June 2, 2022

W.H.P.M., Inc
% Farokh Etemadieh
Manager of Regulatory Affairs and Quality Assurance
W.H.P.M., Inc
5358 North Irwindale Avenue
Irwindale, California 91706

Re: K200754
Trade/Device Name: Hemosure Accu-Reader A100
Regulation Number: 21 CFR 864.6550
Regulation Name: Occult Blood Test
Regulatory Class: Class II
Product Code: OOX
Dated: December 13, 2021
Received: December 13, 2021

Dear Farokh Etemadieh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Min Wu, Ph.D.
Branch Chief
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below

510(k) Number *(if known)*

K200754

Device Name

Hemosure® Accu-Reader™ A100

Indications for Use *(Describe)*

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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human
Services Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.

510(k) Summary

510(k) Submitter Information:

Name: W.H.P.M., Inc.
Chief Executive: John Wan, CEO
Address 5358 North Irwindale Avenue
Irwindale, California 91706
Phone: 626-443-8480
Fax: 626-443-8065
Contact name: Farokh Etemadieh, Regulatory and Quality Manager

Application Correspondent:

Name: Farokh Etemadieh
Contact: Farokh Etemadieh
Address: 5358 North Irwindale Avenue
Irwindale, California 91706
Phone: 626-443-8480
Fax: 626-443-8065

Date Prepared: June 1, 2022

Device Information:

Trade Name: Hemosure® Accu-Reader™ A100
Common Name: Automated Occult Blood Reader
Classification Name: Occult Blood Test (21 CLR 864.6550)
Product Code: OOX

Device Class: Class II

510(k) Number: K200754

Predicate Device Information:

K Number	Device Trade Name	Manufacturer
Primary K041408	OC AUTO MICRO FOB Test and OC Auto Micro 80 Analyzer	POLYMEDCO, Inc.
Reference K041202	Hemosure™ One-Step Fecal Occult Blood (FOB) Test; Occult Blood Test	WHPM, Inc.

Intended 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.

Device Description:

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.

The principle of measurement is 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 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.

The throughput of the instrument is 100 samples per hour. The samples are collected in the sample collection tube “Sample Collection tube”. The sample tube and test cartridge are assembled and placed on the sample tray. The instrument 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 Accu-Reader™ A100.

Components of Hemosure Accu-Reader™ A100 Test System

Hemosure Accu-Reader™ A100 Reader

Automated Camera-based reader. 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 provided on a display screen as well as a printout.

Hemosure Accu-Reader™ A100 Sample Tray

Sample tray which comprises a turntable and a turntable motor with a mechanism that positions and controls the sample diluent with the test strip.

Hemosure Accu-Reader™ A100 Test Cartridge

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

1. **Test cartridge** - The test cartridge 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 1. Colloidal gold is prepared by labeling mouse anti-human hemoglobin monoclonal antibody 2.

2. **Sample Collection Tube** - contains Phosphate-buffered saline.

The sample is collected by the patient inserted into the test cartridge (molded for correct insertion), placed into the Reader sample tray.

Individual Test Calibration - Each time a test is run, the reader calibrates by using a specified blank zone of the test strip that is unaffected by the immunological reaction of the test. This calibration is conducted to mitigate any interference that could be caused by abnormal sample color.

Hemosure Accu-Reader™ A100 Test Positive and Negative Control Solutions

Positive Control – 5mL or 2mL contains purified human hemoglobin, Tris buffer, bovine serum albumin, and 0.05% sodium azide. Store product at 2°C-8°C.

Negative Control - 5mL or 2mL contains Tris buffer, bovine serum albumin, and 0.05% sodium azide. Store product at 2°C-8°C.

Hemosure Accu-Reader™ A100 Calibration Cartridges

Optical System Calibration

The Hemosure® Accu-Reader™ A100 is supplied with a Calibration Cartridge Kit to check the assay reading performance. A calibration check verifies that the internal digital camera is functioning correctly, the lens is free from debris, and the Hemosure® Accu-Reader™ A100 is working to specification.

Predicate Comparison Table- Primary Predicate

Table 1: Comparison Table – Primary Predicate

Description	New Device W.H.P.M., Inc.	Predicate Device POLYMEDCO, Inc.
Similarities		
K Number	K200754	K041408
Brand name	Hemosure® Accu-Reader™ A100	OC AUTO MICRO FOB Test and OC Auto Micro 80 Analyzer TEST
Intended 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	The Polymedco OC Auto Micro 80 Analyzer and OC Auto Micro FOB Test are designed to be used 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 gastrointestinal (GI) bleeding, found in a number of gastrointestinal (GI) disorders, e.g., colitis, polyps, and colorectal cancer.

Description	New Device W.H.P.M., Inc.	Predicate Device POLYMEDCO, Inc.
	Hemosure® Accu-Reader™ A100 Calibration Cartridge Kit. For in vitro diagnostic use. For Prescription use.	
Product Code	OOX	OOX
Intended use environment	Professional Laboratories	Professional Laboratories
Intended user	Laboratory technician	Laboratory technician
Test Sample	Feces in an extraction buffer	Feces in an extraction buffer
Test Principle	Automated sandwich dye conjugate immunoassay for qualitative detection of fecal occult blood in feces	Automated immunoassay using latex fixation for qualitative detection of fecal occult blood in feces
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.
Assay Results	Qualitative	Qualitative
Assay Cut-off	100ng/mL (Human hemoglobin in feces processed in extraction buffer)	100 ng/mL (Human hemoglobin in feces processed in extraction buffer)
Test Time	5-10 minutes	5-10 minutes
Presentation of Test results	Qualitative (Positive or Negative)	Qualitative (Positive or Negative)
Differences		

Description	New Device W.H.P.M., Inc.	Predicate Device POLYMEDCO, Inc.
Test Principle	Automated sandwich dye conjugate immunoassay that employs a combination of monoclonal and polyclonal antibodies to selectively identify and 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.	Automated immunoassay using latex fixation for qualitative detection of fecal occult blood in feces.
Detection Mechanism	Camera-based analysis of a sandwich dye conjugate immunoassay.	Optical measurement of agglutination of latex particles
Test Throughput/Time	100 samples/hour	80 samples/hour
Calibration	A test cartridge with defined standard gray color intensity on its T zone is read by the Accu-Reader™ A100 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.

Reference Predicate

The reference predicate, K041202, is included for the similarities in its technological characteristics of the test cartridge, buffer and controls to support safety claims for the device. The test principle is the same but modifications to the design were made to the test cartridge for the automated processing of samples.

