LeadCarePlus™

Blood Lead Testing System
with DMS

RECORD TEST RESULT
11.6 Mg/dL Pb
THEN REMOVE SENSOR
SENSOR LOT # 0508B

LeadCarePlus™

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 your system for future reference.

IVD | ℞ Only

Magellan
DIAGNOSTICS

Magellan

D I A G N O S T I C S

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

P/N 82-0037 Rev 04

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

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1   Important Safety Information

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

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

WARNING: Blood can transmit infectious *diseases*. Use universal precautions while collecting and handling blood samples. Follow the procedures established by your institution to maintain compliance with federal, state and local regulations.

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

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

1.1 Avoid Injuring Yourself

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

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

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

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

1.2 Avoid Injuring Patients

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

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

1.3 Avoid Damaging the System

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

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

1.4 Avoid Losing Blood Lead Test Result

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

CAUTION: Ensure that results are documented. If operating the LeadCare Plus without utilizing the LeadCare Plus Data Management System (DMS), manually record each test result as it appears on the analyzer screen. **Results are not stored on the analyzer.** If utilizing the DMS make sure results are backed up to the appropriate media. This practice will enable you to retrieve and restore data to the LeadCare Plus System, if necessary. See instructions in Chapter 10 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 to maintain compliance with federal, state, and local regulations.

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

2 About this User's Guide

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

2.1 Intended Use

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

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

2.2 Clinical Laboratory Improvement Amendments (CLIA) Classification

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

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

2.3 Additional Documentation

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

- LeadCare Plus Blood Lead Testing System Package Insert (English)
  – Part Number 82-0038
- LeadCare Plus Quick Start Guide
  – Part Number 82-0010
- Magellan HL7 Interface Specification document
  – Part Number 82-0039

2.4 User Assistance

Should you experience any difficulty installing or operating your LeadCare Plus Blood Lead Testing System, please contact your Magellan Diagnostics, Inc. Product Support Specialist. The Troubleshooting chapter in this guide (Chapter 13) includes a list of potential system problems, possible causes, and corrective actions. Please take some time to review this section 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
DMS	Data Management System
EMR	Electronic Medical Record
LIMS	Laboratory Information Management System
QC	Quality Control
BLL	Blood Lead Level
HCl	Hydrochloric acid
USB	Universal Serial Bus
PC	Personal Computer
LIS	Laboratory Information System

2.6 Compliance Statements

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

2.6.1 EMC Directive

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

2.6.2 Safety

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

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

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

2.6.3 FCC

This device complies with Part 15, Subpart B (2014) of the FCC rules. Operation is subject to the following two rules:

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

2.6.4 Waste Electrical and Electronic Equipment

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

2.6.5 Symbols

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

Symbol	Description
	Temperature Limitation
	Use By
	Manufacturer
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)
R Only	For Prescription Use Only

3   System Overview

3.1 Introduction

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

3.2 About Blood Lead Testing

According to the US Centers for Disease Control (CDC), there is no 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 Plus System Works

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

The diagram below illustrates the methodology.

1 Blood is mixed with treatment reagent and the red blood cells (RBC) are lysed, which releases the lead that is bound to the RBC wall.

Reagent

Pb^{+2}
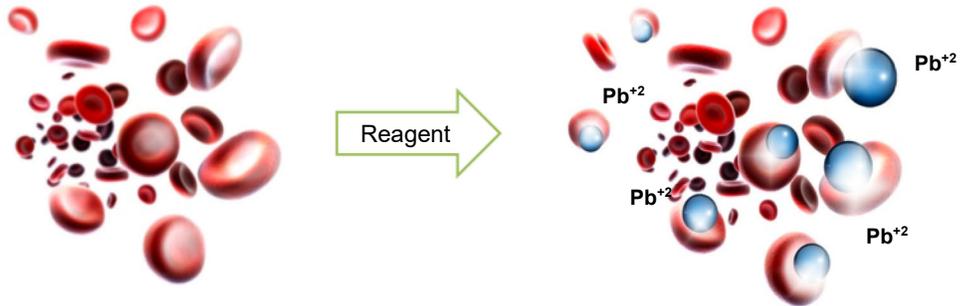
2 A negative potential is applied to the sensor to accumulate lead atoms on the test electrode. The potential is rapidly reversed releasing the lead ions.

Reduction step   **Oxidation (stripping) step**
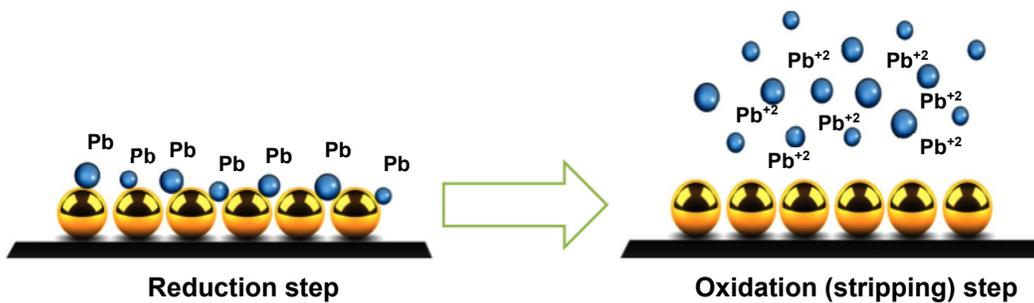
3 The current produced is directly proportional to the amount of lead in the sample. The area underneath the curve is used to calculate a quantitative blood lead result.
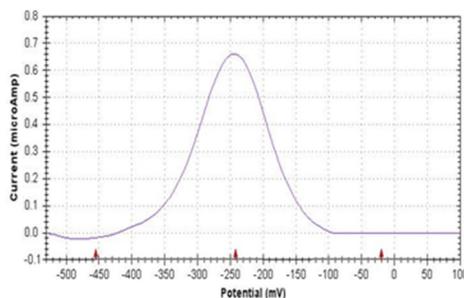
Analysis

Result:
11.3 µg/dL

3.4 System Components

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

1.   LeadCare Plus Analyzer Kit

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

NOTE: The User's Guide and Quick Start Guide provided in the analyzer kit do not include information regarding use of the LeadCare Plus DMS. Information regarding the use and capabilities of the DMS is provided in the LeadCare Plus with DMS User's Guide (this Guide). This Guide is included on the USB drive received when ordering the LeadCare Plus DMS (82-0003).

Figure 3-1   Analyzer Kit Contents

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2.   LeadCare Plus Test Kit

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

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

* LeadCare Plus Level 1 and Level 2 Controls are also referred to as Magellan Controls.

Figure 3-2   Test Kit Contents

Table 3-1: Test Kit Contents

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

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

3. LeadCare Plus DMS Software

    The LeadCare Plus DMS Software enables the download of information from the analyzer to a laboratory computer. The DMS application allows the collection, storage, sorting, and printing of results, and facilitates the transmission of results to an LIS/EMR system using an HL7 interface. The DMS components include a:

    - USB drive containing:
        - LeadCare Plus DMS Software
        - LeadCare Plus with DMS User's Guide
        - LeadCare Plus HL7 Interface Specification document
    - USB cable for connecting the analyzer to a laboratory computer.

NOTE: The DMS software must be installed on a PC with either Windows 7 or 8 (32/64 bit) or Windows 10 (64-bit). The computer is required but not supplied.

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4   Register Your System

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

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

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5   Setting up the Analyzer

5.1 The Work Area

When setting up the LeadCare Plus® Blood Lead Testing System, make sure that the analyzer is placed in an area free of drafts and extreme temperatures. The analyzer needs to be operated under stable temperature. The analyzer may be operated using an AC power adapter or with installed batteries.

5.2 Using the Analyzer with a Power Adapter

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

To use the analyzer with a power adapter:

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

Figure 5-1   Plug in DC Connector/AC Adapter

2.   Plug the adapter into an AC power outlet.

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

5.3 Installing Batteries

CAUTION: When replacing batteries, use only 1.5 V AA size alkaline or lithium batteries (4 each). Power off your analyzer prior to battery removal. Dispose of dead batteries according to local, state and federal regulations.

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

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

1. Turn the analyzer to access the battery area on the rear panel.

2. Remove the DC input connector.

3. Remove the battery cover as shown in Figure 5-2. Press on the locking tab with one or both thumbs (1) and slide cover away from the analyzer (2).

Figure 5-2   Remove Battery Holder Cover

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

Figure 5-3   Insert Batteries

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

5.   Replace the cover by sliding it back on. Make sure it "clicks" into place.

> **NOTE:**   When the analyzer is not in use it will automatically shut off:
> Battery: 15 minutes   AC Adapter: 60 minutes
>
> **Test results are lost and cannot be restored once the analyzer turns off.**

5.4 Operating Requirements

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

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

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

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

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

WARNING
TEMP IS UNSTABLE
TEST MAY FAIL

5.5 Reading the Analyzer Display

The LeadCare Plus Blood Lead Analyzer displays messages that guide you through the test. Do NOT go to the next step until the message tells you to proceed.

Figure 5-4   Message Display

The analyzer monitors the test conditions and displays error messages on the screen if a problem is detected. Chapter 13, Troubleshooting, includes a list of the messages and what to do if they appear.

6   Setting up the DMS

6.1 Overview

The Magellan LeadCare Plus® DMS is a PC-based data management software application. When working with the LeadCare Plus Analyzer, Users will have the option to use the LeadCare Plus DMS software to download and manage their patient and Quality Control results directly on their PC.

To utilize the DMS application the User must have a PC operating on a Windows 7, 8 or 10 system.

- The DMS software must be installed onto the PC.
- The analyzer is connected to the PC via a USB cable.
- A maximum of one analyzer can be connected to the DMS system at any given time.
- In order for data transfer to the DMS to occur, the analyzer must be connected to the PC, with the DMS application opened, while the test is being performed.
- Once the sample data has been downloaded to the DMS, authorized operators can search the results, generate reports, print reports, approve sample results and transmit the results to an EMR/LIS system.
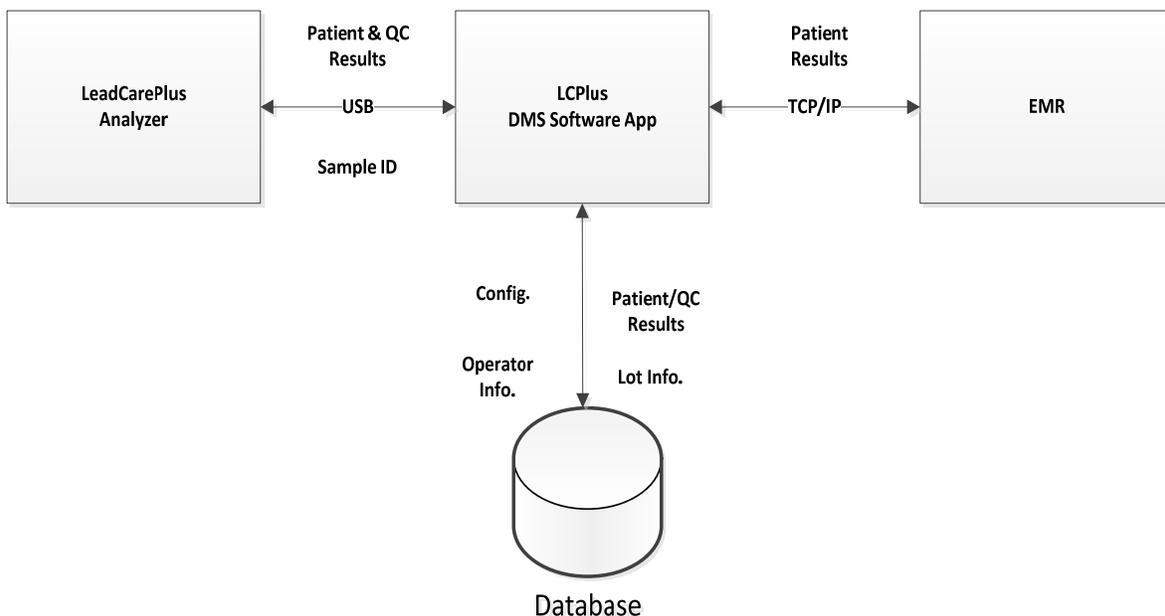
Figure 6-1   Information Flow from Analyzer to DMS to EMR/LIS

6.2 Installation of the DMS

The installation of the DMS involves downloading the DMS software from the USB memory stick to a personal computer (required but not provided) and then attaching the computer to the LeadCare Plus Analyzer via the USB cable provided. To begin this process, remove the USB cable and the USB memory stick from the DMS packaging then follow the steps outlined in the sections below.

Figure 6-2   USB Cable and Memory Stick

6.2.1 Downloading the DMS Software

The DMS software is provided on a USB memory stick. The software must be downloaded from the USB memory stick to your PC. The software must be installed on the computer **before** the LeadCare Plus Analyzer is connected to the PC.

► **Follow These Steps**
1. Make sure your PC is turned on and ready to install the application.

2. Insert the DMS USB memory stick into a USB port on the PC (Figure 6-14).

3. The memory stick contains the DMS Installer file, LCPlusDMSInstaller.

4. For **Windows 7**:

    a. Click the **Start** button in the lower left hand corner of the computer screen.

Figure 6-3   Windows 7 Start Button

    b. Click on the **Documents** folder from the menu that opens.

    c. Locate the USB drive name and icon and click on it to open.

---

d. You will see the LCPlusDMSInstaller name and icon. Double click this icon to open the installer.

Figure 6-4   DMS Installer Icon

5. For **Windows 8**:
   a. Click on the **Start** button in the lower left hand corner of the computer screen.

Figure 6-5   Windows 8 Start Button

b. The LCPlusDMSInstaller name and icon will appear on the screen. Double click this icon to open the installer.

Figure 6-6   Windows 8 Start Screen with LeadCare Plus Icon

6. For **Windows 10**:

   a. Click on the **Start** button in the lower left hand corner of the computer screen.

Figure 6-7   Windows 10 Start Button

b. In the **Documents** folder from the menu that opens, locate the USB drive name and icon and click on it to open.

c. You will see the LCPlusDMSInstaller name and icon. Double click this icon to open the installer:

Figure 6-8   *DMS Installer Icon from Windows 10*

7. A pop-up box displaying the "LeadCare Plus DMS Limited License Agreement" will appear.

Figure 6-9   *Limited License Agreement Box*

8. Scroll through and read the License Agreement. Click the **I agree** button to agree with the Terms and Conditions.

| **NOTE:** | If you do not agree with the Terms and Conditions click the **Close** button. The DMS software will not be installed and you will not have access to this application. |

9. To continue with the DMS installation select the **Install** button. A "Setup Progress" box will appear immediately followed by a "User Account Control Screen":
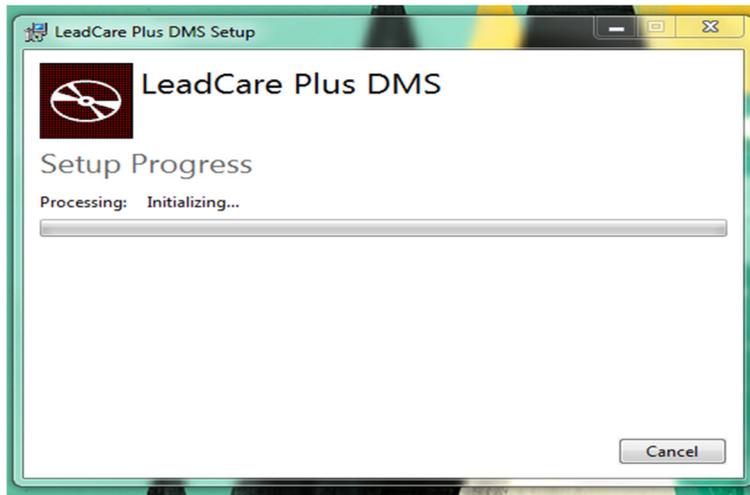
Figure 6-10   Setup Progress Message
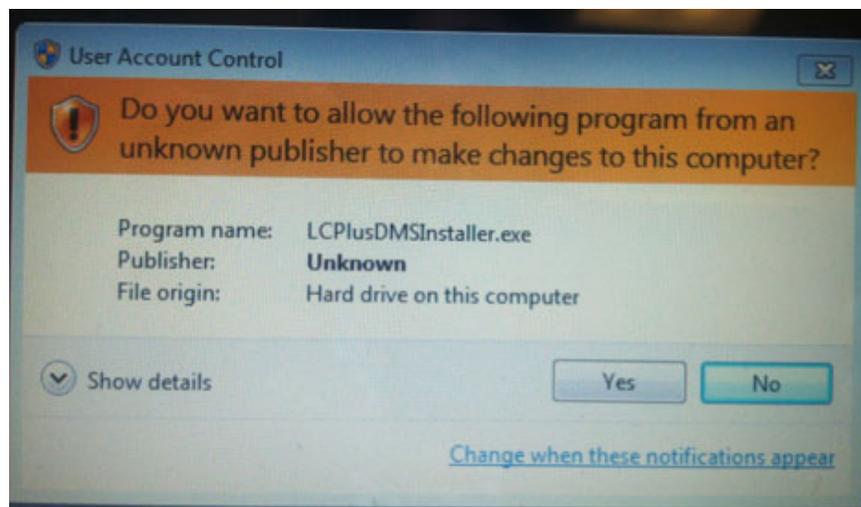
Figure 6-11   User Account Control Box

10. If you select the **No** button in the "User Account Control" box, or if a selection is not made within a few minutes, a "User Cancelled Installation" message will appear. At this point you can select the **Retry** button to continue with installation or select **Cancel**.
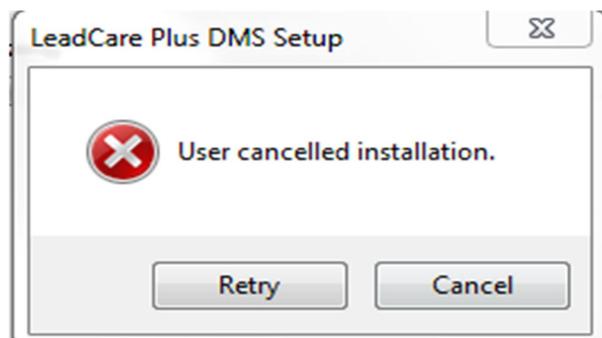
Figure 6-12   Installation Cancelled

11. To continue with the DMS installation select the **Yes** button from the "User Account Control" box. When the setup is complete the following box will appear:
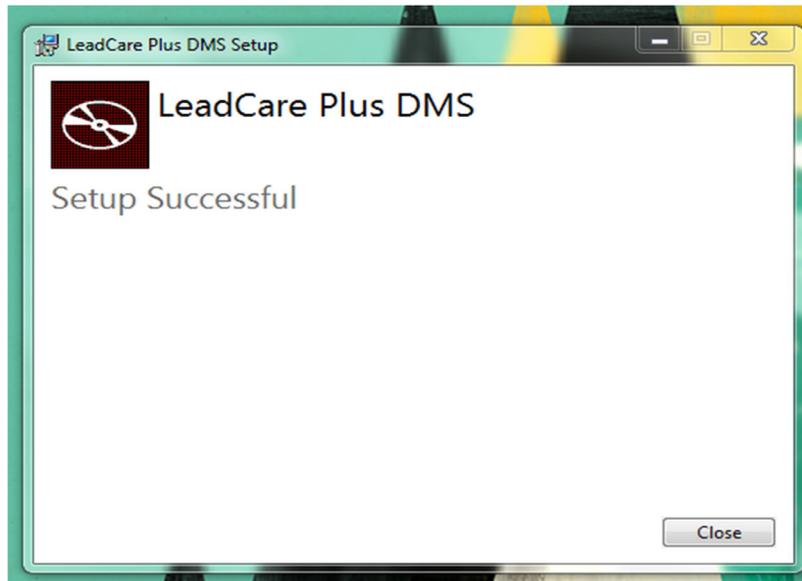
Figure 6-13   Setup Successful Message

12. Select the **Close** button to complete the DMS installation process.

13. After installation, **shut down and restart your PC**.

14. You are now ready to begin using the DMS software.

6.2.2 Connecting the Analyzer to the PC

The LeadCare Plus Analyzer must be connected to the PC to allow transmission of test results immediately after test analysis is complete.

► **Follow These Steps**

1. Make sure the LeadCare Plus Analyzer is turned off.

2. Connect the USB cable to the USB port on the back of the analyzer.

3. Connect the USB cable to a USB port on your PC.

Figure 6-14   USB Cable Connected to LeadCare Plus Analyzer

Figure 6-15 USB Ports on PC	*Figure 6-16 USB Cable and USB Memory Stick Inserted into USB Ports on PC*

NOTE: A barcode reader can be attached to the PC for use with the DMS. If you choose to use a barcode reader, follow the manufacturer's instructions to connect and initialize the barcode reader.

6.2.3 Operating the DMS

After successfully installing the DMS software on your PC, you are ready to operate the DMS.

► Follow These Steps

1. Go to the Local Disk (C:) folder.

2. Select the **Program Files (x86)**

3. Select the **Magellan Diagnostics folder**.

4. Select the **LeadcarePlusDMS folder**.

5. Open the folder and select the **LeadCarePlus DMS icon** to open the application.

> **NOTE:** You may want to select the **Pin to Taskbar** option to place the icon permanently on your taskbar. This will allow you easy access to the application during routine use.

4. When you click on the **DMS icon** the Login screen will appear:
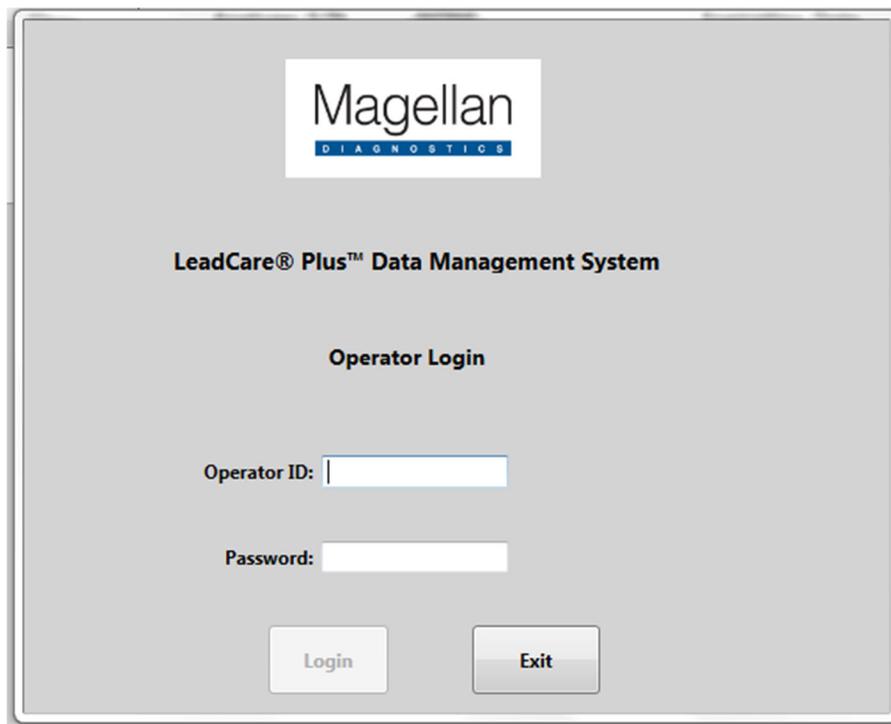
Figure 6-17   DMS Login Screen

6.3 Configuration of the DMS Features

6.3.1 Login and Operator Security

The DMS supports three levels of Users and one fixed Magellan account which is solely for Technical Support purposes. You have the ability to define a User as an Administrator; a Supervisor; or an Operator. Please note that an Administrator has the highest level of User access to the DMS with no restriction. Administrators have the ability to set up User accounts, setting both Supervisor and Operator names and passwords. The access assigned to each level of User is listed in Table 6-1.

Table 6-1: Access Assigned to Each Level of User

Operator ID	Level	Access	Default Password
Administrator	Highest	• No restrictions	123456
Supervisor	Medium	• Create/Modify/Delete User Accounts • Renew User Accounts • Define Controls • Manage Controls • Search Results • Approve/Delete Results • Bypass Approval • Amend Sample Results • View/Print Reports • Export Audit Log • Export Patient/QC Samples • Export Results • Resend Results to EMR • Download Event/POST Logs • Backup/Restore Data	123456
Operator	Lowest	• Search Results • Define Controls • View/Print Reports	None

All Users must be assigned a login name and password. An Administrator can set up all accounts, including a Supervisor account. A Supervisor can set up an Operator account. Operators do not have access to set up accounts.

6.3.2 Managing User Accounts

The DMS is provided with two established active User accounts, an Administrator and a Supervisor account, to allow initial login to the system. These accounts are assigned the default password "123456". As part of the set-up process for the DMS you should determine who will be authorized to use the DMS and the level of security appropriate for each User. Once this is determined, accounts for each User can be created by either an Administrator or Supervisor. Initially, the Administrator of the system must log in using the default password and then personalize their account.

> **NOTE:** Operator IDs must be 6-16 characters in length. Passwords must be 6-12 characters in length.

