ATTACHMENT A

STATEMENT OF FACTS

The following Statement of Facts is incorporated by reference in the Deferred Prosecution Agreement (the "Agreement") between the United States Attorney's Office for the District of Massachusetts (the "Office") and defendant Magellan Diagnostics, Inc. ("Magellan" or the "Company"). The Company hereby agrees and stipulates that the following information is true and accurate. The Company admits, accepts, and acknowledges that it is responsible for the acts of its officers, directors, employees, and agents as set forth below. Should the Office pursue the prosecution that is deferred by the Agreement, the Company agrees that it will neither contest the admissibility of, nor contradict, this Statement of Facts in any such proceeding. The following facts took place in or about and between 2013 and 2018 (the "relevant time period"), unless otherwise noted, and the Company agrees that these facts establish beyond a reasonable doubt the charges set forth in the Felony Information attached to the Agreement.

General Allegations

1. MAGELLAN, headquartered in Billerica, MA, was a medical device company that sold products for detecting lead levels and lead poisoning in the blood of children and adults. MAGELLAN was privately owned by venture capital investors until March 2016, when it was acquired by Meridian Bioscience, Inc., for $66 million.

2. Amy Winslow was an individual residing in Needham Heights, Massachusetts. Winslow was MAGELLAN's President and Chief Executive Officer from in or around 2011 through in or around 2018.

3. Mohammad Hossein Maleknia was an individual residing in North Andover, Massachusetts. Maleknia was MAGELLAN's Chief Operating Officer and Vice President of Operations from in or around 2012 through in or around 2021.

4. Reba Daoust was an individual residing in Amesbury, Massachusetts. Daoust was MAGELLAN's Director of Quality Assurance and Regulatory Affairs from in or around 2012 through in or around July 28, 2017.

5. "Employee A" was a manager in MAGELLAN's Research and Development department.

6. "Employee B" was a manager in MAGELLAN's Technology Development and Assessment department.

7. "Employee C" was MAGELLAN's Marketing Director.

8. "Employee D" was MAGELLAN's Product Support Manager.

9. "Employee E" was Meridian's Executive Vice President of Global Regulatory and Quality Systems.

10. MAGELLAN misled its customers and the FDA about a serious malfunction in the lead testing devices produced by MAGELLAN ("Malfunction"). By hiding the Malfunction and later deceiving customers and the FDA about when it discovered the Malfunction and its nature and extent, MAGELLAN caused an estimated tens of thousands of children and other patients to receive inaccurate lead test results.

Lead Poisoning and Blood Lead Testing

11. According to the Centers for Disease Control and Prevention (CDC), there is no safe level of lead in the blood. Lead exposure may cause irreversible lifelong physical and mental health problems, including damage to the nervous, hematopoietic, endocrine, renal, and

reproductive systems. Lead exposure may also damage children's ability to learn, ability to pay attention, and academic achievement. High levels of lead exposure attack the brain and central nervous system and may cause coma, convulsions, and even death.

12. Young children and pregnant women are most vulnerable to lead exposure because children absorb lead more easily than adults, and their growing bodies are more prone to harm. Children from low-income households and those who live in housing built before 1978 are at the greatest risk of lead exposure because those homes are more likely to contain lead-based paint and have pipes, faucets, and plumbing fixtures containing lead. Lead poisoning also disproportionately impacts refugees and other children who have resettled in the United States because of prior environmental exposure in their countries of origin.

13. Lead poisoning can be difficult to detect—signs and symptoms of lead poisoning usually do not appear until dangerously high amounts of lead have accumulated in the body. Blood lead testing is the best way to detect lead poisoning.

14. In 2012, CDC introduced a medical threshold at blood lead levels of 5 micrograms per deciliter (μg/dL) to identify children and adults who have elevated blood lead levels. At that level, CDC recommended that healthcare providers:

a. Report the test result to their state or local health department;

b. Obtain an environmental exposure history to identify potential sources of lead;

c. Arrange for an environmental investigation of the home, during which professionals would check the child's environment for possible causes of lead exposure and recommend ways to prevent further lead exposure; and

d. Provide follow-up blood lead testing at recommended intervals.

15. CDC recommended additional interventions for higher levels of lead in the blood, including the recommendation that physicians consider the need for hospitalization and chelation therapy to remove lead from the blood if the level reached 45 μg/dL.

16. State agencies promulgated different requirements and recommendations for the frequency of lead testing in children. In Massachusetts, for example, children were required to be screened once between the ages of 9–12 months, again at age 2, and then again at age 3. Children were required to be screened once more at age 4 if they lived in a high-risk community or in a high-risk environment. The Centers for Medicare and Medicaid Services (CMS) required children enrolled in Medicaid to be tested for lead at ages 12 and 24 months, or ages 24–72 months if they had never been tested.

MAGELLAN's Lead-Testing Devices

17. MAGELLAN produced a family of instruments for blood lead analysis using a method called anodic stripping voltammetry. Those devices included, but were not limited to, LeadCare II, LeadCare Ultra, and LeadCare Plus (collectively the "LeadCare Devices").

