LeadCarePlus™

Blood Lead Testing System

User's Guide

WARNING: Read User's Guide before setting up, using, or maintaining this system. Failure to follow instructions and safety precautions could result in serious injury, damage or false readings.

Keep User's Guide near system for future reference.

IVD Rx Only

Magellan DIAGNOSTICS

Magellan
DIAGNOSTICS

Magellan Diagnostics, Inc.
101 Billerica Ave, Building 4
N. Billerica, Massachusetts 01862-1271 USA

www.MagellanDx.com

For use with the LeadCare Plus® Blood Lead Analyzer Kit 82-0001

P/N 82-0011 Rev 07

FDA 510(k) #142705
Patent: : https://www.magellandx.com/patent-marking/

Magellan
DIAGNOSTICS

Table of Contents

Figures

Chapter 3

Chapter 5

Chapter 6

Tables

Chapter 3

Chapter 11

1 Important Safety Information

This chapter provides important safety information you need to know about using the LeadCare Plus® Blood Lead Testing System.

WARNING: A Warning in this User's Guide indicates a potentially hazardous situation that, if not avoided, could result in serious personal injury or death to you or others. Warnings are referenced by the signal word WARNING and the warning symbol to the left.

WARNING: A Biohazard Warning in this User's Guide indicates that the user must use precautions to prevent any infections or hazards that can be caused by biological samples. Biohazard Warnings are referenced by the signal word WARNING and the warning symbol to the left.

CAUTION: A Caution in this User's Guide indicates conditions or practices that could cause erroneous results or damage to the analyzer. Cautions are referenced by the signal word CAUTION and the warning symbol to the left.

NOTE: A NOTE in this User's Guide provides additional information that helps you perform procedures correctly, or may help you understand how the system works.

1.1 Avoid Injuring Yourself

Lab personnel using the LeadCare Plus Blood Lead Testing System must take steps to avoid contact with blood or treatment reagent.

WARNING: Read and follow these safety precautions, and the safety precautions throughout this User's Guide. Failure to do so could result in injury to lab personnel.

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.

WARNING: Be careful when handling the LeadCare Plus Treatment Reagent. The treatment reagent contains dilute hydrochloric acid (HCl). Reagent vials and vial packaging are designed to minimize chances of leaks during shipping or under normal use. Refer to the LeadCare Plus Treatment Reagent Safety Data Sheet that appears in Appendix C of this User's Guide.

1.2 Avoid Injuring Patients

Patients could suffer injury if the LeadCare Plus Blood Lead Testing System is used incorrectly and inaccurate blood lead results are reported.

CAUTION: Read and follow the safety precautions throughout this User's Guide. Failure to do so could result in injury from inaccurate test results.

1.3 Avoid Damaging the System

The LeadCare Plus Blood Lead Testing System contains precision equipment. Follow all operation and maintenance instructions in this User's Guide to avoid damaging it.

CAUTION: Read and follow the manufacturer's instructions for use.

1.4 Avoid Losing Blood Lead Test Result

Patients' health and well-being depends on receiving accurate test results. Always work carefully to avoid losing or damaging test data and records.

CAUTION: Ensure that results are documented. Record each test result as it appears on the analyzer screen.

1.5 Biohazard Warnings

When handling biological samples, use personal protection equipment and other precautions to prevent any infections or hazards that can be caused by the samples.

WARNING: Follow your laboratory's procedures and regulations when handling and disposing of biohazardous materials.

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

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

2 About this User's Guide

This User's Guide is designed to instruct laboratory personnel in the proper and safe use of the LeadCare Plus® Blood Lead Testing System. All operating instructions, product illustrations, screen graphics, troubleshooting or error messages, and other relevant information are contained in this User's Guide. It is the user's responsibility to ensure that all instructions and safety precautions in this User's Guide are strictly followed.

2.1 Intended Use

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

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

2.2 Clinical Laboratory Improvement Amendments (CLIA) Classification

The LeadCare Plus Blood Lead Testing System has been evaluated and cleared by the United States Food and Drug Administration for use as a quantitative blood lead test with the following classification: Moderately Complex. Facilities must be certified according to CLIA guidelines and must comply with all applicable federal, state, and local laws.

WARNING: All laboratories should follow the manufacturer's instructions and safety precautions as specified in the LeadCare Plus User's Guide (this guide) and the other documents listed in Section 2.3.

2.3 Additional Documentation

The following documents provide additional information to users of the LeadCare Plus Blood Lead Testing System:

- LeadCare Plus Blood Lead Testing System Package Insert (English) – Part Number 82-0038
- LeadCare Plus Quick Start Guide – Part Number 82-0010

2.4 User Assistance

Should you experience any difficulty installing or operating your LeadCare Plus Blood Lead Testing System, please contact your Magellan Diagnostics, Inc. representative. The Troubleshooting chapter in this manual (Chapter 11) includes a list of potential system problems, possible causes, and corrective actions. Read that chapter carefully.

If you continue to experience problems with setup, operation, or maintenance, call Magellan Diagnostics, Inc. at 800-275-0102. Product Support Specialists are available to answer your questions 8:00 a.m. to 6:00 p.m. Eastern Standard Time (EST), Monday through Friday. You can also contact Product Support by email at LeadCareSupport@magellandx.com.

2.5 Acronyms

The following acronyms are used in this User's Guide:

Acronym or Term	Definition
EMR	Electronic Medical Record
LIMS	Laboratory Information Management System
QC	Quality Control
BLL	Blood Lead Level
HCl	Hydrochloric acid
USB	Universal Serial Bus

2.6 Compliance Statements

The LeadCare Plus Blood Lead Testing System meets the compliance statements listed below.

2.6.1 EMC Directive

Complies with:
EMC Directive 2004/108/EC
EMC Standard EN 61326, FCC Part 15 Subpart B Class B (2014).
IEC 61326-1, Edition 2.0, 2012-07

2.6.2 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 Plus to the applicable safety standards.

2.6.3 FCC

This device complies with Part 15, Subpart B (2014) 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.

2.6.4 Waste Electrical and Electronic Equipment

This device complies with the Waste Electrical and Electronic Equipment (WEEE) directive of the European Union (EU). For information regarding the proper disposal 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.