6.3.2.1 Initial Login

1. The Account Administrator should log in to the DMS by entering the account name "Administrator" into the "Operator ID" field and entering the default password of "123456" into the "Password" field:
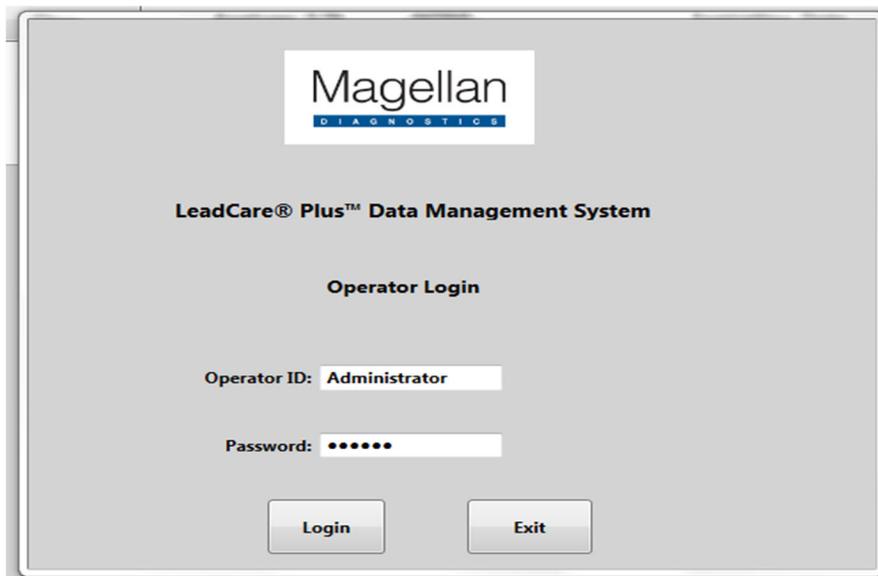
Figure 6-18   Initial Administrator Login

2. Then select the **Login** button.

3. A reminder message box will automatically display stating "Perform QC daily before testing patient samples". Select **OK**.
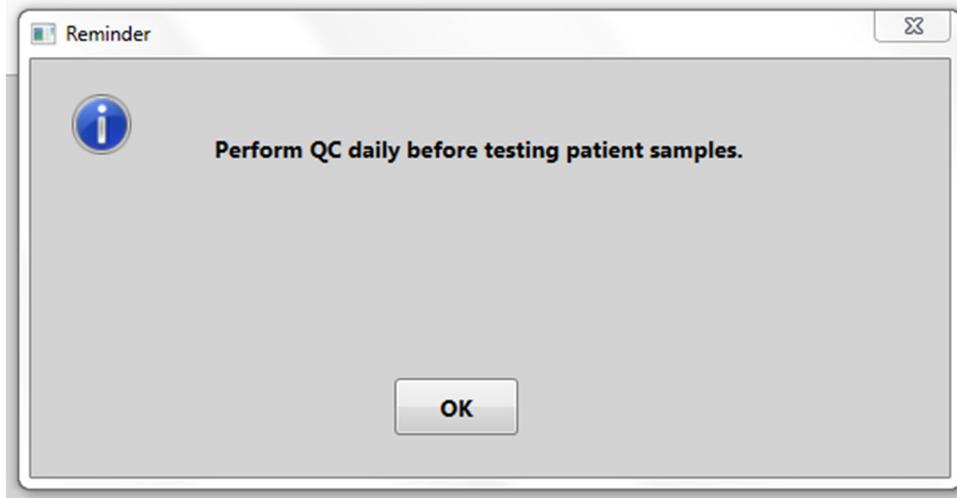
Figure 6-19   Reminder to Perform Daily QC

4. The Administrator is now logged into the DMS and the DMS User Screen will open.

> **NOTE:** After using the default Operator ID and password an Administrator or Supervisor should change the password following the steps outlined in the "Editing/Deleting User Account Information" section (Section 6.3.4).

5. Once logged into the DMS, the User Screen or Main Screen will appear:
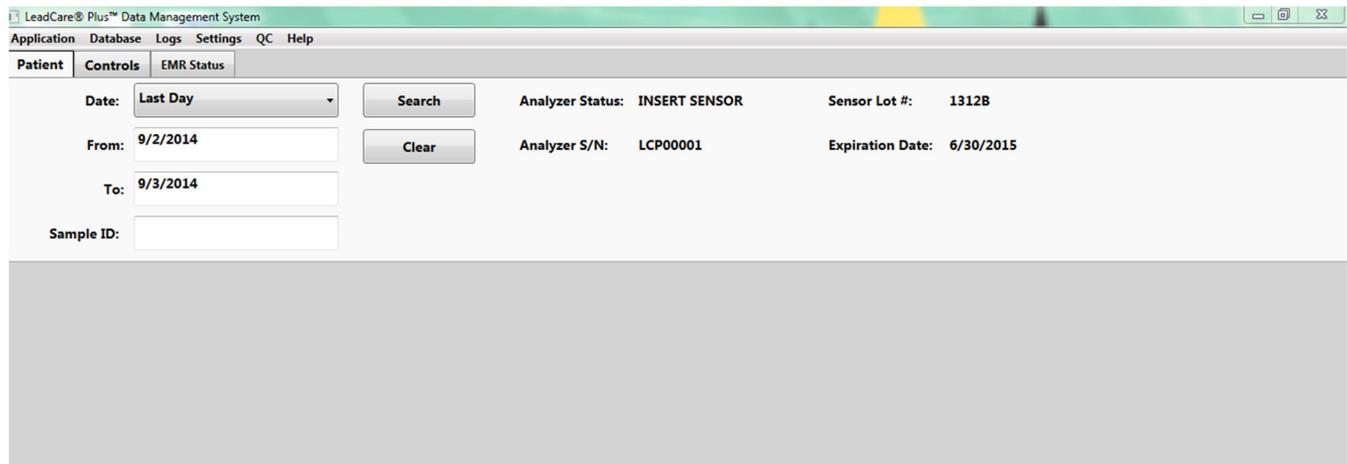
Figure 6-20   DMS User Screen

6. The toolbar on the top of the User Screen has six tabs, each of which lead to additional features of the DMS (Application; Database; Logs; Settings; QC; Help).

Application: 	Database:
Logs: 	Settings:
QC: 	Help:
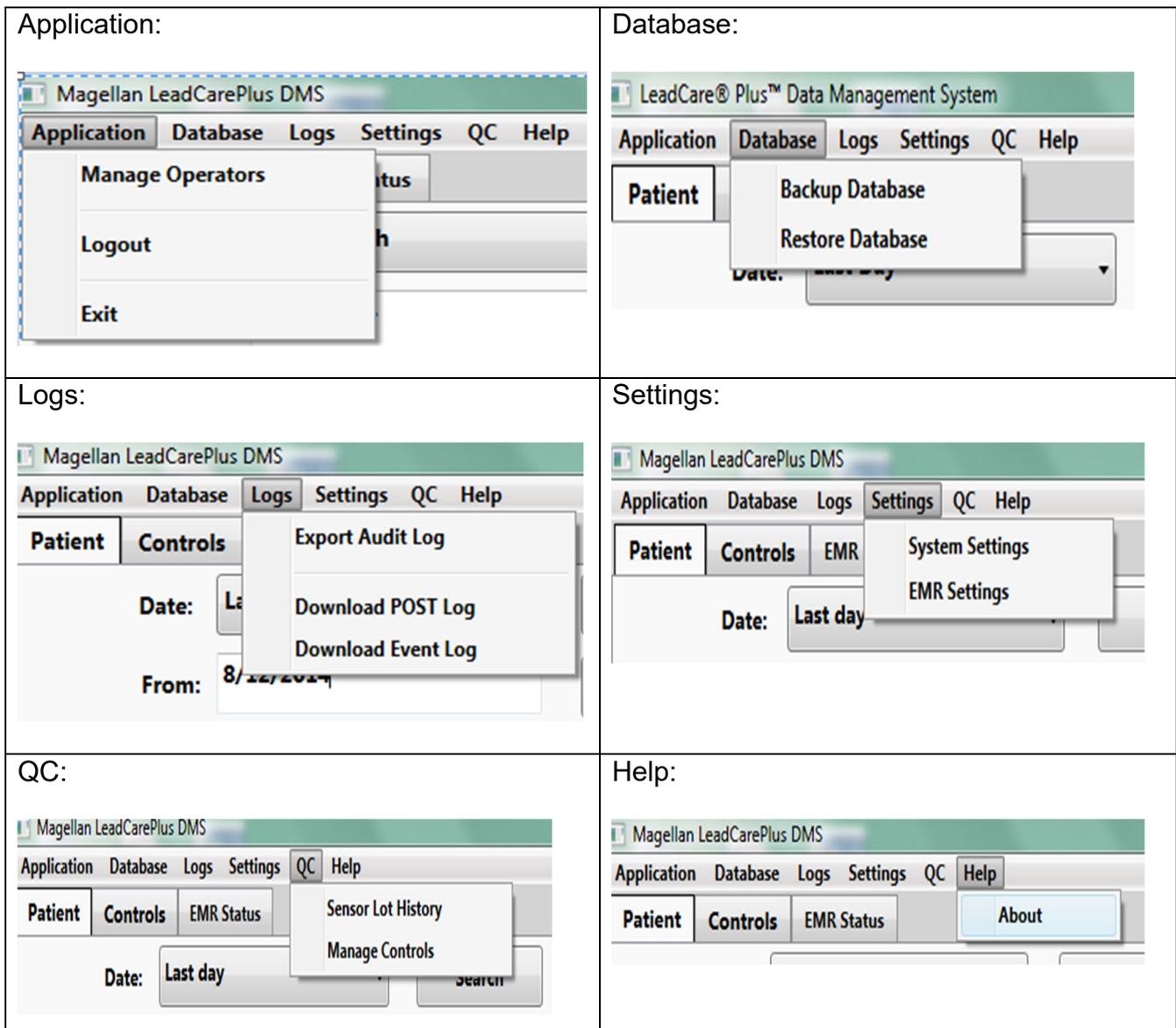
Figure 6-21   Feature Tabs on toolbar

7. Below the toolbar are three key tabs, Patient, Controls, and EMR Status:
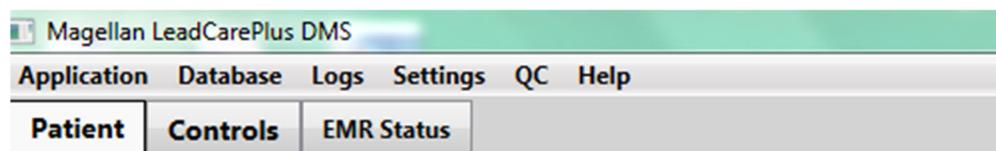
Figure 6-22   Tabs to Access Patient and Controls Data Screens

8. The screens associated with each of these tabs are shown below:
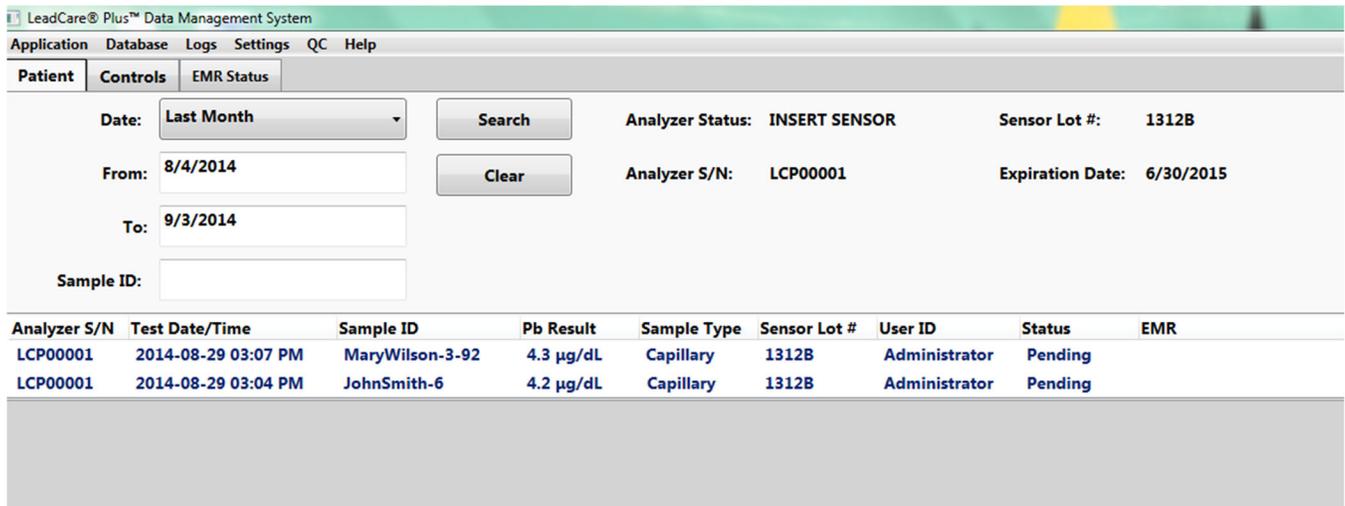
Figure 6-23   Patient Data Screen
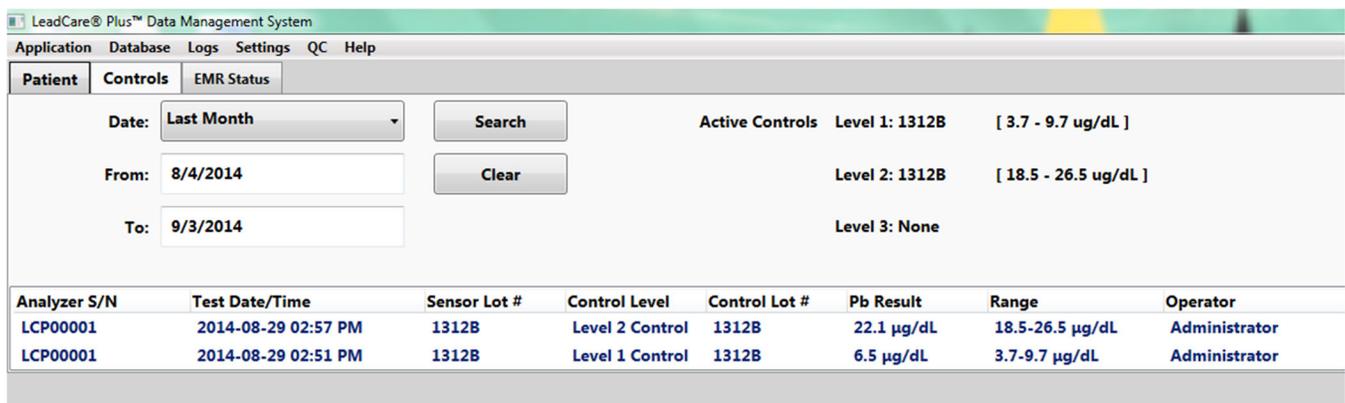
Figure 6-24   Controls Data Screen
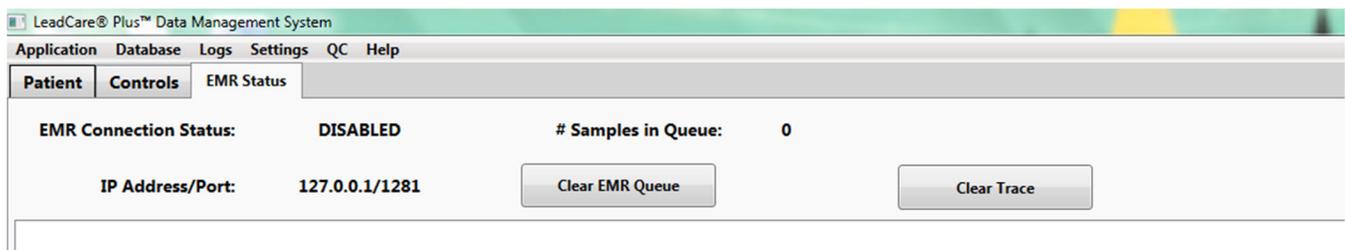
Figure 6-25   EMR Status Screen

9. Each of these screens and their associated functions will be addressed further in this User's Guide.

6.3.2.2 Adding User Accounts

1. Select the **Application** tab on the toolbar and then select **Manage Operators** from the dropdown menu.
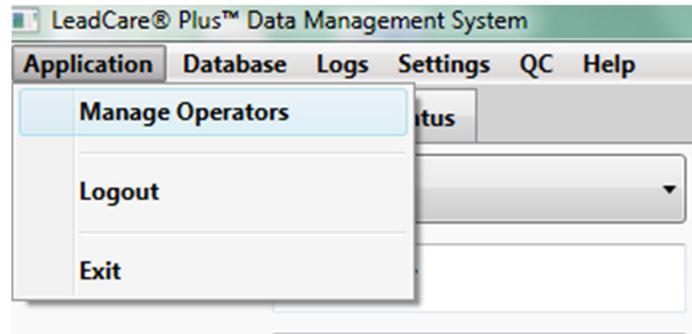
Figure 6-26   Application Tab Dropdown

2. The following "User Account" box will appear.
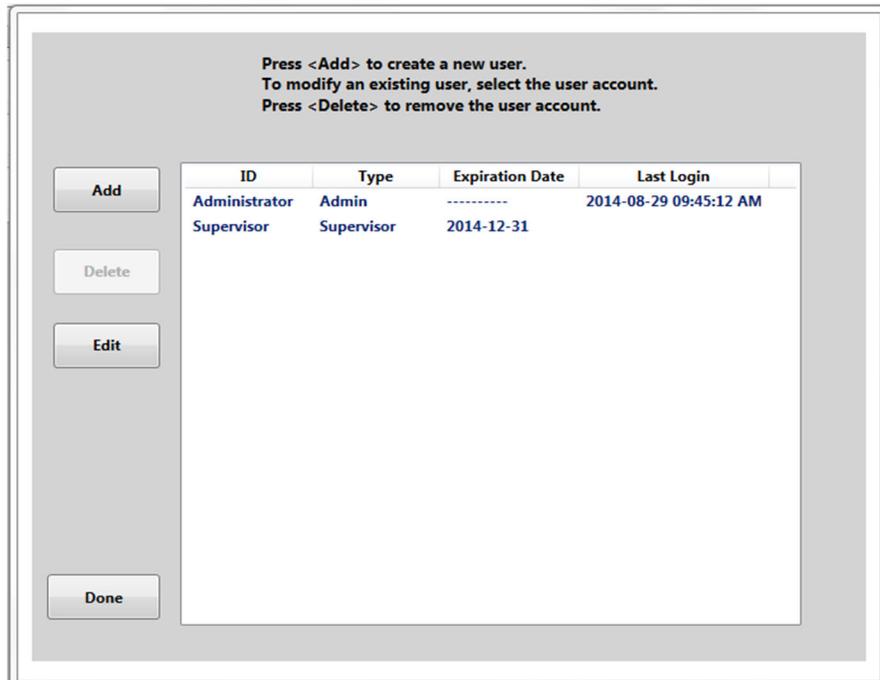
Figure 6-27   User Account Box

3. Select the **Add** button to add a User.

4. The "Create/Modify User Accounts" screen will display.
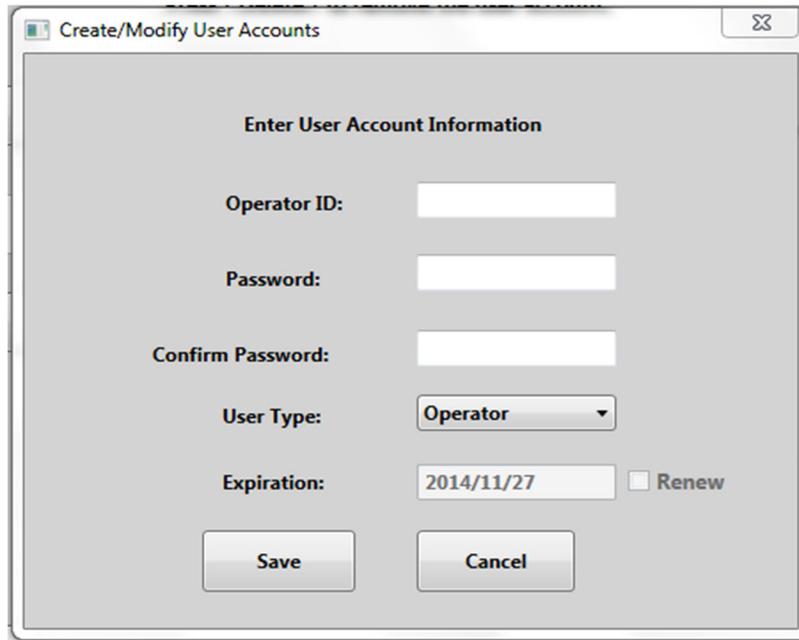
Figure 6-28   Create/Modify User Accounts Screen

5. To create a new User, type in the Operator ID and password for the User in the fields provided.
6. You will be required to confirm the User password and select an Operator or Supervisor from the "User Type" dropdown menu.
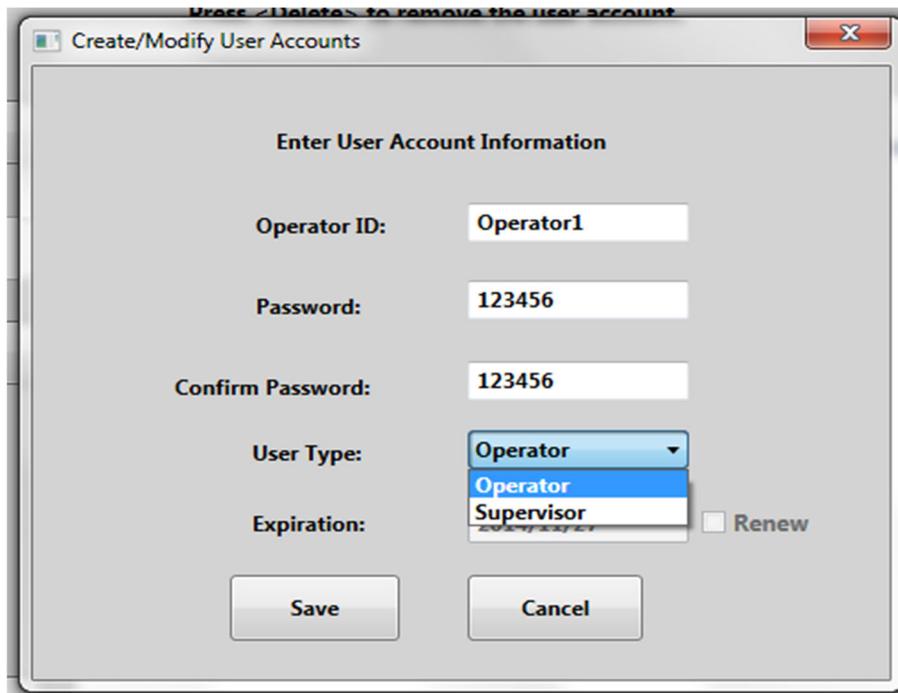
Figure 6-29   Entering User Account Information

NOTE: An Operator ID and password combination must be unique. If you attempt to set up a User Account with an already assigned Operator ID or Password, an error message will display.
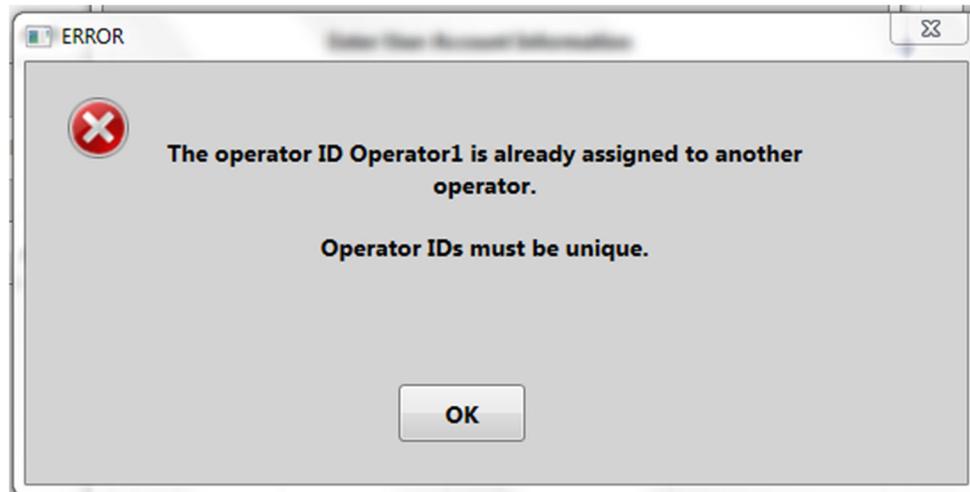
Figure 6-30   Error: Operator IDs Must be Unique

NOTE: The DMS will support a maximum of 1 Administrator; 20 Supervisor and 20 Operator accounts.

