

**UNITED STATES DISTRICT COURT  
FOR THE MASSACHUSETTS**

<b>UNITED STATES OF AMERICA</b>	)	
	)	<b>Criminal No. 23-cr-_____</b>
v.	)	
	)	
<b>MAGELLAN DIAGNOSTICS, INC.</b>	)	
	)	
<b>Defendant.</b>	)	
	)	
_____	)	

**DEFERRED PROSECUTION AGREEMENT**

The United States Attorney’s Office, by its attorney, Joshua S. Levy, Acting United States Attorney for the District of Massachusetts (the “Office”) and defendant Magellan Diagnostics, Inc. (“Magellan” or “the Company”) hereby enter into this Deferred Prosecution Agreement (the “Agreement”). The terms and conditions of this Agreement are as follows:

**Criminal Information and Acceptance of Responsibility**

1. The Company acknowledges and agrees that the Office will file the attached criminal Information in the United States District Court for the District of Massachusetts charging the Company with (1) conspiracy to commit wire fraud in violation of Title 18, United States Code, Section 1349; and (2) conspiracy to defraud the United States in violation of Title 18, United States Code, Section 371 (hereinafter, “the Felony Information”). In so doing, the Company: (a) knowingly waives any right it may have to indictment on these charges, as well as all rights to a speedy trial pursuant to the Sixth Amendment to the United States Constitution, Title 18, United States Code, Section 3161, and Federal Rule of Criminal Procedure 48(b); (b) agrees to venue of the case in the District of Massachusetts and knowingly waives any objection with respect to venue to any charges by the United States arising out of the conduct described in the Statement of Facts attached hereto as Attachment A (“Statement of Facts”); (c) knowingly waives any applicable

statute of limitations and any legal or procedural defects in the Felony Information; and (d) consents to the filing of the Felony Information, as provided under the terms of this Agreement, in the United States District Court for the District of Massachusetts. The Office agrees to defer prosecution of the Company pursuant to the terms and conditions described below.

2. The Company admits, accepts, and acknowledges that it is responsible under United States law for the acts of its officers, directors, employees, and agents as charged in the Felony Information, and as set forth in the Statement of Facts, and that the allegations described in the Felony Information and the facts described in the Statement of Facts are true and accurate. The Company agrees that, as of the Effective Date (as defined herein), in any prosecution that is referenced by this Agreement, it will not dispute the Statement of Facts set forth in this Agreement, and, in any such prosecution, the Statement of Facts shall be admissible as: (a) substantive evidence offered by the government in its case-in-chief and rebuttal case; (b) impeachment evidence offered by the government on cross-examination; and (c) evidence at any sentencing hearing or other hearing. In addition, in connection therewith, the Company agrees not to assert any claim under the United States Constitution, Rule 410 of the Federal Rules of Evidence, Rule 11(f) of the Federal Rules of Criminal Procedure, Section 1B1.1(a) of the United States Sentencing Guidelines, or any other federal rule that the Statement of Facts should be suppressed or is otherwise inadmissible as evidence in any form.

### **Term of the Agreement**

3. This Agreement is effective for a period beginning on the date on which the Information is filed (the “Effective Date”) and ending twenty-four (24) months from the later of the Effective Date or the date on which the independent compliance monitor (the “Monitor”) is retained by the Company, as described in Paragraphs 14–17 below (the “Term”). The Company

agrees, however, that, in the event the Office determines, in its sole discretion, that the Company has knowingly violated any provision of this Agreement or has failed to completely perform or fulfill each of the Company's obligations under this Agreement, an extension or extensions of the Term may be imposed by the Office, in its sole discretion, for up to a total additional time period of one year, without prejudice to the Office's right to proceed as provided in Paragraphs 20–23 below. Any extension of the Agreement extends all terms of this Agreement, including the terms of the reporting requirements and monitorship in Attachment D, for an equivalent period. Conversely, in the event the Office finds, in its sole discretion, independently or after a request by the Company, that there exists a change in circumstances sufficient to eliminate the need for the reporting requirements and monitorship in Attachment D, and that the other provisions of this Agreement have been satisfied, the Agreement may be terminated early. If the Court refuses to grant exclusion of time under the Speedy Trial Act, Title 18, United States Code, Section 3161(h)(2), the Term shall be deemed to have not begun, and all provisions of this Agreement shall be deemed null and void, except: (a) the provisions contained within Paragraph 2 of this Agreement; and (b) the statute of limitations for any prosecution relating to the conduct described in the Statement of Facts shall be tolled from the Effective Date of this Agreement until the date the Court refuses to grant the exclusion of time plus six months.

