DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781)587-7500 Fax:(781)587-7556	5/10/2017-6/29/2017* FEI NUMBER 1218996

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Amy M. Winslow , President & CEO

FIRM NAME	STREET ADDRESS
Magellan Diagnostics, Inc.	101 Billerica Ave Bldg 4
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
North Billerica, MA 01862-1271	Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Design validation did not ensure the device conforms to defined user needs and intended uses.

Specifically,

A. Your firm's original design validation did not account for actual use of the LeadCare systems including immediate analysis of the blood treatment reagent mixture. The intended use of the LeadCare II, Ultra, and Plus systems allow for immediate analysis after thoroughly mixing the blood treatment reagent mixture. Your validation studies did not test under these actual use conditions to ensure test results.

B. Your firm became aware that the original LeadCare Ultra design validation did not conform to the intended use as demonstrated by the study titled "Blood in Treatment Reagent Stability Study", VP # 113, conducted in September 2013. This study concludes that there is a "reproducible trend of increased Pb signal with increased Sample/Treatment Reagent incubation time." However, your firm released the LeadCare Ultra product for commercial distribution in November 2013 without implementing a change to include incubation time.

C. On November 24, 2014, your firm sent a "Notice to Customers" letter instructing them to incubate the blood-treatment reagent mixture for at least 24 hours to prevent underestimation of the lead concentration of blood samples on the LeadCare Ultra system. Your firm failed to

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	James W Whitney, Investigator Suzanne M Healy, Investigator Ian A Pilcher, Non Reporting User 6/29/2017 X James W Whitney James W Whitney Investigator Signed by: James W. Whitney -S	6/29/2017

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validate this incubation to ensure that the design change met the intended use of the device, as well as the needs of the user. The addition of the incubation period for LeadCare Ultra & Plus (24-hours) and LeadCare II (4-hours) does not allow for the immediate analysis needs of the healthcare providers for their patients as reported in Consumer Complaint Case #s 00112233, dated 10/28/14 and 00119771, dated 9/9/15.

OBSERVATION 2

Risk analysis is inadequate.

Specifically,

A. Your firm failed to identify potential risk to patients of a falsely low test result obtained by the LeadCare Ultra Test System. The "LeadCare Ultra Risk Analysis", Rev 10 does not list false negative or erroneous result as a potential hazard. This document has not been updated since 05/31/2013 per the requirements of "Risk Analysis Procedure", SOP 159, Rev 04, which states that product risk analysis should be updated based on post-production information.

B. Your firm failed to adequately evaluate the risk of LeadCare II for falsely low results. The "LeadCare II Risk Analysis", Rev 6 dated 9/8/2005 identifies a false negative result as a (b) (4) severity defined as causing "(b) (4) " and "(b) (4) l" probability of (b) (4) ". This document has not been updated since 9/8/2005 per the requirements of "Risk Analysis Procedure", SOP 159, Rev 04, which states that product risk analysis should be updated based on post-production information.

C. Your firm failed to adequately evaluate the risk of LeadCare Plus for falsely low results. The "LeadCare Plus Risk Management Plan", dated 9/18/2014 identifies "(b) (4) " as a (b) (4) severity defined as failure that "(b) (4) " and "(b) (4) " probability of (b) (4)

(b) (4) [redacted]". This document has not been updated since 9/18/2014 per the requirements of "Risk Analysis Procedure", SOP 159, Rev 04, which states that product risk analysis should be updated based on post-production information.

OBSERVATION 3

Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.

Specifically, your procedure titled "Complaint Procedure", SOP 107, Rev 9 is inadequate for the following reasons:

A. Not all communication alleging deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution are treated as complaints. Some communication is identified as "Support Request / Help Desk" and follows the procedure titled "Non-Complaint Customer Interaction Procedure", SOP 164, Rev 00. Neither this procedure nor the Complaint Procedure defines "Support Request / Help Desk". Customer Complaint Case #s 00099641, 00103942 and 00122401 were classified by your firm as Support Requests. These cases involved customer issues with Level 2 Controls, particulate matter in the treatment reagent, and variation in blood sample results. They were classified as Support Requests even though the issues related to the quality and performance of the device after it was released for distribution. These cases were therefore not treated as complaints, and were not evaluated for MDR reportability or whether they needed to be investigated.

B. Customer Complaint Case #s 00110311, 00114483, 00117184, 00120173, and 00126813 involved "false negative" patient results, but were not evaluated according to the "Complaint Procedure" to determine whether an investigation or MDR was required.

C. Your Product Support staff utilizes the (b) (4) [redacted] complaint handling system, which can link

to the (b) (4) when the Product Support staff determines a complaint investigation may be necessary. However, there are no procedures established that define how complaints or investigations are uniformly entered and evaluated for complaints entered into the (b) (4) " complaint handling system.