18. LeadCare II was released in 2006 and was the only point-of-care lead testing device, which means it was cleared by the United States Food and Drug Administration (FDA) for use in non-laboratory settings such as doctors' offices and clinics. The LeadCare II device could be used to test blood samples drawn from a vein ("venous" samples) and samples drawn from a fingerstick (or heelstick). Most LeadCare II tests were conducted on fingerstick samples; MAGELLAN estimated that approximately 5–8% of LeadCare II users conducted testing with venous blood samples. In 2017, MAGELLAN estimated LeadCare II devices were used to conduct 2.5 million blood lead tests per year—accounting for more than half of all lead tests

conducted in the United States. The LeadCare II system was responsible for a substantial majority of MAGELLAN's revenues.

19. LeadCare Ultra was released in 2013 and was designed for use at medium and large hospitals and reference labs. LeadCare Ultra could be used to test both fingerstick blood samples and venous blood samples but was predominantly used for venous blood samples. In 2017, MAGELLAN estimated LeadCare Ultra devices were used to conduct 420,000 blood lead tests per year.

20. LeadCare Plus was released in 2015 and was designed for use at small hospitals and reference labs. LeadCare Plus could be used to test both fingerstick blood samples and venous blood samples but was predominantly used for venous blood samples. In 2017, MAGELLAN estimated that LeadCare Plus devices were used to conduct 40,000 blood lead tests per year.

FDA and FDCA

21. FDA was responsible for protecting the health and safety of the American public by ensuring, among other things, that medical devices—including diagnostic testing devices—were safe and effective. Under its statutory mandate, FDA regulated the manufacture, processing, packing, labeling, and shipment in interstate commerce of medical devices.

22. The Federal Food, Drug, and Cosmetic Act (FDCA), among other things, governed the manufacture and interstate distribution of medical devices for human use, as codified at 21 U.S.C. §§ 301 et seq.

23. The FDCA required medical devices to bear labeling that is not false or misleading. A device was deemed to be "misbranded" under 21 U.S.C. § 352(a) if its labeling was false or misleading.

24. The FDCA and its implementing regulations required device manufacturers to submit pre-market notifications to the FDA at least 90 days before medical devices were introduced into interstate commerce for commercial distribution. Pre-market notifications were required when a device that was already on the market was about to be significantly changed or modified in design or intended use, and the change could significantly affect the safety or effectiveness of the product. 21 C.F.R. § 807.81. A device was deemed to be "misbranded" under 21 U.S.C. § 352(o) if a device manufacturer failed to submit necessary pre-market notification.

25. The FDCA and its implementing regulations provided a mechanism that allowed FDA, and others, to identify and monitor adverse events and malfunctions involving medical devices. Medical device reports (MDRs) were one of the post-market surveillance tools that FDA used to monitor device performance and detect potential device-related safety issues.

26. Medical device manufacturers were required to submit MDRs within 30 calendar days after becoming aware of a device malfunction pursuant to 21 U.S.C. § 360i(a) and 21 CFR Part 803 if the malfunction was likely to cause or contribute to serious injury or death if it recurred. Device malfunctions were defined as a failure of the device to perform as intended or meet its performance specifications, including all claims made in the device labeling under 21 CFR § 803.3.

27. The FDCA and its implementing regulations required device manufacturers to notify the FDA about device corrections—which included modifications, adjustments, and relabeling—within 10 working days of initiating the device correction if the correction was initiated to reduce a risk to health posed by the device. 21 CFR § 806.10.

28. A device was deemed to be "misbranded" under 21 U.S.C. § 352(t)(2) if the manufacturer failed or refused to file any material or information required by or under 21 U.S.C. § 360i, including an MDR or a device correction.

29. The FDCA prohibited the introduction, or causing the introduction, of misbranded medical devices into interstate commerce, pursuant to 21 U.S.C. § 331(a).

MAGELLAN's Sale Efforts

30. Before MAGELLAN was purchased by Meridian in or around March 2016, MAGELLAN was an investor-owned medical device company, which had been owned by a group of venture capital firms—including a majority owner, "Investor A"—for approximately seven years. MAGELLAN's Board of Directors was almost exclusively made up of representatives from Investor A and the other venture capital firms that owned MAGELLAN. The ultimate goal of MAGELLAN's investors and Board of Directors was to grow MAGELLAN's value and to position MAGELLAN for sale, which included developing new products such as LeadCare Ultra, LeadCare Plus, and another product MAGELLAN tried to develop, PediaStat, and strengthening sales of MAGELLAN's primary revenue-producer, LeadCare II.

31. MAGELLAN's latest effort to market the company for sale began in or around 2015, and MAGELLAN received a letter of intent from Meridian with a purchase price of $62.5 million on or about January 21, 2016. During Meridian's due diligence, MAGELLAN disclosed information about the Malfunction affecting LeadCare Ultra, but MAGELLAN withheld material information about the nature, extent, and discovery of the Malfunction, failed to disclose that it had made false and misleading statements to its customers and the FDA about the

Malfunction in LeadCare Ultra, and failed to disclose that the Malfunction also affected LeadCare II, MAGELLAN'S highest selling product.