6.3.3 User Account Expiration and Renewal

User Accounts are automatically assigned a 90 day expiration date. As a reminder to renew an account, an expiration notification will appear daily starting ten days prior to expiration date.
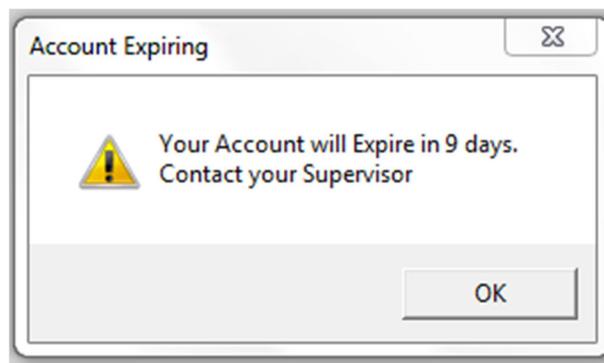
Figure 6-31   Warning: Account Expiring

If the User attempts to log in after the account has expired, the following message will display:
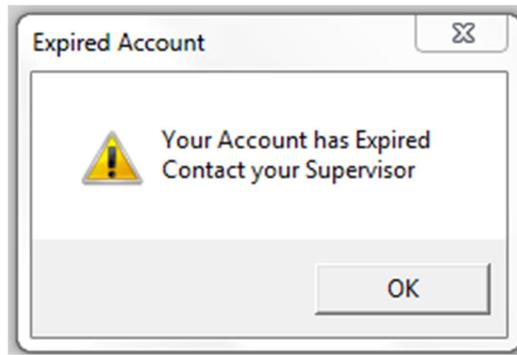
Figure 6-32   Warning: Account Expired

The User will be denied access to the DMS and will encounter an "Authentication Failed" message box. This flags the User that they must log in with a valid ID and password.
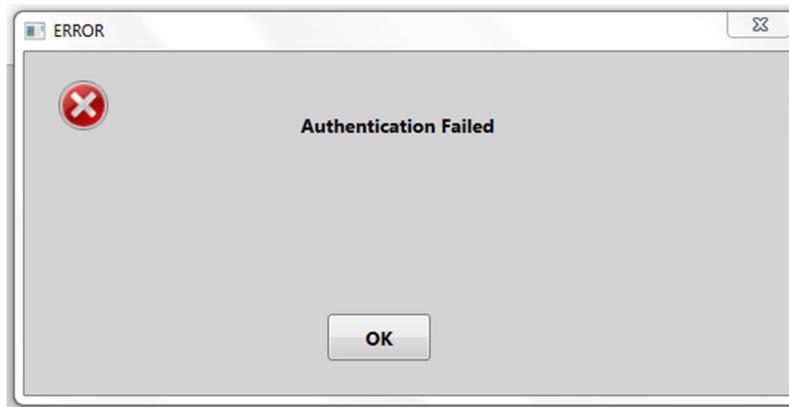
Figure 6-33   Error: Authentication Failed

The Supervisor or Administrator can renew a User Account by following the steps below:

1. Select the **Operator ID** from the "Create/Modify User Account" Screen
2. Scroll to the left and select the **Edit** box.
3. Select the **Renew** check box.
4. When you have entered the User Account Information into the appropriate fields select the **Done** button.

Figure 6-34   Renew Expired Account

To access use of the DMS, each User must log in to the DMS with the Operator ID and password assigned to them. They will be restricted to DMS activities appropriate for the User Type assigned.

6.3.4 Editing/Deleting User Account Information

User Account Information can be changed at any time by an Administrator or Supervisor.

► **Follow These Steps**

1. Select the **Application** tab on the toolbar.

2. Select the **Manage Operators** field.

3. Click on the User Account you wish to modify and select **Edit**.

4. The Account Information will display and the fields can be edited.

5. After you edit the User information as desired select the **Save** button to save your changes.

To delete an account, click on the User Account and select the **Delete** button. An automatic prompt will appear confirming if you intend to delete the selected User. Click **Yes** if you wish to delete the account.
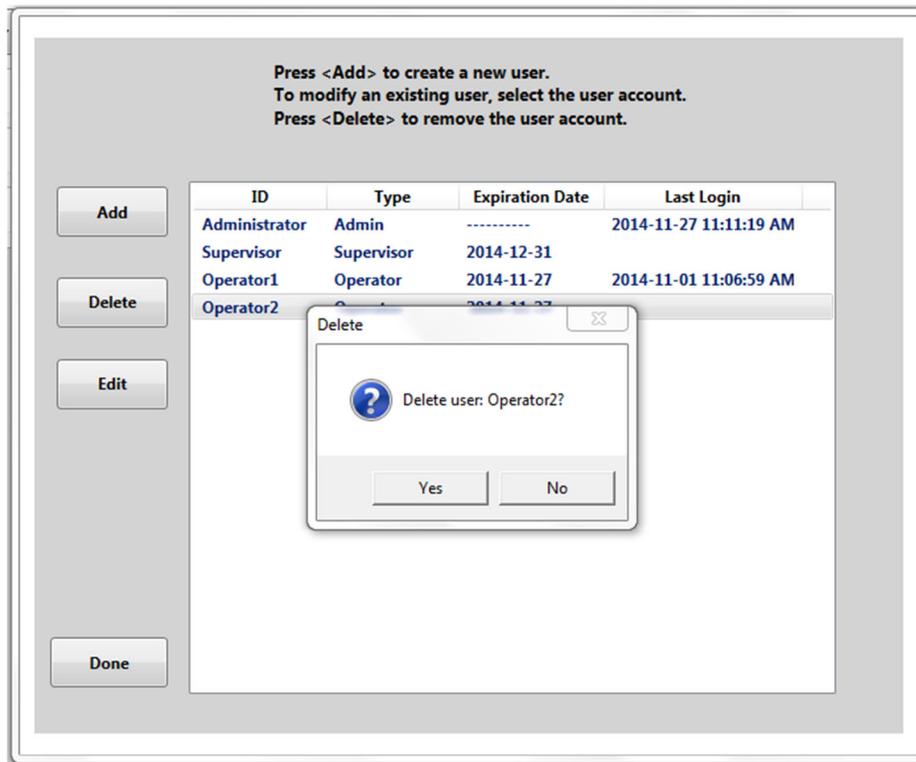
Figure 6-35   Confirmation of Account Deletion

NOTE: The double-clicking feature is not available from this screen. To modify User Accounts, you must scroll over and select the "Add", "Delete" or "Edit" tabs.

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7 Calibrating the Analyzer

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

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

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

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

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

7.1 Turning the Analyzer On and Off

The LeadCare Plus® Blood Lead Analyzer **power switch** is located on the back of the device as shown in Figure 7-1.
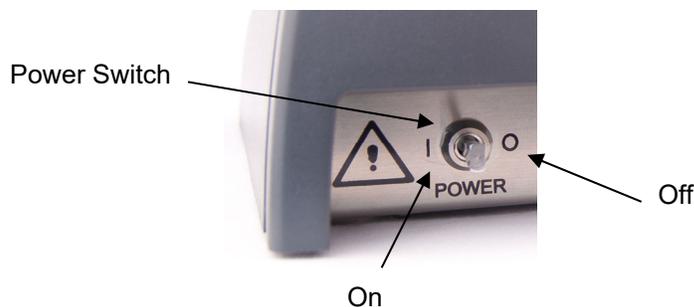
Figure 7-1   Power Switch

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

7.1.1 Turn On the Analyzer

To turn on the analyzer for the first time:

1. Make sure the analyzer is plugged in using the AC adapter, or that batteries are installed.

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

Figure 7-2   Turn Analyzer On

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

3. When you first turn on the analyzer, you will hear a beep and see the startup and self-test messages on the analyzer message display screen. After the system self-tests, the display screen reads:

> PLEASE CALIBRATE
> ANALYZER WITH BUTTON

You can also turn on the analyzer by inserting a sensor. If you insert a sensor to turn on the analyzer, the following message appears:

> ADD SAMPLE
> TO X ON SENSOR
> SENSOR LOT XXXX

NOTE: When using the analyzer with the DMS, it is important to turn the instrument on by the power switch (not with an inserted sensor). After the analyzer is turned on, turn on your PC and log in to the DMS before calibrating.

7.2 About Calibration

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

> PLEASE CALIBRATE
> ANALYZER WITH BUTTON

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

When you touch the calibration button to the button reader on the analyzer, the calibration data for the sensor lot is transferred to the analyzer. When the transfer is complete, an audible tone sounds and a "Calibration Successful" message appears on the analyzer display screen. The sensor lot will also display in the upper right hand corner of the DMS User Screen.

7.3 Calibration Procedure

You must calibrate the analyzer:

- The first time you use the analyzer.

- Each time you change test kit lot numbers.

- Any time the analyzer screen displays a recalibration message.

WARNING:

- Each test kit comes with a calibration button marked with the sensor lot calibration code. Always make sure that the lot numbers labeled on the sensor containers and calibration button match the "Sensor Lot #" on the analyzer display.

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

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

NOTE: **When using the DMS, make sure the analyzer is connected to the PC and you are logged into the DMS before calibrating the analyzer.**

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

2. Hold the calibration button to the button reader until you hear the beep; see Figure 7-3. The button must touch both the center contact and metal side of the button reader. There is no need to apply pressure to the button reader.

Figure 7-3   Holding Calibration Button to Button Reader

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

```
CALIBRATION
SUCCESSFUL
```

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

```
PREPARE SAMPLE USE SENSOR LOT
XXXX
OR RECALIBRATE
THEN INSERT SENSOR
```

5. When the analyzer is calibrated, the DMS requires activation of the appropriate lots of quality control. Prior to testing, proceed to Chapter 8 for information on Performing Quality Control.

8   Performing Quality Control

8.1 Introduction

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

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

8.2 What are Blood Lead Controls?

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

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

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

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

It is possible to employ third party controls (controls not manufactured by Magellan) when using the LeadCare Plus Blood Lead Testing System. However, Magellan will not have performed value assignment to establish the acceptable range for use of these controls with the LeadCare Plus Sensors. The range established by the control manufacturer may or may not agree with the values obtained using the LeadCare Plus. This difference may be attributed to matrix effect resulting from the use of two different technologies in value assignment.

8.3 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.

8.4 Activating Quality Control Lots

1. When the analyzer is calibrated, the DMS requires activation of the appropriate lots of Quality Control.

    a. When the analyzer is calibrated to a new sensor lot, the DMS will display the "Lot Has No Ranges" message screen. This is to remind you that you have calibrated the analyzer and now must define the Control Range Values and activate the lot in the DMS.

    NOTE: If "Third Party Controls" were activated and defined in the system previously, this message prompt may not appear (See Section 8.4.2, Activating Third Party Controls).
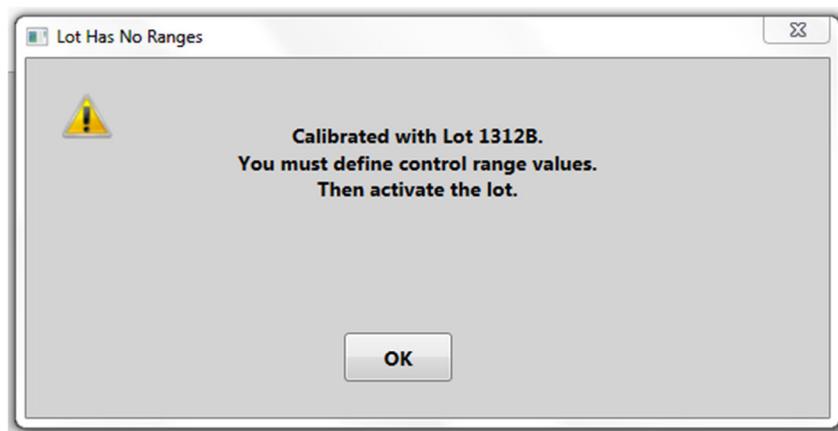
Figure 8-1   Warning: Define Control Range Values and Activate Lot

b. If the analyzer is calibrated and the DMS does not recognize any active Control Lots the "No Ranges" message will display.

Figure 8-2   *Reminder that Controls Must be Defined*

2. Click the **OK** or **YES** button and then perform the following steps:

    a. Select the **QC** tab from the toolbar.

    b. Select **Manage Controls** from the dropdown menu. The "Activate/Deactivate" box will appear.
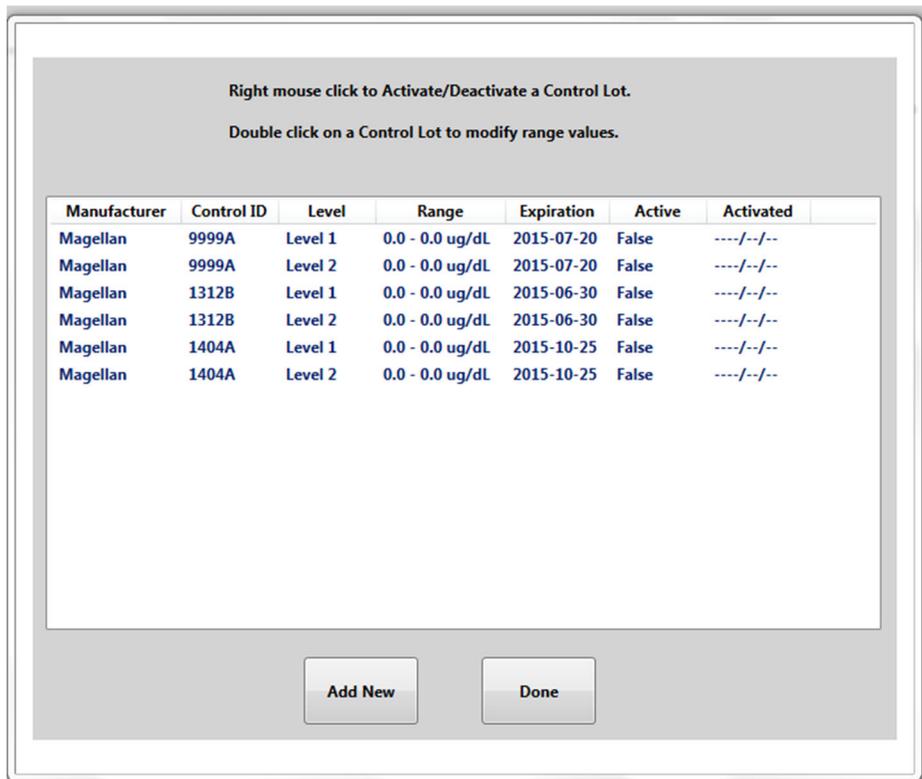
Figure 8-3   *Activate/Deactivate Controls Box*

NOTE: You may use the Quality Control samples provided by Magellan or third party controls. If you are using Level 1 and Level 2 Magellan Controls and want to add a third level of control you **must choose the "Level 3" control name** from the dropdown menu to enter this third control regardless of the Lower and Upper Limits of the control. (See Section 8.4.2, Activating Third Party Controls).

8.4.1 Activating Magellan Controls

1. To activate Magellan (LeadCare Plus) Controls in the DMS, navigate to the "Activate/Deactivate" box from the QC tab, and perform the following steps:

   a. Match the sensor lot and your Level 1 Control Lot from the DMS screen with the calibration code on the analyzer display.

   b. Double click on the **Level 1 Control Lot** to display the "Control Information" box on the User Screen.

Figure 8-4   Control Information Box

   c. Type in the Lower and Upper Limits. To calculate these values, refer to the Target Ranges listed on the outside of the Magellan Control vial.

   Ex. Level 1 Target 6.7 +/- 3.0 = Lower Limit 3.7 to Upper Limit 9.7 µg/dL

Figure 8-5   Enter Control Limits

d. Select the **Save** button after you have entered the Control Limits. A "Lot Activated" message box will appear confirming that the lot is now updated in the DMS. Click **OK**.
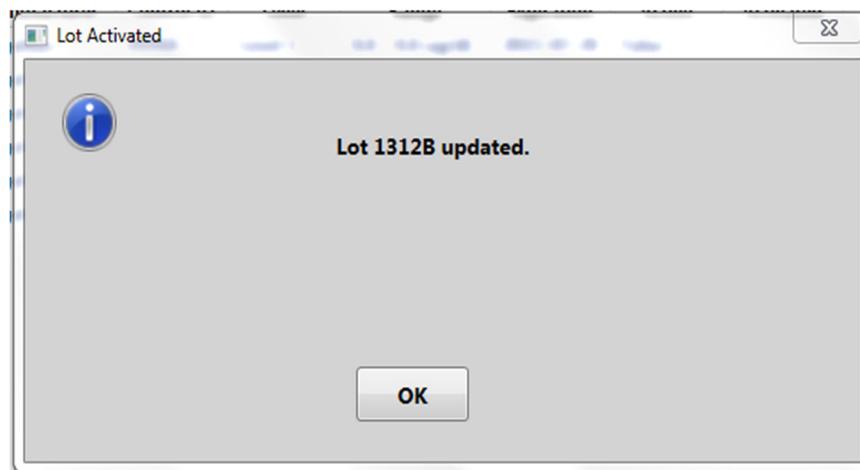
Figure 8-6   Confirmation of Control Lot Update

e. Repeat steps "a" through "d" for the Level 2 Control of the same lot.

f. Next, you must "Activate" the Control Lots. Right click on the **Level 1 Control Lot** and select **Activate** from the dropdown menu.

g. A "Lot Activated" message box will appear confirming the lot has been activated. Click **OK**.
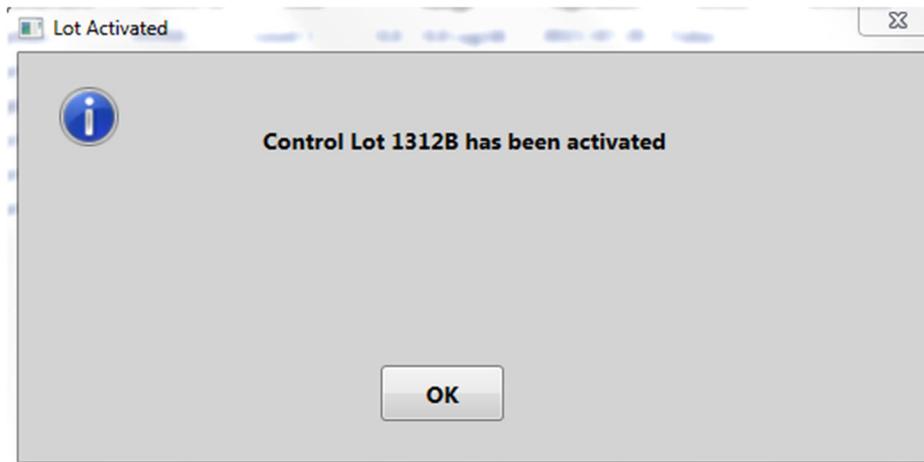
Figure 8-7   Confirmation of Control Lot Activation

h. Confirm that the "Active" status in the Control Lot Table changed from "False" to "True" and select **Done**.

Right mouse click to Activate/Deactivate a Control Lot.

Double click on a Control Lot to modify range values.

Manufacturer	Control ID	Level	Range	Expiration	Active	Activated
Magellan	1312B	Level 1	3.7 - 9.7 ug/dL	2015-06-30	True	2014-08-29
Magellan	1312B	Level 2	18.5 - 26.5 ug/d	2015-06-30	True	2014-08-29
Magellan	9999A	Level 1	0.0 - 0.0 ug/dL	2015-07-20	False	----/--/--
Magellan	9999A	Level 2	0.0 - 0.0 ug/dL	2015-07-20	False	----/--/--
Magellan	1404A	Level 1	0.0 - 0.0 ug/dL	2015-10-25	False	----/--/--
Magellan	1404A	Level 2	0.0 - 0.0 ug/dL	2015-10-25	False	----/--/--

Add New   Done

Figure 8-8   Confirmation of Control Lot Active State is "True"

i. If one Magellan Control Level is activated, the other Magellan Control Level of the same lot will automatically be activated.

NOTE: If the "Active" status remains as "False", an error occurred and the steps to activate the lot **MUST** be repeated.

NOTE: If you try to activate a Magellan Control Lot different from the Sensor Lot displayed on the analyzer screen, you will receive an error message in the DMS.

Click **OK** and activate the Control Lot which corresponds to the Sensor Lot in use.

Once you have activated the control lots, click on the **Patient** tab and confirm that the sensor lot number on the analyzer display matches the sensor lot number on the DMS User Screen.
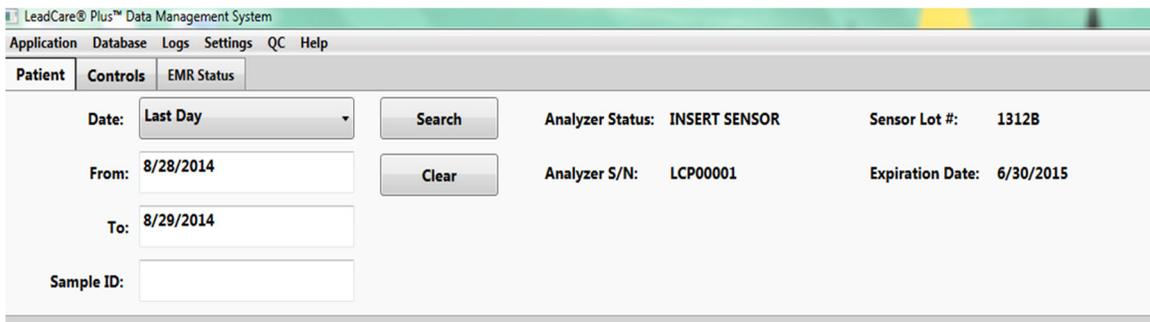
Figure 8-9   Confirmation of Sensor Lot Number

8.4.2 Activating Third Party Controls

NOTE: When entering information for third party controls, it is not possible to add expiration dates.

1. To activate third party controls in the DMS, navigate to the "Activate/Deactivate" box from the QC tab and perform the following steps:
   a. When the Activate/Deactivate box appears on the screen, select the **Add New** button.
   b. The "Control Information" box will appear. The Manufacturer will be listed as "Other" and the "Expiration" field will permanently remain unpopulated.

Figure 8-10   Entering Third Party Controls

c. You may enter up to three levels of control. Select the Control Level from the dropdown menu.

Figure 8-11   Three Levels of Third Party Controls Possible

d. Enter the Control Lot ID and the Lower and Upper Control Limits provided by the control manufacturer.
e. Repeat steps "a" through "d" for each level of control.

NOTE: When using a set of third party controls the "Control Lot ID" should represent the manufacturing lot (e.g. Control Kit Lot Number) and therefore be the same for each control level entered.

Next, you must activate each third party control individually. The third party controls will not activate as a pair or as a set.

a. Right click on each Control Lot and select **Activate** from the dropdown menu. Confirm that the "Active" status in the Control Lot Table changed from "False" to "True" and select **Done**.

NOTE: If the "Active" status remains as "False" an error occurred. Repeat the steps to activate the lot.

Once you have activated the control lots, confirm that the sensor lot number on the analyzer display matches the sensor lot number visible from the Patient tab on the DMS User Screen.

NOTE: The DMS keeps track of the activated and deactivated sensor lots. To view the sensor lot history select the **QC** tab on the toolbar and choose **Sensor Lot History** from the dropdown menu.
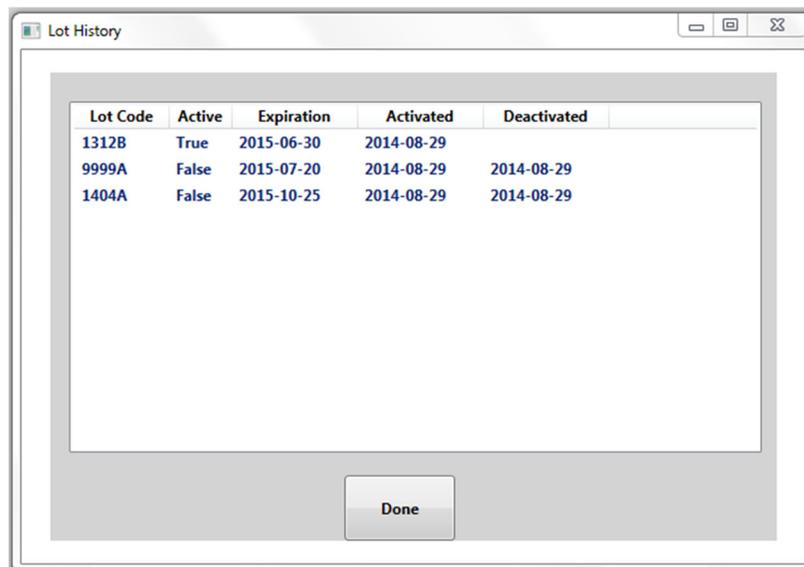
Lot History

Lot Code	Active	Expiration	Activated	Deactivated
1312B	True	2015-06-30	2014-08-29	
9999A	False	2015-07-20	2014-08-29	2014-08-29
1404A	False	2015-10-25	2014-08-29	2014-08-29

Done

Figure 8-12   Sensor Lot History

8.4.3 Activating Magellan Level 1 and 2 Controls and a Level 3 Third Party Control

If you would like to use three levels of control, it is possible to activate the Magellan LeadCare Plus Level 1 and Level 2 Controls and also activate a third party Level 3 Control.

1. You must first follow the instructions for activating the Magellan Level 1 and Level 2 Controls. (Section 8.4.1)

2. After the Magellan Controls are activated, you can then activate the Level 3 third party control.

3. This is the only combination of Magellan and third party controls you can use. The Magellan Level 1 and Level 2 Controls must always be used as a pair. You can never activate only one of the Magellan Controls.

8.4.4 Deactivating Controls

Once control lot information is entered, it will remain in the "Activate/Deactivate" list until it is deleted. To deactivate the current active lot, perform the following steps:

1. To deactivate the controls, select the **QC** tab from the toolbar.

2. Select **Manage Controls** from the dropdown menu. The Activate/Deactivate box will appear.

3. Right click on the control you want to deactivate and select **Deactivate** from the dropdown menu.

Right mouse click to Activate/Deactivate a Control Lot.

