DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 20, 2015

EIKEN CHEMICAL CO., LTD.
Takashi Enomoto, Regulatory Affairs
4-19-9, Taito, Taito-ku
Tokyo 110-8408, Japan

Re: K143325
Trade/Device Name: OC-Light S FIT
Regulation Number: 21 CFR 864.6550
Regulation Name: Occult blood test
Regulatory Class: Class II
Product Code: KHE
Dated: July 15, 2015
Received: July 16, 2015

Dear Mr. Enomoto:

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. 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Leonthena R. Carrington -S

Leonthena R. Carrington, MS, MBA, MT(ASCP)
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostics and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143325

Device Name
OC-Light S FIT

Indications for Use *(Describe)*
OC-Light S FIT (Fecal Immunochemical Test, also known as iFOBT, immunochemical fecal occult blood test) is a qualitative test intended for the immunochemical detection of fecal occult blood (FOB) by professional laboratories and physician office laboratories. Measurement of FOB is useful as an aid to detect blood in stool when gastrointestinal (GI) bleeding may be suspected.
OC-Light S FIT is recommended for use in routine physical examinations.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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"510(k) Summary"

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

510(k) Submitter Information:

Name: EIKEN CHEMICAL CO., LTD
Address: 4-19-9, Taito, Taito-ku, Tokyo 110-8408, Japan
Phone: 81-3-58463479
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Contact Name & Info: Takashi Enomoto
Regulatory Affairs Department
Takashi_Enomoto@eiken.co.jp

Date Prepared: August 20, 2015

Device Information:

Trade Name: OC-Light S FIT
Common Name: Fecal Immunochemical Test
Classification Name: Occult Blood Test (21 CFR 864.6550, Product Code: KHE)
Device Class: Class II
510(k) Number: K143325
Manufacturer: Eiken Chemical Co., Ltd.

Predicate Device Information:

Trade Name: Polymedco OC Light FOB Test
510(k) Number: K041297
510(k) Applicant: Polymedco Inc.
(currently Polymedco Cancer Diagnostic Products LLC)
Manufacturer: Eiken Chemical Co., Ltd.
Repackager/Relabeler: Polymedco Cancer Diagnostic Products LLC

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Device Description:

OC-Light S FIT is an *in vitro* diagnostic device, a qualitative test designed for the immunochemical detection of human hemoglobin (hHb) in stool specimens.

OC-Light S FIT consists of a test strip, and a sampling bottle containing buffer solution. OC-Light S FIT test strip consists of a nitrocellulose membrane with immobilized mouse monoclonal antibodies specific to human hemoglobin at the test region and immobilized rabbit anti-mouse antibodies at the control region, a sample pad, a conjugate pad which contains human hemoglobin specific mouse monoclonal antibodies conjugated with colloidal gold, an absorption pad, and a plastic backing. OC-Light S FIT sampling bottle is a plastic bottle for collecting fecal sample containing 2.0 mL of extraction buffer.

When the sample end of the test strip is dipped in the fecal extract, the liquid fecal extract wicks through a series of absorbent materials and contacts colloidal gold conjugated with monoclonal antibodies specific to hHb. If hHb is present in the sample, it reacts with the antibodies on the colloidal gold. When the gold conjugate with hHb reaches the test region of the membrane, it binds with the immobilized antibodies also specific to hHb to form a visible reddish/pink line. The procedural control region of the membrane contains immobilized anti-mouse antibodies that capture the conjugate independent of the presence of the hHb, thereby always producing a distinct reddish/pink line. The reddish/pink line in the procedural control region demonstrates the validity of the test, and assures the operator that the device is working properly.

Clinical cut-off

The clinical cut-off of OC-Light S FIT is 10 µg hemoglobin /g stool. (50 ng/mL buffer)

Controls

Internal Control: Procedural controls are included in the test device. A reddish/pink line appearing in the control region is serves as the internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

External Control: FOBT-CHEK positive and negative controls, cleared under 510(k) 041297, are available in a separate control kit. The controls are run in the FIT in the same manner as extracted fecal samples. It is recommended that positive and negative controls be performed to verify proper test performance.

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Intended Use:

OC-Light S FIT (Fecal Immunochemical Test, also known as iFOBT, immunochemical fecal occult blood test) is an qualitative test intended for the immunochemical detection of fecal occult blood (FOB) in feces by professional laboratories and physician office laboratories. Measurement of FOB is useful as an aid to detect blood in stool when gastrointestinal (GI) bleeding may be suspected.

OC-Light S FIT is recommended for use in routine physical examinations.

Device Characteristics in Comparison with the Predicate Device:

The table below provides a summary of the device characteristics for OC-Light S FIT and the predicate device.