Table 2: Reference Comparison Chart

Description	Subject Device	Reference Device K041202
Similarities		
Brand name	Hemosure® Accu-Reader™ A100 Test Cartridge	Hemosure™ One-Step Fecal Occult Blood (FOB) Test; Occult Blood Test
Intended Use/Indications 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.	The Hemosure™ One-Step Fecal Occult Blood (FOB) Test is an immunochemical device intended for the qualitative detection of Fecal Occult Blood by laboratories or physicians offices. It is useful to determine gastrointestinal (GI) bleeding found in a number of GI disorders, e.g. diverticulitis, colitis, polyps, and colorectal cancer.
Classification Code	OOX	KHE

Description	Subject Device	Reference Device K041202
Test principle	Qualitative, sandwich dye conjugate immunoassay and employs a combination of monoclonal and polyclonal antibodies to selectively identify 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	Qualitative, sandwich dye conjugate immunoassay and employs a combination of monoclonal and polyclonal antibodies to selectively identify 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
Test Device	Test Cartridge (test strip enclosed in a plastic housing) and sample tube.	Test Cassette (test strip enclosed in a plastic housing) and sample tube.
Test Components	Accu-Reader™ A100 Test Cartridge; Sample Collection Tube; Controls- Positive and Negative Solutions	Test Cassette individually sealed in a foil packet pouch, containing mouse MAB and sheep PAB, directed against human Hemoglobin (hHb) and; Buffer, “Limit Fecal Sample Collection” extraction buffer, 2.0 mL. Controls- Positive and Negative Solutions
Sampling and Sample Processing	Samplings is done with the applicator stick which is part of the Sample Collection Tube	Samplings is done with the applicator stick which is part of the Buffer, “Limit Fecal Sample Collection” tube
Assay results	Qualitative	Qualitative
Assay Cut-off	100 ng/mL (Human hemoglobin in feces processed in extraction buffer)	100 ng/mL (Human hemoglobin in feces processed in extraction buffer)
Detection mechanism	Camera-based analysis of a sandwich dye conjugate immunoassay	Manual observation of a pink-rose color band

Description	Subject Device	Reference Device K041202
Test cassette	Individually sealed in a foil pouch, containing a combination of mouse MAB and sheep or goat PAB, directed against human hemoglobin (hHb);	Individually sealed in a foil pouch, containing a combination of mouse MAB and sheep or goat PAB, directed against human hemoglobin (hHb);
Specimen collector	Fecal Collection Tube of extraction buffer. (2.0 mL)	Fecal Collection Tube of extraction buffer. (2.0 mL)
Controls, Positive and Negative	Same	Same

Performance Characteristics

Precision/Reproducibility Studies

The Accu-Reader™ A100 was tested between test kit lots (one instrument and different lots), between instruments (one lot and different instruments), between sites (different instruments and lots), and between runs with different operators. Testing included 21 replicates across 7 concentrations at 0 ng/mL, 80 ng/mL, 100 ng/mL, 110 ng/mL, 120 ng/mL, 140 ng/mL, and 1000 ng/mL for all studies across repeatability and reproducibility. Precision/reproducibility was assessed by evaluating the positive percentage agreement (PPA) and negative percentage agreement (NPA) of the observed results with expected result values.

Table 3: Intra-Assay Precision/Repeatability Data Summary

Concentration	Expected Results	Observed Results			Positive Percent *(95% CI)*	Negative Percent *(95% CI)*
		Positive	Negative	Total		
0 ng/ml	0% Positive	0	21	21	0	100% (84.5-100)
80 ng/ml	5% Positive	1	20	21	4.8% (0.9-22.7)	95.2% (77.3-99.2)
100 ng/ml	50% Positive	10	11	21	47.6% (28.3-67.6)	52.4% (32.4-71.7)
110 ng/ml	C95 - 20%	15	6	21	71.4% (50.1-86.2)	28.6% (13.8-50)
120 ng/ml	95% Positive	20	1	21	95.2% (77.3-99.2)	4.8% (0.9-22.7)
140 ng/ml	C95 + 20%	21	0	21	100% (84.5-100)	0
1000 ng/ml	100% Positive	21	0	21	100% (84.5-100)	0

Table 4A: Inter-site Repeatability/Reproducibility Data Summary

Site	Sample concentration	Observed Results			Positive Percent *(95% CI)*	Negative Percent *(95% CI)*	Overall Percentage Agreement
		Positive	Negative	Total			
Site 1	0 ng/ml	0	21	21	0	100% (84.5%-100%)	100%
	80 ng/ml	0	21	21	0	100%	100%

Site	Sample concentration	Observed Results			Positive Percent *(95% CI)*	Negative Percent *(95% CI)*	Overall Percentage Agreement
		Positive	Negative	Total			
						(84.5%-100%)	
	100 ng/ml	11	10	21	52.4% (32.4%-71.7%)	47.6% (28.3%-67.6%)	52.4%
	110 ng/ml	15	6	21	71.4% (50.1%-86.2%)	28.6% (13.8%-50%)	71.4%
	120 ng/ml	20	1	21	95.2% (77.3%-99.2%)	4.8% (0.9%-22.7%)	95.2%
	140 ng/ml	21	0	21	100% *(84.5%-100%)*	0	100%
	1000 ng/ml	21	0	21	100% *(84.5%-100%)*	0	100%
Site 2	0ng/ml	0	21	21	0	100% *(84.5%-100%)*	100%
	80 ng/ml	0	21	21	0	100% *(84.5%-100%)*	100%
	100 ng/ml	11	10	21	52.4% *(32.4%-71.7%)*	47.6% *(28.3%-67.6%)*	52.4%
	110 ng/ml	15	6	21	71.4% *(50.1%-86.2%)*	28.6% *(13.8%-50%)*	71.4%
	120 ng/ml	21	0	21	100% *(84.5%-100%)*	0	100%
	140 ng/ml	21	0	21	100% *(84.5%-100%)*	0	100%
	1000 ng/ml	21	0	21	100% *(84.5%-100%)*	0	100%
Site 3	0ng/ml	0	21	21	0	100% *(84.5%-100%)*	100%
	80 ng/ml	1	20	21	4.8% *(0.9%-22.7%)*	95.2% *(77.3%-99.2%)*	95.2%
	100 ng/ml	12	9	21	57.1% *(32.4%-75.5%)*	42.9% *(24.5%-63.5%)*	57.1%
	110 ng/ml	15	6	21	71.4% *(50.1%-86.2%)*	28.6% *(13.8%-50%)*	71.4%
	120 ng/ml	20	1	21	95.2% *(77.3%-99.2%)*	4.8% *(0.9%-22.7%)*	95.2%
	140 ng/ml	21	0	21	100% *(84.5%-100%)*	0	100%
	1000 ng/ml	21	0	21	100% *(84.5%-100%)*	0	100%
Site 4	0ng/ml	0	21	21	0	100% *(84.5%-100%)*	100%
	80 ng/ml	1	20	21	4.8% *(0.9%-22.7%)*	95.2% *(77.3%-99.2%)*	95.2%
	100 ng/ml	12	9	21	57.1% *(28.3%-67.6%)*	42.9% (32.4%-71.7%)	57.1%
	110 ng/ml	15	6	21	71.4% *(47.8%-88.7%)*	28.6% *(11.3%-52.2%)*	71.4%

Site	Sample concentration	Observed Results			Positive Percent *(95% CI)*	Negative Percent *(95% CI)*	Overall Percentage Agreement
		Positive	Negative	Total			
	120 ng/ml	20	1	21	95.2% *(77.3%-99.2%)*	4.8% *(0.9%-22.7%)*	95.2%
	140 ng/ml	21	0	21	100% *(84.5%-100%)*	0	100%
	1000 ng/ml	21	0	21	100% *(84.5%-100%)*	0	100%
All sites	0ng/ml	0	84	84	0	100% *(95.7%-100%)*	100%
	80 ng/ml	2	82	84	2.4% *(0.3%-8.3%)*	97.6% *(91.7%-99.75)*	97.6%
	100 ng/ml	46	38	84	54.8% *(43.5%-65.7%)*	45.2% *(34.3%-56.5%)*	54.8%
	110 ng/ml	60	24	84	71.4% *(60.5%-80.8%)*	24% *(19.2%-39.5%)*	71.4%
	120 ng/ml	82	2	84	97.6% *(91.7%-99.75)*	2.4% *(0.3%-8.3%)*	97.6%
	140 ng/ml	84	0	84	100% *(95.7%-100%)*	0	100%
	1000 ng/ml	84	0	84	100% *(95.7%-100%)*	0	100%