2.6.5 Symbols

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

Symbol	Description
	Temperature Limitation
	Use By
	Manufacturer
	Batch Code
	Biological Risk
	Caution: See Instructions for Use
	Consult Instructions for Use
	Catalog Number
	Serial Number
	In Vitro Diagnostic Medical Device
O	Off (supply)
I	On (supply)
	Prescription Use Only

3 System Overview

3.1 Introduction

This chapter describes the operation and major components of the LeadCare Plus® Blood Lead Testing System. Major components include the analyzer and test kit. The LeadCare Plus Blood Lead Testing System is designed to quantitatively measure the amount of lead in a whole blood sample. The LeadCare Plus Blood Lead Testing System is intended for *in vitro* (external) use only. The test kit components are designed for use with both the LeadCare Plus and LeadCare Ultra® Blood Lead Testing Systems.

3.2 About Blood Lead Testing

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

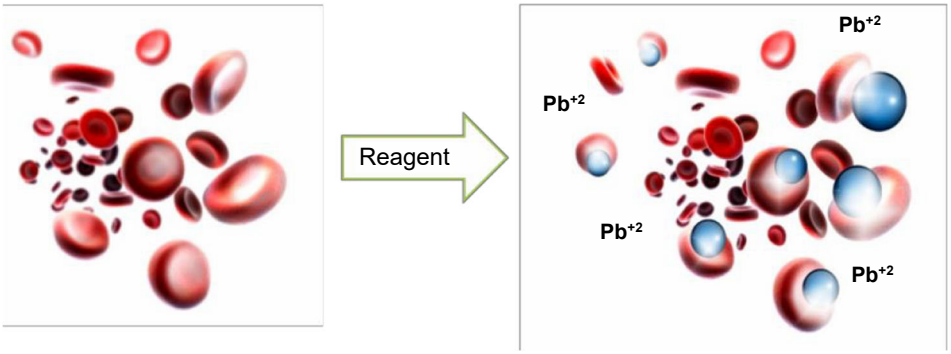
3.3 How the LeadCare Plus System Works

The LeadCare Plus System relies on electrochemistry (Anodic Stripping Voltammetry or ASV) and a unique sensor to detect lead in whole blood. Most lead is carried within red blood cells. When a sample of whole blood is mixed with treatment reagent (a dilute solution of HCl), the red blood cells are lysed and the lead becomes available for detection. When a test is run, the analyzer applies an electrical potential that causes the lead to collect on the sensor. After three minutes, the analyzer measures the amount of lead on the sensor and displays the result in micrograms per deciliter (µg/dL).

The diagram below illustrates the methodology.

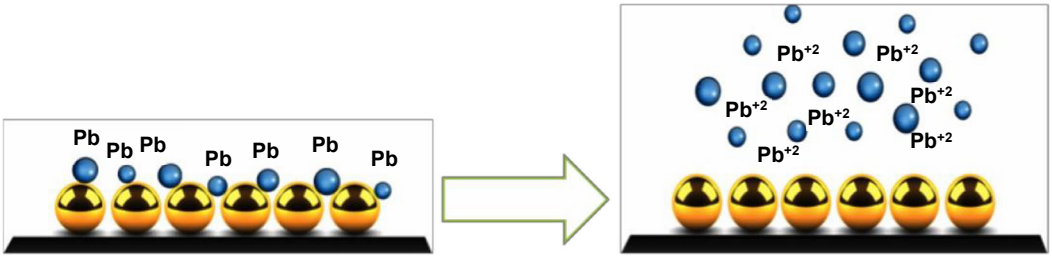
1

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



2

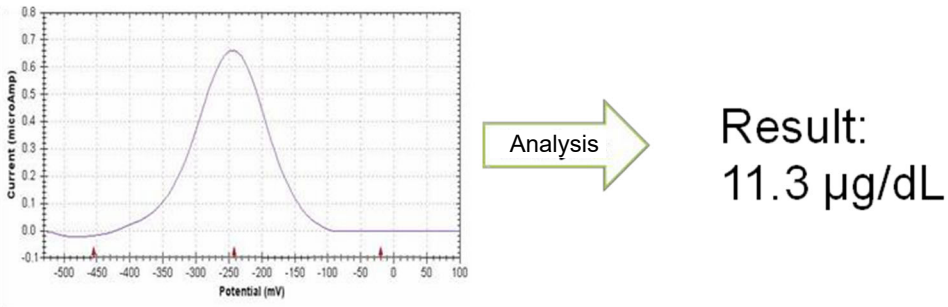
A negative potential is applied to the sensor to accumulate lead atoms on the test electrode. The potential is rapidly reversed releasing the lead ions.



Reduction step **Oxidation (stripping) step**

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.



3.4 System Components

The LeadCare Plus Blood Lead Testing System is comprised of the LeadCare Plus Blood Lead Analyzer and the LeadCare Plus Blood Lead Test Kit. The LeadCare Plus Analyzer is the device that is used to perform the blood lead measurement and calculate the amount of lead in the sample under analysis.

1. LeadCare Plus Analyzer Kit

- Analyzer
  - Features a message display screen to provide prompts to guide you through the testing procedure.
- AC Power Adapter & International Plug Set
- LeadCare Plus USB Drive (contains User's Guide and SDS)
  - Hard copy of the User's Guide is available upon request.
- LeadCare Plus Quick Start Guide

Figure 3-1 Analyzer Kit Contents

2. LeadCare Plus Test Kit

The LeadCare Plus Test Kit contains the reagents required to perform 96 blood lead tests with the LeadCare Plus Analyzer

- 96 Blood Lead Sensors
- 96 Treatment Reagent Tubes
- Level 1 Control
- Level 2 Control
- Calibration Button
- LeadCare Plus Package Insert

Figure 3-2 Test Kit Contents

Table 3-1: Test Kit Contents

	Item Name	*Description*
1	Treatment Reagent	The treatment reagent is a clear liquid (dilute solution of HCl) that contains black particulates (activated carbon). When a treatment reagent vial is agitated, the black particles disperse throughout the liquid, imparting a black color to the resulting suspension. Over time the particles settle to the bottom of the vial, leaving a black solid at the bottom of the clear liquid.
2	Sensors	The sensors are single use electrochemical test strips that are inserted into the LeadCare Plus Analyzer and used for the binding, release and measurement of lead present in a test sample.
3	Control Material	Two control material vials (Level I and Level II) are supplied in each test kit. The controls are buffered aqueous solutions containing bovine serum albumin, dye, and a known quantity of lead. The control material is used to demonstrate that the system is correctly measuring the lead concentration in a sample preparation.
4	Calibration Button	The calibration button is specific for the test kit in which it is supplied. It is used to download all calibration information, analytical test parameters, and expiration date code information for the sensor lot supplied within the test kit. This lot-specific calibration button is held against the calibration reader on the analyzer to calibrate the analyzer for use with a particular test kit.