Comparison of technological characteristics

Device	OC-Light S FIT	Polymedco OC Light FOB Test (Predicate)
Similarities		
Intended Use	A qualitative test intended for the immunochemical detection of fecal occult blood in feces by professional laboratories and physician office laboratories. Measurement of FOB is useful as an aid to detect blood in stool when gastrointestinal (GI) bleeding may be suspected.	An immunological test intended for the detection of fecal occult blood in feces by professional laboratories and physician office labs The test is useful for the determination of gastrointestinal (GI) bleeding, found in a number of gastrointestinal (GI) disorders, e.g., diverticulitis, colitis, polyps, and colorectal cancer.
Indications for Use	Recommended for use in routine physical examinations.	Recommended for use in 1) routine physical examinations, 2) monitoring for bleeding in patients, and 3) screening for colorectal cancer or gastrointestinal bleeding.
Sample Type	Feces in an extraction buffer	Feces in an extraction buffer
Test Principle	Qualitative test system intended for immunochemical detection of fecal occult blood in feces.	Immunological test system intended for qualitative detection of fecal occult blood in feces.
Detection Method	Lateral flow chromatographic immunoassay	Lateral flow chromatographic immunoassay
Detection Level	10μg hemoglobin/g stool (50ng/mL buffer)	50ng/mL hHb in fecal extraction buffer

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Differences		
Detection Antibody Conjugate	Monoclonal anti-hHb conjugated to colloidal gold	Monoclonal and polyclonal anti-hHb conjugated to blue latex
Result Format	Visible reddish/pink line in procedural control region and test region	Visible blue line in procedural control region and test region

Summary of Performance Data:

Cut-off

Cut-off study was conducted in-house with one operator. Hb-free stool specimen was spiked with known levels of hHb to obtain fecal samples with seven different Hb concentrations: 0, 5, 8, 10, 12, 15, and 400 µg/ g stool, that are equivalent to 0, 25 (C5), 40 (C50, C95-20%), 50 (C95, clinical cutoff), 60 (C95+20%), 75 and 2000 ng/mL. Each sample was collected with twenty one OC-Light S FIT sampling bottles and twenty one Polymedco OC Light FOB Test (Predicate) sampling bottles to perform side-by-side tests for comparing the test results of the device with that of the predicate.

The test result of 50ng/mL using OC-Light S FIT was 100.0% positive. The overall agreement between the total results of OC-Light S FIT and the expected results was 99.3% (95% CI 96.2 ~ 100.0%), and the overall agreement between the total results of Polymedco OC Light FOB Test and the expected results was 97.3% (95% CI 93.1 ~ 99.3%)

The cut-off value of OC-Light S FIT was established as 10 µg hemoglobin/g stool (50 ng/mL buffer). No significant difference was observed between the results of OC-Light S FIT and the predicate Polymedco OC Light FOB Test.

Polymedco OC Light FOB Test/OC-Light S FIT
test results in comparison with the expected results

Cut off study	Agreement	Expected Results			Overall Percent Agreement (95% CI)	Positive Percent Agreement (95% CI)	Negative Percent Agreement (95% CI)
		Positive Results	Negative Results	Total Results			
Polymedco OC Light FOB Test	Positive Results	92	1	93	97.3%	96.8%	98.1%
	Negative Results	3	51	54			
	Total Results	95	52	147	(93.1% ~ 99.3%)	(90.9% ~ 99.4%)	(89.5% ~ 100.0%)
OC-Light S FIT	Positive Results	95	1	96	99.3%	100.0%	98.1%
	Negative Results	0	51	51			
	Total Results	95	52	147	(96.2% ~ 100.0%)	(96.2% ~ 100.0%)	(89.5% ~ 100.0%)

Reaction Time

Reaction time study was conducted in-house with one operator to demonstrate that 5

minutes is the appropriate reaction time for OC-Light S FIT. Hb-free stool specimen was spiked with known levels of hHb to obtain fecal samples with seven different Hb concentrations: 0, 5, 8, 10, 12, 15, and 400 µg/ g stool, that are equivalent to 0, 25 (C5), 40 (C50, C95-20%), 50 (C95, clinical cutoff), 60 (C95+20%), 75 and 2000 ng/mL. Twenty-one replicates of each sample for a total of 147 samples were tested in a randomized and blinded fashion with results read at 3, 5, 10, and 30 minutes of reaction.

Positivity rate of 25ng/mL was 0%, positivity rate of 40ng/mL was 43%, and positivity rate of 50ng/mL was 100% at 5 minutes of reaction, and the appropriate reaction time of OC-Light S FIT was demonstrated as 5 minutes.

Reaction time: test results

Reaction time		Hb concentration (ng/ml)						
		0	25	40	50	60	75	2000
3min	Positive	0	0	0	19	21	21	21
	Negative	21	21	21	2	0	0	0
	Positive (%)	0%	0%	0%	90%	100%	100%	100%
	Negative (%)	100%	100%	100%	10%	0%	0%	0%
5min	Positive	0	0	9	21	21	21	21
	Negative	21	21	12	0	0	0	0
	Positive (%)	0%	0%	43%	100%	100%	100%	100%
	Negative (%)	100%	100%	57%	0%	0%	0%	0%
10min	Positive	0	0	17	21	21	21	21
	Negative	21	21	4	0	0	0	0
	Positive (%)	0%	0%	81%	100%	100%	100%	100%
	Negative (%)	100%	100%	19%	0%	0%	0%	0%
30min	Positive	0	2	20	21	21	21	21
	Negative	21	19	1	0	0	0	0
	Positive (%)	0%	10%	95%	100%	100%	100%	100%
	Negative (%)	100%	90%	5%	0%	0%	0%	0%

Precision/Reproducibility

The repeatability and reproducibility of OC-Light S FIT was evaluated by testing twenty-one replicates of fecal samples spiked with hHb to obtain test samples with seven different Hb concentrations: 0, 5, 8, 10, 12, 15, and 400 µg/ g stool, that are equivalent to 0, 25 (C5), 40 (C50, C95-20%), 50 (C95, clinical cutoff), 60 (C95+20%), 75 and 2000 ng/mL.