32. MAGELLAN was acquired by Meridian for $66 million in or around March 2016. The acquisition price was more than $15 million higher than the next highest purchase offer received for MAGELLAN. After MAGELLAN was acquired by Meridian, Winslow received a bonus of approximately $2 million, and Maleknia received a bonus of approximately $448,000.

LeadCare Ultra Application for FDA Clearance

33. In or around November 2012, MAGELLAN sought clearance from FDA to introduce into the market its newly developed LeadCare Ultra device. MAGELLAN submitted a Traditional 510(k) application to FDA (the "LeadCare Ultra 510(k) application"), which claimed that the LeadCare Ultra was substantially equivalent to the already-cleared LeadCare II device. In its application, MAGELLAN described LeadCare Ultra as "an *in vitro* diagnostic device that relies on electrochemistry . . . and a unique sensor to detect lead in whole blood . . . When a sample of whole blood is mixed with Treatment Reagent (a diluted solution of hydrochloric acid), [lead is separated from the red blood cells] and lead becomes available for detection."

34. MAGELLAN's LeadCare Ultra 510(k) application contained performance testing comparing LeadCare Ultra's performance to a reference method for testing blood lead concentrations using standardized blood samples, donor blood, and human and bovine blood spiked to certain lead concentrations. The reference method was called graphite furnace atomic absorption spectrometry (GFAAS). MAGELLAN's performance testing also included a clinical study in which 394 blood samples were collected. Of the 394 blood samples collected, 148 samples were within range (1.9-65 µg/dL). MAGELLAN represented to FDA that the clinical data "met the acceptance criteria, defined as average bias within the range of ±2 µg/dL in the concentration range of 1.9 to 10 µg/dL and ±10% for concentrations above 10 µg/dL."

35. On or about January 14, 2013, FDA issued a Hold Memo for MAGELLAN's LeadCare Ultra 510(k) application, which noted several deficiencies and requested additional studies and documentation. The Hold Memo included the following request:

> In your labeling, [you] provide system operating ranges for LeadCare Ultra system including, altitudes (up to 8,000 feet [] above sea level), relative humidity (12% - 80% …) and temperature (61-82 °F []). However, you did not provide operating range studies in your submission. Please provide operating range study protocol including acceptance criteria and study summary to support your claim.

<u>Discovery of LeadCare Malfunction</u>
(June 2013)

36. While conducting the temperature and humidity studies requested by FDA in the Hold Memo, MAGELLAN discovered a malfunction affecting the LeadCare Ultra device (the "Malfunction"). The Malfunction tended to result in lower blood lead values when the blood sample was tested shortly after it was mixed with treatment reagent (sometimes referred to as "T0" for 0 minutes of incubation) and higher blood lead values if the blood-treatment reagent mixture were allowed to sit, or "incubate," for several hours or days before testing (sometimes referred to as "T[amount of incubation time]," such as "T4" for four hours of incubation time or "T24" for 24 hours of incubation time). When the Malfunction occurred, the lower blood lead value was often below that of the GFAAS device for the same sample. With incubation, the higher blood lead value was often closer to that of GFAAS but could be higher than GFAAS.

37. The Malfunction was first observed in or around June 27, 2013, when a MAGELLAN employee performed the temperature and humidity studies requested by FDA. This employee forwarded the results of this study to Daoust. The temperature and humidity studies measured blood lead levels at different temperature and humidity conditions (a) shortly

after mixing the blood sample with treatment reagent and (b) after letting the blood-treatment reagent mixture incubate for one to two days.

38. After reviewing the results of the temperature and humidity studies, Daoust sent an email to several MAGELLAN employees, including Employee A and Employee B, with the subject line "HELP," writing: "More to come … later. very stressed … Results across all sensors, and 2 Ultra's consistently low." Daoust noted that the blood lead results were "consistently low," but when the same samples were tested a day later, they were within the range of MAGELLAN's acceptance criteria. Daoust asked, "Has there ever been studies at 0 hours, 12, 24, 48 hours, etc.[?]" On or about June 27, 2013, Employee A responded to Daoust, "Yes a time study has been done with carbon in [treatment reagent] … Study was done in 2007." Daoust responded on or about June 28, 2013, "I hope this turns out to be nothing….2007 was 8 years ago." Daoust informed Winslow and Maleknia, among others, at least as early as June 28, 2013 about the Malfunction affecting LeadCare Ultra.

39. MAGELLAN did not notify FDA about the failed results of MAGELLAN's temperature and humidity studies that showed the Malfunction. Instead, MAGELLAN responded to the pertinent portion of FDA's Hold Memo on or about July 10, 2013 by reporting results from a different temperature and humidity study, which confirmed that the LeadCare Ultra device operated at different temperature and humidity conditions, but did not contain any blood lead measurements. MAGELLAN explained that its submitted temperature and humidity study, "demonstrated that the currents and voltages/potentials used to perform the electrochemical blood lead assay/test remained within the required ±2% operating level across the tested conditions, for all analyzer channels." MAGELLAN's submission to FDA did not mention the Malfunction.

FDA Clearance of LeadCare Ultra
(August 2013)

40. FDA—unaware of the Malfunction—cleared the LeadCare Ultra device for marketing and distribution on or about August 20, 2013. In its clearance letter, FDA emphasized, "We remind you, however, that the device labeling must be truthful and not misleading."

