

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

A. 510(k) Number:

K142705

B. Purpose for Submission:

New Device

C. Measurand:

Lead

D. Type of Test:

Quantitative

E. Applicant:

Magellan Diagnostics

F. Proprietary and Established Names:

LeadCare® Plus™ Blood Lead Testing System

G. Regulatory Information:

1. Regulation section:

21 CFR§ 862.3550, Lead test system

2. Classification:

Class II

3. Product code:

DOF

4. Panel:

Toxicology (91)

H. Intended Use:

1. Intended use(s):

See Indications for Use below.

2. Indication(s) for use:

The LeadCare® Plus™ Blood Lead Testing System is intended for the quantitative measurement of lead in a whole blood sample. The LeadCare Plus Blood Lead Testing System is intended for in vitro (external) use only. The test kit components are for use with both the LeadCare Plus and LeadCare Ultra® Blood Lead Testing Systems.

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

3. Special conditions for use statement(s):

- Prescription use only
- This system is not intended for point of care use

4. Special instrument requirements:

LeadCare Plus Blood Lead Analyzer

I. Device Description:

The LeadCare® Plus™ Blood Lead Testing System is a one-channel analyzer system version of the predicate, LeadCare Ultra®, that is a 6-channel analyzer. The new LeadCare Plus Analyzer is used with the same Blood Lead Sensors, Treatment Reagent Tubes, and LeadCare Plus Blood Lead Controls (Level 1 and Level 2) as previously cleared with the predicate device (k123563; LeadCare Ultra® Blood Lead Testing System).

J. Substantial Equivalence Information:

1. Predicate device name(s):

LeadCare Ultra® Blood Lead Testing System

2. Predicate 510(k) number(s):

K123563

3. Comparison with predicate:

Similarities		
Item	Device LeadCare® Plus™	Predicate LeadCare Ultra® (K123563)
Indication For Use	The LeadCare® Plus™ Blood Lead Testing System is intended for the quantitative measurement of lead in a whole blood sample	Same
Methodology	Anodic Stripping Voltammetry	Same
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; up to 72 hours from time of draw	Same
Unit of Measure	Results displayed in micrograms of lead per deciliter of whole blood (µg/dL)	Same
Reportable Range	1.9 – 65 µg/dL	Same
Controls	2 levels of external liquid controls	Same
Power Source	AC Adapter or batteries	Same
Test Time	3 minutes	Same

Differences		
Item	Device LeadCare® Plus™	Predicate LeadCare Ultra® (K123563)
Throughput	1 sample at a time	6 samples at a time

K. Standard/Guidance Document Referenced (if applicable):

- CLSI EP5-A2 Evaluation of Precision Predominance of Quantitative Measurement Methods
- CLSI EP6-A Evaluation of Linearity of Quantitative Measurement procedures: A Statistical Approach
- CLSI EP7-A2 Interference Testing in Clinical Chemistry
- CLSI EP9-A2 Method Comparison and Bias Estimation Using Patient Samples
- CLSI EP17-A2 Protocols for Determination of Limits of Detection and Limits of Quantitation
- FCC 47CFR Part 15, Subpart B (2014)
- CEI/IEC 61010-1: 2001 Safety Requirements for electrical equipment for measurement, control and laboratory use.

- CEI/IEC 61326-2-6:2006 Electrical equipment for measurement control and laboratory use - EMC requirements.

L. Test Principle:

The LeadCare® Plus™ Blood Lead Testing System is an in vitro diagnostic device that relies on electrochemistry (Anodic Stripping Voltammetry or ASV) with a sensor to detect lead in whole blood. 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 electrochemical detection. When a test is run, the analyzer applies an electrical potential that causes the lead to collect on the Sensor. The analyzer measures the amount of lead on the Sensor and displays the result in micrograms per deciliter.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

The LeadCare® Plus™ precision was demonstrated using bovine blood standards at lead concentrations of 3.1, 5.1, 11.7, 24.7 and 45.4 µg/dL. An additional human blood sample at a lead concentration of 59.1 µg/dL was also included to challenge the high end of the range. Eighty (80) data points were collected per concentration level over a 20 day period using two Sensor/Reagent Lot Pairs. The combined data set is shown:

Mean, µg/dL	WR* SD, µg/dL	Total SD, µg/dL	WR CV	Total CV
3.1	0.44	0.49	14.1%	15.6%
5.1	0.44	0.50	8.5%	9.6%
11.7	0.64	0.71	5.3%	6.0%
24.7	0.80	1.00	3.2%	4.0%
45.4	1.61	1.71	3.5%	3.7%
59.1	1.89	2.42	3.2%	4.0%

WR = within run

b. *Linearity/assay reportable range:*

Linearity assessments were performed on two Sensor/Reagent Lot Pairs using nine human donor blood samples, spiked with lead to concentrations of 0-2 µg/dL, 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, 65-70 µg/dL. One whole blood sample, unadulterated in K₂EDTA vacutainers, was also included.

The Linear Regression results for each of the two Sensor/Reagent Lot Pairs are as follows:

Lot Pair #1

$$Y = 1.11x - 1.49$$

$$R^2 = 0.998$$

Lot Pair #2

$$Y = 1.08x - 0.803$$

$$R^2 = 0.997$$

The results of the study support the sponsor's claimed reportable range of 1.9 – 65 $\mu\text{g/dL}$

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

Traceability: The LeadCare® Plus™ system is traceable to the NIST Standard Reference Material 955c analyzed on Graphite Furnace Atomic Absorption Spectrometer (GFAAS).

Test Kit Stability: Protocols and acceptance criteria were previously reviewed and found to be acceptable (k123563) for the test kit. The sponsor's stability claims are for 18 months when stored at 59°F to 80°F (15°C - 27°C). The labeling instructs the user not to freeze or refrigerate the reagent. The sensors should be kept sealed until the sample is prepared and the treatment reagent should be used immediately after opening the tube.

Control Solutions: Two levels of Quality Controls material are provided with the test kit, Level 1 and Level 2. These control solutions were previously cleared k063398. The labeling instructs the user to store the control solutions at: 15°C - 27°C (59°F - 80°F) and not to refrigerate.

Sample stability study protocols and acceptance criteria were reviewed and found to be acceptable to support the claims in the labeling that samples collected in micro-capillary K₂EDTA tubes can be stored for up to 72 hours (3 days) from collection at 33°F - 77°F (1°C - 25°C) prior to being mixed with treatment reagent.

d. Detection limit:

The Limits of Blank, Detection and Quantification were established using the Total Error Analysis Method and by following the CLSI EP17-A2 guidelines.

The Limit of Blank (LoB) was determined by running 60 replicates of near blank bovine blood samples, over 5 days. Samples were analyzed using two Sensor/Reagent Lot Pairs. The average LoB was calculated to be 0.98 $\mu\text{g/dL}$.

The Limit of Detection (LoD) and Limit of Quantification (LoQ) were determined by running 60 replicates of 10 different whole blood samples, collected in K₂EDTA vacutainers. The replicates were run, using two Sensor/Reagent Lot Pairs on

LeadCare Plus analyzers over five days. The average LoD was calculated to be 1.2 µg/dL.

The Limit of Quantification LoQ was calculated using the Total Error equation:

Total Error LoQ = absolute (Bias) + (2 x SD)

The average LoQ was calculated to be 1.6 µg/dL.

The Total Error at the LoQ was 18%.

Obtained LoB, LoD, and LoQ values for the LeadCare® Plus™ differ slightly from those obtained for the predicate, LeadCare Ultra® (See k123563). For product family consistency between LeadCare® Plus™ and LeadCare Ultra®, the claimed values for LoB, LoD and LoQ of the LeadCare® Plus™ are provided in the table below and are identical to the values obtained for the LeadCare Ultra®:

	LeadCare® Plus™
LoB	1.5 µg/dL
LoD	1.9 µg/dL
LoQ	1.9 µg/dL

e. Analytical specificity:

The assay reagents and controls are unchanged from the predicate, therefore please refer to k123563 where analytical specificity was established.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