The repeatability and reproducibility studies were conducted at three POL sites in the US. The test samples were shipped frozen from our laboratory to the clinical coordinator, where they were collated, and then distributed to the POL sites. There were no cases of invalid or indeterminate results throughout the precision studies.

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Repeatability and reproducibility test results in comparison with the expected

Type of Precision Study	Actual Results / OC-Light S FIT	Expected Results: Positive Results	Expected Results: Negative Results	Expected Results: Total	Overall Percent Agreement	Positive Percent Agreement (95% CI)	Negative Percent Agreement (95% CI)
Repeatability	Positive Results	95	1	96	99.3%	100.0% (96.2% - 100.0%)	98.1% (89.5% - 100.0%)
	Negative Results	0	51	51			
	Total Results	95	52	147			
Lot-to-Lot Reproducibility	Positive Results	284	6	290	98.6%	100.0% (98.7% - 100.0%)	96.2% (91.8% - 98.6%)
	Negative Results	0	151	151			
	Total Results	284	157	441			
Between-run Reproducibility	Positive Results	283	0	283	99.8%	99.6% (98.0% - 100.0%)	100.0% (97.7% - 100.0%)
	Negative Results	1	157	158			
	Total Results	284	157	441			
Between Device Reproducibility	Positive Results	284	6	290	98.6%	100.0% (98.7% - 100.0%)	96.2% (91.8% - 98.6%)
	Negative Results	0	151	151			
	Total Results	284	157	441			
Between-site Reproducibility	Positive Results	283	6	289	98.4%	99.6% (98.0% - 100.0%)	96.2% (91.8% - 98.6%)
	Negative Results	1	151	152			
	Total Results	284	157	441			
Combined Reproducibility	Positive Results	1134	18	1152	98.9%	99.8% (99.4% - 100.0%)	97.1% (95.5% - 98.3%)
	Negative Results	2	610	612			
	Total Results	1136	628	1764			

Test Kit Stability (Accelerated)

Accelerated stability study was conducted with 3 lots of OC-Light S FIT test kit (test strips and sampling bottles). The test kit was stored at 60°C for 1.04 months (31 days), 56°C for 1.49 months (45 days), and 50°C for 2.58 months (77 days), which are equivalent to 19 months of storage at 30°C when Arrhenius equation is applied. The test kits stored at above conditions were used to test Hb-free stool specimen spiked with seven different Hb

concentrations: 0, 5, 8, 10, 12, 15, and 400 µg/ g stool, that are equivalent to 0, 25 (C5), 40 (C50, C95-20%), 50 (C95, clinical cutoff), 60 (C95+20%), 75 and 2000 ng/mL.

Overall agreements between the test results and the expected results were statistically over 90% for all of the tests conducted. The results showed that OC-Light S FIT test kit is stable for an estimated period of 19 months at 30°C, enabling claim of 18 months test kit stability at 30°C (room temperature).

Test kit stability (accelerated): test results in comparison with the expected results

Test kit stability (accelerated)	Actual Results	Expected Results			Overall Percent Agreement (95% CI)	Positive Percent Agreement (95% CI)	Negative Percent Agreement (95% CI)
	OC-Light S FIT	Positive Results	Negative Results	Total Results			
initial	Positive Results	283	2	285	99.3%	99.6%	98.7%
	Negative Results	1	155	156			
	Total Results	284	157	441	(98.0% ~ 99.9%)	(98.0% ~ 100.0%)	(95.4% ~ 99.9%)
60℃ 31 days	Positive Results	282	1	283	99.3%	99.3%	99.4%
	Negative Results	2	156	158			
	Total Results	284	157	441	(98.0% ~ 99.9%)	(97.4% ~ 99.9%)	(96.4% ~ 100.0%)
56℃ 45 days	Positive Results	282	0	282	99.5%	99.3%	100.0%
	Negative Results	2	157	159			
	Total Results	284	157	441	(98.3% ~ 100.0%)	(97.4% ~ 99.9%)	(97.7% ~ 100.0%)
50℃ 77 days	Positive Results	283	3	286	99.1%	99.6%	98.1%
	Negative Results	1	154	155			
	Total Results	284	157	441	(97.7% ~ 99.8%)	(98.0% ~ 100.0%)	(94.4% ~ 99.6%)

Sample Stability

Sample stability study was conducted with three lots of OC-Light S FIT test kit to evaluate the stability of fecal samples collected in OC-Light S FIT sampling bottles. OC-Light S FIT sampling bottles containing fecal samples with seven different Hb concentrations; 0, 5, 8, 10, 12, 15, and 400 µg/ g stool, that are equivalent to 0, 25 (C5), 40 (C50, C95-20%), 50 (C95, clinical cutoff), 60 (C95+20%), 75 and 2000 ng/mL, were stored at 2, 4, 8, and 10°C for 31 days, and stored at 15, 25, 30, and 32°C for 16 days. The samples stored at 2, 4, 8, and 10°C were tested at day 30 and day 31, and the samples stored at 15, 25, 30, and 32°C were tested at day 15 and day 16, with OC-Light S FIT test strips stored under room temperature.

