K111128

SEP 13 2012

510(k) Summary

In accordance with the requirements of 21 CFR.807.92, the following information about 510(k) safety and effectiveness is being submitted.

1. Submitter

CERAGEM Medisys Inc.
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2. Date Prepared

August 24, 2012

3. Device Name

Common name : LabonaCheck ™ A1c
Classification : Class II
(Regulation: 21 CFR 864.7470)
Product Code : LCP (Assay, Glycosylated Hemoglobin)

4. Predicate Device

The LabonaCheck™ A1c is substantially equivalent to NycoCard® HbA1c described as below.

(1) Trade Name: NycoCard® HbA1c Glycated Hemoglobin Assay
(2) Applicant: Primus Corporation
(3) 510(K) Number: K993131
(4) Regulatory Class: II
(5) Product Code: LCP

5. Device Description

The system consists of HbA1c Analyzer (MH 200) and HbA1c Test kit.
The LabonaCheck™ A1c HbA1c Analyzer measures the coloured responses of the LabonaCheck™ A1c HbA1c Test Kit by spectral reflectance.

6. Intended Use

1) Intended use(s): See indications for use.

2) Indication(s) for use

The LabonaCheck™ A1c consists of LabonaCheck™ A1c HbA1c analyzer and LabonaCheck™ A1c HbA1c Test kit, is for in-vitro diagnostic use only. LabonaCheck ™A1c HbA1c Analyzer is designed to analyze the LabonaCheck™ A1c HbA1c Test Kit.

The LabonaCheck™ A1c is intended for the quantitative measurement of glycated hemoglobin in venous whole blood and capillary fingerstick samples. This device is intended for multiple patient, professional use. Measurement of percent glycated hemoglobin (HbA1c) is effective in monitoring long-term glucose control in individuals with diabetes mellitus by using the LabonaCheck™ A1c. Only auto-disabling, single use lancing devices should be used with this system.

7. Comparison to Predicate Device

Comparison		
Item	**Device**	**Predicate**
Device Name	LabonaCheck™ A1c	NycoCard® HbA1c
Similarities		
Intended Use	The LabonaCheck A1c is an in-vitro diagnostic test for quantitative measurement of glycated hemoglobin (HbA1c) in venous whole blood and capillary fingerstick samples.	The NycoCard HbA1c is a rapid in vitro test for measurement of glycated hemoglobin in human blood.
Detection Method	Boronate affinity assay	Boronate affinity assay
Analytes	Glycated hemoglobin (HbA1c)	Glycated hemoglobin (HbA1c)
Sample Volume	5 uL	5 uL
Test Time	3 minutes	3 minutes

Measuring range	4 ~ 15%	4 ~ 15%
Storage Condition (Humidity range) (Test kit)	2~8°C, (20~70% R.H)	2~8°C (Below 70%)
Warranty (Analyzer)	1 year	1 year
Differences		
Power (Battery)	CR2032	NiMH
Storage Condition (Humidity range)	HbA1c Analyzer 10~60℃ (15~75% R.H)	Reader II 2~25℃ (20~70% R.H)

Conclusion

As the comparison table, the LabonaCheck™ A1c has same intended use, detection method, analytes, same volume, test time, measuring range, storage condition , humidity range (test kit), warranty (analyzer).

To sum up with the similarities, the LabonaCheck™ A1c is similar with the predicate device because most of the specifications deciding the characteristic of the device same.

In conclusion, despite of the difference such as power (battery) and etc., the LabonaCheck™ A1c is substantially equivalent to NycoCard® HbA1c.

8. Performance characteristics

A. Analytical Performance

a. Precision/Reproducibility

Precision studies were conducted internally by the manufacturer and externally at three POC sites. Precision studies were modeled from the NCCLS guideline EP5-A2.

Internal study performed at CERAGEM Medisys Inc.

Within-run, day to day and total precision were determined for whole blood samples. Test samples were analyzed per day of each sample using two meter and reagents of two lots.

Within-run, day to day and total precision, expressed as Coefficient of Variation (CV) and standard deviation (STD).