#### **Relevant Considerations**

4. The Office enters into this Agreement based on the individual facts and circumstances presented by this case and the Company, including:
  - a. The Company's acknowledgement of its conduct and acceptance of responsibility for that conduct;

b. The Company's cooperation in the investigation of this matter and the Company's commitment to continue cooperation with the government's investigation and prosecution of violations of federal law by individuals associated with Magellan;

c. The Company's commitment to enhanced compliance measures;

d. Remedial measures undertaken by the Company and its parent company and the Company's commitment to undertake additional remediation as identified herein;

e. The Company's guilty plea to two misdemeanor violations of the Food, Drug, and Cosmetic Act ("FDCA"), Title 21, United States Code, Sections 331 and 333 as charged in an information ("FDCA Information") filed by the Office in this matter, and payment of \$32,700,000 in criminal fines and forfeiture in connection with the FDCA Information; and

f. The Company's commitment to fulfill all of the terms of this Agreement;

g. Accordingly, after considering (a) through (f) above, the Office believes that the appropriate resolution in this case is a deferred prosecution agreement with the Company, payment of victim compensation of at least \$9,300,000 as detailed herein and in attachments to this Agreement; and the Company's agreement to report to the Office as set forth in the Compliance Reporting Requirements and to engage an independent compliance Monitor.

#### **Future Cooperation and Disclosure Requirements**

5. The Company shall cooperate fully with the Office in any and all matters relating to the facts and conduct described in this Agreement and the Statement of Facts until all investigations and prosecutions arising out of such conduct are concluded. At the request of the Office, the Company shall also cooperate fully with other domestic or foreign law enforcement and regulatory authorities and agencies in any investigation of the Company, its parent company or subsidiaries, or any of its present or former officers, directors, employees, agents, and

consultants, or any other party, in any and all matters relating to the facts and conduct described in this Agreement and the Statement of Facts. The Company's cooperation pursuant to this Paragraph is subject to applicable law and regulations, as well as valid claims of attorney-client privilege or attorney work product doctrine; however, the Company must provide to the Office a description of any information or cooperation that is not provided based on an assertion of law, regulation, or privilege, and the Company bears the burden of establishing the validity of any such an assertion. The Company agrees that its cooperation pursuant to this paragraph shall include, but not be limited to, the following:

a. The Company shall truthfully disclose all factual information with respect to its activities, those of its parent company and subsidiaries, and those of its present and former directors, officers, employees, agents, and consultants, including any evidence or allegations and internal or external investigations, about which the Company has any knowledge or about which the Office may inquire. This obligation of truthful disclosure includes, but is not limited to, the obligation of the Company to provide to the Office, upon request, any non-privileged document, record, or other tangible evidence about which the Office may inquire of the Company.

b. Upon request of the Office, the Company shall designate knowledgeable employees, agents, or attorneys to provide to the Office the information and materials described in Paragraph 5(a) above on behalf of the Company. The Company agrees that it must at all times provide complete, truthful, and accurate information to the Office.

c. As requested by the Office, the Company shall make available for interviews or testimony any present officers, directors, employees, agents, and consultants of the Company, its parent company and subsidiaries. This obligation includes, but is not limited to, sworn testimony as well as interviews with domestic or foreign law enforcement and regulatory

authorities. Cooperation under this Paragraph shall include identification of witnesses who, to the knowledge of the Company, may have material information regarding the matters under investigation.

d. With respect to any information, testimony, documents, records, or other tangible evidence provided to the Office pursuant to this Agreement, the Company consents to any and all disclosures to other governmental authorities, including United States authorities and those of a foreign government, of such materials as the Office, in its sole discretion, shall deem appropriate.

### **Victim Compensation**

6. The Company agrees to establish a Victim Compensation Fund of at least \$9,300,000 to compensate patients and/or minor patients' legal guardians who were harmed by the conduct described in the Statement of Facts between June 27, 2013 and May 31, 2017. The Company shall establish a dedicated bank account for the Victim Compensation Fund and make deposits to the account according to the following schedule: \$3,000,000 shall be deposited no later than 15 days after the Effective Date of this Agreement; \$3,000,000 shall be deposited no later than one year after the Effective Date of this Agreement; and \$3,300,000 shall be deposited no later than two years after the Effective Date of this Agreement.

