) hematocrits. The blood specimens with these 3 hematocrits were spotted onto 28 collection cassettes each, dried and packaged according to the package insert. Micro serum samples results for the low and high hematocrits were compared to the control group. The difference between the tested hematocrits (35% and 55%) and the control hematocrit (45%) was calculated and the allowable bias difference was based on the NCEP guidelines for each analyte. All the results met the NCEP % bias criteria (criteria: cholesterol is <3%, HDL is <5%, and Triglyceride is <5%). The sponsor concluded that hematocrit range at 35% to 55% do not interfere with any of the measured lipoproteins.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

A method comparison study was conducted based on the CLSI EP9-A2 guideline. The study was performed to compare test results obtained by the lay user's finger-stick samples with the test results by the venous samples using the Roche Cobas Mira analyzer in the clinical laboratory of the Home Access Health Corporation (HAHC). Blood samples were collected by lay user at a clinic and mailed to HAHC for analysis. In addition, professionally collected finger-stick samples were also collected and mailed at the same time. Results of the standard linear regressions were shown below:

Between the lay user's finger-stick and the venous samples:

For total cholesterol: Y= 1.016X-4.4, r^2=0.9836, N=151, sample range was 127-467 mg/dL

For HDL-cholesterol: Y= 0.9937X-0.904, r^2=0.9639, N=137, sample range was 22-141 mg/dL

For triglycerides: Y=0.9798X+7.8, r^2= 0.9771, N=141, sample range was 33-591 mg/dL

Between the professional-collected finger-stick and the venous samples:

For total cholesterol: Y= 0.9863X + 7.486, r^2=0.9814, N=155, sample range was 127-467 mg/dL

For HDL-cholesterol: Y=1.008X + 0.5872, r^2=0.9581, N=142, sample range was 22-141 mg/dL

For triglycerides: Y= 0.9788X + 9.70, r^2= 0.9777, N=147, sample range was 33-875 mg/dL

Between the lay user's finger-stick and the professional's finger-stick:

For total cholesterol: Y= 1.003X – 5.4, r^2=0.9195, N=111, sample range was 127-316 mg/dL

For HDL-cholesterol: Y=0.931X - 1.34, r^2=0.9049, N=110, sample range was 22-129 mg/dL

For triglycerides: Y= 0.9599X + 4.016, r^2= 0.9283, N=107, sample range was 33-506 mg/dL

Approximately 93% of the home users were able to successfully self-collect a dried capillary sample while the professionals' success rate is 92%. In addition, some samples are hemolyzed and cannot be used for analysis; therefore, the sponsor has put a warning statement in their package insert as follows: "Avoid excessive squeezing

or milking of the finger". The sponsor claims that the laboratory will visually inspect all samples and reject those that are hemolyzed.

Laboratory Results Classification as Compared with NCEP Criteria

When 155 individual results for Cholesterol, HDL-cholesterol and Triglycerides were classified according to NCEP criteria, the majority of the results were correctly classified as identified in the chart below.

Results Classification as Compared with NCEP Criteria			
	Cholesterol	HDL-Cholesterol	Triglycerides
Results Correctly Classified	90 %	90 %	91 %
Misclassified high risk (indicates the percentage of the time that your results could actually be lower than the reading you obtain)	5 %	4 %	6 %
Misclassified lower risk (indicates the percentage of the time that your results could actually be higher than the reading you obtain)	5 %	6 %	3%

b. Matrix comparison:

N/A

3. Clinical studies:

a. Clinical Sensitivity:

N/A

b. Clinical specificity:

N/A

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

A HDL cholesterol comparison study was performed with the CRLMN using 55 samples ranged between 24-69 mg/dL. The Home Access candidate device met the NCEP acceptance criteria of ≤ 5% bias and ≤ 4% precision. However, the CRLMN has an additional requirement of R square of >0.975, which the candidate device did not meet. The Home Access candidate device had achieved a R square of 0.9545.

4. Clinical cut-off:

N/A

5. Expected values/Reference range:

*The NCEP ATP III guidelines suggest the following classifications:

Total cholesterol:	<200 mg/dL	Desirable
	200-239 mg/dL	Borderline High
	≥240 mg/dL	High
HDL-cholesterol:	<40 mg/dL	Low
	≥ 60 mg/dL	High
LDL-cholesterol:	<100 mg/dL	Optimal
	100-129 mg/dL	Near Optimal
	130-159 mg/dL	Borderline High
	160-189 mg/dL	High
	≥190 mg/dL	Very High
Triglycerides:	<150 mg/dL	Normal
	150-199 mg/dL	Borderline High
	200-499 mg/dL	High
	≥500 mg/dL	Very High

*The National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) - NIH, May 2001

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.