

## COVER PAGE FOR April 2015 MDR

The FDA received this Medical Device Report (MDR) from Magellan Diagnostics on April 6, 2015, which describes a problem with the LeadCare Ultra Testing System. The MDR reports the problem as a malfunction and describes the level of associated risk as “low.” The MDR reports that implementation of a 24-hour processing delay reduces the total level of risk to zero. The MDR encloses a customer notification, distributed by Magellan in November 2014, characterizing the issue as an infrequent occurrence that could impact a small percentage of patient results.

Regulations specify when a manufacturer must submit a MDR to the FDA, including when a manufacturer must report a death, serious injury, or product malfunction. The FDA typically receives between 800,000 and 1,000,000 MDRs per year. The majority involve device “malfunctions,” which FDA regulations define as a failure of the device to meet its performance specifications or otherwise perform as intended. The FDA routinely uses malfunction reports to conduct trend analysis and identify potential safety issues. Additional information regarding medical device reporting requirements can be found at <https://www.fda.gov/MedicalDevices/Safety/ReportaProblem/ucm2005291.htm#overview>.

U.S. Department of Health and Human Services  
Food and Drug Administration

For use by user-facilities,  
importers, distributors and manufacturers  
for MANDATORY reporting

**MEDWATCH**

FORM FDA 3500A (2/13)

Mfr Report #	1218996-2015-00001
UF/Importer Report #	
FDA Use Only	

A. PATIENT INFORMATION			
1. Patient Identifier	2. Age at Time of Event: or _____ Date of Birth:	3. Sex <input type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight _____ lbs or _____ kgs

**B. ADVERSE EVENT OR PRODUCT PROBLEM**

1.  Adverse Event and/or  Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)

Death: \_\_\_\_\_ (mm/dd/yyyy)  Disability or Permanent Damage

Life-threatening  Congenital Anomaly/Birth Defect

Hospitalization - initial or prolonged  Other Serious (Important Medical Events)

Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy)

4. Date of This Report (mm/dd/yyyy)  
04/02/2015

5. Describe Event or Problem

11/15/2014 Initial Risk Analysis Hazard/Risk Score Total = 1 None/Negligible which is a Non Recall Status The medical decision points of treating lead is per CDC guidelines (see attached letter dated Nov. 29) factored into the decision initially not to file.

3/23/2015 Based on new information a second Risk Analysis was performed which changed our score from a Total Hazard/Risk Score from a 1 to a overall score of 6 which is Low; Recall Class III. Thus we felt that even though we have mitigated the issue completely through our pending labeling change and Customer Letter, it was in compliance with FDA and our internal recall procedure that we chose to file this MDR with FDA.

Please see attached #B.5.Description of event or Problem

Continued to separate Page.

(Continue on page 3)

6. Relevant Tests/Laboratory Data, including Dates

(Continue on page 3)

7. Other Relevant History, including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Medical decision points of treating lead is per CDC guidelines (see attached letter dated Nov. 29) factored into the decision initially not to file.

The LeadCare Ultra intended use is to test for lead levels in whole blood for occupational and pediatric testing. "Based on the prevalence of elevated blood lead levels from the CDC, approximately 2.5% of your patient results may cross the medical decision point of 5 ug/dL."

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

**C. SUSPECT PRODUCT(S)**

1. Name (Give labeled strength & mfr/labeler)

#1 Lead Care Ultra Test System and Kit

#2 \_\_\_\_\_

2. Dose, Frequency & Route Used

#1 \_\_\_\_\_

#2 \_\_\_\_\_

3. Therapy Dates (If unknown, give duration) from/to (or best estimate)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

4. Diagnosis for Use (Indication)

#1 to measure lead in whole blood

#2 \_\_\_\_\_

5. Event Abated After Use Stopped or Dose Reduced?

#1  Yes  No  Doesn't Apply

#2  Yes  No  Doesn't Apply

6. Lot #

#1 \_\_\_\_\_

#2 \_\_\_\_\_

7. Exp. Date

#1 \_\_\_\_\_

#2 \_\_\_\_\_

8. Event Reappeared After Reintroduction?

#1  Yes  No  Doesn't Apply

#2  Yes  No  Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

None.

