leadcare® II

LeadCare® II Blood Lead Analyzer

User's Guide

NOTE:	**Instructions for use with Analyzer Firmware Version 1.09 or higher.** Please check the label on the bottom of your analyzer to determine firmware version.

CE IVD Rx Only

Magellan DIAGNOSTICS

Magellan
DIAGNOSTICS

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For use with the LeadCare II Blood Lead Analyzer Model 70-6529

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EC REP

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Preface

NOTE:

The LeadCare® II Blood Lead Analyzer is a CLIA-waived device. Facilities that perform tests with the LeadCare II system must have a CLIA Certificate of Waiver (COW) or higher, as issued under the authority of the Public Health Service Act (PHSA) (42 U.S.C. 263(a)). In addition to a Certificate of Waiver, all laboratories performing this test must comply with all applicable state and local laws.

All laboratories eligible for a CLIA Certificate of Waiver must follow the manufacturer's instructions as specified in the LeadCare II User's Guide (this guide), LeadCare II Quick Reference Guide and in the LeadCare II Package Insert.

Other LeadCare II Documents

- LeadCare II Quick Reference Guide (English)
- LeadCare II Test Kit Package Insert
- LeadCare II Flash Drive

Troubleshooting

Troubleshooting procedures are described in detail in Chapter 5 of this guide. Read this section carefully. If you continue to experience problems with device operation, contact Magellan Diagnostics Product Support at 1-800-275-0102 or LeadCareSupport@magellandx.com.

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Chapter 1 Before Testing

Read all instructions carefully before you perform a blood lead test.

This chapter contains important information that you need to know before you use the LeadCare® II Blood Lead Analyzer. Please read the following sections before using the analyzer.

- Unpacking the LeadCare II Blood Lead Analyzer
- Setting up the Analyzer
- About the LeadCare II Blood Lead Analyzer
- Intended Use
- Operating Requirements
- Reading the Analyzer Display
- Important Precautions
- How to Get Help

CAUTION: Magellan Diagnostics recommends that you practice using the system before performing a patient test.

Definitions and Precaution Symbols

WARNING: This symbol identifies conditions or practices that could result in injury or loss of life.

CAUTION: This symbol indicates conditions or practices that could cause erroneous results or damage to the analyzer**.**

This symbol indicates that you should read the instructions carefully.

This symbol indicates the potential for electrostatic discharge. Static electricity can damage or destroy the internal components of devices. It can be generated by scuffing shoes on a carpet or brushing some other materials such as fabrics. When running the analyzer, discharge static electricity by touching a metal object (such as the outside of a computer) in your work area.

This symbol indicates a biohazard.

NOTE: A note provides additional information to help you perform procedures correctly, or help you understand how the system works.

Compliance Statements

CE Mark

CE IVD - 98/79/EC (27/10/1998) – Annex I and III

EMC

EMC Standard EN 61326-1 (2005) also FCC Part 15 Subpart B Class B

Safety

Complies with:
Low Voltage Directive 2006/95/EC, EN61010-1:2001 (EU) UL61010-1:2004 (USA) CSA C22.2 No. 61010-1:2004 (Canada) and Requirements for *In Vitro* Diagnostic (IVD) IEC 61010-2-101:2002.

NOTE: Protection of this equipment may be impaired if operated in a way not described in this User's Guide. Use only the accessories and cables supplied or specified.

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

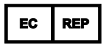
This device complies with Part 15 of the FCC rules. Operation is subject to the following two rules:

1. This device may not cause harmful interference.
2. This device must accept any interference received, including interference that may cause undesired operation.

This device complies with the Waste Electrical and Electronic Equipment (WEEE) directive of the European Union (EU). For information regarding the proper decontamination procedure for this product please contact Magellan Diagnostics. Instruments labeled with the associated symbol (see left) **must not** be disposed of as regular waste material.

Symbols

The following symbols are used in the labeling of the LeadCare II Analyzer and Blood Lead Test Kit.

Symbol	Description
CE	This product fulfills the requirements of Directive 98/79/EC on In Vitro Diagnostic Medical Devices.
	Temperature Limitation
	Use By
	Manufacturer
	Batch Code
	Biological Risk
	Caution: See Instructions for Use
	Caution: Risk of Electric Shock
	Consult Instructions for Use
	Catalog Number
	Serial Number
	In Vitro Diagnostic Medical Device
	Authorized Representative in the European Union
O	Off (supply)
I	On (supply)
	Prescription Use Only

Unpacking the LeadCare II Blood Lead Analyzer

LeadCare II materials are contained in two (2) packages:

1. LeadCare II Analyzer Kit

    - Analyzer
    - AC Adapter & International Power Plug Set
    - 4 AA Alkaline Batteries
    - Quick Reference Guide (not pictured)
    - LeadCare II Flash Drive (contains User's Guide and Instructional Videos)

Figure 1-1 Analyzer Kit Contents

2. LeadCare II Test Kit

- 48 Blood Lead Sensors
- 48 LeadCare Treatment Reagent Tubes
- 50 LeadCare II Heparinized Capillary Tubes and Plungers
- 50 LeadCare II Droppers
- Level 1 Control
- Level 2 Control
- Calibration Button
- LeadCare II Package Insert
- LeadCare Labels, Worksheets and Assayed Control Sheet

Figure 1-2 Test Kit Contents

WARNING: Be careful when handling the LeadCare II Treatment Reagent. This reagent contains dilute Hydrochloric acid. Refer to the LeadCare Treatment Reagent Safety Data Sheet that appears in Appendix D of this manual for safe handling instructions.

Register Your System

Please take a moment to complete the registration form online at: https://www.magellandx.com/leadcare-products/leadcare-ii/support/getting-started/

Registering your analyzer with Magellan Diagnostics will allow you to receive important updates about your LeadCare II Test System.

Setting up the Analyzer

The Work Area

Set up the LeadCare II Blood Lead Analyzer in an area that is free of drafts and temperature extremes. The analyzer needs a stable temperature to operate. You can use the analyzer with an AC power adapter or with batteries.

Using the Analyzer with a Power Adapter

CAUTION: Use only the AC adapter supplied with this unit. Attempting to use a different type of manufacturer's product could damage the analyzer.

To use the analyzer with a power adapter:

1. Plug the DC connector into the back of the analyzer as shown in Figure 1-3.

Figure 1-3 Plug in DC Connector/AC Adapter

2. Plug the adapter into an AC power outlet.

3. Move the power switch to the left to turn the analyzer on.

Installing Batteries

CAUTION: When replacing batteries, use only 1.5 V AA size alkaline or lithium batteries (4 ea). Shut the analyzer off prior to battery removal. Dispose according to local, state and country regulations.

WARNING: Batteries may explode if mishandled or replaced incorrectly. Do NOT dispose of batteries in fire. Do NOT attempt to disassemble or recharge batteries. Keep batteries away from children.

The battery holder is located at the rear of the analyzer. To install the batteries:

1. Turn the analyzer to access the battery area.
2. Remove the DC input connector.
3. Remove the battery cover as shown in Figure 1-4.

Figure 1-4 Remove Battery Holder Cover

4. Press on the locking tab with one or both thumbs and slide it away from the analyzer.
5. Insert four 1.5 V AA size alkaline or lithium batteries as shown in Figure 1-5.

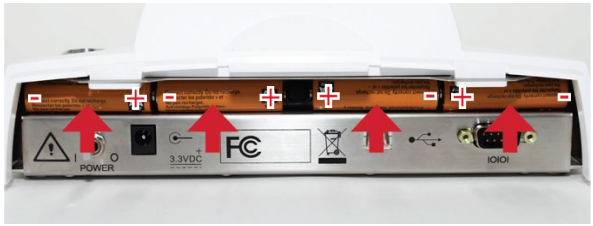


Figure 1-5 Insert Batteries

CAUTION: Observe the polarity of each battery. Inserting one backwards could damage the analyzer.

6. Replace the cover by sliding it back on. Make sure it “clicks” into place.

NOTE: When the analyzer is not in use it will automatically shut off:
Battery: 15 minutes AC Adapter: 60 minutes

Test results are lost when the analyzer becomes idle.

About the LeadCare II Blood Lead Analyzer

The LeadCare II Blood Lead Analyzer is a portable device for testing the amount of lead in capillary whole blood.