D. The following Customer Complaints remained open past the (b) -day goal per section 6.3.6 of your "Complaint Procedure" without documented justification: Case # 00112421 was open for 120 days, Case # 00112802 was open for 365 days, Case # 00124439 was open for 122 days, Case # 00127556 was open for 109 days, and Case # 00124108 was open for 195 days.

E. Section 6.1.7 of your "Complaint Procedure" refers to SOP 160, "*Safety Committee Procedure*". However, per firm management, the correct reference in this section should be SOP 108, *"Adverse Event Reporting"*.

OBSERVATION 4

Procedures for corrective and preventive action have not been adequately established.

Specifically,

A. Your procedure titled "Corrective & Preventive Action Procedure", SOP 128, Rev 6, defines Effectiveness Verification as a "Documented process to establish that the action accomplishes the intended objective and is proven to be effective". It also states that this step is required prior to a CAR/PAR closure. CAR 108 was opened to investigate underestimation of lead concentration readings from the LeadCare II, Ultra, and Plus systems. Your firm issued the November 24, 2014 "Notice to Customers" letter instructing them to incubate the blood-treatment reagent mixture for at least 24 hours as part of the corrective action associated with CAR 108. Customer Complaint Case #s 00116937 and 00132411 were received after this notification on 5/4/2015 and 1/13/2017, respectively. However, CAR 108 was closed on 3/21/2017 despite the lack of verification that the action was effective.

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B. Multiple CARs are opened for similar issues and left opened for extensive periods without activity.

1. CAR 136 was opened on 1/21/2015 for a reported shift in mean of the Level 1 control. This CAR remains open.

2. CAR 1171 was opened on 10/15/2015 for imprecise and out of range controls for Ultra and Plus Kits. This CAR remains open.

3. CAR 1190 was opened on 8/9/2016 for low Level 2 Controls on the LeadCare II. This CAR remains open.

C. Your firm utilizes the (b) (4) from the (b) (4) " complaint handling system to trigger a CAPA and initiate a CAR in the "(b) (4) quality system database, if applicable. However, neither your CAPA procedure nor any other procedure/work instruction identifies how this system should be utilized by your firm to uniformly enter and handle CAPAs.

OBSERVATION 5

A report of the required information regarding device correction and removal actions was not sent to FDA within 10 days of initiating the correction or removal.

Specifically, your firm did not send a report to the FDA within 10 days regarding the below notifications per your firm's procedure titled "Field Corrective Action Procedure", SOP 106, Rev 1.

A. On November 24, 2014, your firm sent a "Notice to Customers" letter instructing them to incubate the blood-treatment reagent mixture for at least 24 hours to prevent underestimation of the lead concentration of blood samples on the LeadCare Ultra system.

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B. On November 4, 2016, your firm sent a "Notice to Customers" letter instructing them to implement a 4-hour incubation of the blood-treatment reagent mixture for venous blood samples on the LeadCare II system.

C. Your firm sent a "Revised Value Assignment - Temperature Correction" work sheet to customers that had previously complained about out-of-range LeadCare II Lead Controls, Level 1 & 2 on:

1. March 11, 2016 for Test Kit lot numbers 1507N and 1508N
2. May 20, 2016 for Test Kit lot number 1510N
3. June 26, 2016 for Test Kit lot numbers 1511M, 1511N, and 1512M

OBSERVATION 6
Procedures for design change have not been adequately established.

Specifically, the design change implemented by your firm to increase incubation time is inadequate for the following reasons:

A. ECO # 7060 dated 11/17/2016 opened to revise the LeadCare II labeling to include incubation

1. On Form 123-02, "Engineering Change Order", Rev 01, Page 2 your firm documented that the change did not require validation/verification of product/process and did not indicate whether an update to Risk Management documentation was required, despite that the change was classified on Form 123-04 as (b) (4) one that "affects the design, production or assessment of product form, fit, or function."
2. Your firm's procedure titled "Engineering Change Order", SOP 123, Rev 01, Section

6.1.6, states that justification of changes, as well as verification/validation reports must be included with every ECO as applicable. However, none was identified.

3. On Form 123-05, "Regulatory Decision", Rev 00, Page 2, your firm documented in the "Decision Summary" section of this ECO that the change was classified as "(b) (4) This change requires submission(s) prior to implementation" and indicates to "Complete a 510(k) Notification and Technical File as required". However, your firm only notes "this is a MEDWATCH (MDR) filing".

B. ECO # 6968 dated 8/4/2015 opened to revise the LeadCare Ultra labeling to include incubation

1. On Form 123-02, "Engineering Change Order", Rev 01, Page 2 your firm documented that the change did not require validation/verification of product/process, and did not indicate whether an update to Risk Management documentation was required, despite that the change was classified on Form 123-04 as (b) (4) one that "does significantly affect the form, fit, function, or regulatory status of the product" and that "may affect product performance."

