Magellan
DIAGNOSTICS

Made in the USA by
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P/N 82-0038 Rev 12 (10/2025)

Intertek

The ETL label on the bottom of the instrument indicates that Intertek Electrical Testing Labs (ETL) has certified the LeadCare Plus to the applicable Safety standards.

IVD Rx Only 15°C 27°C

LeadCare Plus® Blood Lead Test Kit

For use with the LeadCare Plus Blood Lead Testing System to test for lead in capillary whole blood.

For *in vitro* diagnostic testing (external use only).

Read this package insert completely before using the product. Follow the instructions carefully when performing a test. Not doing so may result in inaccurate test results.

COMPLEXITY: Moderately Complex
Facilities must be certified according to CLIA guidelines and must comply with all applicable federal, state, and local laws. All laboratories should follow the manufacturer's instructions as specified in the LeadCare Plus User's Guide.

Note: When using the LeadCare Plus Blood Lead Testing System with the LeadCare Plus DMS for data collection and management, please refer to the LeadCare Plus with DMS User's Guide provided on the DMS Memory Stick. This document contains all the information in the general LeadCare Plus User's Guide as well as DMS specific instructions.

Please read the LeadCare Plus User's Guide before performing any blood lead testing with the LeadCare Plus Blood Lead Testing System.

Questions?
Call the LeadCare Product Support Team
Toll Free Number 1-800-275-0102

INTENDED USE

The LeadCare Plus Blood Lead Testing System is intended for the quantitative measurement of lead in capillary whole blood samples. The LeadCare Plus Blood Lead Testing System is intended for *in vitro* (external) use only. The test kit components are designed for use with 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.

HOW THE LEADCARE PLUS BLOOD LEAD TESTING SYSTEM WORKS

The LeadCare Plus System relies on electrochemistry and a unique Sensor to detect lead in whole blood. Most lead is carried in red blood cells. When a sample of whole blood is mixed with Treatment Reagent, the red blood cells are lysed and the lead is made available for detection. When a test is run, the analyzer applies a potential that causes the lead to collect on the LeadCare Plus Sensor. After 3 minutes the analyzer measures the amount of lead collected on the Sensor and displays the result in µg/dL.

REAGENTS

Sensor Composition: The active electrode area in each Sensor contains a small amount of gold particles in an inert matrix.

Treatment Reagent Composition: The Treatment Reagent contains activated carbon particles in 250 µL of a dilute hydrochloric acid solution in water (0.34 M).

Blood Lead Control Composition: Lead salt in buffered aqueous solution with bovine serum albumin.

Two levels of Quality Control material are provided with the test kit, designated "Level 1" and "Level 2". The actual target values are specified on the labels.

STORAGE AND HANDLING

The test kit has an expiration date assigned. It is printed on the exterior of the box. Do **NOT** use the test kit past the expiration date.
NOTE: The Treatment Reagent, blood lead Controls and the Sensors have separate expiration dates. The earliest expiring component is used to set the test kit expiration date.

To keep the LeadCare Plus Blood Lead Test Kit fresh, observe the following:

- Store in a cool, dry place. Storage temperature should be between 15°C - 27°C (59°F - 80°F). Do **NOT** freeze or refrigerate.
- Store away from direct sunlight.
- Keep Sensors sealed in their container until the sample is prepared and you are ready to perform the test. The container is lined with desiccant to keep the Sensors fresh.
- Use the Treatment Reagent immediately after opening the tube.
- Do **NOT** place any object in the Treatment Reagent tube other than the pipet tip used to transfer the blood. Contamination could occur.
- Do **NOT** use Sensors, blood lead controls, and Treatment Reagent past their expiration dates.
- Blood Lead Controls should be kept at room temperature: 15ºC - 27ºC
  (59ºF - 80ºF). Do **NOT** refrigerate.
- Use caution when handling the LeadCare Plus Treatment Reagent. The reagent contains dilute hydrochloric acid. Reagent vials and vial packaging are designed to minimize chances of leaks during shipping or under normal use. Refer to the LeadCare Plus Treatment Reagent Material Safety Data Sheet that appears in Appendix D of the User's Guide.

PRECAUTIONS

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.