7. The parties agree that the Monitor shall, according to the processes and standards described in Attachments D and F, (i) oversee the Company's efforts to identify and notify potential victims; (ii) review and evaluate victim compensation claims; (iii) oversee the Company's payment of victim compensation claims that the Monitor determines shall be paid; and (iv) resolve any disputes between a victim and the Company concerning the victim's entitlement to compensation. The Company agrees to fully compensate victims the Monitor determines to be

entitled to victim compensation, even if the total compensation requires the Company to add funds to the dedicated bank account.

8. The Company agrees to pay for all costs, fees, and expenses incurred in connection with the dedicated bank account, the Monitor's oversight and administration of the victim compensation process, and any victim outreach efforts.

9. The parties agree that any portion of the Victim Compensation Fund that (a) has not been paid out to victims at the conclusion of the Victim Payment Period (as that term is defined in Attachment F) and (b) is not subject to a pending claim submitted to the Monitor (as specified in Attachment F) shall instead be paid to qualified Childhood Lead Poisoning Prevention Programs ("CLPPPs"). CLPPPs are state and local programs dedicated to reducing childhood lead poisoning as a public health problem through strengthening blood testing, reporting, and surveillance, linking exposed children to recommended services, and targeted population-based interventions. The parties agree that the Monitor shall, according to the processes and standards described in Attachments D and F, determine—subject to approval by the Office—which CLPPPs are qualified to receive payments and the amount each CLPPP shall receive.

#### **Conditional Release from Liability**

10. Subject to Paragraphs 20–23, the Office agrees, except as provided in this Agreement and the Company's plea agreement concerning the FDCA Information, that it will not bring any criminal or civil case against the Company relating to any of the conduct described in the Statement of Facts, the Felony Information, or the FDCA Information filed pursuant to this Agreement. The Office, however, may use any information related to the conduct described in the Statement of Facts against the Company: (a) in a prosecution for perjury or obstruction of justice; (b) in a prosecution for making a false statement; (c) in a prosecution or other proceeding relating

to any crime of violence; or (d) in a prosecution or other proceeding relating to a violation of any provision of Title 26 of the United States Code.

a. This Agreement does not provide any protection against prosecution for any future conduct by the Company.

b. In addition, this Agreement does not provide any protection against prosecution of any individuals, regardless of their affiliation with the Company.

### **Corporate Compliance Program**

11. The Company has implemented and will continue to implement a compliance and ethics program designed to prevent and detect violations of the FDCA and its associated regulations throughout its operations, including those of its subsidiaries, agents, and joint ventures, and those of its contractors and subcontractors whose responsibilities relate to the Company's interactions with domestic government agencies (including the Food and Drug Administration ("FDA")) and the Company's communications with customers about FDA-regulated products, including, but not limited to, the elements set forth in Attachment C.

12. In order to address any deficiencies in its internal controls, policies, and procedures, the Company represents that it has undertaken, and will continue to undertake in the future, in a manner consistent with all of its obligations under this Agreement, a review of its existing internal controls, policies, and procedures regarding compliance with the FDCA, focusing on the Company's interactions with domestic government agencies (including the FDA) and the Company's handling of complaints or malfunction reports concerning FDA-regulated products. Where necessary and appropriate, the Company agrees to adopt a new compliance program, or to modify its existing one, including internal controls, compliance policies, and procedures in order to ensure that it maintains an effective compliance program, including a system of internal



controls, designed to effectively detect and deter violations of the FDCA and its associated regulations. The compliance program, including the internal controls system, will include, but not be limited to, the elements set forth in Attachment C.

### **Corporate Compliance Reporting**

13. The Company agrees that it will report to the Office during the Term regarding remediation and implementation of the compliance measures described in Attachment C. These reports will be prepared in accordance with, and at the frequency defined in, Attachment D.

