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

I Background Information:

A 510(k) Number

K200754

B Applicant

W.H.P.M., Inc

C Proprietary and Established Names

Hemosure Accu-Reader A100

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
OOX	Class II	21 CFR 864.6550 - Occult Blood Test	HE - Hematology

II Submission/Device Overview:

A Purpose for Submission:

Clearance of a new test system

B Measurand:

Human hemoglobin (hHb) in feces

C Type of Test:

Qualitative

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below

B Indication(s) for Use:

Hemosure Accu-Reader A100 is an automated immunochemical fecal occult blood test system intended for the qualitative detection of fecal occult blood in human feces by clinical laboratories.

Hemosure Accu-Reader A100 is comprised of Hemosure Accu-Reader A100 Reader with Sample Tray, Hemosure Accu-Reader A100 Test Cartridge, Sample Collection tube, Hemosure Accu-Reader A100 Control and Hemosure Accu-Reader A100 Calibration Cartridge Kit.

For in vitro diagnostic use. For Prescription use.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

Hemosure Accu-Reader™ A100 Reader with Sample Tray

IV Device/System Characteristics:

A Device Description:

The Hemosure Accu-Reader™ A100 is an automated fecal occult blood test system for the qualitative detection of fecal occult blood. It is intended for professional use only. The test system consists of a test cartridge, a sample collection tube, an analyzer, controls and calibration cartridges. The Hemosure Accu-Reader™ A100 system is a sandwich immunoassay that employs a combination of monoclonal and polyclonal antibodies to selectively identify human hemoglobin (hHb) in test samples. It consists of:

Hemosure Accu-Reader™ A100 Reader with Sample Tray

It is an automated camera-based analyzer. Digital imaging is used to analyze the intensity of the test and control lines resulting from the introduction of the sample to the sandwich dye–conjugate immunoassay. The results (positive, negative, or invalid) are reported on a display screen and as a printout.

The sample tray comprises of a turntable and a turntable motor with a mechanism that positions and controls the sample diluent on the test strip.

Hemosure Accu-Reader™ A100 Test Cartridge Kit

The Hemosure Accu-Reader™ A100 adopts a patented test cartridge system which is comprised of:

Test Cartridge: It is a polystyrene plastic case that contains a test strip composed of a plastic plate, a water absorption plate, a nitrocellulose film, colloidal gold, and water absorption paper. The nitrocellulose membrane consists of a control line (line C) coated with sheep anti-mouse polyclonal antibody and a reaction line (line T) coated with mouse anti-human hemoglobin monoclonal antibody. The test strip and cartridge are assembled and designed to prevent any ingress of liquid or air that affects the performance of the test strip and, when the sample buffer collection tube with the fecal material is inserted, prevents any spill outside the test cartridge, creating a clean-free system for the Hemosure Accu-Reader A100.

Sample Collection tube: It contains phosphate-buffered saline. The sample collected by the patient is inserted into the test cartridge (molded for correct insertion) and is placed into the reader sample tray.

Hemosure Accu-Reader™ A100 Control

The Hemosure Accu-Reader™ A100 Control has two control solutions, positive control solution and negative control solution.

Positive control solutions are supplied as 2 mL or 5 mL, containing purified human hemoglobin, Tris buffer, bovine serum albumin, and 0.05% sodium azide. It is stored at 2–8°C.

Negative control solutions are supplied as 2 mL or 5 mL, containing Tris buffer, bovine serum albumin, and 0.05% sodium azide. It is stored at 2–8°C.

Hemosure Accu-Reader™ A100 Calibration Cartridge Kit

The Hemosure Accu-Reader A100 is supplied with a Calibration Cartridge Kit to check the assay reading performance.

B Principle of Operation:

The assay principle is based on an automated sandwich dye–conjugate immunoassay that employs a combination of monoclonal and polyclonal antibodies to selectively identify and provide qualitative determination of human hemoglobin (hHb) in feces. As the test sample flows through the absorbent device, the labeled antibody-dye conjugate binds to the hemoglobin in the specimen forming an antibody-antigen complex. This complex binds to another anti-hemoglobin antibody in the positive test reaction zone and produces a pink-rose color band. In the absence of hemoglobin, there is no line in the positive test reaction zone. The pink-rose color bands in the control reaction zone demonstrate that the reagents and devices are functioning correctly.