Interval	Reference A1c (%)	Mean(%)	Within run		Day to day run		Total Precision	
			STD	C.V(%)	STD	C.V(%)	STD	C.V(%)
1	4.3	4.4	0.1	3.0	0.1	2.8	0.1	3.0
2	6.2	6.1	0.1	2.2	0.1	2.0	0.2	2.6
3	8.9	9.1	0.2	2.2	0.1	1.5	0.2	1.9
4	11.7	11.6	0.2	2.1	0.2	1.3	0.3	2.2
5	14.3	14.2	0.2	1.6	0.2	1.7	0.2	1.6

External study

An external precision study was performed in three point-of-care sites with six operators (two at each site). Three intervals of HbA1c EDTA blood were analyzed. The results obtained on the A1c for site 1,2,3 are shown in the table below.

Interval		POC Site 1		POC Site 1		POC Site2		POC Site2		POC Site3		POC Site3	
		OP1	OP2	OP5	OP6	OP3	OP4	OP1	OP2	OP5	OP6	OP3	OP4
1	Mean	4.8	4.8	4.9	4.9	4.8	5.0	4.9	4.9	4.9	4.9	4.9	4.9
	STD	0.14	0.15	0.16	0.16	0.14	0.16	0.14	0.16	0.16	0.15	0.17	0.15
	C.V (%)	2.9	3.2	3.3	3.3	2.9	3.2	2.9	3.3	3.3	3.1	3.5	3.1
	Mean	4.8		4.9		4.9		4.9		4.9		4.9	
	STD	0.15		0.16		0.17		0.15		0.16		0.16	
	C.V (%)	3.0		3.2		3.4		3.1		3.2		3.3	
	Mean	4.8				4.9				4.9			
	STD	0.16				0.16				0.16			
	C.V (%)	3.2				3.4				3.3			
2	Mean	8.9	8.7	8.8	8.8	8.8	8.9	8.8	8.8	8.8	8.6	8.8	8.8
	STD	0.25	0.29	0.29	0.28	0.29	0.26	0.26	0.23	0.28	0.26	0.32	0.28
	C.V (%)	2.8	3.3	3.3	3.2	3.3	2.9	2.9	2.7	3.2	3.0	3.6	3.1
	Mean	8.8		8.8		8.9		8.8		8.7		8.8	
	STD	0.28		0.29		0.29		0.25		0.28		0.30	
	C.V (%)	3.2		3.2		3.2		2.8		3.2		3.4	

	Mean	8.8				8.8				8.7			
	STD	0.28				0.27				0.29			
	C.V (%)	3.2				3.0				3.3			
3	Mean	13.1	13.3	13.1	13.3	13.3	13.1	13.3	13.1	13.5	13.2	13.5	13.2
	STD	0.42	0.42	0.43	0.44	0.36	0.43	0.37	0.41	0.44	0.46	0.45	0.44
	C.V (%)	3.2	3.1	3.3	3.3	2.7	3.3	2.8	3.1	3.2	3.5	3.3	3.4
	Mean	13.2		13.2		13.2		13.2		13.3		13.3	
	STD	0.44		0.44		0.41		0.41		0.47		0.46	
	C.V (%)	3.3		3.3		3.1		3.1		3.5		3.4	
	Mean	13.2				13.2				13.3			
	STD	0.43				0.41				0.46			
	C.V (%)	3.3				3.1				3.5			

b. Linearity/Assay Measuring Range

A linearity study across the entire clamed measuring range (4~15%) was evaluated using low (3.2% HbA1c) and high (17.5% HbA1c) control solutions. The low and high control solutions were mixed together in ratios to make five intermediate levels. The control solutions were mixed well and divided into two aliquots. One aliquot was used to perform on the LabonaCheck™ A1c analyzer and the second aliquot was analyzed on the reference HbA1c analyzer. Real value was compared to the theoretical values based upon the dilution factor. The % recovery was calculated with the following formula: Recovery = Real value / Expected % x 100. The percent recovery between the real values verses the expected values are shown in the table below :

Sample No.	Expected (%)	Real Value (%)	Difference (%)	% Recovery
1	3.2	3.5	0.3	108
2	5.6	5.8	0.2	103
3	8.0	8.1	0.1	101

4	10.4	10.5	0.1	101
5	12.7	12.9	0.2	102
6	15.1	15.4	0.3	102
7	17.5	17.5	0	100

The results of the study support the sponsor's claimed that LabonaCheck™ A1c is linear from 4% to 15%.

