SECTION: **PATIENT CARE**

SUB SECTION: **DIAGNOSTIC TESTS AND POINT OF CARE**

SUBJECT: **LeadCare® II BLOOD LEAD ANALYZER**

APPROVED BY: _____
Clinical Director, Ambulatory Services

POLICY

The LeadCare® II Blood Lead Analyzer is a Clinical Laboratory Improvement Act (CLIA) -waived device. The CLIA-waived laboratory test is performed according to the manufacturer's instructions to determine the quantitative measurement of lead in fresh whole blood under the regulations set forth by the CLIA, the Joint Commission, and the State of California Business and Professions Code. Testing is performed in the Primary Care Clinics by clinical staff who have completed the appropriate training and competency: Care Assistants (CAs), Licensed Vocational Nurses (LVN), and Registered Nurses (RN).

TEST PRINCIPLE/PURPOSE

The LeadCare® II Blood Lead Analyzer 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.

PROCEDURES

I. Procedure Precautions.

A. **Precautions**

1. Handle all products and objects containing human blood as if capable of transmitting diseases. Follow established recommendations for prevention of blood-borne transmissible diseases.

    a. For example, consult the "Universal Precautions" issued by the U.S. Public Health Service, Centers for Disease Control.
    b. Review your internal protocol for preventing transmission of blood-borne pathogens and your biohazardous waste disposal procedures prior to implementing the LeadCare II Blood Lead Testing System.

2. Treatment reagent contains 0.34M Hydrochloric Acid which may cause eye, skin, and respiratory system irritation. Avoid contact with skin, eyes and clothing.

    a. Refer to current hospital protocol for the preventing blood-borne pathogens and biohazardous waste disposal.

b. In case of accidental contact, immediately flush skin and eyes with running water for up to 15 minutes and move to fresh air.
c. Seek medical assistance in situations where eye contact, skin irritation or burn, or difficulty breathing occurs. Consult the established policy of your organization for proper laboratory protection.

II. Materials Provided

A. Materials Provided in the Test Kit

1. Sensors (2 containers of 24 each) = 48
2. Treatment Reagent Tubes (250 µL of 0.34 M HCl) = 48
3. Heparinized Capillary Tubes/Plungers = 50 each
4. Transfer Dippers = 50
5. Calibration Button= 1
6. Lead Control Level 1 (2 mL) = 1
7. Lead Control Level 2 (2 mL) = 1

B. Materials Provided in the Analyzer Kit

1. Analyzer
2. AC Adapter and International Power Plug Set
3. Alkaline Batteries (4 x AA)
4. Quick Reference Guide
5. LeadCare II Flash Drive (contains User's Guide and Instructional Videos)

C. Materials Required but not Provided

1. Alcohol Wipes
2. Gauze Pads
3. Powder-Free Gloves

III. Expiration

A. The test kit has an assigned expiration date; see outside of box. DO NOT USE past the expiration date.
B. The test kit and control solutions are kept at room temperature.
C. The treatment reagent, blood lead controls, and the sensors have separate expiration dates.

1. Once blood Lead control solutions are opened, they have a 90-day expiration date or the manufacture date; whichever date comes first.

a. Control solutions once opened are to remain at room temperature.

2. Treatment reagent vials once the package is opened maintain the kit expiration date (manufacture expiration date).
3. The sensor strips expiration date is the manufacture date.

IV. Procedure for Testing the Blood Lead Controls.

A. Calibration: The LeadCare II Analyzer **MUST** be calibrated for the test kit lot in use. Use only the calibration button that comes with the test kit. Confirm that the calibration code on the calibration button matches the lot number on the sensor container and on the controls.

1. Turn on the Analyzer.

    a. Wait for “SELF TEST” to finish.
    b. The analyzer is ready when the “PREPARE SAMPLE” message appears.

2. Calibrate analyzer.

    a. Remove the calibration button from the test kit.
    b. Touch calibration button to the calibration button reader on the analyzer.
    c. Hold calibration button to the reader until analyzer “beeps”.
    d. “CALIBRATION SUCCESSFUL” will appear briefly on the screen.
    e. A reminder message “IF NEW LOT TEST CONTROLS” will display on the screen.
    f. Confirm new calibration code (“sensor lot”) will be displayed on the screen.
    g. Confirm the code matches the calibration button and the lot number of the test kit being used.
    h. Analyzer is now calibrated and ready for a blood test.