(Continue on page 3)

**D. SUSPECT MEDICAL DEVICE**

1. Brand Name  
LeadCare Ultra Test System

2. Common Device Name  
LeadCare Ultra Analyzer

2b. Procode  
DOF

3. Manufacturer Name, City and State  
101 Billerica Ave., Bldg 4  
Billerica, Ma. 01802

4. Model #  
80-0010

Lot #  
N/A

Catalog #  
80-0010, 70-8098

Expiration Date (mm/dd/yyyy)  
N/A

Serial #  
N/A

Unique Identifier (UDI) #

5. Operator of Device

Health Professional

Lay User/Patient

Other

6. If Implanted, Give Date (mm/dd/yyyy)

7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?

Yes  No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? (Do not send to FDA)

Yes  No  Returned to Manufacturer on: \_\_\_\_\_ (mm/dd/yyyy)

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

**E. INITIAL REPORTER**

1. Name and Address

(b)(4) CCI \_\_\_\_\_ Complaint # \_\_\_\_\_ (b)(4) CCI \_\_\_\_\_  
United States \_\_\_\_\_ (b)(4) CCI \_\_\_\_\_

Phone # \_\_\_\_\_ Email Address \_\_\_\_\_  
Phone: (b)(4) CCI \_\_\_\_\_ (b)(4) CCI \_\_\_\_\_

2. Health Professional?  Yes  No

3. Occupation  
Administrator/Supervisor

4. Initial Reporter Also Sent Report to FDA

Yes  No  Unk

PLEASE TYPE OR BLACK INK

### F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

1. Check One <input type="checkbox"/> User Facility <input type="checkbox"/> Importer		2. UF/Importer Report Number			
3. User Facility or Importer Name/Address					
4. Contact Person		5. Phone Number			
6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)		7. Type of Report <input type="checkbox"/> Initial <input type="checkbox"/> Follow-up # _____		8. Date of This Report (mm/dd/yyyy)	
9. Approximate Age of Device		10. Event Problem Codes (Refer to coding manual)			
		Patient Code _____ - _____ - _____ Device Code _____ - _____ - _____			
11. Report Sent to FDA? <input type="checkbox"/> Yes (mm/dd/yyyy) <input type="checkbox"/> No		12. Location Where Event Occurred <input type="checkbox"/> Hospital <input type="checkbox"/> Outpatient Diagnostic Facility <input type="checkbox"/> Home <input type="checkbox"/> Ambulatory Surgical Facility <input type="checkbox"/> Nursing Home <input type="checkbox"/> Outpatient Treatment Facility <input type="checkbox"/> Other: _____ (Specify)			
13. Report Sent to Manufacturer? <input checked="" type="checkbox"/> Yes (mm/dd/yyyy) <input type="checkbox"/> No					
14. Manufacturer Name/Address Magellan Diagnostics 101 Billerica Ave, Bldg. 4 North Billerica, Ma. 01864					

### G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)		2. Phone Number	
Name Magellan Diagnostics		978-248-4811	
Address 101 Billerica Ave, Bldg. 4 North Billerica, Ma. 01864		3. Report Source (Check all that apply) <input type="checkbox"/> Foreign <input type="checkbox"/> Study <input type="checkbox"/> Literature <input type="checkbox"/> Consumer <input checked="" type="checkbox"/> Health Professional <input type="checkbox"/> User Facility <input type="checkbox"/> Company Representative <input type="checkbox"/> Distributor <input type="checkbox"/> Other:	
4. Date Received by Manufacturer (mm/dd/yyyy) Initial complaint 9/18/15		5. (A)NDA # _____ IND # _____ BLA # _____ PMA/510(k) # K123563 Combination Product <input type="checkbox"/> Yes Pre-1938 <input type="checkbox"/> Yes OTC Product <input type="checkbox"/> Yes	
6. If IND, Give Protocol #			
7. Type of Report (Check all that apply) <input type="checkbox"/> 5-day <input type="checkbox"/> 30-day <input type="checkbox"/> 7-day <input type="checkbox"/> Periodic <input type="checkbox"/> 10-day <input checked="" type="checkbox"/> Initial <input type="checkbox"/> 15-day <input type="checkbox"/> Follow-up # _____			
9. Manufacturer Report Number 1218996-2015-00001		8. Adverse Event Term(s)	