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

This page intentionally left blank.

4 Register Your System

Please take a moment to complete the Registration Form online at:
https://www.magellandx.com/leadcare-products/leadcare-plus/support/getting-started/

Registering your analyzer with Magellan Diagnostics will allow you to receive important updates about your LeadCare Plus® Blood Lead Testing System.

This page intentionally left blank.

5 Setting up the Analyzer

5.1 The Work Area

Set up the LeadCare Plus® 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.

5.2 Using the Analyzer with a Power Adapter

CAUTION: Use only the AC adapter supplied with this unit. Attempting to use a different voltage adapter could damage the analyzer and void the warranty.

To use the analyzer with a power adapter:

1. Plug the DC connector into the back of the analyzer as shown in Figure 5-1.

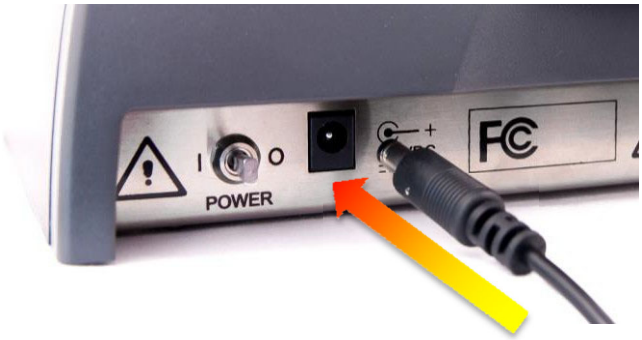


Figure 5-1 Plug in DC Connector/AC Adapter

2. Plug the adapter into an AC power outlet.

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

5.3 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 compartment is located at the rear of the analyzer. To install the batteries:

1. Turn the analyzer to access the battery area on the rear panel.
2. Remove the DC input connector.
3. Remove the battery cover as shown in Figure 5-2. Press on the locking tab with one or both thumbs (1) and slide cover away from the analyzer (2).

Figure 5-2 Remove Battery Holder Cover

4. Insert four 1.5 V AA size alkaline or lithium batteries as shown in Figure 5-3.

Figure 5-3 Insert Batteries

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

5. 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 turns off.

5.4 Operating Requirements

The operating temperature range for the LeadCare Plus is 16°C - 30°C (60.8°F - 86°F).

CAUTION: Do not place the LeadCare Plus 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

5.5 Reading the Analyzer Display

The LeadCare Plus 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.

Figure 5-4 Message Display

The analyzer monitors the test conditions and displays error messages on the screen if a problem is detected. Chapter 11, Troubleshooting, includes a list of the messages and what to do if they appear.

6 Calibrating the Analyzer

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

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

WARNING: 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.

6.1 Turning the Analyzer On and Off

The LeadCare Plus® Blood Lead Analyzer **power switch** is located at the back of the device as shown in Figure 6-1.

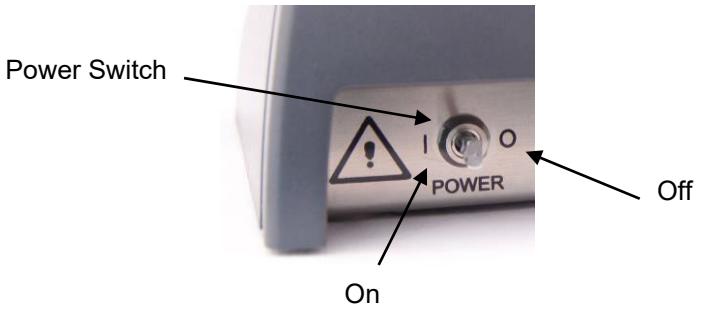


Figure 6-1 Power Switch

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.

6.1.1 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.

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

Figure 6-2 Turn Analyzer On

The analyzer performs a series of self tests. The LeadCare Plus 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.

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

   The first time you turn on the analyzer, after the system self tests, the display screen reads:

```
PLEASE CALIBRATE
ANALYZER WITH BUTTON
```