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

The LabonaCheck™ A1c device has been certified by the National Glycohemoglobin Standardization Program (NGSP). NGSP certifications are renewed annually. Current NGSP certifications are found on the web at http://www.ngsp.org/prog/index.html

d. ***Detection Limit***

The limit of Blank (LoB) and Limit of Detection (LoD) were determined by assaying a zero sample (blank) and five low HbA1c samples according to CLSI guideline EP17-A. A zero sample was Negative or very low concentration sample that is commutable with patient specimen. Each sample was assayed twice a day in replicates of ten (n=60) for three days on the LabonaCheck™ A1c.The detection limits were summarized in the table below :

(N_b=60, Ns=60)

	Blank(%)	Low concentration (%)
Mean %	3.10	4.12
SD	0.080	0.092

This assay has reportable range of 4% to 15% A1c.

e. Analytical Specificity

Interference Study: Interference testing was performed using a protocol based on NCCLS EP7-A. Studies were performed to assess common or known substances that could interfere with the LabonaCheck™ A1c. The interfering substances were evaluated in Interval 1 (4.6~6.6), Interval 2 (7.6~9.6), and Interval 3 (9.8~12.8). Three intervals of whole blood sample pools were spiked with interfering substance. The sponsor states that recovery within 10% of the control results was considered to be non-significant. The following compounds, at the levels indicated, were shown to have no significant interference on the LabonaCheck™ A1c test results : Ascorbic acid: 6mg/dL, Bilirubin (Conjugated): 5mg/dL, Bilirubin (Unconjugated): 5mg/dL, Glucose: 1200mg/dL, Hemoglobin: 20g/dL, Lipid (Triglyceride): 500mg/dL, Albumin: 5g/dL, K_3EDTA: 300 mg/dL, Heparin: 8000 U/dL, Sodium fluoride: 1000 mg/dL, Sodium citrate: 3.20%, Acetaminophen: 30 mg/dL, Metformin: 4 mg/dL, Acetylsalicylic acid: 1000mg/dL, Glybenclamide: 5 mg/dL, Ibuprofen: 40 mg/dL.

To evaluate the effect of Hemoglobin variants (F), Sponsor performed the testing using samples (HbF: 22.3~27.8%) provided by the NGSP. When sponsor compared between test result of candidate device and result of reference device, the average bias caused by the hemoglobin F sample were within ± 10% up to 22.7%. Therefore, sponsor claimed the test results of candidate device is affected by blood sample containing HbF (>20%).

To evaluate the effect of Hemoglobin variants (C, D, E, and S), Sponsor performed the testing using samples provided by the NGSP known to contain variants C, D, E, and, S on the LabonaCheck™ A1c. The results of LabonaCheck™ A1c were compared to NGSP's data (results of Primus). The sponsor's acceptance criteria was within ±10% of reference difference to be considered as no significant interference. Interference testing about Hemoglobin C, D, E, and S satisfied acceptance criteria.

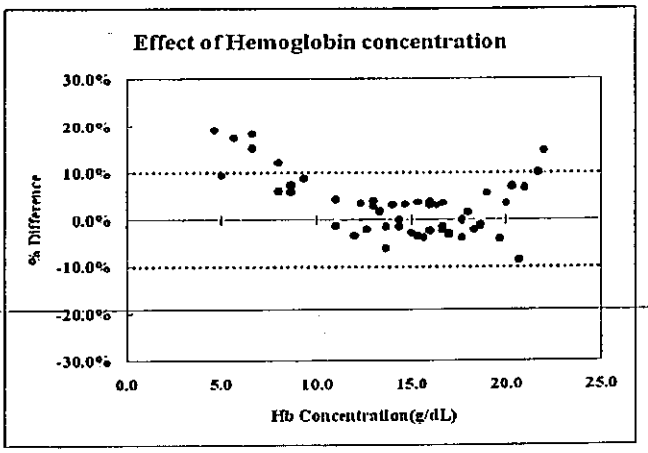
NGSP has hemoglobin variants interference information for method at http://www.ngsp.org/prog/index.html

To evaluate the effect of Carbamylated hemoglobin and Rheumatoid factor, Sponsor

performed the testing using 10 samples on the LabonaCheck™ A1c and reference device (Tosoh G7). The sponsor's acceptance criteria was within ±10% of reference difference to be considered as no significant interference. Interference testing about Carbamylated hemoglobin and Rheumatoid factor satisfied acceptance criteria.