41. The label for the FDA-cleared Ultra device made accuracy claims based on its method comparison study, in which the average bias, or average difference from GFAAS, was less than one microgram per deciliter at each blood lead level tested, and the negative bias from GFAAS was 1% or less at each blood level tested, as shown below:

ACCURACY:
The accuracy of the LeadCare Ultra Blood Lead Testing System was determined by a Method Comparison study at two hospital laboratory sites. Three hundred ninety-four (394) results, from a combination of spiked and unspiked blood samples, were generated. One hundred forty-eight results were within the claimed analytical range of 1.9 – 65.0 µg/dL. The LeadCare Ultra results were plotted versus the results obtained by the Reference Method, GFAAS. The LeadCare Ultra average bias from GFAAS and the scatter plot of LeadCare Ultra vs. GFAAS results, with the linear regression, are provided in Table 2 and Graph 1, respectively.

Table 2: LeadCare Ultra Average Bias from GFAAS

GFAAS (µg/dL)	Predicted LeadCare Ultra (µg/dL)	Avg. Bias (µg/dL)	Bias (%)
1.90	1.95	0.05	2.4%
5.00	5.01	0.01	0.2%
10.00	9.96	-0.04	-0.4%
20.00	19.85	-0.15	-0.7%
30.00	29.74	-0.26	-0.9%
40.00	39.64	-0.36	-0.9%
50.00	49.53	-0.47	-0.9%
60.00	59.42	-0.58	-1.0%
65.00	64.37	-0.63	-1.0%

42. MAGELLAN's method comparison study, however, did not control for the amount of time that the blood-treatment reagent incubated before testing, which is to say that the laboratories participating in the method comparison study were free to run the tests at any time after mixing the blood sample and treatment reagent as permitted by the LeadCare Ultra label. The LeadCare Ultra label's instructions for use stated in part: "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." Thus, if the normal workflow of these laboratories included sufficient incubation time after mixing, the study was unlikely to show the effects of the Malfunction.

43. The label for the FDA-cleared LeadCare Ultra device also stated:

> Childhood lead poisoning is a major, preventable problem in the United States. Numerous studies have shown that exposure to lead can result in damage to the nervous, hematopoietic, endocrine, renal, and reproductive systems causing lifelong physical and mental health problems. Children are particularly susceptible to the effects of lead as their nervous systems are still developing.
>
> In 2012, based on the increased body of evidence demonstrating there is no safe level of lead in the blood, experts established a new reference value to identify children who have elevated blood lead levels (BLL). According to the Centers for Disease Control (CDC) website (www.cdc.gov/nceh/lead), this level is based on the U.S. population of children ages 1-5 years who are in the top 2.5% of children when tested for lead in their blood (when compared to children who are exposed to more lead than most children). Currently this reference value is 5 μg/dL.

Confirmation of the Malfunction and Delayed Release of LeadCare Ultra
(September 2013 – December 2013)

44. Despite its original plans to do so, MAGELLAN did not release LeadCare Ultra to the market shortly after FDA clearance because of concerns about the Malfunction. From in or around August 2013 until in or around December 2013, MAGELLAN designed and conducted multiple studies comparing LeadCare Ultra test results measured (a) immediately after blood samples were mixed with treatment reagent and (b) after allowing the blood-treatment reagent to incubate for various time periods ("the 2013 Malfunction Studies"). While the Malfunction did not appear in every experiment, the 2013 Malfunction Studies repeatedly showed that the Malfunction occurred when testing various types of blood samples, at various lead concentrations, and using various sensors and treatment reagents. Conclusions from some of the 2013 Malfunction Studies included:

a. "[F]resh human samples, unspiked and spiked [samples] all increased in [lead] value during [a] 4 day period with the exception of the [sample spiked to the lead concentration of 50 µg/dL.]"

b. "There is a reproducible trend of increased [lead] signal with increased Sample/Treatment reagent incubation time … Trend is evident: On multiple sensor lots at varying degrees [and with] multiple blood samples … Can create false lows or false highs[.] No one incubation time mitigates the false lows or highs. Although 30 mins looks favorable … Per [Daoust], change of instruction to include incubation time would require resubmitting data to FDA."

c. "Sample/Treatment Reagent Preparations incubated at either Room Temperature or Refrigerated confirms the trend of increased [lead result] from T0 to T 24."

d. "This phenomenon is apparent for all three blood samples tested."

e. "This phenomenon is most evident when assessing the T0 vs. T24 graphs or the Difference Plots of difference from either T0 or GFAAS."

f. "The results of this study demonstrate that, in most cases, overnight incubation of the sample/Treatment Reagent preparations lead to higher LeadCare Ultra results than immediately [testing] the sample after mixing in the Treatment Reagent."

g. "Additionally, when samples that differed ± 2µg/dL between immediate vs. overnight incubation were [retested], the value obtained in the [retest] was many times greater than that obtained after overnight incubation."

45. Despite knowing that the Malfunction could cause inaccurate test results, MAGELLAN released LeadCare Ultra for sale to customers in or around December 2013.