### **Independent Compliance Monitor**

14. Promptly after the Office's selection of a Monitor pursuant to Paragraph 16, the Company agrees to retain the Monitor for the term specified in Paragraph 17. The Monitor's duties and authority, and the obligations of the Company with respect to the Monitor and the Office, are set forth in Attachment D. Within 15 business days after the Effective Date of this Agreement, the Company shall submit a written proposal identifying three Monitor candidates, and, at a minimum, providing the following:

- a. a description of each candidate's qualifications and credentials in support of the evaluative considerations and factors listed below;
- b. a written certification by the Company that it will not employ or be affiliated with the Monitor for a period of not less than two years from the date of the termination of the monitorship;
- c. a written certification by each of the candidates that the candidate is not a current or recent (i.e., within the prior two years) employee, agent, or representative of the Company and holds no interest in, and has no relationship with, the Company, its parent company, subsidiaries, or related entities, or its employees, officers, or directors;

d. a written certification by each of the candidates that the candidate has notified any clients that the candidate represents in a matter involving the Office (or any other Department of Justice component handling the Monitor selection process), and that the candidate has either obtained a waiver from those clients or has withdrawn as counsel in the other matter(s); and

e. A statement identifying the Monitor candidate that is the Company's first, second, and third choice to serve as the Monitor.

15. The Monitor candidates or their team members shall have, at a minimum, the following qualifications:

a. experience and expertise with respect to designing and/or reviewing corporate compliance policies, procedures, and internal controls, including those specific to maintaining compliance with the FDCA and its associated regulations and other applicable laws concerning in vitro diagnostic testing devices;

b. experience and expertise with mass tort litigation, product liability, and/or personal injury;

c. the ability to access and deploy resources as necessary to discharge the Monitor's duties as described in this Agreement; and

d. sufficient independence from the Company to ensure effective and impartial performance of the Monitor's duties as described in this Agreement.

16. The Office retains the right, in its sole discretion, to choose the Monitor from among the candidates proposed by the Company consistent with DOJ policy concerning the selection of corporate monitors. Any submission or selection of a Monitor candidate by either the Company or the Office shall be made without unlawful discrimination against any person or class

of persons. If the Office determines, in its sole discretion, that any or all of the three candidates lack the requisite qualifications, the Office shall notify the Company and request that the Company propose another candidate or candidates within 20 business days. This process shall continue until a Monitor acceptable to both parties is chosen. The Office and the Company will use their best efforts to complete the selection process within 60 calendar days of the Effective Date of this Agreement. The Office retains the right to determine that the Monitor should be removed if, in the Office's sole discretion, the Monitor fails to conduct the monitorship effectively, fails to comply with this Agreement, or no longer meets the qualifications outlined in Paragraph 15. If the Monitor resigns, is removed, or is otherwise unable to fulfill the Monitor's obligations as set out herein and in Attachment D, the Company shall within 20 business days recommend a pool of three qualified Monitor candidates from which the Office will choose a replacement, following the process outlined above.

17. The Monitor's term shall be 24 months from the date on which the Monitor is retained by the Company, subject to extension or early termination as described in Paragraph 3. Notwithstanding the foregoing, the Company agrees that the Monitor's role as claims administrator shall continue for a 36-month period as set forth in Attachment F. The Monitor's powers, duties, and responsibilities, as well as additional circumstances that may support an extension of the Monitor's term, are set forth in Attachment D. The Company agrees that it will not employ or be affiliated with the Monitor or the Monitor's firm for a period of not less than two years from the date on which the Monitor's term expires, nor will the Company discuss with the Monitor or the Monitor's firm the possibility of further employment or affiliation during the Monitor's term. Upon agreement by the parties, this prohibition will not apply to other monitorship responsibilities

that the Monitor or the Monitor's firm may undertake in connection with resolutions with foreign or other domestic authorities.

### **Deferred Prosecution**

18. In consideration of the undertakings agreed to by the Company herein, the Office agrees that any prosecution of the Company for the conduct set forth in the Statement of Facts (other than the FDCA Information, as described in Paragraph 4(e)) be and hereby is deferred for the Term. To the extent there is conduct disclosed by the Company that is not set forth in the Statement of Facts, such conduct will not be exempt from further prosecution and is not within the scope of or relevant to this Agreement.

19. The Office shall, if the Company is in full compliance with all of its obligations under this Agreement, within three months after the expiration of the Term of this Agreement set forth above in Paragraph 3, or earlier at the discretion of the Office, seek dismissal with prejudice of the Felony Information filed against the Company pursuant to Paragraph 1, and this Agreement shall expire and be of no further force and effect. The Office further agrees not to file charges in the future against the Company based on conduct described in this Agreement, the Felony Information, the FDCA Information, or the Statement of Facts. If, however, the Office determines during this three-month period that the Company breached the Agreement during the Term, as described in Paragraph 20, the Office's ability to extend the Term, as described in Paragraph 3, or to pursue other remedies, including those described in Paragraphs 20–23, remains in full effect.