Figure 1-6 LeadCare II Blood Lead Analyzer

About Blood Lead Testing

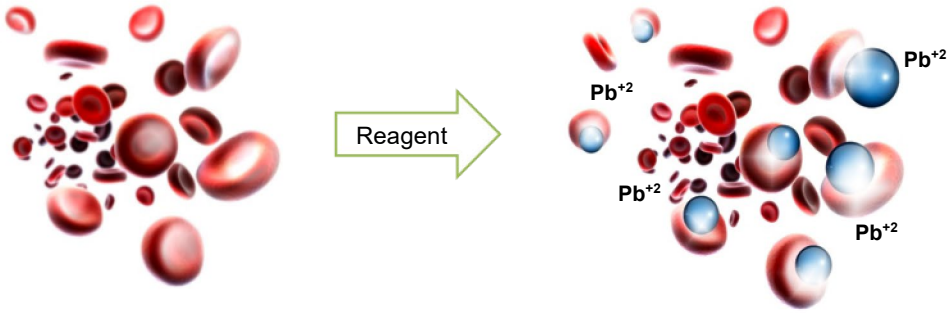
According to the US Centers for Disease Control (CDC), there is no known safe level of lead. Consult your local public health department and/or CDC recommendations for information on the management of blood lead levels.

How the LeadCare II System Works

The LeadCare II System uses an electrochemical technique called Anodic Stripping Voltammetry (ASV) to determine the amount of lead in a blood sample. The diagram below illustrates the methodology.

1

Blood is mixed with LeadCare Treatment Reagent and the red blood cells (RBC) are lysed, which releases the lead that is bound to the RBC wall.

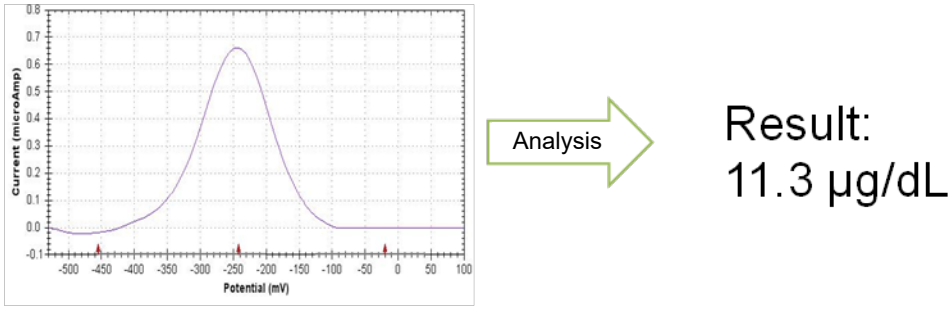


2

A negative potential is applied to the sensor to accumulate lead atoms on the test electrode. The potential is rapidly reversed releasing the lead ions.

3

The current produced is directly proportional to the amount of lead in the sample. The area underneath the curve is used to calculate a quantitative blood lead result.



Intended Use

The LeadCare II Blood Lead Analyzer and Test Kit provide a measurement of the amount of lead in a fresh capillary whole blood sample. The LeadCare II Blood Lead Analyzer is intended for *in vitro* (external) use only. It is for lead testing only. The test kit components are designed for use only with the LeadCare II Blood Lead Analyzer. This test system is for professional use only.

Operating Requirements

CAUTION: Do NOT place the LeadCare II Blood Lead Analyzer in a drafty area. For example, do NOT place the analyzer near air conditioning or heating vents. If the temperature is out of operating range, or if the temperature is unstable, the following messages appear on the display.

TEMP IS TOO HOT
PLEASE WAIT UNTIL
ANALYZER IS IN
TEMP RANGE

TEMP IS TOO COLD
PLEASE WAIT UNTIL
ANALYZER IS IN
TEMP RANGE

If the temperature is unstable, the WARNING message appears on the display and flashes on for 2 seconds. Move the analyzer to a more suitable location and try again later.

WARNING
TEMP IS UNSTABLE
TEST MAY FAIL

Reading the Analyzer Display

The LeadCare II Blood Lead Analyzer displays messages that guide you through the test. Do NOT go to the next step until the message tells you to proceed. The test takes three (3) minutes. When the test is complete, the blood lead level appears on the display. The test result remains on the screen until you insert a new sensor or for a minimum of 15 minutes.

Figure 1-7 Message Display

The analyzer monitors the test conditions and displays error messages on the screen if a problem is detected. Chapter 5, Troubleshooting and Maintenance, includes a list of the messages and what to do if they appear.

Important Precautions

This section lists important things you need to know about using the LeadCare II Blood Lead Analyzer. Understand these precautions.

Precautions When Preparing Samples

WARNING: Use universal precautions while collecting and handling blood samples. Blood can transmit infectious diseases. Follow the procedures set up by your institution for meeting local, state and federal regulations.

CAUTION: When preparing blood samples for testing:

- Wear powder-free gloves to prevent lead contamination. Because there is lead in the environment, it is easy to contaminate blood samples, collection tubes, and test kit items. Contamination of the work environment can cause inaccurate blood lead test results.

- Use only the heparinized capillary tubes provided with the LeadCare II Test Kit. The capillary tube must be filled to the fill line (50 µl) for accurate results. Check to make sure that the tube is free of gaps and bubbles. After collection, wipe off the sides of the capillary tube with a gauze pad (wipe downward). The accuracy of the test depends on a precisely measured sample.

- Use only fresh, unrefrigerated, whole blood with the LeadCare Treatment Reagent. Do NOT refrigerate the blood prior to mixing with the reagent. Blood must be stored at 10º - 32ºC (50º - 90ºF).

- Add blood sample to the treatment reagent within 24 hours of collection. Blood older than 24 hours may produce false negative results. Make sure the blood sample is free of blood clots, which can cause inaccurate results.

- Visual Impairment: Any visual impairment, such as color blindness may affect the operator's ability to detect the sample color change. Operators with vision deficiencies should invert the tube 8 to 10 times to ensure that the sample is properly mixed.

Precautions for Testing a Patient Sample

CAUTION: When testing blood samples:

- Wear powder-free gloves to prevent lead contamination. Because there is lead in the environment, it is easy to contaminate blood samples, collection tubes, and test kit items. Contamination of the work environment can cause inaccurate blood lead test results.

- Do NOT allow the inside of the treatment reagent vial or the vial cap to touch anything. This could cause inaccurate blood lead test results.

- Mix the blood sample with the treatment reagent thoroughly, but do NOT shake the tube. Gently invert the tube ten times until the reagent turns brown. Avoid foam and air bubbles.

CAUTION:

- Do NOT leave the treatment reagent vial uncapped other than to add the sample or remove the sample/reagent solution. The tube and its contents could become contaminated causing inaccurate test results.
- Before placing the sample on the sensor, make sure the display calls for sample addition.
- Keep the sensors in their container until you need them. Do NOT touch “X” on the sensors, except when applying the sample. This could cause contamination and an inaccurate test result.

Precautions When Performing Quality Control Testing

CAUTION: When testing controls, make sure that the value falls within the acceptable range for each control. Do NOT proceed to patient samples if the control results are NOT within acceptable limits. Refer to the Troubleshooting section of the User's Guide, or call Product Support at 1-800-275-0102 to help you resolve any problem.

Using the Control Materials

CAUTION: Treat control material as you would patient samples; add the control to treatment reagent prior to testing. Store the controls at room temperature with all other kit components. Discard unused control material when the kit is finished. Using control material with the wrong kit lot number could yield inaccurate results. Refer to Quality Control chapter for more information about the control test procedures.

More Information

The following references provide additional information about blood sample collection, blood lead testing, and Magellan Diagnostics LeadCare II products.

Blood Sample Collection

Information about sample collection is available from the Clinical Laboratory Standards Institute (CLSI) or the Centers for Disease Control (CDC).

- CLSI (Clinical and Laboratory Standards Institute) GP44-A4: Procedures for the Handling and Processing of Blood Specimens; Approved Guideline – 4th ed. (ISBN 1-56238-724-3). www.clsi.org
- CDC Guidelines for Collecting and Handling Blood Lead Samples - 2004 - Video presentation describes how to collect and handle samples that will be used for blood lead testing. www.cdc.gov/nceh/lead/training/blood_lead_samples.htm

Blood Lead Testing

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.

LeadCare II Product Information

Visit www.leadcare2.com for additional information about our products and resources.

How to Get Help

A Product Support Specialist is available Monday through Friday, 8:00 a.m. to 6:00 p.m. (EST).

Call LeadCare Product Support at 1-800-275-0102.

Email LeadCareSupport@magellandx.com.

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Chapter 2 Calibrating the Analyzer

This chapter describes how to calibrate the analyzer. The analyzer must be calibrated to the lot of sensors to ensure accurate results. This chapter contains the following topics:

- Turning the Analyzer On and Off
- Analyzer Self-Tests
- About Calibration
- Calibrating the Analyzer

CAUTION:

- Calibration is required for each new lot of test kits. Use the calibration button in the test kit. Use only the button packaged with the kit you are using. Failure to use the correct calibration button with the test kit could cause inaccurate results.

- Do NOT use items from more than one test kit at a time.

- Always make sure that the lot numbers on the sensor container and calibration button match the SENSOR LOT number on the analyzer display.

Turning the Analyzer On and Off

The LeadCare® II Blood Lead Analyzer **power switch** is located at the back of the device as shown in Figure 2-1.

