K123563

Magellan
DIAGNOSTICS

510(k) Summary
For The Magellan LeadCare® Ultra™ Blood Lead Testing System

1. SUBMITTER/510(K) HOLDER

Magellan Diagnostics, Inc.
101 Billerica Ave, Building 4
North Billerica, MA 01862

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AUG 2 0 2013

2. DEVICE NAME

Proprietary Name:	LeadCare® Ultra™ Blood Lead Testing System
Common/Usual Name:	Lead Test System
Classification:	Class II
Product Code:	DOF
510(k) Number:	k123563

3. PREDICATE DEVICE

- LeadCare® II Blood Lead Testing System (k052549)

4. DEVICE DESCRIPTION

The LeadCare Ultra System Blood Lead Testing System is an *in vitro* diagnostic device that relies on electrochemistry (Anodic Stripping Voltammetry or ASV) and a unique sensor to detect lead in whole blood. Most lead is carried within red blood cells. When a sample of whole blood is mixed with Treatment Reagent (a dilute solution of hydrochloric acid), the red blood cells are lysed and the lead becomes available for detection. When a test is run, the Analyzer applies an electrical potential that causes the lead to collect on the Sensor. After three minutes, the Analyzer measures the amount of lead on the Sensor and displays the result in micrograms per deciliter (µg/dL).

The multi-channel LeadCare Ultra Analyzer performs up to six blood lead tests simultaneously and uploads the completed test results to the Computer. Test results are stored in the Computer in unique sample records, along with sample ID, comments, test conditions, Sensor lot number, and user ID. The Analyzer is also equipped with a Calibration Button Reader. This Reader allows for the download of all calibration information, analytical test parameters, and date code information for any given Sensor lot. These actions can be accomplished by simply touching the

appropriate Calibration Button to the Reader.

The system's Computer is dedicated to running only blood lead analyses, and sits on a stand directly behind the monitor. The Computer serves as the user interface for entering patient ID information using a keyboard or barcode reader. It also performs data analysis after blood lead measurements are processed by the firmware embedded in the Analyzer. The Computer stores the patient results (and allows for retrieval of stored results) and it allows connectivity via USB ports to a customer-supplied printer and Laboratory Information Management System (LIMS). Peripherals for the computer are a monitor, keyboard, barcode reader and mouse.

The analyzer is used in conjunction with a LeadCare Ultra Blood Lead Test Kit. Materials supplied in the Test Kit include:

	Quantity
• Sensors (8 containers of 24 ea.)	192
• Treatment Reagent Tubes (250µL of 0.34M HCl)	192
• Calibration Button	1
• Lead Control Level 1 (2mL)	1
• Lead Control Level 2 (2mL)	1

The controls supplied in the Test Kit are manufactured by Bionostics, Inc. to Magellan's specifications. The controls are cleared under K063398.

5. INDICATIONS FOR USE/ INTENDED USE

The LeadCare® Ultra™ Blood Lead Testing System is designed to quantitatively measure the amount of lead in a whole blood sample. The LeadCare Ultra Blood Lead Testing System is intended for *in vitro* (external) use only. The test kit components are designed for use only with the LeadCare Ultra Blood Lead Testing System.

This test system is for prescription use only. This system is not intended for point of care use.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICE

The following table summarizes the similarities and differences between the predicate and the LeadCare Ultra device.

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Similarities/Differences of LeadCare® Ultra™ with Predicate Device

Feature	LeadCare® II	LeadCare® Ultra™
Intended Use	The LeadCare II Blood Lead Testing System is an instrumented assay to be used in the quantitation of lead in whole human blood. The LeadCare II System is suitable for use in a Physician's office laboratory (POL).	The LeadCare Ultra Blood Lead Testing System is designed to quantitatively measure the amount of lead in a whole blood sample. The LeadCare Ultra Blood Lead Testing System is intended for *in vitro* (external) use only. The test kit components are designed for use only with the LeadCare Ultra Blood Lead Testing System. This test system is for prescription use only. This system is not intended for point of care use.
Methodology	Anodic Stripping Voltammetry	Same
Throughput	1 sample at a time	6 samples at a time
Sensor (test strip)	Screen printed sensors with conductive inks; plastic spacer and lid; capillary fill	Same
Active Test Electrode area	Thin layer of colloidal gold in an inert polymer matrix	Same
Calibration	Electronic calibration button	Same
Blood Collection	Fingerstick or venipuncture	Same
Sample Matrix	Whole blood collected in EDTA or heparin; fresh up to 24 hours from time of draw	Whole blood collected in EDTA or heparin; up to 72 hours from time of draw
Treatment Reagent	Dilute hydrochloric acid solution in water	Dilute hydrochloric acid solution in water with inert carbon particles
Sample Handling	Uses transfer dropper to transfer sample from reagent tube to sensor	Uses pipet to transfer sample from reagent tube to sensor
Check for Sensor Lot Expiration	Checks sensor lot expiration date passed in on the calibration button	Same