CAUTION LeadCare Plus Treatment Reagent contains 0.34M Hydrochloric Acid which may cause eye, skin, and respiratory system irritation. Avoid contact with skin, eyes and clothing. In case of accidental contact, immediately flush skin and eyes with running water for up to 15 minutes and move to fresh air. Seek medical assistance in situations where eye contact, skin irritation or burn, or difficulty breathing occurs. You **MUST** wear gloves, lab coats, and safety glasses when handling blood and using the LeadCare Plus System. Consult the established policy of your organization for proper laboratory protection.

SAMPLE COLLECTION AND REQUIREMENTS

- **The end user must validate the use of micro collection devices with the LeadCare Plus Blood Lead Testing System in accordance with their laboratory policies and procedures.**
- Use only capillary whole blood. Do **NOT** use plasma or serum. Do **NOT** use venous blood samples.
- Use only EDTA or Heparin as anticoagulants in capillary micro-collection devices.
- Capillary blood samples must be free of clots. Blood clots can lead to erroneous blood lead results.
- Blood must be stored at 1°C - 25°C (33°F - 77°F) from collection up to 72 hours prior to being mixed with Treatment Reagent.

MATERIALS PROVIDED IN THE TEST KIT	QTY
• Sensors (4 containers of 24 ea.)	96
• Treatment Reagent Tubes (250 µL of 0.34 M HCl)	96
• Calibration Button	1
• Lead Control Level 1 (2 mL)	1
• Lead Control Level 2 (2 mL)	1

REQUIRED MATERIALS PROVIDED WITH THE ANALYZER

- LeadCare Plus User's Guide

MATERIALS REQUIRED BUT NOT PROVIDED

- **The end user must validate the use of micro collection devices with the LeadCare Plus Blood Lead Testing System in accordance with their laboratory policies and procedures.**
- 50 µL pipet (adjustable)
- Lead-free pipet tips
- Powder-free gloves
- Absorbent liner

SAMPLE PREPARATION

1. Bring the blood sample to room temperature before use.
2. Label new Treatment Reagent tube with the appropriate sample ID.

3. Use a calibrated pipet to transfer 50 µL of the control or blood sample into the properly labeled Treatment Reagent tube. Use a new pipet tip for each sample.
4. Recap tube and mix the tube contents. Invert tubes 8 - 10 times to thoroughly mix.

Refer to the LeadCare Plus User's Guide for detailed instructions.

CALIBRATION

The LeadCare Plus Analyzer **MUST** be calibrated for the test kit lot in use. Use only the calibration button that comes with the test kit. Make sure that the calibration code on the calibration button matches the lot number on the Sensor container, and on the controls.

1. Turn on analyzer
   - Wait for SELF TEST to finish. The analyzer is ready when the PREPARE SAMPLE message appears.
2. Calibrate analyzer
   - Remove the calibration button from the test kit.
   - Touch calibration button to the calibration button reader on the analyzer.
   - Hold calibration button to the reader until analyzer "beeps". "CALIBRATION SUCCESSFUL" will appear briefly on the screen.
   - A reminder message "Perform QC Daily" will display on the screen.
   - The new calibration code ("Sensor lot") will be displayed on the screen.
   - Make sure the code matches the calibration button and the lot number of the test kit being used.
   - Analyzer is now calibrated and ready for a blood lead test.

Refer to the LeadCare Plus User's Guide for more detailed calibration instructions.

BLOOD LEAD TEST PROCEDURE

Refer to your LeadCare Plus User's Guide for detailed test instructions.

QUALITY CONTROL

Quality Controls should be run on a routine basis to ensure the accuracy of your LeadCare Plus results. Magellan Diagnostics recommends that two levels of Quality Control (Level 1 and Level 2), at minimum, are performed on each day or shift before patient samples are tested.

TEST QUALITY CONTROLS

1. Insert the Sensor into the analyzer making sure it is inserted under the Sensor guides and sits flush on the deck. Insert Sensor until you hear a "beep" and the screen displays the message, "ADD SAMPLE TO X ON SENSOR".

Note: Close the Sensor container after each Sensor is removed to keep the remaining Sensors in a desiccated state until used.

2. Mix the Level 1 / Treatment Reagent mixture thoroughly.
3. Using a clean pipet tip, transfer 30 µL of the Level 1 / Treatment Reagent mixture onto the X on the Sensor. When the sample is added, the analyzer beeps, and begins the test automatically.
4. After 3 minutes, the analyzer beeps and displays the blood lead result on the screen. Read and record the result in µg/dL
5. After a test is completed, remove the Sensor. Discard used materials in appropriate containers.
6. If the Sensor is not removed and discarded 1 minute after the result is displayed, a warning beep will sound. The analyzer will sound two short beeps every 15 seconds until the Sensor is removed.
7. Repeat this process with the Level 2 Control.

