LeadCare Ultra®

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 Ultra Blood Lead Testing System 70-8040

P/N 70-7837 Rev 13 (10/2025)

Table of Contents

1 Important Safety Information

2 About this User's Guide

3 System Overview

4   Calibration and Quality Control Setup

5   Performing Quality Control

6   Performing Blood Lead Testing

7 Troubleshooting

8 Performing Other Tasks

9 Maintaining Test Results

10 Maintenance

11 Reordering Information

12 Technical Service Information

13 Returns

14 LeadCare Ultra Blood Lead Testing System Limited Warranty

Appendix A Specifications, Specimen and Operating Requirements

Appendix B   Setup Guide

Appendix C   Safety Data Sheets (MSDS)

Figures

Chapter 6

Chapter 8

Chapter 9

Appendix B

Tables

1   Important Safety Information

This chapter provides important safety information you need to know about using the LeadCare Ultra® 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 Ultra 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 Ultra 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 Ultra 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 Ultra 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 Ultra 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 Files

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 backed up to the appropriate media. This practice will enable you to retrieve and restore data to the LeadCare Ultra System, if necessary. See instructions in Chapter 9 for details.

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.

2   About this User's Guide

This User's Guide is designed to instruct laboratory personnel on the proper and safe use of the LeadCare Ultra® 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 Ultra Blood Lead Testing System is designed to quantitatively measure the amount of lead in a capillary whole blood sample. The LeadCare Ultra Blood Lead Testing System is intended for *in vitro* (external) use only. The test kit components are designed for use with both the LeadCare Ultra and LeadCare Plus ® 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 Ultra 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 Ultra 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 Ultra Blood Lead Testing System:
- LeadCare Ultra Blood Lead Testing System Package Insert (English) – Part Number 70-8091

2.4 User Assistance

Should you experience any difficulty installing or operating your LeadCare Ultra Blood Lead Testing System, please contact your Magellan Diagnostics, Inc. representative. The Troubleshooting chapter in this manual (Chapter 7) includes a list of potential system problems, possible causes, and corrective actions. Read this 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
UA	LeadCare Ultra User Application Software
LIMS	Laboratory Information Management System
QC	Quality Control
BLL	Blood Lead Level
HCl	Hydrochloric acid
LIS	Laboratory Information System

2.6 Compliance Statements

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

2.6.1 Electromagnetic Compatibility (EMC)

Complies with:
EMC Directive 89/336/EEC EMC Standard EN 61326, FCC Part 15 Subpart B Class B.

2.6.2 Safety

Complies with:

Low Voltage Directive 73/23/EEC, EN61010-1:2001 (EU) UL61010-1:2004 (USA) CSA C22.2 No. 61010-1:2004 (Canada) 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 Ultra to the applicable safety standards.

2.6.3 FCC

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.

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 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.

2.6.5 Part 11 Compliance

The LeadCare Ultra system has been developed to be in compliance with applicable sections of the FDA Electronic Records; Electronic Signatures regulations 21 CFR Part 11. In complying with this regulation, the LeadCare Ultra User Application is designed so that editing of patient results cannot occur. Once a blood lead test has been completed and results obtained on the software, editing functions are restricted to:

- Adding a comment to a result

NOTE:	Currently there is no "audit trail" function associated with patient results data.

User-entered comments and the patient sample type are information provided for reference only and are excluded from the LeadCare Ultra 21 CFR Part 11 compliance.

For electronic signatures the Ultra software uses a combination process of user name and password. User account controls are used to maintain the integrity of each User's account credentials. As part of

this, Administrator and Operator Users of the LeadCare Ultra User Application will be notified that their password is no longer current in instances where:
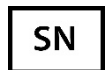
- Their password has expired
- Their password has been changed by the LeadCare Ultra Account Manager

This notification will be provided securely upon entry of the old password. In the case of an expired password, the User will be provided with the opportunity to enter a new password in a secure manner.

The LeadCare Ultra system is intended to be used with LIMS or other third party software for blood lead test result data handling. Magellan Diagnostics' responsibility for compliance with 21 CFR Part 11 compliance ends upon the transfer of results data to the End User's computer network.

2.6.6 Symbols

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

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

This page intentionally left blank.

3 System Overview

3.1 Introduction

This chapter describes the operation and major components of the LeadCare Ultra® Blood Lead Testing System. Major components include the analyzer, monitor and computer with dedicated User Application (UA) software, barcode scanner, keyboard, and test kit. The LeadCare Ultra Blood Lead Testing System is designed to quantitatively measure the amount of lead in a capillary whole blood sample. The LeadCare Ultra Blood Lead Testing System is intended for *in vitro* (external) use only. The test kit components are designed for use with both the LeadCare Ultra and LeadCare® Plus™ Blood Lead Testing Systems.

The LeadCare Ultra System features include:
- User-friendly LeadCare Ultra User Application software.
- Barcode scanner and keyboard for data entry.
- Six channels, allowing you to run six blood lead tests simultaneously.
- Data management system that maintains test records for archiving and uploading to LIS.

NOTE: Power down the LeadCare Ultra System before relocating or moving. Failure to do so could damage the system.

3.2 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.

3.3 How the LeadCare Ultra System Works

The LeadCare Ultra 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).

3.4   System Components

The LeadCare Ultra Blood Lead Testing System is a fully integrated, multi-component sytem. A Magellan Diagnostic, Inc. representative will install your system, assist in setting up User accounts, and provide general on-site user training.

The LeadCare Ultra Blood Lead Testing System is shipped with the following components (see Figure 3-1).

Figure 3-1: Major Components of the LeadCare Ultra Blood Testing System

3.4.1 Analyzer

The six-channel LeadCare Ultra Analyzer performs up to six blood lead tests simultaneously and uploads the completed test results to the computer. Test results are stored in the computer in unique sample records, along with Sample ID, Comments, Test Conditions, Sensor Lot #, and User ID. The analyzer is also equipped with a calibration button reader. This reader allows for the download of all calibration information, analytical test parameters, and date code information for any given sensor lot. These actions can be accomplished by simply touching the appropriate calibration button to the reader.

3.4.2 Flat Screen Monitor

The dedicated UA (User Application) software displays an easy to use operating environment on a flat screen monitor. The monitor sits in back of the analyzer so that the six sensor channels on the analyzer align with the six sensor channels depicted on the monitor screen. This layout allows you to see a direct correlation between instructions on the screen and the individual sensor channels.

3.4.3 Computer

The system's computer is dedicated to running ONLY blood lead analyses, and sits on a stand directly behind the monitor. The computer serves as the user interface for entering patient ID information. It also performs data analysis after blood lead measurements are processed by the firmware embedded in the analyzer. The computer stores the patient results allowing for retrieval at a later date and time. The computer also allows connectivity via USB ports to a customer-supplied printer and LIS.

NOTE: Power down the LeadCare Ultra System before relocating or moving. Failure to do so could damage the system.

3.4.4 Barcode Scanner

The barcode scanner is designed as the primary method for entering Sample ID information automatically without manual keying of data. For initialization instructions, please refer to Appendix B Setup Guide.

3.4.5 Keyboard

A keyboard allows you to log in to the system, enter sample information, and type comments about a particular sample.

3.4.6 Test Kit

The LeadCare Ultra Test Kit contains the supplies (treatment reagent, sensors, control material and a calibration button) and instructions for use, required to perform 192 blood lead tests. The complimentary test kit allows the lab to perform validation studies. Figure 3-2 and Table 3-1 illustrate and describe the contents of a test kit.

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 Ultra 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 amount 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.

3.4.7 User Application (UA) Software

The User Application (UA) software is a Microsoft Windows-based application dedicated to blood lead testing. Figure 3-3 shows the Main UA screen, and Table 3-2 identifies and describes the major software menus and options.
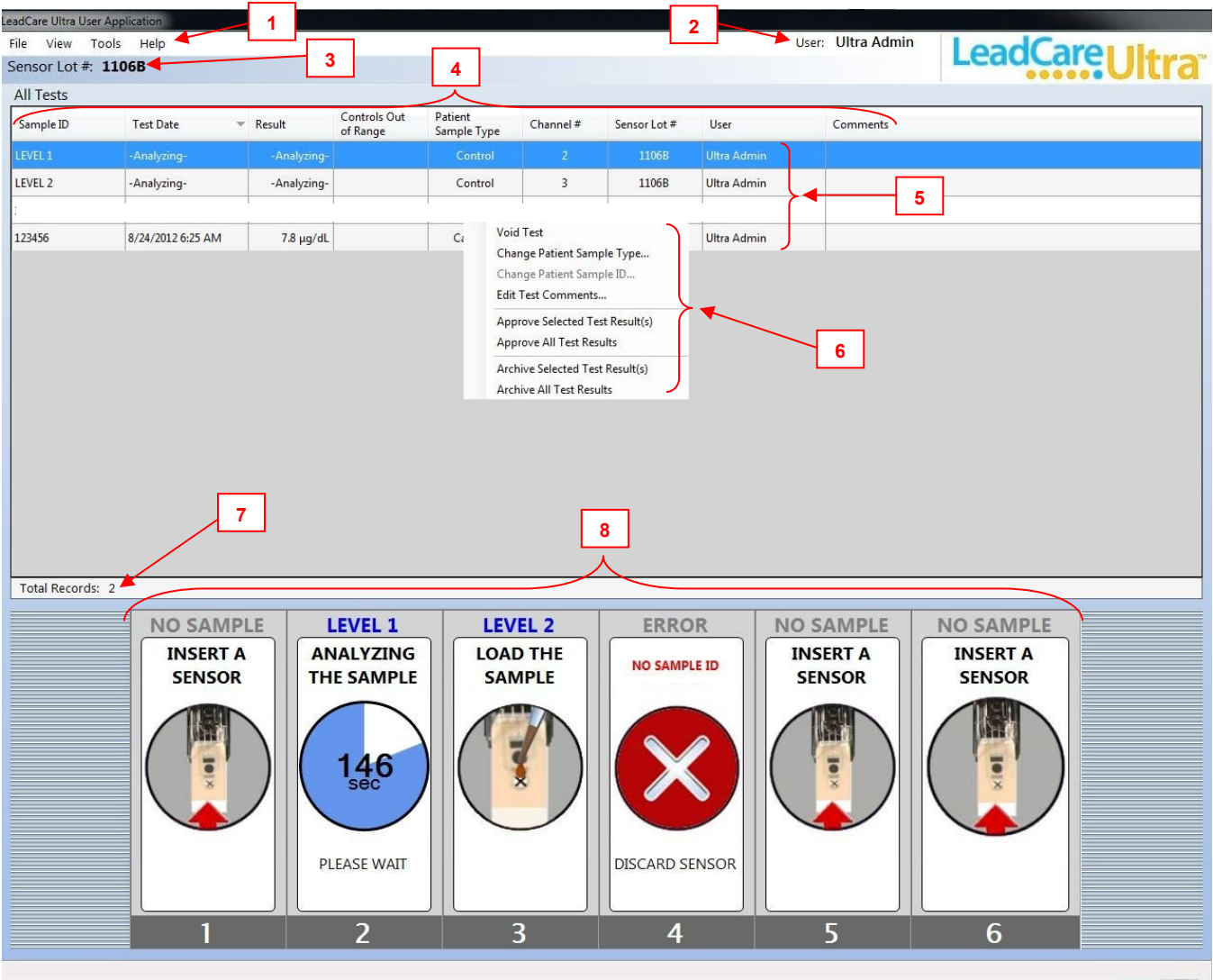
Figure 3-3: LeadCare Ultra UA Software Screen

Table 3-2: Main UA Screen Components

	Name	Description
1	Menu Bar	Use the menu bar to access LeadCare Ultra System functions. The top-level menu includes these options: File, View, Tools, and Help. See Table 3-3 for descriptions of all menu functionality.
2	User	The person currently logged into the system.
3	Sensor Lot #	Indicates the current lot of sensors in use, as determined during calibration.
4	All Tests Menu Bar	Displays column headers of; Sample ID, Test Date, Result, Controls Out of Range, Patient Sample Type, Channel #, Sensor Lot #, User, and Comments. In addition, allows the user to "sort" by any of these options.
5	All Tests List	Displays all test results that have not been approved or archived.
6	Result Options Menu	Activated by right-clicking on a sample record in the data table on the main UA screen. Options allow you to Void a Test, Change Patient Sample Type, Edit Test Comments, and Approve/Archive Selected or All Test Results.
7	Total Records	Displays the total number of unapproved test results.
8	Sensor Channels	Represents the six channels where testing takes place.

NOTE: The UA functions are operable when the power to the analyzer is turned off. However, power to the analyzer must be on to perform blood lead testing.

Table 3-3: LeadCare Ultra Main Screen Major Elements

Menu	Option	Description
File	Backup Records	Lets you backup test records to a CD/DVD media via a standard Windows dialog box. (see Section 9.1.1) (Admin only)
	Restore Records	Lets you restore (copy) test results stored on a CD/DVD media via a standard Windows dialog box. (see Section 9.1.2) (Admin only)
	Exit	Lets you exit the LeadCare Ultra UA.
View	Unapproved Tests	Displays a dialog box that lets you search for and display unapproved test results; you can search by test date range or by specific values.
	Archived Tests	Displays a dialog box that lets you search for and display archived tests; you can search by test date range or by specified values (see Section 6.7.1.)
	Quality Control Tests	Displays a dialog box that lets you search for and display Quality Control tests; you can search by all QC values, by test date range, or by specified values (see Section 5.8).
	Error History	Displays a dialog box that lets you search for and display error history; you can search by all errors or by specified values (see Section 8.2). (Admin and/or Operator Accessible)
	Calibration History	Displays a dialog box that lets you search for and display calibration records; you can search by all calibration records or by specified values (see Section 8.1). (Admin and/or Operator Accessible)
	User Login History	Displays a dialog box that lets you search for and display User login history; you can search by all User login records or by specified values (see Section 8.3). (Admin and/or Operator Accessible)
Tools	Set the Quality Control Levels	Displays a dialog box that lets you specify QC levels for a particular QC lot code. You can also specify the number of QC levels and the accepted tolerance range in µg/dL. (see Section 4.4)
	Set the Patient Test Limits	Displays a dialog box that lets you specify the number of test limits, a particular limit name, and the accepted tolerance range in µg/dL (see Section 4.5).
	Set the Default Patient Sample Type	Set the default patient sample type to capillary. Select capillary. Do **NOT** use venous samples.
	Set Approved Tests File Type	Displays a dialog box that lets you choose between CSV or XML as a file type (see Section 6.7.2). (Admin only)
	LIS > Settings	Displays a dialog box that lets you Enable the LIS interface, set the TCP Port number, and change OBX-5 message segment format. (see Section 8.5). (Admin only; Users can view settings.)
	LIS > Status	Displays a dialog box that lets you view the status of the connection status, TCP Address, TCP Port and the Queue.

Menu	Option	Description
Help	About LeadCare Ultra	Displays the version numbers of the software and firmware of the analyzer.

3.4.8 Printer

A printer can be connected to the LeadCare Ultra System. See Appendix B for instructions.

4 Calibration and Quality Control Setup

4.1 Introduction

Once the LeadCare Ultra® System has been installed and User accounts have been established, the system is ready for daily use. This chapter describes calibration, entering quality control settings, and setting patient test limits. These steps are required prior to testing.

4.2 How Calibration Works

Each LeadCare Ultra 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. The lot number from the calibration button is then displayed in the upper left-hand corner of the UA.

4.3 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 UA displays a recalibration message.

CAUTION:

- 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 false results.

► Follow These Steps

1. Power on the computer, monitor, and analyzer. The main "Windows" Login Screen will appear (Figure 4-1).

Figure 4-1: The Main "Windows" Login Screen

2. Select your user icon, type in your password, and press Enter. The LeadCare Ultra main screen (Figure 4-2) appears. After 20-30 seconds, the UA initializes the analyzer.
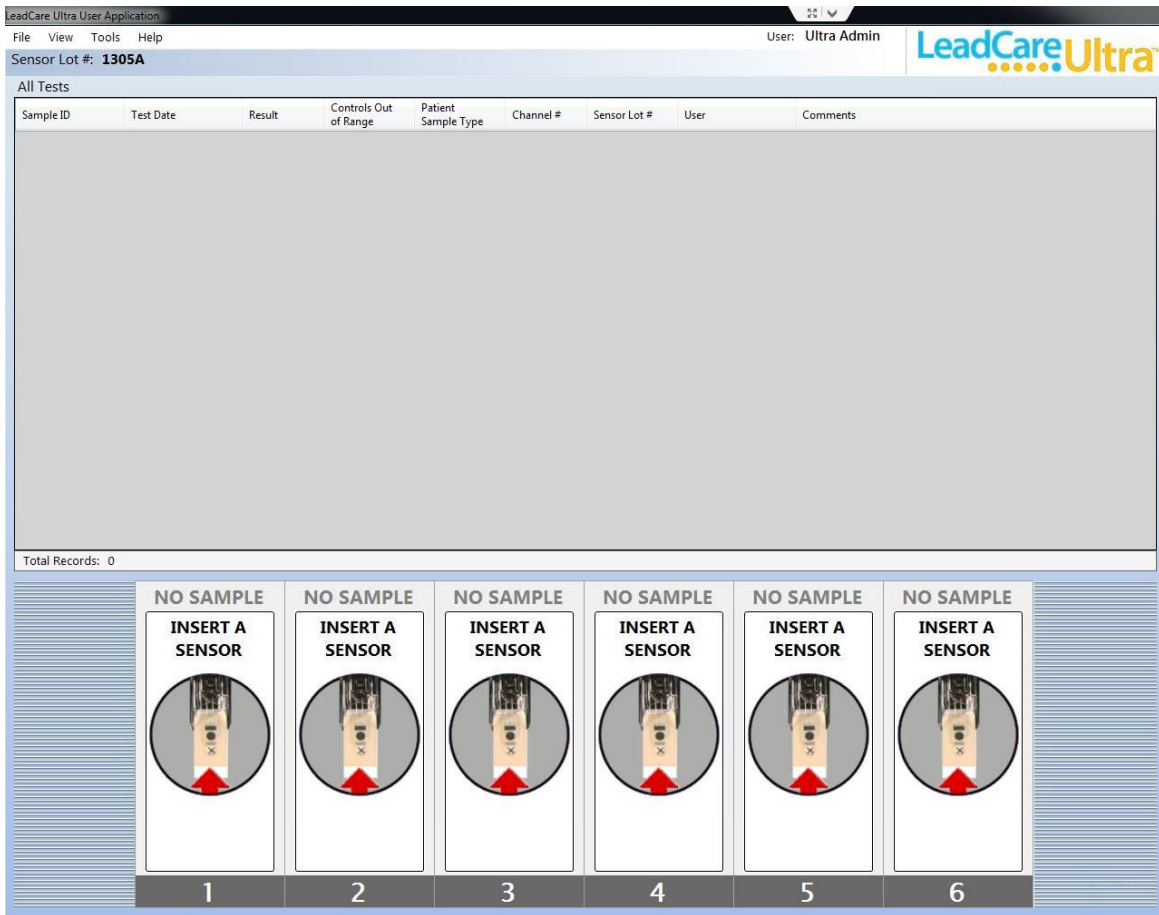
Figure 4-2: LeadCare Ultra UA Main Screen

NOTES: • The first time you turn on the analyzer after installation, the "Calibration Required" dialog box appears:
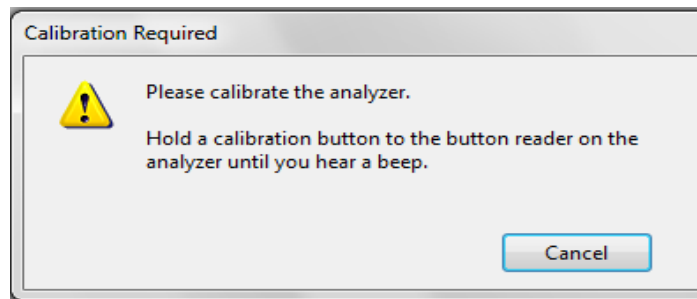
Figure 4-3: Calibration Required Screen

• Once the system has been calibrated, the lot number of the calibration button is displayed in the upper left corner of the main screen (Sensor Lot #).