The Hemosure Accu-Reader™ A100 Reader with Sample Tray is an automated camera-based analyzer. Digital imaging is used to analyze the intensity of the test and control lines resulting from the introduction of the sample to the sandwich dye-conjugate immunoassay.

The samples are collected in the Sample Collection tube that is sent home with the patient. On return, the sample tube and test cartridge are assembled and placed on the sample tray. The analyzer positions the test cartridge to the plunger station to initiate the test cartridge testing by plunging the sample collection buffer tube into the chamber of the cartridge and thereby piercing its aluminum seal. The test fecal sample buffer is released into the test cartridge and fecal sample buffer will migrate on the enclosed test strip affixed on the test cartridge. Results are read after the tray makes one full rotation which takes 5 minutes. Immediately after sample reading, the result (positive, negative, or invalid) is displayed on the touchscreen and printed on paper whose dispensing slot is situated at the top of the Hemosure Accu-Reader A100.

C Instrument Description Information:

1. Instrument Name:
   Hemosure® Accu-Reader™ A100 Reader with Sample Tray

2. Specimen Identification:
   The feces samples are collected into the Sample Collection tube, each of which includes a barcode. If patient sample ID barcodes are not available, patient sample information must be

manually recorded by the operator after each sample run. Patient sample results can be manually identified by the sample location numbers imprinted on the sample tray.

3. Specimen Sampling and Handling:
   Samplings is done with the applicator stick which is part of the Sample Collection tube.

4. Calibration:
   The Hemosure Accu-Reader A100 is supplied with a Hemosure Accu-Reader A100 Calibration Cartridge Kit to check the analyzer performance. The kit includes a set of 10 calibration cartridges. It is recommended that Accu-Reader A100 calibration procedure must be conducted every 90 days. The calibration checks if the internal digital camera is functioning correctly, the lens is free from debris, and the Hemosure Accu-Reader A100 is working as per the specification.

5. Quality Control:
   Internal control: The test strip within the Hemosure Accu-Reader A100 Test Cartridge contains internal control lines to determine whether or not the test has run properly.

   External control: Hemosure Accu-Reader A100 Control is used in an external control procedure. The control solutions should be run each day before testing patient samples.

   - Positive Control: two or five milliliters of solution containing purified human hemoglobin, Tris buffer, bovine serum albumin, and 0.05% sodium azide.
   - Negative Control: two or five milliliters of solution containing Tris buffer, bovine serum albumin, and 0.05% sodium azide.

V Substantial Equivalence Information:

A Predicate Device Name(s):
OC AUTO MICRO FOB Test and OC Auto Micro 80 Analyzer

B Predicate 510(k) Number(s):
K041408, K041202

C Comparison with Predicate(s):

Device & Predicate Device(s):	K200754	K041408	K041202
Device Trade Name	Hemosure Accu-Reader A100	OC AUTO MICRO FOB Test and Polymedco OC Auto Micro 80 Analyzer	Hemosure™ One-Step Fecal Occult Blood (FOB) Test; Occult Blood Test
General Device Characteristic Similarities			
Intended Use/Indications For Use	Hemosure Accu-Reader A100 is an automated immunochemical fecal occult blood test system intended for the	The Polymedco OC Auto Micro 80 Analyzer and OC Auto Micro FOB Test are designed to be used	The Hemosure™ One-Step Fecal Occult Blood (FOB) Test is an immunochemical device intended for the