EXPECTED RESULTS

LeadCare Plus Control target values and acceptable limits are provided on the control label. If the reported value is within the acceptable limits, your LeadCare Plus System is operating properly. You may now test patient samples.

If the reported lead level is not within the acceptable range for the control, refer to the troubleshooting section in Chapter 11 of the LeadCare Plus User's Guide. If, after following the instructions, the control value is still out of range please contact LeadCare Product Support at 1-800-275-0102.

IMPORTANT: Do NOT proceed to patient samples unless the control results are within the acceptable ranges.

PATIENT SAMPLES

1. Insert the Sensor into the analyzer making sure it is inserted under the Sensor guides and sits flush on the deck. Insert Sensor until you hear a "beep" and the screen displays the message, "ADD SAMPLE TO X ON SENSOR".

Note: Close the Sensor container after each Sensor is removed to keep the remaining Sensors in a desiccated state until used.

2. Mix the blood / Treatment Reagent mixture thoroughly.
3. Using a clean pipet tip, transfer 30 µL of the blood / Treatment Reagent mixture onto the X on the Sensor. When the sample is added, the analyzer beeps, and begins the test automatically.
4. After 3 minutes, the analyzer beeps and displays the blood lead result on the screen. Read and record the result in µg/dL
5. After a test is completed, remove the Sensor. Discard used materials in appropriate containers.
6. If the Sensor is not removed and discarded 1 minute after the result is displayed, a warning beep will sound. The analyzer will sound two short beeps every 15 seconds until the Sensor is removed.
7. Continue this process until all patient samples have been analyzed.

TEST RESULTS

The analyzer's display window shows the blood lead result. The result is displayed in micrograms (µg) of lead per deciliter (dL) of whole blood. No calculation is needed. Results are displayed to one decimal place. The reportable range of the test is 1.9 - 65.0 µg/dL.

"Low" in the display window indicates a blood lead test result less than 1.9 µg /dL. When this occurs, report the blood lead result as less than (<) 1.9 µg /dL

"High" in the display window indicates a blood lead test result greater than 65 µg /dL. If this occurs, report the blood lead result as greater than (>) 65 µg /dL.

Blood lead test results should be shared with the patient's physician for interpretation, and to determine when retesting and follow-up care are necessary.

IMPORTANT: Report all blood lead results to the proper state or federal agency.

QUESTIONABLE RESULTS

Incorrect test results may have an adverse medical outcome. If test results are questionable or inconsistent, follow the suggestions below:

1. Make sure the expiration date of the kit has not passed.
2. Check that the analyzer is properly calibrated. The lot number displayed on the screen should match the lot number printed on the Sensor container, the control vials and test kit.
3. Check the analyzer and kit contents using proper control material. Acceptable performance is assured if results of the controls are within the proper range.
4. If the above steps result in unacceptable performance, see the LeadCare Plus User's Guide for further steps to be taken.

BLOOD LEAD REFERENCE VALUE

According to the US Centers for Disease Control (CDC), there is no known safe level of lead. Consult your local public health department and/or CDC recommendations for information on the management of blood lead levels.

MAINTENANCE

The LeadCare Plus System needs very little maintenance. Follow the maintenance procedures listed in Chapter 12 (Maintenance) of the User's Guide.

LIMITATIONS OF THE TEST

- **The user must validate the use of micro collection devices with the LeadCare Plus Blood Lead Testing System in accordance with their laboratory policies and procedures**
- Use only capillary whole blood stored at 1°C - 25°C (33°F - 77°F) from collection up to 72 hours prior to being mixed with Treatment Reagent.
- Do **NOT** use plasma or serum. Do **NOT** use venous blood samples.
- Use a calibrated pipet to transfer 50 µL of blood from the collection device into the Treatment Reagent tube.
- After mixing the blood with the Treatment Reagent, analyze it in less than 48 hours if stored at room temperature. If stored refrigerated, analyze it within 7 days.

NOTE: Allow mixture to reach room temperature before analyzing.