### H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event <input type="checkbox"/> Death <input type="checkbox"/> Serious Injury <input checked="" type="checkbox"/> Malfunction		2. If Follow-up, What Type? <input type="checkbox"/> Correction <input type="checkbox"/> Additional Information <input type="checkbox"/> Response to FDA Request <input type="checkbox"/> Device Evaluation	
3. Device Evaluated by Manufacturer? <input type="checkbox"/> Not Returned to Manufacturer <input checked="" type="checkbox"/> Yes <input type="checkbox"/> Evaluation Summary Attached <input type="checkbox"/> No (Attach page to explain why not) or provide code:		4. Device Manufacture Date (mm/yyyy) 08/2014	
		5. Labeled for Single Use? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
6. Event Problem and Evaluation Codes (Refer to coding manual)			
Patient Code _____ - _____ - _____			
Device Code    13    -    31    -    36			
Method    31    -    _____ - _____ - _____			
Results    57    -    78    -    75    -    _____			
Conclusions    150    -    160    -    _____ - _____			
7. If Remedial Action Initiated, Check Type <input type="checkbox"/> Recall <input type="checkbox"/> Notification <input type="checkbox"/> Repair <input type="checkbox"/> Inspection <input type="checkbox"/> Replace <input type="checkbox"/> Patient Monitoring <input type="checkbox"/> Relabeling <input type="checkbox"/> Modification/Adjustment <input checked="" type="checkbox"/> Other: Letter to Customer		8. Usage of Device <input checked="" type="checkbox"/> Initial Use of Device <input type="checkbox"/> Reuse <input type="checkbox"/> Unknown	
9. If action reported to FDA under 21 USC 360(f), list correction/removal reporting number:			

### 10. Additional Manufacturer Narrative and / or 11. Corrected Data

See Section B.5 attachment.

Statistical analysis of additional data revealed an increased rate of occurrence and an increased magnitude of bias with immediate running of the assay across the population of samples tested. Running the assay immediately upon reagent mixing (Tzero) leads to the highest frequency of this issue. This does not represent typical customer processing time. Underestimation of a blood lead result at immediate incubation times could indicate that a larger population of samples would appear to have lead levels below the medical decision point and possibly not be retested or treated. Based on these new data, the Risk Assessment was updated. The Total Hazard/Risk Score was increased from a score of 1 (None/Negligible) to an overall score of 6 (Low) and a Recall Class III. With this increased level of risk and in compliance with Magellan's Adverse Events procedure and FDA 820.30, Magellan is filing this MDR with FDA.

Please note that with the Customer Letter requiring a 24 hour incubation period the Total Hazard/Risk Score is reduced to 0.

This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
PRAStaff@fda.hhs.gov  
Please DO NOT RETURN this form to the above PRA Staff email address.

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

KAR  
08/18/2015

(CONTINUATION PAGE)

For use by user-facilities,  
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# MEDWATCH

FORM FDA 3500A (2/13) (continued)

**B.5. Describe Event or Problem (continued)**

See attached B.5 Document.

Back to Item B.5

**B.6. Relevant Tests/Laboratory Data, Including Dates (continued)**

Back to Item B.6

**B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)**

Back to Item B.7

**Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish)**

Back to Item C.10  
Back to Item D.11

**Other Remarks**

See Attached:

1. Section B.5
2. Customer Letter dated Nov 29, 2014

## SECTION B5

### Description of Problem and Events:

In November of last year, we determined that blood lead results were being underestimated by LeadCare® Ultra as compared to the reference method, GFAAS. This occurred when the sample was analyzed immediately after being mixed with the LeadCare Ultra treatment reagent. We did not observe this in our clinical studies prior to product release, and we are working to identify the root cause of the phenomenon. Our investigation is ongoing. A Risk Assessment was performed and the Total Hazard/Risk Score was calculated to be 1 (None/Negligible). During our investigation new data indicated the frequency of this occurrence had increased. The Total Hazard/Risk Score was reassessed and recalculated to a 6 which is Low, Recall Level III. Based on this increased level of risk and in compliance with Magellan's Adverse Events procedure and FDA 820.30, Magellan is filing this MDR with FDA.

In Magellan's investigational studies it was determined that allowing the blood-treatment reagent mixture to sit (a process we have termed "incubation") for a minimum of 24 hours prior to analysis mitigates this problem. This reduces the Total Hazard/Risk Score back to a 0. The company is performing additional studies to determine the root cause. In the interim, all customers have been advised to implement a minimum 24-hour incubation of the blood-treatment reagent mixture prior to analysis.

### Dates of Events

**8/13/2014** We received initial **Complaints** # **b(4) CCI**; from **b(4) CCI**; and # **b(4) CCI** from **b(4) CCI**; that indicated they were getting slightly higher results when repeating the tests with the LeadCare Ultra. Magellan could not confirm the differences that the customers were seeing when reviewing internal data.