	qualitative detection of fecal occult blood in human feces by clinical laboratories. Hemosure Accu-Reader A100 is comprised of Hemosure Accu-Reader A100 Reader with Sample Tray, Hemosure Accu-Reader A100 Test Cartridge, Sample Collection tube, Hemosure Accu-Reader A100 Control and Hemosure Accu-Reader A100 Calibration Cartridge Kit. For in vitro diagnostic use. For Prescription use.	together as an immunological test system intended for the qualitative detection of fecal occult blood in feces by professional laboratories. The automated test is useful for the determination of GI bleeding, found in a number of GI disorders, e.g., colitis, polyps, and colorectal cancer.	qualitative detection of fecal occult blood by laboratories or physicians' offices. It is useful to determine GI bleeding found in a number of GI disorders, e.g., diverticulitis, colitis, polyps, and colorectal cancer.
Test Sample	Feces in extraction buffer	Same	Same
Sampling and Sample Processing	Sampling is done with the help of the stool collection rod which is a part of the Sample Collection tube. The fecal sample is delivered into the sampling tube containing the buffer which extracts it.	Sampling is done with the help of the Sampling Probe which is a part of the OC-Auto Sampling Bottle. The fecal sample is delivered into the sampling bottle containing the buffer which extracts it.	Same
Assay Results	Qualitative	Same	Same
Assay Cut-off	100 ng/mL (hHb in feces processed in extraction buffer).	Same	Same
General Device Characteristic Differences			
Test Principle	Automated sandwich dye-conjugate immunoassay that employs a combination of monoclonal and polyclonal antibodies to selectively identify and	Automated immunoassay using latex fixation for qualitative detection of fecal occult blood in feces.	Qualitative, sandwich dye-conjugate immunoassay and employs a combination of monoclonal and polyclonal antibodies to selectively identify

	provide qualitative determination of human hemoglobin in feces. As the test sample flows up through the absorbent device, the labeled antibody-dye conjugate binds to the hemoglobin in the specimen forming an antibody-antigen complex. This complex binds to anti-hemoglobin antibody in the positive test reaction zone and produces a pink-rose color band. In the absence of hemoglobin, there is no line in the positive test reaction zone. The pink-rose color bands in the control reaction zone demonstrate that the reagents and devices are functioning correctly.		hemoglobin in test samples. As the test sample flows up through the absorbent device, the labeled antibody-dye conjugate binds to the hemoglobin in the specimen forming an antibody-antigen complex. This complex binds to anti–hemoglobin antibody in the positive test reaction zone and produces a pink-rose color band. In the absence of hemoglobin, there is no line in the positive test reaction zone. The pink–rose color bands in the control reaction zone demonstrate that the reagents and devices are functioning correctly.
Detection Mechanism	Camera-based analysis of a sandwich dye conjugate immunoassay.	Optical measurement of agglutination of latex particles.	Manual observation of a pink-rose color band.
Calibration	Test cartridge with defined standard gray color intensity on its T zone is read by the Hemosure Accu-Reader A100 Reader with Sample Tray and adjustment is made according to this standard gray scale intensity.	Calibrator containing hHb A0 is serially diluted prior to analysis to construct a calibration curve.	

VI Standards/Guidance Documents Referenced:

- CLSI EP12-A2: User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline–Second Edition.
- CLSI EP25-A: Evaluation of Stability of *In Vitro* Diagnostic Reagents; Approved Guideline.

- CLSI EP07: Interference Testing in Clinical Chemistry; 3rd Edition.
- CLSI EP09c: Measurement Procedure Comparison and Bias Estimation Using Patient Samples; 3rd Edition.
- Guidance for the Content of Premarket Submission for Software Contained in Medical Devices.
- IEC 60601-1-2 Edition 4.0 2014-02 Medical Electrical Equipment- Part 1-2: General Requirements for Basic Safety and Essential Performance- Collateral Standard: Electromagnetic Disturbances – Requirements and tests.
- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1:2005, MOD)

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Precision studies were designed in accordance with CLSI EP12-A2. The repeatability study was performed at a single site using a single lot of test cartridge on a single instrument by an operator. 21 replicates for each of seven contrived human hemoglobin (hHb) samples were tested. Samples were prepared in the Sample Collection tubes by spiking hHb into Hb-free stool giving the following concentrations: 0, 80, 100, 110, 120, 140 and 1000 ngHb/mL. Between-lot (one instrument, one operator and three lots of the test cartridge), between-instrument (three instruments, one operator and one lot of the test cartridge) and between-run (one instrument, three operators and three lots of the test cartridge) variabilities were also evaluated for the Hemosure Accu-Reader A100. All results met the pre-defined acceptance criteria.

The multi-site reproducibility study was conducted at four sites utilizing four instruments, one instrument per site, with four lots of test cartridge and each site tested one lot. One operator at each site performed the study. Seven contrived human hemoglobin samples were prepared in the Sample Collection tubes by spiking human Hb into Hb-free stool giving samples concentrations of 0, 80, 100, 110, 120, 140 and 1000 ng Hb/mL. Testing included 21 replicates for each concentration level. All results met the pre-defined acceptance criteria.

