Health. Each site had one operator except for site number ten, Chicago Department of Health, which had two operators.

The twelve participants who were not given any training on the use of the test operated the LeadCare II device at the ten clinical sites. The study involved running 462 samples (352 patient samples and 110 spiked samples) over a two-month period at 10 sites. Additionally, 85 patients' samples from battery workers in Canada were included in the study. The comparative method was Graphite Furnace Atomic Absorption Spectroscopy (GFAAS). Specimens were collected by both venous and capillary methods. 50 µL of sample was tested by LeadCare II and the remaining portion of the original sample was sent to ESA Laboratories Inc. for analysis by GFAAS.

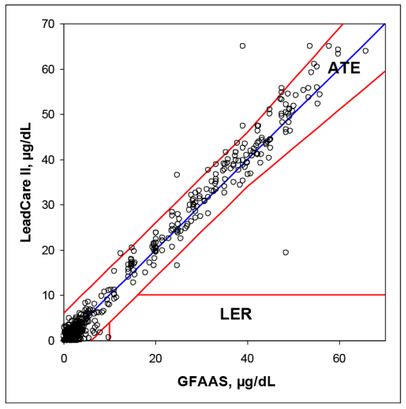
Of the 547 samples run on LeadCare II, 516 (94.3%) were analyzed by GFAAS. Samples that could not be analyzed by GFAAS were due to clotted samples or a procedure error.

The study was intended to demonstrate that after reading only the test instructions, participants were able to obtain results on the LeadCare II that were as accurate as those obtained on GFAAS using the following performance limits: Allowable Total Error (ATE) is defined as (GFAAS result ± 6 µg/dL) for GFAAS results ≤ 40 µg/dL and (GFAAS result ± 15%) for GFAAS results > 40 µg/dL (Occupational Safety and Health Administration of U.S. Department of Labor (OSHA) recommendations for blood lead proficiency testing). The results of the study were as follows:

Range of GFAAS values (µg/dL)	Total number of samples	Number of samples within ATE	Percent of samples within ATE
0 to 10.0	314	312	99.4%
10.1 to 40.0	138	132	95.7%
40.1 to 65.0	64	61	95.3%
0 to 65.0	516	505	97.9%

The percentage of samples over the entire range that fall within the ATE zone is 97.9% (505/516) with a lower bound of 95% confidence interval of 96.6%. Values in the zones of Limits for Erroneous Results (LER) are considered dangerous. Any samples in the LER zone indicate a failure by LeadCare II to properly identify hazardous blood lead concentrations. In the study, no samples were in the LER zone (0% with an upper bound of 95% confidence interval of 0.5%).

The scatter plot of the study results with ATE and LER zones is presented in the figure below:



The descriptive statistics of the differences between LeadCare II and GFAAS results are presented in the table below:

Range of GFAAS values (µg/dL)	Average difference	2.5th percentile of differences	97.5th percentile of differences
0 to 10.0	-0.5 µg/dL	-4.0 µg/dL	2.3 µg/dL
10.1 to 40.0	1.3 µg/dL	-3.8 µg/dL	6.5 µg/dL
40.1 to 65.0	1.9%	-28.8%	18.5%

The LeadCare II and GFAAS results were compared by ordinary least squares regression analysis: the slope was 1.04 with 95% CI: 1.03 to 1.06; with an intercept of -0.46 with 95% CI: -0.77 to -0.14.

The systematic differences between LeadCare II and GFAAS results estimated by regression analysis are presented in the table below:

GFAAS (µg/dL)	Systematic difference between LeadCare II and GFAAS (µg/dL)
10	-0.0
20	0.4
45	1.5

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3. CDC (Centers for Disease Control) Guidelines for Collecting and Handling Blood Lead Samples 2004, www.cdc.gov/nceh/lead/training/blood_lead_samples.htm (Video presentation describes how to collect and handle samples that will be used for blood lead testing.)
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P/N 70-6869 Rev 07 (04/2021)

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

Intertek

IVD Rx Only

LeadCare® II Blood Lead Test Kit

NOTE: Instructions for use with Analyzer Firmware Version 1.05 or higher. Please check the label on the bottom of your analyzer to determine firmware version.