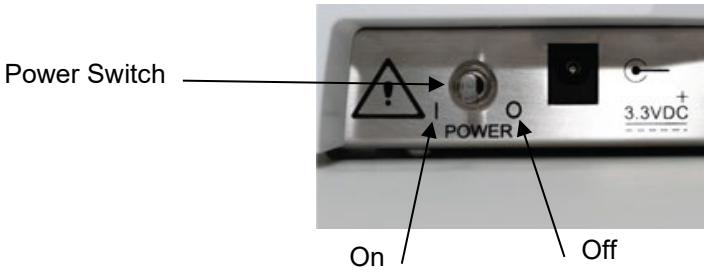


Figure 2-1 Power Switch

If the analyzer is not in use for 15 minutes (battery operation) or 60 minutes (AC operation), it will go into “sleep” mode. Inserting a sensor or moving the power switch to the ON position will restart the analyzer.

Turn On the Analyzer

To turn on the analyzer for the first time:

1. Make sure the analyzer is plugged in using the AC adapter, or that batteries are installed if you are using the analyzer in a remote location.

2. Move the switch on the back of the analyzer to the ON (|) position.

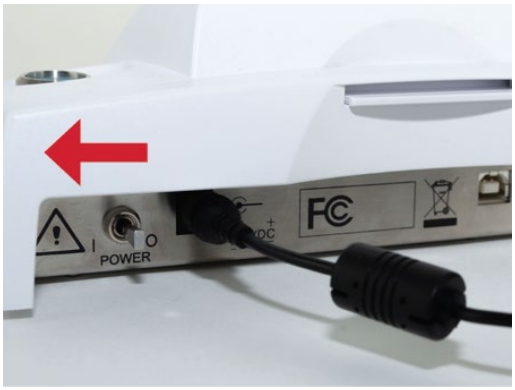


Figure 2-2 Turn Analyzer On

Analyzer Self-Tests

When you first turn on the analyzer, you will hear a beep and see the startup and self-test messages.

The analyzer performs a series of self-tests. The LeadCare II self-test is a set of internal electrical and software checks that ensure the proper operation of the system's electronic components. The purpose of the tests is to ensure that each critical hardware component of the system is operating at the correct level. If any one component of the system fails this initial self-test, the user is warned that the unit requires service and the user is prevented from running any patient samples.

The first time you turn on the analyzer, the screen reads:

PLEASE CALIBRATE
ANALYZER WITH BUTTON

Once the analyzer has been calibrated, the following message appears.

CALIBRATION
SUCCESSFUL

IF NEW LOT
TEST CONTROLS

PREPARE SAMPLE
USE SENSOR LOT XXXX
OR RECALIBRATE
THEN INSERT SENSOR

You can also turn on the analyzer by inserting a sensor.

If you insert a sensor to turn on the analyzer, the following message appears:

ADD SAMPLE
TO X ON SENSOR
SENSOR LOT XXXX

About Calibration

Why Calibration is Important

The analyzer must be calibrated to the lot of sensors to ensure accurate results. You must calibrate the analyzer:

- The first time you use the analyzer.
- Each time you start a new lot of test kits.
- Any time the analyzer displays a recalibration message.

The Calibration Button

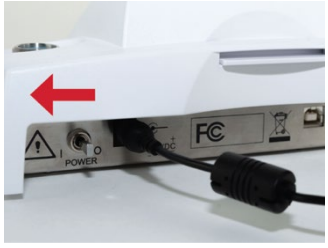
Each LeadCare II Test Kit comes with 48 sensors and a calibration button. The button transfers calibration and expiration information to the analyzer. When you touch the calibration button to the button reader, you will hear an audible beep. The lot number appears on the screen to verify that the button was read properly. The CALIBRATION SUCCESSFUL message flashes for 2 seconds.

Calibrating the Analyzer

CAUTION:

- Calibration is required for each new lot of test kits. Use only the calibration button packaged with the test kit you are using. Failure to use the correct calibration button could cause inaccurate results.
- Do NOT use items from more than one test kit at a time.
- Each test kit comes with a calibration button marked with the sensor lot calibration code. Always make sure that the lot numbers on the sensor container and calibration button match the SENSOR LOT number on the analyzer display.

See calibration instructions below.



1. Turn on the analyzer. The analyzer is ready when the “Prepare Sample” message appears.

NOTE: ***The first time you turn on the analyzer, you will see the “PLEASE CALIBRATE” message.***

PREPARE SAMPLE
USE SENSOR LOT XXXX
OR RECALIBRATE
THEN INSERT SENSOR

2. Locate the calibration button in the test kit. Remove the calibration button from the test kit package.

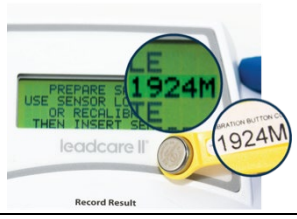
3. Match the lot number on the sensor container with the calibration code on the button.

4. Hold the calibration button to the button reader until you hear the beep. The button must touch both the center contact and metal side of the button reader.

   There is no need to apply pressure.

5. Calibration takes a few seconds. When calibration is complete, the screen briefly reads “CALIBRATION SUCCESSFUL”. Then the screen reads “IF NEW LOT TEST CONTROLS”, followed by the “PREPARE SAMPLE...” message.

CALIBRATION SUCCESSFUL



6. Make sure the number of the button matches the display.

The LeadCare II Blood Lead Analyzer is now ready for testing.

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Chapter 3 Quality Control Procedure

Magellan Diagnostics provides the LeadCare® II Controls in the test kit for quality control. The Level 1 and Level 2 controls are used to verify system performance and accuracy. This chapter covers the following information:

- What is a LeadCare II Lead Control
- Storage and Handling
- How Often Should You Test Controls
- Testing Controls
- Interpreting the Control Test Results

What is a LeadCare II Lead Control

A control is a standard against which test results can be evaluated. The LeadCare II controls are room temperature stable solutions designed to mimic blood, and spiked with lead to specific target values. The product is supplied in a two level format. Each is assigned a target lead value with an associated acceptable range.

The testing of controls will ensure your LeadCare II Blood Lead Analyzer is reporting accurate results.

Storage and Handling

The control material is supplied in liquid form and ready to use. It should be stored at room temperature and should not be used beyond its expiration date.

CAUTION: Controls should only be used with sensors of the same lot number. Discard remaining control solutions when the sensors are gone. Failure to do so may result in inaccurate patient results.

How Often Should You Test Controls

According to CLIA guidelines for Waived Laboratories, controls should be run according to the manufacturer's instructions, which are:[1]

- Each new lot.
- Each new shipment of materials, even if it's the same lot previously received.
- Each new operator (i.e., operator who has not performed the test recently).
- Monthly, as a check on continued storage conditions.
- When problems (storage, operator, instrument, or other) are suspected or identified.
- If otherwise required by your laboratory's standard QC procedures.

NOTE for Non-Waived Laboratories:	Some certification programs may have additional quality control requirements. Follow your federal, state and local guidelines to ensure compliance.

Testing Controls

Test the LeadCare II Lead Control material as you would any whole blood sample. You must run both the Level 1 and Level 2 controls to verify the performance of the system.

CAUTION: When testing controls, make sure that the value falls within the acceptable range for each control. Do NOT proceed to patient samples if the control results are outside acceptable limits. Refer to the Troubleshooting section of the User's Guide, or call Product Support at 1-800-275-0102 to help you resolve any problem.

Testing controls consists of the following steps:

A) Prepare the Sample

1. Label a treatment reagent tube, "Level 1".
2. Gently swirl the control vial. Remove the cap from the Level 1 control and place it *top down* on a clean surface.
3. Fill one capillary tube with the control material. 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. Capillary action will fill the tube to the black line.
4. Use a clean wipe to remove excess control material from the outside of the capillary tube.

[1] Benson, Carol 2008, 'Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for manufacturers of in Vitro Diagnostic Devices', Guidance for Industry and FDA Staff:, p.34, viewed 26 January 2009.

B) Mix with Treatment Reagent

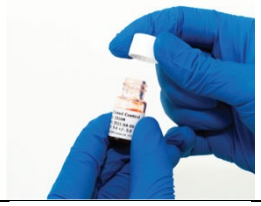
1. Remove the cap from the treatment reagent tube and place it *top down* on a clean surface.
2. Place the full capillary tube into the treatment reagent. Insert a plunger into the top of the capillary tube and push down, ensuring the entire volume of control is dispensed into the treatment reagent.
3. Remove the empty capillary tube and recap the treatment reagent.
4. Invert the treatment reagent tube 8 – 10 times to thoroughly mix the two. The resulting mixture will be red.