Statistical Analysis of Repeatability and Reproducibility Studies of Hemosure Accu-Reader™ A100

Type of Precision Study	Actual Results	Results			Overall Percent Agreement	Positive Percent Agreement (95% CI)	Negative Percent Agreement (95% CI)
		Positive	Negative	Total			
Repeatability	Positive	87	1	88	98.63%	98.86% (93.84, 99.80%)	98.31% (90.91, 99.70%)
	Negative	1	58	59			
	Total	88	59	147			

Between-Run	**Positive**	266	2	285	99.09 %	99.25% (97.32, 99.80%)	98.84% (95.88, 99.68%)
	Negative	2	171	156			
	Total	268	173	441			
Between Instrument	**Positive**	264	2	266	99.09 %	99.24% (97.31, 99.78 %)	98.86 % (95.93, 99.69%)
	Negative	2	173	175			
	Total	266	175	441			
Between-Lot	**Positive**	268	2	270	99.32 %	99.63% (97.92, 99.93%)	98.84% (95.86, 99.69%)
	Negative	1	170	171			
	Total	269	172	441			
Between–Site	**Positive**	356	2	358	99.32 %	99.44% (89.00, 99.93%)	99.13% (96.89, 99.89%)
	Negative	2	228	230			
	Total	358	230	588			

2. Linearity:

Not applicable

3. Analytical Specificity/Interference:

a) Human Hemoglobin Variant

The ability of Hemosure Accu-Reader A100 to detect abnormal human hemoglobin variants was determined by testing a series of concentrations of Hemoglobin-S (HbS) spiked into human fecal samples. 21 replicates of fecal samples spiked with Hb-S for each concentration were prepared and tested using one lot of test cartridge. The concentrations tested include: 0, 80, 100, 110, 120, 140 and 1000 ng HbS/mL. At the concentration of 140 ng/mL, the Hemosure Accu-Reader A100 was consistently positive. The study results suggest that Hemosure Accu-Reader A100 is equally sensitive to detect HbS as to human hemoglobin (hHb).

b) Cross Reactivity

i. Animal Hemoglobin

The cross-reactivity of Hemosure Accu-Reader A100 with non-human hemoglobin was evaluated by using one lot of test cartridge. Human hemoglobin (hHb) fecal samples at different concentrations (0, 80, 100, 110, 120, 140 and 1000 ng/mL) were spiked with 500 µg/mL hemoglobin from bovine, porcine, fish, equine, goat, rabbit and sheep. All samples were tested in 21 replicates. The results demonstrate no cross-reactivity of Hemosure Accu-Reader A100 with any of the tested animal hemoglobins.

ii. Dietary Substance and Vegetable Extracts

The cross-reactivity of Hemosure Accu-Reader A100 with dietary substances and vegetable extracts were evaluated by using one lot of test cartridge. Hemoglobin free stool samples were spiked with hHb to obtain seven concentrations (0, 80, 100, 110,

120, 140, and 1000 ng/mL). Samples at different concentration were then spiked with each of the following: 0.5% (by weight) iron, 0.5% (by weight) vitamin C (sodium L-ascorbate), 2.5% (by weight) of broccoli extracts, 2.5% (by weight) cantaloupe extracts, 2.5% (by weight) horseradish extracts, 2.5% (by weight) red radish extracts, 2.5% (by weight) parsnip extracts, 2.5% (by weight) turnip extracts and 2.5% (by weight) cauliflower extracts. All samples were tested in 21 replicates. The results demonstrate no cross-reactivity of Hemosure Accu-Reader A100 with the dietary substances and vegetable extracts at the tested concentrations.

c) Interference

Interference of Hemosure Accu-Reader A100 with animal meat extracts, toilet cleaners and contaminants were evaluated using one lot of test cartridge. Hemoglobin free stool samples were spiked with normal Hb to obtain seven concentrations: 0, 80, 100, 110, 120, 140, and 1000 ng/mL. Samples at each concentration were then spiked with the following animal meat extracts: 2.5% of beef, 2.5% of pork, 2.5% of fish, 2.5% of chicken, 2.5% of lamb, 2.5% of horse, 2.5% of goat and 2.5% of rabbit. The results demonstrate no interference of Hemosure Accu-Reader A100 with animal meat extracts at the tested concentration.