2. Your firm's procedure titled "Engineering Change Order", SOP 123, Rev 01, Section 6.1.6, states that justification of changes, as well as verification/validation reports must be included with every ECO as applicable. ECO # 6968 lists "see Validation Report 157" in the justification/test report reference section. Your firm stated that V/V #157 was cancelled.

3. On Form 123-05, "Regulatory Decision", Rev 00, your firm misclassified the change as (b) (4) where it was classified as (b) (4) on Form 123-04. In addition, #5 of Section III B and #3 of Section III D were answered "Yes", which should lead to (b) (4) requiring submission prior to implementation. However, (b) (4) is checked off on page 2, which states that the change required updated documentation justification.

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C. ECO # 6944 dated 5/5/2015 opened to revise the LeadCare Plus labeling to include incubation

1. On Form 123-02, "Engineering Change Order", Rev 01, Page 2 your firm documented that the change did not require validation/verification of product/process. However, under a similar ECO for the same change to the LeadCare Ultra (ECO # 6968), the change was determined as one that "may affect product performance."

2. On Form 123-04, "Classification of Changes", Rev 00, the change was misclassified as a "(b) (4)" change that "does not significantly affect the design, production, or assessment of form, fit, function, and regulatory status of the product". However, per the conclusions of the "Blood in Treatment Reagent Stability Study Part 1 – 090513 Report", a "change of instruction to include incubation time would require resubmitting data to FDA". In addition, under a similar ECO for the same change to the LeadCare Ultra (ECO # 6968), it was classified as (b) (4) one that "does significantly affect the form, fit, function, or regulatory status of the product" and that "may affect product performance."

3. Your firm's procedure titled "Engineering Change Order", SOP 123, Rev 01, Section 6.1.6, states that justification of changes, as well as, verification/validation reports must be included with every ECO as applicable. ECO # 6944 lists "see V/V Report # 157" in the justification/test report reference section. Your firm stated that V/V #157 was cancelled.

OBSERVATION 7

Acceptance criteria were not established prior to the performance of validation activities.

Specifically, your validation study titled "Blood in Treatment Reagent Stability Study Part-2-091113 Report" expands the original acceptance criteria documented in the study protocol. Assay sample

results that failed the original predetermined acceptance limits at Time Zero (T0) were later accepted because they passed at later time points under the expanded acceptance criteria.

OBSERVATION 8

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Specifically,

A. On August 13, 2014, your firm received two separate complaints concerning the underestimation of blood lead results by the LeadCare Ultra Test System. A single device malfunction MDR # 1218996-2015-00001 was submitted for Customer Complaint Case #s 00110598 and 00110639, on 4/2/2015, 201 calendar days late. Your firm's procedure titled "Adverse Events Procedure", SOP 108, Rev 4, states that reports will be sent to the FDA within 30 calendar days of becoming aware.

B. Your firm failed to report separate MDRs for individual events involving underestimation of blood lead results from the LeadCare Ultra system. Customer Complaint Case # 00112168 received on 10/23/2014 involved 8 events with 8 different patients, Case # 00132411 received on 1/13/2017 involved 5 events with 5 different patients. No MDR reports for any of these events have been submitted as of 6/15/2017.

OBSERVATION 9

Procedures have not been established to control product that does not conform to specified requirements.

Specifically, your procedure titled "Non-Conforming Material Procedure", SOP 113, Rev 2, defines "Use-As-Is" as "(b) (4) [redacted] Your firm chose to "use-as-is" the Controls, but changed the LeadCare II Lead Control Level 1 average value assignment for Lot #

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1507N (NCP ID # 1175 opened 9/24/2015) and Lot # 1511N (NCP ID # 1193 opened 12/29/2015) without verifying that the Controls would be acceptable for use. The lots identified in these non-conformance reports were later the subject of 71 Customer Complaints regarding customers unable to use their analyzers, due to the Controls being out-of-range.

Annotations to Observations

Observation 1: Promised to correct
Observation 2: Promised to correct
Observation 3: Promised to correct
Observation 4: Promised to correct
Observation 5: Promised to correct
Observation 6: Promised to correct
Observation 7: Promised to correct
Observation 8: Promised to correct
Observation 9: Promised to correct

*DATES OF INSPECTION

5/10/2017(Wed),5/11/2017(Thu),5/15/2017(Mon),5/16/2017(Tue),5/17/2017(Wed),5/18/2017(Thu),5/19/2017(Fri),5/22/2017(Mon),5/30/2017(Tue),5/31/2017(Wed),6/01/2017(Thu),6/08/2017(Thu),6/13/2017(Tue),6/15/2017(Thu),6/29/2017(Thu)

6/29/2017

X Suzanne M Healy
Suzanne M Healy
Investigator
Signed by: Suzanne M. Healy -S

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
James W Whitney, Investigator
Suzanne M Healy, Investigator
Ian A Pilcher, Non Reporting User

6/29/2017
X James W Whitney
James W Whitney
Investigator
Signed by: James W. Whitney -S

DATE ISSUED
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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."