C) Test

1. Insert a fresh sensor into the LeadCare II Analyzer.
2. Ensure the lot number on the display matches the sensor lot you are using. It must also match the lot number on the control vial.
3. Invert your sample to ensure the sample is well mixed, then remove the cap.
4. Using a dropper, transfer the sample to the X on the sensor.
5. When the three minute countdown is complete, record your lead result in micrograms per deciliter (µg/dL).
6. Repeat this process for the Level 2 control.

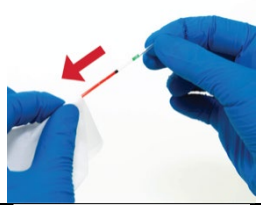
Testing Controls:

1. Label a fresh treatment reagent tube "Level 1 control".

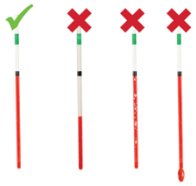


2. Swirl the control vial gently. Remove the cap from the control and place it *top down* on a clean laboratory wipe. Ensure the lot number on the control vial matches the sensor lot number you will be testing.

3. Holding the capillary tube almost horizontally with the green band on top, fill it to the 50 µL ***black*** *line*. Replace the cap on the control vial.

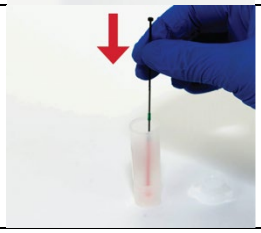


4. Use a downward motion to remove excess control from the outside of the tube with a clean wipe or gauze pad. Use caution not to absorb the control from the end of the capillary tube.

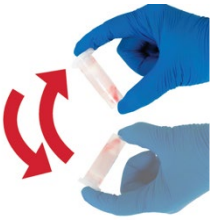


5. Inspect the capillary tube for proper filling. Make sure there are no gaps or bubbles, or any excess control on the outside of the capillary tube.

6. Remove the cap from a vial of treatment reagent and place it *top down* on a clean surface. Do NOT allow the inside of the cap to touch anything. This could cause inaccurate test results.



7. Place the capillary tube into the treatment reagent tube. Insert a plunger into the top of the capillary tube and push down ensuring the entire volume of control is dispensed into the treatment reagent.



8. Replace the tube cap. Invert the tube 8 to 10 times to mix the sample completely. The mixture will remain red.
9. Repeat this process (steps 1 thru 8) for the Level 2 control.
10. Analyze control samples according to the instructions provided in Chapter 4.

Interpreting the Control Test Results

The target values are printed on the control vials. The blood lead level that appears on the LeadCare II Analyzer should be within the acceptable range provided for that control. If the reported value is within the acceptable limits for both the Level 1 and Level 2 controls, your LeadCare II System is operating properly. You may now test patient samples.

If the reported value for the Level 1 and/or Level 2 control is outside the acceptable range, refer to the troubleshooting section of the LeadCare II 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.

CAUTION: Do NOT proceed to patient samples unless both the Level 1 and Level 2 control results are within the acceptable ranges.

How Magellan Diagnostics Assigns Lead Level Ranges

Acceptable ranges for each lot and lead level are established by Magellan Diagnostics using LeadCare II Blood Lead Testing Systems. Magellan Diagnostics establishes these ranges using extensive replicate analyses and rigid quality control.

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Chapter 4 Blood Lead Testing

Read all instructions carefully before you perform a blood lead test.

This chapter describes how to test a patient's blood for lead. It contains the following topics:

- Overview of the Testing Procedure
- The LeadCare® II Message Display
- Required Materials
- Precautions
- Testing Procedure
- Interpreting Patient Test Results
- Follow-up Testing
- Printing Test Results
- References

Overview of the Testing Procedure

Testing for lead in blood with the LeadCare II Blood Lead Analyzer is fast and easy. Practice lead testing with the control samples or other samples before you perform a blood lead test.

The testing procedure consists of the following steps:

1. Verify you have the required materials.
2. Perform quality control testing on both levels of quality control and verify the results are within the acceptable ranges.
3. Collect capillary blood sample. Check the capillary tube for correct filling.
4. Add blood to the treatment reagent tube.
5. Insert a sensor and match the sensor lot number with the display.
6. Using a dropper, obtain sample from the treatment reagent tube, touch the dropper tip to the X on the sensor and squeeze the walls to dispense the sample.
7. Read and record the test result.
8. Remove used sensor.

The LeadCare II Message Display

The message display screen is designed to guide you through the testing process. Remember to read the display messages.

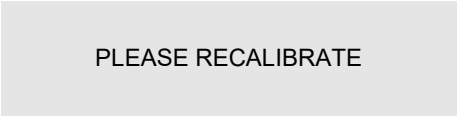


Figure 4-1 Message Display

Required Materials

CAUTION: Make sure the analyzer, test kit, and samples are at room temperature before testing.

- Protective Powder-free Gloves
- Alcohol Wipes, Gauze Pads, Lead Free Wipes (optional)
- Lancets
- Absorbent Liner and Biohazard Waste Container
- LeadCare II Analyzer and Power Cord or Batteries
- LeadCare II Quick Reference Guide
- LeadCare II User's Guide
- LeadCare Test Kit Items:
  - Heparinized Capillary Tubes/Plungers
  - Treatment Reagent Tubes
  - Blood Lead Sensors
  - Calibration Button
  - LeadCare II Lead Controls, Level 1 & 2
  - Droppers

Precautions

Observe the precautions listed throughout this section. Failure to follow these precautions could result in inaccurate test results.

Important precautions for testing are also listed in Chapter 1, Important Precautions.

WARNING:

- Blood can transmit infectious diseases. Use universal precautions while collecting and handling blood samples. Follow the procedures set up by your institution for meeting federal, state, and local regulations.

- Dispose of sensors, capillary tubes, plungers, and droppers in biohazard container.

- Use caution when handling the LeadCare II Treatment Reagent. This reagent contains dilute hydrochloric acid. Refer to the LeadCare Treatment Reagent Safety Data Sheet that appears in Appendix E of this manual for safe handling instructions.

CAUTION:

- Do NOT use sensors that have been dropped, previously handled, broken, scratched or damaged in any way. This could cause inaccurate test results.

- Make sure the sensor is inserted under the sensor guides and sits flush on the sensor deck. Inserting the sensor above the guides could cause inaccurate test results.

- Do NOT use any test kit or its components past the expiration date. This could cause inaccurate test results.

- Do NOT leave the treatment reagent vial uncapped other than to add the sample or remove the sample/reagent solution. The tube and its contents could be contaminated causing inaccurate test results.

Testing Procedure

CAUTION: Do Not proceed to patient testing if the control results are outside acceptable limits. Refer to the Troubleshooting section of the User's Guide, or call Product Support at 1-800-275-0102 to help you resolve any problem.

Gather Testing Materials

NOTE: **Be sure the following items are part of the same test kit. Do NOT mix components from different test kits.**

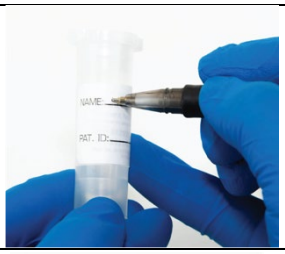
Place the following items in front of you in a clean work space:

- Container with heparinized capillary tubes/plungers
- Treatment reagent tube
- Sensor container
- Dropper for depositing sample on the sensor
- LeadCare II Blood Lead Analyzer

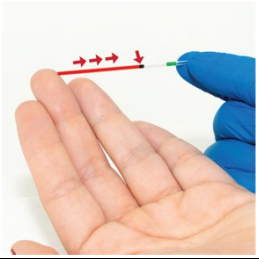
WARNING: Use universal precautions while collecting and handling blood samples. Blood can transmit infectious diseases. Follow the procedures set up by your institution to meet local, state and federal regulations.

Step 1: Collect Blood

CAUTION: Only use the heparinized capillary tubes provided with the LeadCare II Test Kit. The capillary tube must be filled to the fill line (50 µl) for accurate results. Check to make sure that the tube is free of gaps and bubbles. After collection, wipe the capillary tube with a gauze pad (wipe downward). The accuracy of the test depends on a precisely measured sample.

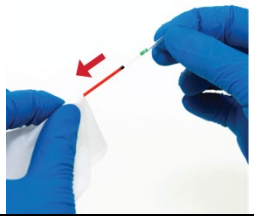


1. Label a treatment reagent tube with the patient ID using the label provided.



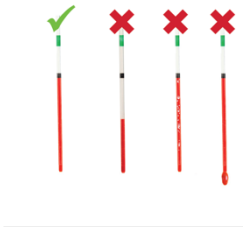
2. Holding the heparinized capillary tube almost horizontally with the green band on top, fill to the 50 µL black line. Filling stops when the sample reaches the black line.

   Do NOT use plasma or serum. Do NOT use venous blood samples.



3. Remove excess blood from the outside of the tube with a clean wipe or gauze pad. Use a downward motion to wipe excess blood from the capillary tube.