B. Quality Control (QC) using Lead Control material (Level 1 & 2) should be run on a routine basis to ensure the accuracy of your LeadCare II results. According to CLIA guidelines for **Waived Laboratories**, QCs should be run according to the manufacturer's instructions which are:

1. Each Test Kit.
2. When training new operators in correct use of the LeadCare II System.
3. Every 30 days as a check on continued storage conditions.
4. When problems are suspected or identified.
5. If otherwise required by your laboratory’s standard QC procedures.
6. The blood lead level that appears on the analyzer display should be within the acceptable range provided for that control.

    a. If the blood lead levels displayed are within the range listed for the control, your LeadCare II System is working properly.
    a. If the reported blood lead levels are *not* within the listed range, refer to the troubleshooting section of the User’s Guide.
    b. If, after following the instructions, the controls are still out of range, call LeadCare Product Support: **1-800-275-0102**.

C. Prepare the Sample.

1. Label a treatment reagent tube “Level 1”.
2. Gently swirl the Level 1 Control Vial. Remove the cap from the vial and place it top down on a clean surface.
3. Fill one of the capillary tubes with Level 1 control solution.

    a. To accomplish this, tilt the control vial, insert the capillary tube into the liquid while holding the green end of the capillary tube almost horizontally.
    b. Capillary action will fill the tube to the 50 µL black line.

4. Use a clean wipe to remove excess control material from the outside of the capillary tube.

5. Mix the Control Material with treatment reagent.

    a. Remove the cap from the treatment reagent tube and place it top down on a clean surface. Do NOT allow the inside part of the cap to touch anything.
    b. Place the Capillary Tube into the treatment reagent tube.
    c. Insert a plunger into the top of the Capillary Tube.
    d. Dispense all the Control Material into the treatment reagent.
    e. Remove the empty Capillary Tube and replace the cap on the treatment reagent tube.
    f. Invert the tube 8 to 10 times to mix the sample completely.
    g. The resulting mixture will be red.
    h. Apply treatment reagent and control and control mixture to a sensor.

D. Prepare the Sensor

1. Open a sensor container, remove a sensor, and close the container.
2. Insert the sensor into the analyzer, confirm it is inserted under the sensor guides and sits flush on the deck.
3. Insert sensor until you hear a “beep”, and the screen displays the message, “ADD SAMPLE TO ‘X’ ON SENSOR”.
4. Confirm that the sensor lot number matches the number on the display.
5. Make sure the sample is thoroughly mixed, Control Solution Mixture should be red.
6. Remove the cap from the tube.

    a. Insert a transfer dropper into the tube.
    b. Squeeze the dropper and insert into the sample.
    c. Release the pressure to draw the sample into the dropper.
    d. Place the dropper on the “X” of the sensor and squeeze the dropper to dispense the sample onto the sensor.
    e. When the sample is added, the analyzer beeps, and the test begins automatically.

7. Read the Blood Lead Test Result

    a. After 3 minutes, the analyzer beeps and displays the blood lead result on the screen
    b. Read and record the result in micrograms per deciliter (µg/dL) on the QC LOG sheet.

8. Discard Used Materials.

    a. After the test is completed, remove the sensor.
    b. Discard used materials in appropriate containers.

9. Warning beep.

    a. If the sensor is not removed and discarded 1 minute after the result is displayed a warning beep will sound.

        1. The analyzer will sound two short beeps every 15 seconds until the sensor is removed.

    b. Repeat this process for the Level 2 control solution.

E. Expected Quality Control Results.

1. Lead control target values and acceptable limits are provided on the control label.

    a. If the reported value is within acceptable limits for both Level 1 and Level 2 Controls, your LeadCare II System is operating properly.

2. You may now test patient samples.
3. If the reported blood lead level is not within the acceptable range for the Control Level, refer to the troubleshooting section of the LeadCare II User's Guide.

    a. If, after following instructions, the control value is still out of range, contact **LeadCare Product Support at 1-800-275-0102.**
    b. DO NOT proceed with patient samples unless BOTH Level 1 and Level 2 Control results are within the acceptable ranges.

V. Procedure for Testing Patient Samples.

A. Specimen Collection and Requirements.

1. The risk of contamination to the specimen is large when dealing with a sample only 5 µg/dL. It is critical to keep extraneous lead out of the sample.
2. Confirm order from the practitioner
3. Confirm patient identification.
4. Wash hands and put on gloves.
5. Label a treatment reagent tube with the patient ID.
6. Have patient wash hands with soap and water.

    a. Shake hands dry, do not use paper towels to dry.
    b. Do not let patient touch anything after hands are washed.
    c. Wipe the finger pad with alcohol and allow hands to air dry.

7. Use the lateral part of the finger pad from the ring or middle finger.
8. Gently massage the finger to stimulate blood flow. Do not touch finger pad or the specimen site.
9. Use the appropriate depth option on the lancet for the patient
10. Do not wipe away the first drop of blood but allow the first drop of blood to drop onto a gauze pad.
11. Position the blood capillary collection tool at a 10-degree angle to collect the whole blood sample without touching the tool to the finger.

    a. Use whole blood. Do not use plasma, serum, or venous blood samples.