**9/23/2014** Complaints were closed to a **Complaint Investigation** which in turn generated a CAR in Magellan's Quality System. Data was reviewed and work was started to try to evaluate the issue.

**10/23/2014** **Complaint** # was filed from **b(4) CCI**; which indicated during their validation protocols they were getting a difference between LeadCare Ultra and their current Blood Lead clinical analyzer, Model 3010B. There were no patient results being tested as this was part of their validation.

**11/07/2014** **Initial Risk Analysis** Hazard/Risk Score Total = 1. None / Negligible which is a Non Recall Status. The medical decision points of treating lead is per CDC guidelines (see attached letter dated Nov. 29) factored into the initial decision not to file.

This Risk Assessment was supported by a review of Customer LeadCare Ultra Validation studies. While incubation time was not controlled, these validation studies were deemed to be representative of how customers perform the test in their clinical laboratories and the data showed no pattern of underestimation of the results and met the product performance criteria.

**11/29/2014** – Based on data collected by Magellan, from carefully controlled time course studies, a Customer Letter was issued to all [REDACTED] LeadCare Ultra customers to recommend that they incubate the sample in reagent for a minimum of 24 hours. This letter was issued with a "Faxback" form and to date [REDACTED] out of [REDACTED] (100 %) customers have signed the form or responded.

As of 4/2/15 [REDACTED] notifications were sent to LeadCare Ultra customers. Response FaxBack forms received from [REDACTED] and verbal confirmation from 2, pending receipt of the FaxBack form.

**Conclusion of Customer Letter:** This data demonstrates that incubation of the sample-treatment reagent mixture for 24 hours prior to analysis minimizes bias and generates results that are comparable to the reference method, GFAAS. We are performing additional validation studies to determine if the 24-hour minimum incubation time can be reduced or eliminated, and will notify you of our final resolution."

**3/15/2015** Statistical analysis of additional data revealed an increased rate of occurrence and an increased magnitude of bias with immediate running of the assay across the population of samples tested. Running the assay immediately upon reagent mixing (Tzero) leads to the highest frequency of this issue. This does not represent typical customer processing time.

Underestimation of a blood lead result at Tzero could indicate that a larger population of samples would appear to have lead levels below the medical decision point and possibly not be retested or treated. Based on these new data, the Risk Assessment was updated. The Total Hazard/Risk Score was increased from a score of 1 (None/Negligible) to an overall score of 6 (Low) and a Recall Class III. With this increased level of risk and in compliance with Magellan's Adverse Events procedure and FDA 820.30, Magellan is filing this MDR with FDA.





## Notice to Customers

November 24, 2014

Dear Customer:

This letter is to inform you of an infrequent occurrence observed with the LeadCare Ultra Blood Lead Testing System, which could impact a small percentage of your patient results (see page 2 for details).

We have recently identified cases where the LeadCare Ultra System underestimates the lead concentration of some blood samples when the sample is analyzed immediately after being mixed with the LeadCare Ultra treatment reagent. In these cases, if the LeadCare Ultra System reported a value just below a diagnostic threshold (see page 2), it is possible that the true lead concentration was above the threshold. We did not observe this in our clinical studies prior to product release, and we are working to identify the root cause of the phenomenon. Our investigation is ongoing, however we felt that it was important to inform you of this as quickly as possible.

In an investigational study we have determined that allowing the blood-treatment reagent mixture to sit for 24 hours prior to analysis mitigates this problem. (Incubation times greater than 24 hours are also acceptable.) We are performing additional validation studies to determine if the 24-hour minimum incubation time can be reduced or eliminated. In the interim, **we advise all customers to implement a minimum 24-hour incubation of the blood-treatment reagent mixture prior to analysis.**

This phenomenon appears to be limited to a small percentage of samples and is dependent on the incubation time of the blood-treatment reagent mixture. A review of your laboratory's work flow and method comparison data will be the best way to determine the likely impact on your lab's results. We would like to review this information with you to help determine if patient results may have been affected and to provide recommendations for follow up. I will be in touch with you shortly to schedule this discussion. In the meantime, please feel free to contact me at 978-250-7072 or [rmorse@magellandx.com](mailto:rmorse@magellandx.com). We are committed to working with you to help to reduce the burden of this unexpected situation on your lab.