- Extremes in humidity may affect the blood lead results. Performance has been validated from 12% - 80% Relative Humidity (non-condensing). Use of the LeadCare Plus System outside of this range is not recommended.
- Do **NOT** use the LeadCare Plus System above altitudes of 8,000 feet.
- Do **NOT** use the LeadCare Plus System in drafts. This could lead to inaccurate results.
- Keep the LeadCare Plus System out of direct sunlight.
- The analyzer will only function in the temperature range of 16°C - 30°C (60.8°F - 86°F). Otherwise the system will display a temperature error. Refer to error messages in the User's Guide (Chapter 11).
- Allow all of the LeadCare Plus System components to reach a steady temperature before using.
- Use the Sensors and the Treatment Reagent tubes, only once.
  Do **NOT** reuse. Reuse could lead to erroneous results.
- Do **NOT** use damaged (bent, scratched, cut, etc.) Sensors.

INTERFERENCES

- The following substances (at the concentrations listed) do **NOT** affect the results of the LeadCare Plus System: copper (2µg/mL), zinc (10 µg/mL), arsenic (0.005 µg/mL), cadmium (0.05 µg/mL), aluminum (10 µg/mL), ascorbic acid (100 µg/mL), and uric acid (100 µg/mL).
- The drugs listed below, commonly found in pediatric blood samples, do **NOT** affect the LeadCare Plus Blood Lead Testing System at the following concentrations: acetaminophen (500 µg/mL), acetylsalicylic acid (599 µg/mL), ibuprofen (250 µg/mL), succimer (DMSA) (100 µg/mL), D-penicillamine (25 µg/mL), Thiamine (20 µg/mL).
- If the user does not validate the use of micro collection devices with the LeadCare Plus Blood Lead Testing System in accordance with their laboratory policies and procedures it may affect test results.

Refer to the User's Guide for a complete list of drugs and substances tested.

PERFORMANCE CHARACTERISTICS

Consult the LeadCare Plus User's Guide for the complete product specifications.

PRECISION

The precision of the LeadCare Plus Blood Lead Testing System was determined by testing samples at six concentration levels over twenty days. The results are provided below. Table 1a demonstrates within run standard deviation (WR SD) and within run percent coefficient of variation (CV). Table 1b demonstrates total standard deviation (Total SD) and total coefficient of variation (Total CV).

Table 1a: Within Run Precision Results

Mean, µg/dL	WR SD, µg/dL	WR % CV	95%CI for WR SD, **µg/dL**
3.1	0.44	14.1%	0.36 to 0.56
5.1	0.44	8.5%	0.36 to 0.56
11.7	0.64	5.3%	0.50 to 0.78
24.7	0.80	3.2%	0.66 to 1.02
45.4	1.61	3.5%	1.31 to 2.04
59.1	1.89	3.2%	1.53 to 2.39

Table 1b: Total precision Results

Mean, µg/dL	Total SD, µg/dL	Total CV	95%CI for Total SD, **µg/dL**
3.1	0.49	15.6%	0.44 to 0.57
5.1	0.50	9.6%	0.44 to 0.61
11.7	0.71	6.0%	0.62 to 0.86
24.7	1.00	4.0%	0.86 to 1.27
45.4	1.71	3.7%	1.49 to 2.09
59.1	2.42	4.0%	2.09 to 3.03

ACCURACY

The accuracy of the LeadCare Plus Blood Lead Testing System was determined by a Method Comparison study in two labs at one site. One hundred sixty-nine results, from a combination of spiked and unspiked blood samples, were generated. These results were within the claimed analytical range of 1.9 - 65.0 µg/dL. The LeadCare Plus results were plotted versus the results obtained by the Reference Method, GFAAS. The LeadCare Plus average bias from GFAAS and the scatter plot of LeadCare Plus vs. GFAAS results, with the linear regression, are provided in Table 2 and Graph 1, respectively.

Table 2: LeadCare Plus Average Bias from GFAAS

GFAAS (µg/dL)	Predicted LeadCare Plus (µg/dL)	Avg. Bias (µg/dL)	Bias (%)
1.9	1.0	-0.9	-48.4%
5	4.2	-0.8	-16.6%
10	9.3	-0.7	-6.9%
20	19.6	-0.4	-2.0%
30	29.9	-0.1	-0.4%
40	40.2	0.2	-0.5%
50	50.5	0.5	0.9%
60	60.8	0.8	1.3%
65	65.9	0.9	1.4%

Graph 1: Scatter Plot of LeadCare Plus Results vs. GFAAS