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.

APR 06 2015

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

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

MEDWATCH

FORM FDA 3500A (2/13)

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

Mfr Report # 1218996-2015-00001

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: or Date of Birth:	3. Sex	4. Weight
In confidence		☐ Female ☐ Male	____ 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)*
☐ Life-threatening
☐ Hospitalization - initial or prolonged
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☑ Other Serious (Important Medical Events)

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	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#1	#1
#2	#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 #	7. Exp. Date
#1	#1
#2	#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	2b. Procode
LeadCare Ultra Analyzer	DOF

3. Manufacturer Name, City and State
101 Billerica Ave., Bldg 4
Billerica, Ma. 01862

4. Model #	Lot #	5. Operator of Device
80-0010	N/A	☑ Health Professional
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Lay User/Patient
80-0010,70-8098	N/A	☐ Other:
Serial #	Unique Identifier (UDI) #	
N/A		

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 [redacted] Complaint # [redacted] b(4) CCI
b(4) CCI [redacted]
United States

Phone #	Email Address
Phone: b(4) CCI [redacted]	b(4) CCI [redacted]

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☑ Yes ☐ No	Administrator/Supervisor	☐ Yes ☑ No ☐ Unk

MEDWATCH

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

FDA USE ONLY

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

1. **Check One** ☐ User Facility ☐ 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** ☐ Initial ☐ 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?** ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. **Location Where Event Occurred** ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: ____ *(Specify)*
13. **Report Sent to Manufacturer?** ☑ Yes ____ *(mm/dd/yyyy)* ☐ 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)**
Name: Magellan Diagnostics
Address: 101 Billerica Ave, Bldg. 4
North Billerica, Ma. 01864
Email Address: rdaoust@magellandx.com
2. **Phone Number**: 978-248-4811
3. **Report Source** *(Check all that apply)*
☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☑ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. **Date Received by Manufacturer** *(mm/dd/yyyy)*
Initial complaint 9/
5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # K123563
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☐ Yes
6. **If IND, Give Protocol #**
7. **Type of Report** *(Check all that apply)*
☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☐ 15-day ☐ Follow-up # ____
8. **Adverse Event Term(s)**
9. **Manufacturer Report Number**: 1218996-2015-00001

H. DEVICE MANUFACTURERS ONLY

1. **Type of Reportable Event** ☐ Death ☐ Serious Injury ☑ Malfunction
2. **If Follow-up, What Type?** ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. **Device Evaluated by Manufacturer?** ☐ Not Returned to Manufacturer ☑ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____
4. **Device Manufacture Date** *(mm/yyyy)*: 08/2014
5. **Labeled for Single Use?** ☐ Yes ☑ 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** ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☑ Other: Letter to Customer
8. **Usage of Device** ☑ Initial Use of Device ☐ Reuse ☐ Unknown
9. **If action reported to FDA under 21 USC 360i(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.

1542
10/18/2015

(CONTINUATION PAGE)
For use by user-facilities,
importers, distributors, and manufacturers
for MANDATORY reporting

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

Back to Item B.5

B.5. **Describe Event or Problem** *(continued)*
See attached B.5 Document.

Back to Item B.6

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

Back to Item B.7

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 C.10

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

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** b(4) 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 # b(4) 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 b(4) CC 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 b(4) CC out of b(4) CC (100 %) customers have signed the form or responded.

> **As of 4/2/15** b(4) notifications were sent to LeadCare Ultra customers. Response FaxBack forms received from b(4) CC 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.

RDavust

Magellan

DIAGNOSTICS

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. 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,

Robb Morse
Director of Marketing
Magellan Diagnostics, Inc.

101 Billerica Ave, Building 4, North Billerica, Massachusetts 01862 · Telephone: 978.856.2345 · Fax: 978.856.2335 · www.Magellandx.com

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.

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

1) http://www.aoec.org/pehsu/documents/medical-mgmnt-childhood-lead-exposure-June-2013.pdf

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.

Contact Magellan Diagnostics with any questions.

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

Institution Name _____

Street Address _____

City _____ State/Province _____

Country _____ Zip/Postal Code _____ Date _____

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. _____

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)

101 Billerica Ave, Building 4, North Billerica, Massachusetts 01862 · Telephone: 978.856.2345 · Fax: 978.856.2335 · www.Magellandx.com