3. 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
```

6.2 About Calibration

As discussed, the first time you turn on the analyzer, the display screen reads:

PLEASE CALIBRATE
ANALYZER WITH BUTTON

Each LeadCare Plus Test Kit comes with one calibration button for the sensors. The calibration button is coded with the data required for the analyzer to translate the raw signal measured on the sensor into the actual lead concentration of blood samples.

When you touch the calibration button to the button reader on the analyzer, the calibration data for the sensor lot is transferred to the analyzer. When the transfer is complete, an audible tone sounds and a “Calibration Successful” message appears on the analyzer display screen.

6.3 Calibration Procedure

You must calibrate the analyzer:

- The first time you use the analyzer
- Each time you change test kit lot numbers
- Any time the analyzer screen displays a recalibration message

WARNING:

- 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 containers and calibration button match the “Sensor Lot #” on the analyzer display.
- Do not use items from more than one test kit at a time.
- Calibration is required for each new lot of sensors. Use only the calibration button packaged with the test kit you are using. Failure to use the correct calibration button could generate inaccurate results.

1. Remove the calibration button from the test kit you are going to use.
2. Hold the calibration button to the button reader until you hear the beep; see Figure 6-3. The button must touch both the center contact and metal side of the button reader. There is no need to apply pressure to the button reader.

Figure 6-3 Holding Calibration Button to Button Reader

3. Calibration can take up to 5 seconds. When calibration is complete, the analyzer beeps and the screen briefly displays a message stating that the analyzer was calibrated successfully.

CALIBRATION SUCCESSFUL

4. Next the analyzer screen will prompt you to prepare a sample using the sensor lot which matches the calibration button.

PREPARE SAMPLE USE SENSOR LOT XXXX OR RECALIBRATE THEN INSERT SENSOR

5. Make sure the number of the button matches the display or recalibrate to the correct lot number.
6. The LeadCare Plus Blood Lead Analyzer is now ready for testing.

7 Performing Quality Control

7.1 Introduction

Quality controls are used to verify that the system and procedures in place are generating accurate results.

NOTE: The LeadCare Plus® Controls are for *in vitro* (external) use only.

7.2 What are Blood Lead Controls?

A control is a standard against which test results can be evaluated. The LeadCare Plus Blood Lead Controls are buffered aqueous solutions containing bovine serum albumin and dye. These Quality Control (QC) solutions contain a known quantity of lead. To ensure that your patient test results are accurate, you must periodically run the LeadCare Plus Control samples.

Acceptable ranges for each lot and lead level are established by Magellan Diagnostics, Inc. using the LeadCare Plus Blood Lead Testing System. Magellan Diagnostics, Inc. establishes these ranges using extensive replicate analyses and rigid QC.

CLIA guidelines recommend that a minimum of two levels of QC be performed with each analytical run. Two levels of QC are included in the LeadCare Plus Test Kit. Each control has an assigned target range (target value +/- tolerance value).

NOTES:

- Any QC result which falls within the assigned target range for that specific QC Level and lot is determined to be “in range” and therefore, acceptable.
- Any QC result which falls outside of the assigned target range for that specific QC level and lot is determined to be “out of range” and therefore, unacceptable.
- The QC results should be within range before patient samples are tested.

7.3 How Often Should You Test Controls?

According to CLIA guidelines for Moderately Complex tests, a minimum of two levels of controls should be:

- Tested each day or shift before patient samples are tested for lead concentration
- Prepared and tested by each analyst who prepares samples
- Run to test the technique of new users
- Run at any other time you wish to verify system performance

NOTE: Some certification programs may have additional QC requirements. Follow the applicable federal, state, and local guidelines to ensure compliance.

For additional important information on QC, refer to the package insert provided with the test kit.

7.4 Safety Precautions

You must understand and follow these precautions when performing QC testing using the LeadCare Plus Blood Lead Testing System.

CAUTION: When performing QC testing:

- Keep the sensors in their container and the container closed until you need them. The sensor vial contains a desiccant which controls the humidity. If the sensors are exposed to humidity for an extended period of time this could lead to a false test result.
- Do not touch the “X” on the sensors, except when applying the control. This could cause contamination and a false test result.
- 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 allow the inside of the treatment reagent vial or the vial cap to touch anything. This could cause false blood lead test results.
- Mix the control with the treatment reagent thoroughly. Gently invert the tube 10 times to mix thoroughly. Avoid creating foam and air bubbles.
- Do not leave the treatment reagent vial uncapped other than to add the control or remove the control/reagent solution. The tube and its contents could be contaminated causing false test results.
- Before placing the mixture on the sensor, make sure the “Add Sample to “X” on Sensor” message appears on the analyzer display.

- Wear powder-free gloves to prevent lead contamination. Because there is lead in the environment, it is easy to contaminate controls, collection tubes, and test kit items. Contamination of the work environment can cause inaccurate blood lead test results.
- When testing controls, make sure that the result is 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 (Chapter 11) of this User's Guide or call Product Support at 800-275-0102 to help you resolve the problem.

7.5 Storing and Handling the Controls

Store LeadCare Plus Controls at room temperature.

CAUTION: The control expiration date is printed on the control label. Do NOT use the controls past the expiration date; expired controls could cause inaccurate test results.

CAUTION: Use controls only with sensors of the same lot number. Discard remaining control solutions when the sensors from the kit are gone.

7.6 Control Procedure

Use this procedure to perform a QC test to help ensure accurate blood lead testing results. The LeadCare Plus Test Kit is supplied with two levels of QC, each representative of different levels of lead. Level 1 represents a lower lead concentration, while Level 2 represents a higher lead concentration.

NOTE: If you are using control material not included with the LeadCare Plus Test Kit, prepare according to manufacturer's instructions. Bring the controls to room temperature and thoroughly mix before following the instructions below.

► Follow These Steps

1. Label a fresh treatment reagent tube **Level 1 Control**. Invert the Level 1 Control vial 8-10 times at a minimum to ensure homogeneity of the control material.
2. Remove the cap from the treatment reagent tube and place it face up on a clean absorbent liner. Do not allow the inside of the cap to touch anything. This could cause false test results.
3. Using a calibrated pipette, withdraw 50 µL of control material from the control vial.