All analyzed overall agreements between the expected results and test results of OC-Light S FIT utilizing fecal samples in OC-Light S FIT sampling bottles were statistically over 90%. The results showed that the collected fecal samples were stable for 31 days when

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stored at 2, 4, 8, 10°C, and were stable for 16 days when stored at 15, 25, 30, 32°C, enabling to claim that fecal sample collected in OC-Light S FIT sampling bottle is stable up to 30 days when stored at 2 to 8°C, and is stable up to 15 days when stored at room temperature.

Sample stability: test results in comparison with the expected results

Day 30 Sample Stability	Actual Results: OC-Light S FIT	Expected Results: Positive Results	Expected Results: Negative Results	Expected Results: Total Results	Overall Percent Agreement (95% CI)	Positive Percent Agreement (95% CI)	Negative Percent Agreement (95% CI)
2℃	Positive Results	283	6	289	98.4%	99.6%	96.2%
	Negative Results	1	151	152			
	Total Results	284	157	441	(96.7% ~ 99.4%)	(98.0% ~ 100.0%)	(91.8% ~ 98.6%)
4℃	Positive Results	284	4	288	99.1%	100.0%	97.5%
	Negative Results	0	153	153			
	Total Results	284	157	441	(97.7% ~ 99.8%)	(98.7% ~ 100.0%)	(93.5% ~ 99.3%)
8℃	Positive Results	280	0	280	99.1%	98.6%	100.0%
	Negative Results	4	157	161			
	Total Results	284	157	441	(97.7% ~ 99.8%)	(96.4% ~ 99.6%)	(97.7% ~ 100.0%)
10℃	Positive Results	284	2	286	99.5%	100.0%	98.7%
	Negative Results	0	155	155			
	Total Results	284	157	441	(98.3% ~ 100.0%)	(98.7% ~ 100.0%)	(95.4% ~ 99.9%)

Day 31 Sample Stability	Actual Results: OC-Light S FIT	Expected Results: Positive Results	Expected Results: Negative Results	Expected Results: Total Results	Overall Percent Agreement (95% CI)	Positive Percent Agreement (95% CI)	Negative Percent Agreement (95% CI)
2℃	Positive Results	283	3	286	99.1%	99.6%	98.1%
	Negative Results	1	154	155			
	Total Results	284	157	441	(97.7% ~ 99.8%)	(98.0% ~ 100.0%)	(94.4% ~ 99.6%)
4℃	Positive Results	284	2	286	99.5%	100.0%	98.7%
	Negative Results	0	155	155			
	Total Results	284	157	441	(98.3% ~ 100.0%)	(98.7% ~ 100.0%)	(95.4% ~ 99.9%)
8℃	Positive Results	283	3	286	99.1%	99.6%	98.1%
	Negative Results	1	154	155			
	Total Results	284	157	441	(97.7% ~ 99.8%)	(98.0% ~ 100.0%)	(94.4% ~ 99.6%)
10℃	Positive Results	280	0	280	99.1%	98.6%	100.0%
	Negative Results	4	157	161			
	Total Results	284	157	441	(97.7% ~ 99.8%)	(96.4% ~ 99.6%)	(97.7% ~ 100.0%)

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Day 15 Sample Stability	Actual Results / OC-Light S FIT	Expected Results: Positive Results	Expected Results: Negative Results	Expected Results: Total Results	Overall Percent Agreement (95% CI)	Positive Percent Agreement (95% CI)	Negative Percent Agreement (95% CI)
15℃	Positive Results	284	3	287	99.3%	100.0%	98.1%
	Negative Results	0	154	154			
	Total Results	284	157	441	(98.0% ~ 99.9%)	(98.7% ~ 100.0%)	(94.4% ~ 99.6%)
25℃	Positive Results	284	2	286	99.5%	100.0%	98.7%
	Negative Results	0	155	155			
	Total Results	284	157	441	(98.3% ~ 100.0%)	(98.7% ~ 100.0%)	(95.4% ~ 99.9%)
30℃	Positive Results	283	0	283	99.8%	99.6%	100.0%
	Negative Results	1	157	158			
	Total Results	284	157	441	(98.7% ~ 100.0%)	(98.0% ~ 100.0%)	(97.7% ~ 100.0%)
32℃	Positive Results	284	2	286	99.5%	100.0%	98.7%
	Negative Results	0	155	155			
	Total Results	284	157	441	(98.3% ~ 100.0%)	(98.7% ~ 100.0%)	(95.4% ~ 99.9%)