Double click on a Control Lot to modify range values.

Manufacturer	Control ID	Level	Range	Expiration	Active	Activated
Other	TP6535-1	Level 1	6.0 - 9.0 ug/dL	----/--/	True	2014-08-20
Other	TP6535-2	Level 2	19.0 - 26.0 ug/d	----/--		
Other	TP6535-3	Level 3	27.0 - 33.0 ug/d	----/--		
Magellan	9999A	Level 1	0.0 - 0.0 ug/dL	2015-(		
Magellan	9999A	Level 2	0.0 - 0.0 ug/dL	2015-(		
Magellan	1312B	Level 1	3.7 - 9.7 ug/dL	2015-(		
Magellan	1312B	Level 2	18.5 - 26.5 ug/d	2015-00-30	False	2014-08-29
Magellan	1404A	Level 1	5.0 - 8.0 ug/dL	2015-10-25	False	----/--/--
Magellan	1404A	Level 2	13.0 - 21.0 ug/d	2015-10-25	False	----/--/--

Activate Control
Deactivate Control
Deactivate All Controls
Remove Control
Remove All Controls

When one control level gets deactivated, the second control level from the same lot # gets auto-deactivated as well.

Add New   Done

Figure 8-13   Deactivate Control Dropdown Menu

4. A pop-up message will appear requesting you to confirm if you want to deactivate the lot.
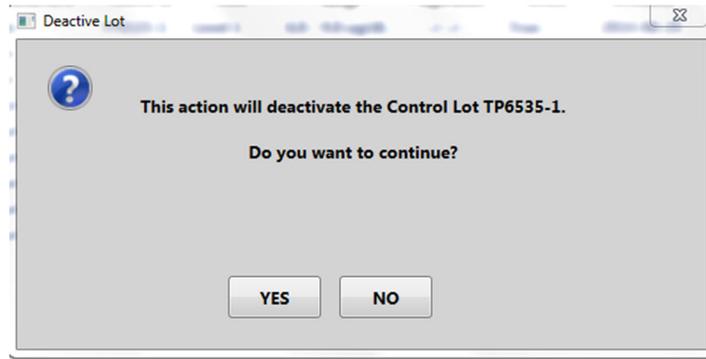
Figure 8-14   Confirmation of Control Deactivation

5. The lot will be deactivated and an information box confirming this action will appear.
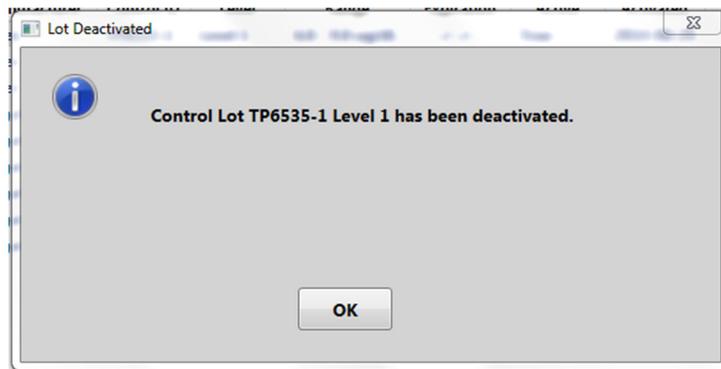
Figure 8-15   Deactivation Complete

6. Confirm that the "Active" status in the Control Lot Table changed from "True" to "False" and select **Done**.

7. If you deactivate one Magellan Control Level, the other Magellan Control Level of the same lot will automatically become deactivated.

8. To deactivate third party controls, each control must be deactivated separately.

NOTE: If you calibrate the analyzer to a new control lot, you will be required to activate the control lot in the DMS before you can perform testing.

8.4.5 Confirmation of Active Sensor and Control Lots

Once control lots are entered into the Manage Control Activate/Deactivate field, they will remain stored there until you delete them. It is important to make sure you use the intended calibration lot (sensor lot) and control combination. The LeadCare Plus DMS allows you to utilize the following control combinations:

- Level 1 and Level 2 Magellan (LeadCare Plus) Controls
- Level 1 and Level 2 LeadCare Plus Controls and a Level 3 Third Party Control
- Level 1 and Level 2 Third Party Controls
- Level 1, Level 2 and Level 3 Third Party Controls

Upon calibration there are a number of possible DMS prompts that will display providing information regarding the active sensor and control lots. It is important that you confirm that the intended sensor and control lots are active **BEFORE** you begin testing. These screens are reviewed in Table 8-1.

Table 8-1: Sensor and Control Prompts
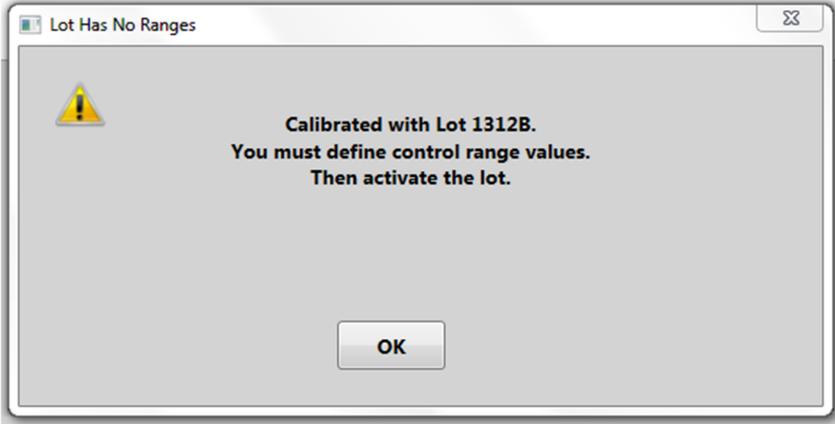
DMS Message	Action
Lot Has No Ranges ⚠ Calibrated with Lot 1312B. You must define control range values. Then activate the lot. OK	Notes sensor lot used for calibration. Must go to "Manage Controls" under QC tab. Define controls by entering control values. Then activate lot.
No Ranges ❓ No active controls found. Would you like to define controls now? YES NO	Must go to "Manage Controls" under QC tab. Define controls by entering control values. Then activate lot. If you say "No", then you will not be able to run controls.

ERROR ❌ The active sensor lot does not match the active Control Lot 1312B. [OK]	*This is a prompt specific to Leadcare Plus (Magellan) Controls. The DMS will not allow you to activate a LeadCare Plus Control Lot unless the analyzer is calibrated with the same sensor lot number.* Must either: 1. Re-calibrate with a sensor lot that matches the active control, or; 2. Go to "Manage Controls" under QC tab and activate the appropriate controls.
Control Lot Active ℹ️ Active Sensor Lot: 1312B Level 1 Active Control: 1312B Level 2 Active Control: 1312B Level 3 Active Control: None Ready For Testing [OK] Example: Two LeadCare Plus Controls Active	*Informs you which sensor lot and controls are activated and being applied.* If correct, proceed to testing. If not correct, must either: 1. Re-calibrate with a sensor lot that matches the active control, or; 2. Go to "Manage Controls" under QC tab and activate the appropriate controls.
Control Lot Active ℹ️ Active Sensor Lot: 1312B Level 1 Active Control: 1312B Level 2 Active Control: 1312B Level 3 Active Control: ThirdParty Ready For Testing [OK] Example: Two Magellan Controls and a Level 3 Third Party Control Active	*Informs you which sensor lot and controls are activated and being applied.* If correct, proceed to testing. If not correct, must either: 1. Re-calibrate with a sensor lot that matches the active control, or; 2. Go to "Manage Controls" under QC tab and activate the appropriate controls.
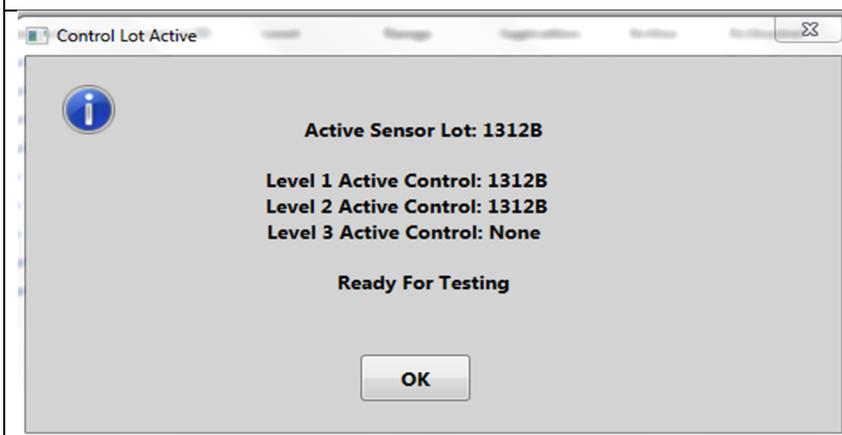
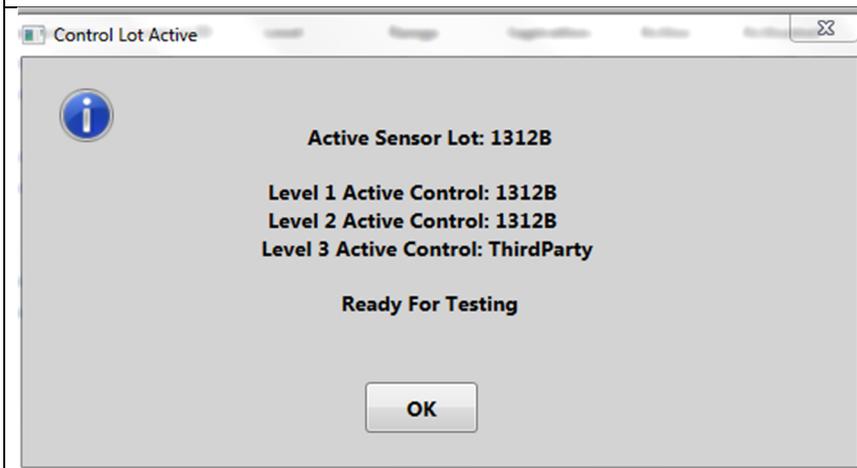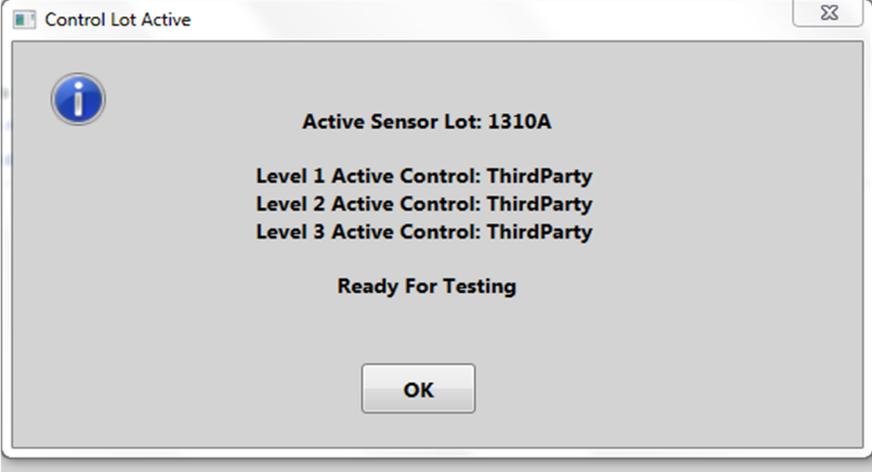|	
Control Lot Active ✕ ⓘ **Active Sensor Lot: 1310A** **Level 1 Active Control: ThirdParty** **Level 2 Active Control: ThirdParty** **Level 3 Active Control: None** **Ready For Testing** **OK** Example: Two Levels of Third Party Controls Active	*Informs you which sensor lot and controls are activated and being applied.* If correct, proceed to testing. If not correct, must either: 1. Re-calibrate with a sensor lot that matches the active control, or; 2. Go to "Manage Controls" under QC tab and activate the appropriate controls.
Control Lot Active ✕ ⓘ **Active Sensor Lot: 1310A** **Level 1 Active Control: ThirdParty** **Level 2 Active Control: ThirdParty** **Level 3 Active Control: ThirdParty** **Ready For Testing** **OK** Example: Three Levels of Third Party Controls Active	*Informs you which sensor lot and controls are activated and being applied.* If correct, proceed to testing. If not correct, must either: 1. Re-calibrate with a sensor lot that matches the active control, or; 2. Go to "Manage Controls" under QC tab and activate the appropriate controls.

8.5 Safety Precautions

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

⚠️ **CAUTION:** When performing QC testing:

- Keep the sensors in their container and the container closed until you need them. The sensor vial contains a desiccant which controls the humidity. If the sensors are exposed to humidity for an extended period of time this could lead to an inaccurate 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.

- During sample preparation, place the inside of the treatment reagent vial cap facing up on a clean absorbent liner. Do NOT allow the inside of the treatment reagent vial or the vial cap to touch anything. This could cause inaccurate blood lead test results.

- Mix the control with the treatment reagent thoroughly. Gently invert the tube 8-10 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 inaccurate test results.

- Before placing the mixture on the sensor, make sure the "Add Sample to "X" on Sensor" message appears on the analyzer display.

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

- When testing controls, make sure that the result is within the acceptable range for each control. DO NOT proceed with patient testing if the control results are NOT within acceptable limits. Refer to the Troubleshooting section (Chapter 13) of this User's Guide, or call Product Support at 800-275-0102 to help you resolve the problem.

8.6 Storing and Handling the Controls

Store LeadCare Plus Controls at room temperature.

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

CAUTION: Controls and sensors are provided with the test kit and share the same lot number as the test kit. Use controls only with sensors of the same lot number. Discard remaining control solutions when the sensors from the kit are gone.

8.7 Control Procedure

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

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

► **Follow These Steps**

1. Label a fresh treatment reagent tube **Level 1 Control**. Invert the Level 1 Control vial 8-10 times at a minimum to ensure homogeneity of the control material.

2. Remove the cap from the treatment reagent tube and place it face up on a clean absorbent liner. Do NOT allow the inside of the cap to touch anything. This could cause inaccurate test results.

3. Using a calibrated pipette, withdraw 50 μL of control material from the control vial.

4. Dispense the entire 50 μL aliquot of control solution into the treatment reagent tube.

5. Replace the control vial cap and the treatment reagent tube cap. Mix the control/treatment reagent mixture by holding the tube horizontally and gently shaking until the entire inside walls are evenly coated with a reddish solution.

6. Repeat this process (steps 1 through 5) for the **Level 2 Control**.

7. Analyze both control samples according to the instructions provided in Chapter 9, Step D: Analyze the Sample.

8.8 Understanding the Quality Control Results

Control target ranges are provided on the control label, affixed to the outside of the control vial. Additionally, the control ranges of the "Active Controls" are listed in the upper right hand corner of the DMS User Screen and in the "Range column" of the Control Data Screen.

Figure 8-16   Active Controls Listed in Control Data Screen

Compare the results you obtained with the provided target ranges. If the control results are within the range listed for the control, your LeadCare Plus System is working properly.

If the reported control results are not within the listed range, first confirm that the target ranges for the controls were input into the DMS correctly by comparing the numbers listed on the Control screen with the values on the control vials of the lot in use. If the values are correct, refer to the Troubleshooting section in Chapter 13 of this guide or contact Magellan Diagnostics, Inc. Product Support at 800-275-0102 or LeadCareSupport@magellandx.com for further assistance.

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

> ⚠️ **CAUTION: Alert messages will not appear even if control level results are outside the specified target ranges. The User must confirm that the controls are within the acceptable target ranges.**

8.8.1 Viewing and Printing Quality Control Test Records

Using the search features available in the LeadCare Plus DMS, it is possible to view and print Quality Control results. To print reports, your computer must be connected to an external printer. Additionally, you will need to have Adobe PDF software (or an alternative PDF reader software) installed on your computer to print out reports.

NOTE: To connect the PC to a printer, follow the manufacturer instructions provided with your printer.

NOTE: For printing capabilities, Adobe PDF or PDF reader software must be installed with the DMS. Follow the manufacturer's instructions for complete information on how to install PDF software.

To view and print results follow the steps below:

1. Select the **Controls** tab under the toolbar on the User Screen.

Figure 8-17   Controls Tab on User Screen

2. Clear any previous search criteria from the search fields by selecting the **Clear** button.

3. Choose your desired search criteria by selecting the dropdown tab on the "Date" box and selecting **Last Day**, **Last Week** or **Last Month** from the dropdown menu.

4. Alternatively you can type in a specific date or time period, using the month/day/year format, in the "From" and "To" boxes.

   a. To obtain results from a single day, enter the date of testing in the "From" box and the next day into the "To" box.

Figure 8-18   Search Results Using Date Fields

5. It is possible to view or print a report for a single result (Control Sample Report) or all the results in your search (Control Summary Report).

    a. To view a report of a single date, double click on that specific entry and the "Control Sample Information" box will display.
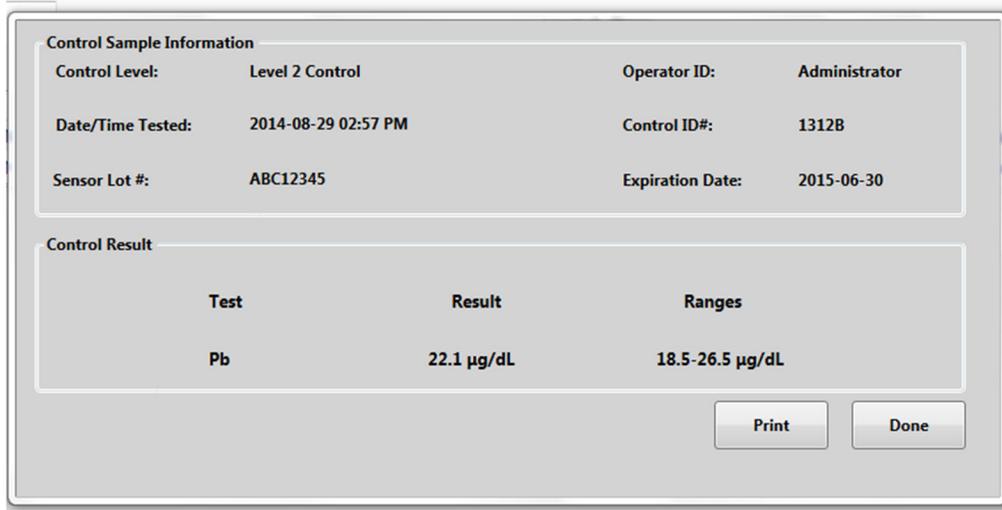
Figure 8-19   Control Sample Information Box

    b. To print this information, select the **Print** button.

    c. To exit the box, select the **Done** button.

6. You can also right click on the date and choose "Print Control Sample Report" from the dropdown menu.

    a. A "Control Sample Report" will appear as a pdf file.
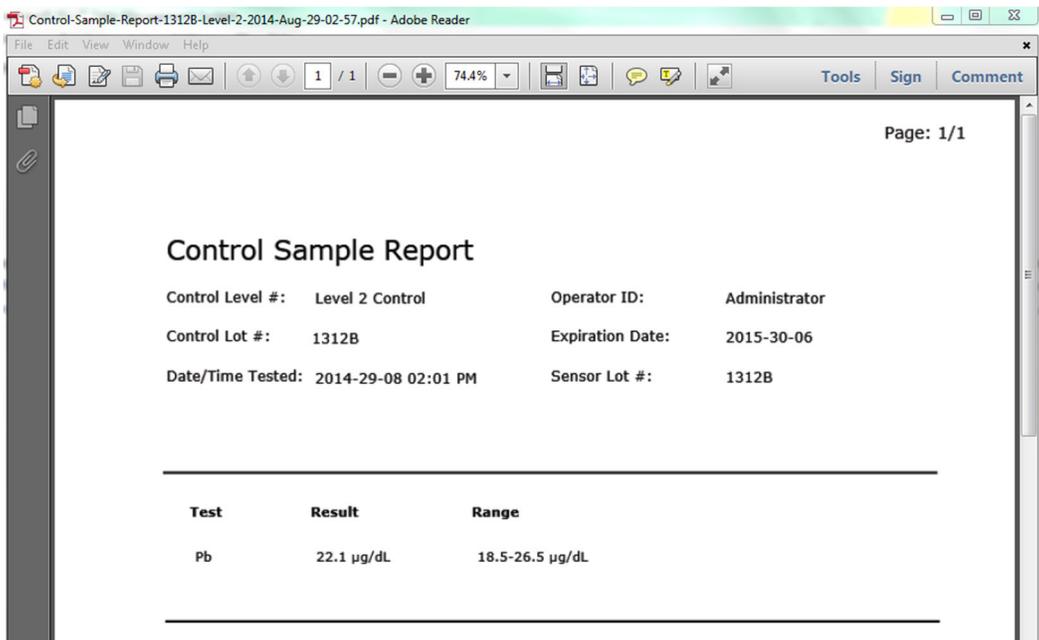
Figure 8-20   Control Sample Report

b. Click on **File** in the upper left of the toolbar and select **Print** from the dropdown menu.

7. To view a report of all the results in your search right click on the mouse and choose **Print Control Summary Report** from the dropdown menu.

8. A "Control Summary Report" will appear as a pdf file.

9. You can right click on the pdf document as another option to print.
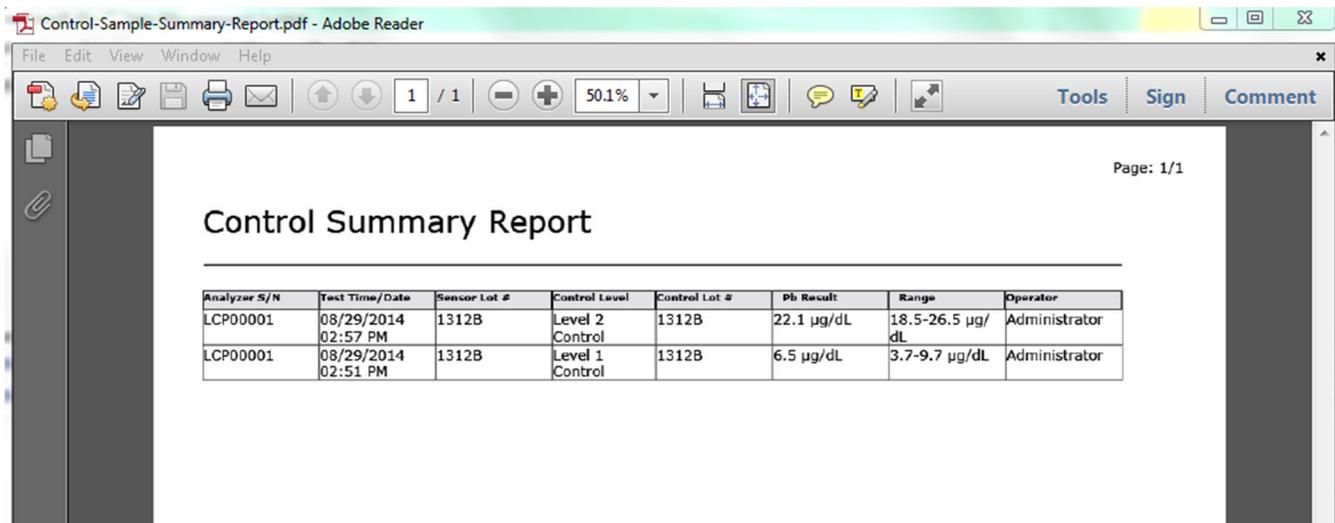
Figure 8-21   Control Summary Report

10. To print out these results, click on **File** in the upper left of the toolbar and select **Print** from the dropdown menu. You can also right click on the mouse to obtain a menu which allows you to "Print Control Sample Report"; "Print Control Summary Report"; or "Export the Results".

9   Performing Blood Lead Testing

9.1 Introduction

Once your LeadCare Plus® Blood Lead Testing System has been set up, calibrated, and has passed its QC testing, 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
- Processing Blood Lead Test Results
- Viewing and Printing Blood Lead Test Results
- Exporting Test Results

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.

9.2 Specimen Requirements

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

9.2.1 Acceptable Anticoagulants and Collection Devices

Acceptable anticoagulants for blood lead samples:

- EDTA
- Heparin

Acceptable collection devices with blood lead samples:

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

9.2.2 Collection and Storage Conditions

Capillary blood samples must be collected and stored properly in order for lead testing to be performed.

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

- The whole blood sample must be free of blood clots.

- When EDTA capillary blood collection devices are used for sample collection, **the EDTA capillary blood collection devices must be at least half full** for the sample to be appropriate for use.

- Whole blood samples collected with EDTA or Heparin as anticoagulant **must** be:

  - Shipped and stored between 1°C - 25°C (33°F - 77°F) (refrigerated or room temperature conditions).

  - Mixed with treatment reagent within 72 hours from time of blood collection.

- The whole blood sample must be brought to room temperature and thoroughly mixed prior to addition to treatment reagent.

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

9.3   Limitations of the Test

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

- Use only capillary whole blood stored at 1°C - 25°C (33°F - 77°F) from collection up to 72 hours prior to being mixed with treatment reagent.

- Do **NOT** use plasma or serum.

- Use a calibrated pipette to transfer 50 µL of blood from the collection device into the treatment reagent tube.