For use with LeadCare II Blood Lead Testing System to test for lead in capillary whole blood.

For *in vitro* diagnostic testing (external use only).

Read this package insert completely before using the product. Follow the instructions carefully when performing a test. Not doing so may result in inaccurate test results.

COMPLEXITY: WAIVED
Any modification by the laboratory to the test system or the manufacturer's instructions will result in the test no longer meeting the requirements of the waived category.

All laboratories eligible for a CLIA Certificate of Waiver (COW) must follow the manufacturer's instructions as specified in the LeadCare® II User's Guide, LeadCare® II Quick Reference Guide and in the LeadCare® II Blood Lead Test Kit package insert.

Please read the LeadCare II User's Guide before performing any blood lead testing with the LeadCare II Blood Lead Testing System.

QUESTIONS?
Call the LeadCare Technical Support Team
Toll Free Number 1-800-275-0102

INTENDED USE
The LeadCare II Blood Lead Test Kit is for *in vitro* diagnostic use only. The test kit is for the quantitative measurement of lead in capillary whole blood. This product is for professional use only. Sensors and Treatment Reagent of the test kit are specific for **lead** only. Contents of the LeadCare II Blood Lead Test Kit must only be used with a LeadCare II Analyzer. Do not mix components from separate kit lot numbers.

HOW THE LEADCARE II BLOOD LEAD TESTING SYSTEM WORKS
The LeadCare II System relies on electrochemistry and a unique Sensor to detect lead in whole blood. Most lead is carried in red blood cells. When a sample of whole blood is mixed with Treatment Reagent, the red blood cells are lysed and the lead is made available for detection. When a test is run, the analyzer applies a potential that causes the lead to collect on the LeadCare II Sensor. After 3 minutes the analyzer measures the amount of lead collected on the Sensor and displays the result in µg/dL.

REAGENTS
Sensor Composition: The active electrode area in each Sensor contains a small amount of gold particles in an inert matrix.

Treatment Reagent Composition: The Treatment Reagent contains 250 µL of a dilute hydrochloric acid solution in water (0.34 M).

Blood Lead Control Composition: Lead salt in buffered aqueous solution with bovine serum albumin. Two levels of quality control material are provided with the test kit, designated "Level 1" and "Level 2". The actual target values are specified on the labels.

STORAGE AND HANDLING
The test kit has an expiration date assigned. It is printed on the exterior of the box. Do **NOT** use the test kit past the expiration date.
NOTE: The Treatment Reagent, Blood Lead Controls and the Sensors have separate expiration dates. The earliest expiring component is used to set the test kits expiration date.

To keep the LeadCare II Blood Lead Test Kit fresh, observe the following:

- Store in a cool, dry place. Storage temperature should be between 60°-80°F (15°-27°C). Do NOT freeze or refrigerate.
- Store away from direct sunlight.
- Keep Sensors sealed in their container until the sample is prepared and you are ready to perform the test. The container is lined with desiccant to keep the Sensors fresh.
- Use the Treatment Reagent immediately after opening the tube.
- Do **NOT** place any object in the Treatment Reagent tube other than the capillary and dropper provided with this test kit. Contamination could occur.
- Do **NOT** use Sensors, Blood Lead Controls and Treatment Reagent past their expiration dates.
- Blood Lead Controls should be kept at room temperature: 60-80°F (15-27°C). Do **NOT** refrigerate.
- Precautions: SDS sheet can be found in the User's Guide.
- Treatment Reagent may be harmful if swallowed. Keep out of reach of children. If swallowed, consult a physician. If there is contact with skin or eyes, flush with water.
- Blood Lead Control material may be harmful if it comes in contact with the eyes or an open wound. Practice universal precautions when handling. If there is contact with skin or eyes, flush with water.

