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

<table>
<thead>
<tr>
<th>Range of VFAAS values (μg/dL)</th>
<th>Average difference</th>
<th>2.5% percentile of differences</th>
<th>97.5% percentile of differences</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 to 10.0</td>
<td>-0.5 μg/dL</td>
<td>-4.9 μg/dL</td>
<td>2.3 μg/dL</td>
</tr>
<tr>
<td>10.1 to 40.0</td>
<td>1.3 μg/dL</td>
<td>-3.8 μg/dL</td>
<td>6.9 μg/dL</td>
</tr>
<tr>
<td>40.1 to 65.9</td>
<td>10.2 μg/dL</td>
<td>-28.1 μg/dL</td>
<td>18.3 μg/dL</td>
</tr>
</tbody>
</table>

The LeadCare II and GFAAS results were compared by ordinary least squares regression analysis. Each sample was tested with 95% CI. 1.03 to 1.06; with an interquartile range of -0.46 with 95% CI. -0.17 to -0.14.

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

**Notes:**

1. Do NOT place any object in the treatment reagent tube other than the capillary and dropper provided with this test kit. Contamination could occur.
2. Do NOT use sensors, blood lead controls and treatment reagents past their expiration dates.
3. The expiration sheet can be found in the User’s Guide.
4. 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.
5. Blood lead control material may be harmful if it comes in contact with the eyes or skin. Do not use without eye protection. For eye or nose irritation when handling. If there is contact with skin or eyes, flush with water.

**SPECIMEN COLLECTION AND HANDLING**

The LeadCare II Blood Lead Test Kit includes capillary tubes for the collection of a whole blood sample directly from the patient’s finger. The system is also compatible with whole blood samples.

1. Proper preparation of the puncture area is important. Refer to CDC guidelines, “Steps for Collecting Fingerstick Blood Samples in Micro-Vials for Lead Testing” 2. These guidelines are provided in Appendix C of the LeadCare II User’s Guide.

**FOR SAMPLES COLLECTED IN MICRO-VIALS OR VACUUM COLLECTION TUBES**

- Use only heparin or EDTA as anticoagulants. If you use EDTA collection tubes, they must be at least one half full otherwise you could obtain falsely low results.
- For venous samples that are shipped or rocked, allow the blood-lead treatment mixture to stand at room temperature prior to analysis.
- Use only fresh whole blood. Use the within 24 hours of collection.
- Do NOT use plasma or serum.
- Do NOT refrigerate the whole blood prior to mixing with treatment reagents.
- Make sure to insert the specimen container multiple times to thoroughly mix the blood before testing.
- Make sure the blood sample does not contain clots. Blood clots can lead to falsely lower blood lead results.
- Use the capillary tube and plunger provided with the test kit to remove 50 μL of blood from the collection tube and dispense it into the treatment reagent tube.

**PRECAUTIONS**

Handle all products and objects containing human blood as if capable of transmitting infectious 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 biocidalwash disposal procedures prior to implementing the LeadCare II Blood Lead Testing System.**

**CAUTION** – contains 0.34 M Hydrochloric Acid which may cause eye, skin, and respiratory tract 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 situations where eye contact; skin inflammation or burn; or difficulty breathing occurs. You MUST wear gloves, lab coats, and safety glasses when handling blood and using the LeadCare II System. Contact your local health authority to establish policy of your organization for proper laboratory protection.

**MATERIALS PROVIDED IN THE TEST KIT**

- Sensors (2 containers of 24 ea.)
- Treatment Reagent Tubes (10 x 5 ml; 0.34 M HCl)
- Heparinized Capillary Tubes/Pluggers
- Test Capillary Tubes
- Calibration Button
- Lead Control Level 1 (2 ml)
- Lead Control Level 2 (2 ml)

**REQUIRED MATERIALS PROVIDED WITH THE ANALYZER**

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

The LeadCare II Blood Lead Test Kit

**NOTES:**

1. For use with LeadCare II Blood Lead Testing System to test lead in whole blood.
2. For in vitro diagnostic testing (exempt use only).
3. Read this package insert completely before using the product. Follow the instructions carefully when performing a test. Do 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 Product Support Team
Toll Free Number 1-800-275-0102

**LEDRENSE**

Magellan Diagnostics, Inc.
101 Billerica Ave., Building 4
Billerica, MA 01821
Patent: www.leadcare2.com/patemarketing
Magellan Diagnostics is a registered trademark of Magellan Diagnostics, Inc.
PN# 70-6889 Rev 04/11/2000

**SPECIMEN COLLECTION**

- Sites included in the study were a variety of different clinics in various regions of the United States. The first WI site was in the Department of Health of the United States and the other two sites were in the Department of Health of the United States. The first WI site was in the Department of Health of the United States and the other two sites were in the Department of Health of the United States.
- The study involved 354 samples from 110 spiked samples across two different months in the lead collection site.
- The evaluation was conducted on a total of 354 spiked samples from the lead collection site.
- The study included 354 samples from 110 spiked samples across two different months in the lead collection site.
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Inverting a venous tube 8 to 10 times to mix the sample completely. The target value is printed on the label on a clean surface. Do not allow the inside part of the cap to dry out. Follow your federal, state, and local guidelines to ensure compliance.

**LIMITATIONS OF THE TEST RESULT**

- 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 to transfer the whole blood into the treatment reagent. Do not use a capillary tube from another source. Do not use the LeadCare II System in drafts or 90°F (32°C) or higher temperatures. Extremes in humidity may affect the blood lead results. Performance has been validated from 12% to 90% RH (non-condensing). Use the LeadCare II System outside of this range at your own risk.

- The analyzer will only function in the temperature range of 54° to 95°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).

- Do not use the LeadCare II System components to prepare for a quality control sample. Extremes in humidity may affect the blood lead results. Performance has been validated from 12% to 90% RH (non-condensing). Use the LeadCare II System outside of this range at your own risk.

- The LeadCare II System is designed to test whole blood. Do not test serum, plasma, or capillary blood (finger stick, heel stick, or venous blood) in the LeadCare II System. Capillary blood cannot be used in the LeadCare II System. For blood collected in other collection devices: Use only fresh, uncontaminated whole blood within 24 hours stored at 50°-90°F (10°-32°C) with the LeadCare II System. Do not use plasma or serum. Use the capillary tubes and plungers provided with the test kit to transfer the whole blood from the collection device into the treatment reagent tube. For venous blood, use the capillary tubes and plungers provided with the test kit to transfer whole blood from the venous blood into the treatment reagent mixture to stand at room temperature for 4 hours prior to analysis. After 4 hours when stored at 50°-90°F (10°-32°C) discard the blood. Place the lead sample in the LeadCare II System for 48 hours if stored at room temperature. If stored refrigerated analyze within 3 days.

**NOTE:** Allow mixture to reach room temperature before analyzing.

**EXTREME LIMITATIONS**

- Turn on the analyzer. Wait for SELF TEST to finish. The analyzer is ready when the PREPARATION COMPLETE message appears.

**BLOOD LEAD TEST PROCEDURE**

1. Turn on the analyzer.
   - Ingredients available in the kit for patient ID.
   - Use the heparinized capillary tube provided. Hold it almost horizontally, fit the 50 µL black line within the 50 µL black line.