Table 4B: Summary of Repeatability/Reproducibility Studies Data

Sample Concentration	Factor	Number Positive (%), 95%CI			Number Negative (%), 95%CI		
		1	2	3	1	2	3
0 ng/mL	Run	0	0	0	21(100), 84.5-100	21(100), 84.5-100	21(100), 84.5-100
	Device	0	0	0	21(100), 84.5-100	21(100), 84.5-100	21(100), 84.5-100
	Lot	0	0	0	21(100), 84.5-100	21(100), 84.5-100	21(100), 84.5-100
80 ng/mL	Run	1 (4.8), 0.9-22.7	0	1 (4.8), 0.9-22.7	20(95.2), 77.3-99.2	21(100), 84.5-100	20(95.2), 77.3-99.2
	Device	0	1 (4.8), 0.9-22.7	1 (4.8), 0.9-22.7	21(100), 84.5-100	20(95.2), 77.3-99.2	20(95.2), 77.3-99.2
	Lot	1 (4.8), 0.9-22.7	1 (4.8), 0.9-22.7	0	20(95.2), 77.3-99.2	20(95.2), 77.3-99.2	21(100), 84.5-100
100 ng/mL	Run	11(52.4), 32.4-71.7	11(52.4), 32.4-71.7	11(52.4), 32.4-71.7	10(47.6), 28.3-67.6	10(47.6), 28.3-67.6	10(47.6), 28.3-67.6
	Device	11(52.4), 32.4-71.7	10(47.6), 28.3-67.6	11(52.4), 32.4-71.7	10(47.6), 28.3-67.6	11(52.4), 32.4-71.7	10(47.6), 28.3-67.6
	Lot	12(57.1), 36.5-75.5	11(52.4), 32.4-71.7	11(52.4), 32.4-71.7	9(42.9), 24.5-63.5	10(47.6), 28.3-67.6	10(47.6), 28.3-67.6
110 ng/mL	Run	15(71.4), 50.1-86.2	16(76.2), 54.9-89.4	15(71.4), 50.1-86.2	6(28.6), 13.8-50	5(23.8), 10.6-45.1	6(28.6), 13.8-50
	Device	15(71.4), 50.1-86.2	15(71.4), 50.1-86.2	15(71.4), 50.1-86.2	6(28.6), 13.8-50	6(28.6), 13.8-50	6(28.6), 13.8-50
	Lot	16(76.2), 54.9-89.4	15(71.4), 50.1-86.2	15(71.4), 50.1-86.2	5(23.8), 10.6-45.1	6(28.6), 13.8-50	6(28.6), 13.8-50

Sample Concentration	Factor	Number Positive (%), 95%CI			Number Negative (%), 95%CI		
		1	2	3	1	2	3
120 ng/mL	Run	20(95.2), 77.3-99.2	20(95.2), 77.3-99.2	21(100), 84.5-100	1 (4.8%), 0.9-22.7	1 (4.8%), 0.9-22.7	0
	Device	20(95.2), 77.3-99.2	21(100), 84.5-100	20(95.2), 77.3-99.2	1 (4.8%), 0.9-22.7	0	1 (4.8), 0.9-22.7
	Lot	21(100), 84.5-100	20(95.2), 77.3-99.2	21(100), 84.5-100	0	1 (4.8), 0.9-22.7	0
140 ng/mL	Run	21(100), 84.5-100	21(100), 84.5-100	21(100), 84.5-100	0	0	0
	Device	21(100), 84.5-100	21(100), 84.5-100	21(100), 84.5-100	0	0	0
	Lot	21(100), 84.5-100	21(100), 84.5-100	21(100), 84.5-100	0	0	0
1000 ng/mL	Run	21(100), 84.5-100	21(100), 84.5-100	21(100), 84.5-100	0	0	0
	Device	21(100), 84.5-100	21(100), 84.5-100	21(100), 84.5-100	0	0	0
	Lot	21(100), 84.5-100	21(100), 84.5-100	21(100), 84.5-100	0	0	0

Results: Statistical analysis of repeatability and reproducibility studies of the Accu-Reader™ A100.

Table 5: PPA/NPA

Precision Study	Observed Results	Expected Results			Overall Percent Agreement	Positive Percent Agreement (95% CI)	Negative Percent Agreement (95% CI)
		Positive Results	Negative Results	Total Results			
Repeatability	Positive Results	87	1	88	98.63%	98.86% (93.84%~99.80%)	98.31% (90.91%~99.70%)
	Negative Results	1	58	59			
	Total Results	88	59	147			
Between-run Reproducibility	Positive Results	266	2	268	99.09% (97.69%~99.75%)	99.25% (97.33%~99.91%)	98.84% (95.89%~99.86%)
	Negative Results	2	171	173			
	Total Results	268	173	441			
Between Instrument Reproducibility	Positive Results	264	2	266	99.09% (97.69%~99.75%)	99.25% (97.31%~99.78%)	98.86% (95.93%~99.86%)
	Negative Results	2	173	175			
	Total Results	266	175	441			
Lot-to-Lot Reproducibility	Positive Results	268	2	270	99.32%	99.63% (97.92%~ 99.93%)	98.84% (95.86%~ 99.69%)
	Negative Results	1	170	171			
	Total Results	269	172	441			

Precision Study	Observed Results	Expected Results			Overall Percent Agreement	Positive Percent Agreement (95% CI)	Negative Percent Agreement (95% CI)
		Positive Results	Negative Results	Total Results			
Between-site Reproducibility	Positive Results	356	2	358	99.32%	99.44% (98.00%~99.93%)	99.13% (96.89%~99.89%)
	Negative Results	2	228	230			
	Total Results	358	230	588			

Assay Cut-off Study

The assay cut-off performance evaluation for the Accu-Reader™ A100 was executed side-by-side with the predicate device to compare the test results of both devices. Based on the results, the overall percent agreement of the Accu-Reader™ A100 is more than 95%; thus, this agreement describes the validity of the data collection and analysis. The data indicates that the Accu-Reader™ A100 performs similarly to the predicate device, with the analytical cut-off of 100ng/mL results (hemoglobin in fecal mixed with the detection buffer), which is equivalent to 0.0156 mg Hb per gram or 15.6 µg Hb per gram of human stool.

Prozone Effect Study

The Accu-Reader™ A100 was found to not be susceptible to the Hook effect up to a concentration of 3000ng/mL as 21 replicates across eight increasing concentrations of fecal samples containing human blood were tested, which resulted in zero false negatives.