   Use caution not to absorb the blood from the end of the capillary tube.



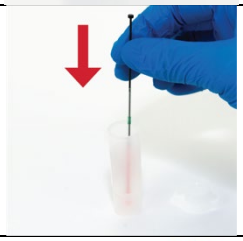
4. Inspect the capillary tube for proper filling. Make sure there are no gaps, air bubbles, or any excess blood on the outside of the capillary tube.

Step 2: Prepare Sample

CAUTION:

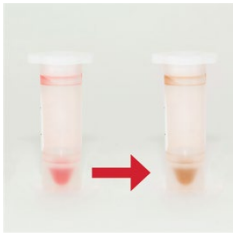
- The system is intended to test fresh capillary whole blood (collected in either EDTA or Heparin). Add the blood to the treatment reagent within 24 hours of collection. Blood older than 24 hours may produce false negative results.
- Use only fresh, unrefrigerated, whole blood with the LeadCare Treatment Reagent. Blood must be stored at 10° - 32°C (50° - 90°F) prior to mixing with treatment reagent.
- Make sure the whole blood sample is free of clots, which can cause inaccurate results.

1. 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.



2. Place the full capillary tube in the treatment reagent. Insert a plunger into the top of the capillary tube and push down, ensuring to dispense the entire volume into the treatment reagent.

3. Replace the tube cap. Invert the tube 8 to 10 times to mix the sample completely.



4. The test sample is ready when the mixture turns brown. Repeat sample collection and preparation for each sample to be tested.

CAUTION: ***Any visual impairment, such as color blindness may affect the operator's ability to detect the sample color change. Operators with vision deficiencies should invert the tube 8 to 10 times to ensure that the sample is properly mixed.***

Storing Samples

You do not need to test the prepared sample immediately. The mixture of blood and treatment reagent is stable for up to 48 hours at room temperature and up to 7 days refrigerated. If refrigerated, bring to room temperature prior to analysis.

Step 3: Analyze the Sample

1. Remove one sensor from the sensor container. Close the container immediately. Grasp the sensor at the end without the black bars.

⚠ **CAUTION:** ***Keep the sensors in their container until you are ready to use them. Minimize handling to prevent contamination which could cause an inaccurate test result.***

2. Insert a sensor (with the black bars facing up) completely into the analyzer. Make sure the sensor is inserted under the sensor guides and sits flush on the analyzer deck. When the sensor is inserted properly the analyzer beeps and displays the message to the right.

ADD SAMPLE
TO X ON SENSOR

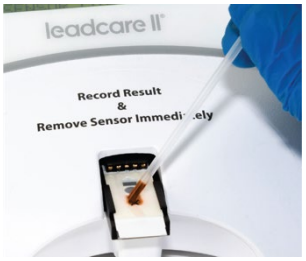
SENSOR LOT 0018A

3. Make sure the sensor lot number matches the lot number on the display. If the number does not match, recalibrate the analyzer and test controls (refer to Chapter 3).

⚠ **CAUTION:** ***The control lot number must match the sensor lot number and the calibration button code.***

4. Make sure that the sample mixture is at room temperature and uniformly mixed before testing.

5. Remove the cap from the treatment reagent. Remove a transfer dropper from its container. Squeeze the walls of the dropper and insert the tip into the sample. Release the pressure to draw the sample into the dropper. There should be approximately ½" of sample in the dropper.

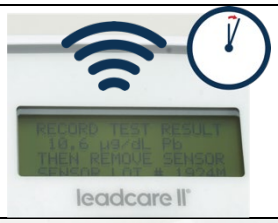
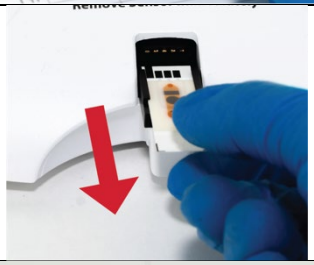
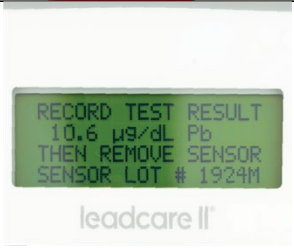
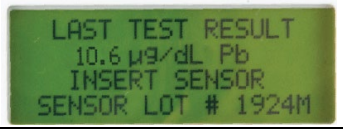


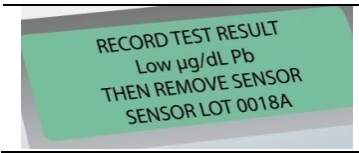
⚠ **CAUTION:** ***Make sure the message to the right is displayed on the screen before adding the sample.***

ADD SAMPLE
TO X ON SENSOR

SENSOR LOT 0018A

6. Touch the dropper tip to the X on the sensor and squeeze the walls to dispense the sample.

	7. The analyzer will beep when it has enough sample. It will display the message to the right. After 3 minutes (180 seconds) the analyzer will beep again to indicate that the test is done.	TESTING XXX SECONDS TO GO SENSOR LOT 0018A
	8. Record the test results.	RECORD TEST RESULT 7.5 µg/dL Pb THEN REMOVE SENSOR SENSOR LOT 0018A
	9. Remove the used sensor immediately after recording the result.	
	10. Discard the used materials in an appropriate biohazard container.	
	11. If you do not remove the sensor after recording your last result, within one minute the analyzer will sound two short warning beeps every 15 seconds until the sensor is removed or until the unit powers down.	
	Once the warning beep begins the message on the screen changes to “RECORD TEST RESULT XXXX µg/dL Pb PLEASE REMOVE SENSOR IMMEDIATELY”. The beep stops when the sensor is removed.	RECORD TEST RESULT XXXX µg/dL Pb PLEASE REMOVE SENSOR IMMEDIATELY
	12. The analyzer is ready for the next sample when the “LAST TEST RESULT” message appears on the screen.	LAST TEST RESULT 7.5 µg/dL Pb INSERT SENSOR SENSOR LOT 0018A



NOTE: The analyzer displays "Low" when it detects a blood lead level below 3.3 µg/dL. "Low" results should be recorded as "<3.3 µg/dL". It is not uncommon to obtain patient results that read "Low".

If you do not run another test within 60 minutes (15 minutes when using batteries), the analyzer will automatically go into "sleep" mode. If you have not recorded your test result, it will be lost. You will have to repeat the analysis.

Interpreting Patient Test Results

The analyzer's display window shows the blood lead result. The result is 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 LeadCare II system is 3.3 to 65 µg/dL.

"Low" in the display window indicates a blood lead test result less than 3.3 µg/dL. When this occurs, report the blood lead result as less than (<) 3.3 µg/dL.

"High" in the display window indicates a blood lead test result greater than 65 µg/dL. When this occurs, report the blood lead result as greater than (>) 65 µg/dL. **"High" results on LeadCare II should be followed up immediately as an emergency laboratory test.**

Follow-up Testing

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. A capillary blood sample that generates an elevated lead level should be confirmed with a venous sample. The venous sample should be run at a reference laboratory using a high complexity testing method.

In cases where the capillary specimen demonstrates an elevated lead level but the confirmation venous sample does not, it is important to recognize that the child may live in a lead-contaminated environment that resulted in contamination of the fingertip. Efforts should be made to identify and eliminate the source of lead in these cases.

Report all blood lead test results to the appropriate local, state or federal agency.

Printing Test Results

You can print the results by connecting the analyzer to a compatible label printer. Refer to Appendix A: Connecting a Printer.

References

Additional information about lead poisoning is available through the Centers for Disease Control and Prevention at www.cdc.gov/nceh/lead/

Chapter 5 Troubleshooting and Maintenance

Several factors contribute to inaccurate blood lead testing and control testing. This chapter provides steps you can take if your patient blood lead tests or control tests are out of range. This chapter contains the following topics:

Calling LeadCare Product Support

If you cannot determine why your system is giving you a problem, call LeadCare Product Support at 1-800-275-0102 or email LeadCareSupport@magellandx.com.

Please collect this information and have it ready before you call:

- Serial No. of LeadCare II (on bottom of analyzer) _____
- Test kit lot number (on end of box) _____
- Calibration code on calibration button * _____
- When did you last test with controls? Date: _____
- Control results last recorded: Level 1 ____ Level 2 ____
- Control lot number * _____
- Control expiration date _____
- Sensor lot number * _____

***NOTE:** **Calibration code, control lot number and sensor lot number should all be the same.**

Troubleshooting Results Below the Target or Expected Value

Possible causes include:

- Less than 50 µL of blood was transferred to the treatment reagent tube.
- Analyzer is not calibrated properly.
- The sample is cold.
- The sensor is not inserted properly.

See detailed precautions below:

Blood Sampling

- Less than 50 µL in the capillary tube will lower blood lead level results.
- Make sure that there are no clots or bubbles in the tube.
- Use only fresh, capillary whole blood from patients collected in heparin or EDTA. Do NOT use venous samples. Do NOT use plasma or serum.