Day 16 Sample Stability	Actual Results / OC-Light S FIT	Expected Results: Positive Results	Expected Results: Negative Results	Expected Results: Total Results	Overall Percent Agreement (95% CI)	Positive Percent Agreement (95% CI)	Negative Percent Agreement (95% CI)
15℃	Positive Results	284	2	286	99.5%	100.0%	98.7%
	Negative Results	0	155	155			
	Total Results	284	157	441	(98.3% ~ 100.0%)	(98.7% ~ 100.0%)	(95.4% ~ 99.9%)
25℃	Positive Results	283	2	285	99.3%	99.6%	98.7%
	Negative Results	1	155	156			
	Total Results	284	157	441	(98.0% ~ 99.9%)	(98.0% ~ 100.0%)	(95.4% ~ 99.9%)
30℃	Positive Results	284	1	285	99.8%	100.0%	99.4%
	Negative Results	0	156	156			
	Total Results	284	157	441	(98.7% ~ 100.0%)	(98.7% ~ 100.0%)	(96.4% ~ 100.0%)
32℃	Positive Results	284	5	289	98.9%	100.0%	96.8%
	Negative Results	0	152	152			
	Total Results	284	157	441	(97.4% ~ 99.6%)	(98.7% ~ 100.0%)	(92.7% ~ 99.9%)

Test Kit Shipping Stress Test

Test kit shipping stress test was conducted to evaluate the effect of exposure to transportation stress during product shipping on OC-Light S FIT test kit. Unused OC-Light S FIT test strips and sampling bottles (containing no fecal samples) were stored under extreme temperature conditions. The measurements were then performed using stressed test strips after fecal samples with seven different Hb concentrations were collected with stressed sampling bottles.

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All analyzed overall agreements between the test results of OC-Light S FIT and the expected results were statistically over 90%. The results showed that the test kit was stable for 4 days when stored at -40, -20, 30, 45, and 50°C, enabling to claim that OC-Light S FIT test kit is stable for 3 days of storage at 45°C, and is stable for 3 days of with 3 freeze/thaw cycles.

Test kit shipping stress test: test results in comparison with the expected results

Day 2 Test kit shipping stress test	Actual Results: OC-Light S FIT	Expected Results: Positive Results	Expected Results: Negative Results	Expected Results: Total Results	Overall Percent Agreement (95% CI)	Positive Percent Agreement (95% CI)	Negative Percent Agreement (95% CI)
-40℃	Positive Results	283	4	287	98.9%	99.6%	97.5%
	Negative Results	1	153	154			
	Total Results	284	157	441	(97.4% ~ 99.6%)	(98.0% ~ 100.0%)	(93.5% ~ 99.3%)
-20℃	Positive Results	284	0	284	100.0%	100.0%	100.0%
	Negative Results	0	157	157			
	Total Results	284	157	441	(99.2% ~ 100.0%)	(98.7% ~ 100.0%)	(97.7% ~ 100.0%)
30℃	Positive Results	283	3	286	99.1%	99.6%	98.1%
	Negative Results	1	154	155			
	Total Results	284	157	441	(97.7% ~ 99.8%)	(98.0% ~ 100.0%)	(94.4% ~ 99.6%)
45℃	Positive Results	284	4	288	99.1%	100.0%	97.5%
	Negative Results	0	153	153			
	Total Results	284	157	441	(97.7% ~ 99.8%)	(98.7% ~ 100.0%)	(93.5% ~ 99.3%)
50℃	Positive Results	282	0	282	99.5%	99.3%	100.0%
	Negative Results	2	157	159			
	Total Results	284	157	441	(98.3% ~ 100.0%)	(97.4% ~ 99.9%)	(97.7% ~ 100.0%)

Day 3 Test kit shipping stress test	Actual Results: OC-Light S FIT	Expected Results: Positive Results	Expected Results: Negative Results	Expected Results: Total Results	Overall Percent Agreement (95% CI)	Positive Percent Agreement (95% CI)	Negative Percent Agreement (95% CI)
-40℃	Positive Results	283	2	285	99.3%	99.6%	98.7%
	Negative Results	1	155	156			
	Total Results	284	157	441	(98.0% ~ 99.9%)	(98.0% ~ 100.0%)	(95.4% ~ 99.9%)
-20℃	Positive Results	284	0	284	100.0%	100.0%	100.0%
	Negative Results	0	157	157			
	Total Results	284	157	441	(99.2% ~ 100.0%)	(98.7% ~ 100.0%)	(97.7% ~ 100.0%)
30℃	Positive Results	284	5	289	98.9%	100.0%	96.8%
	Negative Results	0	152	152			
	Total Results	284	157	441	(97.4% ~ 99.6%)	(98.7% ~ 100.0%)	(92.7% ~ 99.0%)
45℃	Positive Results	284	2	286	99.5%	100.0%	98.7%
	Negative Results	0	155	155			
	Total Results	284	157	441	(98.3% ~ 100.0%)	(98.7% ~ 100.0%)	(95.4% ~ 99.9%)
50℃	Positive Results	279	0	279	98.9%	98.2%	100.0%
	Negative Results	5	157	162			
	Total Results	284	157	441	(97.4% ~ 99.6%)	(95.9% ~ 99.4%)	(97.7% ~ 100.0%)