Internal Self-Test	Self-test checks electronic functions of analyzer each time it is turned ON	Self-test checks electronic functions of analyzer each time it is turned ON and on each channel following a sensor insertion
Sensor Connector	Makes electrical contact with sensor. Sensor insertion detection.	Same
Unit of Measure	Results displayed in micrograms of lead per deciliter of whole blood (µg/dL)	Same
Displayed Result	Lead result is displayed until new sensor is inserted	Lead results displayed via User Interface and stored in computer
Reportable Range	3.3 – 65 µg/dL	1.9 – 65 µg/dL
Controls	2 levels of external liquid controls	Same
Power Source	AC Adapter or 4 AA batteries	AC Adapter
Test Time	3 minutes	Same
Software	Software is in the form of firmware only, installed onto the analyzer's microprocessor. All functions (analyzer control, User Interface display control, blood lead algorithm calculation) are executed by this firmware	Software is in the form of firmware installed onto the analyzer's microprocessor, and .NET based software installed onto an accompanying computer workstation with Windows 7 Embedded POS Ready operating system. The firmware is used for the low level control of the analyzer only. The software on the computer workstation is used to run the system User Interface software and perform the blood lead algorithm calculations, receiving raw data from the firmware
Lead Test Algorithm	ASV routine; Pb peak identified and quantified; blood Pb result assigned using lookup tables	Same
User Interface	Alphanumeric display, 4 lines by 20 characters allows useful messages to guide users through procedure	Graphical user interface with messages and graphics to guide users through procedure

System Operating Range	Temperature range of 54° to 97°F (12° to 36°C); Relative Humidity 12%-80% non-condensing to accommodate field portability	Temperature range of 60° to 82°F (16° to 28°C); Relative Humidity 12%-80% non-condensing to accommodate typical laboratory use
Limit of Detection	3.3 µg/dL	1.9 µg/dL

7. SUMMARY OF NON-CLINICAL AND CLINICAL PERFORMANCE TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

A. Non-Clinical Results

Precision

The LeadCare Ultra Precision Study was performed using bovine blood standards at lead concentrations of 4.5, 6.4, 10.8, 24.4, 44.2, and 62.1 µg/dL. Eighty (80) data points were collected per concentration level over a 20 day period. Samples were prepped two times per day and each sample was run in duplicate on alternating channels such that all channels were used equally during the study. For concentrations of 4.5, 6.4 and 62.1 µg/dL, three sensor lots were utilized. For the remaining concentrations, one representative sensor lot was used. The combined data set is shown.

LeadCare Ultra Precision Data

Mean, µg/dL	WR SD, µg/dL	Total SD, µg/dL	WR CV	Total CV	95%CI for WR SD, µg/dL	95%CI for Total SD, µg/dL
4.5	0.36	0.49	8.0%	10.9%	0.32 to 0.42	0.45 to 0.55
6.4	0.55	0.60	8.7%	9.4%	0.49 to 0.63	0.55 to 0.67
10.8	0.79	0.90	7.4%	8.3%	0.65 to 1.03	0.78 to 1.08
24.4	1.20	1.43	4.9%	5.9%	0.99 to 1.54	1.22 to 1.73
44.2	1.55	1.62	3.5%	3.7%	1.28 to 1.99	1.40 to 1.93
62.1	1.90	3.19	3.1%	5.1%	1.69 to 2.18	2.91 to 3.54

Linearity

Linearity assessments were performed on three Sensor lots using nine donor blood samples spiked with lead to concentrations of 2-5 µg/dL, 5-10 µg/dL, 15-25 µg/dL, 25-35 µg/dL, 35-45 µg/dL, 45-55 µg/dL & 55-65 µg/dL. The concentrations used span the claimed measuring range of the LeadCare Ultra System. Linearity was evaluated by performing polynomial regression and determining whether higher order coefficients were statistically significant as per CLSI EP6-A Section 5.32.

The Linear Regression results for each of the three Sensor lots are as follows:

1208A	1211B	1305A
$Y = 1.04x - 1.17$	$Y = 1.10x - 1.71$	$Y=1.04x - 0.58$
$R^2 = 0.997$	$R^2 = 0.996$	$R^2 = 0.998$
$Sy.x = 1.41$	$Sy.x = 1.64$	$Sy.x = 1.05$

For each of the three lots, the average of the LeadCare Ultra replicates was analyzed against the average reference method (GFAAS) results using polynomial regression analysis. The (p) values for the higher order coefficients of the polynomial regressions were calculated for three lots of Sensors. All p values were greater than 0.05, demonstrating no statistically significant nonlinearity for the range 1 – 66 µg/dL.