Blood Sample Preparation

- Every sample must be mixed in treatment reagent. You cannot test untreated whole blood.

Equipment Setup, Calibration and Testing Materials

- Check the expiration date on the test kit box. Do NOT use a test kit that is beyond the expiration date. When calibrated properly, the analyzer will not initiate a test with expired sensors.
- Make sure the analyzer is calibrated properly. Use the calibration button supplied with the test kit you are using. When processing the sample verify the code on the analyzer screen matches the code of the of the sensor lot in use.

Testing Conditions

- Operate the analyzer only within the specified humidity range: (12 to 80% Relative Humidity).
- Avoid operating the LeadCare II System in drafts or in locations with low humidity.
- Make sure that the analyzer and the test kit are maintained at a constant temperature. If you move any part of the system from one place to another (for example, from outside into a laboratory) wait for the analyzer and kit components to reach a stable temperature.

User Technique

- Make sure the sample/treatment reagent mixture is room temperature before placing it onto a sensor. This is only relevant when testing samples that were previously mixed with treatment reagent and stored refrigerated.
- Make sure the blood and treatment reagent is thoroughly mixed before placing it onto the sensor. The mixture should appear brown, confirming that the red blood cells have been lysed.
- Make sure the sensor is inserted under the sensor guides and sits flush on the sensor deck.
- Do NOT touch the sensor while the analyzer is running a test.

Troubleshooting Results Above the Target or Expected Value

Possible causes include:

- Contamination of blood sample.
- Excess blood on the capillary tube.
- Sample not mixed properly.
- The analyzer is not calibrated properly.

See detailed precautions below:

Blood Sampling

- Lead is widespread in the environment. It is easy to contaminate a blood sample. Thoroughly clean the collection site with soap and water followed by a clean alcohol wipe prior to puncture. Use clean powder-free gloves during testing and keep your gloved hands clean.
- Make sure you are using lead-free collection devices.
- Make sure the capillary tube is filled properly. Be sure to wipe excess blood from the capillary tube with a downward motion. The accuracy of the test depends on filling the capillary tube with 50 µL. Excess blood on the outside of the capillary tube will tend to produce higher blood lead results.

Blood Sample Preparation

- Do NOT use clotted blood. If there are clots in the blood, obtain a new sample.
- Make sure to transfer 50 µL of blood into the treatment reagent. Wipe the end of the capillary tube with a gauze pad, using a downward motion before adding the blood to the treatment reagent.

Equipment Setup, Calibration and Testing Materials

- Check the expiration date on the test kit. Do NOT use test kit materials that are beyond the expiration date. When calibrated properly the analyzer will not initiate a test with expired sensors.
- Make sure the analyzer is calibrated properly. Use the calibration button supplied with the test kit in use. When processing the sample, check to make sure the code on the analyzer screen matches the code of the calibration button for the test kit.
- Make sure you are using lead-free collection devices.

Testing Conditions

- Operate the analyzer only within the specified humidity range: (12 to 80% Relative Humidity).
- Make sure that the analyzer and the test kit are maintained at a constant temperature. If you move any part of the system from one place to another, (for example, from outside into a laboratory) wait for the analyzer and components to reach a stable temperature.

User Technique

- Do NOT touch the black bars on the sensor. This could damage the sensor.
- Do NOT touch the ends of the capillary tubes or the plungers. This could cause contamination.
- Make sure to thoroughly mix patient blood with the treatment reagent. The mixture should turn brown.
- Do NOT leave the treatment reagent tube uncapped other than to add the whole blood sample or to remove the sample for testing.
- Do NOT touch the sensor while running a test.

Control Test Results Below the Target Range: Possible Causes

Possible causes of low control test results include:

- Control lot number does not match the sensor lot and calibration code.
- Less than 50 µL of control material was transferred to treatment reagent
- The test sample is colder than detected by the analyzer.
- The analyzer is not calibrated properly.
- The sensor is not inserted properly.

See detailed precautions below:

Control Sample Preparation

- Use the capillary tubes and plungers provided with the test kit to transfer 50 µL of control into the treatment reagent tube.
- Always mix the control material with treatment reagent. Control material delivered directly to the sensor will not yield an accurate result.

Equipment Setup, Calibration and Testing Materials

- Make sure the controls were properly stored: Room temperature storage is considered 15 - 27ºC (59 - 80ºF).
- Check the expiration date on the control vial to verify the controls have not expired.
- Check the expiration on the test kit box to make sure the test kit materials have not expired.

NOTE:	**The controls are only intended for use with the test kit in which they come. When the other reagents included in the test kit are used up, discard the controls.**

- Make sure the analyzer is calibrated properly. Use the calibration button supplied with the test kit in use. When processing the sample, check to make sure the code on the analyzer screen matches the code of the calibration button for the test kit.

Testing Conditions

- Do NOT operate the LeadCare II System in drafty locations.
- Make sure that the analyzer and the test kit are maintained at a constant temperature. If you move any part of the system from one place to another, (for example, from outside into a laboratory) wait for the analyzer and components to reach a stable temperature.

User Technique

- Do NOT touch the black bars on the sensor.
- Make sure the sensor is inserted under the sensor guides and sits flush on the sensor deck.
- Do NOT touch the sensor while the analyzer is running a test.
- Make sure the control and treatment reagent is thoroughly mixed before placing onto the sensor. The mixture will appear red.

Control Test Results Above the Target Range: Possible Causes

Possible causes of high control test results include:

- Control lot number does not match the sensor lot and calibration code.
- More than 50 µL of control material was transferred to treatment reagent.
- The test sample is warmer than detected by the analyzer.
- The analyzer is not properly calibrated.

See detailed precautions below:

Control Sample Preparation

- Use the capillary tube and plunger to transfer 50 µL of blood into the treatment reagent vial.
- Wipe excess sample off the outside of the capillary tube with a clean gauze pad or laboratory wipe before adding the control to treatment reagent.

Equipment Setup, Calibration and Testing Materials

- Make sure the controls were properly stored: Room temperature storage is considered 15 - 27ºC (59 - 80ºF).
- Check the expiration date on the control vial to verify the controls have not expired.
- Make sure that the lot number of the control matches the lot number on the sensor container and the lot number on the display screen.

NOTE: **The controls are only intended for use with the test kit in which they come. When the other reagents included in the test kit are used up, discard the controls.**

- Make sure the analyzer is calibrated properly. Use the calibration button supplied with the test kit. When processing the sample, check to make sure the code on the analyzer screen matches the code of the calibration button for the test kit.

Testing Conditions

- Do NOT operate the LeadCare II System in drafty locations.
- Make sure that the analyzer and the test kit are maintained at a constant temperature. If you move any part of the system from one place to another (for example, from outside into a laboratory) wait for the analyzer and components to reach a stable temperature.

User Technique

- Do NOT leave the treatment reagent tube uncapped other than to add the control sample or to remove the sample for testing.
- Do NOT touch the black bars on the sensor.
- Do NOT touch the sensor while the analyzer is running a test.
- Make sure the control and treatment reagent is thoroughly mixed before placing onto the sensor. The mixture will appear red.

Screen Display Messages

There are a number of standard screen display messages that appear during the routine testing procedure. However, other messages may appear if the analyzer detects a condition that prevents normal operation. The following table shows some of the display messages.

NOTE: Occasionally, error messages not noted in this guide may appear on the display. Please note what error message was displayed and call Product Support for additional instructions. New users may want to check that the sensor was completely inserted into the analyzer first. Product Support can be reached at 1-800-275-0102.