MAGELLAN did not notify customers or FDA in 2013 that the Malfunction could cause false lows and false highs, especially if testing was conducted immediately after mixing blood samples with treatment reagent.

46. In or around June 2014, Employee A and Employee B briefed MAGELLAN executives, including Winslow, Maleknia, and Daoust, on a MAGELLAN study using LeadCare Ultra to test lead levels, without incubation, in 10 blood samples collected from employees at battery manufacturing facilities (battery workers) who were exposed to high levels of lead in their occupation. The slide deck from this briefing warned that: "[A]ll 10 samples demonstrated extremely negative bias vs GFAAS;" there was an "increased signal with increased incubation time;" there was an "inherent risk for false negative blood lead results;" and MAGELLAN "must identify root cause."

Discovery and Confirmation of the Malfunction in LeadCare II
(2013—November 2014)

47. During the 2013 Malfunction Studies, MAGELLAN conducted studies to determine whether the Malfunction affected LeadCare II sensors and treatment reagent as well as LeadCare Ultra.

a. On or about October 23, 2013, for example, MAGELLAN tested blood samples after they incubated in LeadCare Ultra treatment reagent and LeadCare II treatment reagent. The results showed that the blood lead levels increased after overnight incubation in both the LeadCare Ultra and LeadCare II treatment reagent. MAGELLAN's report concluded, "Increased signal after overnight incubation in LCII [treatment reagent] suggests this is a general phenomenon not related to the carbon in the Ultra [treatment reagent.]"

b. On or about November 13, 2013, MAGELLAN conducted a study to "understand if the [LeadCare Ultra] correlation issues are isolated to [LeadCare Ultra] or if [LeadCare II] … sensors show the same results." The study found:

> Both [LeadCare Ultra] and [LeadCare II] using their [respective] treatment reagents produced the same data for the 23 blood samples. … Both [LeadCare II] and [LeadCare Ultra] again produced the same results after analyzing the same samples after 24 hours. The bias after overnight incubation for [LeadCare II] and [LeadCare Ultra] was in most cases lower than that obtained with immediate assay. … There is a negative bias in this group of battery workers blood and all three products [LeadCare II, LeadCare Ultra, and a prior generation LeadCare Device] exhibit this negative bias. The bias for [LeadCare II] and [LeadCare Ultra] are similar, however less bias is observed with [the prior generation LeadCare Device] sensor.

48. Despite knowing that the Malfunction could cause inaccurate LeadCare II test results, MAGELLAN did not continue conducting experiments to confirm, analyze, and quantify the effect of the Malfunction on LeadCare II, which was MAGELLAN's top-selling product responsible for a substantial majority of MAGELLAN's revenue. In or around Spring of 2015, Winslow directed Employee B not to include LeadCare II in a Malfunction study so that the company could maintain "plausible deniability."

49. Prior to November 2016, MAGELLAN did not inform customers and FDA that the Malfunction was likely to cause inaccurate test results when LeadCare II was tested using venous samples.

<u>LeadCare Ultra Customer Complaints</u>
(August 2014—November 2014)

50. Beginning in or around August 2014, certain LeadCare Ultra customers independently discovered the Malfunction after they observed inaccurate and changing lead test results. On or about August 13, 2014, MAGELLAN received complaints from two customers, "Hospital A" in Baltimore, Maryland, and "Medical Laboratory A" in Washington, D.C. Both

Hospital A and Medical Laboratory A complained about receiving unexpectedly low test results when samples were tested immediately after being mixed with treatment reagent, as the label allowed. Hospital A and Medical Laboratory A found that the lead test result was higher if the sample was tested an hour after the sample was mixed with treatment reagent. Employee D, MAGELLAN's Product Support Manager, summarized the customer complaints in an email to Daoust, Maleknia, and others. In response, Daoust wrote, "Here we go again……please call a meeting together so we can discuss this. This is what we were afraid of."

51. MAGELLAN received other complaints from customers through in or about October 2014. Customers reported that they were receiving inaccurate lead test results, test results that were significantly lower than the expected value, and false lows that were below CDC's medical threshold of 5 μg/dL while the value on reference methods was greater than 5 μg/dL. MAGELLAN did not tell customers that MAGELLAN had been aware of the Malfunction for more than a year. On the contrary, MAGELLAN directed its employees to provide materially false and misleading responses to complaining customers by, among other things, stating that MAGELLAN was surprised to learn about the Malfunction from its customers. For instance, after Employee D advised the first complaining customer to incubate after mixing the sample and reagent, Daoust responded to the same customer with knowingly and materially false and misleading information, saying: "Just to clarify, [Employee D]'s suggestion that you extend the incubation time is based exclusively on the results you have shared with us. To date, we have not been able to replicate the large differences you have observed based upon incubation time." Daoust continued, "[w]e are continuing our investigation in-house to find the root cause, and to determine if there is an aging issue that will require a change [to] our instructions. Thank you for bringing this issue to our attention."