Random error was evaluated by estimating precision from replicates. These precision data met the precision goals.

Analysis of samples from 1.9 µg/dL to 65 µg/dL was performed to demonstrate linearity across the claimed measuring range. Quadratic and Cubic regression results are shown in the table below:

Quadratic and Cubic Regression Data (range 1.9 µg/dL – 65 µg/dL)

	Quadratic Regression	**Cubic Regression**	
	Quad Coefficient	**Quad Coefficient**	**Cubic Coefficient**
Lot	**p value**	**p value**	**p value**
1208A	0.13	0.39	0.27
1211B	0.85	0.60	0.58
1305A	0.69	0.22	0.20

The LeadCare Ultra system demonstrated linearity for three lots across the claimed analytical range of 1.9-65 µg/dL.

Linearity was also demonstrated for each of the six channels on the LeadCare Ultra analyzer. Replicate data on each channel met precision goals.

Limit of Blank, Limit of Detection & Limit of Quantification

The limit of blank LoB was determined by running 70 replicates of a near blank NIST blood sample, 0.3 µg/dL, over 5 days. Samples were analyzed using two Sensor lots across all Analyzer channels.

The LoB was calculated to be 1.5 µg/dL.

Replicates of the low samples were run on the LeadCare Ultra Analyzer over five days. Seventy (70) data points were collected using all channels of the Analyzer. Two Sensor lots were used.

The LoD was calculated to be 1.9 µg/dL.

The limit of quantification LoQ was calculated using the Total Error equation: Total Error LoQ = absolute (Bias) + (2 x SD). The bias of 58 samples that contained lead concentrations between 1 and 6 µg/dL, according to GFAAS, was calculated to be 0.02 µg/dL.

The Standard Deviation at the LoD (1.9 µg/dL) is calculated to be 0.25 µg/dL. Based on the equation above, the Total Error LoQ is calculated to be:

Total Error LoQ = 0.02 + (2 x 0.25)
Total Error LoQ = 0.52

The LoQ is equal to the LoD (1.9 µg/dL).

Matrix Comparison

Matrix Comparisons were made for the following blood collection devices:

- K_3EDTA, K_2EDTA Vacutainers
- Sodium Heparin Vacutainers
- Micro-capillary tubes with K_2EDTA

Linear Regression Results of LeadCare Ultra compared to GFAAS met the acceptance criteria, defined as average bias within ±2 µg/dL in the concentration range 1.9 to 10 µg/dL and ±10% for concentrations above 10 µg/dL.

Micro-capillary tubes with K_2EDTA (N=72 tubes)

GFAAS, µg/dL	Predicted Ultra µg/dL	Bias, µg/dL	Percent Bias
1.9	1.7	-0.2	-10.3%
5	5.0	0.0	-0.6%
10	10.2	0.2	2.4%
20	20.8	0.8	3.9%
30	31.3	1.3	4.4%
40	41.8	1.8	4.6%
50	52.4	2.4	4.8%
60	62.9	2.9	4.9%
65	68.2	3.2	4.9%

K_3EDTA, K_2EDTA and Sodium Heparin Vacutainers (N=39 vacutainers each)

GFAAS	Calculated EDTA Bias		Calculated Heparin Bias	
µg/dL	µg/dL	Percent Bias	µg/dL	Percent Bias
0	-0.02	---	0.03	---
5	-0.05	-1.02%	0.16	3.20%
10	-0.08	-0.80%	0.29	2.93%
15	-0.11	-0.72%	0.43	2.84%
20	-0.14	-0.69%	0.56	2.80%
25	-0.17	-0.67%	0.69	2.77%
30	-0.20	-0.65%	0.83	2.75%
35	-0.22	-0.64%	0.96	2.74%
40	-0.25	-0.63%	1.09	2.73%
45	-0.28	-0.63%	1.23	2.72%
50	-0.31	-0.62%	1.36	2.72%
55	-0.34	-0.62%	1.49	2.71%
60	-0.37	-0.61%	1.63	2.71%

Sensor Lot Calibration and Traceability

Calibration of sensor lots, traceable to NIST Standard Reference Material 955c (Lead in Caprine Blood) is performed using four concentrations of control samples. The control samples are used to calibrate a GFAAS instrument, used for comparison with the LeadCare Ultra system. As part of the calibration, blood samples spiked at 8 concentrations are analyzed by both the LeadCare Ultra system and GFAAS, run in duplicate on 2 separate days.