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Day 4 Test kit shipping stress test	Actual Results: OC-Light S FIT	Expected Results: Positive Results	Expected Results: Negative Results	Expected Results: Total Results	Overall Percent Agreement (95% CI)	Positive Percent Agreement (95% CI)	Negative Percent Agreement (95% CI)
-40℃	Positive Results	273	0	273	97.5%	96.1%	100.0%
	Negative Results	11	157	168			
	Total Results	284	157	441	(95.6% ~ 98.8%)	(93.2% ~ 98.1%)	(97.7% ~ 100.0%)
-20℃	Positive Results	281	0	281	99.3%	98.9%	100.0%
	Negative Results	3	157	160			
	Total Results	284	157	441	(98.0% ~ 99.9%)	(96.9% ~ 99.8%)	(97.7% ~ 100.0%)
30℃	Positive Results	284	2	286	99.5%	100.0%	98.7%
	Negative Results	0	155	155			
	Total Results	284	157	441	(98.3% ~ 100.0%)	(98.7% ~ 100.0%)	(95.4% ~ 99.9%)
45℃	Positive Results	278	0	278	98.6%	97.9%	100.0%
	Negative Results	6	157	163			
	Total Results	284	157	441	(97.0% ~ 99.5%)	(95.4% ~ 99.2%)	(97.7% ~ 100.0%)
50℃	Positive Results	280	0	280	99.1%	98.6%	100.0%
	Negative Results	4	157	161			
	Total Results	284	157	441	(97.7% ~ 99.8%)	(96.4% ~ 99.6%)	(97.7% ~ 100.0%)

Sample Shipping Stress Test

Sample shipping stress test was conducted to evaluate the effect of exposure to transportation stress during sample shipping on the stability of fecal samples collected in OC-Light S FIT sampling bottles. OC-Light S FIT sampling bottles containing fecal samples with seven different Hb concentrations were stored under extreme temperature conditions. The measurements were then performed on the stressed samples with unstressed OC-Light S FIT test strips.

All analyzed overall agreements between the test results using OC-Light S FIT and the expected results were statistically over 90% for all of the tests conducted. The results showed that fecal sample in OC-Light S FIT sampling bottle was stable for 4 days when stored at -40, -20, 30, 45, and 50°C, enabling to claim that fecal sample collected in OC-Light S FIT sampling bottle is stable for 3 days of storage at 45°C, and is stable for 3 days of with 3 freeze/thaw cycles.

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Sample shipping stress test: test results in comparison with the expected results

Day 2 Sample shipping stress test	Actual Results / OC-Light S FIT	Expected Results: Positive Results	Expected Results: Negative Results	Expected Results: Total Results	Overall Percent Agreement (95% CI)	Positive Percent Agreement (95% CI)	Negative Percent Agreement (95% CI)
-40℃	Positive Results	284	3	287	99.3%	100.0%	98.1%
	Negative Results	0	154	154			
	Total Results	284	157	441	(98.0% ~ 99.9%)	(98.7% ~ 100.0%)	(94.4% ~ 99.6%)
-20℃	Positive Results	284	5	289	98.9%	100.0%	96.8%
	Negative Results	0	152	152			
	Total Results	284	157	441	(97.4% ~ 99.6%)	(98.7% ~ 100.0%)	(92.7% ~ 99.0%)
30℃	Positive Results	284	3	287	99.3%	100.0%	98.1%
	Negative Results	0	154	154			
	Total Results	284	157	441	(98.0% ~ 99.9%)	(98.7% ~ 100.0%)	(94.4% ~ 99.6%)
45℃	Positive Results	284	6	290	98.6%	100.0%	96.2%
	Negative Results	0	151	151			
	Total Results	284	157	441	(97.0% ~ 99.5%)	(98.7% ~ 100.0%)	(91.8% ~ 98.6%)
50℃	Positive Results	284	6	290	98.6%	100.0%	96.2%
	Negative Results	0	151	151			
	Total Results	284	157	441	(97.0% ~ 99.5%)	(98.7% ~ 100.0%)	(91.8% ~ 98.6%)

Day 3 Sample shipping stress test	Actual Results / OC-Light S FIT	Expected Results: Positive Results	Expected Results: Negative Results	Expected Results: Total Results	Overall Percent Agreement (95% CI)	Positive Percent Agreement (95% CI)	Negative Percent Agreement (95% CI)
-40℃	Positive Results	283	0	283	99.8%	99.6%	100.0%
	Negative Results	1	157	158			
	Total Results	284	157	441	(98.7% ~ 100.0%)	(98.0% ~ 100.0%)	(97.7% ~ 100.0%)
-20℃	Positive Results	282	0	282	99.5%	99.3%	100.0%
	Negative Results	2	157	159			
	Total Results	284	157	441	(98.3% ~ 100.0%)	(97.4% ~ 99.9%)	(97.7% ~ 100.0%)
30℃	Positive Results	283	3	286	99.1%	99.6%	98.1%
	Negative Results	1	154	155			
	Total Results	284	157	441	(97.7% ~ 99.8%)	(98.0% ~ 100.0%)	(94.4% ~ 99.6%)
45℃	Positive Results	284	4	288	99.1%	100.0%	97.5%
	Negative Results	0	153	153			
	Total Results	284	157	441	(97.7% ~ 99.8%)	(98.7% ~ 100.0%)	(93.5% ~ 99.3%)
50℃	Positive Results	284	7	291	98.4%	100.0%	95.5%
	Negative Results	0	150	150			
	Total Results	284	157	441	(96.7% ~ 99.4%)	(98.7% ~ 100.0%)	(91.0% ~ 98.2%)