Analytic Sensitivity Study: Human Hemoglobin Variant

The ability to detect human hemoglobin-s variant was determined by testing a series of concentrations of Hemoglobin-S spiked with human stool samples. Twenty-one (21) replicates of fecal samples spiked with Hb-S for each concentration were prepared. The concentrations were at 0, 12, 16, 17, 19, 22 and 156 µg HbS/g stool, and equivalent to 0, 80, 100, 110, 120, 140 and 1000 ng HbS/ml. The Accu-Reader™ A100 was found to be sensitive to the abnormal hemoglobin associated with sickle cell anemia (Hb-S variant).

Table 6: hHb variant summary

Concentration	0ng/ml Pos/Neg (% Pos)	80ng/mL Pos/Neg (% Pos)	100ng/mL Pos/Neg (% Pos)	110ng/mL Pos/Neg (% Pos)	120ng/mL Pos/Neg (% Pos)	140ng/mL Pos/Neg (% Pos)	1000ng/mL Pos/Neg (% Pos)
Test Result	0/21 (0%)	1/20 (5%)	10/11 (48%)	14/7 (67%0)	20/1 (95%)	21/0 (100%)	21/0 (100%)

Cross Reactivity - Animal Hemoglobin Analytical Specificity/Exclusivity

The cross-reactivity of the Accu-Reader™ A100 was tested with eight (8) animal hemoglobin samples by testing21 replicates of fecal samples spiked with human hemoglobin at several concentrations (0, 80, 100, 110, 120, 140 and 1000ng/mL). Each contrived fecal sample was prepared with 500 µg/mL of animal hemoglobin and included the following animals: Bovine, Poultry, Fish, Horse/Equine, Goat, Pig, Rabbit and Sheep. The Accu-Reader™ A100 did not show significant cross-reactivity with any of the animal hemoglobin proteins tested.

Table 7: Cross Reactivity Summary

Analytical Specificity	Observed Results	Expected Results			Overall Percent Agreement	Positive Percent Agreement	Negative Percent Agreement
	Accu-Reader™ A100	Positive Results	Negative Results	Total Results			
Bovine Hemoglobin 500 µg/ml	Positive Results	84	1	85	98.6%	98.8%	98.4%
	Negative Results	1	61	62			
	Total Results	85	62	147			
Equine Hemoglobin 500 µg/ml	Positive Results	88	1	89	98.6%	98.9%	98.3%
	Negative Results	1	57	58			
	Total Results	89	58	147			
Goat Hemoglobin 500 µg/ml	Positive Results	88	0	88	100%	100%	100%
	Negative Results	0	59	59			
	Total Results	88	59	147			
Porcine Hemoglobin 500 µg/ml	Positive Results	88	1	89	98.6%	98.9%	98.3%
	Negative Results	1	57	58			
	Total Results	89	58	147			
Sheep Hemoglobin 500 µg/ml	Positive Results	89	0	89	99.3%	98.9%	100%
	Negative Results	1	57	58			
	Total Results	90	57	147			
Turkey Hemoglobin 500 µg/ml	Positive Results	89	1	90	98.6%	98.9%	98.2%
	Negative Results	1	56	57			
	Total Results	90	57	147			
Fish Hemoglobin 500 µg/ml	Positive Results	89	1	90	99.3%	100%	98.3%
	Negative Results	0	57	57			
	Total Results	89	58	147			
Rabbit Hemoglobin 500 µg/ml	Positive Results	88	0	88	99.3%	98.9%	100%
	Negative Results	1	58	59			
	Total Results	89	58	147			

Interfering Substances

The Interference substances studies for Accu-Reader™ A100 test kit were conducted with Animal Meat Extracts, Dietary Substances, Vegetable Extracts, Toilet Water and Contaminants by testing 21 replicates of fecal samples spiked with human hemoglobin at concentrations of 0, 80, 100, 110, 120, 140 and 1000 ng/mL. No significant interference was observed with the substances listed above.

Table 8: Summary - Meat Extracts

Meat Extracts	Sample concentration	Expected result	Observed positive results	Observed negative results	Total number	Positive percent agreement (95 % CI)	Negative percent agreement (95 % CI)	Overall percentage agreement
	0ng/ml	0% positive	0	21	21	0	21(100) 84.5-100	100%
	80 ng/ml	5%positive	1	20	21	1(4.8) 0.9-22.7	20(95.2) 84.5-100	95.2%
	100 ng/ml	50%positive	10	11	21	10(47.6) 28.3-67.6	11(52.4) 32.4-71.7	47.6%

Meat Extracts	Sample concentration	Expected result	Observed positive results	Observed negative results	Total number	Positive percent agreement (95 % CI)	Negative percent agreement (95 % CI)	Overall percentage agreement
Beef Meat Extract 2.5%	110 ng/ml	C95-20%	14	7	21	14(66.7) 50.1-86.2	7(33.3) 13.8-50	66.7%
	120 ng/ml	95%positive	20	1	21	20(95.2) 77.3-99.2	1(4.8) 0.9-22.7	95.2%
	140 ng/ml	C95+20%	21	0	21	21(100) 84.5-100	0	100%
	1000 ng/ml	100% positive	21	0	21	21(100) 84.5-100	0	100%
Pork Meat Extract 2.5%	0ng/ml	0% positive	0	21	21	0	21(100) 84.5-100	100%
	80 ng/ml	5%positive	0	21	21	0	21(100) 84.5-100	100%
	100 ng/ml	50%positive	11	10	21	11(52.4) 32.4-71.7	10(47.6) 28.3-67.6	52.4%
	110 ng/ml	C95-20%	15	6	21	15(71.4) 50.1-86.2	6(28.6) 13.8-50	71.4%
	120 ng/ml	95%positive	21	0	21	21(100) 84.5-100	0	100%
	140 ng/ml	C95+20%	21	0	21	21(100) 84.5-100	0	100%
	1000 ng/ml	100% positive	21	0	21	21(100) 84.5-100	0	100%
Fish Meat Extract 2.5%	0ng/ml	0% positive	0	21	21	0	21(100) 84.5-100	100%
	80 ng/ml	5%positive	0	21	21	0	21(100) 84.5-100	100%
	100 ng/ml	50%positive	11	10	21	11(52.4) 32.4-71.7	10(47.6) 28.3-67.6	52.4%
	110 ng/ml	C95-20%	15	6	21	15(71.4) 50.1-86.2	6(28.6) 13.8-50	71.4%
	120 ng/ml	95%positive	20	1	21	20(95.2) 77.3-99.2	1(4.8) 0.9-22.7	95.2%
	140 ng/ml	C95+20%	21	0	21	21(100) 84.5-100	0	100%
	1000 ng/ml	100% positive	21	0	21	21(100) 84.5-100	0	100%