### **Breach of the Agreement**

20. If, during the Term, the Company (a) commits any felony under U.S. federal law; (b) provides in connection with this Agreement deliberately false, incomplete, or misleading information, including in connection with its disclosure of information about individual

culpability; (c) fails to abide by its plea agreement concerning the FDCA Information; (d) fails to cooperate as set forth in Paragraph 5 of this Agreement; (e) fails to implement a compliance program as set forth in Paragraphs 11–12 of this Agreement and Attachment C; (f) fails to make any reports as set forth in Paragraph 13 of this Agreement and Attachment D; or (g) otherwise fails to completely perform or fulfill each of the Company’s obligations under the Agreement and its duties to the Monitor, regardless of whether the Office becomes aware of such a breach after the Term is complete, the Company shall thereafter be subject to prosecution for any federal criminal violation of which the Office has knowledge, including, but not limited to, the charges in the Felony Information described in Paragraph 1, which may be pursued by the Office in the U.S. District Court for the District of Massachusetts or any other appropriate venue. Determination of whether the Company has breached the Agreement and whether to pursue prosecution of the Company shall be in the Office’s sole discretion. Any such prosecution may be premised on information provided by the Company or its personnel. Any such prosecution relating to the conduct described in the Statement of Facts or relating to conduct known to the Office prior to the Effective Date of this Agreement that is not time-barred by the applicable statute of limitations on the Effective Date of this Agreement may be commenced against the Company, notwithstanding the expiration of the statute of limitations, between the Effective Date and the expiration of the Term plus one year. By signing this Agreement, the Company agrees that the statute of limitations with respect to any such prosecution that is not time-barred on the Effective Date of this Agreement shall be tolled for the Term plus one year. In addition, the Company agrees that the statute of limitations as to any violation of U.S. federal law that occurs during the Term will be tolled from the date upon which the violation occurs until the earlier of the date upon which the Office is made

aware of the violation or the duration of the Term plus five years, and that this period shall be excluded from any calculation of time for purposes of the application of the statute of limitations.

21. In the event the Office determines that the Company has breached this Agreement, the Office agrees to provide the Company with written notice of such alleged breach prior to instituting any prosecution resulting from such breach. Within 15 calendar days of receipt of such notice, unless the government agrees to a different period, the Company shall have the opportunity to respond to the Office in writing to explain the nature and circumstances of such alleged breach, as well as the actions the Company has taken to address and remediate the situation, which explanation the Office shall consider in determining whether to pursue prosecution of the Company. The parties expressly understand and agree that if the Company fails to make the above-noted presentation within such period, it shall be presumed that the Company is in willful and material breach of this Agreement. The parties further understand and agree that the Office's exercise of discretion under this paragraph is not subject to review in any court or tribunal outside the Department of Justice and the Office.

22. In the event that the Office determines that the Company has breached this Agreement: (a) all statements made by or on behalf of the Company to the Office or to the Court and any testimony given by the Company before a grand jury, a court, or any tribunal, or at any legislative hearings, whether prior or subsequent to this Agreement, and any leads derived from such statements or testimony, shall be admissible in evidence in any and all criminal proceedings brought by the Office against the Company; and (b) the Company shall not assert any claim under the United States Constitution, Rule 11(f) of the Federal Rules of Criminal Procedure, Rule 410 of the Federal Rules of Evidence, or any other federal rule that any such statements or testimony made by or on behalf of the Company prior or subsequent to this Agreement, or any leads derived

therefrom, should be suppressed or are otherwise inadmissible. The decision whether conduct or statements of any current director, officer, or employee, or any person acting on behalf of, or at the direction of, the Company, will be imputed to the Company for the purpose of determining whether the Company has violated any provision of this Agreement shall be in the sole discretion of the Office.

23. The Company acknowledges that the Office has made no representations, assurances, or promises concerning what sentence may be imposed by the Court if the Company breaches this Agreement and this matter proceeds to judgment. The Company further acknowledges that any such sentence is solely within the discretion of the Court and that nothing in this Agreement binds or restricts the Court in the exercise of such discretion.