• If the "Sensor Lot #" displayed does not match the kit lot number you intend to use, you must recalibrate the analyzer with the calibration button from the kit lot you intend to use.

3. Remove the calibration button from the test kit you are going to use.

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

Figure 4-4: Holding Calibration Button to Button Reader

5. 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 (see Figure 4-5).

The analyzer is calibrated for
sensor lot #: 1305A
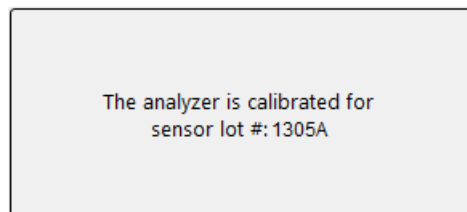
Figure 4-5: Successful Calibration Message

The Sensor Lot #: appears in the upper left corner of the main screen (see Figure 4-6).

LeadCare Ultra User Application
File   View   Tools   Help
Sensor Lot #: **1305A**

Figure 4-6: Sensor Lot #

6. Once the calibration is successful, the "Quality Control Settings" dialog box displays. See Section 4.4, Entering Quality Control Settings, to proceed.

4.4 Entering Quality Control Settings
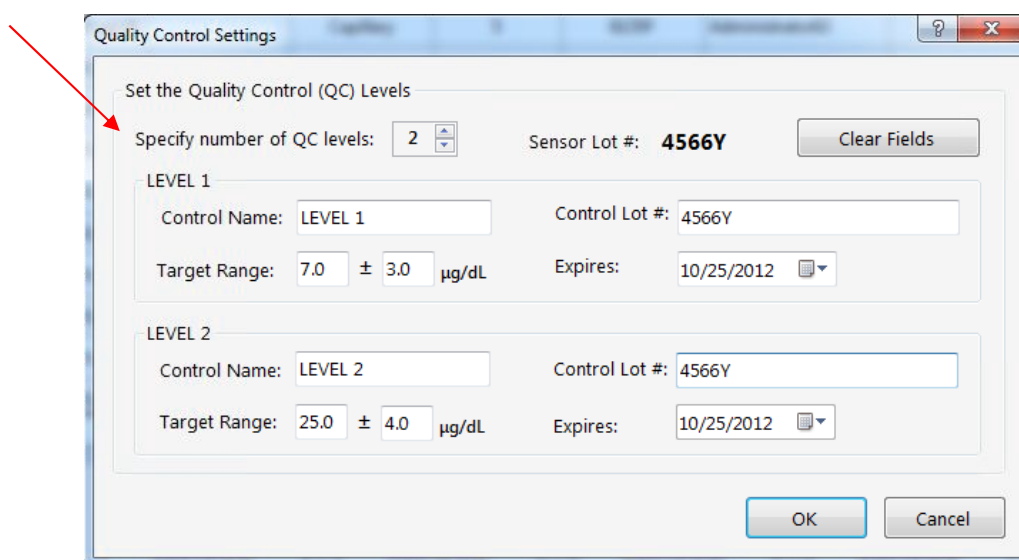
Quality control information can be entered anytime. When calibrating the analyzer with a new button, the "Quality Control Settings" dialog box opens automatically (Figure 4-7).

If the QC lot has expired, the associated expiration date in the "Quality Control Settings" dialog box will turn red, flagging you to update the QC information.

NOTE: At any other time, to access the Quality Control Settings, click **Tools** > **Set the QC Levels** from the UA.

► **Follow These Steps**

1. Using the arrows, select the desired number of QC levels. You have the ability to enter up to three levels of quality control.

Figure 4-7: New QC Lot Dialog Box

2. Enter the information for the new QC lot in the appropriate box:

   a. Control Name: Defaults to "LEVEL 1, LEVEL 2", etc., for each level. To rename, delete the default name and enter the new name in the field.

   b. Control Lot #: Enter the lot number in the field.

   c. Target Range: Enter the **target value** in the first field and the **tolerance** in the second field. For example, a control with a target value of 7.0 ± 3.0 is entered as shown in Figure 4-8.

Figure 4-8: New QC Lot Dialog Box

     d. Expires: Enter the expiration date of the control in the field by updating the month, day, and year (for example, 4/23/2017), or click on the down arrow to the right of the field to use the calendar feature.

3. Repeat this process for each control level.

NOTE: The Target and Tolerance values for each successive level must be higher than those set for the lowest level, and the ranges set for each level should not overlap.

NOTE: The Target and/or Tolerance values can be changed without creating a new QC lot code. However, this change affects the QC charts for the QC levels. For example, if the target and/or tolerance values are changed, the QC results before and after the change will be on separate QC charts.

NOTE: The Target or Tolerance values for a QC lot may be slightly different for other sensor lots.

If target and/or tolerance values are to be changed while keeping the same QC Lot #:

    a. Select **Tools > Set Quality Control Levels**.

    b. Add a letter to the original Control Lot #. For instance, if the original Control Lot # was 031507, type in 031507A. Then change the target and/or tolerance values (see Figures 4-9 & 4-10).

Figure 4-9: Editing Original Control Lot Target Values

Figure 4-10: Entering New Target Values

4. Once all Quality Control Settings fields are updated, click the **OK** button.

5. The "Confirm Quality Control Level Information" dialog box appears (Figure 4-11). Review the information and select **Yes** if the information is correct. If the information is not correct, select **No**. This returns you to the "Quality Control Settings" dialog box to make the necessary corrections.

6. The LeadCare Ultra Blood Lead Testing System is now ready for testing (see Figure 4-12).
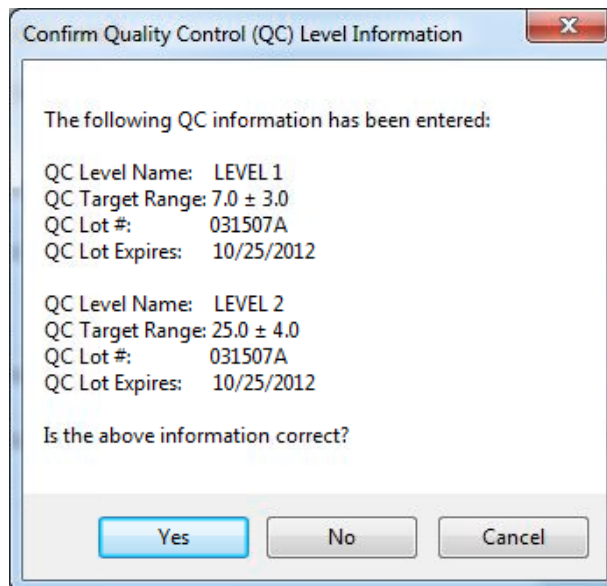
Figure 4-11: Confirm Quality Control Level Information Dialog Box
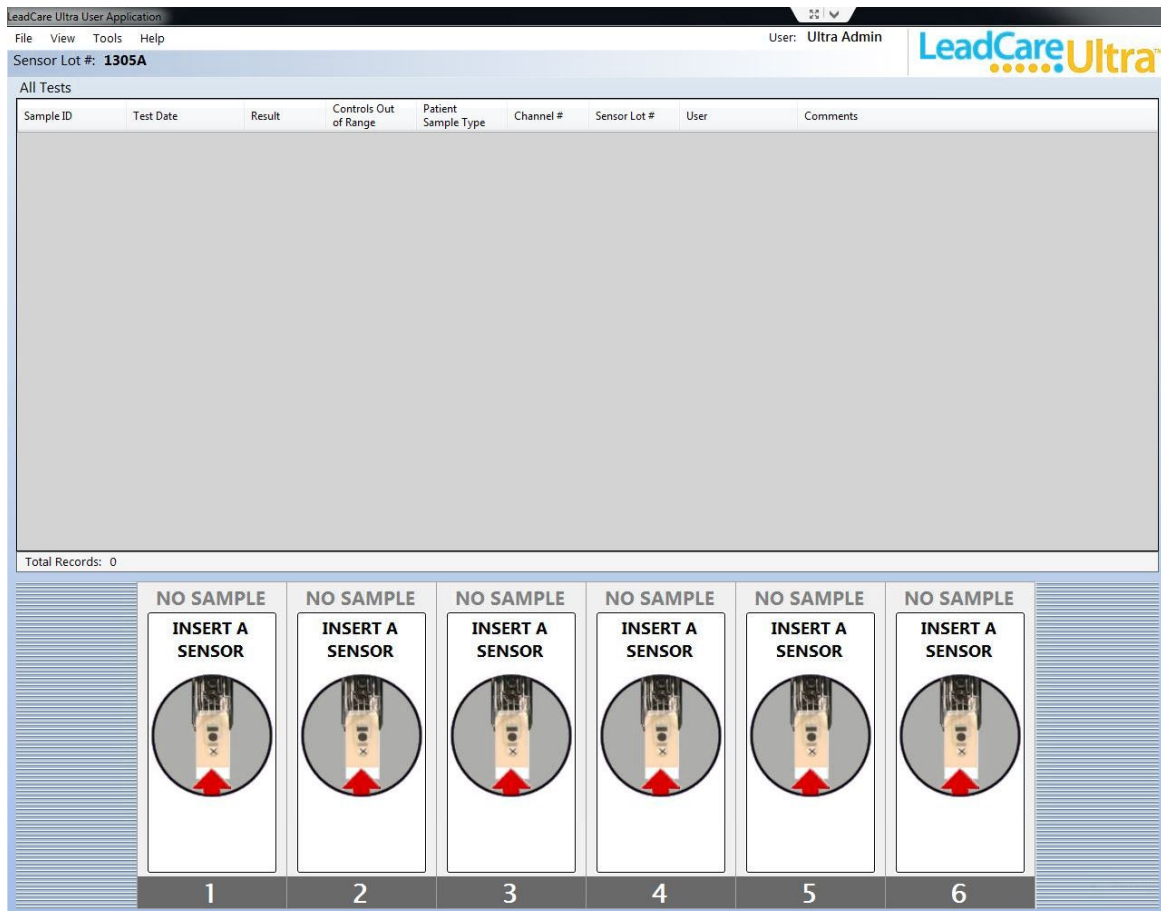
Figure 4-12: LeadCare Ultra UA Ready for Sensors

4.5   Setting a Patient Test Limit (optional)

The Set Patient Test Limit option allows you to flag a patient result that is above a user-specified level. Each laboratory should establish its own limits according to its Standard Operating Procedure (SOP).

> **NOTE:**   Limits do NOT have to be set to run the LeadCare Ultra Blood Lead Testing System.

► **Follow These Steps**

1. Click **Tools** > **Set the Patient Test Limits**. The "Patient Test Limits" dialog box displays (Figure 4-13).

2. Specify the number of test limits to be set (up to three).

3. For each limit to be set, enter the name of the limit, the target lead concentration, and instructions to be displayed in the comment field when the limit is exceeded. If you are adding multiple target values, each successive target value must be larger than the previous target value.

> **NOTE:**   Only one instruction per test result displays.

4. Click the **OK** button when done.
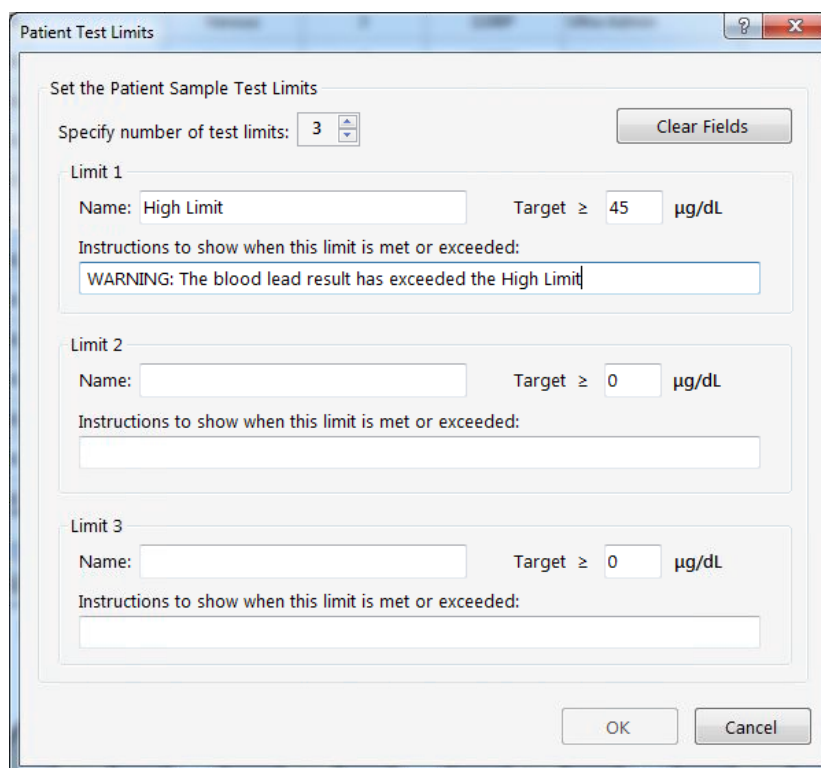
Figure 4-13: Patient Test Limits Dialog Box

5. The "Confirm Patient Test Limit Information" dialog box appears (Figure 4-14).
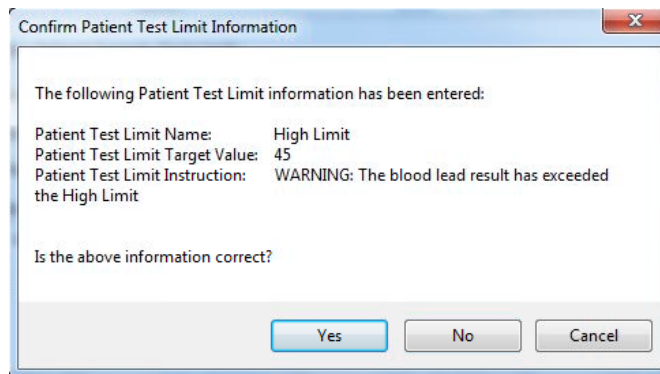
Figure 4-14: Confirm Patient Test Limit Dialog Box

6. Review the information and select **Yes** if the information is correct. If the information is not correct, select **No**. This returns you to the "Patient Test Limits" dialog box to make the necessary corrections.

NOTE: If a blood lead result exceeds a limit entered, the typed instructions appear in the Comment field of the sample record on the main screen.

5 Performing Quality Control

5.1 Introduction

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

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

5.2 What are Blood Lead Controls?

A control is a standard against which test results can be evaluated. The LeadCare Ultra 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 Ultra Control samples.

Acceptable ranges for each lot and lead level are established by Magellan Diagnostics using the LeadCare Ultra 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 Ultra 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.

5.3　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.

5.4　Safety Precautions

You must understand and follow these precautions when performing QC testing using the LeadCare Ultra 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 "Load the Sample" message appears in the channel box.
- 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 7) of this User's Guide, or call Product Support at 800-275-0102 to help you resolve the problem.

5.5 Storing and Handling the Controls

Store LeadCare Ultra 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.

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

5.6 Control Procedure

Use this procedure to perform a QC test to help ensure accurate blood lead testing results.

The LeadCare Ultra 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: To enter QC target values, see Section 4.4.

NOTE: If you are using control material not included with the LeadCare Ultra 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 gauze pad. 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 7) for the **Level 2 Control**.

7. Analyze both control samples according to the instructions provided in Chapter 6 (Step D: Analyze the Sample) on page 6-8.

NOTE:	Prior to testing, the LeadCare Ultra Level 1 and Level 2 Controls must be mixed with treatment reagent (50 µL of control into a fresh treatment reagent tube). Quality control samples can be prepared and analyzed immediately, or prepared with patient samples.