52. On or about November 24, 2014, MAGELLAN sent LeadCare Ultra customers a letter about the Malfunction (the "LeadCare Ultra Customer Letter"). The LeadCare Ultra Customer Letter advised customers to allow the blood-treatment reagent mixture to sit for a minimum of 24 hours before testing. This advice contradicted the LeadCare Ultra label, which permitted users to analyze the sample immediately after mixing the blood sample and treatment reagent and permitted users to analyze the mixture within 48 hours if the mixture was kept at room temperature or within seven days if the mixture was refrigerated.

53. The LeadCare Ultra Customer Letter also contained several materially false and misleading statements, and concealed material facts, about the Malfunction and MAGELLAN's discovery of the Malfunction, including those in bold type and italics below:

a. "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." This statement was materially false and misleading because MAGELLAN had no basis for estimating the frequency of the Malfunction.

b. "This phenomenon appears to be limited to a ***small percentage*** of samples." This statement was materially false and misleading because, based on MAGELLAN's internal testing, the Malfunction had the potential to affect 100% of a customer's samples. In fact, in MAGELLAN's largest study conducted shortly before the LeadCare Ultra Customer Letter was sent, the Malfunction appeared in 100% of the samples tested at T0.

c. "We have ***recently*** identified cases where the LeadCare Ultra System underestimates the lead concentration of some blood samples when the sample is analyzed immediately." This statement was materially false and misleading because

MAGELLAN identified the Malfunction in or around June 2013 and confirmed the existence of the Malfunction in tests conducted in or around the 2013 Malfunction Studies, which concluded approximately one year before MAGELLAN sent the LeadCare Ultra Customer Letter to its customers.

d. "***We did not observe this in our clinical trials prior to the product release***." This statement was materially false and misleading because (a) MAGELLAN's method comparison study for LeadCare Ultra did not control for the amount of time that the blood sample incubated in the treatment reagent and thus was unlikely to have revealed the Malfunction, and (b) MAGELLAN did observe the Malfunction in temperature and humidity studies requested by FDA and in the 2013 Malfunction Studies before product release.

Overdue Filing of the LeadCare Ultra MDR
(April 2015)

54. Despite the LeadCare Ultra Customer Letter, MAGELLAN did not notify FDA about (a) MAGELLAN's discovery of the Malfunction and (b) MAGELLAN's change to the LeadCare Ultra user instructions for over four months.

55. In or around March 2015, MAGELLAN engaged an outside statistician ("Consultant A") to review the results from MAGELLAN's largest study related to the Malfunction. This study had been conducted in November 2014, prior to the issuance of the LeadCare Ultra Customer Letter. Consultant A concluded that when the blood-treatment reagent was tested immediately after mixing, the test results were on average 53% below the GFAAS expected reference value. Consultant A warned that the Malfunction could cause false lows: "That is, a true value above 5 [μg/dL], would likely show up as a normal value (below [5 μg/dL]) and a value that requires emergency treatment (>45 μg/dL) might be reported well below 45

[μg/dL].” Consultant A concluded that “MAGELLAN needs to determine whether the FDA needs to be notified according to the Medical Device Reporting law (Code of Federal Regulations, title 21, part 803).”

56. In subsequent communications related to his report, Consultant A repeatedly advised MAGELLAN to report the Malfunction to FDA. In a conference call, Consultant A gave MAGELLAN an ultimatum, saying in words and substance: “If you do not tell the FDA, I will.” This ultimatum prompted MAGELLAN to file an MDR for LeadCare Ultra.

57. On or about April 2, 2015, MAGELLAN submitted an MDR about the Malfunction (the “LeadCare Ultra MDR”). The LeadCare Ultra MDR contained several materially false and misleading statements and concealed material facts about the Malfunction and MAGELLAN’s discovery of the Malfunction. For instance, the LeadCare Ultra MDR stated:

a. “[On March 23, 2015, b]ased on new information, a second Risk Analysis was performed…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. … During our investigation [after November 2014] new data indicated the frequency of this occurrence had increased.” These statements were materially false and misleading because (a) the data reviewed by Consultant A for his report was not new data, but data collected before November 2014, and (b) MAGELLAN had not received any data since then that showed an increased magnitude of bias from, or an increased rate in the occurrence of, the Malfunction. These materially false and misleading statements were made to conceal the fact that the actual

precipitating factor for MAGELLAN's decision to file the MDR was Consultant A's ultimatum.

b. "In November of [2014], we determined that blood lead results were being underestimated… We did not observe this in our clinical studies prior to product release." This statement was materially false and misleading because (a) MAGELLAN's method comparison study for LeadCare Ultra did not control for the amount of time that the blood sample incubated in the treatment reagent and thus was unlikely to have revealed the Malfunction, and (b) MAGELLAN did observe the Malfunction in temperature and humidity studies requested by FDA and in the 2013 Malfunction Studies before product release.

c. "8/13/2014 We received initial [complaints] from [Hospital A] and [Medical Laboratory A] 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." This statement was materially false and misleading because MAGELLAN actually identified the Malfunction in or around June 2013 and confirmed the existence of the Malfunction in the 2013 Malfunction Studies, which concluded approximately nine months before MAGELLAN received the customer complaints in August 2014.