- After mixing the blood with the treatment reagent, it is stable for up to 48 hours at room temperature and up to 7 days if you refrigerate it immediately.

NOTE: Allow mixture to reach room temperature before analyzing

- Extremes in humidity may affect the blood lead results. Performance has been validated from 12% - 80% Relative Humidity (non-condensing). Use of the LeadCare Plus System outside of this range is not recommended.

- Do **NOT** use the LeadCare Plus System above altitudes of 8,000 feet.

- Do **NOT** use the LeadCare Plus System in drafts. This could lead to inaccurate results.

- Keep the LeadCare Plus System out of direct sunlight.

- The analyzer will only function in the temperature range of 16°C - 30°C (60.8°F - 86°F). Otherwise the system will display a temperature error. Refer to error messages in the User's Guide (Chapter 13).

- Allow all of the LeadCare Plus System components to reach a steady temperature before using.

- Use the sensors and the treatment reagent tubes, only once. Do **NOT** reuse. Reuse could lead to erroneous results.

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

9.4 Overview of the Testing Procedure

Testing for lead in blood with the LeadCare Plus Blood Lead Testing System is comprised of the following steps. For detailed step-by-step instructions, refer to Section 9.6:

1. Make sure you have the required materials.

2. Use whole blood samples (capillary) collected with EDTA or Heparin anticoagulant.

3. Using a calibrated pipette, add 50 µL of a blood sample to a labeled treatment reagent tube, recap, and mix thoroughly. The sample preparation will turn brown.

4. Match the sensor vial lot number with the displayed lot number and insert a sensor into the analyzer.

5. Using a calibrated pipette, draw 30 µL of the sample mixture from the treatment reagent tube and dispense on the (X) on the sensor.

6. The analyzer automatically starts the 3-minute analysis. Test results are displayed on the analyzer display screen and in the DMS User Screen.

9.5 Safety Precautions

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

9.5.1 General Precautions

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

WARNINGS:

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

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

- Use caution when handling the LeadCare Plus Treatment Reagent. This reagent solution contains dilute HCl. Reagent vials and vial packaging are designed to minimize chances of leaks during shipping or under normal use. For more information, refer to the LeadCare Plus Treatment Reagent Safety Data Sheet that appears in Appendix C.

WARNINGS: Failure to adhere to the following directions may result in specimen contamination and inaccurate test results.

- Do NOT use sensors that have been dropped, previously handled, broken, scratched, or damaged in any way.

- Do NOT use any test kit or controls past its expiration date.

- Do NOT leave the treatment reagent vial uncapped other than to add the sample or remove the sample/reagent solution.

9.5.2 Precautions when Preparing Patient Samples

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

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

WARNING: Be careful when handling the LeadCare Plus Treatment Reagent. This treatment reagent solution contains dilute HCl. Reagent vials and vial packaging are designed to minimize chances of leaks during shipping or under normal use. For more information, refer to the LeadCare Plus Treatment Reagent Safety Data Sheet in Appendix C.

CAUTION: When preparing blood samples for testing:

- Wear powder-free gloves to prevent lead contamination. Due to external sources of lead in the environment, it is easy to contaminate blood samples,

collection tubes and test kit items. Contamination of the work environment can cause inaccurate blood lead test results.

- Whole blood samples must be mixed with an acceptable anticoagulant and stored properly before testing. Make sure the blood sample meets all specimen requirements detailed in Section 9.2 of this User's Guide.

9.5.3 Precautions when Testing a Patient Sample

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

CAUTION: When testing blood samples:

- Keep the sensors in their container and the container closed until you need them. The sensor vial contains a desiccant which controls the humidity. If the sensors are exposed to humidity for an extended period of time this could lead to an inaccurate test result.

- Do NOT touch the "X" on the sensors, except when applying the sample. This could cause contamination and an inaccurate test result.

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

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

- Mix the control with the treatment reagent thoroughly. 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 inaccurate test results.

- Before placing the sample on the sensor, make sure the "Add Sample to X on Sensor" message appears on the analyzer display.

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

9.6 Testing Procedure

To perform a blood lead test follow Steps A through D, below.

9.6.1 Step A: Gather Required Test Materials

► **Follow These Steps**

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

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

   - Absorbent Liner and Bio-hazard Waste Container
   - Protective Gloves (powder-free)
   - LeadCare Plus Blood Lead Testing System
   - LeadCare Plus Blood Lead Test Kit, which includes:
     - o Treatment reagent tubes
     - o Sensor vials
     - o Quality controls
     - o Calibration button
   - 50 µL pipette and disposable pipette tips
   - 30 µL pipette and disposable pipette tips
   - Blood samples

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

NOTE: Before you test, make sure the LeadCare Plus Blood Lead Test Kit items are all from the same test kit. Do NOT mix items from different test kits.

9.6.2 Step B: Prepare the Sample

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

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

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

CAUTION: Make sure pipettes are calibrated properly on a routine basis.

► **Follow These Steps**

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

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

9.6.3 Step C: Turn the System ON

► **Follow These Steps**

1. Make sure the analyzer is connected to your PC via the USB cable provided with the DMS. Log in to your computer and log in to the DMS to access the User Screen.
2. Turn ON the analyzer. The analyzer is ready when the "Prepare Sample" message appears on display screen.

```
PREPARE SAMPLE
USE SENSOR LOT XXXXX
OR RECALIBRATE
THEN INSERT SENSOR
```

3. Select the **Patient** button on the User Screen if testing a Patient Sample. If testing a Control sample, select the **Controls** button.
4. Check that the calibration code of the sensor lot in use matches the calibration code displayed on the analyzer and in the upper right-hand corner of the DMS User Screen. Recalibrate if necessary.

9.6.4 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 container.

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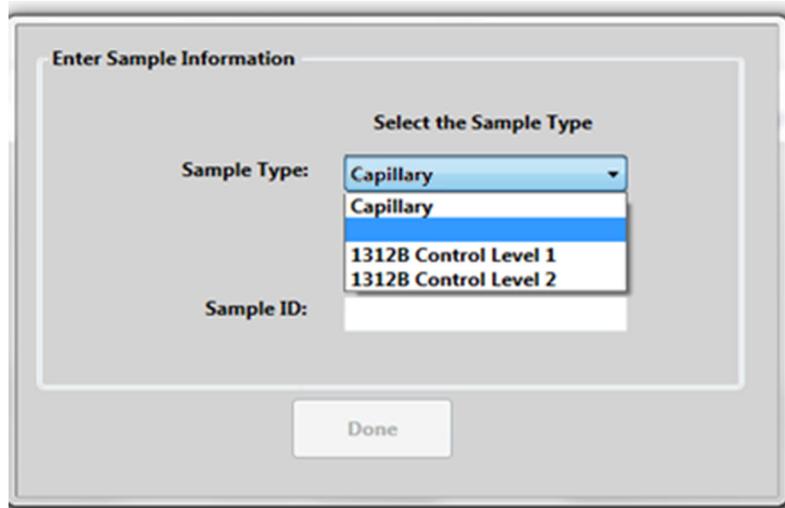

> **CAUTION:** Keep the sensors in their container until you are ready to use them. Minimize handling to prevent contamination which could cause an inaccurate test result. Ensure that the lot number on the sensor vial matches the lot number displayed on the analyzer screen.

4. The "Enter Sample Information" screen will appear on the DMS User Screen.

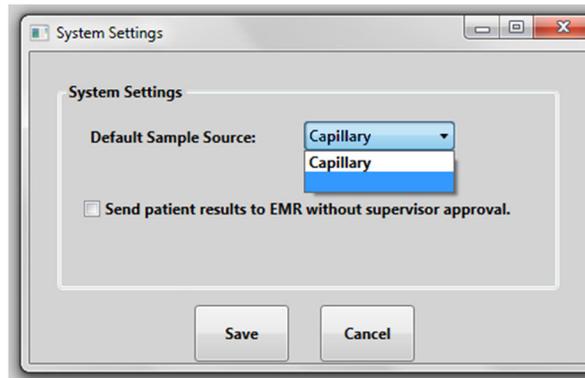5. Select the sample type (Capillary or Control Lots) from the dropdown menu.

Figure 9-1   Sample Information Box

NOTE: Select only "Capillary" samples as the sample type. This option is available by accessing the "Systems Setting" screen from the dropdown menu of the "Settings" tab on the toolbar.

6. If you are testing a Patient Sample, enter the Patient ID in the "Sample ID" box using the keyboard or a barcode reader. Then select **Done**.
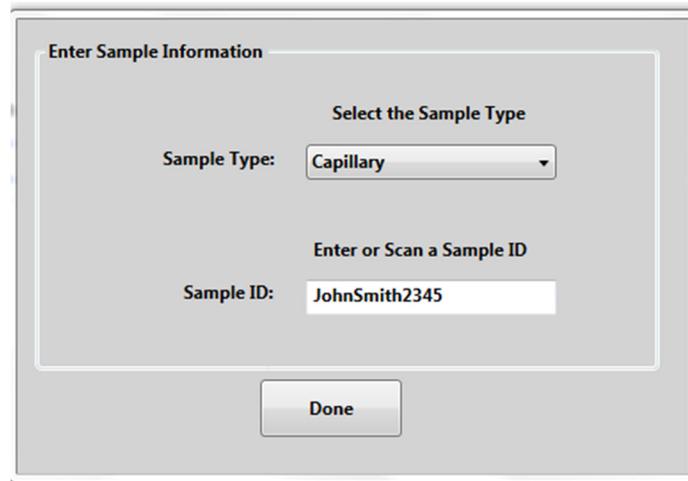

Figure 9-2   Enter Patient Sample Information

7. If the sample type selected is an active control, the Control Lot and Level will populate the "Sample Type" field automatically. Then select **Done**.
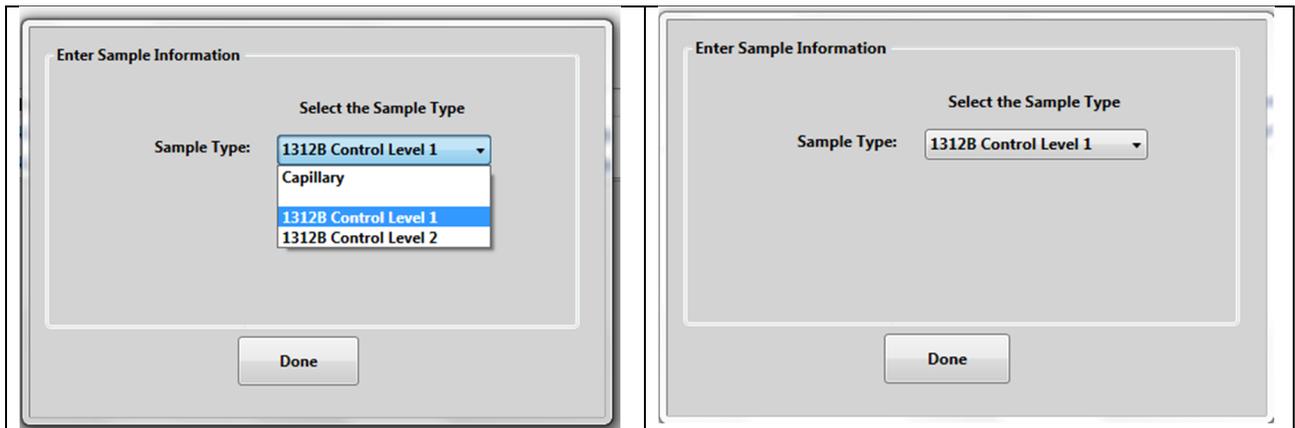
Figure 9-3   Control Lot Sample Information

8. The DMS User Screen will display the "Add Sample" screen.
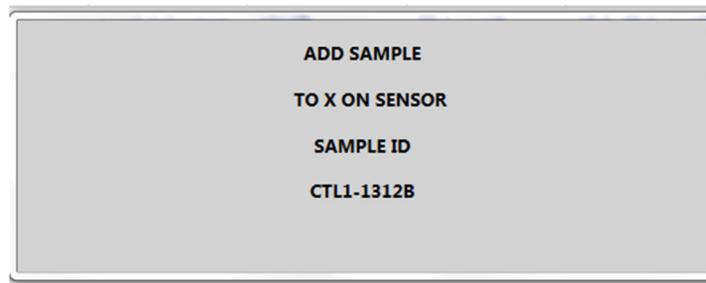

Figure 9-4   Add Sample Screen

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

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

10. The analyzer will beep when it has enough sample and both the Analyzer Display Screen and DMS User Screen will display the messages below:

Analyzer Display
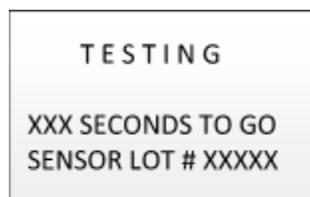
DMS Display

Figure 9-5   Testing Sample Message

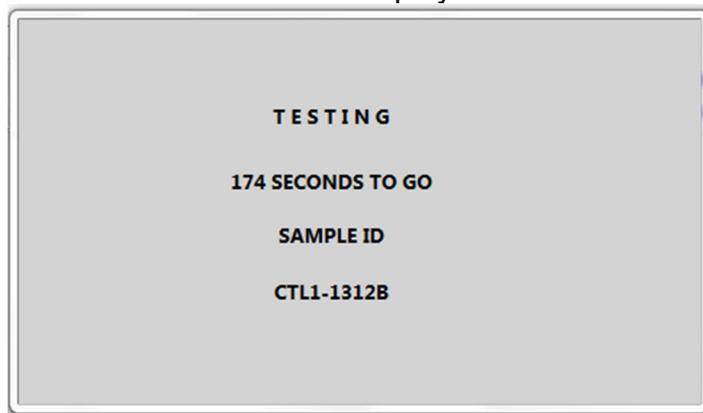11. Confirm that the Sample ID displayed on the analyzer screen and in the Data Table is correct. If it is incorrect a User with either Supervisor or Administrator privileges can edit the record after analysis. (See Section 9.7.4 "Editing Sample Information".)

12. After the 180 seconds analysis, the analyzer screen will display and alternate every 2 seconds between the test result and message, "Result Sent Successfully". Additionally, the sample information and result will be recorded in the Data Table. The results are reported in micrograms (μg) of lead (Pb) per deciliter (dL) of whole human blood. Results are displayed to one decimal point.

The analyzer flashes every two seconds between these two messages:

Figure 9-6   Control Result Displayed in Control Data Table

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

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

The analyzer displays "High" when it detects a blood lead level above 65.0 µg/dL. "High" results should be recorded as ">65.0 µg/dL". The DMS will record HIGH values as >65 µg/dL.

Analyzer S/N	Test Date/Time	Sample ID	Pb Result	Sample Type	Sensor Lot #	User ID	Status	EMR
LCP00001	2014-09-04 02:30 PM	over65Test	> 65.0 µg/dL	Capillary	1312B	Administrator	Pending	
LCP00001	2014-09-04 02:14 PM	Over 65 samp	< 1.9 µg/dL	Capillary	1312B	Administrator	Pending	
LCP00001	2014-09-04 09:41 AM	SPatel90	< 1.9 µg/dL	Capillary	1312B	Administrator	Pending	
LCP00001	2014-09-04 09:37 AM	G3-Pine	3.0 µg/dL	Capillary	1312B	Administrator	Pending	

Figure 9-7   Out of Range Results: Reported as <1.9 µg/dL (if LOW) or >65 µg/dL (if HIGH) in Patient Data Table

If no Sample ID was entered prior to the end of the 3-minute sample analysis period, the analyzer screen will display, alternating every 2 seconds with the "RESULTS" screen, the warning screen "No Sample ID Entered. Patient Result Not Sent".

RECORD TEST RESULT 6.3 µg/dL THEN REMOVE SENSOR SENSOR LOT #1312B	NO SAMPLE ID ENTERED PATIENT RESULT NOT SENT

13. If a disruption in communication occurred between the PC and the analyzer during sample analysis or results transmission, the analyzer screen will alternate every 2 seconds between the "RESULTS" screen and warning screen, "Communications Failure

no	RECORD TEST RESULT 6.3 µg/dL THEN REMOVE SENSOR SENSOR LOT #1312B	Not	COMMUNICATIONS FAILURE PATIENT RESULT NOT SENT	Sample Result Sent". If sample

result was sent to the DMS, make sure you record the test result manually.

14. Remove the used sensors.

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

15. Discard the materials in an appropriate biohazard container.

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

```
LAST TEST RESULT
6.3 µg/dL
INSERT SENSOR
SENSOR LOT #1312B
```

16. Repeat steps 1-15 to analyze additional samples.

17. The "Status" of Patient sample results will be designated as "Pending" in the Data Table until the results are approved by a Supervisor or Administrator.

18. See Section 9.7, "Processing Blood Lead Test Results" for information on approving results and sending results to an EMR/LIS system.

19. See Chapters 11 and 12 for state reporting and follow-up lead testing requirements.

9.7 Processing Blood Lead Test Results

All completed blood lead test results are listed in the DMS Patient Data Table in the User Screen (Figure 9.7). These results remain on the User Screen until they are approved. It is recommended that you approve the blood lead results after all samples have been processed for the day. In this way, the Patient Data Table on the User Screen will be cleared for the next day's samples.

> **NOTE:** Once you exit the DMS, approved results are archived and will not appear in the Patient Data Table when the system is turned on again. Archived results can be accessed by retrieving data using the "Date" or "From"; the "To" or the "Sample ID" search features.

All results can easily be viewed, sorted, and printed at any time. For more information see Section 9.8 "Viewing and Printing Blood Lead Results."

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

9.7.1 Approving Test Results

The LeadCare Plus DMS offers three options for approving test results. These options are only accessible by Users with Supervisor or Administrator privileges.

- Approve Selected Test Result(s)
- Approve All Pending Results
- Bypass Approval

9.7.1.1 Approve Selected Test Result(s)

► **Follow These Steps**

1. To approve a single result:
   a. Right click on the sample entry in the Patient Data Table and select **Approve Selected Test Result(s)** from the dropdown menu (Figure 9-8).
2. To approve more than one test result:
   a. Press and hold the CTRL key.
   b. Highlight the test results you are interested in approving and then right click on the sample entry in the Patient Data Table.
3. Select **Approve Selected Test Result(s)** from the dropdown menu. You can also approve test results by double clicking on the selected box.

Figure 9-8   Select Tests to "Approve"

The status of "Approved" results will change from Pending to Approved in the Patient Data Table (Figure 9-9).

Figure 9-9   Approved Results WILL be Transferred to EMR/LIS if EMR Status is Connected

9.7.1.2 Approve All Pending Results

► Follow These Steps

1. To approve all "Pending" results in the Data Table:
    a. Right click on a sample entry in the table and select **Approve All Pending Results** from the dropdown menu

The status of "Approved" results will change from Pending to Approved in the Data Table.

NOTE:	When the DMS is exited or turned off, Approved results are archived. Once the system is turned on again, only pending results will display in the Data Table. Approved results are available for review by performing a database search.

9.7.1.3 Bypass Approval

The LeadCare Plus DMS has a feature which allows a Supervisor or Administrator to bypass the requirement to Approve samples prior to the result being transmitted to a connected EMR/LIS.

► Follow These Steps

1. To Bypass Approval:
    a. Select the **Settings** tab in the toolbar.
    b. The "System Settings" box will appear.
    c. Click on the **Send patient samples to EMR without supervisor approval** box.
    d. Then select the **Save** button.
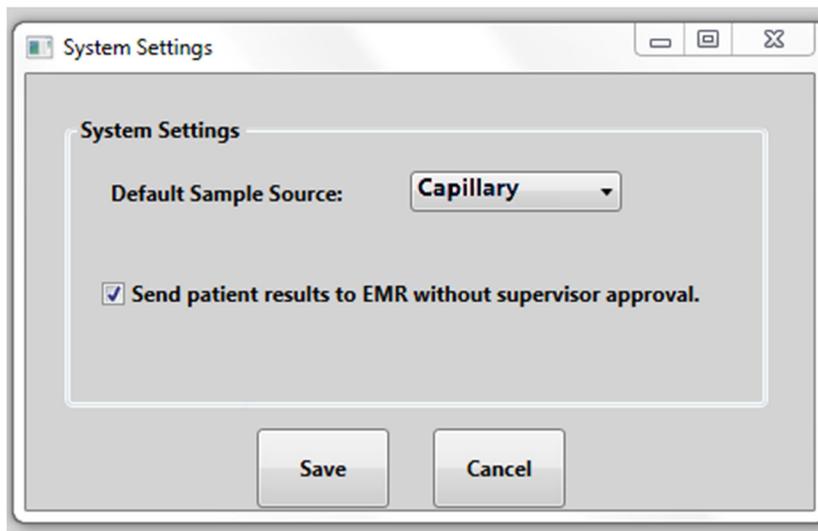
Figure 9-10   "Bypass Approval" Requirement Prior to Transmission to EMR/LIS

When this selection is activated, all patient results will immediately be transmitted to the EMR/LIS. Upon transmission a date and time stamp will appear in the Status column.

NOTE: In order to bypass approval and have patient results transmitted automatically, Administrators and Supervisors MUST have an active EMR/LIS connection and the "Send patient results to EMR…" box checked off.
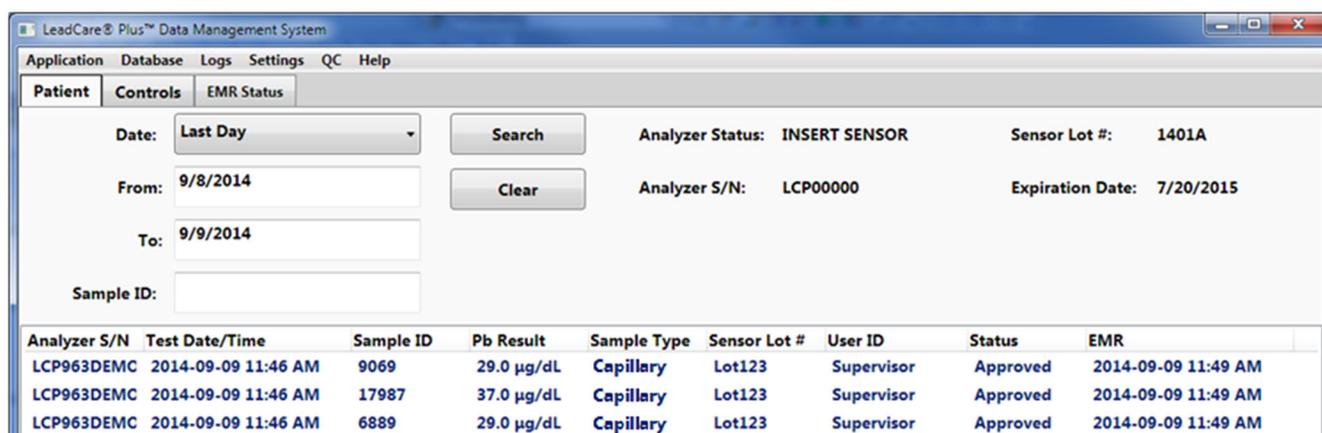
Figure 9-11   Date and Time Stamp with Transmission to EMR/LIS

9.7.2 Result Transmission to EMR/LIS

9.7.2.1 Enabling the EMR/LIS Connection

The LeadCare Plus DMS system can communicate with an EMR/LIS system using an HL7 interface as defined in the LeadCare Plus HL7 Interface Specification document provided on the USB drive of the DMS. The DMS will only send patient results to the EMR/LIS. QC results

will not be transmitted. The DMS is configured such that it will only transmit patient sample results which have been Approved unless the Bypass Approval option is enabled.

► **Follow These Steps**

1. To enable the EMR/LIS interface:
   a. Select the **Settings** tab on the toolbar.
   b. Select the **EMR Settings** option from the dropdown menu. Click on **Enable EMR Interface**.
   c. Enter the port number, configured by your IT department, into the "TCP Port Used By DMS" box.
   d. Select the **DMS IP Address** from the dropdown box.
   e. Select **Save** to enable the EMR.

NOTE: An HL7 Interface Specification document is provided on the LeadCare Plus DMS USB memory drive. Provide this file/document to your IT department when operating the DMS with the EMR enabled. This document provides necessary information for connectivity with your EMR/LIS system.
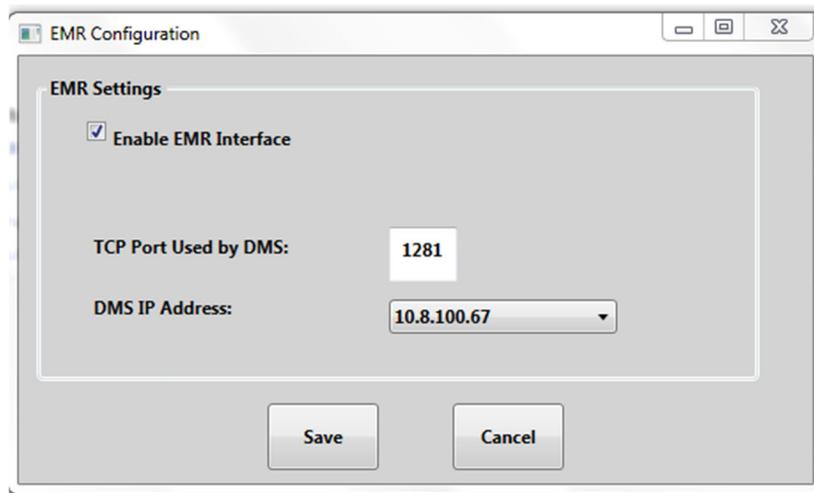
Figure 9-12   EMR Configuration

NOTE: The IP Address is the assigned network address of the PC the DMS is running on. Some computers can have more than one IP Address (i.e. computers that use a VPN). The DMS software allows the User to select the IP address they want to use to communicate with the EMR.