12. Minimize the chance of contamination by not allowing the sampling collection materials to touch anything except for the blood drop.
13. If using a microcontainer with a capillary collector, avoid placing the capillary collector on the finger.
14. Fill the capillary tube to the black 50 µl fill line: avoid air bubbles.
15. Wipe any excess blood from the capillary tube with a clean gauze pad in a downward direction taking care not to drain blood from the end of tube.
16. Dispense the collected blood sample from the capillary tube into a treatment reagent tube within 10 minutes of collection to prevent clotting of the sample.
17. Remove the treatment reagent cap from the tube and place it top down on a clean surface. Do not allow the inside of the cap to touch anything. This could contaminate the sample.

18. Place the capillary tube in the reagent vial.
19. Insert plunger into capillary tube, push down; confirm entire contents is dispensed into reagent.

    a. The accuracy of the blood lead test depends on properly transferring 50 µL of blood into the treatment reagent.

20. Replace reagent tube cap, invert tube 8 to 10 times to mix completely
21. Sample is ready when the Patient Sample Mixture turns brown.

    a. The mixture of blood and treatment reagent is stable for up to 48 hours at room temperature.
    b. The mixture of blood and treatment reagent is stable for up to 7 days refrigerated.

22. Remove a sensor from the container and close the container to ensure sensors stay fresh.
23. Insert sensor black bars first. The analyzer beeps when the sensor is fully inserted.
24. Take dropper from blue container, squeeze walls of dropper and insert into treatment reagent, release to fill.
25. Dispense onto sensor. Touch dropper tip to “X” on sensor, squeeze to dispense.
26. Analysis of sample begins automatically. A 180 second countdown begins.
27. When the countdown finishes, the analyzer beeps, and the result is displayed.
28. Record result.

    a. “LOW” should be recorded as (less than) <3.3 µg/dL
    b. “HIGH” should be recorded as (greater than) > 65 µg/dL
    c. “HIGH” results should be followed up immediately with a practitioner and an emergency lab test.

29. Discard used sensor per facility instructions.
30. Leaving a sensor in the analyzer can damage the instrument

    a. If a used sensor is left in the analyzer, the instrument will beep until the sensor is removed.

VI. Expected Patient Results

A. Reference Range

    1. Blood Lead Results (less than) < 3.5 µg/dL

B. For cases where a blood “finger stick” test result is equal to or greater (= to or >) than 3.5 mcg/dL, the result must be confirmed through a venous blood draw analyzed by a reference laboratory that runs inductively coupled plasma mass spectrometry (ICP-MS) or graphite furnace atomic absorption spectrometry (GFAAS).

C. When the LeadCare II display reads “High”, the analyzer has detected a blood level greater than 65 µg/dL.

    1. “High” results on LeadCare II should be followed up immediately as an emergency laboratory test.

D. **Report all blood lead results to the proper State or Federal Agency.**

E. **Important:** According to Section 124130 of the California Health and Safety Code, users of any blood lead testing device are considered "laboratories" and must electronically report all blood lead results drawn in California to the Electronic Blood Lead Reporting (EBLR) System.

1. The EBLR system provides a secure method to electronically submit blood lead results.
2. Laboratories and health care providers will need to register for an account before accessing EBLR system.

F. Contact your state's Lead Poisoning Program for details. For assistance, contact the Product Support Team at (800) 275-0102 or email us at LeadCareSupport@meridianbioscience.com

G. Reporting timeframe for ALL BLOOD LEAD RESULTS:

1. Greater than or equal to (> or =) 3.5 µg/dL must be reported within 3 working days of analysis.
2. Less than (<) 3.5 µg/dL must be reported within 30 calendar days of analysis.

H. Consult your local Public Health Department or the Centers for Disease Control and Prevention (CDC) for further information and actions to be taken for blood lead results greater than 3.5 µg/dL.

1. The CDC established 3.5 µg/dL as the new "reference Level" for lead in blood in October 2021.
2. Blood Lead Reference Value (BLRV) is updated periodically to reflect changes in the population.

VII. Questionable Results

A. Inaccurate test results may have an adverse medical outcome. If test results are questionable or inconsistent, follow these suggestions:

1. Confirm the expiration date of the kit has not passed.
2. Confirm the analyzer is properly calibrated.

a. 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.

a. Acceptable performance is assured if results of the controls are within the proper range.
b. The target value is printed on the label.
c. The control lot number must match the sensor lot number for a valid test result.
d. If the above steps result in unacceptable performance, see the LeadCare II User's Guide for further steps to be taken.

VIII. Maintenance

A. The LeadCare II System Analyzer will function in the temperature range of 54°- 97°F (12°- 36°C).

1. Allow all the LeadCare II System components to reach a steady temperature before using.

B. Keep the LeadCare II System out of direct sunlight or away from drafty areas.
C. Remove used sensors from the analyzer as soon as a result is recorded.
D. Clean the analyzer with damp cloth and warm, soapy water. Do not immerse in water.
E. Disinfect with dilute (10%) bleach solution.
F. Do Not leave soap on the analyzer.
G. Do Not allow liquid of any kind into the sensor connector.
H. Do Not get the metal pins in the sensor connector wet.
I. Do not wash the inside of the calibration button reader.