Meat Extracts	Sample concentration	Expected result	Observed positive results	Observed negative results	Total number	Positive percent agreement (95 % CI)	Negative percent agreement (95 % CI)	Overall percentage agreement
Horse Meat Extract 2.5%	0ng/ml	0% positive	0	21	21	0	21(100) 84.5-100	100%
	80 ng/ml	5%positive	1	20	21	1(4.8) 0.9-22.7	20(95.2) 84.5-100	95.2%
	100 ng/ml	50%positive	11	10	21	11(52.4) 32.4-71.7	10(47.6) 28.3-67.6	52.4%
	110 ng/ml	C95-20%	14	7	21	14(66.7) 50.1-86.2	7(33.3) 13.8-50	66.7%
	120 ng/ml	95%positive	20	1	21	20(95.2) 77.3-99.2	1(4.8) 0.9-22.7	95.2%
	140 ng/ml	C95+20%	21	0	21	21(100) 84.5-100	0	100%
	1000 ng/ml	100% positive	21	0	21	21(100) 84.5-100	0	100%
Goat Meat Extract 2.5%	0ng/ml	0% positive	0	21	21	0	21(100) 84.5-100	100%
	80 ng/ml	5%positive	1	20	21	1(4.8) 0.9-22.7	20(95.2) 84.5-100	95.2%
	100 ng/ml	50%positive	12	9	21	12(57.1) 36.6-75.5	9(42.9) 24.5-63.4	57.1%
	110 ng/ml	C95-20%	15	6	21	15(71.4) 50.1-86.2	6(28.6) 13.8-50	71.4%
	120 ng/ml	95%positive	21	0	21	21(100) 84.5-100	0	100%
	140 ng/ml	C95+20%	21	0	21	21(100) 84.5-100	0	100%
	1000 ng/ml	100% positive	21	0	21	21(100) 84.5-100	0	100%
Rabbit Meat Extract	0ng/ml	0% positive	0	21	21	0	21(100) 84.5-100	100%
	80 ng/ml	5%positive	0	21	21	0	21(100) 84.5-100	100%
	100 ng/ml	50%positive	11	10	21	11(52.4) 32.4-71.7	10(47.6) 28.3-67.6	52.4%
	110 ng/ml	C95-20%	16	5	21	16(76.2) 50.1-86.2	6(23.8) 10.6-45.1	76.2%

Meat Extracts	Sample concentration	Expected result	Observed positive results	Observed negative results	Total number	Positive percent agreement (95 % CI)	Negative percent agreement (95 % CI)	Overall percentage agreement
2.5%	120 ng/ml	95%positive	20	1	21	20(95.2) 77.3-99.2	1(4.8) 0.9-22.7	95.2%
	140 ng/ml	C95+20%	21	0	21	21(100) 84.5-100	0	100%
	1000 ng/ml	100% positive	21	0	21	21(100) 84.5-100	0	100%
Lamb Meat Extract 2.5%	0ng/ml	0% positive	0	21	21	0	21(100) 84.5-100	100%
	80 ng/ml	5%positive	1	20	21	1(4.8) 0.9-22.7	20(95.2) 84.5-100	95.2%
	100 ng/ml	50%positive	11	10	21	11(52.4) 32.4-71.7	10(47.6) 28.3-67.6	52.4%
	110 ng/ml	C95-20%	14	7	21	14(66.7) 50.1-86.2	7(33.3) 13.8-50	66.7%
	120 ng/ml	95%positive	20	1	21	20(95.2) 77.3-99.2	1(4.8) 0.9-22.7	95.2%
	140 ng/ml	C95+20%	21	0	21	21(100) 84.5-100	0	100%
	1000 ng/ml	100% positive	21	0	21	21(100) 84.5-100	0	100%
Chicken Meat Extract 2.5%	0ng/ml	0% positive	0	21	21	0	21(100) 84.5-100	100%
	80 ng/ml	5%positive	1	20	21	1(4.8) 0.9-22.7	20(95.2) 84.5-100	95.2%
	100 ng/ml	50%positive	12	9	21	12(57.1) 36.6-75.5	9(42.9) 24.5-63.4	57.1%
	110 ng/ml	C95-20%	15	6	21	15(71.4) 50.1-86.2	6(28.6) 13.8-50	71.4%
	120 ng/ml	95%positive	20	1	21	20(95.2) 77.3-99.2	1(4.8) 0.9-22.7	95.2%
	140 ng/ml	C95+20%	21	0	21	21(100) 84.5-100	0	100%
	1000 ng/ml	100% positive	21	0	21	21(100) 84.5-100	0	100%

Table 9: Summary - Vegetable Extracts

Vegetable Extracts	Sample concentration n	Expected result	Observed positive results	Observed negative results	Total number	Positive percent agreement (95 % CI)	Negative percent agreement (95 % CI)	Overall percentage agreement
Broccoli Extract 2.5%	0ng/ml	0% positive	0	21	21	0	21(100) 84.5-100	100%
	80 ng/ml	5%positive	1	20	21	1(4.8) 0.9-22.7	20(95.2) 84.5-100	95.2%
	100 ng/ml	50%positive	11	10	21	11(52.4) 32.4-71.7	10(47.6) 28.3-67.6	52.4%
	110 ng/ml	C95-20%	14	7	21	14(66.7) 50.1-86.2	7(33.3) 13.8-50	66.7%
	120 ng/ml	95%positive	20	1	21	20(95.2) 77.3-99.2	1(4.8) 0.9-22.7	95.2%
	140 ng/ml	C95+20%	21	0	21	21(100) 84.5-100	0	100%
	1000 ng/ml	100% positive	21	0	21	21(100) 84.5-100	0	100%
Cantaloupe Extract 2.5%	0ng/ml	0% positive	0	21	21	0	21(100) 84.5-100	100%
	80 ng/ml	5%positive	0	21	21	0	21(100) 84.5-100	100%
	100 ng/ml	50%positive	11	10	21	11(52.4) 32.4-71.7	10(47.6) 28.3-67.6	52.4%
	110 ng/ml	C95-20%	15	6	21	15(71.4) 50.1-86.2	6(28.6) 13.8-50	71.4%
	120 ng/ml	95%positive	21	0	21	21(100) 84.5-100	0	100%
	140 ng/ml	C95+20%	21	0	21	21(100) 84.5-100	0	100%
	1000 ng/ml	100% positive	21	0	21	21(100) 84.5-100	0	100%
	0ng/ml	0% positive	0	21	21	0	21(100) 84.5-100	100%
	80 ng/ml	5%positive	1	20	21	1(4.8) 0.9-22.7	20(95.2) 84.5-100	95.2%
	100 ng/ml	50%positive	11	10	21	11(52.4) 32.4-71.7	10(47.6) 28.3-67.6	52.4%

Cauliflower Extract 2.5%	110 ng/ml	C95-20%	16	5	21	16(76.2) 50.1-86.2	6(23.8) 10.6-45.1	76.2%
	120 ng/ml	95%positive	20	1	21	20(95.2) 77.3-99.2	1(4.8) 0.9-22.7	95.2%
	140 ng/ml	C95+20%	21	0	21	21(100) 84.5-100	0	100%
	1000 ng/ml	100% positive	21	0	21	21(100) 84.5-100	0	100%
Horseradish Extract 2.5%	0ng/ml	0% positive	0	21	21	0	21(100) 84.5-100	100%
	80 ng/ml	5%positive	1	20	21	1(4.8) 0.9-22.7	20(95.2) 84.5-100	95.2%
	100 ng/ml	50%positive	11	10	21	11(52.4) 32.4-71.7	10(47.6) 28.3-67.6	52.4%
	110 ng/ml	C95-20%	15	6	21	15(71.4) 50.1-86.2	6(28.6) 13.8-50	71.4%
	120 ng/ml	95%positive	20	1	21	20(95.2) 77.3-99.2	1(4.8) 0.9-22.7	95.2%
	140 ng/ml	C95+20%	21	0	21	21(100) 84.5-100	0	100%
	1000 ng/ml	100% positive	21	0	21	21(100) 84.5-100	0	100%
Parsnip Extract 2.5%	0ng/ml	0% positive	0	21	21	0	21(100) 84.5-100	100%
	80 ng/ml	5%positive	1	20	21	1(4.8) 0.9-22.7	20(95.2) 84.5-100	95.2%
	100 ng/ml	50%positive	11	10	21	11(52.4) 32.4-71.7	10(47.6) 28.3-67.6	52.4%
	110 ng/ml	C95-20%	16	5	21	16(76.2) 50.1-86.2	6(23.8) 10.6-45.1	76.2%
	120 ng/ml	95%positive	20	1	21	20(95.2) 77.3-99.2	1(4.8) 0.9-22.7	95.2%
	140 ng/ml	C95+20%	21	0	21	21(100) 84.5-100	0	100%
	1000 ng/ml	100% positive	21	0	21	21(100) 84.5-100	0	100%
	0ng/ml	0% positive	0	21	21	0	21(100) 84.5-100	100%
	80 ng/ml	5%positive	1	20	21	1(4.8) 0.9-22.7	20(95.2) 84.5-100	95.2%