SPECIMEN COLLECTION AND HANDLING[1,2]

- The LeadCare II test kit includes capillary tubes for the collection of a whole blood sample directly from the patient's finger. In addition, the system is also compatible with other micro-collection devices for the collection of capillary samples.
- Proper preparation of the puncture area is important. Refer to CDC guidelines, "Steps for Collecting Fingerstick Blood Samples in Micro-Vials for Lead Testing"[3]. These guidelines are provided in Appendix D of the LeadCare II User's Guide.

FOR SAMPLES COLLECTED IN MICRO-COLLECTION DEVICES

- Use only heparin or EDTA as anticoagulants. If you use EDTA micro-collection tubes, they must be at least one half full otherwise you could obtain falsely lower blood lead results.
- Use only fresh whole blood. Use the blood within 24 hours of collection. Store at 50°-90°F (10°-32°C).
- Do **NOT** use plasma or serum. Do **NOT** use venous blood samples.
- Do **NOT** refrigerate the whole blood prior to mixing with Treatment Reagent.
- Make sure to invert the specimen container multiple times to thoroughly mix the blood before filling the capillary tube.
- Make sure the blood sample does not contain clots. Blood clots can lead to erroneous blood lead results.
- Use the capillary tube and plunger provided with the test kit to remove 50 µl of blood from the micro-collection tube and dispense it into the Treatment Reagent tube.

PRECAUTIONS
Handle all products and objects containing human blood as if capable of transmitting diseases. Follow established recommendations for prevention of blood-borne transmissible diseases. For example, consult the "Universal Precautions" issued by the U.S. Public Health Service, Centers for Disease Control. Review your internal protocol for preventing transmission of blood-borne pathogens and your biohazardous waste disposal procedures prior to implementing the LeadCare II blood lead testing system.[4] You **MUST** wear gloves, lab coats, and safety glasses when handling blood and using the LeadCare II System. Consult the established policy of your organization for proper laboratory protection.

CAUTION: Treatment Reagent contains 0.34 M Hydrochloric acid which may cause eye, skin and respiratory system irritation. Avoid contact with skin, eyes and clothing. In case of accidental contact, immediately flush skin and eyes with running water for up to 15 minutes and move to fresh air. Seek medical assistance in situation where eye contact, skin irritation or burn, or difficulty breathing occurs.

MATERIALS PROVIDED IN THE TEST KIT	**QTY**
Sensors (2 containers of 24 ea.)	48
Treatment Reagent Tubes	48
Heparinized Capillary Tubes/Plungers	50 ea.
Transfer Droppers	50
Calibration Button	1
Lead Control Level 1 (2 mL)	1
Lead Control Level 2 (2 mL)	1

REQUIRED MATERIALS PROVIDED WITH THE ANALYZER

- Analyzer (using 4 AA batteries or the AC Adapter)
- LeadCare II User's Guide
- LeadCare II Quick Reference Guide
- LeadCare II Flash Drive
  (contains User's Guide and instructional videos)

MATERIALS REQUIRED BUT NOT PROVIDED

- Alcohol wipes
- Gauze pads
- Powder-free gloves

CALIBRATION

The LeadCare II Analyzer **MUST** be calibrated for the test kit lot in use. Use only the calibration button that comes with the test kit. Make sure that the calibration code on the calibration button matches the lot number on the Sensor container, and on the controls.

1. Turn on Analyzer
   - Wait for SELF TEST to finish. The analyzer is ready when the PREPARE SAMPLE message appears.
2. Calibrate Analyzer
   - Remove the calibration button from the test kit.
   - Touch calibration button to the calibration button reader on the analyzer.
   - Hold calibration button to the reader until analyzer "beeps". "CALIBRATION SUCCESSFUL" will appear briefly on the screen.
   - The new calibration code ("Sensor lot") will be displayed on the screen.
   - Make sure the code matches the calibration button and the lot number of the test kit being used.
   - Analyzer is now calibrated and ready for a blood lead test.

BLOOD LEAD TEST PROCEDURE

Refer to your LeadCare II Quick Reference Guide and User's Guide for detailed test instructions.