5.7 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 Ultra System is working properly.

If the reported control results are not within the listed range, refer to the Troubleshooting section in Chapter 7 of this guide or call Magellan Diagnostics Product Support at 800-275-0102.

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

5.8 Viewing Quality Control Test Records

The Quality Control Tests option displays a dialog box in which you can enter search criteria to search for and display all, or specific, quality control test records. It also contains an option that lets you view quality control charts, which provides a useful graphic of the selected QC data.

► **Follow These Steps**

1. To display quality control test records, click **View** > **Quality Control Tests**. The "Quality Control Test View" dialog box opens (Figure 5-1).

Figure 5-1: Quality Control Test View Dialog Box

2. Use the mouse to select one of the following search (filter) criteria:

   a. Show all tests

   b. Filter records by specified values

3. If you selected "Filter records by specified values" you can further refine your search by:

   a. QC Level

   b. QC Lot #

   c. Test Date Range

   d. Result Range

   e. Controls Out of Range

   f. Channel #

   g. Sensor Lot #

   h. User

   i. Comments

4. Enter your search criteria and select the **Apply Filter** button.

5. Select the **View Report** button in the lower right corner.

6. The "Custom Report Header Information" screen opens (Figure 5-2).

Figure 5-2: Custom Report Header Information Screen

7. Enter the desired report headers (Lines 2 and 3 are provided for multi-part headers), and click **Done**.

8. Based on the search criteria, the quality control test results are filtered and those results that meet your search criteria are displayed. A sample "QC Test Report" is shown below in Figure 5-3.

Figure 5-3: Sample Quality Control Test Report

9. The **Binoculars** icon in the menu bar allows you to search the report for specific text.

10. The **Zoom** icon in the menu bar allows you to increase the font size of the report.

11. To print the report, click the **Print** icon in the menu bar, and then enter the desired print parameters in the standard Windows "Print" dialog box that appears.

5.8.1 Displaying Quality Control Charts

Quality control charts allow you to view each result in comparison to the target value for any given lot number.

► Follow These Steps

1. To display quality control charts, click **View** > **Quality Control Tests**. The "Quality Control Test View" dialog box displays as shown in Figure 5-1.

2. Use filters to choose which QC results to view as described in Section 5.8, (steps 2-4); then, click the **View Charts** button to generate graphs of the selected QC data.

3. In the "Quality Control Chart Viewer", a separate chart is created for each control level and sensor lot (see Figure 5-4). The description for each chart generated appears in a column on the left-hand side of the display. The chart displayed to the right corresponds to the highlighted chart description.
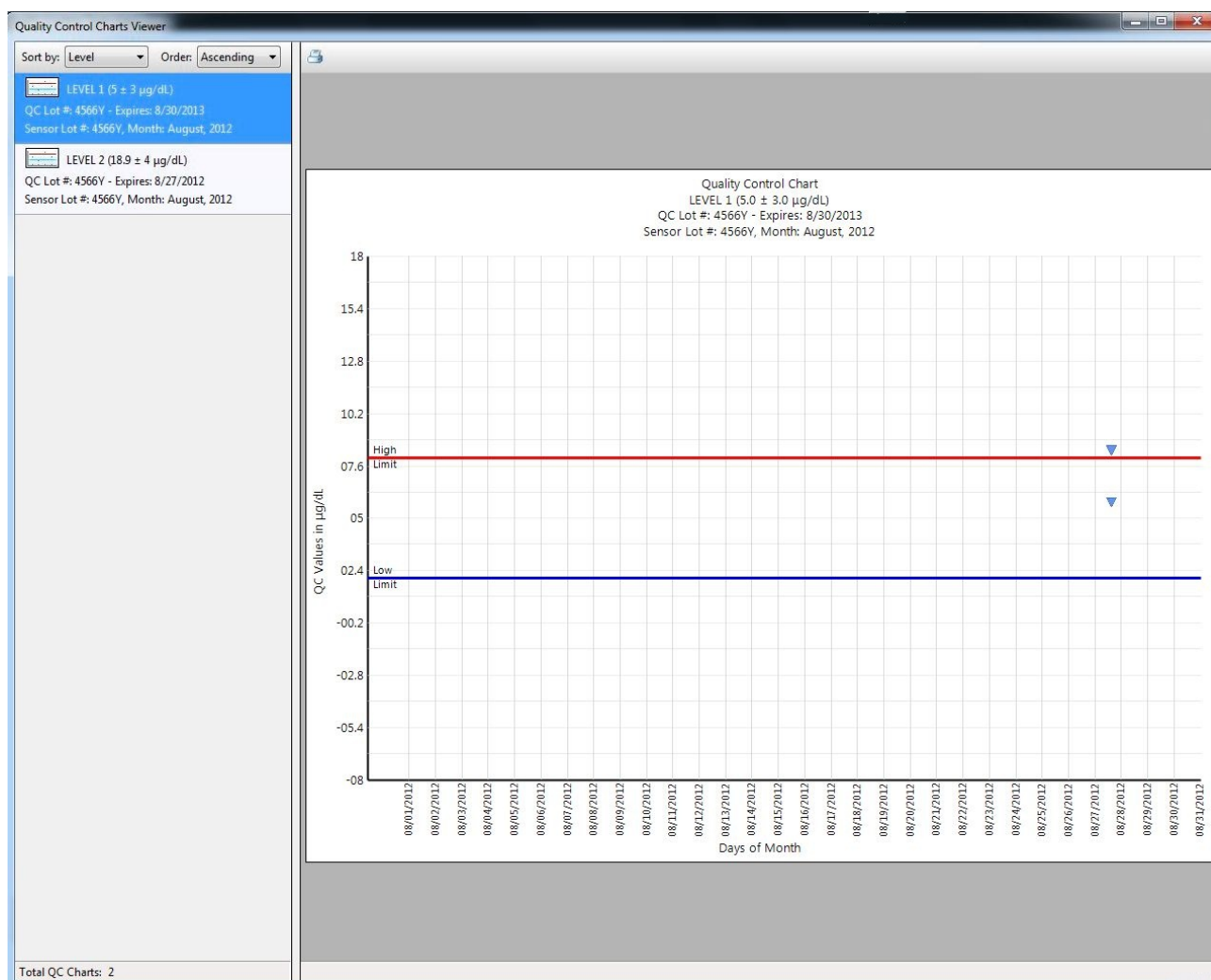
Figure 5-4: Quality Control Charts

4. To view a different chart, click on the chart description in the left column.

5. The "Sort by:" feature in the upper left corner allows you to sort the charts by:

    a. Level

    b. Lot Code (should be "QC Lot #")

    c. Sensor Lot

    d. Month/Year

6. The "Order:" feature sorts the charts in ascending or descending order.

7. To print a quality control chart, click the **Printer** icon above the displayed chart, then enter the desired print parameters in the standard Windows "Print" dialog box that appears.

6 Performing Blood Lead Testing

6.1 Introduction

When your LeadCare Ultra® Blood Lead Testing System has been installed, calibrated, and had 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
- Required Materials
- Testing Procedure
- Processing Blood Lead Test Results
- Viewing and Printing Blood Lead Test Results
- State Reporting of Blood Lead Test Results
- Follow-up Testing

⚠️ **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.

6.2 Specimen Requirements

Capillary whole blood samples must be collected with an acceptable anticoagulant and stored properly before testing.

6.2.1 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 Ultra Blood Lead Testing System in accordance with their laboratory policies and procedures.**

6.2.2 Collection and Storage Conditions

Capillary blood samples must be collected and stored properly in order for lead testing to be performed. **Refer to the LeadCare Ultra Blood Lead Test Kit Package Insert for detailed requirements.**

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 tube must be at least half full** for the sample to be appropriate for use. EDTA in high concentrations can lower the blood lead value. Reject any sample less than half full.
- 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.

6.3   Limitations of the Test

- **The end user must validate the use of micro collection devices with the LeadCare Ultra Blood Lead Testing System in accordance with their laboratory policies and procedures.**
- Use only 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. 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.
- Refer to the LeadCare Ultra Test Kit Package Insert for detailed instructions on sample storage and analysis.

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 Ultra System outside of this range is not recommended.
- Use the LeadCare Ultra System above altitudes of 8,000 feet has not been validated and is therefore not recommended.
- Do **NOT** use the LeadCare Ultra System in drafts. This could lead to inaccurate results.
- Keep the LeadCare Ultra 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 7).
- Allow all of the LeadCare Ultra System components to reach a steady temperature before using.
- Use the sensors and the treatment reagent tubes, only once. Do **NOT** reuse. Reuse could lead to erroneous results.
- Do **NOT** use damaged (bent, scratched, cut, etc.) sensors.

6.4   Overview of the Testing Procedure

Testing for lead in blood with the LeadCare Ultra Blood Lead Testing System consists of the following steps. See Section 6.7 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. When EDTA capillary blood collection devices are used for sample collection, **the tube must be at least half full** for the sample to be appropriate for use. EDTA in high concentrations can lower the blood lead value. Reject any sample less than half full.
4. Add 50 µL of a blood sample to a labeled treatment reagent tube, recap, and mix thoroughly. The sample preparation will turn brown.
5. Match the sensor vial lot number with the displayed lot number and insert a sensor into the analyzer.
6. Enter the Sample ID, either using the barcode scanner or by typing the entry on the keyboard.
7. Remix the tube contents by inverting the tube before sampling. Draw 30 µL of the sample mixture with a pipette from the treatment reagent tube and dispense on the (X) on the sensor.
8. The analyzer starts the 3-minute analysis automatically. Test results are displayed both in the appropriate channel box and in the data table field on the LeadCare Ultra UA main screen. Results are also saved to the hard drive along with all other pertinent Sample ID data, Analysis Comments, Operator ID, and Date and Time.

6.5   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 Chapter 1, Important Safety Information.

6.5.1 General Precautions

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

WARNINGS:

- Dispose of sensors, pipette tips, and other materials exposed to human blood in a biohazard container.

- Use caution when handling the LeadCare Ultra Treatment Reagent. The 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 Ultra Treatment Reagent Safety Data Sheet that appears in Appendix C of this manual.

CAUTIONS:

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

6.5.2 Precautions when Preparing Patient Samples

You must understand and follow these precautions when preparing blood samples to be tested using the LeadCare Ultra 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 Ultra 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 Ultra 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 the LeadCare Ultra Blood Lead Test Kit Package Insert.

6.5.3 Precautions when Testing a Patient Sample

You must understand and follow these precautions when using the LeadCare Ultra 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. Exposing the sensors to humidity for an extended period of time could lead to a false 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 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 sample or remove the sample/reagent solution. The tube and its contents could be contaminated, causing false test results.

- Before placing the sample on the sensor, make sure the "Load the Sample" message appears in the channel box.

- 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.

6.6   Required Materials

Have the following materials gathered before starting a blood lead test:

- Protective gloves (powder-free)
- Absorbent liner and biohazard waste container
- LeadCare Ultra System
- LeadCare Ultra User's Guide
- LeadCare Ultra Test Kit items
  - Treatment reagent tubes
  - Blood lead sensors
  - Calibration button
  - Package Insert
  - Two quality control samples

6.7   Testing Procedure

Perform a blood lead test by following Steps A-D, below.

6.7.1 Step A: Gather Test Materials

► Follow These Steps

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

   - LeadCare Ultra Blood Lead Testing System
   - LeadCare Ultra 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 (61°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 Ultra Blood Lead Test Kit items all come from the same test kit. Do NOT mix items from different test kits.

6.7.2 Step B: Prepare the Sample

CAUTION:

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

- Use only capillary whole blood with the LeadCare 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.

- 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.

Please refer to the LeadCare Ultra Test Kit Package Insert for detailed instructions on preparing a sample.

► Follow These Steps

1. Bring the blood samples to room temperature and mix thoroughly.

2. Label a treatment reagent tube with the Sample ID (or barcode label, if applicable).

3. Remove the cap from the tube and place it face up on a clean gauze pad.

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.

6. Repeat steps 1 - 5 for each sample to be tested.

6.7.3 Step C: Turn the System ON

► Follow These Steps

1. Turn ON the analyzer and login to the LeadCare Ultra System.

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

3. Enter Patient Test Limit, if desired. For details, see Section 4.5.

6.7.4 Step D: Analyze the Sample

► Follow These Steps

1. Remove a sensor from one of the sensor vials by grasping the sensor at the end with the alphanumeric designation.

2. Close the vial.
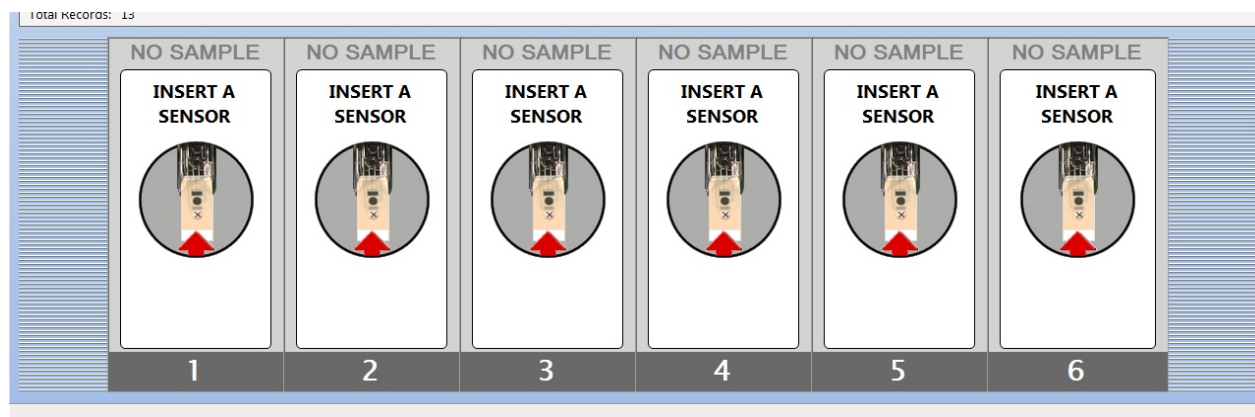
Figure 6-1: UA Ready to Accept Sensors

3. 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 sensor deck. When the sensor is inserted properly, the analyzer beeps and displays the "Scan a Barcode" message shown in Figure 6-2. Insert as many sensors as needed, up to a maximum of six.

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 monitor.
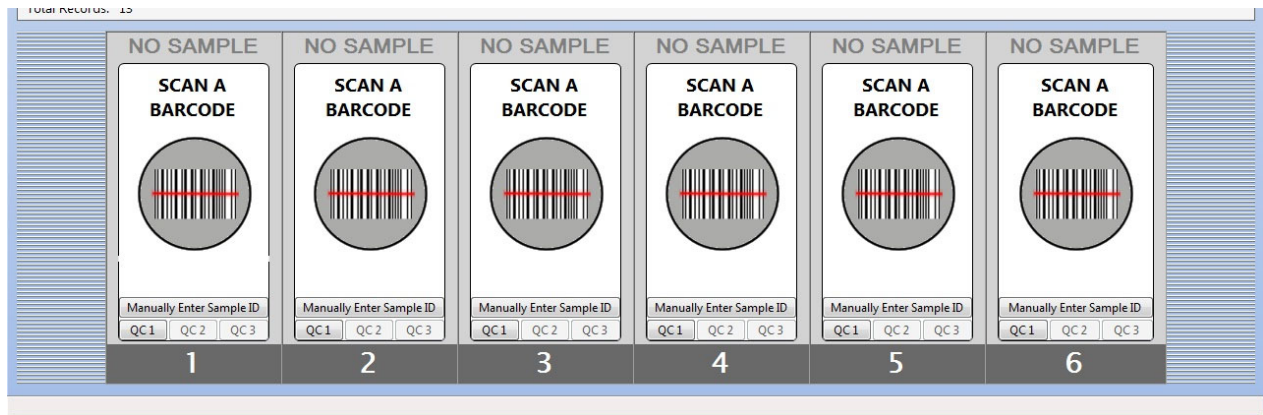
Figure 6-2: UA Waiting for Barcodes

4. Enter a Sample ID, using either the barcode scanner or manual entry mode, for each sample to be tested. When this is completed, you are prompted to add the sample mixture to the sensor; the channel messages change to "Load the Sample" and the Sample ID information you just entered appears at the top of the main screen (see Figure 6-3).

NOTE: Verify that the Sample ID displayed for the channel matches the Sample ID on the treatment reagent/blood preparation.

NOTE: **Editing Sample ID** – You can edit a Sample ID BEFORE the analysis starts and while it is in progress. Once the analysis is complete, the Sample ID cannot be changed. To edit a Sample ID, right click on the Sample ID in the main data table (THIS TABLE IS CALLED "ALL TESTS") of the user screen. Select **Change Patient Sample ID** and type in the new Sample ID in the field "New Sample ID". Click **OK**. The new Sample ID will appear in the Sample ID box of the main data table.

NOTE: **Barcode Scanner Not Connected** – The barcode scanner does not need to be connected to the system in order to use the LeadCare Ultra UA. The UA defaults to manual entry mode when the barcode scanner is not connected. Specifically, if the scanner is not connected when the UA starts, the "BAR CODE READER FAILED" message displays. Click **OK** in response. The UA can then be used to run samples; you enter Sample ID and other information manually via the keypad.