	Carbamylated hemoglobin	Rheumatiod factor
Control sample	Whole blood sample	Whole blood sample
Test sample 1 (Low)	Whole blood sample + 2.5 mmol/L of sodium cyanate	Whole blood sample + 100 IU/mL of rheumatoid factor
Test sample 2 (High)	Whole blood sample + 5 mmol/L of sodium cyanate	Whole blood sample + 300 IU/mL of rheumatoid factor

Hemoglobin Study: The hemoglobin study was performed with 50 whole blood samples. We selected samples ranged from 4.6 to 22g/dL over a wide range of HbA1c concentrations. According to the results, LabonaCheckTM A1c satisfied the acceptance criteria (within 10% difference) at hemoglobin concentrations ranged from 8.7g/dL to 21.0g/dL. Sponsor claimed that the hemoglobin range for HbA1c measurement of the LabonaCheckTMA1c is 10.0g/dL - 20.0g/dL. Lower than 10.0g/dL or higher than 20.0g/dL of hemoglobin concentration will lead to inaccurate result.



Incubation time study: The purpose of this testing is to evaluate incubation time between HbA1c in whole blood and R1 reagent have an effect on the LabonaCheck™ A1c. Each meter were performed 3 measurements using whole blood samples of 3 HbA1c concentrations (Low, Medium, High) for incubation times. According to test result, when R1 reagent and the whole blood sample incubated for 2 to 3 minutes, reference difference was within 5%. Incubated samples for 2 minutes to 3minutes were satisfied acceptance criteria.

f. Assay cut-off

Not applicable.

B. Comparison studies

a. Method comparison with predicate device

Accuracy: A method comparison study was performed with performed with 50 EDTA venous whole blood patient samples in two point of care sites (two at each site). The testing was performed by comparing the venous whole blood results of 50 samples (25 at each site) that spanned the claimed assay range to the results obtained by the predicate device, NycoCard®HbA1c. Samples ranged from 4.2-14.5 as measured by the reference device. The difference % are as follows:

	Difference between LabonaCheck™A1c and Tosoh G7	Difference between NycoCard and Tosoh G7	Difference between LabonaCheck™A1c and NycoCard
within ± 10%	100% (50/50)	96% (48/50)	96% (48/50)

The linear regression and correlation coefficient are as follow:

	Slope	Intercept	Correlation coefficient
LabonaCheck vs Tosoh G7	1.0552	-0.4360	0.9708
NycoCard vs Tosoh G7	1.0613	-0.3304	0.9695

LabonaCheck vs NycoCard	0.9873	-0.0516	0.9873

b. Point-of-Care study

Accuracy (using venous blood samples): POC study was performed with 120 EDTA venous whole blood samples in three point of care sites by 6 intended users (two at each site) on one meters. Total of 120 measurements are obtained (40 results of testing at each site) samples ranged from 4.5-14.6 as measured by the reference device. The linear regressions are as follows:

		Slope (95% confidence interval)	Intercept	Correlation coefficient
Site 1		1.0225 (0.9850~1.0600)	-0.2129 (-0.5291~0.1034)	0.9877
Site 2		0.9868 (0.9466~1.0271)	0.0516 (-0.2768~0.3801)	0.9848
Site 3		0.9915 (0.9565~1.0265)	0.0756 (-0.2172~0.3683)	0.9886
All site combined	Site 1+2+3	1.0005 (0.9796~1.0215)	-0.0292 (-0.2036~0.1451)	0.9870