9.7.2.2 Confirming the EMR/LIS Connection Status

To confirm the EMR/LIS connection status select the **EMR Status** tab under the toolbar.

This screen provides information on whether the EMR/LIS is connected or disconnected; which IP port/address is in use; and the number of samples in queue waiting to be sent to the EMR/LIS once a connection is established.
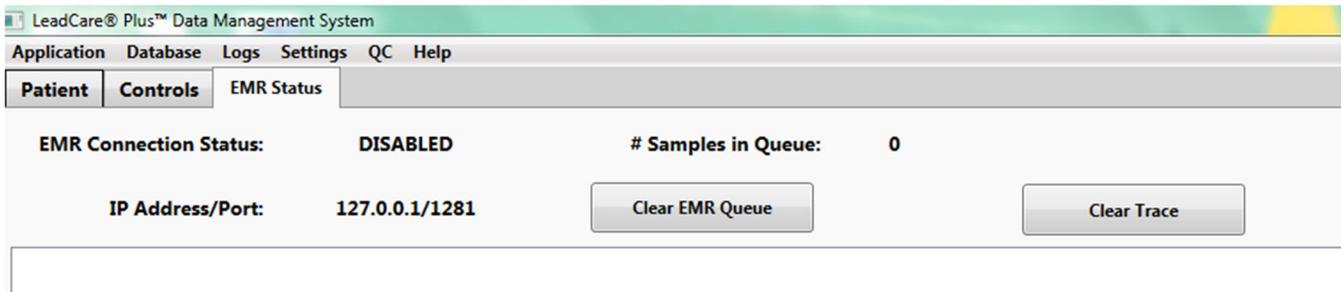
Figure 9-13   EMR Status

It is possible to clear the queue of samples awaiting transmission by selecting the **Clear EMR Queue** button. When this button is selected a message box will ask you to confirm this action:
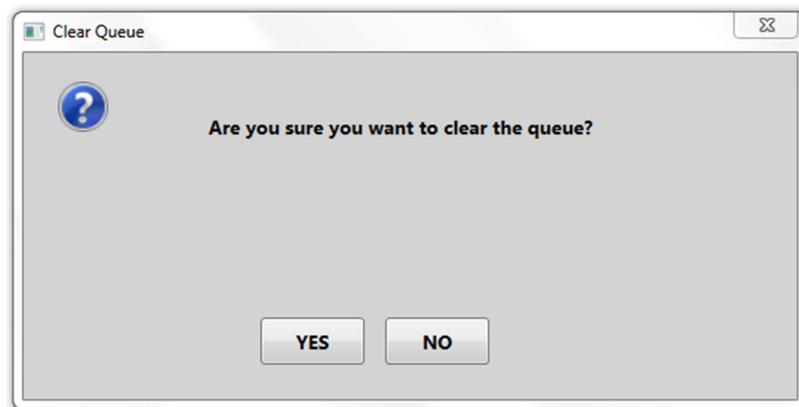
Figure 9-14   Clear EMR/LIS Queue

Select the **Yes** button to clear the queue.

Also the "EMR Status" screen has a "Clear Trace" button option. This is a diagnostic tool designed for the *IT department only* and provides a means to monitor the activity between the DMS and the EMR/LIS.

9.7.3 Voiding a Test Result

Test results which have not been approved may be voided, if desired. To void a test result, an Administrator or Supervisor may right-click on a selected Sample ID listed in the Data Table on the User Screen, then select **Void Result** from the dropdown menu, as shown in Figure 9-15.
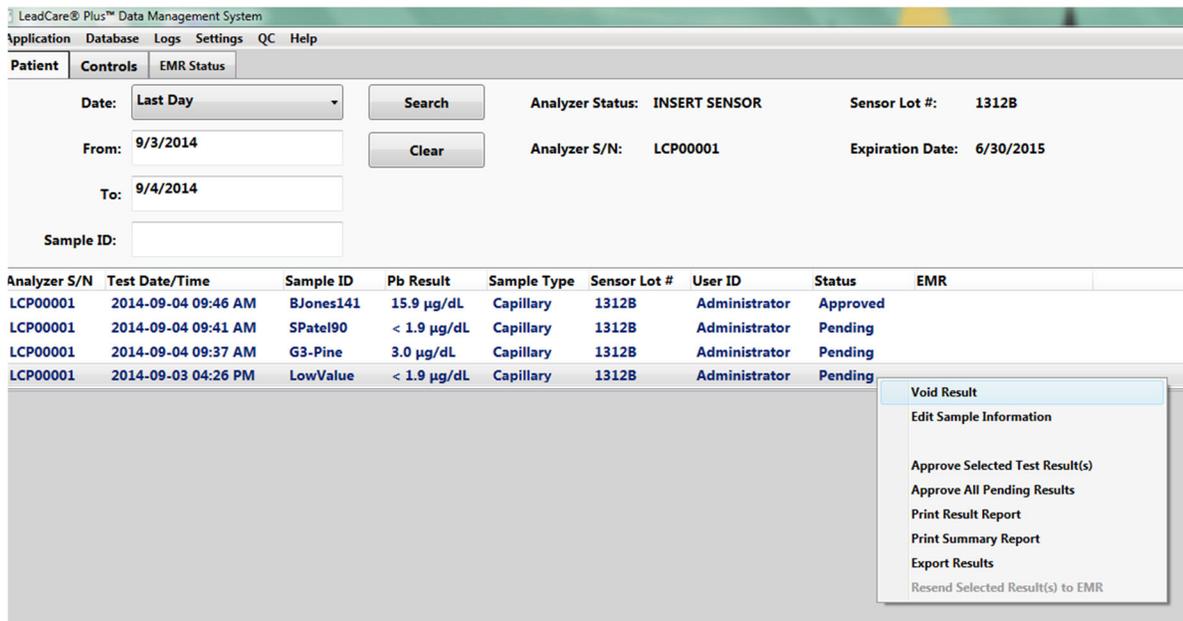
Figure 9-15   Void Result

A question box will appear asking you to confirm that you want to void the result.
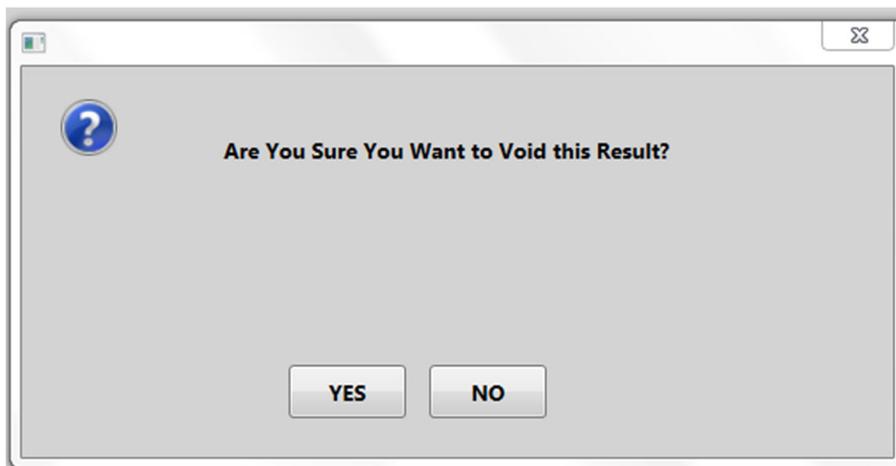
Figure 9-16   Confirmation to Void Result

Select the **Yes** button if you want to void the result. **A result cannot be restored once it has been voided.**

Analyzer S/N	Test Date/Time	Sample ID	Pb Result	Sample Type	Sensor Lot #	User ID	Status	EMR
LCP00001	2014-09-04 09:46 AM	BJones141	15.9 µg/dL	Capillary	1312B	Administrator	Approved	
LCP00001	2014-09-04 09:41 AM	SPatel90	< 1.9 µg/dL	Capillary	1312B	Administrator	Pending	
LCP00001	2014-09-04 09:37 AM	G3-Pine	3.0 µg/dL	Capillary	1312B	Administrator	Pending	
LCP00001	2014-09-03 04:26 PM	LowValue	< 1.9 µg/dL	Capillary	1312B	Administrator	Voided	

Figure 9-17   Voided Status

9.7.4 Editing Sample Information

A User with Supervisor or Administrator privileges may edit the Sample Type chosen or the Sample ID if this sample information was entered incorrectly. To edit sample information, right click on the entry in the Data Table that requires editing. Select **Edit Sample Information** from the dropdown menu.

Figure 9-18   Edit Sample Information

The "Edit Sample Information" box will display. From here you may select a different Sample Type from the dropdown menu and edit the Sample ID by typing the correct information in the text box. When the edits are complete, press the **Save** button to save the changes and return to the User Screen.

Figure 9-19   Edit Sample Information Fields

9.8 Viewing and Printing Blood Lead Test Results

Using the search features available in the LeadCare Plus DMS, it is possible to view, search, create reports and print results for archived and approved blood lead test results. To print reports your computer must be connected to an external printer.

NOTE: To connect the PC to a printer, follow the manufacturer instructions provided with your printer.

To view and print results follow the steps below:

1. Select the **Patient** tab on the User Screen.

Figure 9-20   Printing Patient Results from Patient Data Table

2. To view or print a report of any of the samples currently visible in the Patient Data Table, follow steps 7-12, as appropriate

3. To view or print a patient result that is no longer visible from the Patient Data Screen, clear any previous search criteria from the search fields by selecting the **Clear** button.

4. Choose your desired search criteria by selecting the dropdown tab on the "Date" box and selecting **Last Day**, **Last Week** or **Last Month** from the dropdown menu. Press **Search**.

5. Alternatively, you can type in a specific date or time period using the month/day/year format, in the "From" and "To" boxes. Click **Search**.

   a. For results from a single day, type the day of testing you are interested in the "From" box and the next day into the "To" box.

6. To search for a specific Patient ID, enter the Patient ID in the "Sample ID" box and **Search** as shown in Figure 9-21.
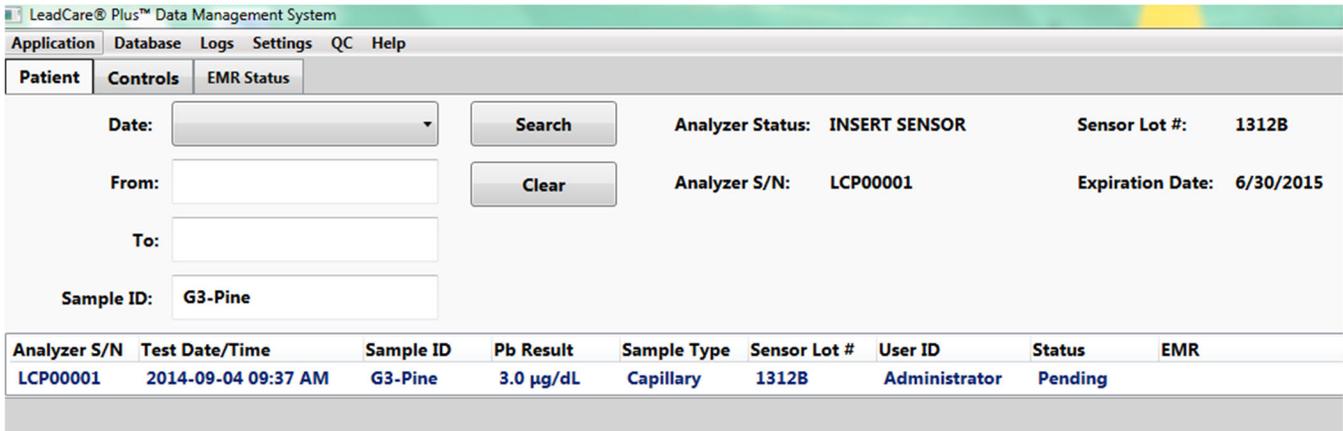
Figure 9-21   Searching by Patient ID

7. It is possible to view or print a report for a single result (Patient Sample Report) or all the results in your search (Patient Summary Report).
    a. To view a report of a single entry, double click on that specific entry and the "Patient Sample Information" box will display.
    b. To print this information select the **Print** button.
    c. To exit the box select the **Done** button.

8. You can also right click on the entry and choose **Print Result Report** from the dropdown menu.
    a. A Patient Sample Report will appear as a pdf file.
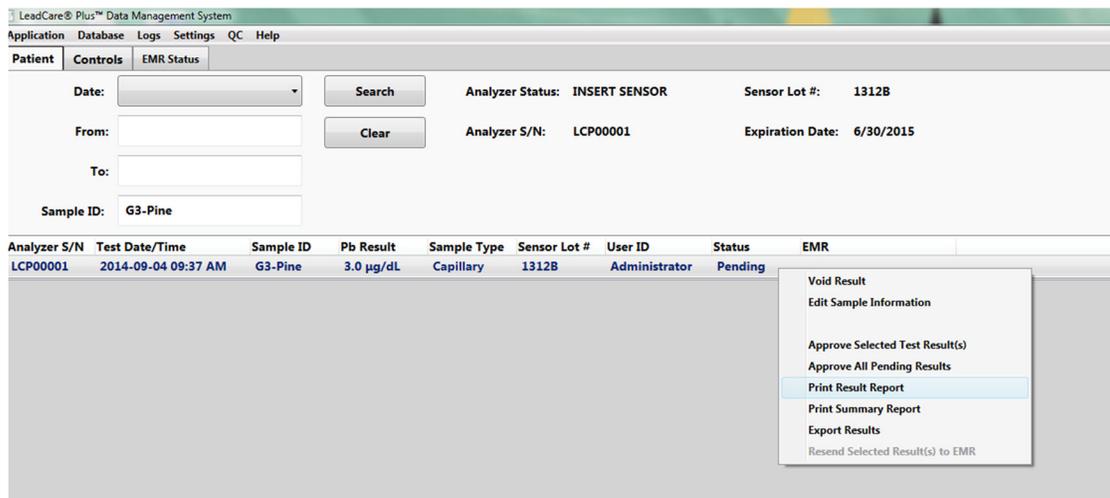
Figure 9-22   Print Single Patient Result
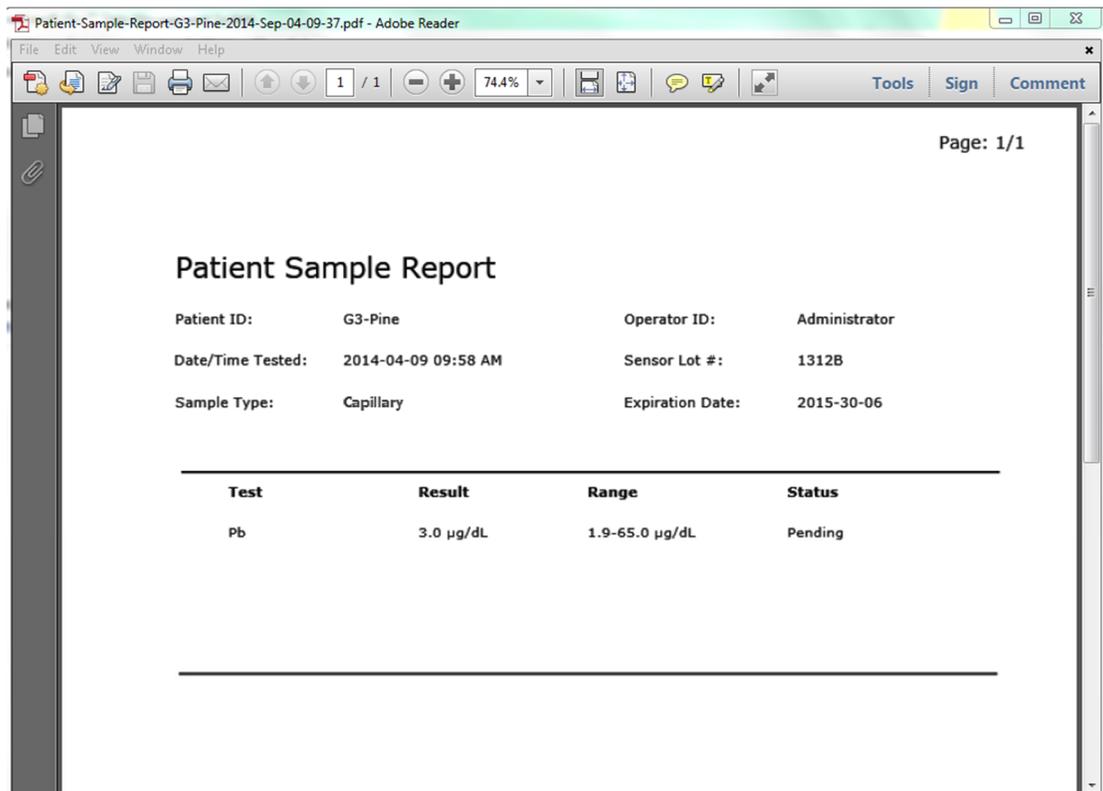
Figure 9-23   Patient Sample Report

    b. Click on **File** in the upper left of the toolbar and select **Print** from the dropdown menu.

9. To view a report of all the results in your search, right click on the mouse and choose **Print Summary Report** from the dropdown menu.

10. A Patient Summary Report will appear as a pdf file.

11. If you would like a printout of this report, click on **File** in the upper left of the toolbar and select **Print** from the dropdown menu.
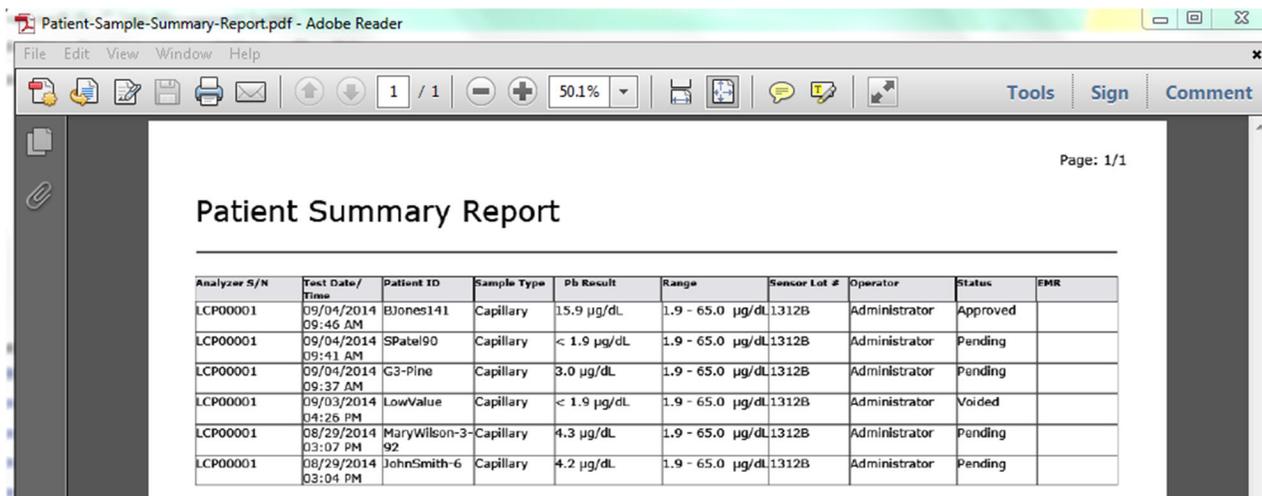
Figure 9-24   Patient Summary Report

12. You can also right click on the mouse to obtain a menu that allows you to "Print Patient Sample Report"; "Print Patient Summary Report"; or "Export the Results".

9.9 Exporting Test Results

The LeadCare Plus DMS provides the capability to export Patient and QC results to a CSV (Comma Separated Values) formatted file. Only Supervisors and Administrators have the privilege level to export files.

When the DMS exports a Patient Sample result, the export file contains the following information:
- Analyzer Serial Number
- Test Date/Time
- Sample ID
- Pb Result
- Sample Type (Capillary)
- Sensor Lot #
- Operator ID
- Sample Status (Pending, Accepted or Voided)
- Timestamp when result was received by EMR

When the DMS exports a Control Sample result, the export file contains the following information:
- Analyzer Serial Number
- Test Date/Time
- Sensor Lot #
- Control Level
- Control Lot #
- Pb Result
- Control Range Values
- Operator ID

To export file results, perform the following steps:

1. Click on the result or highlight and click on the set of results you would like to export.

2. Right click and select **Export Result** from the dropdown menu.
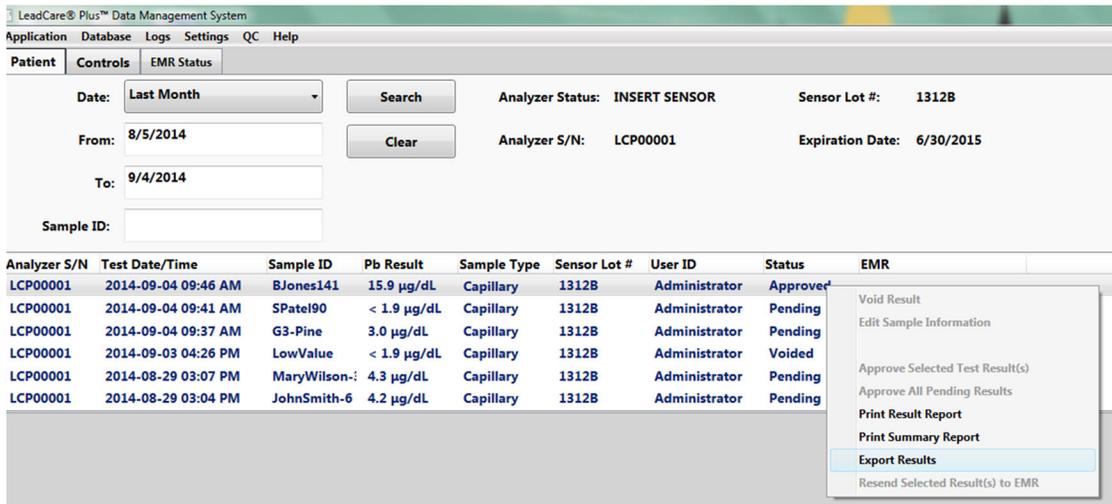
Figure 9-25   Export Results Dropdown

3. The "Browse For Folder" will appear asking you to select the directory to store the exported file.
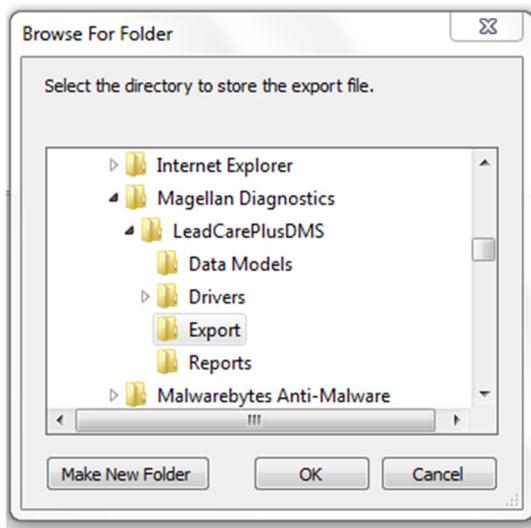
Figure 9-26   Storing Exported File

4. The Export folder in the LeadCarePlus DMS folder will be highlighted.

5. Choose the **Export folder** and select the **OK** button.

6. An information box will appear providing you with the location and name of the exported file:
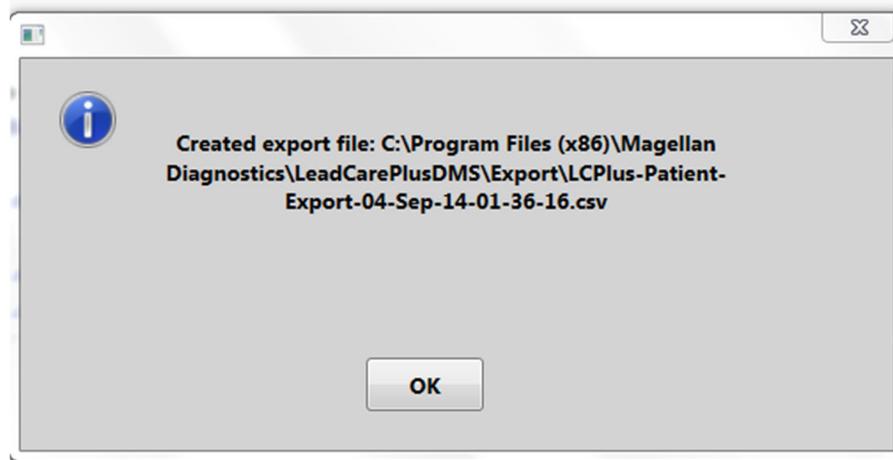
Figure 9-27   Exported File Name and Location

7. Select **OK**

9.9.1 Accessing an Exported Results File

After a file is exported, you may access it to view, print or save to another location.