---

5. After assigning the Sample ID, select the Sample Type by clicking on the Capillary radio button.

Figure 6-3: UA Waiting for Samples

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

Figure 6-4: UA Analyzing Samples

7. The system shows a graphic of the analysis countdown as analysis proceeds, from 180 seconds to 0 seconds.

Figure 6-5: UA Analysis Complete

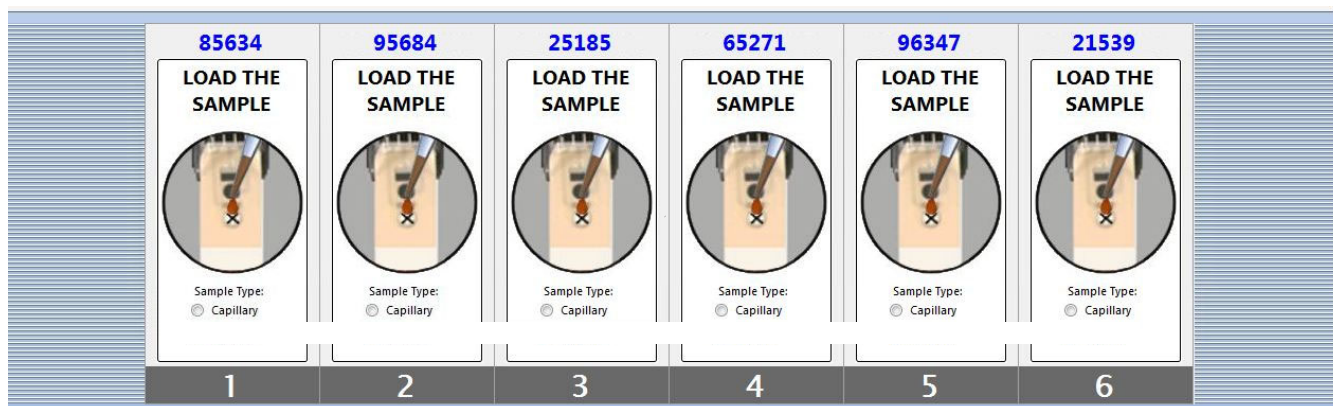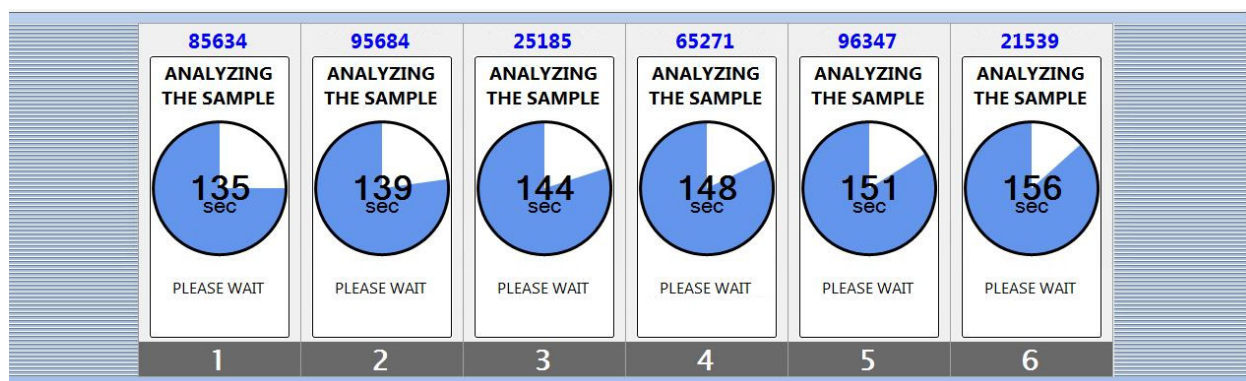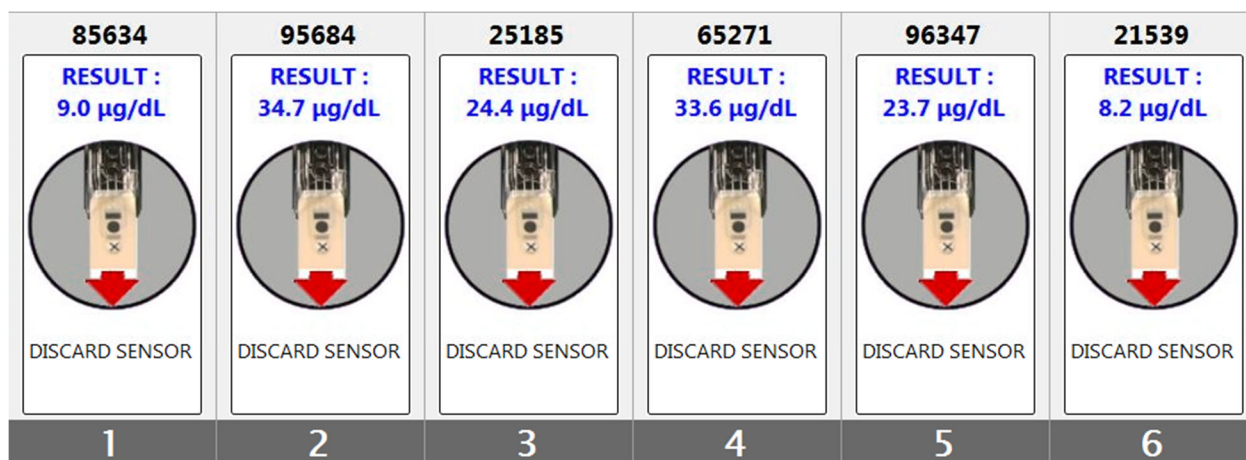8. When analysis is complete, blood lead concentrations display in the channel boxes and in the main data table at the top of the screen. The results are reported in micrograms (µg) of lead (Pb) per deciliter (dL) of whole human blood.

9. Remove the used sensors.

NOTE: **A warning beep will sound if the used sensors are not removed from the analyzer after 20 minutes. The beep will continue to sound until all of the used sensors are removed.**

---

10. Discard the materials in an appropriate biohazard container.

11. Repeat steps 1-10 to analyze additional samples.

12. View the test results. Blood lead levels in the "Results" column appear in the main data table. Results are reported in micrograms (µg) of lead (Pb) per deciliter (dL) of whole human blood. Results are displayed to one decimal place. The reportable range of the LeadCare Ultra is 1.9 µg/dL to 65.0 µg/dL. Results lower than the limit of detection will be displayed as '<1.9'. Results higher than the analytical range will be displayed as '>65'.

13. Process the test results by approving or archiving the data. See Section 6.8, Processing Blood Lead Test Results. All test results remain as "unapproved" until the "approval/archiving" process is performed by the user.

14. See Sections 6.10 and 6.11 for state reporting and follow-up lead testing requirements.

6.8   Processing Blood Lead Test Results

All completed blood lead test results are listed in the main data table in the user screen (see Figure 6-6). These results remain on the main screen until they are either approved or archived. It is recommended that you approve or archive the blood lead results after all samples have been processed for the day. This way, the data table on the main screen can be cleared for the next day's samples.

Results can easily be viewed, sorted, and printed after either approving or archiving. Results remaining in the data table on the main screen can also be sorted and printed.

NOTE: **Sorting Results** – You can sort results in the main data table by clicking on any column header. The default sort for "Results" is run order noted by test date and time in the "Test Date" Column of the main data table.
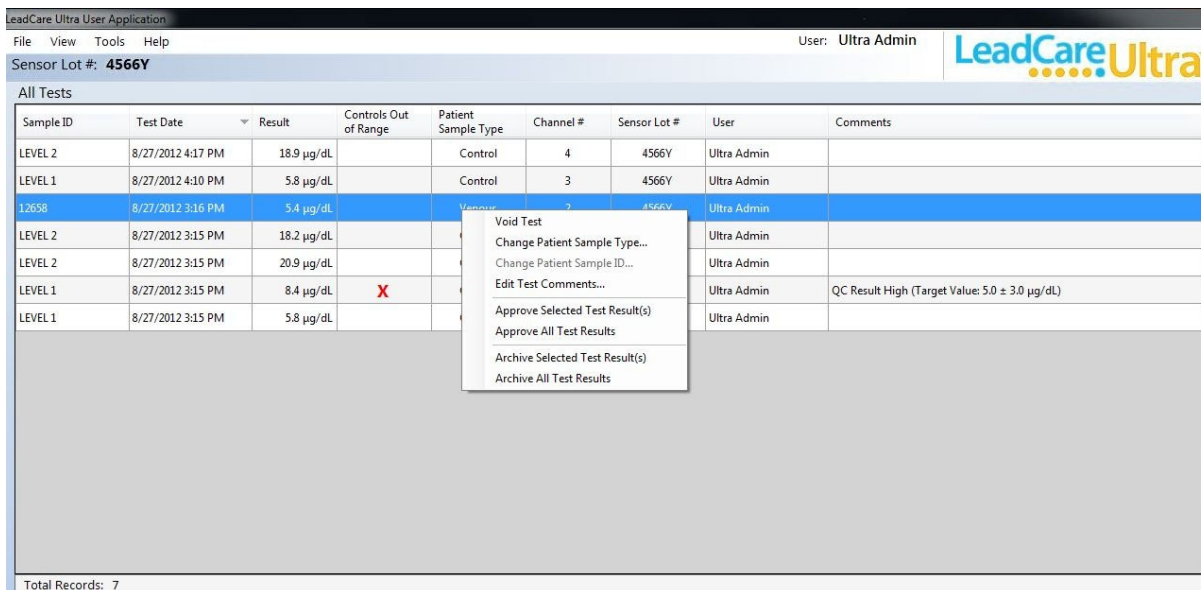
Figure 6-6: Approve & Archive Pop-up Menu

NOTE:	If power to the analyzer is turned OFF, you can still work with all the UA functions except performing new blood lead tests.

6.8.1 Archiving Test Results

Results in the main data table can be archived; whereby they will remain on the LeadCare Ultra Blood Lead Testing System indefinitely. If your LeadCare Ultra Blood Lead Testing System is **NOT** connected to an LIS, follow steps 1 and 2 to archive your results.

Archiving results achieves the following:

1. Clears the results from the main data table (worklist).

2. Places the results in the "Archived Test View", an option available on the **View** menu.

► **Follow These Steps**

1. You can archive all test results or select specific results for archival:

   • To archive all test results, select a test in the main data table and then right click on the desired Sample ID. Select **Archive All Test Results** from the dialog box displayed.

   • To archive selected test results select the test results to be archived by holding down the **Ctrl** key, selecting the desired Sample ID(s) by right clicking on the desired Sample ID(s). Select **Archive Selected Test Result(s)** from the dialog box displayed.

2. The "Confirm Archived Test(s)" dialog box (Figure 6-7) indicates the number of test results selected for archival. Click **OK** to archive the desired test(s). The results are now moved to the Archived Test View.
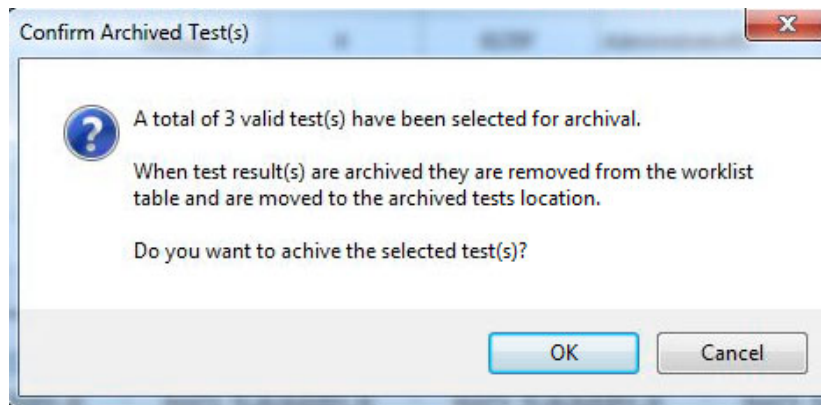
Figure 6-7: Archive Tests Dialog Box

6.8.2 Approving Test Results

Test results can be approved either from the main data table (worklist) or from the "Archived Test View". If your LeadCare Ultra System is connected to an LIS, use the following steps, steps 1-3, to approve your test results and to make the results available for access by the LIS.

► Follow These Steps

1. You can approve all test results or select specific results for approval:

    •   To approve all test results select a test in the main data table and then right click on the desired Sample ID. Select **Approve All Test Results** from the dialog box displayed.

    •   To approve selected test results select the test results to be approved by holding down the **Ctrl** key, selecting the desired Sample ID(s) by right clicking on the desired Sample ID(s). Select **Approve Selected Test Result(s)** from the dialog box displayed.

2. The "Confirm Approved Test(s)" dialog box (Figure 6-8) indicates the number of test results selected for approval. You are reminded that the results will be removed from the worklist; moved to a published location on disk; and a copy of the data is saved in the archived test location.

3. Click **OK** to approve the desired test(s).
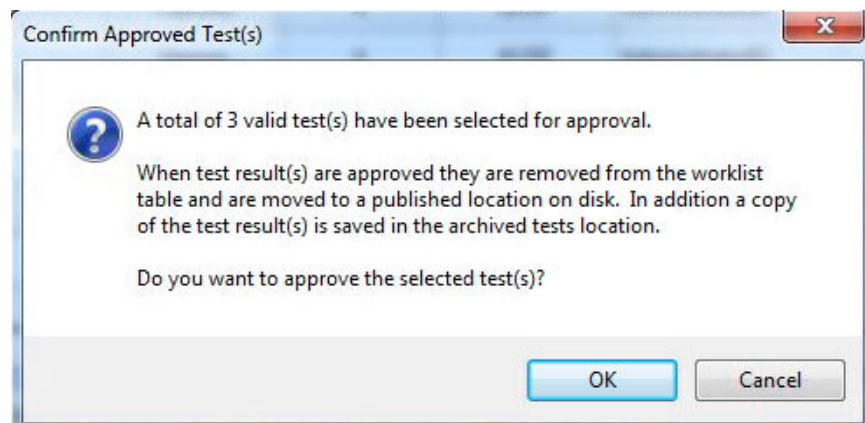
Figure 6-8: Approve Tests Dialog Box

4. To re-send results to the LIS after they have already been approved, go to the archived test view, select the results you want to re-send and right click. Click on "Send Selected Test (s) to LIS," or "Send All Approved Test(s) to LIS" to re-send all previously approved results to the LIS.

6.8.3 Voiding/Unvoiding a Test Result

Test results may be voided or unvoided at any time. To void a test result, right-click on the Sample ID you wish to void in the test data table on the main UA screen, then select **Void Test** from the pop-up menu shown in Figure 6-9.

Figure 6-9: Void Test Pop-Up Menu

To unvoid a voided test result (Admins and/or User Accessible), right-click on the voided Sample ID you wish to unvoid in the main data table, then select **Unvoid Test** from the pop-up (Figure 6-10).

Figure 6-10: Unvoid Test Pop-Up Menu

6.8.4 Editing Test Result Comments

You may edit the "Comments" field for any test result by right-clicking on the desired Sample ID Next, select **Edit Comments** from the pop-up menu shown in Figure 6-11. Click in the "Edit Test Comments" box and type in your new comments as desired. Click **OK to accept**.
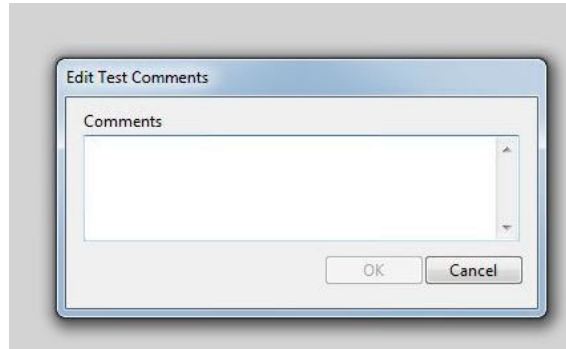
Figure 6-11: Edit Test Comments Box

NOTE: "Edit Test Comments" is also available for QC results.

6.9   Viewing and Printing Blood Lead Test Results

You may view, search, and create reports for archived and approved blood lead test results stored on the computer. If you have a printer connected, you may print reports.

► **Follow These Steps**
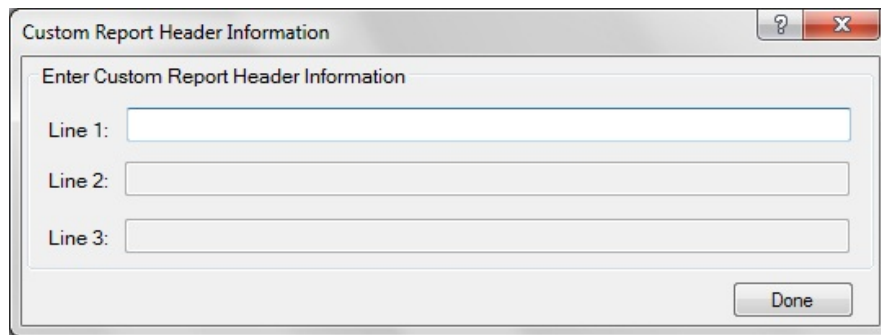
1. To view blood lead test results, click **View** > **Archived Tests**. An "Archived Tests View" viewer displays all blood lead test results stored on the computer (see Figure 6-12).

Sample ID	Test Date	Result	Controls Out of Range	Channel #	Sensor Lot #	User	Date Approved	Approved By	Comments
12658	8/27/2012 3:16 PM	5.4 µg/dL		2	4566Y	Ultra Admin	8/27/2012 5:06 PM	Ultra Admin	
LEVEL 2	8/27/2012 3:15 PM	18.2 µg/dL		6	4566Y	Ultra Admin	8/27/2012 5:06 PM	Ultra Admin	
LEVEL 1	8/27/2012 3:15 PM	5.8 µg/dL		3	4566Y	Ultra Admin	8/27/2012 5:06 PM	Ultra Admin	

Figure 6-12: Archived Test View Dialog Box

2. Use the mouse to select one of the following search (filter) criteria:

    a. Show all tests

    b. Filter tests by specified values

3. If you selected "Filter records by specified values", you can further refine your search by:

    a. Sample ID

    b. Test Date range

    c. Result range

d. Controls Out of Range

e. Channel #

f. Sensor Lot #

g. User

h. Approved

i. Approver

j. Comments

4. Enter your search criteria and select the **Apply Filter** button. The data meeting your search criteria will appear on the right hand side of the "Archived Test View" window.

5. To obtain a report of this data select the **View Report** button in the lower right hand corner of the screen. The "Custom Report Header Information" screen displays (Figure 6-13).