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Day 4 Sample shipping stress test	Actual Results: OC-Light S FIT	Expected Results: Positive Results	Expected Results: Negative Results	Expected Results: Total Results	Overall Percent Agreement (95% CI)	Positive Percent Agreement (95% CI)	Negative Percent Agreement (95% CI)
-40℃	Positive Results	284	3	287	99.3%	100.0%	98.1%
	Negative Results	0	154	154			
	Total Results	284	157	441	(98.0% ~ 99.9%)	(98.7% ~ 100.0%)	(94.4% ~ 99.6%)
-20℃	Positive Results	284	4	288	99.1%	100.0%	97.5%
	Negative Results	0	153	153			
	Total Results	284	157	441	(97.7% ~ 99.8%)	(98.7% ~ 100.0%)	(93.5% ~ 99.3%)
30℃	Positive Results	284	7	291	98.4%	100.0%	95.5%
	Negative Results	0	150	150			
	Total Results	284	157	441	(96.7% ~ 99.4%)	(98.7% ~ 100.0%)	(91.0% ~ 98.2%)
45℃	Positive Results	284	4	288	99.1%	100.0%	97.5%
	Negative Results	0	153	153			
	Total Results	284	157	441	(97.7% ~ 99.8%)	(98.7% ~ 100.0%)	(93.5% ~ 99.3%)
50℃	Positive Results	284	4	288	99.1%	100.0%	97.5%
	Negative Results	0	153	153			
	Total Results	284	157	441	(97.7% ~ 99.8%)	(98.7% ~ 100.0%)	(93.5% ~ 99.3%)

Hemoglobin Variants

The ability of OC-Light S FIT to detect human hemoglobin variants was determined by testing hemoglobin-S (HbS) and hemoglobin-C (HbC) of known concentrations (0, 25, 40, 50, 75, 100, 500, 750, 1000, 1250, 1500, and 2000 ng/mL). OC-Light S FIT equivalently detected variants of hemoglobin (HbA0, HbS and HbC).

Cross-Reactivity

The following non-human hemoglobin and meat extracts were added to fecal samples with seven different hHb concentrations: 0, 5, 8, 10, 12, 15, and 400 µg/ g stool, that are equivalent to 0, 25 (C5), 40 (C50, C95-20%), 50 (C95, clinical cutoff), 60 (C95+20%), 75 and 2000 ng/mL. OC-Light S FIT was not interfered by any of the added substances.

Potentially cross-reactive substances

Substance	Concentration
Bovine Hb	500 µg/mL
Equine Hb	500 µg/mL
Goat Hb	500 µg/mL
Porcine Hb	500 µg/mL
Sheep Hb	500 µg/mL
Turkey Hb	500 µg/mL
Fish Hb	500 µg/mL
Rabbit Hb	200 µg/mL

Beef meat extract	2.5%
Pork meat extract	2.5%
Chicken meat extract	2.5%
Rabbit meat extract	2.5%
Fish meat extract	2.5%
Goat meat extract	2.5%
Horse meat extract	2.5%
Lamb meat extract	2.5%

Interference of Other Dietary Substances

The following dietary substances were added to fecal samples with seven different hHb concentrations: 0, 5, 8, 10, 12, 15, and 400 µg/ g stool, that are equivalent to 0, 25 (C5), 40 (C50, C95-20%), 50 (C95, clinical cutoff), 60 (C95+20%), 75 and 2000 ng/mL. OC-Light S FIT was not interfered by any of the added substances.

Potentially interfering substances

Substance	Concentration
Broccoli extract	2.5%
Cantaloupe extract	2.5%
Cauliflower extract	2.5%
Horseradish extract	2.5%
Parsnip extract	2.5%
Red radish extract	2.5%
Turnip extract	2.5%
Ascorbic acid (Vitamin C)	0.5 % (w/v)
Iron	0.5 % (w/v)

Interference of Substances Contained in Toilet Cleaners

A variety of toilet cleaners was added to fecal samples with seven different hHb concentrations: 0, 5, 8, 10, 12, 15, and 400 µg/ g stool, that are equivalent to 0, 25 (C5), 40 (C50, C95-20%), 50 (C95, clinical cutoff), 60 (C95+20%), 75 and 2000 ng/mL. OC-Light S FIT was not interfered by any of the added substances.

Prozone Effect

Samples with elevated levels of hHbA0, hHbS and hHbC at the concentrations of 0, 20, 100, 150, 200, 250, 300, and 400 µg/ g stool, that are equivalent to 0, 100, 500, 750, 1000, 1250, 1500, and 2000 ng/mL, were tested for prozone effect determination. The test results

of all samples were positive, demonstrating that there is no prozone effect at these hemoglobin levels.

Intensity Reading

Reader variability of OC-Light S FIT test results was characterized. Hb-free stool suspension was spiked with hHb to prepare seven different concentrations: 0, 25, 37.5, 50, 62.5, 75, and 2000 ng/mL. 35 replicates were prepared for each concentration, and were tested in a randomized and blinded fashion by 5 readers at one physician office laboratory. Each reader graded the intensity of the test line from 6 levels (Negative, Faint, 1+, 2+, 3+, and 4+). Intensity of the test line increased in correlation with the Hb concentration of samples.