**Sale, Merger, or Other Change in Corporate Form of Company**

24. Except as may otherwise be agreed by the parties in connection with a particular transaction, the Company agrees that in the event that, during the Term, it undertakes any change in corporate form, including if it sells, merges, or transfers business operations that are material to the Company's operations, or to the operations of any parent company or subsidiaries involved in the conduct described in the Statement of Facts, as they exist as of the Effective Date of this Agreement, whether such sale is structured as a sale, asset sale, merger, transfer, or other change in corporate form, it shall include in any contract for sale, merger, transfer, or other change in corporate form a provision binding the purchaser, or any successor in interest thereto, to the obligations described in this Agreement. The purchaser or successor in interest must also agree in writing that the Office's ability to determine a breach under this Agreement is applicable in full force to that entity. The Company agrees that the failure to include these provisions in the transaction will make any such transaction null and void. The Company shall provide notice to the

Office at least 30 business days prior to undertaking any such sale, merger, transfer, or other change in corporate form. The Office shall notify the Company prior to such transaction (or series of transactions) if the Office determines that the transaction(s) will have the effect of circumventing or frustrating the enforcement purposes of this Agreement. At any time during the Term the Company engages in a transaction(s) that has the effect of circumventing or frustrating the enforcement purposes of this Agreement, the Office may deem it a breach of this Agreement pursuant to Paragraph 20 of this Agreement. Nothing herein shall restrict the Company from indemnifying (or otherwise holding harmless) the purchaser or successor in interest for penalties or other costs arising from any conduct that may have occurred prior to the date of the transaction, so long as such indemnification does not have the effect of circumventing or frustrating the enforcement purposes of this Agreement, as determined by the Office.

#### **Insolvency Proceedings**

25. The Company agrees that in the event that, during the Term, the Company or a third party commences a case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors seeking any order for relief of the Company's debts, or to adjudicate the Company as bankrupt or insolvent; or seeking appointment of a receiver, trustee, custodian, or other similar official for the Company or for all or any substantial part of the Company's assets (collectively an "Insolvency Proceeding") or if the Company's obligations under this Agreement are avoided for any reason, including but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code in an Insolvency Proceeding or in any other case, proceeding or action:

a. The Office, at its sole option, may subject the Company to prosecution for any federal criminal violation of which the Office has knowledge, including, but not limited to,



the charges in the Felony Information described in Paragraph 1, pursuant to the terms further set forth in Paragraphs 20–23 of this Agreement.

b. The Company shall take such actions as may be reasonably necessary or appropriate in an Insolvency Proceeding to ensure the Company will be able to comply with its obligations under this Agreement, including, without limitation, assuming its obligations under this Agreement and any agreements required pursuant to Paragraphs 14–17, including any agreements with the Monitor.

c. The terms of Paragraph 24 of this Agreement shall apply to any sale, merger, or other change in corporate form effectuated through an Insolvency Proceeding, including a sale of all or substantially of the Company’s assets.

d. Any Definitive Documents<sup>1</sup> related to an Insolvency Proceeding shall be consistent in all material respects with this Agreement and shall not in any manner, by their terms, contain any provisions that amend, modify, supplement, supersede, or conflict with any of the provisions of this Agreement. Any Definitive Documents related to an Insolvency Proceeding shall be in form and substance reasonably acceptable to the United States.

e. In any Insolvency Proceeding in which this Agreement is not assumed and the Company’s criminal fine and forfeiture obligations under the plea agreement concerning the FDCA Information are not otherwise paid in full, the United States shall be entitled to an

---

<sup>1</sup> Definitive Documents means all material agreements, schedules, and judicial or regulatory orders related to an Insolvency Proceeding that are necessary to implement this Agreement or materially affect this Agreement, including without limitation any plan of reorganization or liquidation and any order confirming such plan, and any motion to sell the Company or to sell all or substantially all of the Company’s assets and any order approving such sale.

undisputed, noncontingent, and liquidated claim that is not subject to reconsideration or subordination against the Company for the then-unpaid balance of the criminal fine and forfeiture.

f. The Company shall not argue or otherwise contend in an Insolvency Proceeding that the United States' claim, action, or proceeding with respect of the matters covered by this Agreement is subject to an automatic stay and, to the extent necessary, consents to relief from the automatic stay for cause under 11 U.S.C. § 362(d)(1).

g. The Company shall not argue that the dedicated bank account described in Paragraph 6 of this Agreement is property of the estate or that any agreement with respect to such account is an executory contract. Further, the Company shall not argue or otherwise contend in an Insolvency Proceeding that distributions from the dedicated bank account pursuant to Paragraphs 14–17 of this Agreement are subject to the automatic stay and, to the extent necessary, consents to relief from the automatic stay for cause under 11 U.S.C. § 362(d)(1).