NOTE: Properly calibrate the analyzer with the calibration button that comes with each test kit.

1. Turn on analyzer
   - Wait for SELF TEST to finish.
   - Make sure the Sensor lot number (printed on the Sensor container) matches the number displayed on the screen.
2. Refer to the **Quality Control** section of this package insert for important information about when and how to perform quality control testing to ensure the accuracy of your lead results. Perform quality control testing if necessary.
3. Obtain a capillary *whole* blood sample[1,2]
   - Label a Treatment Reagent tube with the patient ID.
   - Use the heparinized capillary tube provided. Holding it almost horizontally, fill to the 50 µL black line with fresh capillary whole blood. Make sure there are no gaps or bubbles.
   - Use a clean gauze pad to remove any excess blood from the outside of the capillary tube.

NOTE: The accuracy of the test depends on filling the capillary tube properly. Make sure the blood reaches the 50 µL black line without gaps or bubbles.

4. Mix the whole blood sample with Treatment Reagent
   - Remove the cap from the Treatment Reagent tube and place it *top down* on a clean surface. Do not allow the inside part of the cap to touch anything.
   - Place the capillary tube into the Treatment Reagent tube. Insert a plunger into the top of the capillary tube. Dispense all of the blood into the Treatment Reagent.
   - Remove the empty capillary tube and replace the cap on the Treatment Reagent tube.
   - Invert the tube 8 to 10 times to mix the sample completely. The sample is ready when the mixture turns brown. (Control material mixed in Treatment Reagent will be red.)

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

NOTE: The accuracy of the blood lead test depends on properly transferring 50 µL of blood into the Treatment Reagent. Use the capillary tubes and plungers provided with the test kit as instructed to ensure the accuracy of your results. A capillary tube should also be used to prepare controls and proficiency samples for analysis.

5. Apply Treatment Reagent and blood mixture to a Sensor
   - Open a Sensor container, remove a Sensor, and re-close the container.
   - Insert the Sensor into the analyzer until you hear a "beep", and the screen displays the message, "ADD 1 DROP OF SAMPLE".
   - Make sure the Sensor lot number matches the number on the display.
   - Make sure the sample is thoroughly mixed.
   - Remove the cap from the tube. Insert a transfer dropper into the tube. Squeeze the dropper and insert into the sample. Release the pressure to draw the sample into the dropper.
   - Place the dropper on the "X" of the Sensor and squeeze to dispense the sample onto the Sensor. When the sample is added, the analyzer beeps, and begins the test automatically.
6. Read the blood lead result
   - After 3 minutes, the analyzer beeps and displays the blood lead result on the screen. Read and record the result in µg/dL on the sheet provided.
7. Discard Used Materials
   - After the test is completed, remove the Sensor. Discard used materials in appropriate containers.

TEST RESULTS

The analyzer's display window shows the blood lead result. The result is in micrograms (µg) of lead per deciliter (dL) of whole blood. No calculation is needed. Results are displayed to one decimal place. The reportable range of the test is 3.3 to 65 µg/dL.

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

"**High**" in the display window indicates a blood lead test result greater than 65.0 µg/dL. If this occurs, report the blood lead result as greater than (>) 65 µg/dL.

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.

IMPORTANT: Report all blood lead results to the proper state or federal agency.

EXPECTED RESULTS

When the LeadCare II display reads "High", the analyzer has detected a blood lead level greater than 65 µg/dL, **"High" results on LeadCare II should be followed up immediately as an emergency laboratory test.**

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.

QUESTIONABLE RESULTS

Incorrect test results may have an adverse medical outcome. If test results are questionable or inconsistent, follow the suggestions below:

1. Make sure the expiration date of the kit has not passed.
2. Check that the analyzer is properly calibrated. The lot number displayed on the screen should match the lot number printed on the Sensor container, the control vials and test kit.
3. Check the analyzer and kit contents using proper control material. Acceptable performance is assured if results of the controls are within the proper range. The target value is printed on the label. The control lot number must match the Sensor lot number for a valid test result.
4. If the above steps result in unacceptable performance, see the LeadCare II User's Guide for further steps to be taken.