Figure 6-13: Custom Report Header Information Screen

6. Enter the desired report header on line 1 and then click **Done**. (Lines 2 and 3 are provided for multi-part headers). The specified report is displayed. A sample Archived Test Report is shown in Figure 6-14.

Figure 6-14: Archived Test Report

7. The **Binoculars** icon in the menu bar allows you to search the report for specific text.

8. The **Zoom** icon (magnifying glass) in the menu bar allows you to increase the font size of the report.

9. To print the report, click the **Print** icon in the menu bar, and then enter the desired print parameters in the standard Windows "Print" dialog box that appears.

6.10 State Reporting of 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 Product Support at 800-275-0102 or LeadCareSupport@magellandx.com.

6.11 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.

7 Troubleshooting

7.1 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.

7.2 Troubleshooting

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

Table 7-1: 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 SAMPLE:
	    o The end user must validate the use of micro collection devices with the LeadCare Ultra 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. 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 $\leq$ 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 main screen matches the lot number of the calibration button for the test kit.
Testing Conditions	• Avoid operating the LeadCare Ultra System in drafts or outside the specified temperature range 16°C - 30°C (61°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 any part of 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.
	• Make sure the collection container is at least half full.

Table 7-2: 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 capillary whole human blood collected with EDTA or Heparin anticoagulant. Do **NOT** use venous. Do NOT use plasma or serum.
	    o Make sure the sample is free of clots.
	    o Make sure the sample is $\leq$ 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.

Problem Area	Check the Following
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. The accuracy of the test depends on filling the pipette tip with 50 μL. Excess blood on the outside of the pipette tip 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. The accuracy of the test depends on filling the pipette tip with 50 μL. Excess sample on the outside of the pipette tip may produce higher test results. • Always add the control or blood sample to treatment reagent and mix thoroughly.
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 main screen matches the code of the calibration button for the test kit.
Testing Conditions	• Avoid operating the LeadCare Ultra System in drafts or outside the specified temperature range (16°C - 30°C / 61°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 any part of the system from one place to another, wait for the analyzer and components to reach a stable temperature.

Problem Area	Check the Following

User Technique	• Do NOT touch the black bars or the black cross 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.

7.3   Summary of Display Messages
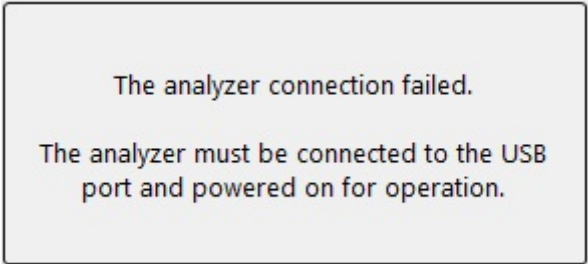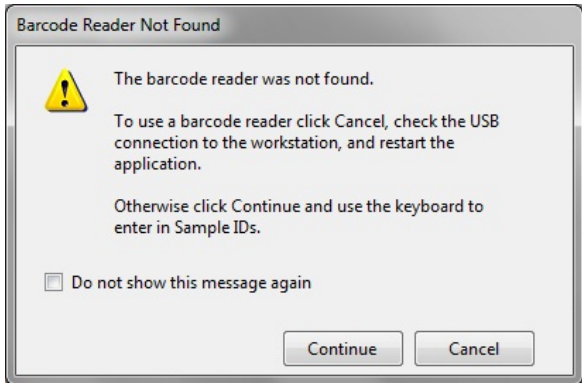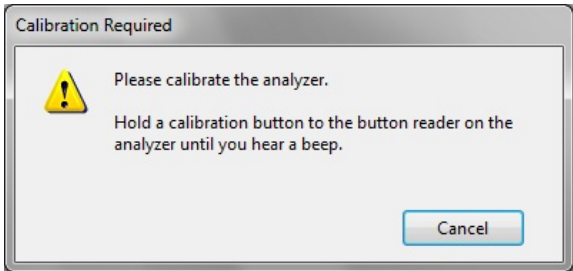
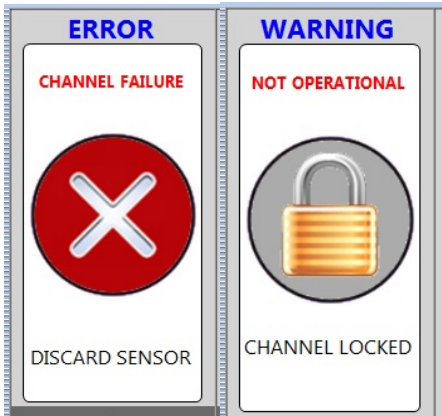Normally, only five messages are displayed during the test process:
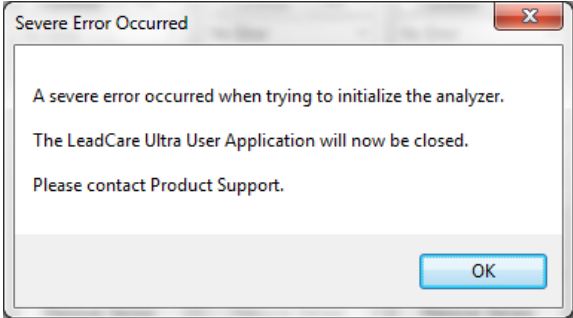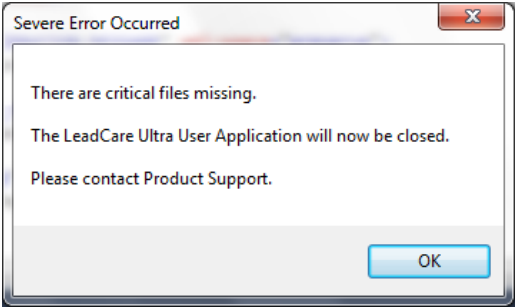
- "INSERT A SENSOR"
- "SCAN A BARCODE"
- "LOAD THE SAMPLE"
- "ANALYZING THE SAMPLE"
- "RESULT"
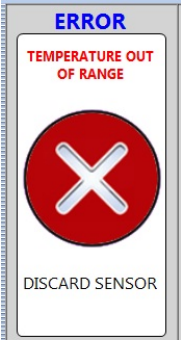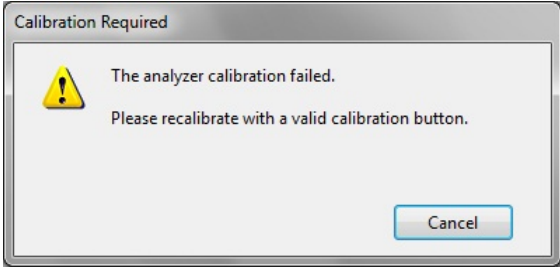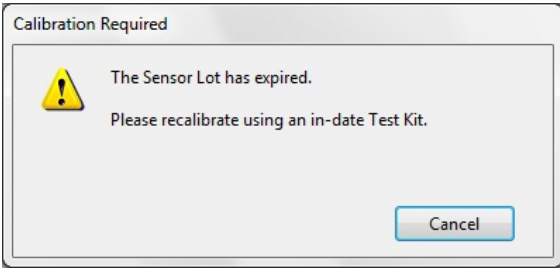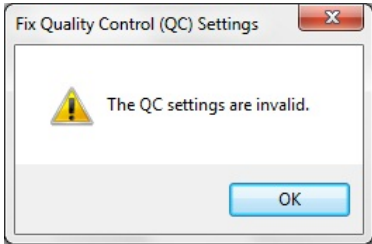
However, other messages may appear if the analyzer detects a condition that prevents normal operation. Table 7-3 shows the possible display messages.
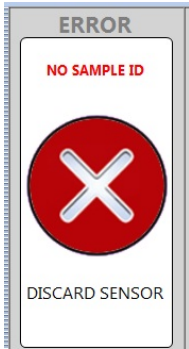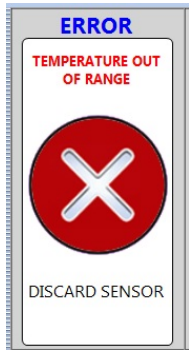
Table 7-3: UA Error Messages
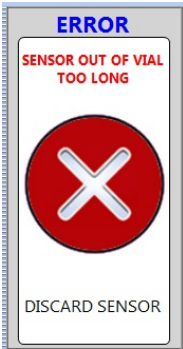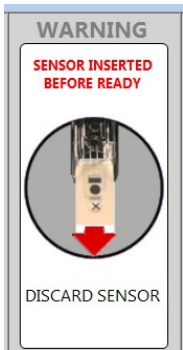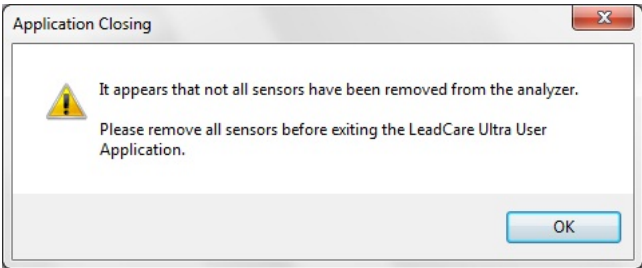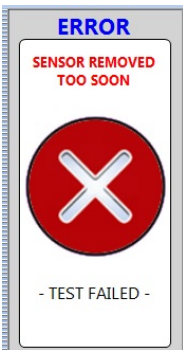
Error Type/Message	Reason(s)	Fix
System Errors		
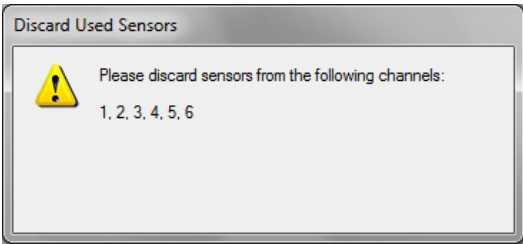
Error Type/Message	Reason(s)	Fix
Analyzer Connection to Computer Workstation The analyzer connection failed. The analyzer must be connected to the USB port and powered on for operation.	• The analyzer is turned OFF when UA is open. • The analyzer is disconnected from power source when UA is open • The analyzer is not connected to the computer workstation by the USB cable.	• Confirm the power switch on the back of the analyzer is set to the ON position. • Confirm the power socket/outlet connection to the analyzer power supply is set to the ON position. • Confirm that the analyzer is connected to the computer via the USB cable.
Barcode Scanner Failed Barcode Reader Not Found ⚠ The barcode reader was not found. To use a barcode reader click Cancel, check the USB connection to the workstation, and restart the application. Otherwise click Continue and use the keyboard to enter in Sample IDs. ☐ Do not show this message again Continue Cancel	• Upon starting the UA, the barcode scanner was not detected. • The barcode scanner is not configured correctly.	• Click **Cancel** button • Make sure the barcode scanner is connected to a USB port on the computer and that the green LED on the barcode scanner is lit. Make sure the computer is ON. • Restart the UA. Scan the barcode below. The scanner makes three rapid "beeps". ‖‖‖‖‖‖‖‖‖‖‖ IBM HAND-HELD USB
Calibrating Analyzer Calibration Required ⚠ Please calibrate the analyzer. Hold a calibration button to the button reader on the analyzer until you hear a beep. Cancel	• Analyzer cannot be used until it is calibrated with a valid calibration button.	• Calibrate the analyzer with a valid calibration button.
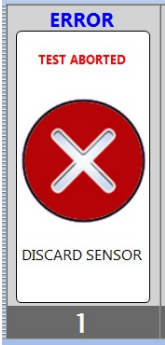
Error Type/Message	Reason(s)	Fix
Channel Locked **ERROR** — CHANNEL FAILURE — DISCARD SENSOR **WARNING** — NOT OPERATIONAL — CHANNEL LOCKED	• Internal check of the channel failed.	• Remove sensor, turn analyzer OFF, then turn analyzer ON. Wait ~10 seconds for the UA to initialize the analyzer. Insert a new sensor. • If the error continues, call Product Support.
Analyzer Not Operational Severe Error Occurred A severe error occurred when trying to initialize the analyzer. The LeadCare Ultra User Application will now be closed. Please contact Product Support. OK	• Hardware or low level firmware malfunction of the analyzer.	• Call Product Support.
System Not Operational Severe Error Occurred There are critical files missing. The LeadCare Ultra User Application will now be closed. Please contact Product Support. OK	• Files on data drive are missing or incomplete. • Files on data drive not protected.	• Call Product Support.

Error Type/Message	Reason(s)	Fix
Temperature Below Limit or Temperature Above Limit **ERROR** **TEMPERATURE OUT OF RANGE** ❌ DISCARD SENSOR	• The temperature of the analyzer is outside of its operational temperature range.	• Place the system in an environment of ambient temperature 16°C to 30°C. Allow the analyzer to adjust to ambient temperature.

Analyzer Calibration Failed
 	
Calibration Required
⚠ The analyzer calibration failed.
Please recalibrate with a valid calibration button.
Cancel
	• The analyzer failed to calibrate.
	  o Button did not make sufficient contact in button reader port
	  o Defective calibration button
		• Attempt to re-calibrate using the calibration button.
		• If the error continues, call Magellan Product Support.

Process Errors		
Sensor Lot Expired Calibration Required ⚠ The Sensor Lot has expired. Please recalibrate using an in-date Test Kit. Cancel	• The expiration date for the sensor lot has passed. • The expiration date for the test kit has passed.	• Discard the expired test kit.
QC Lot Expired Fix Quality Control (QC) Settings ✖ ⚠ The QC settings are invalid. OK	• The expiration date for the QC lot was input incorrectly. • The expiration date for the QC lot has passed. • QC information was never entered.	• Confirm the QC Lot expiration date was input correctly. • If the QC Lot has expired, discard the material.

Error Type/Message	Reason(s)	Fix
No Sample ID ERROR NO SAMPLE ID ❌ DISCARD SENSOR	• Sample ID must be entered into the UA before testing a sample.	• A Sample ID was not entered before putting the sample on the sensor. Remove and discard the sensor, insert a fresh sensor and enter the Sample ID before adding sample to the sensor.
Temperature is Unstable During Blood Lead Test ERROR TEMPERATURE NOT STABLE ❌ DISCARD SENSOR	• The ambient temperature around the analyzer changed too much to perform the test.	• Move the analyzer away from drafty area. Allow the analyzer to adjust to the ambient temperature.
Temperature Below Limit or Temperature Above Limit During Blood Lead Test ERROR TEMPERATURE OUT OF RANGE ❌ DISCARD SENSOR	• The temperature of the analyzer is outside of its operational temperature range.	• Place the system in an environment of ambient temperature 16°C - 30°C. Allow the analyzer to adjust to ambient temperature.

Error Type/Message	Reason(s)	Fix
Sensor Out of Vial Too Long **ERROR** SENSOR OUT OF VIAL TOO LONG ✖ DISCARD SENSOR	• Sensor was left in the analyzer for more than five (5) minutes without use. Sensor performance may be compromised.	• Remove and discard sensor. Insert a fresh sensor, enter Sample ID and add sample to sensor without delay.
Sensor Inserted Before Ready WARNING SENSOR INSERTED BEFORE READY ⬇ DISCARD SENSOR	• One or more sensors were detected in the analyzer as the analyzer was turned ON.	• Remove and re-insert sensor. If the error continues, call Magellan Product Support.
Sensor(s) Inserted on Exit Application Closing ✖ ⚠ It appears that not all sensors have been removed from the analyzer. Please remove all sensors before exiting the LeadCare Ultra User Application. OK	• One or more sensors were detected in the analyzer as the analyzer was turned OFF.	• Remove and discard sensors.
Sensor Removed **ERROR** SENSOR REMOVED TOO SOON ✖ - TEST FAILED -	• A sensor was removed before sample analysis was complete.	• Discard the sensor. Insert a new sensor and repeat the test. Allow the test to complete before removing the sensor.

Error Type/Message	Reason(s)	Fix
Used Sensor ERROR **USED SENSOR** ❌ DISCARD SENSOR 1	• A used sensor was inserted into the analyzer.	• Remove and discard the used sensor.
Sensor(s) Not Removed from Analyzer Discard Used Sensors ⚠ Please discard sensors from the following channels: 1, 2, 3, 4, 5, 6	• Sensors are left in the analyzer for too long after analysis.	• Remove and discard the sensors. • Do NOT leave sensors in the analyzer.
Test Failed – Insufficient Sample Volume ERROR **INSUFFICIENT SAMPLE VOLUME** ❌ DISCARD SENSOR 1	• Not enough sample was put on the sensor to start the test.	• Remove and discard sensor. • Confirm pipette delivers at least 30 µL. • Repeat test, verifying sample fills the channel on the sensor.
Sensor Error ERROR **SENSOR ERROR** ❌ DISCARD SENSOR 1	• Analyzer detects a problem with the sensor.	• Remove and discard the sensor. Repeat the test. • If the error persists call Magellan Product Support.

Error Type/Message	Reason(s)	Fix
Test Aborted **ERROR** **TEST ABORTED** DISCARD SENSOR 1	• A problem was detected during analysis. The test was terminated.	• Remove and discard the sensor. Repeat the test. • If the error persists call Magellan Product Support.

7.4 Calling Magellan Diagnostics Product Support

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

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

- Serial Number of Analyzer (on bottom of Analyzer and under Help > About)
- Installation Date
- Application Version Number (under **Help > About**)
- Firmware Version Number (under **Help > About**)
- Test Kit Lot # (on end of box)
- Calibration Code on Calibration Button
- Did you test with Controls?   Yes   No
    - o If yes, were they LeadCare Ultra Controls?   Yes   No
- Control Results Last Recorded (Level 1, Level 2):
- Control Lot #:
- Control Expiration Date

8   Performing Other Tasks

This section describes how to perform a number of common tasks on the LeadCare Ultra® UA. These tasks can be performed by the system administrator or an operator.

8.1   Viewing Calibration History

The Calibration History option displays a dialog box in which you enter search criteria to search for and display calibration records.