4. Dispense the entire 50 µL aliquot of control solution into the treatment reagent tube.

5. Replace the control vial cap and the treatment reagent tube cap. Mix the control/treatment reagent mixture by holding the tube horizontally and gently shaking until the entire inside walls are evenly coated with a reddish solution.
6. Repeat this process (steps 1 through 5) for the **Level 2 Control**.
7. Analyze both control samples according to the instructions provided in Chapter 8, Step D: Analyze the Sample.

7.7 Understanding the Quality Control Results

Control target ranges are provided on the control label. If the control results are within the range listed for the control, your LeadCare Plus System is working properly.

If the reported control results are not within the listed range, refer to the Troubleshooting section in Chapter 11 of this guide or contact Magellan Diagnostics, Inc. Product Support at 800-275-0102 or LeadCareSupport@magellandx.com.

CAUTION: Do NOT proceed to testing patient samples unless all control level results are within the acceptable ranges.

8 Performing Blood Lead Testing

8.1 Introduction

When your LeadCare Plus® Blood Lead Testing System has been set up, calibrated, and QC performed, blood lead tests can be conducted. This chapter describes how to test a patient's blood for lead. It contains the following topics:

- Specimen Requirements
- Limitations of the Test
- Overview of the Testing Procedure
- Safety Precautions
- Testing Procedure

WARNING: Read all instructions carefully before you perform a blood lead test. Failure to follow these instructions could result in injury from inaccurate results or injury to lab personnel.

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.

8.2 Specimen Requirements

Whole blood samples must be mixed with an acceptable anticoagulant and stored properly before testing.

Acceptable Anticoagulants and Collection Devices

Acceptable anticoagulants for blood lead samples:

- EDTA
- Heparin

Acceptable collection devices for blood lead samples:

- Capillary blood collection devices.
- **The end user must validate the use of micro collection devices with the LeadCare Plus Blood Lead Testing System in accordance with their laboratory policies and procedures.**

Collection and Storage Conditions

Blood samples must be collected and stored properly for lead testing to be performed.

CAUTION: Blood samples must meet the following standards in order to be tested for lead. Failure to observe these conditions may cause inaccurate results:

- The whole blood sample must be free of blood clots.
- When EDTA capillary blood collection devices are used for sample collection, **the EDTA capillary blood collection devices must be at least half full** for the sample to be appropriate for use.
- Whole blood samples collected with EDTA or Heparin as anticoagulant **must** be:
    - Shipped and stored between 1°C - 25°C (33°F - 77°F) (refrigerated or room temperature conditions).
    - Mixed with treatment reagent within 72 hours from time of blood collection.
- The whole blood sample must be brought to room temperature and thoroughly mixed prior to addition to treatment reagent.
- The mixture of blood and Treatment Reagent is stable for up to 48 hours at room temperature and up to 7 days if you refrigerate it immediately.

Limitations of the Test

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

NOTE: Allow mixture to reach room temperature before analyzing

- Extremes in humidity may affect the blood lead results. Performance has been validated from 12% - 80% Relative Humidity (non-condensing). Use of the LeadCare Plus System outside of this range is not recommended.
- Do **NOT** use the LeadCare Plus System above altitudes of 8,000 feet.

- Do **NOT** use the LeadCare Plus System in drafts. This could lead to inaccurate results.
- Keep the LeadCare Plus System out of direct sunlight.
- The analyzer will only function in the temperature range of 16°C - 30°C (60.8°F - 86°F). Otherwise the system will display a temperature error. Refer to error messages in the User's Guide (Chapter 11).
- Allow all the LeadCare Plus System components to reach a steady temperature before using.
- Use the sensors and the treatment reagent tubes, only once. Do **NOT** reuse. Reuse could lead to erroneous results.
- Do **NOT** use damaged (bent, scratched, cut, etc.) sensors.

Overview of the Testing Procedure

Testing for lead in blood with the LeadCare Plus Blood Lead Testing System consists of the following steps. See Section 8.6 for detailed step-by-step procedures:

1. Make sure you have the required materials.
2. Use whole blood samples (capillary) collected with EDTA or Heparin anticoagulant.
3. Using a calibrated pipette, add 50 µL of a blood sample to a labeled treatment reagent tube, recap, and mix thoroughly. The sample preparation will turn brown.
4. Match the sensor vial lot number with the displayed lot number and insert a sensor into the analyzer.
5. Using a calibrated pipette, draw 30 µL of the sample mixture from the treatment reagent tube and dispense on the (X) on the sensor.
6. The analyzer starts the 3-minute analysis automatically. Test results are displayed on the analyzer display screen.

Safety Precautions

Observe the precautions listed throughout this section. Failure to follow these precautions may cause inaccurate results. Important precautions for testing are also listed in "Important Safety Information" in Chapter 1.

General Precautions

Follow these safety precautions any time you are working with the LeadCare Plus Blood Lead Testing System.

WARNINGS:

- 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, pipette tips, and other materials exposed to human blood in a biohazard container.
- Use caution when handling the LeadCare Plus reagent. The treatment reagent contains dilute HCl. Reagent vials and vial packaging are designed to minimize chances of leaks during shipping or under normal use. Refer to the LeadCare Plus Treatment Reagent Safety Data Sheet that appears in Appendix C of this manual.

WARNINGS:

- Do not use sensors that have been dropped, previously handled, broken, scratched, or damaged in any way. This could cause inaccurate test results.
- Do not use any test kit or controls past the expiration date. This could cause false 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.

Precautions when Preparing Patient Samples

You must understand and follow these precautions when preparing blood samples to be tested using the LeadCare Plus Blood Lead Testing System.

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.

WARNING: Be careful when handling the LeadCare Plus Treatment Reagent. The treatment reagent contains dilute HCl. Reagent vials and vial packaging are designed to minimize chances of leaks during shipping or under normal use. Refer to the LeadCare Plus Treatment Reagent Safety Data Sheet that appears in Appendix C of this User's Guide.

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.
- Whole blood samples must be mixed with an acceptable anticoagulant and stored properly before testing. Make sure the blood sample meets all specimen requirements detailed in Section 8.2 of this User's Guide.

Precautions when Testing a Patient Sample

You must understand and follow these precautions when using the LeadCare Plus Blood Lead Testing System to test patient blood samples.

CAUTION: When testing blood samples:

- Keep the sensors in their container and the container closed until you need them. The sensor vial contains a desiccant which controls the humidity. If the sensors are exposed to humidity for an extended period of time this could lead to an inaccurate test result.