► **Follow These Steps**

1. Press the **Start** icon on the computer.
2. Go to Computer and select the **OS(C:)**.
3. Select the **Program Files (x86)** folder.
4. Scroll down and select the **Magellan Diagnostics** folder.
5. Select the **LeadCarePlusDMS** folder.
6. Scroll down and select the **Export** folder.
7. Select your exported file. Look for the export with the correct name, date and time.
8. You can now print or use the file as desired.
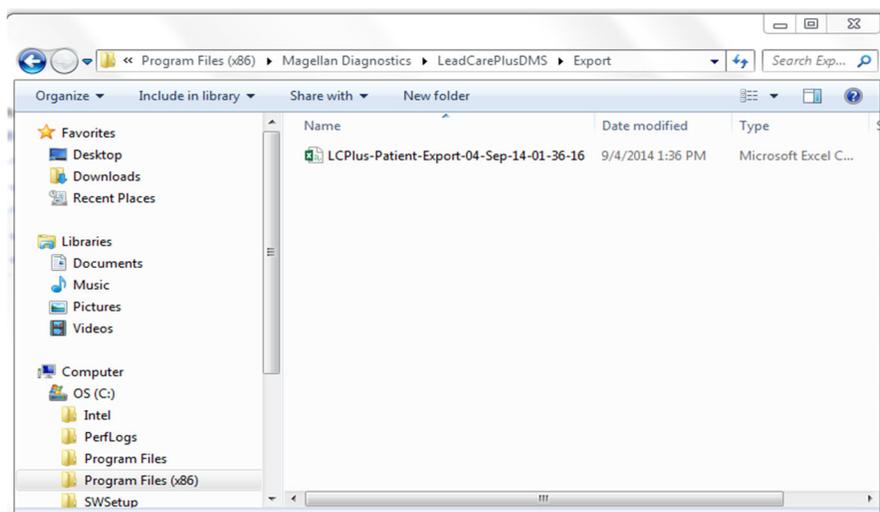
Figure 9-28   Accessing Exported File

10 Maintaining Test Results

The LeadCare Plus® DMS provides the capability to backup and restore the data collected on the system as a safety feature for the preservation of data. Only Users with Supervisor or Administrator privileges may perform the backup and restore functions.

10.1 Backing Up Blood Lead Sample Test Results

The DMS is configured to allow a simple data backup which copies the information in the Data Tables to a file on the "C:" drive of the PC. To perform a backup follow these steps:

1. Select the **Database** tab on the toolbar and choose **Backup Database** from the dropdown menu.

2. The "Browse For Folder" window will appear.

3. Scroll down to the Backup folder. The Backup folder resides in the following location on the PC "C:" drive:

OS (C:) > Program Files (x86) > Magellan Diagnostics > LeadCarePlusDMS > Backup Folder

| NOTE: | Every time you perform this backup operation the data is saved to a new file in this location. |
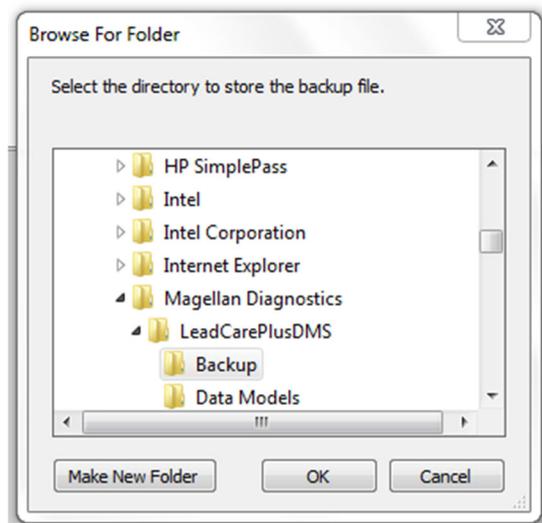
Figure 10-1   Backup Folder

4. Select the **Backup folder** and click the **OK** button.

5. A message box will display informing you that the database backup has completed and providing the name and location of the DMS backup file.
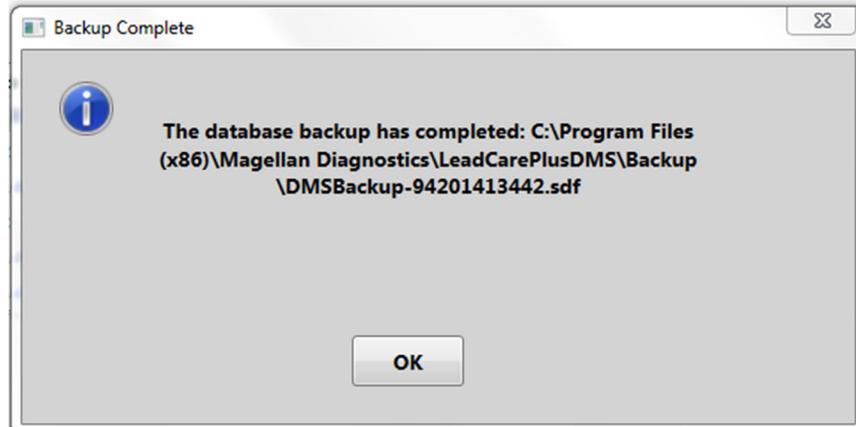
Figure 10-2   Backup Folder Name and Location

6. This action will be recorded in the DMS Audit Log (See Section 10.3)

7. The User can then save this backed up file to a USB stick or other media, separate from the computer hard drive, for an additional safety measure, if desired.

8. Select **OK** to close the information box and return to the User Screen.

10.2 Restoring Blood Lead Sample Test Results

In the event of a system failure resulting in loss of information, the User can reload historical information that was previously backed-up onto the PC "C:" drive.

The Restore process places previously backed-up information, into the LeadCare Plus System DMS.

To perform a database restore follow these steps:

1. Select the **Database** tab on the toolbar and choose **Restore Database** from the dropdown menu.

2. A folder location on the "C:" drive will appear with the names and dates of all Backup files created.
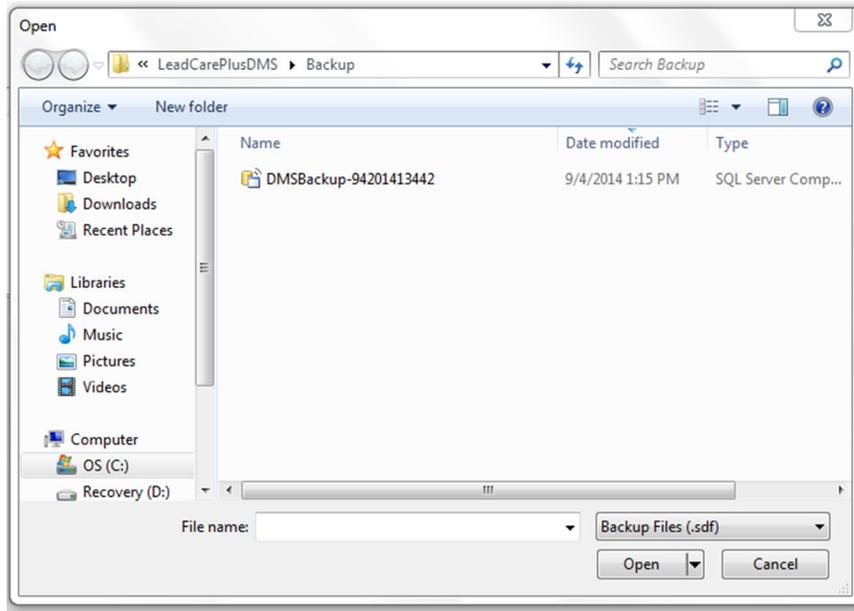
Figure 10-3   Accessing Backup Folders

OS (C:) > Program Files (x86) > Magellan Diagnostics > LeadCarePlusDMS > Backup Folder

3. Select and double click on the most recent Backup file.

4. A question box will appear explaining that this operation will overwrite the current database and asks if you would like to proceed.
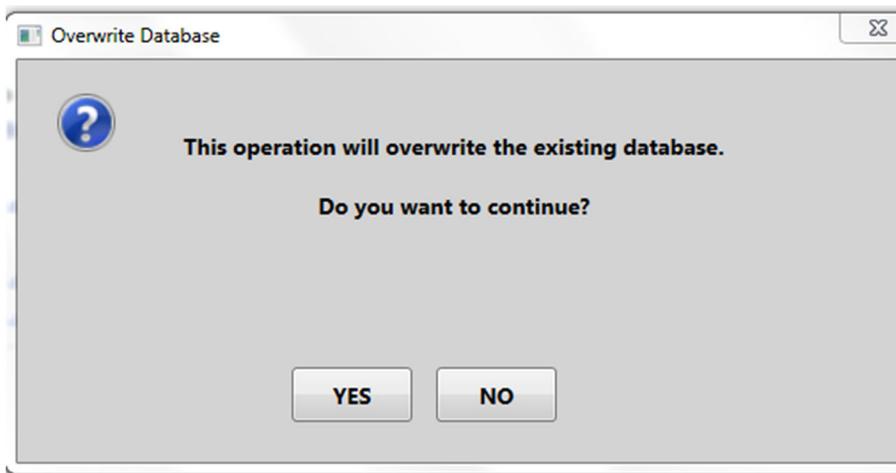
Figure 10-4   Confirming Database Restore

NOTE: Performing a database Restore will replace any data remaining in the Data Table with the information stored in the backup file.

5. Select the **Yes** button.

---

5. An information box will appear telling you that the database was restored successfully and you will be told to restart the DMS application.
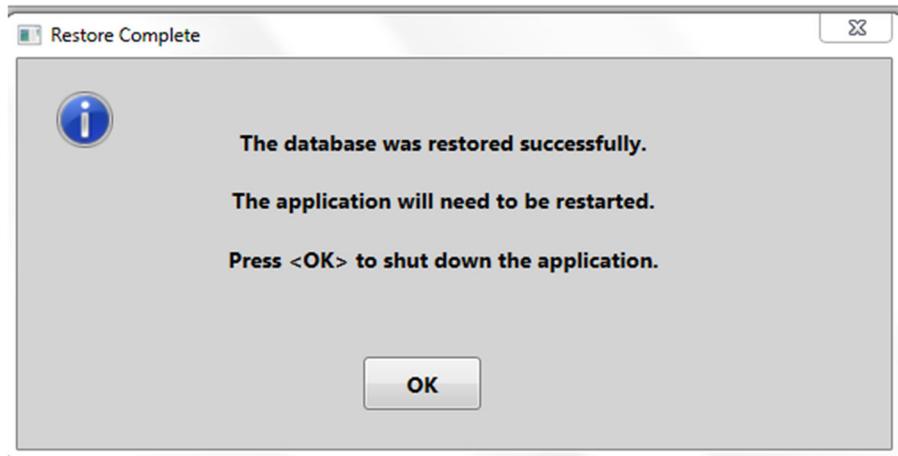
Figure 10-5 Database Restored Successfully

6. Select the **OK** button.
7. The application will then shut down and you will be required to re-open the application and log in to the DMS.

10.3 Audit Log to Track Modifications

The LeadCare Plus allows Users with Supervisor and Administrator privileges to edit certain sample information and results entered into the DMS. These modifications are tracked using the Audit Log feature.

An entry will automatically be made in the Audit Log when:
- A Patient ID associated with a sample result is modified.
- A sample result is approved.
- A sample result is voided.
- A Sample Type is modified.
- A database backup is performed.
- A database restore operation is performed.

For each audit entry the LeadCare Plus DMS will record the following information:
- A timestamp of the action.
- The Operator ID of the person who performed the action.
- The type of action.
- The sample result timestamp associated with the action.
- Analyzer serial number.

10.3.1 Exporting the Audit Log

A Supervisor or Administrator has the ability to export the Audit Log to a CSV formatted file.

To export the Audit Log follow the steps below:

1. Select the **Log** tab under the toolbar on the User Screen.

2. Select **Export Audit Log** from the dropdown menu.

3. The "Browse For Folder" will appear on the screen.
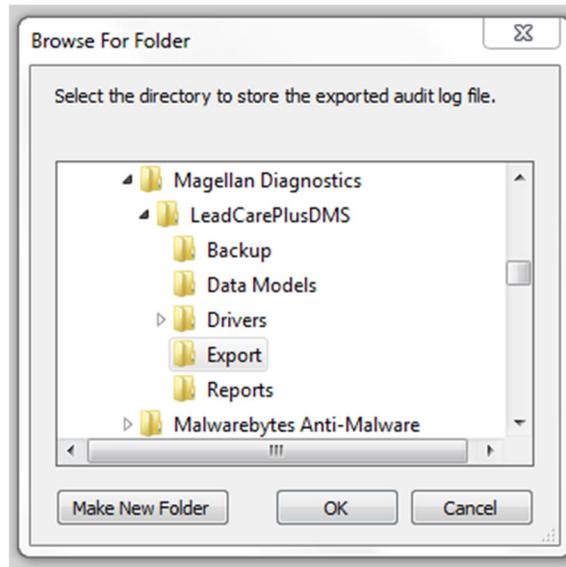
Figure 10-6   Audit Logs Stored in Audit File

4. Scroll down to the Export file. The Export folder resides in the following location on the PC "C:" drive:

OS (C:) > Program Files (x86) > Magellan Diagnostics > LeadCarePlusDMS > Export folder

5. Select the **Export folder** and click the **OK** button.

6. A message box will display informing you that the Audit Log has been exported and providing the name and location of the exported Audit Log file.
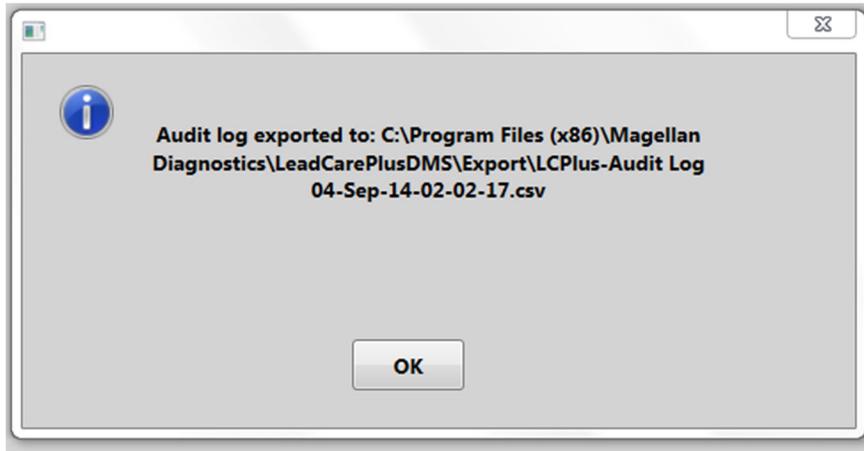
Figure 10-7   Audit Log Location and Name

10.3.2 Accessing an Exported Audit Log

After an Audit Log is exported you may access it to view, print or save to another location. Follow these steps:

1. Press the **Start** icon on the computer.

2. Go to Computer and select the **OS(C:)**.

3. Select the **Program Files (x86)** folder.

4. Scroll down and select the **Magellan Diagnostics** folder.

5. Select the **LeadCarePlusDMS** folder.

6. Scroll down and select the **Export** folder. Select your exported file and look for the export with the correct name, date and time.
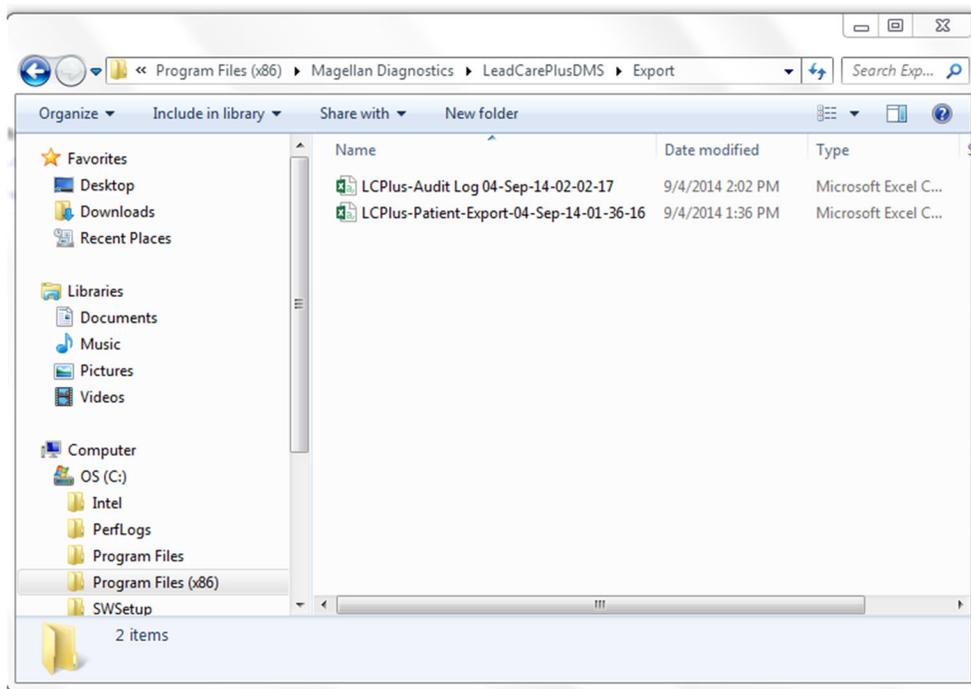
Figure 10-8   Accessing an Audit Log

7. You can now print or use the file as desired.

Figure 10-9   Example: Audit Log

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11 State Reporting of Blood Lead Test Results

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

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

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

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12 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.

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13   Troubleshooting

13.1 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.

13.2 Troubleshooting

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

Table 13-1: Results Below the Target Range or Expected Value

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

Problem Area	Check the Following
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. • Adding less than 50 µL of control or blood sample may lead to inaccurate results.
Equipment Setup and Calibration	• Check the expiration on the test kit box to make sure the test kit materials have not expired. • Make sure the analyzer is calibrated properly using the calibration button from the kit being used. • When processing controls, check to make sure the sensor lot number on the display screen matches the lot number of the control and the sensors.
Testing Conditions	• Avoid operating the LeadCare Plus Blood Lead Testing System in drafts or outside the specified temperature range 16°C - 30°C (60.8°F - 86°F) and specified humidity range (12 - 80%, Relative humidity). • Make sure that the system and the test kit are maintained at a constant temperature. If you move the system from one place to another, wait for the analyzer and components to reach a stable temperature.

User Technique	• Make sure the control or blood sample and treatment reagent mixture is thoroughly mixed before placing onto the sensor.
	  o A control in treatment reagent mixture will remain red after mixing.
	  o A blood sample in treatment reagent will turn brown after mixing.
	• Make sure the sample mixture is at room temperature before placing onto the sensors.
	• Keep sensor vial closed. Remove sensors from vial only when ready to run samples.
	• Add 30 µL of the sample/treatment reagent or control/treatment reagent mixture to the sensor.
	• Do NOT touch the sensor while the analyzer is running a test.

Table 13-2: Results Above the Target Range or Expected Value

Problem Area	Check the Following

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

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

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

User Technique	• Do NOT touch the black bars or the black 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.
	   ○ The control in treatment reagent mixture will remain red after mixing.
	   ○ 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.
	• To initiate analysis, 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.

13.3 Display Messages

Both the LeadCare Plus Analyzer and the LeadCare Plus DMS utilize display messages to help guide the User through the normal steps of operation. Additionally, both will display error messages if the system detects an operational problem.

13.3.1 Standard Analyzer Screen Display Messages

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

NOTE: Occasionally, error messages not noted in this guide may appear on the display. Please note what error message was displayed and call Product Support for additional instructions. New Users may want to check that the sensor was completely inserted into the analyzer prior to calling.

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

Screen Display Messages

Message	Definition	What to Do
PLEASE CALIBRATE ANALYZER WITH BUTTON	The analyzer must be calibrated the first time you use it and for each new sensor lot.	Calibrate the analyzer. Refer to the calibration instructions in Chapter 7
ELECTRONIC QC CHECK FAILED CALL TECH SERVICE ERROR X	The internal quality control check failed.	Record the error number & call Product Support at 800-275-0102.
TEMP IS TOO HOT PLEASE WAIT UNTIL ANALYZER IS IN TEMP RANGE	The temperature is too hot for testing.	Wait until the screen display the PREPARE SAMPLE message.
TEMP IS TOO COLD PLEASE WAIT UNTIL ANALYZER IS IN TEMP RANGE	The temperature is too cold for testing.	Wait until the screen display the PREPARE SAMPLE message.
WARNING TEMP IS UNSTABLE TEST MAY FAIL	The temperature is too unstable for testing.	Wait until the screen display the PREPARE SAMPLE message.
THIS IS A USED SENSOR PLEASE REMOVE SENSOR	The sensor in the analyzer is wet or previously used.	Remove the used sensor and insert a new sensor COMPLETELY into the analyzer to retest.
PLEASE REMOVE SENSOR	A sensor was left in the analyzer.	Remove the sensor.
SENSOR OUT OF VIAL TOO LONG PLEASE REMOVE SENSOR	The sensor in the analyzer has been out of the vial too long (more than 5 minutes) and cannot be used.	Remove the sensor and insert a new sensor.
TEST FAILED PLEASE REMOVE SENSOR	There is not enough sample on the sensor or the sensor failed.	Remove the sensor, discard it, and insert a new sensor. When adding the sample to the sensor, make sure the sample completely covers the X area.
SENSOR FAILED PLEASE REMOVE SENSOR	A sensor failure occurred, invalidating the sample analysis.	Remove the sensor, discard it, and insert a new sensor.
SENSOR REMOVED TOO SOON	The sensor was removed from the analyzer before the end of the test.	Remove the sensor. Insert a new sensor and add another drop of sample. Wait 180 seconds (3 minutes) for the test to finish.

Message	Definition	What to Do
TEMP IS UNSTABLE RESULT DISCARDED PLEASE REMOVE SENSOR	The temperature in the room is too unstable to yield accurate test results.	Move the analyzer to an area where there are fewer temperature changes (away from sources of cold or heat). The temperature is stable enough when the PREPARE SAMPLE message indicates that the analyzer is ready.
PLEASE RECALIBRATE	There was a problem transferring the calibration data from the calibration button to the analyzer.	Repeat the calibration procedure. Refer to Chapter 7, Calibrating the Analyzer.
SYSTEM FAILURE ERROR 500 CALL TECH SERVICE	The integrity of the calibration button may be compromised.	Call Product Support at 800-275-0102.
SENSOR LOT TOO OLD PLEASE RECALIBRATE	The sensor is from a lot that has expired.	Discard the sensor and the expired lot. Use a sensor from a new lot and recalibrate the analyzer.
SYSTEM FAILURE CALL TECH SERVICE	One of the main system components failed.	Power analyzer off & on. If error persists, call Product Support at 800-275-0102.
CHANGE BATTERIES SOON *(Message flashes before or after a test)*	Voltage too low for the analyzer to run a test.	Change the batteries. Use four 1.5 V AA alkaline or lithium batteries.
PLEASE CHANGE BATTERIES	The battery voltage is too low.	Change the batteries. Analyzer uses four 1.5 V AA alkaline or lithium batteries.
LOW POWER CHECK POWER CORD	This message flashes for 2 seconds if the voltage from the AC adapter is low.	You can run a test.
LOW POWER CHECK POWER CORD OR CALL TECH SERVICE	The voltage from the AC adapter is too low. The lead test is NOT allowed.	Call Product Support at 800-275-0102.

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

13.3.1 DMS Related Analyzer Screen Display Messages

There are some messages that will display on the analyzer screen only if there is a connection between the analyzer and the DMS. The following table shows these display messages:

Message	When Message Displays	Action
SAMPLE ID XXXXXXXXXXX RESULT SENT SUCCESSFULLY	This message will be displayed every two seconds alternating with the RECORD TEST RESULT message.	The sample result will be transmitted and appear in the DMS Data Table.
NO SAMPLE ID ENTERED SAMPLE RESULT NOT SENT	This message will be displayed every two seconds alternating with the RECORD TEST RESULT message.	The sample result will display on the analyzer but will NOT be transmitted to the DMS.
COMMUNICATIONS FAILURE SAMPLE RESULT NOT SENT	This message will be displayed every two seconds alternating with the RECORD TEST RESULT message.	The sample result will display on the analyzer but will NOT be transmitted to the DMS. If the analyzer is reconnected to the DMS prior to another test being run, the result will then be transmitted and appear in the DMS Data Table.

13.3.2 DMS Message Boxes

The DMS also will display messages to assist the User during the operation of the DMS. Some of these messages are simply pop-up boxes that contain instruction for associated tasks while others are designated as providing information, asking a question to confirm an action, identifying an error and providing a warning.

The following symbols denote these designations:

Information Box

Question Box

Error Box

Warning Box

	NOTE:	The use of the warning symbol in the DMS does not symbolize possible harm to the User or the system. This is used to highlight an activity that may interfere with result display.

Table 13-3 shows some of the possible DMS display messages.