► **Follow These Steps**

1. To display calibration records, click **View** > **Calibration History**. The "Calibration History" dialog box (Figure 8-1) displays, showing calibration records identified by Calibration Date & Time, Calibration Expires, Sensor Lot #, and User.

Figure 8-1: Calibration History Dialog Box

---

2. Use the mouse to select the search criteria from the following choices:

    a. Show all calibration records.

    b. Filter calibration records by specified values.

3. If you select the second search option, you can further refine your search criteria by "Date-From-To" range, "Sensor Lot #", and "User". Enter your search criteria and click the **View Report** button. The Custom Report Header Information screen displays (Figure 8-2).

Figure 8-2: Custom Report Header Information Screen

4. Enter the desired report header on line 1. Lines 2 and 3 are provided for if you have more lines of header information.

5. Once all of the desired information has been entered, click **Done**.

Based on your search criteria, the calibration records are filtered and those results that meet your search criteria display in the viewer. A sample Calibration History Report is shown in Figure 8-3.

Figure 8-3: Sample Calibration History Report

6. Click the **Zoom** icon in the menu bar to zoom in on (magnify) the results for a specific calibration record; click the **Binoculars** icon in the menu bar to search the results for a specific calibration record.

7. To print the report, click the **Print** icon in the menu bar, and then enter the desired print parameters in the standard Windows "Print" dialog box that appears.

8.2 Viewing Error History

Use the Error History option to search for and display error records.

► Follow These Steps

1. To display error records, click **View >Error History**.

    The "View Error History" dialog box can display error records such as:

    - Error
    - Error Type
    - Code
    - Channel
    - Date of Error
    - Channel #
    - Locked
    - Sensor Lot #
    - User
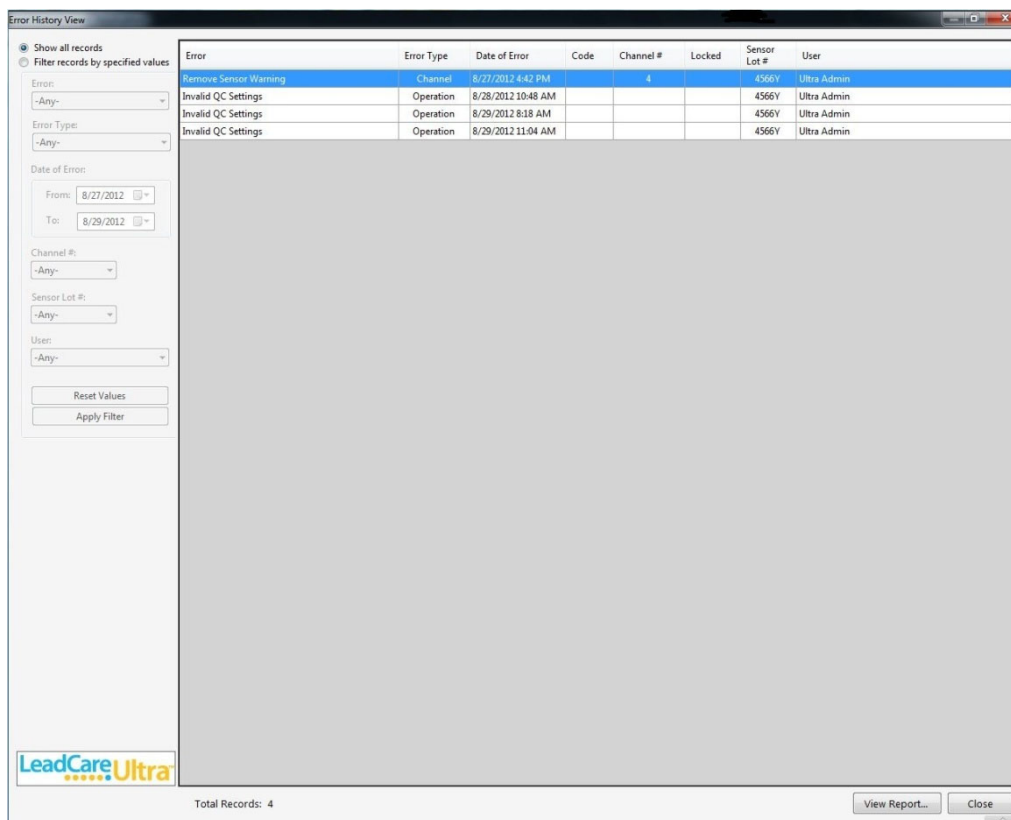
Figure 8-4: Error History View Dialog Box

2. Use the mouse to select one of the following search (filter) criteria:

    a. Show all records

    b. Filter records by specified values

3. The "Filter records by specified values" tabs option will allow you to refine your search according to the types of error records mentioned on the previous page.

4. Enter your search criteria and select the **Apply Filter** button. The data meeting your search criteria will appear on the right hand side of the "View Error History" window.

5. To obtain a report of this data select the **View Report** button in the lower right hand corner of the screen. The Custom Report Header Information screen displays (Figure 8-5).

6. Enter your search criteria and click the **View Report** button. The Custom Report Header Information screen displays (Figure 8-5).

Figure 8-5: Custom Report Header Information Screen

7. Enter the desired report header on line 1 and then click **Done**. (Lines 2 and 3 are provided for multi-part headers. If you have more lines of header information go ahead and enter them. If not, click **Done**.)

   If entering the report for troubleshooting purposes, please enter:

          Line 1: Organization name
          Line 2: Problem description

8. The specified report is displayed. A sample Error History Report is shown in Figure 8-6.

Figure 8-6: Sample Error History Report

8. Click the **Zoom** icon in the menu bar to zoom in on the results for a specific error record; click the **Binoculars** icon in the menu bar to search the results for a specific error record.

9. To print the report, click the **Print** icon in the menu bar, and then enter the desired print parameters in the standard Windows "Print" dialog box that appears.

8.3   Viewing User Login History

The User Login History option displays a dialog box in which you enter search criteria to search for and display user login records.

► **Follow These Steps**

1. To display user login records, click **View** > **User Login History**. The "User Login History" dialog box displays (Figure 8-7), showing user login records identified by User Name, User Type, Logged In On, and Logged Out On.

Figure 8-7: User Login History Dialog Box

2. Use the mouse to select the search criteria from the following choices:

    a. Show all user login records.

    b. Filter user login records by specified values.

3. If you select the second search option, you can further refine your search criteria by Date-From-To range, User Name and User Type. Enter your search criteria and click the **View Report** button. The Custom Report Header Information screen displays (Figure 8-8).

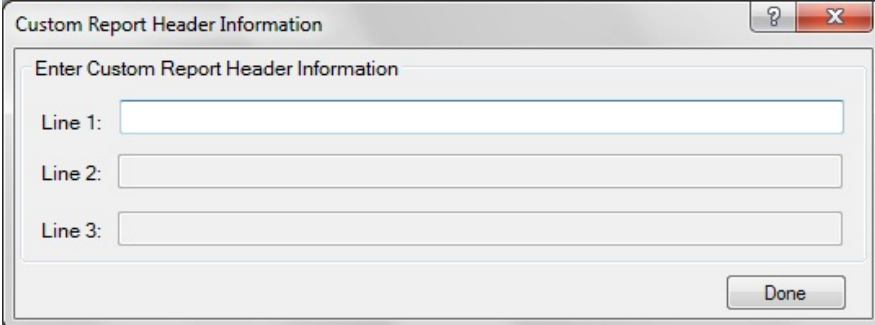*Figure 8-8: Custom Report Header Information Screen*

4. Enter the desired report header on line 1. Lines 2 and 3 are provided for additional lines of header information.

5. Once all of the desired information has been entered, click **Done**.

   Based on your search criteria, the user login records are filtered and those results that meet your search criteria display in the viewer. A sample user login history report is shown in Figure 8-9.

Figure 8-9: Sample User Login History Report

6. Click the **Zoom** icon in the menu bar to zoom in on (magnify) the results for a specific user login record; click the **Binoculars** icon in the menu bar to search the results for a specific user login.

7. To print the report, click the **Print** icon in the menu bar, and then enter the desired print parameters in the standard Windows "Print" dialog box that appears.

8.4 Creating User Accounts

The Laboratory Manager or another laboratory designee with "Account Manager" privileges may assign or delete accounts, as well as change user passwords for the LeadCare Ultra software. **If you are setting up the LeadCare Ultra System without the help of a Magellan Diagnostic Representative, or if you want to add or change User Accounts, please follow the steps below.**

► **Follow These Steps**

1. Power on the computer, monitor, and analyzer. The main login screen will appear.

Figure 8-10: Main Login Screen

2. Select the Account Manager User icon, type in the password, and press Enter.

    The LeadCare Ultra User Account Manager dialogue box appears, containing a chart with User Name, User Type, and Description fields (see Figure 8-11).

NOTE:	A password list will be provided by a Magellan Diagnostics Representative.
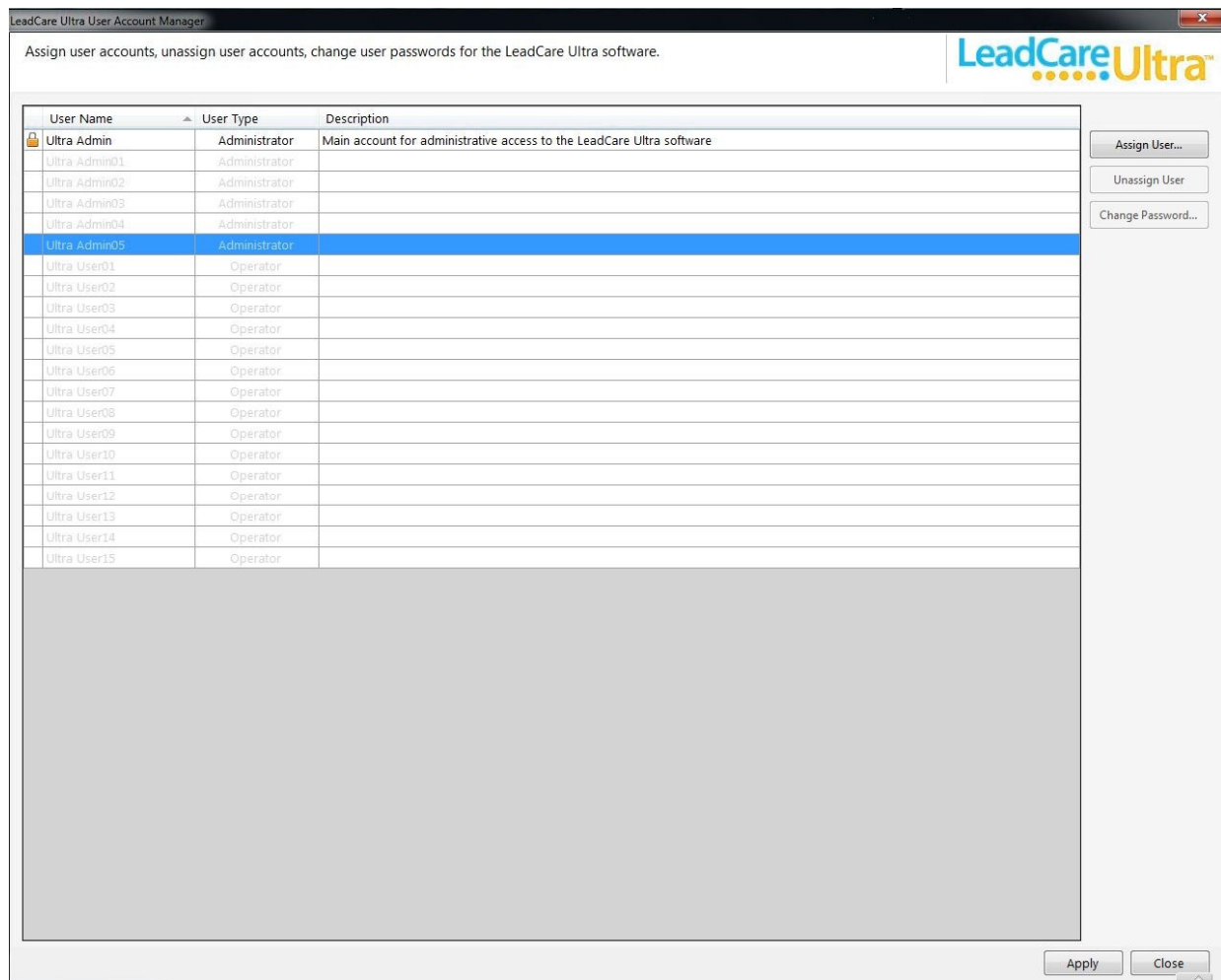
Figure 8-11: Account Manager Dialog Box

NOTE: The LeadCare Ultra User Account Manager has five pre-defined Administrator fields and fifteen pre-defined Operator fields.

---

3. Select an appropriate New User, either an Operator or an Administrator. When the field is selected it will be highlighted and the "Assign User" field will become active.

4. Enter the information for User Name; Password; Confirm Password; and Description. "User Type" is pre-defined. Then click **OK**.

5. Click on **Apply** to save changes.

NOTE: Once a password is set it can be changed by logging into the Account Manager, selecting the appropriate User Name, and selecting the **Change Password** button. Type in the new password in the Change Password field. Confirm the password and click **OK**.

8.5 LIS Interface

The Ultra User Application provides the capability to transmit approved patient test results using the HL7 v2.5.1 standard. The LIS initiates the connection over TCP/IP on a specified port. Valid ports range from 1 – 65535. Once the connection has been established, the Ultra User Application will transmit all approved results per the format detailed in the document titled Connectivity to LIS.

> **NOTE:** Refer to the Connectivity to LIS document for LeadCare Ultra which describes how data is transmitted between the Ultra application and an external system such as LIS. If you need this document, please contact Product Support.

To configure the parameters in the Ultra User App go to **Tools > LIS > Settings**

- In the LIS Configuration Box that opens (Figure 8-12), check the Enable LIS Interface option.

- Enter the TCP port to be used for transfer of results. Valid ports range from1 – 65535.

- Click the **Save** button.

> **NOTE:** **The Ultra User Application MUST BE RESTARTED** if one of the parameters has been modified.

> **NOTE:** Only Admin accounts have the privileges to modify the LIS settings. All User accounts can view the settings.
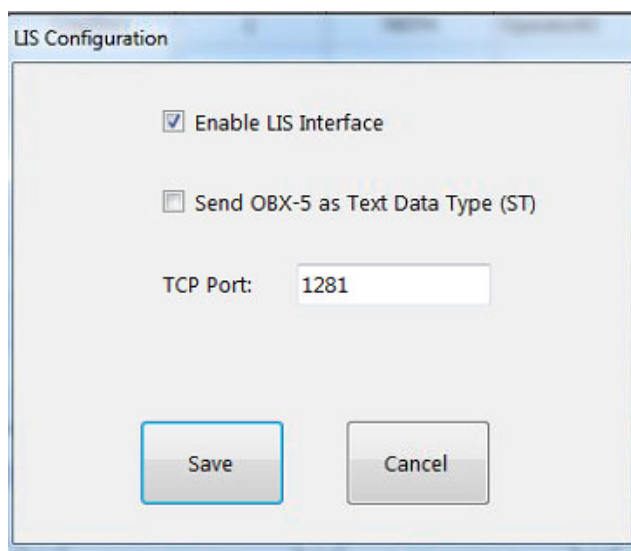
Figure 8-12: LIS Configuration

To View the status of the connection in the Ultra User App select **Tools > LIS > Status**.

The LIS Interface Status box will open and display (Figure 8-13):

- Current status of the connection between the Ultra and the LIS.
- IP Address assigned to the LeadCare Ultra computer.
- TCP Port.
- Status of the pending Queue.

Figure 8-13: LIS Interface Status

The Ultra User Application maintains a persistent queue of approved results to account for loss of connection or power outages. Results are removed from the queue once the LIS acknowledges receipt of the result. If for any reason a result cannot be transmitted or is rejected by the LIS, the result will remain in the queue.

The queue contents can be cleared by clicking the **Clear Queue** button (Admin only).

The LIS Interface Status box can be closed by clicking **OK** button.

9 Maintaining Test Results

The LeadCare Ultra® UA contains both Backup and Restore features for use with writeable and re-writeable CD/DVD media. These features can be used to:

- Back-up data to writeable CD/DVD type media.
- Restore previously backed up data from a CD/DVD type media onto the LeadCare Ultra UA.

These features are only available to Users with Administrator access credentials. They can be accessed by selecting:

- **Tools > Backup**
- **Tools > Restore**

9.1 Backing Up Blood Lead Sample Test Results

There are two types of backup processes available to the User:

- A Simple Backup – Backing up of data to a blank CD/DVD media.
- An Over-Write Backup – Backing up of data to a re-writeable CD/DVD media, used previously to back-up data.
  - o The Over-Write backup operation will simply save the data files over the old ones (the CD is updated).

NOTE: Please be advised when performing an Over-Write Backup:
- A second set of data is not saved.
- Merging of the two sets of data is not performed.

NOTE: The Backup process DOES NOT remove any information from the system. It simply saves the information to the CD/DVD.

If laboratory protocol requires maintaining a record of the daily test results, a new CD/DVD should be used each time the Backup feature is used.

The Backup function can be accessed by selecting **Tools > Backup**.