26. The Company's obligations under this Agreement may not be avoided pursuant to 11 U.S.C. § 547 or 11 U.S.C. § 548(a)(1), and the Company shall not argue or otherwise take the position in any Insolvency Proceeding or in any other case, proceeding, or action that: (i) the Company's obligations under this Agreement may be avoided under 11 U.S.C. § 547; (ii) the mutual promises, covenants, and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to the Company; or (iii) the mutual promises, covenants, and obligations set forth herein are not intended to and do not, in fact, represent a reasonably equivalent exchange of value or that such mutual promises, covenants, and obligations are intended to hinder, delay, or defraud any entity to which the Company was or became indebted to on or after the date of this Agreement, within the meaning of 11 U.S.C. § 548(a)(1).

27. In evaluating whether to execute this Agreement, the Company and the Office warrant that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to the Company, within the meaning of 11 U.S.C. § 547(c)(1), and the Company and the Office conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Company and the Office warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which the Company was or became indebted to on or after the date of this transfer, within the meaning of 11 U.S.C. § 548(a)(1).

28. The Company shall provide notice to the Office at least 30 business days prior to commencing an Insolvency Proceeding.

#### **Public Statements by Company**

29. The Company expressly agrees that it shall not, through present or future attorneys, officers, directors, employees, agents, or any other person authorized to speak for the Company make any public statement, in litigation or otherwise, contradicting the acceptance of responsibility by the Company set forth above or the facts described in the Statement of Facts. Any such contradictory statement shall, subject to cure rights of the Company described below, constitute a breach of this Agreement, and the Company thereafter shall be subject to prosecution as set forth in Paragraphs 20–23 of this Agreement. The decision whether any public statement by any such person contradicting a fact contained in the Statement of Facts will be imputed to the Company for the purpose of determining whether it has breached this Agreement shall be at the sole discretion of the Office. If the Office determines that a public statement by any such person contradicts in whole or in part a statement contained in the Statement of Facts, the Office shall so

notify the Company, and the Company may avoid a breach of this Agreement by publicly repudiating such statement(s) within five business days after notification. The Company shall be permitted to raise defenses and to assert affirmative claims in other proceedings relating to the matters set forth in the Statement of Facts provided that such defenses and claims do not contradict, in whole or in part, a statement contained in the Statement of Facts. This Paragraph does not apply to any statement made by the Company in litigation against its former employees, or made by any present or former officer, director, employee, or agent of the Company in the course of any criminal, regulatory, or civil case initiated against such individual, unless such individual is speaking on behalf of the Company.

30. The Company agrees that if it, its parent company, or any of its direct or indirect subsidiaries issues a press release or holds any press conference in connection with this Agreement, the Company shall first consult with the Office to determine (a) whether the text of the release or proposed statements at the press conference are true and accurate with respect to matters between the Office and the Company; and (b) whether the Office has any objection to the release.

31. The Office agrees, if requested, to bring to the attention of law enforcement and regulatory authorities the facts and circumstances relating to the nature of the conduct underlying this Agreement, including the nature and quality of the Company's cooperation and remediation. By agreeing to provide this information to such authorities, the Office is not agreeing to advocate on behalf of the Company, but rather is agreeing to provide facts to be evaluated independently by such authorities.

### **Publication**

32. Within 10 business days of the Effective Date of this Agreement, the Company agrees to make the Information and this Agreement available to the public on its website in a

conspicuous location to the Office's reasonable satisfaction for 24 months after the Effective Date of this Agreement.

**Limitations on Binding Effect of Agreement**

33. This Agreement is binding on the Company and the Office but specifically does not bind any other component of the Department of Justice, other federal agencies, or any state, local, or foreign law enforcement or regulatory agencies, or any other authorities, although the Office will bring the cooperation of the Company and its compliance with its other obligations under this Agreement to the attention of such agencies and authorities if requested to do so by the Company.