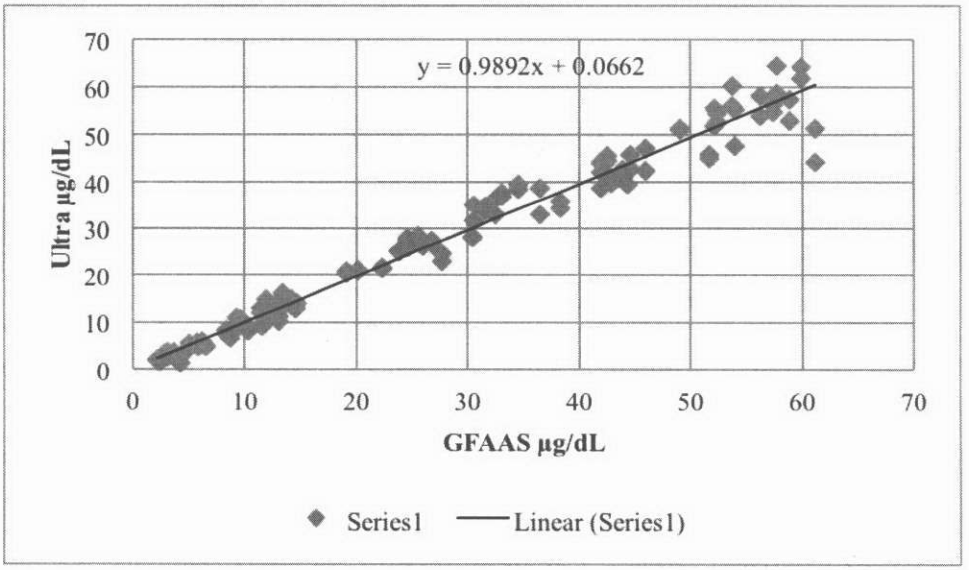
B. Clinical Results

Method Comparison

The LeadCare Ultra method comparison study was conducted at two sites. Samples collected in EDTA vacutainers, were run in duplicate on GFAAS, the reference method and once on the LeadCare Ultra system. Three hundred ninety four (394) results were generated and 148 were within the claimed analytical range of 1.9-65 µg/dL.

The average of the two GFAAS results was plotted against the LeadCare Ultra result for each sample. Regression analysis for the 148 results is presented.

LeadCare Ultra Results vs. GFAAS average. (R^2 = 0.978; N=148 data points).



The predicted bias for various lead concentrations (LeadCare Ultra) across the analytical range are shown below:

LeadCare Ultra Average Bias from GFAAS

GFAAS, µg/dL	Predicted Ultra, µg/dL	Average Bias, µg/dL	Percent Bias
1.9	1.9	0.05	2.4%
5	5.0	0.01	0.2%
10	10.0	-0.04	-0.4%
20	19.9	-0.15	-0.7%
30	29.7	-0.26	-0.9%
40	39.6	-0.36	-0.9%
50	49.5	-0.47	-0.9%
60	59.4	-0.58	-1.0%
65	64.4	-0.63	-1.0%

The clinical data met the acceptance criteria, defined as average bias within the range of ±2 µg/dL in the concentration range 1.9 to 10 µg/dL and ±10% for concentrations above 10 µg/dL.

8. SUMMARY OF OTHER INFORMATION

This submission included a comparison of intended use statements, proposed product labeling, environmental testing and software validation.

9. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTS

Based on the information provided in this 510(k), Magellan believes that the proposed LeadCare Ultra Application is substantially equivalent to the previously cleared predicate product. The proposed device raises no new issues of safety and effectiveness. The non-clinical and clinical testing performed demonstrates that the proposed device met all the specifications and is suitable for its intended use.

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, 2013

Magellan Diagnostics, Inc.
C/O Stuart Naylor
101 Billerica Ave, Building 4
NORTH BILLERICA MA 01862-1271

Re: K123563
Trade/Device Name: LeadCare® Ultra™ Blood Lead Testing System
Regulation Number: 21 CFR 862.3550
Regulation Name: Lead test system
Regulatory Class: II
Product Code: DOF
Dated: July 10, 2013
Received: July 11, 2013

Dear Stuart Naylor:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for

the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123563

Device Name: LeadCare Ultra Blood Lead Testing System

Indications for Use:

The LeadCare® Ultra™ Blood Lead Testing System is designed to quantitatively measure the amount of lead in a whole blood sample. The LeadCare® Ultra™ Blood Lead Testing System is intended for *in vitro* (external) use only. The test kit components are designed for use only with the LeadCare® Ultra™ Blood Lead Testing System.

This test system is for prescription use only. This system is not intended for point of care use.

Prescription Use ___X___ (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 Diagnostics and Radiological Health (OIR)

Ruth A. Chesler -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k123563