The "Confirm Backup Operation" dialog box (Figure 9-1) will appear on the screen to guide you through the process.
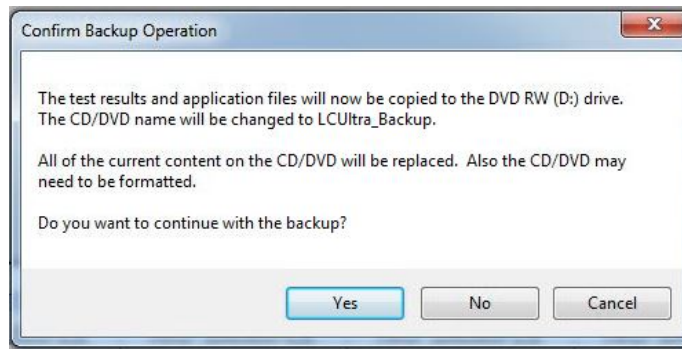
Figure 9-1: Confirm Backup Operation Dialog Box

Upon completion of the backup process, the following notification will appear on the screen (Figure 9-2) and the CD/DVD will be automatically ejected.
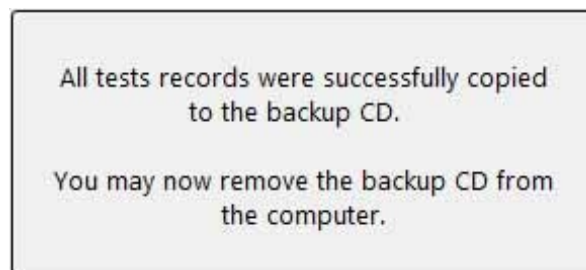
Figure 9-2: Backup Successful Dialog Box

9.2 Restoring Blood Lead Sample Test Results

In the event of a system failure resulting in loss of information, there are two "Restore" processes available which enable the User to reload historical information onto the system:

- A Simple Restore – Restoring data onto a blank/empty LeadCare Ultra system.
- A Merge Restore – Restoring data onto a LeadCare Ultra system already containing data.

The Restore process places previously backed-up information, onto the LeadCare Ultra System:

- The software has been designed to perform "checks" on the current information on the UA against the information being restored to the system.
- If the information on the UA has been changed since the time of backup, the more current information will remain on the system – the restore will not "over write" these updates.

Table 9-1: Examples of Maintaining Updated Information During Merge Restore

	Situation	Outcome
1	An unapproved record is backed up and then subsequently approved or archived within the UA (where the approved results are still present within the Archived View, for non-LIMS users).	The approved and/or archived record present within the UA record will be maintained and applied. The original unapproved record present in the backup will not be applied to the Unapproved Tests. (UltraSampleRecords.xml file)
2	A record has been backed-up and then subsequently edited within the UA. Editing functions are restricted to: • Editing a comment • Changing the sample type	The comment and/or sample type present within the UA record will be maintained and applied.
3	A voided record has been backed up and then subsequently un-voided within the UA.	The un-voided record present within the UA records will be maintained and applied.
4	An un-voided record has been backed up and then subsequently voided within the UA.	The voided record present within the UA records will be maintained and applied.
5	Limit files information is backed up and then subsequently updated (such as through recalibration) within the UA.	The limit files information present within the UA shall be maintained and applied.

The Restore function can be accessed by selecting **Tools > Restore**.

The "Confirm Restore Operation" dialog box (Figure 9-3) will appear on the screen to guide the user through the Restore process:
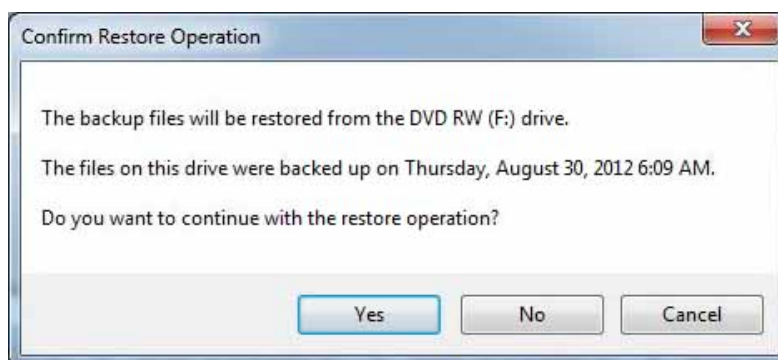
Figure 9-3: Confirm Restore Operation Dialog Box

Upon completion of the Restore process, the following notification will appear on the screen and the CD/DVD will be automatically ejected:

The backup files were successfully restored.
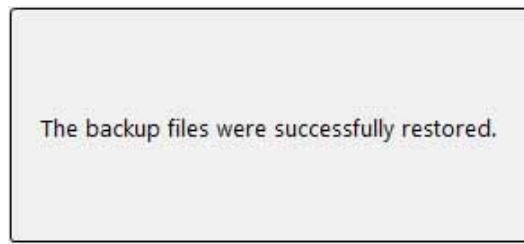
Figure 9-4: Restore Successful Dialog Box

10 Maintenance

For optimum performance, the LeadCare Ultra® Blood Lead Testing System must be properly maintained. This chapter contains maintenance procedures that should be performed on a regular basis.

> **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 Ultra Analyzer.

10.1 Cleaning Procedures

10.1.1 Cleaning the Analyzer

The exterior case of the analyzer can be cleaned using a lint-free cloth dampened with a 10% bleach solution.

- Do **NOT** clean the sensor connector (gold pins) present inside the analyzer channels. 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.

10.1.2 Cleaning the Barcode Scanner

The window of the barcode scanner should be cleaned periodically to assure scanning accuracy. Do **NOT** allow any abrasive material to touch the window.

- Remove any dirt particles with a damp cloth.
- Wipe the window using a lint-free cloth moistened with ammonia/water.
- Do **NOT** spray water or other cleaning liquids directly into the window.

10.1.3 Cleaning the Keyboard

The keyboard should be thoroughly cleaned and disinfected on a regular basis.

- Unplug the keyboard and clean the surface by lightly spraying, wiping or gently brushing.
- Use only cloth rags, sponges or soft bristle brushes.
- The manufacturer's recommended disinfectants include:
  - Alcohol based cleaning products
  - Phenol based cleaning products

- o Chlorine based cleaning products

- o 10% bleach

- o 70% Isopropyl alcohol solution

- o Disinfectant wipes

- Blood products can remain on the disinfected areas after use of these products. If there is the possibility of blood contamination, you should remove all blood traces and ensure that blood-borne diseases are eliminated; cleaning with a 10% solution of bleach is required. (Freshly prepare a 10% solution of household bleach, using 1 part bleach and 9 parts water, or add ½ cup bleach to 1 quart water.)

- It is best to use a cotton swab to massage the bleach solution between the keys of the keyboard.

10.1.4 Cleaning Other System Components

Follow the manufacturer's instructions to clean the exterior surfaces of the computer screen and mouse.

11 Reordering Information

Ordering replacement parts for your LeadCare Ultra® Blood Lead Testing System is simple. If you know the item number, please contact our Customer Service Department at 800-959-5095 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-ultra/support/parts-service/.

This page intentionally left blank.

12 Technical Service Information

12.1 Technical Service Policy

To contact Magellan Diagnostics Product Support Department, call 800-275-0102 Monday through Friday, or email LeadCareSupport@magellandx.com. A Product Support Specialist 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 1-800-959-5095 to:

- Place an order.
- Track a shipment.
- Determine availability.
- Check on installation.

12.2 Preparing for a Technical Service Call

Before you make a technical service call, be sure to obtain the following information, as appropriate, to submit with your request or question:

- **System version number**. In the UA, select **Help > About LeadCare Ultra**, to display this information.
- **Serial number of the analyzer.**
- **Test kit lot number.**
- **The name and contact telephone number of the person who asked the question or detected the problem.** This allows us to contact the person if we need more information, and to notify the person when an answer or correction is ready. If limited hours of contact are available, please include suggested contact times.
- **The date and time the problem was detected**. This is not required for a simple question, but may be important in the case of a problem report.

- **A question or description of the problem**. When reporting a problem, the description should include:

  - What happened?
  - What did you expect to have happen?
  - What is the sensor lot number in use?
  - Did you find a work-around you can use until the problem is resolved?
  - Have you had this problem before?

- **Steps to reproduce the problem.** THIS IS VERY IMPORTANT. Not having this information may mean that the problem cannot be corrected. It allows us to detect and reproduce the problem so that we can (a) determine which product versions are affected, (b) identify the problem and find its cause, and (c) verify that the problem is actually corrected when the correction work is done.

- **The date of the installation.** How long has the system been installed? Has the software been updated?

- You should include any other information that you think is important.

- **If you are submitting the request by fax, please write the information LEGIBLY in dark ink on light paper or type it.** Do not use yellow pad paper or a pencil because the fax may not be legible when we receive it.

- If you are reporting a problem that you have experienced before, please have your case number available.

Product Support
800-275-0102
LeadCareSupport@magellandx.com

13 Returns

A Return Materials Authorization (RMA) number must be issued by Magellan Diagnostics 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 with shipment both ways at Buyer's expense for repair work.

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

4. 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.

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

6. The remedies are available only to the original Buyer. Buyer agrees to accept billing for service expense for service call resulting from other than a Magellan Diagnostics goods failure or other Magellan Diagnostics fault.

This page intentionally left blank.

14 LeadCare Ultra Blood Lead Testing System Limited Warranty

IMPORTANT – READ CAREFULLY THE FOLLOWING TERMS AND CONDITIONS. BY INSTALLING AND USING THE SOFTWARE, YOU ARE AGREEING TO BE BOUND BY THE TERMS OF THIS AGREEMENT:

Magellan Diagnostics, Inc. ("Seller") hereby sells the LeadCare Ultra® Blood Lead Testing System (the "System") to you ("Buyer"), and Buyer purchases the System on the following terms and conditions:

a. Seller warrants to Buyer that the following components of the System will materially conform to the specifications set forth in this User's Guide and be free from defects in material and workmanship in normal use for one year from the date of delivery to Buyer as the original purchaser: analyzer, flat-screen monitor, computer, software, barcode scanner, keyboard. This warranty does not cover, and no warranty is provided for, anything else, including without limitation elements of the test kit, 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 Seller determines to its satisfaction that such component did not materially conform to the specifications set forth in this User's Guide or was defective in material or workmanship, Seller will, at its option, repair or replace the component or the defective part thereof or refund the original purchase price of the component. The foregoing notwithstanding, Seller will not be responsible for and the foregoing warranties will not apply to damage to or defect in any component of the System resulting from misuse, negligence, accident, each whether in transit or at Buyer's place of operations, failure to use, maintain or calibrate the System or component thereof in a manner consistent with the User's Guide, exposure of the System to environmental conditions beyond those specified by the documentation, or repairs, alterations or installation made by any person or firm not duly authorized by Seller in writing this warranty shall be void. EXCEPT AS EXPRESSLY STATED IN PARAGRAPH A, ABOVE, SELLER EXPRESSLY DISCLAIMS ANY AND ALL REPRESENTATIONS AND WARRANTIES, EXPRESS OR IMPLIED, BY OPERATION OF LAW OR OTHERWISE, REGARDING OR RELATING TO THE SYSTEM OR ANY COMPONENTS THEREOF. SELLER SPECIFICALLY DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE (IRRESPECTIVE OF ANY PREVIOUS COURSE OF DEALING BETWEEN THE PARTIES OR CUSTOM OR USAGE OF TRADE) OR RESULTS TO BE DERIVED FROM USE OF THE SYSTEM OR ANY COMPONENTS THEREOF OR NON-INFRINGEMENT OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS. NO REPRESENTATION OR OTHER AFFIRMATION OF FACT, INCLUDING WITHOUT LIMITATION STATEMENTS REGARDING CAPACITY, SUITABILITY OF USE OR PERFORMANCE OF THIS SYSTEM OR COMPONENTS THEREOF, WHETHER MADE BY SELLER EMPLOYEES OR OTHERWISE, WHICH IS NOT SET FORTH ABOVE IN THIS PARAGRAPH , SHALL BE DEEMED A WARRANTY BY SELLER FOR ANY PURPOSE OR GIVE RISE TO ANY LIABILITY OF SELLER WHATSOEVER. BUYER'S EXCLUSIVE REMEDIES AND SELLER'S SOLE LIABILITY FOR ANY NON-CONFORMITY OR DEFECT IN THE SYSTEM WILL BE THOSE EXPRESSED HEREIN.

b. Seller does not warrant that the operation of the System will be uninterrupted or error free. The System is not designed, manufactured or intended for delivering or ensuring the delivery of critical medical care or for use requiring fail-safe performance in which failure could lead directly to death, personal injury or severe physical or environmental damage. Seller's warranty does not apply insofar as claims result from acts or omissions caused by persons other than Seller or from products, material or software not provided by Seller.

c. Buyer is responsible for the supervision, management and control of the use of the System, and output thereof, including, but not limited to: (a) selection of the System to achieve Buyer's intended results; (b) determining the appropriate uses of the System in Buyer's business or clinical setting; (c) establishing adequate independent procedures for testing the accuracy of the System; and (d) establishing and making use of adequate backup to obtain accurate data and prevent the loss of data in the event of a malfunction of the System.

d. By purchasing the System, Buyer is not permitted to and agrees not to (a) reverse compile, reverse assemble, reverse engineer, modify, or incorporate the software embedded in the System (the "Software") in whole or in part in any other product or create derivative works based on all or any part of the Software, (b) remove any copyright, trademark, proprietary rights, disclaimer or warning notice included on or embedded in any part of the Software, (c) sell, license, sublicense, assign, rent, or otherwise transfer the System, any components thereof or the Software without the written permission of Seller, or (d) otherwise tamper with the Software or workings of the System.

e. If Buyer breaches Paragraph (d) or fails to pay when due any portion of the purchase price of the System or any component thereof or any other payment required from Buyer to Seller, whether under the contract or otherwise, all warranties and remedies granted in this section and all of Seller's warranties and obligations to service, repair, replace, correct or otherwise remedy defects, errors or failures under any other contract between Buyer and Seller may, at Seller's option, be terminated.

f. LIMITATIONS ON REMEDIES. Seller's liability in contract, tort or otherwise arising out of or in connection with use of the System, any component or output thereof, shall not exceed the amount that Buyer has paid Seller or its authorized distributor. An essential purpose of the limitation on remedies provided in this paragraph is the allocation of risks between Buyer and Seller. IN NO EVENT INCLUDING NEGLIGENCE SHALL SELLER BE LIABLE FOR SPECIAL, INCIDENTAL, TORT, CONSEQUENTIAL OR ANALOGOUS DAMAGES (INCLUDING, WITHOUT LIMITATION, ANY DAMAGES RESULTING FROM LOSS OF USE, LOSS OF DATA, LOSS OF PROFITS, LOSS OF GOODWILL, OR LOSS OF BUSINESS) ARISING OUT OF OR IN CONNECTION WITH THE PERFORMANCE OF THE SYSTEM AND/OR SELLER'S PERFORMANCE OF SERVICES, EVEN IF SELLER HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. SOME JURISDICTIONS DO NOT ALLOW THE LIMITATION OF INCIDENTAL OR CONSEQUENTIAL DAMAGES SO THIS LIMITATION MAY NOT APPLY TO CERTAIN BUYERS. IN NO EVENT SHALL SELLER'S TOTAL LIABILITY TO BUYER FOR ALL DAMAGES EXCEED THE AMOUNT BUYER HAS PAID SELLER OR ITS AUTHORIZED DISTRIBUTOR.

Appendix A Specifications, Specimen and Operating Requirements

This chapter provides specifications for the LeadCare Ultra® Blood Lead Testing System.

Table A-1: LeadCare Ultra System Specifications

Overview	
System Description	6-channel, electrochemical blood lead analyzer
Throughput	Up to 90 tests per hour
Analysis Time	3 min. (180 sec.)
Analytical Range	1.9 µg/dL - 65.0 µg/dL
LoD	1.9 µg/dL
LoQ	1.9 µg/dL
Calibration	Electronic calibration; Lot specific
Barcodes	UPC/EAN, Code 39, Code 32, Code 128, Code 93, Codabar/NW7, Interleaved 2 of 5, MSI Plessey, GS1 DataBar
Certifications	ETL, FDA-cleared
General Specifications	
Dimensions (approximate, system)	Height 58 cm 23 in (23 in.) Width 46 cm (18 in.) Depth 56 cm (22 in.)
Weight (approximate, system)	15.4 kg (34 lbs)
Electrical Specifications (Power adapters are included with system)	
External Power Source, Analyzer	Switching power supply (AC input 100/240V, .1A max, 50-60Hz, DC output +15V @ 2A max)
DC Input Power (External Mode)	Less than 180mA
Specimen Requirements	
Sample Type	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.
Sample Volume	50 µL

System Operating Ranges	
Temperature	16°C - 30°C (61°F - 86°F)
Relative Humidity	12% - 80% Relative Humidity (non-condensing)
Altitude	LeadCare Ultra System can be operated in altitudes up to 8,000 feet (2,440 meters) above sea level.
Storage Ranges	
Analyzer	15°C - 30°C (59°F - 86°F) Up to 80% Relative Humidity
Test Kit	15°C - 27°C (60°F - 80°F) 12% - 80% Relative Humidity
Shipping Environmental Ranges	
Analyzer	-30°C - +40°C (-22°F - +104°F) 10% to 80% Relative Humidity, non-condensing
Test Kit	15°C - 27°C (59°F - 80°F)

A.1   Interference Substances

Tests were conducted by adding the potential interferences at the concentrations listed below to bovine and/or human lyophilized 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 Ultra Blood Lead Testing 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 B Setup Guide

In the event it is necessary for your laboratory personnel to set up the system on their own, follow the steps detailed in this Setup Guide. If you have any questions during the process please contact Magellan Diagnostics Product Support at 800-275-0102 or LeadCareSupport@magellandx.com.

B.1 Establishing the Work Area

The following parameters should be considered when choosing the placement of the LeadCare Ultra® System within the laboratory:

- The system occupies an approximate bench space of 21 inches wide by 25 inches deep by 18 inches high.

- The system requires two (2) grounded electrical outlets.

- Set up the LeadCare Ultra Blood Lead Testing system in an area that is free of drafts and temperature extremes. For best results, the analyzer needs to operate in a stable temperature environment:

    - 16°C - 30°C (61°F - 86°F)

    - 12% - 80% Relative Humidity (non-condensing)

B.2 Setting Up the Analyzer and Computer Components

B.2.1 Unpacking the System

LeadCare Ultra materials are contained in two separate main packages, the Analyzer Kit box and the Computer System Kit box, each containing multiple components as described in Tables 1 and 2.