**Notice**

34. Unless otherwise directed by the Office in writing, any notice to the Office under this Agreement shall be given by personal delivery by a recognized delivery service, or registered or certified mail, addressed to:

Chief, Health Care Fraud Unit  
U.S. Attorney's Office for the District of Massachusetts  
John Joseph Moakley Federal Courthouse  
One Courthouse Way  
Boston, MA 02210

35. Any notice to the Company under this Agreement shall be given by personal delivery, overnight delivery by a recognized delivery service, or registered or certified mail, addressed to:

Legal Department  
Magellan Diagnostics, Inc.  
101 Billerica Avenue  
North Billerica, MA 01862

Adam J. Hollingsworth  
Jones Day  
901 Lakeside Avenue  
Cleveland, OH 44114

**Complete Agreement**

36. This Agreement, including its attachments, sets forth all the terms of the agreement between the Company and the Office. No amendments, modifications, or additions to this Agreement shall be valid unless they are in writing and signed by the Office, the attorneys for the Company, and a duly authorized representative of the Company.

\* \* \*

**FOR THE UNITED STATES ATTORNEY'S OFFICE  
FOR THE DISTRICT OF MASSACHUSETTS**

Date: 5/21/24

JOSHUA S. LEVY  
Acting United States Attorney

By: 

JAMES D. HERBERT  
KELLY BEGG LAWRENCE  
ELYSA Q. WAN  
LESLIE A. WRIGHT  
Assistant U.S. Attorneys

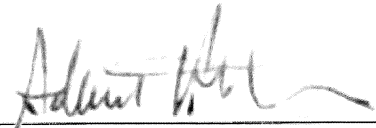
**FOR MAGELLAN DIAGNOSTICS, INC.**

Date: 5/21/24

By: 

EMERSON C. MOSER  
Senior Vice President and General Counsel  
Magellan Diagnostics, Inc.

Date: \_\_\_\_\_

By: 

ADAM J. HOLLINGSWORTH  
Counsel for Magellan Diagnostics, Inc.  
Jones Day

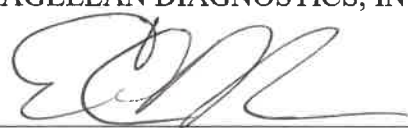
## COMPANY OFFICER'S CERTIFICATE

I have read this Agreement and carefully reviewed every part of it with outside counsel for Magellan Diagnostics, Inc. (the "Company"). I understand the terms of this Agreement and voluntarily agree, on behalf of the Company, to each of its terms. Before signing this Agreement, I consulted outside counsel for the Company. Counsel fully advised me of the rights of the Company, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into this Agreement.

I have carefully reviewed the terms of this Agreement with the Board of Directors of the Company. I have advised and caused outside counsel for the Company to advise the Board of Directors fully of the rights of the Company, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into this Agreement.

No promises or inducements have been made other than those described in this Agreement. Furthermore, no one has threatened or forced me, or to my knowledge any person authorizing this Agreement on behalf of the Company, in any way to enter into this Agreement. I am also satisfied with outside counsel's representation in this matter. I certify that I am the Senior Vice President and General Counsel for the Company and that I have been duly authorized by the Company to execute this Agreement on behalf of the Company.

Date: 5/21/24


MAGELLAN DIAGNOSTICS, INC.  
  
By: \_\_\_\_\_  
EMERSON C. MOSER  
Senior Vice President and General Counsel  
Magellan Diagnostics, Inc.



## CERTIFICATE OF COUNSEL

I am counsel for Magellan Diagnostics, Inc. (the “Company”) in the matter covered by this Agreement. In connection with such representation, I have examined relevant Company documents and have discussed the terms of this Agreement with the Company Board of Directors. Based on our review of the foregoing materials and discussions, it is my opinion that the representative of the Company signing this Agreement has been duly authorized to enter into this Agreement on behalf of the Company and that this Agreement has been duly and validly authorized, executed, and delivered on behalf of the Company and is a valid and binding obligation of the Company. Further, I have carefully reviewed the terms of this Agreement with the Board of Directors and the Senior Vice President and General Counsel of the Company. I have fully advised them of the rights of the Company, of possible defenses, of the Sentencing Guidelines’ provisions, and of the consequences of entering into this Agreement. To my knowledge, the decision of the Company to enter into this Agreement, based on the authorization of the Board of Directors, is an informed and voluntary one.

Date: 5/21/2024

By:   
ADAM J. HOLLINGSWORTH  
Jones Day  
Counsel for Magellan Diagnostics, Inc.