IX. Limitations

A. For blood collected in the capillary tubes provided with the test kit: Dispense the blood from the capillary tube into a treatment reagent tube within 10 minutes of collection, and mix well, to prevent the blood from clotting inside the heparinized capillary tube.
B. For blood collected in other collection devices: Use only fresh, unrefrigerated whole blood within 24 hours stored at 50°- 90°F (10°- 32°C) with the LeadCare II System. Do NOT use plasma or serum. Use the capillary tubes and plungers provided with the test kit to transfer 50 µl of blood from the collection device into the treatment reagent tube.
C. 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.
D. Extremes in humidity may affect the blood lead results. Performance has been validated from 12% to 80% RH (non-condensing). Use of the LeadCare II System outside of this range is not recommended.
E. Do NOT use the LeadCare II System in drafty areas. This could lead to inaccurate results.
F. Keep the LeadCare II System out of direct sunlight.
G. The analyzer will only function in the temperature range of 54°- 97°F (12°- 36°C). Otherwise, the analyzer will display a temperature error code. Refer to analyzer display messages in the User's Guide (Chapter 5).
H. Allow all the LeadCare II System components to reach a steady temperature before using.
I. Clinical testing demonstrates that altitudes up to 8,000 feet (2,440 meters) above sea level do not affect results obtained with the LeadCare II System.

1. Use the sensors, the treatment reagent tubes, capillary tubes and transfer droppers only once. Do NOT reuse. Reuse could lead to erroneous results.

J. Do NOT use damaged (bent, scratched, cut, etc.) sensors.

X. Interferences

A. The following substances (at the concentrations listed) do not affect the results of the LeadCare II System: copper (90 µmol/L), zinc (54 µmol/L), arsenic (0.78 µmol/L), cadmium (0.27 µmol/L), aluminum (0.45 µmol/L), ascorbic acid (0.30 mmol/L), uric acid (1.5 mmol/L).
B. The LeadCare II System was also tested in the presence of 37 drugs commonly found in pediatric blood samples. The following concentrations do not affect the results of the LeadCare II System: acetaminophen (396 µmol/L), acetylsalicylic acid (6.0 mmol/L), ibuprofen (396 µmol/L), heparin (80,000 units/L), calcium sodium EDTA (6.7 mmol/L), succimer (DMSA) (78 µmol/L), DMPS (2,3-dimercapto-1-propane sulfonic acid) (78 µmol/L), D-penicillamine (0.17 mmol/L), BAL (2,3-imercaptopropanol) (0.97 µmol/L). Refer to the User's Guide for a complete list of drugs tested.

XI. Product Support

A. Monday – Friday 8 am to 8 pm Eastern Time.
B. Phone: 800-275-0102.
C. Fax: 800-600-1480
D. Email: LeadCareSupport@magellandx.com

REFERENCES: **MERIDIAN Bioscience LeadCare II User's Guide and Quick Reference Guide 2023**

DEFINITIONS: **The LeadCare II Blood Lead Test Kit is for *in vitro* diagnostic use only; the quantitative measurement of lead in fresh whole blood.**
"Whole blood" is simply the blood that flows through your veins. It contains red cells, white cells, and platelets, suspended in plasma.
When a test is run, the analyzer applies a potential that causes the lead to collect on the LeadCare II Sensor.
The analyzer measures the amount of lead collected on the sensor and displays the result in µg/dL.
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. In 2012, the Centers for Disease Control (CDC) established 5 µg/dL as the new "reference level" for lead in blood. The reference level is based on the U.S. population ages 1-5 years who are in the top 2.5% of children when tested for blood lead.

ATTACHMENTS: **N/A**

APPROVAL DATE:

3/11/2025	**Kristy Byers, Clinical Director II** Department/Service Director, Manager or Supervisor
3/11/2025	**Ambulatory Work Group** Applicable Administrator, Hospital or Medical Committee
3/18/2025	**Nursing Standards Committee** Applicable Administrator, Hospital or Medical Committee
3/26/2025	**Patient Safety and Quality Committee** Applicable Administrator, Hospital or Medical Committee
5/1/2025	**Quality Management Committee** Applicable Administrator, Hospital or Medical Committee
5/29/2025	**Medical Executive Committee** Applicable Administrator, Hospital or Medical Committee
3/10/2026	**Board of Supervisors** Approved by the Governing Body

REPLACES: **N/A**

EFFECTIVE: **5/1/2025**

REVISED: **N/A**

REVIEWED: **N/A**