58. MAGELLAN did not receive a response from FDA following its submission of the LeadCare Ultra MDR in April 2015.

59. In or around August 2015, MAGELLAN approved an engineering change order (ECO) that changed the LeadCare Ultra label, user guide, and website to incorporate the 24-hour incubation instruction. MAGELLAN did not notify FDA of the change to the device and product

insert, nor did FDA clear the significantly changed device. Daoust completed the ECO in a materially false and misleading way to support the conclusion that FDA clearance was not necessary, even though she was well aware that FDA clearance was needed for a significant labeling or design change such as this.

LeadCare Plus Application
(August 2014)

60. As part of MAGELLAN's corporate effort to grow its share in the lead testing market, MAGELLAN developed a new product, LeadCare Plus, which was marketed to small and medium-sized laboratories and hospitals.

61. MAGELLAN submitted a Special 510(k) application to FDA for the LeadCare Plus product in or around August 2014. Because LeadCare Plus's sensor technology and treatment reagent were substantially equivalent to those of LeadCare Ultra and LeadCare II, MAGELLAN expected that LeadCare Plus would also be affected by the Malfunction. As a result, Winslow and Maleknia directed that the method comparison study for LeadCare Plus not be run at T0, because they believed the study would fail.

62. MAGELLAN's original LeadCare Plus Special 510(k) application did not include an incubation time in the label's instructions for use. In or around May 2015, MAGELLAN resubmitted to FDA a new label for LeadCare Plus that included a 24-hour incubation time but did not alert FDA to the change in its proposed labeling or to the fact that the Malfunction was likely to affect the LeadCare Plus device. FDA cleared the LeadCare Plus in or around July 2015.

Test Tube Experiments
(2015)

63. In or around 2015, MAGELLAN scientists continued to conduct studies to identify the most likely root cause of the Malfunction, focusing on whether a substance in the

rubber stopper of commonly used test tubes made by COMPANY A interfered with the LeadCare Device sensors and caused test results to be lower than expected. MAGELLAN did not notify customers or FDA immediately of the results of their studies into the root cause of the Malfunction. Because the majority of venous blood samples analyzed by the LeadCare Devices were collected in COMPANY A test tubes, MAGELLAN did not want to prohibit the use of COMPANY A tubes. MAGELLAN continued to test incubation times and methods in the hopes of finding an alternate way of addressing the Malfunction.

64. MAGELLAN's internal testing also revealed a separate issue involving tubes manufactured by COMPANY B and marketed under the BRAND X name in or around June through August 2015. Studies indicated that LeadCare results for high lead concentration samples collected in BRAND X tubes were initially accurate, but after approximately 48 hours of incubation, the test results decreased substantially to inaccurate, unacceptably low values. MAGELLAN employees referred to this as the "BRAND X Cliff effect." MAGELLAN did not notify customers and FDA of the separate malfunction affecting BRAND X tubes.

Overdue Notification to FDA about LeadCare II Malfunction
(November 2016)

65. In or around November 2016, approximately three years after MAGELLAN discovered the Malfunction in LeadCare II treatment reagent and sensors and more than two years after conducting additional validation studies in which the Malfunction appeared in LeadCare II as well as LeadCare Ultra, MAGELLAN submitted an amendment to the LeadCare Ultra MDR disclosing that the Malfunction also affected LeadCare II (the "LeadCare II MDR"). The LeadCare II MDR and its cover letter contained materially false and misleading statements and concealed material facts about MAGELLAN's discovery of the Malfunction in LeadCare II, including the following:

a. "The original Medwatch [MDR] was submitted for the LeadCareUltra. Through extensive testing the root cause was finally isolated. Once MAGELLAN found out the root cause we retested the LeadCare II which originally did not exhibit this issue." This statement was materially false and misleading because MAGELLAN was aware that LeadCare II was affected by the Malfunction as early as in or around October and November 2013, long before it discovered the most likely root cause of the Malfunction in LeadCare Ultra.

b. "MAGELLAN Diagnostics felt that although the risk of this issue was small, out of an abundance of caution we are notifying those customers that use venous blood draw tubes only. Capillary tubes do not exhibit this phenomenon." These statements were materially false and misleading because (a) MAGELLAN was aware that the risk of this issue was not small, and (b) MAGELLAN had conducted studies of microcapillary tubes used to collect fingerstick blood samples that showed that blood lead test results from LeadCare II changed depending on incubation time.

c. "Once MAGELLAN found out the root cause we retested the LeadCare II which originally did not exhibit this issue." "Once root cause was found LeadCare II was investigated and found to have the same problem but at lesser impact." These statements in the MDR were materially false and misleading because MAGELLAN was aware that LeadCare II was affected by the Malfunction as early as in or around October and November 2013, long before it discovered the most likely root cause of the Malfunction in LeadCare Ultra.

d. "PLEASE NOTE: Capillary tubes and finger sticks do NOT exhibit this phenomenon as there are no rubber stoppers to contact the blood and leach the interfering

substance." This statement was materially false and misleading because MAGELLAN had conducted studies of microcapillary tubes used to collect fingerstick blood samples that showed that blood lead test results from LeadCare II changed depending on incubation time.