Red radish Extract 2.5%	100 ng/ml	50%positive	11	10	21	11(52.4) 32.4-71.7	10(47.6) 28.3-67.6	52.4%
	110 ng/ml	C95-20%	16	5	21	16(76.2) 50.1-86.2	6(23.8) 10.6-45.1	76.2%
	120 ng/ml	95%positive	20	1	21	20(95.2) 77.3-99.2	1(4.8) 0.9-22.7	95.2%
	140 ng/ml	C95+20%	21	0	21	21(100) 84.5-100	0	100%
	1000 ng/ml	100% positive	21	0	21	21(100) 84.5-100	0	100%
Turnip Extract 2.5%	0ng/ml	0% positive	0	21	21	0	21(100) 84.5-100	100%
	80 ng/ml	5%positive	1	20	21	1(4.8) 0.9-22.7	20(95.2) 84.5-100	95.2%
	100 ng/ml	50%positive	11	10	21	11(52.4) 32.4-71.7	10(47.6) 28.3-67.6	52.4%
	110 ng/ml	C95-20%	15	6	21	15(71.4) 50.1-86.2	6(28.6) 13.8-50	71.4%
	120 ng/ml	95%positive	20	1	21	20(95.2) 77.3-99.2	1(4.8) 0.9-22.7	95.2%
	140 ng/ml	C95+20%	21	0	21	21(100) 84.5-100	0	100%
	1000 ng/ml	100% positive	21	0	21	21(100) 84.5-100	0	100%

Table 10: Summary - Drugs and Dietary Supplements

Dietary Supplements	Sample concentration	Expected result	Observed positive results	Observed negative results	Total number	Positive percent agreement (95 % CI)	Negative percent agreement (95 % CI)	Overall percentage agreement
Iron 0.5%	0ng/ml	0% positive	0	21	21	0	21(100) 84.5-100	100%
	80 ng/ml	5%positive	1	20	21	1(4.8) 0.9-22.7	20(95.2) 84.5-100	95.2%
	100 ng/ml	50%positive	10	11	21	10(47.6) 28.3-67.6	11(52.4) 32.4-71.7	47.6%
	110 ng/ml	C95-20%	15	6	21	15(71.4) 50.1-86.2	6(28.6) 13.8-50	71.4%
	120 ng/ml	95% positive	20	1	21	20(95.2) 77.3-99.2	1(4.8) 0.9-22.7	95.2%
	140 ng/ml	C95+20%	21	0	21	21(100) 84.5-100	0	100%

	1000 ng/ml	100% positive	21	0	21	21(100) 84.5-100	0	100%
Sodium Lascorbate 0.5%	0ng/ml	0% positive	0	21	21	0	21(100) 84.5-100	100%
	80 ng/ml	5% positive	1	20	21	1(4.8) 0.9-22.7	20(95.2) 84.5-100	95.2%
	100 ng/ml	50% positive	11	10	21	11(52.4) 32.4-71.7	10(47.6) 28.3-67.6	52.4%
	110 ng/ml	C95-20%	15	6	21	15(71.4) 50.1-86.2	6(28.6) 13.8-50	71.4%
	120 ng/ml	95% positive	20	1	21	20(95.2) 77.3-99.2	1(4.8) 0.9-22.7	95.2%
	140 ng/ml	C95+20%	21	0	21	21(100) 84.5-100	0	100%
	1000 ng/ml	100% positive	21	0	21	21(100) 84.5-100	0	100%
Bisacodyl Enteric-coated tablets 2.5%	0ng/ml	0% positive	0	21	21	0	21(100) 84.5-100	100%
	80 ng/ml	5% positive	1	20	21	1(4.8) 0.9-22.7	20(95.2) 84.5-100	95.2%
	100 ng/ml	50% positive	12	9	21	12(57.1) 36.6-75.5	9(42.9) 24.5-63.4	57.1%
	110 ng/ml	C95-20%	16	5	21	16(76.2) 50.1-86.2	6(23.8) 10.6-45.1	76.2%
	120 ng/ml	95% positive	20	1	21	20(95.2) 77.3-99.2	1(4.8) 0.9-22.7	95.2%
	140 ng/ml	C95+20%	21	0	21	21(100) 84.5-100	0	100%
	1000 ng/ml	100% positive	21	0	21	21(100) 84.5-100	0	100%
Sennoside tablets 2.5%	0ng/ml	0% positive	0	21	21	0	21(100) 84.5-100	100%
	80 ng/ml	5%positive	1	20	21	1(4.8) 0.9-22.7	20(95.2) 84.5-100	95.2%
	100 ng/ml	50% positive	10	11	21	10(47.6) 28.3-67.6	11(52.4) 32.4-71.7	47.6%
	110 ng/ml	C95-20%	14	7	21	14(66.7) 50.1-86.2	7(33.3) 13.8-50	66.7%
	120 ng/ml	95% positive	20	1	21	20(95.2) 77.3-99.2	1(4.8) 0.9-22.7	95.2%
	140 ng/ml	C95+20%	21	0	21	21(100) 84.5-100	0	100%
	1000 ng/ml	100% positive	21	0	21	21(100) 84.5-100	0	100%
Glycerol enema 2.5%	0ng/ml	0% positive	0	21	21	0	21(100) 84.5-100	100%
	80 ng/ml	5%positive	1	20	21	1(4.8) 0.9-22.7	20(95.2) 84.5-100	95.2%

	100 ng/ml	50%positive	9	12	21	9(42.9) 24.5-63.5	12(57.1) 36.5-75.5	42.9%
	110 ng/ml	C95-20%	14	7	21	14(66.7) 50.1-86.2	7(33.3) 13.8-50	66.7%
	120 ng/ml	95%positive	20	1	21	20(95.2) 77.3-99.2	1(4.8) 0.9-22.7	95.2%
	140 ng/ml	C95+20%	21	0	21	21(100) 84.5-100	0	100%
	1000 ng/ml	100% positive	21	0	21	21(100) 84.5-100	0	100%
Hydrogen peroxide enema 2.5%	0ng/ml	0% positive	0	21	21	0	21(100) 84.5-100	100%
	80 ng/ml	5%positive	0	21	21	0	21(100) 84.5-100	100%
	100 ng/ml	50%positive	10	11	21	10(47.6) 28.3-67.6	11(52.4) 32.4-71.7	47.6%
	110 ng/ml	C95-20%	14	7	21	14(66.7) 50.1-86.2	7(33.3) 13.8-50	66.7%
	120 ng/ml	95%positive	21	0	21	21(100) 84.5-100	0	100%
	140 ng/ml	C95+20%	21	0	21	21(100) 84.5-100	0	100%
	1000 ng/ml	100% positive	21	0	21	21(100) 84.5-100	0	100%