Screen Display Messages

Message	Definition	What to Do
PLEASE CALIBRATE ANALYZER WITH BUTTON	The analyzer must be calibrated the first time you use it and for each new sensor lot.	Calibrate the analyzer. Refer to the calibration instructions in Chapter 2.
ELECTRONIC QC CHECK FAILED CALL TECH SERVICE ERROR X	The internal quality control check failed.	Record the error number & call Product Support at 1-800-275-0102.
TEMP IS TOO HOT PLEASE WAIT UNTIL ANALYZER IS IN TEMP RANGE	The temperature is too hot for testing.	Wait until the screen display the PREPARE SAMPLE message.
TEMP IS TOO COLD PLEASE WAIT UNTIL ANALYZER IS IN TEMP RANGE	The temperature is too cold for testing.	Wait until the screen display the PREPARE SAMPLE message.
WARNING TEMP IS UNSTABLE TEST MAY FAIL	The temperature is too unstable for testing.	Wait until the screen display the PREPARE SAMPLE message.
THIS IS A USED SENSOR PLEASE REMOVE SENSOR	The sensor in the analyzer is wet or previously used.	Remove the used sensor and insert a new sensor COMPLETELY into the analyzer to retest.
PLEASE REMOVE SENSOR	A sensor was left in the analyzer.	Remove the sensor.
SENSOR OUT OF VIAL TOO LONG PLEASE REMOVE SENSOR	The sensor in the analyzer has been out of the tube too long and cannot be used.	Remove the sensor and insert a new sensor.
TEST FAILED PLEASE REMOVE SENSOR	There is not enough sample on the sensor or the sensor failed.	Remove the sensor, discard it, and insert a new sensor. When adding the sample to the sensor, make sure the sample completely covers the X area.
SENSOR REMOVED TOO SOON	The sensor was removed from the analyzer before the end of the test.	Remove the sensor. Insert a new sensor and add another drop of sample. Wait 180 seconds (3 minutes) for the test to finish.
TEMP IS UNSTABLE RESULT DISCARDED PLEASE REMOVE SENSOR	The temperature in the room is too unstable to yield accurate test results.	Move the analyzer to an area where there are fewer temperature changes (away from sources of cold or heat). The temperature is stable enough when the PREPARE SAMPLE message indicates that the analyzer is ready.
PLEASE RECALIBRATE	There was a problem transferring the calibration data from the calibration button to the analyzer.	Repeat the calibration procedure. Refer to Chapter 2, Calibrating the analyzer.
SENSOR LOT TOO OLD PLEASE RECALIBRATE	The sensor is from a lot that has expired.	Discard the sensor and the expired lot. Use a sensor from a new lot and recalibrate the analyzer.
SYSTEM FAILURE CALL TECH SERVICE	One of the main system components failed.	Power analyzer off & on. If error persists, call Product Support at 1-800-275-0102.
CHANGE BATTERIES SOON (Message flashes before or after a test)	Voltage too low for the analyzer to run a test.	Change the batteries. Use four 1.5 V AA alkaline or lithium batteries.
PLEASE CHANGE BATTERIES	The battery voltage is too low.	Change the batteries. Analyzer uses four 1.5 V AA alkaline or lithium batteries.
LOW POWER CHECK POWER CORD	This message flashes for 2 seconds if the voltage from the AC adapter is low.	You can run a test.
LOW POWER CHECK POWER CORD OR CALL TECH SERVICE	The voltage from the AC adapter is too low. The lead test is NOT allowed.	Call Product Support at 1-800-275-0102.

***If an error message is encountered repeatedly, contact Product Support at 1-800-275-0102.**

Maintaining the Analyzer

Cleaning the Analyzer

- Remove used sensors from the analyzer as soon as a result is recorded.
- Clean the analyzer with a damp cloth and warm, soapy water. Do NOT immerse in water.
- Disinfect with dilute (10%) bleach solution.
- Do NOT leave any soap film on the analyzer.
- Do NOT allow liquid of any kind into the sensor connector.
- Do NOT get the metal pins in the sensor connector wet.
- Do NOT wash the inside of the calibration button reader.

Chapter 6 LeadCare II Blood Lead Testing System Limited Warranty

Magellan Diagnostics, Inc. (Magellan) warrants that each product manufactured and sold by it will be free from defects in material and workmanship in normal use and service from the date of delivery to you as the original purchaser for the following periods: Magellan Instruments - one year; Sensors and Electrodes - 90 days. This warranty does not cover, and no warranty is provided for, consumables and parts that by their nature are normally required to be replaced periodically consistent with normal maintenance. If any product covered by this warranty is returned to the original shipping point, transportation charges prepaid, within the applicable warranty period set forth above and upon examination Magellan determines to its satisfaction that such product was defective in material or workmanship Magellan will, at its option, repair or replace the product or defective part thereof or refund the original purchase price of the product to you. The foregoing notwithstanding, Magellan will not be responsible for damage to any product resulting from misuse, negligence or accident or resulting from repairs, alterations or installation made by any person or firm not duly authorized by Magellan in writing.

If, at any time during the period ending ninety (90) days after delivery of any product to you, you report and document any error in any software provided with the product and developed by Magellan or any failure of any such software substantially to conform to Magellan's software documentation that limits or prevents use of the software by you, Magellan, at its option, will use reasonable efforts to correct any such error or failure, will replace such software, or will terminate your license to use the software and refund the price of the related product. In connection with any such termination and refund, you will return the related product to Magellan forthwith upon request. This warranty shall apply only to those portions of the software that were developed by Magellan and that incorporate all program corrections and modifications, if any, delivered to you. It shall not apply to any error or failure due to machine error or to the misuse by or negligence of any person or entity other than Magellan or to any software which is modified by any person or entity other than Magellan.

With respect to products sold to you but not manufactured by Magellan, MAGELLAN MAKES NO WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, but will make available to you, to the extent permitted, the warranties of the manufacturer of the relevant products .

THIS LIMITED WARRANTY IS THE ONLY WARRANTY GIVEN BY MAGELLAN WITH RESPECT TO THE PRODUCTS AND SOFTWARE AND IS GIVEN IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. YOUR EXCLUSIVE REMEDIES AND MAGELLAN'S SOLE LIABILITY FOR ANY NON-CONFORMITY OR DEFECT IN THE PRODUCTS AND SOFTWARE WILL BE THOSE EXPRESSED HEREIN. UNDER NO CIRCUMSTANCES WILL MAGELLAN'S LIABILITY ARISING FROM THE PERFORMANCE OR FAILURE TO PERFORM OF ANY PRODUCT OR SOFTWARE IN CONTRACT, IN TORT (INCLUDING NEGLIGENCE), OR OTHERWISE, EXCEED THE PURCHASE PRICE OF THE PRODUCT. IN NO EVENT WILL MAGELLAN BE LIABLE FOR SPECIAL, INCIDENTAL, CONSEQUENTIAL, OR ANALOGOUS DAMAGES, INCLUDING, WITHOUT LIMITATION, DAMAGES RESULTING FROM LOSS OF USE, LOSS OF PROFITS, LOSS OF BUSINESS OR LOSS OF GOODWILL, EVEN IF MAGELLAN HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

This warranty shall be governed by and construed and enforced in accordance with, the substantive laws of the Commonwealth of Massachusetts, excluding its conflict of law principles. This warranty shall be non-transferable and shall run to the benefit of the original purchaser only.

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Appendix A Connecting a Compatible Serial Printer

CAUTION: The LeadCare® II Analyzer must run on AC power in order to generate a label. Battery power is insufficient to generate a label.

The LeadCare II Analyzer has printing capabilities. After a result is generated the information is transmitted via a serial connection to a label printer. The USB connection cannot be utilized for printing purposes.

Connections

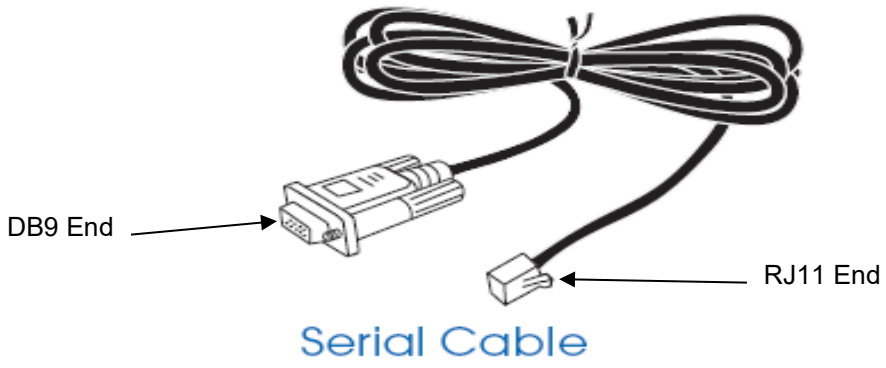

Figure A-1 Serial Cable

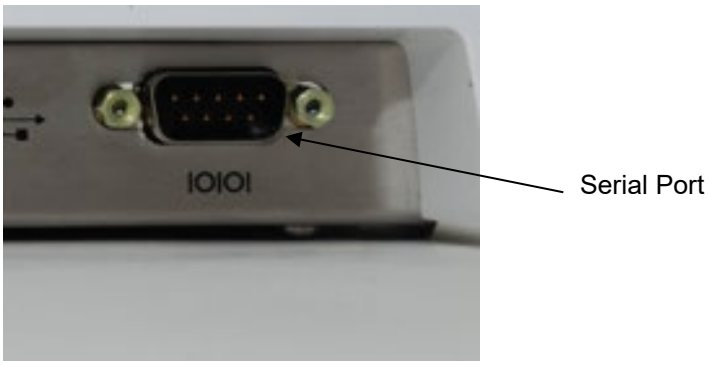

Figure A-2 Rear Panel of the LeadCare II

1. Using the serial cable supplied with the printer, connect the DB9 end to the LeadCare II's serial port.
2. Connect the RJ11 end of the cable to the printer's serial (telephone jack) connection port.
3. Plug the printer's AC adapter into a power outlet. Label the adapter so it only gets plugged into the SLP printer.
4. Ensure the LeadCare II is plugged into a power outlet with its appropriate adapter. Note: Battery operation is insufficient to generate a label.