66. The LeadCare II MDR was submitted by MAGELLAN on or around November 7, 2016. However, MAGELLAN mailed the LeadCare II MDR and did not file it electronically as required by FDA. The LeadCare II MDR was not properly filed and was not received by FDA until in or around 2017.

67. On or about November 4, 2016, MAGELLAN caused a letter (the "LeadCare II Customer Letter") to be sent to laboratory customers believed to be using LeadCare II with venous samples (which accounted for approximately 8% of its customers) advising those customers to let blood-treatment reagent samples incubate for four hours before testing. MAGELLAN ensured that this letter was not sent to customers believed to be using LeadCare II with capillary samples.

The 2017 Recall

68. MAGELLAN continued to search for ways of shortening the 24-hour incubation time that they instituted for LeadCare Ultra and LeadCare Plus to address the Malfunction. On or about March 3, 2017, MAGELLAN filed a Special 510(k) with FDA to change the labels for LeadCare Ultra and LeadCare Plus to allow customers to test the blood-treatment reagent sample after just one hour if the sample was heated to 60 degrees Centigrade (the "LeadCare Ultra and LeadCare Plus Special 510(k) application").

69. Soon after receiving the LeadCare Ultra and LeadCare Plus Special 510(k) application, FDA contacted MAGELLAN with urgent questions about the Malfunction, its effect

on the precision and accuracy of LeadCare Devices, and whether MAGELLAN's data supported the proposed labeling changes.

70. One issue that FDA focused on was when MAGELLAN discovered the Malfunction, because the date of discovery determined the number of patients that could have received false test results. On or about April 20, 2017, during a call that was attended by Daoust, Maleknia, Employee A, Employee D, and a regulatory consultant for MAGELLAN ("Consultant B"), FDA asked when MAGELLAN first discovered the Malfunction. Based on input from Daoust and Maleknia before the call, and at the direction of Daoust during the call, Consultant B falsely told FDA that MAGELLAN first discovered the problem in late 2014 after receiving customer complaints and shortly before the LeadCare Ultra MDR was filed. This statement was materially false and misleading because MAGELLAN actually discovered the Malfunction in 2013.

71. FDA ultimately found that MAGELLAN's data showed that LeadCare Devices could not accurately test venous samples, regardless of MAGELLAN's recommended incubation times. In or around May 2017, FDA recommended a recall of all LeadCare Devices using venous samples and warned the public not to use LeadCare Ultra, LeadCare II, and LeadCare Plus for venous blood samples because of the Malfunction.

72. As a result of the recall, FDA also conducted an on-site inspection of MAGELLAN's facility and issued a report summarizing its findings on or about June 29, 2017. The report stated, in part:

a. "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 [lead] 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."

b. "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 validate this incubation to ensure that the design change met the intended use of the device, as well as the needs of the user."

c. "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."

d. "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 'Marginal' severity defined as causing 'minor injury, temporary impairment, reversible, minor intervention required' and 'Occasional' probability of 'Likely to occur sometimes'."

73. Even after FDA determined that MAGELLAN was aware of the Malfunction in or around September 2013, Winslow continued to provide the materially false and misleading information that MAGELLAN first discovered the Malfunction in 2014 after receiving complaints from LeadCare Ultra customers. On or about July 11, 2017, Winslow and Employee E met with U.S. congressional staff members in response to a June 12, 2017, letter written by 12 U.S. Senators to FDA and CDC expressing concern about public health issues in light of the

recall of LeadCare Devices. Winslow falsely told congressional staff members that MAGELLAN first became aware of the Malfunction in 2014, and she did not disclose that MAGELLAN had been untruthful and misleading to FDA about material issues related to the Malfunction.

74. On or about December 21, 2017, MAGELLAN sent a letter to an international charitable organization ("Aid Organization A") that provided humanitarian medical care, including lead testing for children whose lead levels put them at risk of permanent brain damage and death. The letter addressed Aid Organization A's "concerns [about] how MAGELLAN handled its corrective actions associated with venous blood testing, including the failure to notify your organization directly of the labeling changes that ultimately resulted in the May 17, 2017 Field Safety Notice issued by the US Food and Drug Administration."

75. The letter to Aid Organization A contained materially false and misleading statements, and concealed material facts, about the Malfunction and MAGELLAN's discovery of the Malfunction. For instance, the letter stated:

> In the Summer/Fall of 2014, MAGELLAN became aware of customer complaints related to suppressed low test results for some venous samples with the LeadCare Ultra System. Suppression of test results was unexpected based on prior clinical trials, was not observed with capillary bloods, and suppression did not appear to be related to lot-specific reagent issues.

This statement was materially false and misleading because suppression of test results was not unexpected and was observed as early as in or around June 2013, before FDA clearance and release of the LeadCare Ultra devices.

76. In or around September 2017, CDC recommended retesting all children under age 6 who had been tested on a LeadCare Ultra, LeadCare II, or LeadCare Plus device using venous samples. However, many states agencies did not track which blood lead samples were tested

using LeadCare Devices. In one state that did identify the patients who were tested using venous samples on LeadCare Devices, the retesting rate was exceedingly low: only 18% of qualified patients were retested. CDC and FDA estimated that the Malfunction caused tens of thousands of children and adults to receive false blood lead results.