Table 11: Summary - Other Contaminants

Contaminants	Sample concentration	Expected result	Observed positive results	Observed negative results	Total number	Positive percent agreement (95 % CI)	Negative percent agreement (95 % CI)	Overall percentage agreement
Lime-A-Way 5mg/ml	0ng/ml	0% positive	0	21	21	0	21(100) 84.5-100	100%
	80 ng/ml	5%positive	1	20	21	1(4.8) 0.9-22.7	20(95.2) 84.5-100	95.2%
	100 ng/ml	50%positive	11	10	21	11(52.4) 32.4-71.7	10(47.6) 28.3-67.6	52.4%
	110 ng/ml	C95-20%	16	5	21	16(76.2) 50.1-86.2	6(23.8) 10.6-45.1	76.2%
	120 ng/ml	95%positive	21	0	21	21(100) 84.5-100	0	100%

Contaminants	Sample concentration	Expected result	Observed positive results	Observed negative results	Total number	Positive percent agreement (95 % CI)	Negative percent agreement (95 % CI)	Overall percentage agreement
	140 ng/ml	C95+20 %	21	0	21	21(100) 84.5-100	0	100%
	1000 ng/ml	100% positive	21	0	21	21(100) 84.5-100	0	100%
Clorox 5mg/ml	0ng/ml	0% positive	0	21	21	0	21(100) 84.5-100	100%
	80 ng/ml	5%positi ve	0	21	21	0	21(100) 84.5-100	100%
	100 ng/ml	50%posit ive	11	10	21	11(52.4) 32.4-71.7	10(47.6) 28.3-67.6	52.4%
	110 ng/ml	C95-20%	15	6	21	15(71.4) 50.1-86.2	6(28.6) 13.8-50	71.4%
	120 ng/ml	95%posit ive	21	0	21	21(100) 84.5-100	0	100%
	140 ng/ml	C95+20 %	21	0	21	21(100) 84.5-100	0	100%
	1000 ng/ml	100% positive	21	0	21	21(100) 84.5-100	0	100%
Lysol Bleach 5mg/ml	0ng/ml	0% positive	0	21	21	0	21(100) 84.5-100	100%
	80 ng/ml	5%positi ve	1	20	21	1(4.8) 0.9-22.7	20(95.2) 84.5-100	95.2%
	100 ng/ml	50%posit ive	11	10	21	11(52.4) 32.4-71.7	10(47.6) 28.3-67.6	52.4%
	110 ng/ml	C95-20%	15	6	21	15(71.4) 50.1-86.2	6(28.6) 13.8-50	71.4%
	120 ng/ml	95%posit ive	20	1	21	20(95.2) 77.3-99.2	1(4.8) 0.9-22.7	95.2%
	140 ng/ml	C95+20 %	21	0	21	21(100) 84.5-100	0	100%
	1000 ng/ml	100% positive	21	0	21	21(100) 84.5-100	0	100%
	0ng/ml	0% positive	0	21	21	0	21(100) 84.5-100	100%
	80 ng/ml	5%positi ve	1	20	21	1(4.8) 0.9-22.7	20(95.2) 84.5-100	95.2%

Contaminants	Sample concentration	Expected result	Observed positive results	Observed negative results	Total number	Positive percent agreement (95 % CI)	Negative percent agreement (95 % CI)	Overall percentage agreement
Lysol Cleaner 5mg/ml	100 ng/ml	50%positive	11	10	21	11(52.4) 32.4-71.7	10(47.6) 28.3-67.6	52.4%
	110 ng/ml	C95-20%	14	7	21	14(66.7) 50.1-86.2	7(33.3) 13.8-50	66.7%
	120 ng/ml	95%positive	21	0	21	21(100) 84.5-100	0	100%
	140 ng/ml	C95+20 %	21	0	21	21(100) 84.5-100	0	100%
	1000 ng/ml	100% positive	21	0	21	21(100) 84.5-100	0	100%
Scrubbing Bubbles 5mg/ml	0ng/ml	0% positive	0	21	21	0	21(100) 84.5-100	100%
	80 ng/ml	5%positive	0	21	21	0	21(100) 84.5-100	100%
	100 ng/ml	50%positive	11	10	21	11(52.4) 32.4-71.7	10(47.6) 28.3-67.6	52.4 %
	110 ng/ml	C95-20%	15	6	21	15(71.4) 50.1-86.2	6(28.6) 13.8-50	71.4 %
	120 ng/ml	95%positive	21	0	21	21(100) 84.5-100	0	100%
	140 ng/ml	C95+20 %	21	0	21	21(100) 84.5-100	0	100%
	1000 ng/ml	100% positive	21	0	21	21(100) 84.5-100	0	100%

Sample Collection Study

Twenty Laypersons were recruited to collect the human fecal samples of negative (Hemoglobin-free) and positive (known Hemoglobin concentration: 1000ng/mL) into the fecal sample collection tube of Accu-Reader™ A100 according to the Instructions For Use (IFU). Hemoglobin negative and hemoglobin positive human fecal samples were prepared. Five positive and five negative samples were collected by each layperson for a total of 200 samples (100 positive and 100 negative). The sample collection tubes loaded with the fecal sample were tested on the Accu-Reader™ A100 after weighing and calculating the weight of feces in sample collection tubes. The results of the sample collection study show a high degree of accuracy of results and consistency of the amount of stool collected.

Specimen Stability Studies

Stool samples were spiked with several concentrations of human hemoglobin and stored in the Sample Collection tube at different temperatures for up to 30 days after sampling. Testing was then performed on the Accu-Reader™ A100 according to the instructions for use. Twenty-one replicates of each of the following hemoglobin concentrations were tested: 0 ng/mL, 80 ng/mL, 100 ng/mL, 110 ng/mL, 120 ng/mL, 140 ng/mL and 1000 ng/mL. Three kit lots were included in the testing. The temperature at which the samples were stored were 2-8ºC, -10- (-)20ºC, 30 ºC and 40 ºC.

Based on the test results, the data demonstrates that the devices of Accu-Reader are within acceptable criteria and the agreement over 95%. It is noted that sample storage at 40°C did begin to show false negative results when stored for 15 days. The fecal sample in collection tube will be stored at 30°C and 40°C no more than 14 days after sampling.

Shipping Studies

The shipping study was conducted to evaluate the shipping stress to the sample and test kit and their endurance under extreme temperatures. Fecal samples contained in sample collection buffer tubes and unused Accu-Reader™ A100 sample collection buffer tubes and cartridges (containing no fecal samples) were stored under extreme temperatures up to 5 days. Test point 0 days, 3 days, 5 days and 6 days. The four temperature points of -10°C, 2~8°C, 25°C and 40°C were adopted in this shipping study. There were 21 replicates at each of the seven concentrations. There was one operator, one site, one device, and one lots of the Accu-Reader™ A100 test kits employed in this study.