- Do not touch the “X” on the sensors, except when applying the sample. This could cause contamination and a false test result.
- 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 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 control with the treatment reagent thoroughly. Invert the tube 10 times to mix thoroughly. Avoid creating foam and air bubbles.
- 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.
- Before placing the sample on the sensor, make sure the “Add Sample to “X” on Sensor” message appears on the analyzer display.
- 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.

Testing Procedure

Perform a blood lead test by following Step A through Step D, below.

Step A: Gather Required Test Materials

► **Follow These Steps**

The end user must validate the use of micro collection devices with the LeadCare Plus Blood Lead Testing System in accordance with their laboratory policies and procedures.

1. Place the following items in front of you in a clean work space:
   - Liner and Bio-hazard Waste Container
   - Protective Gloves (powder-free)
   - LeadCare Plus Blood Lead Testing System
   - LeadCare Plus Blood Lead Test Kit, which includes:
     - Treatment reagent tubes
     - Sensor vials
     - Quality controls
     - Calibration button
   - 50 µL pipette and disposable pipette tips
   - 30 µL pipette and disposable pipette tips
   - Capillary blood samples

CAUTION: Allow the analyzer, test kit, and samples to reach room temperature before testing. Operating outside the temperature range of 16°C - 30°C (60.8°F - 86°F) and 12% - 80% relative humidity, or in conditions of fluctuating temperature and humidity, may lead to inaccurate results.

NOTE: Be sure the LeadCare Plus Blood Lead Test Kit items all come from the same test kit. Do not mix items from different test kits.

Step B: Prepare the Sample

CAUTION: Add blood sample to the treatment reagent within 72 hours of collection. Blood older than 72 hours may produce inaccurate results.

CAUTION: Use only capillary whole blood with the LeadCare Plus/Ultra Treatment Reagent. Blood may be stored at room temperature or refrigerated for up to 72 hours before use. The whole blood sample must be brought to room temperature and thoroughly mixed prior to addition to treatment reagent.

CAUTION: Make sure the blood sample is free of blood clots, which can cause inaccurate results. Make sure to dispense exactly 50 µL of blood into the treatment reagent.

► **Follow These Steps**

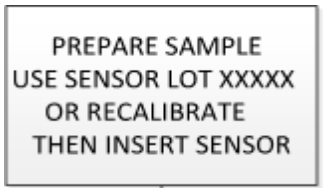
1. Bring the blood sample to room temperature and mix thoroughly.
2. Label a treatment reagent tube with the Sample ID.
3. Remove the cap from the tube and place it face up on a clean absorbent liner.
4. Transfer 50 µL of the whole blood sample into the treatment reagent tube.
5. Recap the tube and invert a minimum of 8 to 10 times to mix the sample completely. The sample mixture should turn brown.
6. Repeat steps 1 through 5 for each sample to be tested.

NOTE: The mixture of blood and Treatment Reagent is stable for up to 48 hours at room temperature and up to 7 days if you refrigerate it immediately.

Step C: Turn the System ON

► Follow These Steps

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



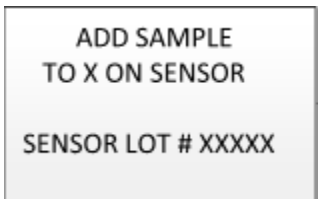
2. Check that the calibration code of the sensors in use matches the calibration code displayed on the analyzer. Recalibrate if necessary.

Step D: Analyze the Sample

► **Follow These Steps**

1. Remove a sensor from one of the sensor containers by grasping the sensor at the end with the alphanumeric designation.
2. Close the container.

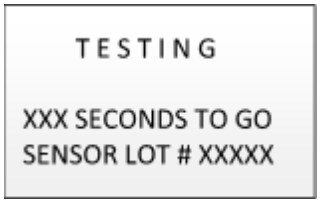
3. Insert the sensor (with the black bars facing up) completely into the analyzer. Make sure the sensor is inserted under the sensor guides and sits flush on the sensor deck. When the sensor is inserted properly, the analyzer beeps and displays the “Add Sample to “X” on sensor message shown below:



CAUTION: Keep the sensors in their container until you are ready to use them. Minimize handling to prevent contamination which could cause a false test result. Ensure that the lot number on the sensor vial matches the lot number displayed on the analyzer screen.

4. Remix sample/treatment reagent mixture, then pipet 30 µL onto the (X) on the sensor. Analysis begins automatically.

5. The analyzer will beep when it has enough sample and will display the message “Testing XXX seconds to go” below:

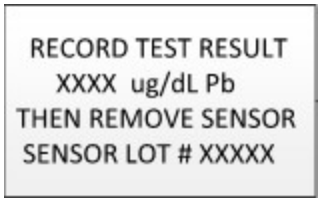


6. After 180 seconds the analysis is complete. The blood lead concentration will display on the analyzer screen. Results are reported in micrograms (µg) of lead (Pb) per deciliter (dL) of whole blood. Results are displayed to one decimal point.

NOTE: The reportable range of the LeadCare Plus is 1.9 µg/dL to 65.0 µg/dL.

The analyzer displays “Low” when it detects a blood lead level below 1.9 µg/dL. “Low” results should be recorded as “<1.9 µg/dL”. It is not uncommon to obtain patient results that read “Low”.

The analyzer displays “High” when it detects a blood lead level above 65.0 µg/dL. “High” results should be recorded as “>65.0 µg/dL”.

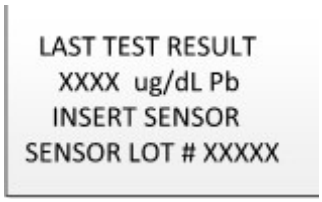


7. Record the result.
8. Remove the used sensor.

NOTE: A warning beep will sound if the used sensor is not removed from the analyzer after 2 minutes. The beep will continue to sound until the used sensor is removed.

9. Discard the materials in an appropriate biohazard container.

   When the used sensor is removed, the analyzer will indicate it is ready for the next sample with the “LAST TEST RESULT” message below:



10. Repeat steps 1–9 to analyze additional samples.
11. See Chapters 9 and 10 for state reporting and follow-up lead testing requirements.

This page intentionally left blank.

9 State Reporting of Blood Lead Test Results

Lead poisoning remains the number one environmental threat to children and is a major health concern. Most states require that results be submitted to the state's health department. Contact your state's Childhood Lead Poisoning Prevention Program for the specific reporting guidelines that apply to your blood lead results.

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

Additional questions can be directed to Magellan Diagnostics, Inc. Product Support at 800-275-0102 or LeadCareSupport@magellandx.com.

This page intentionally left blank.

10 Follow-up 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.

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 run at a reference laboratory using a high complexity testing method.

For the most current information regarding blood lead testing guidelines, please refer to the CDC's website and specific regulations in your State.

This page intentionally left blank.

11 Troubleshooting

11.1 Introduction

Several factors may contribute to inaccurate blood lead patient sample and control test results. This chapter provides steps you can take if you obtain unexpected patient blood lead or control test results. Also provided is a list of error messages you may encounter in the event a problem occurs during testing. Error definitions and possible remedies are provided in this section.

11.2 Troubleshooting

The following tables provide possible causes of, and remedies for, inaccurate test results or control results.

Table 11-1: Results Below the Target Range or Expected Value

Problem Area	*Check the Following*