MAINTENANCE

The LeadCare II System needs very little maintenance. Follow the maintenance procedures listed in Chapter 5 (Troubleshooting and Maintenance) of the User's Guide.

QUALITY CONTROL

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

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

The blood lead level that appears on the analyzer display should be within the acceptable range provided for that control. If the blood lead levels displayed are within the range listed for the control, your LeadCare® II system is working properly. If the reported blood lead levels are *not* within the listed range, refer to the troubleshooting section of the User's Guide. If, after following the instructions, the controls are still out of range, call LeadCare Product Support at **1-800-275-0102.**

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

PROCEDURE FOR USING THE BLOOD LEAD CONTROLS

1. Prepare the sample
   - Label a Treatment Reagent tube "Level 1".
   - Gently swirl the Level 1 control vial. Remove the cap from the Level 1 control and place it *top down* on a clean surface.
   - Fill one of the capillary tubes with the control you are testing. To accomplish this, tilt the control vial, insert the capillary tube into the liquid while holding the green end of the capillary tube almost horizontally. Capillary action will fill the tube to the 50 µL black line.
   - Use a clean wipe to remove excess control material from the outside of the capillary tube.
2. Mix the control material with Treatment Reagent
   - Remove the cap from the Treatment Reagent tube and place it *top down* on a clean surface. Do NOT allow the inside of the cap to touch anything.
   - Place the full capillary tube into the Treatment Reagent tube. Insert a plunger into the top of the capillary tube. Dispense all of the control into the Treatment Reagent.
   - Remove the empty capillary tube and recap the Treatment Reagent tube.
3. Invert the Treatment Reagent tube 8 to 10 times to thoroughly mix. The resulting mixture will be red. Apply Treatment Reagent and control mix to Sensor.
   - Open a Sensor container, remove a Sensor, and reclose the container
   - Insert a fresh Sensor into the LeadCare II analyzer until you hear a "beep" and the analyzer screen displays the message "ADD 1 DROP OF SAMPLE TO X ON SENSOR.".
   - Make sure the Sensor lot number matches the lot number on the display.
   - Invert your sample to ensure the sample is well mixed
   - Remove the cap from the Treatment Reagent tube. Insert a transfer dropper into the tube. Squeeze the dropper and insert it into the sample. Release the pressure to draw the sample into the dropper.
   - Place the dropper on the "X" of the Sensor and squeeze to dispense sample the sample onto the Sensor. When the sample is added, the analyzer beeps and begins the test automatically.
4. Read the blood lead result.
   - After 3 minutes, the analyzer beeps and displays the blood lead result on the screen. Read and record the lead result in µg/dL.
5. Discard used materials
   - After the test is completed, immediately remove the sensor. Discard used materials in appropriate containers.
6. Repeat this process for the Level 2 control.

EXPECTED RESULTS

Lead control target values and acceptable limits are provided on the control label. If the reported value is within the acceptable limits for both the Level 1 and Level 2 controls, your LeadCare II system is operating properly. You may now test patient samples.

If the reported blood lead level is not within the acceptable range for the control, refer to the troubleshooting section of the LeadCare II User's Guide. If, after following the instructions, the control value is still out of range please contact LeadCare Product Support at 1-800-275-0102.