1. Carefully remove the packages from the shipping boxes and inspect them for damage. If you notice any damage, report it to Magellan Diagnostics, Inc. immediately.

2. Unpack the boxes keeping the components from the Analyzer Kit box together, and the components from the Computer System Kit box together, for easy access and identification during equipment set-up. Use the checklists below to confirm that all components are present.

3. Record all serial numbers of the components on the Installation Checklist provided by Magellan Diagnostics.

4. Review the manufacturer's instruction for setting up the AIO stand, monitor and soundbar. Review the LS9208 Quick Start Guide for Connecting the Barcode Scanner. These documents can be found in the corresponding boxes.

5. If you are connecting an optional printer, follow the installation guidelines in Section B.4.

Table B-1: Analyzer Kit Box Contents

Box	Analyzer Kit	Check
1	Analyzer Power Cable and Adapter USB Cable User's Guide	☐ ☐ ☐ ☐

Table B-2: Computer System Kit Contents

Box	Computer System Kit	Check
1	Soundbar Box • Soundbar • USB Extension Cable	☐ ☐
2	Monitor Box • Monitor • VGA Monitor Cable • USB Upstream Cable • Power Supply	☐ ☐ ☐ ☐
3	Keyboard Box • Keyboard with USB cable attached	☐
4	AIO Stand Box • AIO Stand	☐
5	Computer Box • Computer • Mouse and extra power cord • Barcode Scanner and hands-free stand • Serial/USB cable (Grey)	☐ ☐ ☐ ☐

NOTE: The following items included in the LeadCare Ultra boxes, are **NOT** necessary for setup:
- Cable cover for monitor, silver monitor stand, and display port cable. (All found in Monitor box.)
- Computer cable cover. (Found in AIO box.)

B.2.2 Manufacturer's Instruction for Setup

Follow the manufacturer's instruction for setting up the AIO Stand, Monitor and Soundbar. Follow the LS9208 Quick Start Guide for connecting the Barcode Scanner.

Prior to beginning system setup please read the following important information regarding the power cords and cables supplied with the system:

NOTE: Use only the AC power adapters supplied with this system. Attempting to use adapters from different manufacturers could damage the analyzer or the computer.

The power adapter carries appropriate ratings for safety, immunity and emissions.

NOTE: During setup please make note of model numbers and serial numbers on the Installation Checklist found in the Validation Booklet provided by Magellan Diagnostics.

Set Up AIO Stand and Connect the Monitor

Refer to the instructions provided in the monitor box. Place the AIO stand on a stable, level surface.

1. Attach the monitor to the stand.
2. Connect the power cable from the stand to the monitor.
3. Connect the VGA cable to the monitor.
4. Route the VGA cable through the front slot of the stand. Leaving sufficient slack, tuck the monitor cable into the cable channel.
5. Connect the USB upstream cable to the USB upstream port on the monitor. Leaving sufficient slack, tuck into the cable channel.

Connect the Soundbar

Refer to the instructions provided with the soundbar.

1. Remove the slot covers found at the bottom of the Dell Monitor.
2. Attach the soundbar to the monitor by sliding it to the right to lock into place.
3. Connect the attached USB cable to USB port on the back of the computer.

Set Up the Computer

1. Slide the computer chassis into the AIO stand.
2. Slide the switch to lock the computer to the AIO stand.
3. Plug in the power supply from the AIO stand to the computer
4. Connect cables from the monitor to the back of the computer.
5. Discard the cable cover for the computer chassis. Do **NOT** Install.

Set Up the Mouse and Keyboard

1. Connect the USB cables from the mouse and keyboard to the back of the computer.

Connect the Barcode Scanner

Refer to the "LS9208 Quick Start Guide" to connect the scanner to the computer

1. Connect the Ethernet end of the cable to the base of the barcode scanner.
2. Connect the USB end of the cable to the back of the computer.

Connect the LeadCare Ultra Analyzer

1. Set the analyzer up in front of the monitor.
2. Connect the B type end of the USB cable to the back of the analyzer.
3. Connect the USB end of the cable to the back of the computer.
4. Connect the power adapter to the back of the analyzer.
5. Connect the AC adapter into a wall outlet.

B.3 Registering Your System

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

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

B.4 Preparing for Operation

At this point, you have set up and installed the LeadCare Ultra Blood Lead Testing System successfully as a stand-alone device. Follow the procedures outlined below to confirm the system is operational and prepare for daily use:

a. Power On the System
b. Initialize the Barcode Scanner
c. Create User Accounts
d. Calibrate the System
e. Install a Printer (optional)

a. Power On the System

► **Follow These Steps**

1. Power on the computer, monitor, and analyzer (On/Off switch shown in Figure B-1).
2. The main login screen will appear (Figure B-2).

On/Off   Adapter   USB
Switch   Cable   Cable
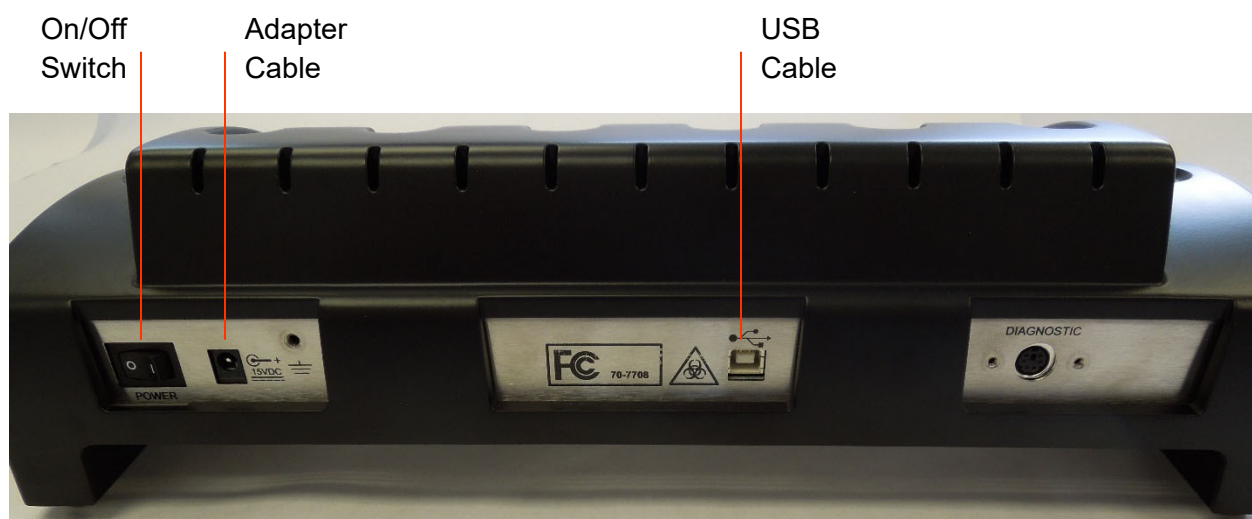
Figure B-1: Back of Analyzer

Figure B-2: LeadCare Ultra Blood Lead Testing System with Main Log In Screen

In order to use the LeadCare Ultra Blood Lead Testing System software you must establish a User Account. The Laboratory Manager or another laboratory designee with "Account Manager" privileges may assign or delete accounts, as well as change User passwords for the LeadCare Ultra software.

The computer must be updated to reflect the proper time zone. Log in as the LIMS Administrator to change the Date/Time settings. This will be particularly important if your system is linked to LIS.

If you are setting up the LeadCare Ultra System without the help of a Magellan Diagnostic Representative, or if you want to add or change User accounts, please follow the steps below. These steps can also be found in the chapter entitled Performing Other Tasks in the User's Guide.
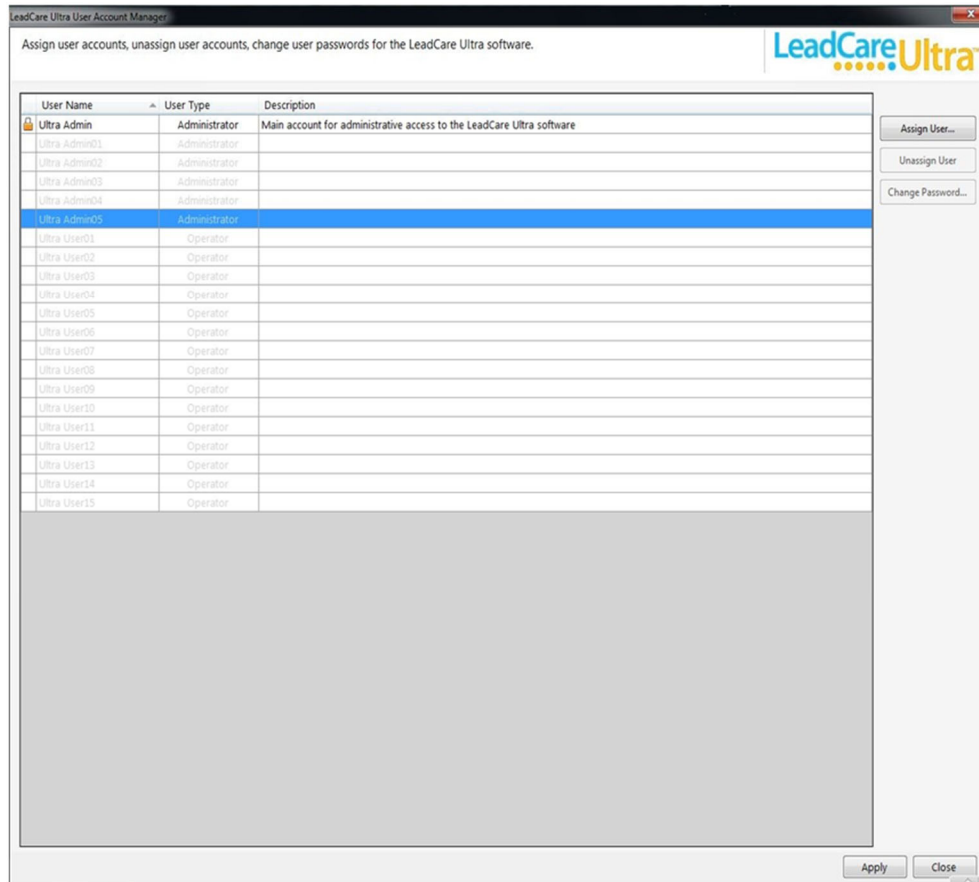
NOTE: The LeadCare Ultra User Account Manager has five pre-defined Administrator fields and fifteen pre-defined Operator fields.

b. Initialize the Barcode Scanner

If you installed your LeadCare Ultra System on your own, or if the barcode scanner was not initialized by the Magellan Diagnostic Representative, you must scan the barcode below to initialize the scanner before use. (Figure B-3)

IBM HAND-HELD USB

Figure B-3: Barcode for Initializing Barcode Scanner

The scanner makes three rapid beeps. The barcode scanner can now be used with the LeadCare Ultra System.

NOTE:	If the scanner beeps once, it has been previously initialized.
	The computer must be ON when scanning the barcode.

NOTE:	**Barcode Scanner Not Connected** – The Barcode Scanner does not need to be connected to the system in order to use the LeadCare Ultra User Application. The User Application defaults to manual entry mode when the barcode scanner is not connected. Specifically, if the scanner is not connected when the User Application starts, the "Barcode Reader Not Found" message will appear. Click **Continue** in response. The User Application can then be used to run samples; enter sample ID and other information manually via the keyboard.

If you choose to install the barcode scanner at a later time, you must exit the LeadCare Ultra Application, follow the instructions in User's Guide, and restart the application.

c. Create User Accounts
► Follow These Steps

1. Select the Account Manager User icon, type in the password, and press **Enter**.

2. The LeadCare Ultra User Account Manager dialogue box appears, containing a chart with User Name, User Type, and Description fields.

3. Select an appropriate User type, either an Operator or an Administrator. When the field is selected it will be highlighted and the Assign User field will become active.

4. Enter the information for User Name; Password; Confirm Password; and Description. User Type is pre-defined. Then select **OK**.

5. Click **Apply** to save changes.

6. The User created will be on the Login screen. To get to the Login screen select **Close** on the bottom left of the "LeadCare Ultra User Account Manager" screen.

d. Calibrate the System

Once the LeadCare Ultra System has been installed and User accounts have been established, the system is ready for initial calibration. Log in to proceed.

What is Calibration?

Each LeadCare Ultra Test Kit comes with a specific calibration button coded for the sensors provided for that sensor lot #. 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 the calibration button is held to the button reader on the analyzer, the calibration data for the sensor lot is transferred to the analyzer. When the transfer is complete, a beep sound and a "Calibration Successful" message appears. The lot number from the calibration button then appears in the upper left-hand corner of the User Application to verify that the calibration was read properly.

Calibration Procedure

The first time you log onto the analyzer after installation, the "Calibration Required" dialog box appears. (Figure B-4)
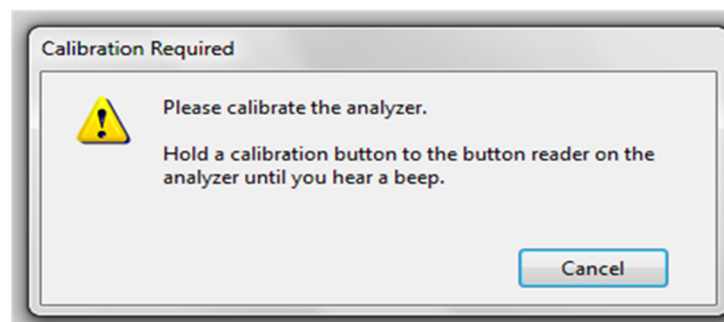

Figure B-4: Calibration Required Dialog Box

1. Remove the calibration button from the test kit you are going to use. (Figure B-5)
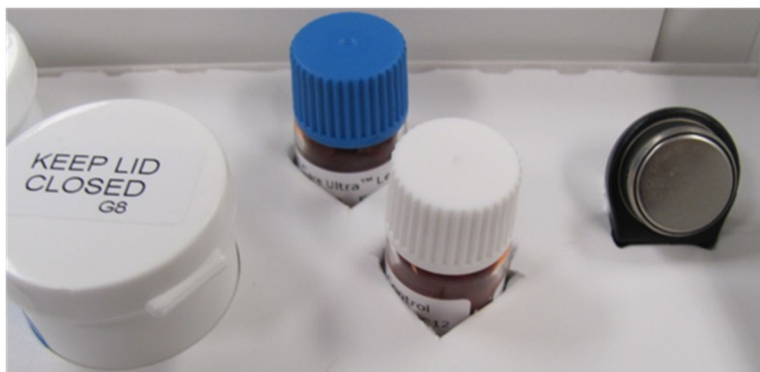

Figure B-5: Calibration Button

2. Hold the calibration button to the button reader until you hear the beep. (Figure B-6) The button must touch both the center contact and metal side of the button reader.

Figure B-6: Holding Calibration Button to Button Reader

3. Calibration takes a few seconds. When calibration is complete, the analyzer beeps and the screen briefly shows a message stating that the analyzer was calibrated successfully. (Figure B-7).
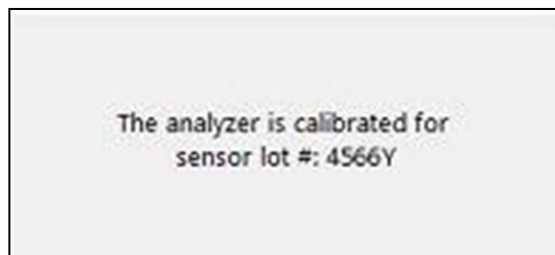

The analyzer is calibrated for
sensor lot #: 4566Y

Figure B-7: Successful Calibration Message

NOTE: Prior to beginning testing please review the important information regarding calibration outlined in the User's Guide provided with the system.

4. After the analyzer calibrates the Quality Control (QC) Information screen will pop up. For step-by-step instruction on entering QC information see Section 4.4 in the User's Guide.

e. Install a Printer (optional)

We recommend HP LaserJet P1102w (or similar).

Before connecting anything to the LeadCare Ultra System:

1. Unpack the printer and remove packing material.

2. Read the manufacturer's instructions for an overview.

3. Remove film from the ink cartridge per manufacturer's instruction.

4. Connect the power cord and adapter. **Do NOT connect the USB cord.**

5. Turn on the printer.

6. Load paper.

► Follow These Steps

1. Log into the System is as the LIMS ADMIN.

2. Insert the Disk into the LeadCare Ultra Computer (D Drive).

NOTE: The LeadCare Ultra User Application (UA) has disabled the auto-start function, therefore you will have to double click the drive in order to open it. *(If you don't see it, reboot the system.)*

3. **Auto-run** the set-up wizard to start the installation process.

4. Connect the printer's USB cable to the LeadCare Ultra Computer when requested.

5. Say NO to any add-on features and NO to updates.

6. When prompted, say YES to sharing. *(If you don't check off sharing, LeadCare Ultra operators will not have access to the printer.)*

7. Upon completion of the installation, print a Test Page.

8. Log out of LIMS Admin account and log in as a User.

9. Print a LeadCare Ultra report from the UA to confirm functionality.

If you accidentally selected the "Do not allow sharing" option, the LIMS Admin must:

1. Login to the LIMS application
2. Select **Devices and Printer**
3. Go to Printer Properties
4. Select **Sharing** Tab
5. Click **Share Printer**

The installation and set-up of your LeadCare Ultra Blood Lead Testing System is now complete.

Please read the information detailed in the User's Guide prior to performing testing.

If you have any questions, contact Magellan Diagnostics Product Support at 800-275-0102 Monday through Friday between 8 AM and 6 PM (EST) or by email at LeadCareSupport@magellandx.com.

This page intentionally left blank.

Appendix C Safety Data Sheets (SDS)

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

- [LeadCare Ultra/Plus Controls](#)
- [LeadCare Ultra/Plus Treatment Reagent](#)

This page intentionally left blank.