For testing interference with toilet cleaners and other contaminants, Lime-A-Way (5 mg/mL), Clorox (5 mg/mL), Lysol bleach (5 mg/mL), Lysol cleaner (5 mg/mL), Scrubbing Bubbles (5 mg/mL), Bisacodyl enteric coated tablets (25 mg/mL), Sennoside tablets (25 mg/mL), glycerol enema (25 mg/mL), and hydrogen peroxide enema (25 mg/mL) were tested. All samples were tested in 21 replicates. The results demonstrate no interference of Hemosure Accu-Reader A100 with the interferents at the tested concentration.

4. Assay Reportable Range:
Not applicable

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

The Hemosure Accu-Reader™ A100 Control has two control solutions, a positive control and a negative control. The negative control contains 5 mL standard dilution buffer. The positive control contains purified human hemoglobin in standard dilution buffer. The positive control is prepared from material derived from human blood. The source materials were tested for the presence of antibodies to human immunodeficiency virus (HIV), Hepatitis B Surface antigens (HBSAg), Hepatitis C virus (HCV), and found to be negative.

The quality control stability study was performed using three lots of the Hemosure Accu-Reader A100 Control (three lots of liquid negative control and three lots of liquid positive control) with three replicates per test. One lot of the Hemosure Accu-Reader A100 Test Cartridge Kit and one Hemosure Accu-Reader A100 Analyzer were used. The study was conducted at 2–8°C over 25 months (tests on months 0, 3, 6, 9, 12, 15, 18, 21, 24 and 25). The control solutions were determined to be stable for 24 months at 2–8°C.

6. Detection Limit:
Not applicable

7. Assay Cut-Off:
   The assay cut-off study was performed with a single lot of the Hemosure Accu-Reader A100 Test Cartridge Kit. Hemoglobin free stool samples were spiked with human hemoglobin to obtain seven concentrations: 50, 80, 90, 100, 110, 130, and 150 ng/mL. 21 replicates were evaluated at each tested concentration. The cut-off was chosen when the sensitivity and specificity were maximized. The results established the Hemosure Accu-Reader A100 with the analytical cut-off of 100 ng/mL, which is equivalent to 15.6 µg Hb/g of human stool.

8. Accuracy (Instrument):
   Not applicable

9. Carry-Over:
   Not applicable

B Comparison Studies:

1. Method Comparison with Predicate Device:
   A method comparison study was performed to demonstrate the equivalency between Hemosure Accu-Reader A100 and the OC Auto Micro FOB Test on the OC Auto Micro 80 Analyzer. A total of 377 clinical fecal samples were tested from individuals that had recently been screened by colonoscopy. The patient population included high risk individuals (subjects with positive diagnoses i.e., diagnosed with ulcerative colitis, Crohn's disease, rectal adenomas/adenomatous polyps, Gardner syndrome, colorectal cancer, etc.) and asymptomatic individuals (subjects with negative diagnoses i.e., individuals without any of the above clinical conditions). The study was performed at three external sites, each site with one Hemosure Accu-Reader A100 Reader. One lot of Hemosure Accu-Reader A100 Test Cartridge Kit per site was used to analyze the samples. The method comparison study as summarized below showed an overall percent agreement (OPA) of 98.67% (96.93%, 99.43%), with positive percent agreement (PPA) 98.63% (93.51%, 99.97%), and negative percent agreement (NPA) 98.71% (96.87, 99.76%) between the candidate and the predicate devices.

Study site		Hemosure Accu-Reader™ A100			Overall Percent Agreement (95% CI)	Positive Percent Agreement (95% CI)	Negative Percent Agreement (95% CI)
	OC Auto Micro FOB	Positive	Negative	Total			
All Sites	Positive	144	2	146	98.67% (96.93, 99.43%)	98.63% (93.51, 99.97%)	98.71% (96.87, 99.76%)
	Negative	3	228	231			
	Total	147	230	377			

2. Matrix Comparison:
   Not applicable

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable

2. Clinical Specificity:
   Not applicable

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):
   Not applicable

D Clinical Cut-Off:

Not applicable

E Expected Values/Reference Range:

Not applicable

F Other Supportive Instrument Performance Characteristics Data:

Prozone Effect (Hook-Effect)

The prozone study was conducted to determine the effects of high concentrations of human hemoglobin on the Hemosure Accu-Reader A100 test results. Hemoglobin-free stool sample was spiked with human blood of known hemoglobin concentration to achieve following concentrations: 500, 800, 1000, 1200, 1500, 2000, 2500 and 3000 ng/mL. A total of 21 replicates were tested at each hemoglobin concentration with one lot of the Hemosure Accu-Reader A100 Test Cartridge Kit. The Hemosure Accu-Reader A100 was not susceptible to the Hook effect up to a concentration of 3000 ng/mL.

Sample Stability Studies

Stool samples were spiked with different concentrations of human hemoglobin and stored in the Sample Collection tubes at different temperatures for up to 30 days after sampling using three lots of Hemosure Accu-Reader A100 Test Cartridge Kits (including the Test Cartridge and the Sample Collection tube). 21 replicates of each of the following hemoglobin concentrations were tested: 0, 80, 100, 110, 120, 140 and 1000 ng/mL.

a. The samples stored at 30ºC and 40ºC were tested on 0, 6, 11, 14 and 15 days with sample stability in the Sample Collection tube was acceptable for up to 14 days.

b. For refrigerated conditions, two temperature conditions were tested. Samples were stored at 2–8°C and -10 to -20ºC and testing was performed at 0, 30 and 32 days. Based on the results, the fecal sample in the Sample Collection tube can be stored for up to 30 days under refrigerated conditions.

Reagent Stability Studies

a. Realtime Shelf-life Stability Studies
   The real time stability study was conducted with three lots of Hemosure Accu-Reader A100 Test Cartridge Kits (including the Test Cartridge and the Sample Collection tube). A total of three operators at a single site with one device of the Hemosure Accu-Reader A100 Reader

with Sample Tray was used to perform the study. Two storage temperatures (4°C and 30°C) were tested. Time points used in the real-time stability study included: 0, 6, 12, 18, 24, 30, 36 and 37 months. Test cartridge kits were retrieved and tested with different hemoglobin concentrations at the end of each designated time point in the study. Seven hemoglobin concentrations of 0, 80, 100, 110, 120, 140 and 1000 ng/mL were used. The testing was done with 21 replicates for each concentration level. Based on the real-time stability results, the current data supports the shelf-life of Hemosure Accu-Reader A100 Test Cartridge Kits (including the Test Cartridge and the Sample Collection tube) for up to 24 months at both 4°C and 30°C.

b. Transportation Stability Studies
The shipping study was conducted to evaluate the shipping stress to the Hemosure Accu-Reader A100 Sample Collection tube and its endurance under extreme temperatures.

Before sampling: The Hemosure Accu-Reader A100 Sample Collection tubes (containing no fecal samples) were stored at -10°C, 2–8°C, 25°C and 40°C for different time points (0, 3, 5 and 6 days). Tests were performed with 21 replicates of each hemoglobin concentration (0, 80, 100, 110, 120, 140 and 1000 ng/mL) at the end of each designed time point of the study. The study was conducted at one site with one lot of Hemosure Accu-Reader A100 Test Cartridge Kit on a single analyzer. The results demonstrate that the Hemosure Accu-Reader A100 Sample Collection tubes (before sampling) can be stable for five days under the shipping temperatures of -10°C to 40°C.

After sampling: The Hemosure Accu-Reader A100 Sample Collection tubes were tested by 21 replicates of hemoglobin free fecal samples spiked with seven different concentrations of hemoglobin (0, 80, 100, 110, 120, 140 and 1000 ng/mL). After sampling, the Hemosure Accu-Reader A100 Sample Collection tubes were stored at -10°C, 2–8°C, 25°C and 40°C for different time points (0, 3, 5 and 6 days). Tests were performed with 21 replicates of each hemoglobin concentration at the end of each designed time point of the study. The study was conducted at one site with one lot of Hemosure Accu-Reader A100 Test Cartridge Kit on a single analyzer. The results demonstrate that the Accu-Reader A100 Sample Collection tubes (after sampling) can be stable for five days under the shipping temperatures of -10°C to 40°C.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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