Table 13-3: Possible DMS Display Messages

Error Type/Message	Reason(s)	Fix
	The User did not agree to the Terms of Agreement for use of the DMS.	Check the box designating agreement with the Terms of Agreement for the use of the DMS.
	An attempt was made to set up a User Account using an Operator ID that is already assigned to another account holder.	Assign an Operator ID that is not assigned to another User of the system.
	The User did not enter a Patient ID prior to the end of the 3-minute countdown. Results are not transmitted to the DMS without an associated ID.	Record the result manually or rerun the Patient sample and enter the Patient ID prior to the end of the 3-minute countdown.
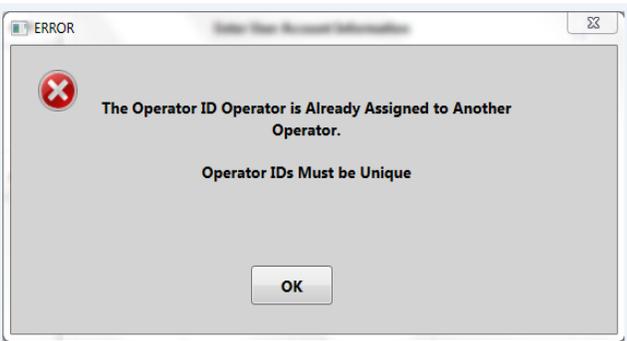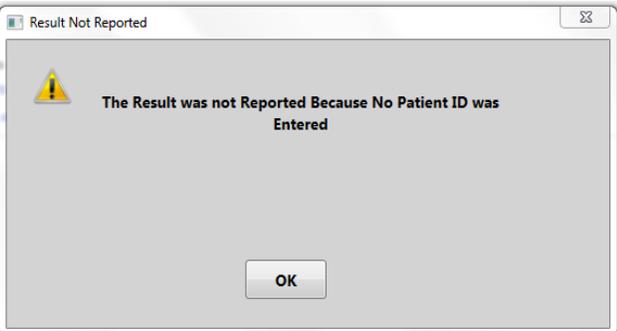
	The operator entered a lot number or name that is already defined in the Manage Controls list.	Activate the controls in the Manage Controls list or re-name control lots and enter.
ERROR ☒ — ⊗ Duplicate lots are not allowed. Lot ID ThirdParty14 and Level 1 has already been defined. [OK]		
ERROR ✕ — ⊗ Invalid Password Provided Passwords Must be a Minimum of 6 and Maximum of 12 Characters Long. [OK]	The Password entered or assigned does not meet the required number of characters.	Enter a Password 6-12 characters long.
ERROR ☒ — ⊗ Invalid operator ID provided. Operator IDs must be A minimum of 6 and maximum of 16 characters. [OK]	The Operator ID entered or assigned does not meet the required number of characters.	Enter an Operator ID 6-16 characters long.
No Results Found ☒ — ⓘ No Results Were Found that Match the Selected Criteria. [OK]	The User selected search criteria (time period or Patient ID) for which no results exist in the DMS.	Check the date, time period or Patient ID and re-enter the search criteria.
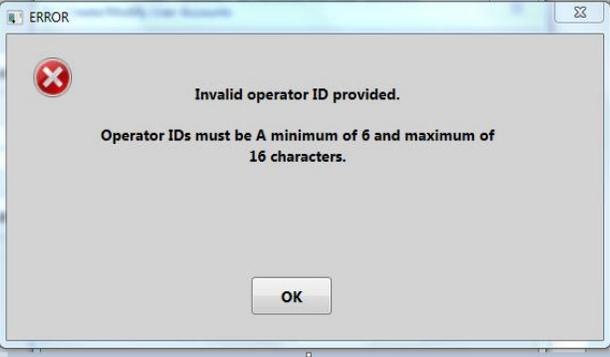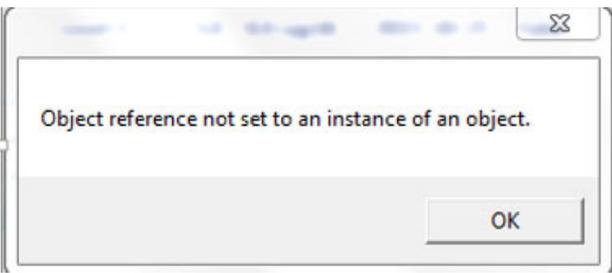
Object reference not set to an instance of an object. OK	Generally denotes the analyzer lost connection with the DMS.	Check analyzer power and connection between the analyzer and the DMS.
Database Backup Reminder ⚠ The Last Database Backup Occured > 30 Days Ago on 8/12/2014 Please Backup the Database. OK	The DMS database has not been backed up in the last 30 days.	The User should perform a Database Backup.
ERROR ✖ Invalid IP Address OK	The IP address chosen for EMR/LIS connectivity is invalid.	Consult your IT department for the appropriate IP address to use for EMR/LIS connectivity.
ERROR ✖ Patient ID must be a maximum of 20 characters in length OK	The Patient ID entered exceeds the 20 character maximum.	Enter a Patient ID less than or equal to 20 characters in length.
ERROR ✖ Sensor Out of Vial Too Long. Please Remove Sensor OK	The sensor was left in the analyzer for ≥5 minutes without sample application.	Discard sensor. Insert a new sensor for accurate assay results.
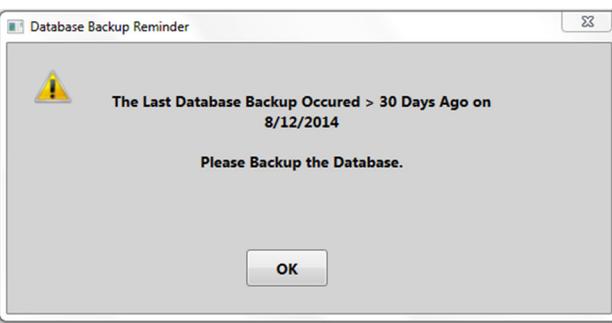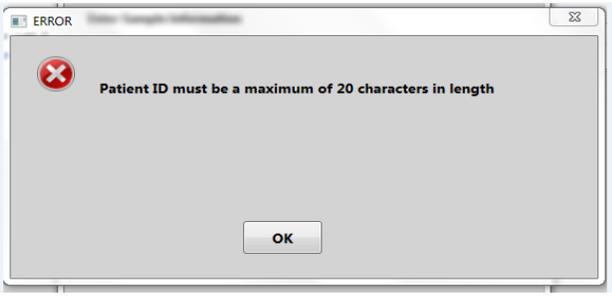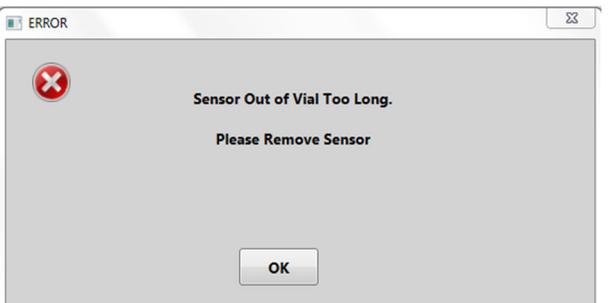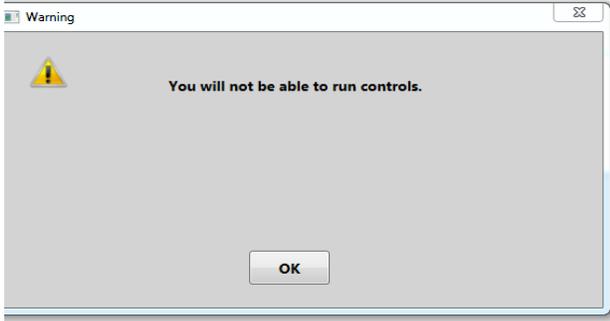
	No active controls found upon startup of the LeadCare Plus DMS.	To avoid encountering this message, must define controls first.
	This is a system error.	Click **OK** and try to proceed to next step. If not possible, restart the DMS.
	This is a system error.	Restart the DMS.
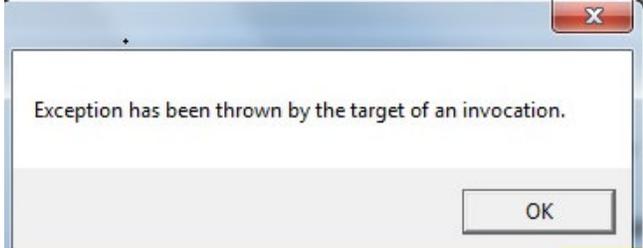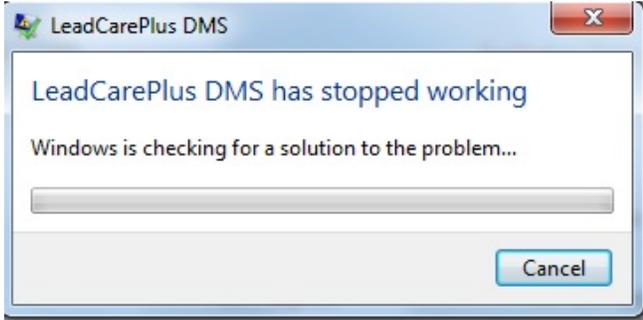
	This error can occur in two situations:	1. Before an existing User logs off, they must exit the DMS.
ERROR ⓧ ⓘ An Instance of the LeadCarePlus DMS is already running. OK	This error can occur in two situations: 1. When a User has logged off but did not formally exit the LeadCare Plus DMS software prior to the next User logging on. 2. More than one copy (instance) of the DMS software was installed on the computer.	1. Before an existing User logs off, they must exit the DMS. 2. Only one version and/or file of the DMS should be installed on your computer. Installation of more than one instance of the DMS will result in an error message. It will be necessary to uninstall the second instance of the DMS to use the program. If, when attempting to uninstall the second instance, you receive an error regarding denied access/privileges, please contact your IT support to obtain local Admin rights
Windows Security Alert ⓧ 🛡 Windows Firewall has blocked some features of this program Windows Firewall has blocked some features of LeadCarePlus DMS on all public, private and domain networks. Name: LeadCarePlus DMS Publisher: Magellan Diagnostics, Inc. Path: C:\program files (x86)\magellan diagnostics \leadcareplusdms\leadcareplusdms.exe Allow LeadCarePlus DMS to communicate on these networks: ☑ Domain networks, such as a workplace network ☐ Private networks, such as my home or work network ☐ Public networks, such as those in airports and coffee shops (not recommended because these networks often have little or no security) What are the risks of allowing a program through a firewall? Allow access Cancel	Windows Firewall has blocked some of the features of the LeadCare Plus DMS software.	The User must check off the "Domain networks, such as workplace network" option, then select "Allow access" in order to operate the LeadCare Plus DMS software.

13.4 Calling LeadCare Product Support

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

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

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

13.5 Downloading Event Logs and Post Logs

At times, to assist with troubleshooting efforts, Magellan Product Support will request that you download the analyzer Event Log and POST Log and send the files to them for review.

13.5.1 Event Log

An Event Log tracks the activity on the analyzer by date and time. The Event Log contains information regarding:

- Analyzer Serial Number
- Power On and Off of the Analyzer
- Analyzer Calibration
- Calibration Lot Number
- Control Results
- Patient Sample Results

13.5.2 POST Log

The POST Log tracks the activity associated with the Power On self-test checks. As described in Chapter 7, every time the analyzer is turned on it performs a series of electrical and software checks to ensure that each critical component of the system is operating correctly. If any one component of the system fails this initial self-test, the User is warned, by a display message,

that the unit requires service and the User is prevented from running patient samples. Any error is recorded in the POST Log.

13.5.3 Download/Export Procedure

A Supervisor or Administrator has the ability to download and export both the Event Log and the POST Log to a CSV formatted file.

To download the Event Log or POST Log follow the steps below:

1. Select the **Log** tab under the toolbar on the main data screen.
2. Select either **Download Event Log** or **Download POST Log** from the dropdown menu.
3. The "Browse For Folder" will appear on the screen.
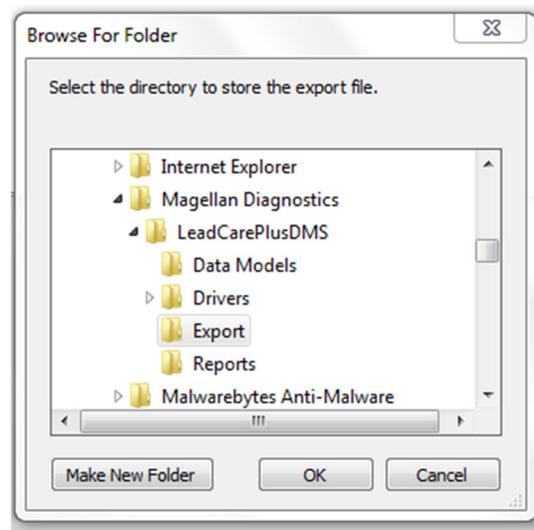
Figure 13-1   POST and EVENT Logs are stored in Export Folder

4. Scroll down to the Export file. The Export folder resides in the following location on the PC "C:" drive:

OS (C:) > Program Files (x86) > Magellan Diagnostics > LeadCarePlusDMS > Export folder

5. Select the **Export** folder and click the **OK** button.
6. A message box will display informing you that the downloaded Log has been exported and providing the name and location of the exported Log file.

13.5.4 Accessing an Exported Event or POST Log

After an Event Log or POST Log is exported you may access it to view, print or save to another location. Follow these steps:

1. Press the **Start** icon on the computer.
2. Go to Computer and select the **OS(C:)**.
3. Select the **Program Files (x86)** folder.

4. Scroll down and select the **Magellan Diagnostics** folder.

5. Select the **LeadCarePlusDMS** folder.

6. Scroll down and select the **Export** folder.

7. Select your exported file. Look for the export with the correct name, date and time.

8. You can now print or use the file as desired.
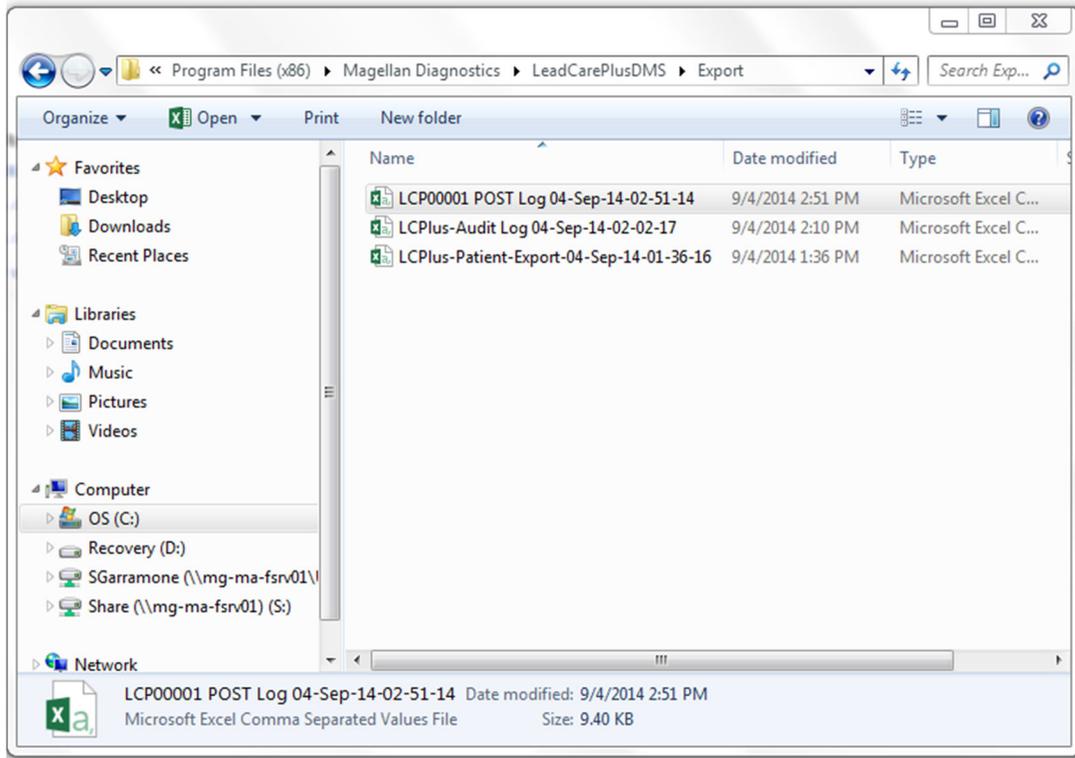
Figure 13-2   Accessing POST and EVENT Logs

Figure 13-3   Example: POST Log

Figure 13-4 Example: Event Log

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14   Maintenance

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

NOTE: Maintenance activities relating to the analyzer do not require the analyzer enclosure to be opened.

There are no user serviceable parts inside the LeadCare Plus Analyzer.

14.1 Cleaning and Decontamination Procedures

14.1.1 Cleaning the Analyzer

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

- Do NOT clean the sensor connector (gold pins) present inside the analyzer sensor connector port. In the case of accidental spill, dry the area immediately.

- Do NOT leave any soap residue or residual liquid on the analyzer.

- Do NOT wash the inside of the calibration button reader.

> ⚠ **WARNING: Failure to comply with these instructions may impact the system's performance.**

14.1.2 Decontamination of the Analyzer

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

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

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

In order to comply with Department of Transportation guidelines, analyzers must be decontaminated prior to returning the instrument to Magellan Diagnostics, Inc. Please refer to Chapter 16 for more information regarding product returns.

15 Reordering Information

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

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16 Returns

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

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

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

3. Prior to returning an analyzer to Magellan Diagnostics, Inc., please follow the decontamination procedure provided in Section 14.1.2.

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

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

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

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

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17   Service and Support

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

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

Please contact our Customer Service Department directly at 800-959-5095 to:

- Place an order
- Track a shipment

Reminder:

Before contacting Product Support, please have the following information ready:

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

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18 LeadCare Plus Blood Lead Testing System Limited Warranty

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

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

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

This limited warranty is the only warranty given by Magellan with respect to the products and software and is given in lieu of all other warranties, express or implied, including, without limitation, any warranty of merchantability or fitness for a particular purpose. Your exclusive remedies and Magellan's sole liability for any non-conformity or defect in the products and software will be those expressed herein. Under no circumstances will Magellan's liability arising from the performance or failure to perform or any product or software in contract, in tort (including negligence), or otherwise, exceed the purchase price of the product. In no event will Magellan be liable for special, incidental, consequential, or analogous damages, including, without limitation, damages resulting from loss of use, loss of profits, loss of business or loss of goodwill, even if Magellan has been advised of the possibility of such damages.

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

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19 The LeadCare Plus DMS Limited License Agreement

To complete installation of the LeadCare Plus® DMS, it is necessary read and indicate agreement with the LeadCare Plus DMS Limited License Agreement by checking off the "I agree" box. For convenience and greater "readability" the LeadCare Plus DMS Limited License Agreement is also provided below:

Limited License Agreement
(Read this license carefully.)

You ("Licensee") agree that by installing and/or using this LeadCare Plus Data Management System software package (the "Licensed Software"), you have agreed to the terms and conditions of this limited license agreement (the "License"). The License constitutes the complete and entire agreement between Licensee and Magellan Diagnostics, Inc. (the "Company") with respect to the Licensed Software.

1. The Company hereby grants to Licensee a nonexclusive, non-transferable, limited license to use the Licensed Software for the sole purpose of operating the Company's LeadCare Plus device.

2. Under the limited license granted herein, Licensee may use the machine readable (executable code) copy of the Licensed Software, including subsequent updates, if any, which are provided by the Company. Licensee shall not, without the Company's prior written consent: (a) rent, lease, lend, sublease, assign or otherwise transfer the Licensed Software or any part thereof; (b) remove or obscure proprietary or copyright notices which may be set forth on the Licensed Software; or (c) alter, decompile, reverse engineer or disassemble the Licensed Software.

3. Licensee may make no more than one (1) copy of the Licensed Software for backup purposes only. No other copies may be made or used without the written consent of the Company.

4. No title to ownership of any Licensed Software is transferred to Licensee. The Company retains all ownership rights in and to the Licensed Software.

5. License upgrades may become available for the Licensed Software. Any cost associated with such upgrades will be determined solely by the Company.

6. The Company makes, and Licensee receives, no warranty, express or implied, with respect to the Licensed Software, and there are expressly excluded all warranties of merchantability, fitness for a particular purpose and non-infringement.

7. Licensee shall have the sole responsibility for adequate protection and backup of its data in connection with the Licensed Software. In no event shall the Company be liable for: (a) special, indirect or consequential damages; (b) any damages whatsoever resulting from loss of use, data, or profits, product, inaccurate input or output, work delays, or any property damage arising out of or in connection with this License or the use or performance of the Licensed Software; or (c) end patient or other customer claims for damages of any nature. Licensee understands this limitation of liability and has secured adequate insurance to mitigate any exposures resulting therefrom.

8. The Company may terminate this License and require return of the Licensed Software if Licensee fails to comply with the terms and conditions set forth herein.

9. Licensee acknowledges that it has read and understood this agreement and agrees to be bound by its terms and conditions. Licensee further agrees that this is the complete and exclusive statement of the License between the Company and Licensee, which supersedes and merges all prior proposals, understandings and other agreements, oral or written, between the parties relating to the Licensed Software. This License may not be modified or altered except by written instrument duly executed by both parties.

10. This Agreement and performance hereunder shall be construed and interpreted under the laws of the Commonwealth of Massachusetts. The courts located in Boston, Massachusetts have exclusive jurisdiction over any disputes arising under or with respect to this License. The parties each waive any right to trial by jury.

11. If any provision of this agreement is determined to be invalid under any applicable statute or rule of law, it is to that extent deemed omitted from the License and the remaining provisions hereof shall constitute this License.

12. Without the prior written consent of the Company, Licensee may not directly or indirectly, in whole or in part, assign, transfer, sublicense or otherwise convey its rights, duties or obligations under this License to any person or entity.

13. The waiver or failure of the Company to exercise in any respect any right provided herein shall not be deemed a waiver of any further right hereunder.

Appendix A Specifications, Operating Requirements, and Performance Characteristics

Specifications

Physical Dimensions	
Dimensions (Approximate, analyzer only)	Height 9 cm (3.5 in.) Width 17 cm (6.5 in.) Depth 23 cm (9 in.)
Weight (Approximate, analyzer with batteries)	1.13 kg (2.5 lb)

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

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

Operating Requirements

Storage and System Operating Ranges

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

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

Shipping Environment Ranges

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

DMS Requirements

PC Operating System	Windows 7 & 8 (32/64 bit), or Windows 10 (64-bit)

Appendix B Interference Substances

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

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

- 5,5-Diphenylhydantoin (phenytoin), 100 µg/mL
- Acetominophen, 500 µg/mL
- Acetylsalicylic Acid, 599 µg/mL
- Aluminum, 10 µg/mL
- Amoxicillin, 100 µg/mL
- Amphotericin, 50 µg/mL
- Arsenic III, 0.01 µg/mL
- Arsenic V, 0.005 µg/mL
- Ascorbic Acid, 100 µg/mL
- Cadmium, 0.05 µg/mL
- Carbamazepine, 100 µg/mL
- Carboplatin, 0.5 µg/mL
- Cephalexin (Keflex), 120 µg/mL
- Ciprofloxacin, 100 µg/mL
- Clondine, 100 µg/mL
- Copper, 2 µg/mL
- Cyclophosphamide, 500 µg/mL
- d-Amphetamine Sulfate, 100 µg/mL
- Diphenylhydramine Hydrochloride, 100 µg/mL
- Doxorubicin, 100 µg/mL
- Doxycycline, 100 µg/mL
- Erythromycin, 100 µg/mL
- Ferric Chloride, 100 µg/mL
- Ferrous Sulfate, 100 µg/mL
- Fexofenadine HCl (Allegra), 50 µg/mL
- Fluconazole (Diflucan), 100 µg/mL
- Gabapentin, 100 µg/mL
- Ganciclovir (AZT), 100 µg/mL
- Glyburide, 100 µg/mL
- Guanfacine, 100 µg/mL
- Hydroxyurea, 250 µg/mL
- Ibuprofen, 500 µg/mL
- Indinavir Hydrate, 100 µg/mL
- Isoniazid, 100 µg/mL
- Loratadine, 100 µg/mL
- Methotrexate, 250 µg/mL
- Methyl Phenidate (Ritalin) HCl, 100 µg/mL
- Metronidazole, 50 µg/mL
- Naproxen sodium, 500 µg/mL
- Niacin, 100 µg/mL
- Nicotine, 5 µg/mL
- Nystatin, 100 µg/mL
- Penicillamine, 25 µg/mL
- Phenylephrine, 100 µg/mL
- Piperazine, 100 µg/mL
- Pseudoephedrine (guiafenesin), 100 µg/mL
- Pyridoxine, 100 µg/mL
- Riboflavin, 6 µg/mL
- Rifampicin, 100 µg/mL
- Salicylic acid, 600 µg/mL
- Sitagliptin, 50 µg/mL
- Succimer (Dimercaptosuccinic acid), 100 µg/mL
- Sulfamethoxazole, 400 µg/mL
- Thiamine, 20 µg/mL
- Trimethoprim, 100 µg/mL
- Uric Acid, 100 µg/mL
- Valproic Acid, Na salt, 500 µg/mL
- Vitamin D3, 100 µg/mL
- Wafarin (Coumadin), 100 µg/mL
- Zinc, 10 µg/mL

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Appendix C Safety Data Sheets (SDS)

This chapter contains the following LeadCare Plus® Safety Data Sheets, provided to help laboratory personnel work safely at all times:

- LeadCare Ultra/Plus Controls
- LeadCare Ultra/Plus Treatment Reagent

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