The tested data demonstrates that the sample result passed the acceptance criteria and the agreement is more than 95%.

Stability Studies – Accelerated Stability Studies

The study was conducted to support the shelf life of Accu-Reader™ A100 test kits up to 24 months at room temperature. Accelerated stability study was conducted with three lots of Accu-Reader™ A100 test kits. Test kits were stored at 45°C for 75 days and six test points adopted: 0 days, 20 days, 40 days, 55 days, 65 days and 76 days. The 21 replicates for each concentration with seven known levels (0 ng/mL, 80 ng/mL, 100 ng/mL, 110 ng/mL, 120 ng/mL, 140 ng/mL, 1000 ng/mL) of human hemoglobin were prepared for using to the study. Device test kits were stored at 45°C for 75 days duration and temperature translate to 24 months of stability at room temperature (25°C). Hemoglobin standard concentration: 0, 80, 100, 110, 120, 140 and 1000 ng/mL, with 21 aliquots respectively.

Based on the tested results, the data supported the shelf life of Accu-Reader™ A100 test kits up to 24 months at room temperature.

Stability Studies – Real Time

The real time stability study was conducted to verify the test kits are stable up to 36 months when stored at temperatures between 4°C and 30°C. The on-going real time study has completed studies up to 18 months.

The study was conducted with 3 different lots of Hemosure® Accu-Reader™ A100 test kits (test cartridge and sample tube). Measurements were performed at day 0, after 12 months, 18 months, 24 months, and 30 months using stool samples spiked with the seven known concentrations of human hemoglobin (0, 80, 100, 110, 120, 140, and 1000 ng/ml). The samples were measured in 21 replicates. The test results showed that the Hemosure® Accu-Reader™ A100 test kits (test cartridge and sample tube) are stable for 24 months at 4-30°C.

Clinical Performance: Method Comparison Study

A clinical method comparison study was performed in order to demonstrate the equivalency between Hemosure Accu-Reader™ A100 automated fecal occult blood detection device and a predicate device.

A total of 377 clinical fecal samples were collected from individuals who had previously been screened by colonoscopy in the recent past. The Accu Reader™ A100's capability and consistency were tested and compared against a predicate device. Patient samples were tested side-by-side in the Accu Reader™ A100 and the predicate device with human stool samples reconstituted in buffer. The machines processed these samples screening for human hemoglobin in the stools, and the Accu Reader™ A100 has shown to be well in agreement regarding its sensitivity to hemoglobin relative to the predicate device.

Table 12: Number of clinical fecal samples tested during clinical method comparison study of Accu-Reader A100

Study Site	Clinical samples tested by site & unique operator											
	Operator 1			Operator 2			Operator 3			Operator 1+2+3		
	Positive	Negative	Total	Positive	Negative	Total	Positive	Negative	Total	Positive	Negative	Total
Site 1	31	11	42	17	6	23	13	40	53	60	58	118
Site 2	36	29	65	25	25	50	19	5	24	80	59	139
Site 3	2	38	40	5	35	40	0	40	40	7	113	120
Total										147	230	377

Table 13: Statistical analysis of clinical method comparison study of Accu-Reader™ A100

Study site		Accu-Reader™ A100			Overall Percent Agreement	Positive Percent Agreement (95% CI)	Negative Percent Agreement (95% CI)
	OC-Auto Micro FOB	Positive	Negative	Total			
Site 1	Positive	59	1	60	98.31% (94.03%~99.54%)	98.33% (91.15%~99.70%)	98.27% (90.76%~99.96%)
	Negative	1	57	58			
	Total	60	58	118			
Site 2	Positive	78	1	79	97.84% (94.21%~98.90%)	97.5% (90.14%~99.31%)	93.22% (91.01%~99.70%)

Study site		Accu-Reader™ A100			Overall Percent Agreement	Positive Percent Agreement (95% CI)	Negative Percent Agreement (95% CI)
	OC-Auto Micro FOB	Positive	Negative	Total			
	Negative	2	58	60			
	Total	80	59	139			
Site 3	Positive	7	0	7	100% (96.23%~100%)	100% (56.96%~100%)	100% (96.01%~100%)
	Negative	0	113	113			
	Total	7	113	120			
Total	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			

The Accu-Reader™ A100's capability and consistency were tested and compared against a predicate device. Patient samples were tested side-by-side in the Accu-Reader™ A100 and the predicate device with human stool samples reconstituted in buffer. For a total of 377 samples between the results obtained with the device and the predicate, the overall percent agreement (OPA) was 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%). As our agreements are above 98%, the machines processed these samples screening for human hemoglobin in the stools, and the Accu-Reader™ A100 has shown to be well in agreement regarding its sensitivity to hemoglobin relative to the predicate device.

Cybersecurity

Hemosure® Accu-Reader™ A100 reader has USB and network capabilities. Data security vulnerability was evaluated and mitigation to risks were incorporated into the device software.

Electromagnetic Compatibility (EMC)

IEC 61326-1:2005, Electrical equipment for measurement, control and laboratory use – EMC requirements - Part 1: General requirements. Edition 2.0 was published in 2012. It was also tested to the IEC 60601-1-2:2014, Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –Collateral Standard: Electromagnetic disturbances – Requirements and tests.

Table 14: EMC Testing Summary

Clause	Description	Test	Results
4.1.1	Harmonics on AC Mains	IEC 61000-3-2:2005+A1+A2	Pass
4.1.2	Voltage Changes, Voltage Fluctuations and Flicker on AC Mains	IEC 61000-3-3:2008	Pass
4.1.3	Mains Terminal Continuous Disturbance Voltage	IEC61326-1:2012, IEC 61326-2-6:2012	Pass
4.2.1	Radiated Electromagnetic Field Emission	IEC 61326-1:2012, IEC 61326-2-6:2012	Pass
5.1.1	Electrostatic Discharge	IEC 61000-4-2:2008	Pass
5.1.2	Radio Frequency Electromagnetic Field Immunity Test	IEC 61000-4-3:2006+A1+A2	Pass
5.1.3	Proximity Fields From RF Wireless Communication Equipment	IEC 61000-4-8:2009	Pass
5.1.4	Power Frequency Magnetic Field	IEC 61000-4-8:2009	Pass
5.2.1	Electrical Fast Transients on AC Power Line, Signal Line and Interconnecting Line	IEC 61000-4-4:2004+A1	Pass
5.2.2	Conducted Disturbances Induced by RF Fields Into AC Power Line, Signal Line and Patient Coupling Line	IEC 61000-4-5:2005	Pass
5.2.3	Surges to AC Power Port, Signal Line and Interconnecting Line	IEC 61000-4-6: 2008	Pass
5.2.4	Voltage Dips and Interruptions to AC Power Port	IEC 61000-4-11:2004	Pass
5.2.5	Safety Standard For Medical Devices	IEC 60601-1:2010+ CORR.1(2011)+CORR.2(2013) ANSI/AAMI ES 60601 1:2005+ A2(R2012)+A1	Pass
5.2.6	Radiated Electromagnetic Field Emission	IEC 60601-1-2:2014	Pass

Conclusion

Hemosure Accu-Reader™ A100 does not constitute a new intended use and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and as effective as the predicate and does not raise new questions of safety and effectiveness.