Intensity grading by five participant readers at a POL

	Intensity Levels					
Hb Concentrations	N	F	1+	2+	3+	4+
0 ng/mL	35	0	0	0	0	0
25 ng/mL	35	0	0	0	0	0
37.5 ng/mL	30	5	0	0	0	0
50 ng/mL	0	22	12	1	0	0
62.5 ng/mL	0	9	22	3	1	0
75 ng/mL	0	3	15	14	3	0
2000 ng/mL	0	0	0	0	0	35

FOBT-CHEK (external control) Repeatability

The repeatability study of FOBT-CHEK controls were conducted with OC-Light S FIT test kit for over twenty days. The results of all positive controls tested were positive, and the results of all negative controls tested were negative, demonstrating that FOBT-CHEK indicates satisfactory repeatability. None of the tests showed invalid results.

FOBT-CHEK (external control) Reproducibility

The reproducibility study of FOBT-CHEK controls were conducted with OC-Light S FIT test kit at three POL sites for over five days. The results of all positive controls tested were positive, and the results of all negative controls tested were negative, demonstrating that FOBT-CHEK indicates satisfactory reproducibility. None of the tests showed invalid results.

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Method Comparison Study with the Predicate Device

Method comparison study was conducted to determine the performance of OC-Light S FIT in Physician Office Laboratory (POL) and Professional Medical Laboratory (PML) settings. OC-Light S FIT was compared with a commercially available device, Polymedco OC Light FOB Test, using 953 specimens. The study was performed at three POL sites and three PML sites.

The overall percent agreement between the results obtained by OC-Light S FIT and the results obtained by Polymedco OC Light FOB Test was 99.9% (95% CI: 99.4 ~ 100.0%), with positive percent agreement 100.0% (95% CI: 97.0 ~ 100.0%) and negative percent agreement 99.9% (95% CI: 99.3 ~ 100.0%), demonstrating that analytical performance of OC-Light S FIT is substantially equivalent to the predicate Polymedco OC Light FOB Test.

Method comparison study: test results

POLs Method comaprison study	New Test	Predicate Test			Overall Percent Agreement (95% CI)	Positive Percent Agreement (95% CI)	Negative Percent Agreement (95% CI)
	OC-Light S FIT	Polymedco OC Light FOB Test					
		Positive Results	Negative Results	Total Results			
POL 1	Positive Results	17	0	17	100.0%	100.0%	100.0%
	Negative Results	0	90	90			
	Total Results	17	90	107	(96.6% ~ 100.0%)	(83.8% ~ 100.0%)	(96.0% ~ 100.0%)
POL 2	Positive Results	13	1	14	99.1%	100.0%	99.0%
	Negative Results	0	95	95			
	Total Results	13	96	109	(94.9% ~ 100.0%)	(79.4% ~ 100.0%)	(94.2% ~ 100.0%)
POL 3	Positive Results	15	0	15	100.0%	100.0%	100.0%
	Negative Results	0	85	85			
	Total Results	15	85	100	(96.4% ~ 100.0%)	(81.8% ~ 100.0%)	(95.8% ~ 100.0%)
POLs combined	Positive Results	45	1	46	99.7%	100.0%	99.6%
	Negative Results	0	270	270			
	Total Results	45	271	316	(98.2% ~ 100.0%)	(92.1% ~ 100.0%)	(97.9% ~ 100.0%)

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PMLs Method comparison study	New Test	Predicate Test			Overall Percent Agreement (95% CI)	Positive Percent Agreement (95% CI)	Negative Percent Agreement (95% CI)
	OC-Light S FIT	Polymedco OC Light FOB Test					
		Positive Results	Negative Results	Total Results			
PML 1	Positive Results	21	0	21	100.0%	100.0%	100.0%
	Negative Results	0	194	194			
	Total Results	21	194	215	(98.3% ~ 100.0%)	(86.7% ~ 100.0%)	(98.1% ~ 100.0%)
PML 2	Positive Results	18	0	18	100.0%	100.0%	100.0%
	Negative Results	0	193	193			
	Total Results	18	193	211	(98.3% ~ 100.0%)	(84.6% ~ 100.0%)	(98.1% ~ 100.0%)
PML 3	Positive Results	37	0	37	100.0%	100.0%	100.0%
	Negative Results	0	174	174			
	Total Results	37	174	211	(98.3% ~ 100.0%)	(90.5% ~ 100.0%)	(97.9% ~ 100.0%)
PMLs combined	Positive Results	76	0	76	100.0%	100.0%	100.0%
	Negative Results	0	561	561			
	Total Results	76	561	637	(99.4% ~ 100.0%)	(95.3% ~ 100.0%)	(99.3% ~ 100.0%)

POLs &PMLs combined	Positive Results	121	1	122	99.9%	100.0%	99.9%
	Negative Results	0	831	831			
	Total Results	121	832	953	(99.4% ~ 100.0%)	(97.0% ~ 100.0%)	(99.3% ~ 100.0%)

Conclusion:

OC-Light S FIT 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 effective as the predicate and do not raise different questions of safety and effectiveness than the predicate.