**This correspondence is being tracked for notification purposes. To acknowledge receipt of this notice, please complete the enclosed form and fax it to our Quality Assurance Department.**

Upon completion of further studies, we will update the package insert if necessary and provide you with any required documentation.

We sincerely apologize for this issue and assure you of our commitment to providing as complete and rapid a resolution as possible.

Sincerely,

A handwritten signature in black ink, appearing to read "Robb Morse", is written over a light blue horizontal line.

Robb Morse  
Director of Marketing  
Magellan Diagnostics, Inc.

### Prevalence of Samples and Medical Decision Points

The table below shows the current recommendations from the American Academy of Pediatrics (AAP) for management of blood lead levels.

Based on the prevalence of elevated blood lead levels from the CDC, approximately 2.5% of your patient results may cross the medical decision point of 5 ug/dL.

<b>BLL</b>	<b>Recommendations<sup>1</sup></b>
< 5 ug/dL	<p>Review lab results with family.</p> <p>Repeat the blood lead level in 6-12 months if the child is at high risk or risk changes during the timeframe. Ensure levels are done at 1 and 2 years of age.</p> <p>For children screened at age &lt; 12 months, consider retesting in 3-6 months as lead exposure may increase as mobility increases.</p> <p>Perform routine health maintenance including assessment of nutrition, physical and mental development, as well as iron deficiency risk factors.</p> <p>Provide anticipatory guidance on common sources of environmental lead exposure.</p>
5-14 ug/dL	<p>Perform steps as described above for levels &lt; 5 mcg/dL.</p> <p>Re-test venous blood lead level within 1-3 months</p> <p>Take a careful environmental history to identify potential sources of exposures and provide preliminary advice about reducing/eliminating exposures.</p> <p>Provide nutritional counseling related to calcium and iron.</p> <p>Ensure iron sufficiency with adequate laboratory testing (CBC, Ferritin, CRP). Consider starting a multivitamin with iron.</p> <p>Perform structured developmental screening evaluations at child health maintenance visits.</p>
15-44 ug/dL	<p>Perform steps as described above for levels 5-14 mcg/dL.</p> <p>Confirm the blood lead level with repeat venous sample within 1 to 4 weeks.</p> <p>Additional, specific evaluation of the child, such as abdominal x-ray should be considered based on the environmental investigation and history.</p> <p>Any treatment for blood lead levels in this range should be done in consultation with an expert.</p>
> 44 ug/dL	<p>Follow guidance for BLL 15-44 mcg/dL as listed above.</p> <p>Confirm the blood lead level with repeat venous lead level within 48 hours.</p> <p>Consider hospitalization and/or chelation therapy (managed with the assistance of an experienced provider).</p>
1) <a href="http://www.aacc.org/pchsu/documents/medical-mgmt-childhood-lead-exposure-June-2013.pdf">http://www.aacc.org/pchsu/documents/medical-mgmt-childhood-lead-exposure-June-2013.pdf</a>	



FAX FORM RECORD  
Notification on the LeadCare Ultra System

The enclosed notification is intended to alert your facility regarding an issue identified with the LeadCare Ultra system where the instrument may underestimate the blood lead result when the sample-treatment reagent mixture is not allowed to incubate for a period of time prior to analysis.

This is being tracked for notification purposes. Please complete this fax form record acknowledging receipt of the notification and fax the signed copy to the indicated fax number.

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Contact Magellan Diagnostics with any questions.

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Please return via fax to **978-600-1480**

Institution Name \_\_\_\_\_

Street Address \_\_\_\_\_

City \_\_\_\_\_ State/Province \_\_\_\_\_

Country \_\_\_\_\_ Zip/Postal Code \_\_\_\_\_ Date \_\_\_\_\_

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Please verify with a check (✓) that the following actions were taken by your facility:

- We read and understand the notification and the recommended protocol:
- **Magellan Diagnostics recommends a minimum 24-hour incubation of the blood-treatment reagent mixture prior to analysis on the LeadCare Ultra System to ensure complete recovery.**
  - **The notification was reviewed with the laboratory staff.**

Name (please print) \_\_\_\_\_ Title \_\_\_\_\_

Signature \_\_\_\_\_ Phone No. \_\_\_\_\_

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Please fax this record back to:

Attention: **Reba Daoust, Quality Assurance**

**Fax No.: 978-600-1480**

Phone No.: 978-856-2345 (for transmission problems only)