Sample Type	• CONTROLS: o Make sure the control lot being used is the same lot number of the sensors in the kit being used. • PATIENT BLOOD SAMPLE: o **The end user must validate the use of micro collection devices with the LeadCare Plus Blood Lead Testing System in accordance with their laboratory policies and procedures.** o Use only capillary whole human blood collected with EDTA or Heparin anticoagulant. Do **NOT** use venous samples. Do NOT use plasma or serum. o Use only capillary blood collection devices for whole blood sample collection. o Make sure the sample is free of clots. o Make sure the sample is ≤ 72 hours old and has been stored at room temperature or in the refrigerator. o Bring the sample to room temperature before use. o Make sure EDTA capillary blood collection devices are at least half full to be considered an acceptable sample.

Sample Preparation	• Use calibrated pipettes and pipette tips to transfer precisely 50 µL of control or blood sample into the treatment reagent tube. • Always add the control or blood sample to treatment reagent and mix thoroughly.

Problem Area	*Check the Following*
Equipment Setup and Calibration	• Check the expiration on the test kit box to make sure the test kit materials have not expired. • Make sure the analyzer is calibrated properly using the calibration button from the kit being used. • When processing controls, check to make sure the sensor lot number on the display screen matches the lot number of the control and the sensors.
Testing Conditions	• Avoid operating the LeadCare Plus Blood Lead Testing System in drafts or outside the specified temperature range 16°C - 30°C (60.8°F - 86°F) and specified humidity range (12 - 80%, Relative humidity). • Make sure that the system and the test kit are maintained at a constant temperature. If you move the system from one place to another, wait for the analyzer and components to reach a stable temperature.
User Technique	• Make sure the control or blood sample and treatment reagent mixture is thoroughly mixed before placing onto the sensor. o A control in treatment reagent mixture will remain red after mixing. o A blood sample in treatment reagent will turn brown after mixing. • Make sure the sample mixture is at room temperature before placing onto the sensors. • Keep sensor vial closed. Remove sensors from vial only when ready to run samples. • Add 30 µL of the sample/treatment reagent or control/treatment reagent mixture to the sensor. • Do not touch the sensor while the analyzer is running a test.

Table 11-2: Results Above the Target Range or Expected Value

Problem Area	*Check the Following*

Sample Type	• CONTROLS:
	  o Make sure the control lot being used is the same lot number of the sensors in the kit being used.
	• PATIENT BLOOD SAMPLE:
	  o Use only whole human blood collected with EDTA or Heparin anticoagulant. Do **NOT** use venous samples. Do NOT use plasma or serum.
	  o Make sure the sample is free of clots.
	  o Make sure the sample is ≤ 72 hours old and has been stored at room temperature or in the refrigerator.
	  o Bring the sample to room temperature before use.
	  o Make sure EDTA capillary blood collection devices are at least half full to be considered an acceptable sample.

Blood Sampling	• Lead is widespread in the environment. It is easy to contaminate a blood sample. Ensure that the sample being tested came from a collection site that was thoroughly cleaned with soap and water followed by a clean alcohol wipe prior to capillary blood collection. • Use clean powder-free gloves during testing. • Use calibrated pipettes and pipette tips to transfer precisely 50 µL of control into the treatment reagent tube. • Make sure the pipette tip is filled properly. Be sure to wipe excess blood from the tip with a downward motion. The accuracy of the test depends on filling the pipette tip with 50 µL. Excess blood may produce higher blood lead test results.
Sample Preparation	• Use clean powder-free gloves during testing and keep your gloved hands clean. • Use calibrated pipettes and pipette tips to transfer precisely 50 µL of control or blood sample into the treatment reagent tube. • Make sure the pipette tip is filled properly. Be sure to wipe excess blood sample or control from the tip with a downward motion. The accuracy of the test depends on filling the pipette tip with 50 µL. Excess blood may produce higher blood lead test results. • Always add the control or blood sample to treatment reagent and mix thoroughly.

Problem Area	*Check the Following*
Equipment Setup and Calibration	• Check the expiration on the test kit box to make sure the test kit materials have not expired. • Make sure the analyzer is calibrated properly. Use the calibration button that came with the test kit you are using. • When processing controls, check to make sure the code on the display screen matches the code of the calibration button for the test kit.
Testing Conditions	• Avoid operating the LeadCare Plus Blood Lead Testing System in drafts or outside the specified temperature range 16°C - 30°C (60.8°F - 86°F) and specified humidity range (12 - 80%, Relative humidity). • Make sure that the system and the test kit are maintained at a constant temperature. If you move the system from one place to another, wait for the analyzer and components to reach a stable temperature.

User Technique	• Do not touch the black bars or the black “X” on the sensor. This could damage or contaminate the sensor.
	• Do not touch the ends of the pipette tips. This could cause contamination.
	• When uncapping the treatment reagent tube, place cap, inside facing up, on a clean surface.
	• Do not leave the treatment reagent tube uncapped other than to add or remove sample to/from the treatment reagent tube.
	• Make sure the control or blood sample and treatment reagent mixture is thoroughly mixed before placing onto the sensor.
	  o The control in treatment reagent mixture will remain red after mixing.
	  o A blood sample in treatment reagent will turn brown after mixing.
	• Make sure the sample mixture is at room temperature before placing onto the sensors.
	• Keep sensor vial closed. Remove sensors from vial only when ready to run samples.
	• If you drop a sensor, do not use it.
	• Make sure 30 µL of the sample/treatment reagent or control/treatment reagent mixture is added to the sensor.
	• Do not touch the sensor while the analyzer is running a test.

11.3 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 prior to calling.

Product Support can be reached at 800-275-0102 or LeadCareSupport@magellandx.com.

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 6.
ELECTRONIC QC CHECK FAILED CALL TECH SERVICE ERROR X	The internal quality control check failed.	Record the error number & call Product Support at 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 vial 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 FAILED PLEASE REMOVE SENSOR	A sensor failure occurred, invalidating the sample analysis.	Remove the sensor, discard it, and insert a new sensor.
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 6, Calibrating the Analyzer.
SYSTEM FAILURE ERROR 500 CALL TECH SERVICE	The integrity of the calibration button may be compromised.	Call Product Support at 800-275-0102.
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 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 800-275-0102.

*** If an error message is encountered repeatedly, contact Product Support at 800-275-0102 or LeadCareSupport@magellandx.com.**

11.4 Calling LeadCare Product Support

After troubleshooting, if you are unable to resolve your issue, call Magellan Diagnostics, Inc. Product Support at 800-275-0102 or LeadCareSupport@magellandx.com.

Please write down this information and have it ready before you call:

- Serial Number of Analyzer (on bottom of analyzer)
- Installation Date