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

LIMITATIONS OF THE TEST

- **For blood collected in the capillary tubes provided with the test kit:** Dispense the blood from the capillary tube into a Treatment Reagent tube within 10 minutes of collection, and mix well, to prevent the blood from clotting inside the heparinized capillary tube.
- **For blood collected in other micro-collection devices:** Use only fresh, unrefrigerated whole blood within 24 hours stored at 50°-90°F (10°-32°C) with the LeadCare II System. Do NOT use venous samples. Do **NOT** use plasma or serum. Use the capillary tubes and plungers provided with the test kit to transfer 50 µl of blood from the micro-collection device into the Treatment Reagent tube.
- After mixing the blood with the Treatment Reagent, analyze it in less than 48 hours if stored at room temperature. If stored refrigerated analyze within 7 days. **NOTE:** Allow mixture to reach room temperature before analyzing.
- Extremes in humidity may affect the blood lead results. Performance has been validated from 12% to 80% RH (non-condensing). Use of the LeadCare II system outside of this range is not recommended.
- Do **NOT** use the LeadCare II System in drafts. This could lead to falsely low results.
- Keep the LeadCare II System out of direct sunlight.
- The analyzer will only function in the temperature range of 54°- 97°F (12°-36°C). Otherwise the analyzer will display a temperature error code. Refer to analyzer display messages in the User's Guide (Chapter 5).
- Allow all of the LeadCare II System components to reach a steady temperature before using.
- Clinical testing demonstrates that altitudes up to 8,000 feet (2,440 meters) above sea level do not affect results obtained with the LeadCare II System.
- Use the Sensors, the Treatment Reagent tubes, capillary tubes and transfer droppers only once. Do **NOT** reuse. Reuse could lead to erroneous results.
- Do **NOT** use damaged (bent, scratched, cut, etc.) Sensors.
- The following substances (at the concentrations listed) do **NOT** affect the results of the LeadCare II system: copper (90 µmol/L), zinc (54 µmol/L), arsenic (0.78 µmol/L), cadmium (0.27 µmol/L), aluminum (0.45 µmol/L), ascorbic acid (0.30 mmol/L), uric acid (1.5 mmol/L).
- The LeadCare® II system was also tested in the presence of 37 drugs commonly found in pediatric blood samples. The following concentrations do **NOT** affect the results of the LeadCare II system: acetaminophen (396 µmol/L), acetylsalicylic acid (6.0 mmol/L), ibuprofen (396 µmol/L), heparin (80,000 units/L), calcium sodium EDTA (6.7 mmol/L), succimer (DMSA) (78 µmol/L), DMPS (2,3-dimercapto-1-propane sulfonic acid) (78 µmol/L), D-penicillamine (0.17 mmol/L), BAL (2,3-dimercaptopropanol) (0.97 µmol/L). Refer to the User's Guide for a complete list of drugs tested.

PERFORMANCE CHARACTERISTICS

Consult the LeadCare II User's Guide for the complete product specifications.

PRECISION

The precision of the LeadCare II Blood Lead Testing System was determined by testing samples at four concentration levels on six LeadCare II analyzers over twenty days. The results are provided in the table below.

Table 1: Precision Pooled Across LeadCare II Instruments

LC II Avg. (µg/dL)	Pooled Total CV	Pooled Total SD	N
5.3	12.1%	0.64	120
11.0	7.6%	0.83	120
22.9	5.5%	1.26	120
51.7	3.5%	1.80	120

ACCURACY

The accuracy of the LeadCare II Blood Lead Testing System was determined by a method comparison study in which 108 human samples were run on six LeadCare II analyzers over five days and compared with results run by Graphite Furnace Atomic Absorption Spectroscopy (GFAAS). Of the 108 samples, 22 were spiked (86 were unspiked).

The results from this study gave the following regression:

Y (LeadCare II) = 1.040 x GFAAS + 0.12, $s_{y.x}$ =1.30 , r^2 = 0.992

The average LeadCare II bias from reference is shown in Table 2 for three ranges.

Table 2: Average LeadCare® II Average Bias from GFAAS

Lead Concentration (µg/dL)	LeadCare II Bias from GFAAS	LeadCare II % Bias from GFAAS
0 – 10	0.07	-----
10.1 – 25.0	-----	4.7%
25.1 – 65	-----	5.0%

Results of CLIA Waiver Study

A clinical study was conducted at ten sites located in three different regions of the United States. Five neighborhood health centers in Brooklyn, New York, administered by Lutheran Healthcare; three Women, Infant and Children's clinics in Vermont administered by the Vermont State Health Department; and two clinics in Chicago, Illinois, administered by the Chicago Department of Health.