Magellan
DIAGNOSTICS

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

IVD Rx Only

LeadCare Ultra® Blood Lead Test Kit

For use with the LeadCare Ultra 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 Ultra User's Guide.

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

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

INTENDED USE

The LeadCare Ultra Blood Lead Testing System is designed to quantitatively measure the amount of lead in capillary whole blood samples. 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.

HOW THE LEADCARE ULTRA BLOOD LEAD TESTING SYSTEM WORKS

The LeadCare Ultra 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 Ultra 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 (0.34M).

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 Ultra Blood Lead Test Kit fresh, observe the following:

- Store in a cool, dry place. Storage temperature should be between 60°- 80°F (15°-27°C). 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 **th**e 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: 60-80 ºF (15-27 ºC). Do NOT refrigerate.
- Use caution when handling the LeadCare Ultra reagent. The Treatment Reagent contains dilute hydrochloric acid. Reagent vials and vial packaging designed to minimize chances of leaks during shipping or under normal use. Refer to the LeadCare Ultra Treatment Reagent 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 Ultra blood lead testing system.

CAUTION LeadCare Ultra 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 Ultra System. Consult the established policy of your organization for proper laboratory protection.

SAMPLE COLLECTION AND REQUIREMENTS

- Use only capillary whole blood. Do NOT use plasma or serum. Do NOT use venous blood.
- Use only EDTA or Heparin as anticoagulants in capillary microcollection devices.
- Blood sample must be free of clots. Blood clots can lead to erroneous blood lead results.
- Blood must be stored at 33° - 77°F (1° - 25°C) from collection up to 72 hours prior to being mixed with Treatment Reagent.

MATERIALS PROVIDED IN THE TEST KIT	QTY.
• 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

REQUIRED MATERIALS PROVIDED WITH THE ANALYZER

- LeadCare Ultra User's Guide
- LeadCare Ultra Installation Guide

MATERIALS REQUIRED BUT NOT PROVIDED

- 50 µl pipet (adjustable)
- Lead-free pipet tips
- Powder-free gloves

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 at least 10 times to thoroughly mix. Do not vigorously shake to avoid creating foam.
5. The sample is ready for analysis.

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

SYSTEM OPERATION

During installation, the software will be configured to the preferences of the laboratory. Refer to the User's Guide for a complete list of setup options.

1. Power on the analyzer and the computer.
2. Enter User ID and password.
3. The LeadCare Ultra main screen appears.
4. Proceed to Calibration, as required.

CALIBRATION

The LeadCare Ultra 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.

NOTE: The User Application software interface will prompt you if the calibrated lot has expired, or if the system requires recalibration.

1. The Sensor lot number is displayed in the upper left corner of the main screen. Compare this number to the kit lot number of the test kit to be used. If they match, proceed to the BLOOD LEAD TEST PROCEDURE section.
2. If the Sensor lot number displayed does not match the lot number of the test kit to be used, or if the analyzer displays a "Please calibrate" message, you must calibrate the analyzer before testing.
3. Remove the calibration button from the test kit.
4. Hold the calibration button to the button reader until you hear a beep.
5. Verify that the Sensor lot number in the upper left corner of the screen matches the lot number on the calibration button AND the lot number on the Sensor container.
6. When the analyzer is calibrated to a new lot, the Quality Control window opens automatically. Enter the lot numbers and target values of the Controls into the appropriate fields.

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

BLOOD LEAD TEST PROCEDURE

Refer to your LeadCare Ultra 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 Ultra 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 any Channel of the analyzer making sure it is inserted under the sensor guides and sits flush on the deck.
   Note: Close the Sensor container after each Sensor is removed to keep the remaining Sensors in a desiccated state until used.
2. Use the mouse to select QC1.
3. Mix the Level 1 / Treatment Reagent mixture thoroughly.
4. Using a clean pipet tip, transfer 30 µL of the Level 1 / Treatment Reagent mixture onto the X on the Sensor. The system will beep and the Channel graphic will change to a 180-second countdown, indicating that sample analysis is underway.
5. While the Level 1 Control is being analyzed, repeat steps 1 through 4 with the Level 2 Control on any other channel of the analyzer. When prompted to enter the sample ID, be sure to select QC 2 for the Level 2 Control.
6. When analysis is complete, lead concentrations display in the Channel graphic and in the main data table at the top of the screen.
7. After a test is completed, remove the Sensor. Discard used materials in appropriate containers.