- Firmware Version Number (On analyzer display screen upon powering on)
- Test Kit Lot # (on end of box)
- Calibration Code on Calibration Button
- Did you test with Controls? Yes No
    - If yes, were they LeadCare Plus Controls? Yes No
- Control Results Last Recorded (Level 1, Level 2)
- Control Lot #
- Control Expiration Date
- Sensor Lot Number

12 Maintenance

For optimum performance, the LeadCare Plus® Blood Lead Testing System must be properly maintained.

NOTE:	Maintenance activities relating to the analyzer do not require the analyzer enclosure to be opened. There are no user serviceable parts inside the LeadCare Plus Analyzer.

12.1 Cleaning and Decontamination Procedures

12.1.1 Cleaning the Analyzer

The exterior case of the analyzer can be cleaned using a lint-free cloth dampened with warm, soapy water.

- Do not clean the sensor connector (gold pins) present inside the analyzer sensor connector port. In the case of accidental spill, dry the area immediately.
- Do not leave any soap residue or residual liquid on the analyzer.
- Do not wash the inside of the calibration button reader.

12.1.2 Decontamination of the Analyzer

WARNING: If there is the possibility of blood contamination on the analyzer, you should decontaminate the analyzer using a 10% bleach solution.

If there is the possibility of blood contamination on the analyzer, you should remove all blood traces and ensure that blood-borne diseases are eliminated by following the decontamination procedure below:

- Prepare a fresh 10% solution of household bleach, using 1 part bleach and 9 parts water, or by adding a ½ cup bleach to 1 quart of water.
- Wipe the exterior case and sensor deck thoroughly using a lint-free cloth dampened with the 10% bleach solution.
- Do not clean the sensor connector (gold pins) present inside the analyzer sensor connector port. In the case of accidental spill, dry the area immediately.
- Do not leave any residual liquid on the analyzer.
- Do not wash the inside of the calibration button reader.

In order to comply with Department of Transportation guidelines, analyzers must be decontaminated prior to returning the instrument to Magellan Diagnostics, Inc. Please refer to Chapter 14 for more information regarding product returns.

13 Reordering Information

Ordering replacement parts for your LeadCare Plus® Blood Lead Testing System is simple. If you know the item number, please contact our Customer Service Department at 800-543-1980 to complete your order.

If you are unsure of the item number or for a complete list of parts, please visit https://www.magellandx.com/leadcare-products/leadcare-plus/support/parts-service/

This page intentionally left blank.

14 Returns

A Return Materials Authorization (RMA) number must be issued by Magellan Product Support and clearly attached to the product before it is returned.

1. Within the warranty period any part of the goods that prove to be defective in material or workmanship may be repaired or replaced on an exchange basis with a new or functionally operative part free of charge.

2. After such warranty period, any labor, transportation, and subsistence expense shall be borne by the Buyer. If preferred, Buyer may return goods to Magellan Diagnostics, Inc. with shipment both ways at Buyer's expense for repair work.

3. Prior to returning an analyzer to Magellan Diagnostics, Inc., please follow the decontamination procedure provided in Section 12.1.2.

4. Parts returned damaged due to poor or insufficient packaging by the Buyer will not be accepted for service unless otherwise agreed.

5. Any time parts are returned where no problems are found, a service/handling charge, which will reflect the labor to test and verify the parts as well as other incurred expenses will be borne by the Buyer.

6. In no event shall Magellan Diagnostics, Inc. be liable for incidental or consequential damages, including, but not limited to, costs, or removal and reinstallation or such goods, good will, overhead expenses, loss of profit, and loss of use.

7. The remedies are available only to the original Buyer.

This page intentionally left blank.

15 Service and Support

To contact Magellan Diagnostics, Inc. Product Support, call 800-275-0102, or email LeadCareSupport@magellandx.com, Monday through Friday. A Product Support Representative is available from 8:00 a.m. to 6:00 p.m. (EST) for you to:

- Request technical assistance
- Request product and procedure training
- Report a problem
- Return products

Please contact our Customer Service Department directly at 800-543-1980 to:

- Place an order
- Track a shipment

This page intentionally left blank.

16 LeadCare Plus 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 or 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.

This page intentionally left blank.

Appendix A Specifications, Operating Requirements, and Performance Characteristics

Specifications

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)

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

Other Specifications	
CPT Code	83655 (Quantitative Blood Lead Analysis)
CLIA Complexity	Moderate
Reportable Range	1.9 - 65.0 µg/dL Note: Displays "Low" below 1.9 µg/dL Displays "High" above 65.0 µg/dL
Blood Sample	50 µL
Test Sample	30 µL
Test Time	3 minutes (180 seconds)
Calibration	Electronic calibration; calibration button included with each test kit

Operating Requirements

Storage and System Operating Ranges	
Storage Ranges	
Analyzer	15°C - 30°C (59°F - 86°F) up to 80% Relative humidity, non-condensing
Test Kit	15°C - 27°C (59°F - 80°F) 12% - 80% Relative humidity, non-condensing
Whole Blood Sample (human) EDTA or Heparin anticoagulants	Capillary whole blood (EDTA or Heparin) that is: • Free of blood clots. • Shipped and stored between 1°C - 25°C, (33°F - 77°F), refrigerated or room temperature conditions. Mixed with treatment reagent within 72 hours from time of blood collection.

System Operating Ranges	
Temperature	16°C - 30°C (60.8°F - 86°F)
Relative Humidity	12% - 80%, non-condensing
Altitude	Operating up to 2,440 meters (8,000 feet) above sea level does not affect results.

Shipping Environment Ranges	
Shipping Ranges	
Analyzer	-30°C - +40°C (-22°F - +104°F) 10% - 85% Relative humidity, non-condensing
Test Kit	15°C - 27°C (59°F - 80°F)

Appendix B 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 unadulterated samples.

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

- 5,5-Diphenylhydantoin (phenytoin), 100 µg/mL
- Acetominophen, 500 µg/mL
- Acetylsalicylic Acid, 599 µg/mL
- Aluminum, 10 µg/mL
- Amoxicillin, 100 µg/mL
- Amphotericin, 50 µg/mL
- Arsenic III, 0.01 µg/mL
- Arsenic V, 0.005 µg/mL
- Ascorbic Acid, 100 µg/mL
- Cadmium, 0.05 µg/mL
- Carbamazepine, 100 µg/mL
- Carboplatin, 0.5 µg/mL
- Cephalexin (Keflex), 120 µg/mL
- Ciprofloxacin, 100 µg/mL
- Clondine, 100 µg/mL
- Copper, 2 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, 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
- Methotrexate, 250 µg/mL
- Methyl Phenidate (Ritalin) HCl,100 µg/mL
- Metronidazole, 50 µg/mL
- Naproxen sodium, 500 µg/mL
- Niacin, 100 µg/mL
- Nicotine, 5 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, 6 µg/mL
- Rifampicin, 100 µg/mL
- Salicylic acid, 600 µg/mL
- Sitagliptin, 50 µg/mL
- Succimer (Dimercaptosuccinic acid),100 µg/mL
- Sulfamethoxazole, 400 µg/mL
- Thiamine, 20 µg/mL
- Trimethoprim, 100 µg/mL
- Uric Acid, 100 µg/mL
- Valproic Acid, Na salt, 500 µg/mL
- Vitamin D3, 100 µg/mL
- Wafarin (Coumadin), 100 µg/mL
- Zinc, 10 µg/mL

This page intentionally left blank.

Appendix C Safety Data Sheets (SDS)

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