Accuracy (using capillary blood samples): POC study was performed with 120 capillary blood samples in three point of care sites on two meters. Total of 120 measurements are obtained (40 result of testing at each site) samples ranged from 4.2 %to 14.8 % as measured by the reference device. The linear regressions are as follows:

	Slope (95% confidence interval)	Intercept	Correlation coefficient
Site 1	1.0020 (0.9629~1.0411)	0.1670 (-0.4805~0.1465)	0.9861
Site 2	0.9576 (0.9185~0.9967)	0.5119 (0.1959~0.8280)	0.9848

Site 3		0.9524 (0.9180~0.9869)	0.5584 (0.2773~0.8396)	0.9880
All site combined	Site 1+2+3	0.9692 (0.9481~0.9903)	0.4230 (0.2523~0.5937)	0.9859

According to the above results, the slope (0.9-1.1), intercept (less than 1%), correlation coefficient results of three POC sites satisfied the acceptance criteria.

c. Matrix comparison

Venous whole blood samples (K_3EDTA, Sodium heparin, NaF) collected from 40 donors were assayed on the LabonaCheck™ A1c and compared to the reference device (Tosoh G7). Samples ranged from 4.5-14.1%. The results of the studies are presented below:

(1) Linear regression analysis

		Slope (95% confidence interval)	Intercept (95% confidence interval)	Correlation coefficient
K_3EDTA vs Sodium Heparin	Result 1	0.9661 (0.9088~1.0234)	0.2442 (-0.2949~0.7833)	0.9685
	Result 2	0.9721 (0.9140~1.0301)	0.3790 (-0.1587~0.9166)	0.9681
	Result 1+2	0.9682 (0.9279~1.0085)	0.3190 (-0.0570~0.6951)	0.9670
K_3EDTA vs NaF	Result 1	0.9486 (0.8834~1.0139)	0.3807 (-0.2332~0.9946)	0.9579
	Result 2	0.9498 (0.8834~1.0162)	0.4832 (-0.1318~1.0983)	0.9567
	Result 1+2	0.9487 (0.9033~0.9941)	0.4364 (0.0127~0.8602)	0.9569

A1c: The sponsor concluded that the following anticoagulants can be used with their A1c device: K_3EDTA, Sodium heparin, NaF.

C. Safety and Reliability

Equipment temperature exposure limits: Repeatability precision using three levels of control solutions was evaluated before and after challenge with temperature change. The testing degrees of high temperature limits were 30±2℃, and testing degrees of low temperature limits were 4±2℃.

There is no significant difference or tendency between the each test result measured on the each condition, 4℃ and 30℃, on LabonaCheck™ A1c.

Equipment Humidity exposure limits: The humidity test was evaluated using three levels of control solutions. The testing degrees of high humidity were 80%RH±5 %, and the testing degrees of normal humidity limits were 40%RH±5 %, and the testing degrees of low humidity were 10%RH±5 %. There is no significant difference or tendency on the each test result at 10%RH, 40%RH, and 80%RH.

D. Clinical studies

(1) Clinical sensitivity

Not Applicable

(2) Clinical specificity:

Not Applicable

(3) Other clinical supportable data(when a and b are not applicable)

Not Applicable

E. Clinical cut-off:

Not Applicable

F. Appendix

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

CERAGEM International
c/o Raymond Chung
3699 Wilshire Blvd., Suite 930
Los Angeles, CA 90010

SEP 13 2012

Re: k111128
Trade Name: LabonaCheck™ Alc
Regulation Number: 21 CFR §864.7470
Regulation Name: Quantitative, Hemoglobin Alc Test System
Regulatory Class: Class II
Product Codes: LCP
Dated: September 4, 2012
Received: September 10, 2012

Dear Raymond Chung:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K111128

Device Name: **LabonaCheck™ A1c**

Indication For Use:

The LabonaCheck™ A1c is intended for the quantitative measurement of glycated hemoglobin in venous whole blood and capillary fingerstick samples. This device is intended for multiple patient, professional use. Measurement of percent glycated hemoglobin (HbA1c) is effective in monitoring long-term glucose control in individuals with diabetes mellitus by using the LabonaCheck™ A1c. Only auto-disabling, single use lancing devices should be used with this system.

Prescription Use ___√___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ___. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K111128