EXPECTED RESULTS

LeadCare Ultra Control target values and acceptable limits are provided on the Control label. If the Control target values were entered into the system following calibration, the User Application interface software will notify you whether the results are in or out of range. If the reported value is within the acceptable limits, your LeadCare Ultra 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 7 of the LeadCare Ultra 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 any Channel of the analyzer making sure it is inserted under the sensor guides and sits flush on the deck.
   Note: Close the Sensor container after each Sensor is removed to keep the remaining Sensors in a desiccated state until use.
2. Scan the sample barcode or enter the sample ID using the Keyboard.
3. Mix the Sample / Treatment Reagent thoroughly.
4. Using a clean pipet tip, transfer 30 µL of the Sample / Treatment Reagent mixture onto the X on the Sensor. The system will beep and the Channel graphic will change to a 180-second countdown, indicating that sample analysis is underway.
5. While the first sample is being analyzed, repeat steps 1 through 4 with the next 5 patient samples using the remaining channels of the analyzer.
6. When analysis is complete, blood lead concentrations display in the Channel boxes and in the main data table at the top of the screen
7. After a test is completed, remove the Sensor. Discard the used materials in appropriate waste disposal container.
8. Continue this process until all patient samples have been analyzed.

TEST RESULTS

The blood lead 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 analytical range of the test is 1.9 to 65.0 µg/dL.

Results lower than the limit of detection will be displayed as "<1.9".

Results higher than the analytical range will be displayed as ">65"

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. Run quality controls to confirm the analyzer and test kit are functioning properly.
4. If the above steps result in unacceptable performance, see the LeadCare Ultra 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 Ultra System needs very little maintenance. Follow the maintenance procedures listed in Chapter 7 (Troubleshooting and Maintenance) of the User's Guide.

LIMITATIONS OF THE TEST

- Use only whole blood stored at 33°F - 77°F (1°C -25°C) 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 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% to 80% RH (non-condensing). Use of the LeadCare Ultra system outside of this range is not recommended.
- Do **NOT** use the LeadCare Ultra System above altitudes of 8,000 feet.
- Do **NOT** use the LeadCare Ultra System in drafts. This could lead to false results.
- Keep the LeadCare Ultra System out of direct sunlight.
- The analyzer will only function in the temperature range of 61° to 82°F (16° to 28°C). Otherwise the system will display a temperature error. Refer to error messages in the User's Guide (Chapters 7).
- Allow all of the LeadCare Ultra 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 Ultra 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 Ultra Blood Lead Testing System at the following concentrations: acetaminophen (251 µg/mL), acetylsalicylic acid (599 µg/mL), ibuprofen (500 µg/mL), succimer (DMSA) (100 µg/mL), D-penicillamine (100 µg/mL).
- Refer to the User's Guide for a complete list of drugs and substances tested.

PERFORMANCE CHARACTERISTICS

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

PRECISION

The precision of the LeadCare Ultra Blood Lead Testing System was determined by testing samples at six concentration levels over twenty days. The results are provided below. The Confidence Interval (CI) at 95% was calculated for each level.

Table 1a: Total Precision Results

Mean (µg/dL)	Total SD (µg/dL)	Total % CV	95% CI for Total SD (µg/dL)
4.5	0.49	10.90%	0.45 to 0.55
6.4	0.6	9.40%	0.55 to 0.67
10.8	0.9	8.30%	0.78 to 1.08
24.4	1.43	5.90%	1.22 to 1.73
44.2	1.62	3.70%	1.40 to 1.93
62.1	3.19	5.10%	2.91 to 3.54

Table 1b: Repeatability Results

Mean (µg/dL)	Within Run (WR) SD (µg/dL)	WR CV (%)	95% CI for WR SD (µg/dL)
4.5	0.36	8.00%	0.32 to 0.42
6.4	0.55	8.70%	0.49 to 0.63
10.8	0.79	7.40%	0.65 to 1.03
24.4	1.20	4.90%	0.99 to 1.54
44.2	1.55	3.50%	1.28 to 1.99
62.1	1.90	3.10%	1.69 to 2.18

ACCURACY

The accuracy of the LeadCare Ultra Blood Lead Testing System was determined by a Method Comparison study at two hospital laboratory sites. Three hundred ninety-four (394) results, from a combination of spiked and unspiked blood samples, were generated. One hundred forty-eight results were within the claimed analytical range of 1.9 – 65.0 µg/dL. The LeadCare Ultra results were plotted versus the results obtained by the Reference Method, GFAAS. The LeadCare Ultra average bias from GFAAS and the scatter plot of LeadCare Ultra vs. GFAAS results, with the linear regression, are provided in Table 2 and Graph 1, respectively.

Table 2: LeadCare Ultra Average Bias from GFAAS

GFAAS (µg/dL)	Predicted LeadCare Ultra (µg/dL)	Avg. Bias (µg/dL)	Bias (%)
1.90	1.95	0.05	2.4%
5.00	5.01	0.01	0.2%
10.00	9.96	-0.04	-0.4%
20.00	19.85	-0.15	-0.7%
30.00	29.74	-0.26	-0.9%
40.00	39.64	-0.36	-0.9%
50.00	49.53	-0.47	-0.9%
60.00	59.42	-0.58	-1.0%
65.00	64.37	-0.63	-1.0%

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