A method comparison study was conducted at one site with two Sensor/Reagent Lot Pairs, two labs, two users and two stations of six LeadCare Plus analyzers. To assess system accuracy 169 whole blood samples collected in K₂EDTA Vacutainers with lead concentrations within the claimed analytical range of 1.9 - 65 µg/dL were run on the LeadCare® Plus™ system and the results were compared to the reference method, Graphite Furnace Atomic Absorption Spectroscopy (GFAAS). The LeadCare® Plus™ results from each sample were compared to the average of two GFAAS results. The linear regression results are as follows:

$$y = 1.029x - 0.98, R^2 = 0.994$$

b. Matrix comparison:

A total of 50 micro-capillary tubes with K₂EDTA fingerstick samples were spiked with lead to achieve concentrations of 1.9-63.1 µg/dL lead as measured by GFAAS. Samples tested included unaltered native patient samples and spiked samples. These samples were analyzed on the LeadCare® Plus™ system and compared to values obtained from GFAAS. The linear regression results are as follows:

$$y = 1.018X - 0.023; R^2 = 0.983$$

The assay reagents and controls are unchanged from the predicate, therefore please refer to k123563 for matrix comparison information for EDTA Vacutainer and Heparin Vacutainer samples.

3. Clinical studies:

a. *Clinical Sensitivity:*

Not applicable.

b. *Clinical specificity:*

Not applicable.

c. *Other clinical supportive data (when a. and b. are not applicable):*

Not applicable.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

The current labeling includes the following:

In 2012, based on the increased body of evidence demonstrating there is no safe level of lead in the blood, experts established a new reference value to identify children who have elevated blood lead levels (BLL). According to the Centers for Disease Control (CDC) website, this level is based on the U.S. population of children ages 1-5 years who are in the top 2.5% of children when tested for lead in their blood (when compared to children who are exposed to more lead than most children). Currently this reference value is 5 µg/dL, a change from the previously utilized “level of concern” set at 10 µg/dL.*

*CDC Response to Advisory Committee on Childhood Lead Poisoning Prevention Recommendations in “*Low Level Lead Exposure Harms Children: A Renewed Call of Primary Prevention.*” June 7, 2012.

The labeling also includes a note that it is important to check the CDC website, as well as specific state regulations, for up-to-date information regarding blood lead testing and provides the following website link, (www.cdc.gov/nceh/lead/acclpp/blood_lead_levels.htm).

N. Instrument Name:

LeadCare Plus Blood Lead Analyzer

O. System Descriptions:

1. Modes of Operation:

Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

Yes or No

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

Yes or No .

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes or No

3. Specimen Identification:

Specimen identification is based on sample ID, sensor lot number, and user ID.

4. Specimen Sampling and Handling:

The labeling provides instructions on specimen sampling and handling and states the following user instructions: Handle all products and objects containing human blood as if capable of transmitting diseases. Follow established recommendations for prevention of blood-borne transmissible diseases. For example, consult the "Universal Precautions" issued by the U.S. Public Health Service, Centers for Disease Control. Review your internal protocol for preventing transmission of blood-borne pathogens and your biohazardous waste disposal procedures prior to implementing the LeadCare® Plus™ Blood Lead Testing System.

5. Calibration:

Calibration is done using the calibration button which is supplied in each test kit. The calibration button is specific for the test kit in which it is supplied. It is used to download all calibration information, analytical test parameters, and expiration date code information for the sensor lot supplied within the test kit. This lot specific calibration button is held against the calibration reader on the analyzer to calibrate the analyzer for use with a particular test kit. The labeling states that the analyzer must be calibrated for each test kit lot and instructs the user to make sure the calibration code on the calibration button matches the lot number on the sensor container and on the controls.

6. Quality Control:

Two levels of liquid Quality Controls (Level 1 and Level2) are supplied with the Test Kit. The labeling states that controls should be tested, at a minimum, as follows: each day or shift before patient samples are tested.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The “Performance Characteristics” Section above:

The sponsor provided the appropriate documentation certifying that acceptable electromagnetic testing (EMC) had been performed.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

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