NOTE: **The USB port cannot be used for printing LeadCare II results.**

Power On Cycle

1. Turn on the printer. A steady green light indicates ready mode.
2. Turn on the LeadCare II Analyzer.
3. Analyze a sample. The result will generate a label with the following information: :

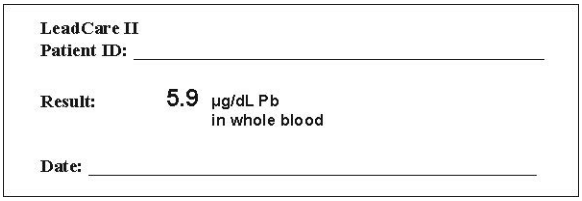

Figure A-3 LeadCare II Label

Power Off Cycle

1. Turn off the LeadCare II.
2. Turn off the printer.

Note on Labels: The SmartLabels have a mark on the backing of each label that the SLP 650SE and future models use for top of label alignment. Check to be sure the labels have this mark before loading them into the printer.

Loading Labels

1. Power on the printer. The green status light will flash until labels are loaded.
2. Lift the left side of the roll cover to open. Remove the spindle and place a roll of labels on the spindle. (The LeadCare II utilizes shipping labels: 2 1/8" W X 4" L label stock.) Adjust the guides to fit the labels (see below).

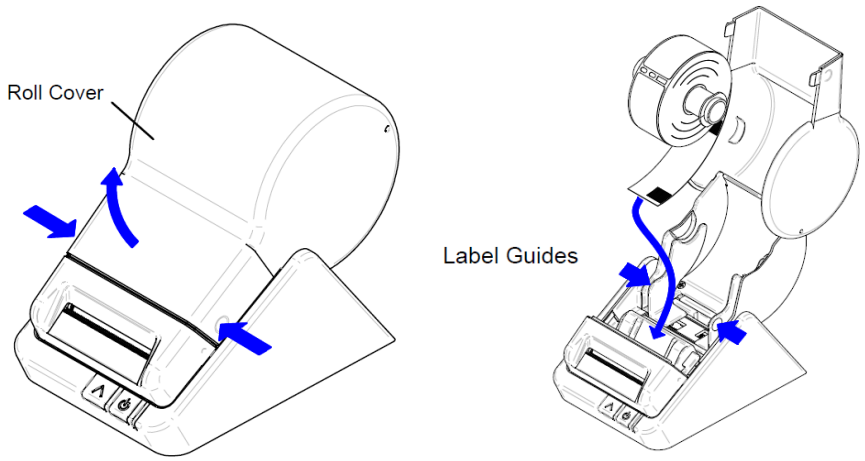

Figure A-4 Label Placement

3. Feed the labels into the entrance slot, label side down. The labels will automatically feed and align the end in the exit slot.
4. Close the roll cover.

Troubleshooting Information

- Steady green light indicates the printer is on-line.
- Blinking green light indicates the printer is awaiting labels.
- Blinking yellow indicates a label jam.
- Blinking red indicates a voltage error or print head error.
- Steady yellow light indicates the printer is off-line.

Call LeadCare Product Support for additional assistance: 1-800-275-0102.

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Appendix B Specifications, Operating Requirements, and Performance Characteristics

Specifications

Table B-1 Physical Dimensions	
Dimensions (Approximate, Analyzer Only)	Height 9 cm (3.5 in.) Width 17 cm (6.5 in.) Depth 23 cm (9 in.)
Weight (Approximate, Analyzer with Batteries)	1.13 kg (2.5 lb)

Table B-2 Electrical Specifications	
Power Requirements	Switching power supply (AC input 100-240 V, 0.25 A, 50-60 Hz, DC output +3.3 V-1.2 A) or 1.5 V AA alkaline or lithium batteries (4 each) The correct power adapter is included in the analyzer kit.
DC Input Power (External Mode)	Less than 600 mA
DC Input Power (Battery Mode)	Less than 400 mA
Battery Life	Up to 80 tests (7 hours)
Automatic Shutoff	15 minutes after last use with batteries 60 minutes after last use with AC adapter

Table B-3 Other Specifications	
CPT Code	83655 (Quantitative Blood Lead Analysis)
CLIA Complexity	Waived
Reportable Range	3.3 - 65.0 µg/dL Note: Displays "Low" below 3.3 µg/dL Displays "High" above 65.0 µg/dL
Sample Volume	50 µL
Test Time	3 minutes (180 seconds)
Calibration	Electronic calibration; calibration button included with each test kit

Operating Requirements

Table B-4 Storage and System Operating Ranges

Storage Ranges	
Analyzer	15°C to 30°C (59°F to 86°F) Up to 80% Relative humidity
Test Kit	15°C to 27°C (59°F to 80°F)
Capillary Whole Blood Sample (human) EDTA or Heparin are the anticoagulants of choice	Store at room temperature (RT) prior to mixing with Treatment Reagent. RT is 10°C to 32°C (50°F to 90°F)

System Operating Ranges	
Temperature	15°C to 27°C (59°F to 80°F)
Relative Humidity	12%-80%, non-condensing
Altitude	Operating up to 2,440 meters (8,000 feet) above sea level does not affect results.

Interference Substances

Tests were conducted by adding the potential interferences at the concentrations listed below to bovine blood with elevated lead levels. Lead results for samples with each potential interference did not differ statistically from lead results obtained on unadultered samples.

The following substances at the following concentrations do NOT affect the results of the LeadCare® II System:

- 5,5-Diphenylhydantoin (phenytoin), 100 µg/mL
- Acetominophen, 500 µg/mL
- Amoxicillin, 100 µg/mL
- Amphotericin, 50 µg/mL
- Arsenic III, 0.01 µg/mL
- Arsenic V, 0.005 µg/mL
- Carboplatin, 0.25 µg/mL
- Cephalexin (Keflex), 60 µg/mL
- Ciprofloxacin, 100 µg/mL
- Clondine, 100 µg/mL
- Cyclophosphamide, 500 µg/mL
- d-Amphetamine Sulfate, 100 µg/mL
- Diphenylhydramine Hydrochloride, 100 µg/mL
- Doxorubicin, 100 µg/mL
- Doxycycline, 100 µg/mL
- Erythromycin, 100 µg/mL
- Ferric chloride, 100 µg/mL
- Ferrous sulfate, 100 µg/mL
- Fexofenadine HCl (Allegra), 50 µg/mL
- Fluconazole (Diflucan), 100 µg/mL
- Gabapentin (Neurontin), 100 µg/mL
- Ganciclovir (AZT), 100 µg/mL
- Glyburide, 100 µg/mL
- Guanfacine, 100 µg/mL
- Hydroxyurea, 250 µg/mL
- Ibuprofen, 500 µg/mL
- Indinavir Hydrate, 100 µg/mL
- Isoniazid, 100 µg/mL
- Loratadine, 100 µg/mL
- Methyl Phenidate (Ritalin) HCl, 100 µg/mL
- Methotrexate, 60 µg/mL
- Metronidazole, 100 µg/mL
- Niacin, 100 µg/mL
- Nicotine , 10 µg/mL
- Nystatin, 100 µg/mL
- Penicillamine, 25 µg/mL
- Phenylephrine, 100 µg/mL
- Piperazine, 100 µg/mL
- Pseudoephedrine (guiafenesin), 100 µg/mL
- Pyridoxine, 100 µg/mL
- Riboflavin, 0.5 µg/mL
- Rifampicin, 100 µg/mL
- Sitagliptin, 100 µg/mL
- Thiamine, 50 µg/mL
- Trimethoprim, 100 µg/mL
- Valproic Acid, Na salt, 500 µg/mL
- Vitamin D3, 100 µg/mL

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Appendix C Steps for Collecting Fingerstick Blood Samples in Micro-Vials for Lead Testing

The following references provide additional information about blood sample collection, blood lead testing, and Magellan Diagnostics LeadCare II products.

Blood Sample Collection

Information about sample collection is available from the Clinical Laboratory Standards Institute (CLSI) or the Centers for Disease Control (CDC).

- CLSI (Clinical and Laboratory Standards Institute) GP44-A4: Procedures for the Handling and Processing of Blood Specimens; Approved Guideline – 4th ed. (ISBN 1-56238-724-3). www.clsi.org
- CDC Guidelines for Collecting and Handling Blood Lead Samples – 2004 - Video presentation describes how to collect and handle samples that will be used for blood lead testing. www.cdc.gov/nceh/lead/training/blood_lead_samples.htm

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Appendix D Safety Data Sheets (SDS)

This chapter contains the following LeadCare® II Safety Data Sheets:

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