

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
QUEST DIAGNOSTICS INCORPORATED**

I. PREAMBLE

Quest Diagnostics Incorporated hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements), and with the statutes, regulations, and written directives of the Food and Drug Administration (FDA requirements). Contemporaneously with this CIA, Quest is entering into a Settlement Agreement with the United States. Quest will also enter into settlement agreements with various states and Quest's agreement to this CIA is a condition precedent to those settlement agreements.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Quest under this CIA shall be 5 years from the effective date of this CIA, unless otherwise specified. The effective date shall be the date on which the final signatory of this CIA executes this CIA (Effective Date). Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Quest's final annual report; or (2) any additional materials submitted by Quest pursuant to OIG's request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. The term "IVD Product" means in vitro diagnostic test kits that have been cleared or approved by the Food and Drug Administration pursuant to the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, et

seq., and that have been commercially distributed by IVD Subsidiaries to a third party for use in Government-Reimbursed Laboratory Tests.

2. Quest

- a. "Quest" means the United States (U.S.)-based operations of Quest Diagnostics Incorporated and all Quest Affiliates.
- b. "Quest Affiliates" means (i) all subsidiaries of Quest Diagnostics Incorporated, (ii) all joint ventures in which Quest Diagnostics Incorporated has the right of control, as listed in Appendix A, and (iii) any subsidiaries or joint ventures (in which Quest Diagnostics has the right of control) acquired by Quest Diagnostics Incorporated or a Quest Affiliate during the term of this CIA.
- c. "IVD Subsidiaries" means the U.S.-based IVD Product manufacturing operations of Hemocue, Inc., Enterix, Inc., and Focus Diagnostics, Inc., and any U.S.-based IVD Product manufacturing entity acquired by Quest during the term of this CIA.
- d. "Quest Diagnostics" means Quest Diagnostics Incorporated without any Quest Affiliates.

3. "Covered Persons" means

- a. all owners of Quest who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5%; and (2) acquired the ownership interest through public trading);
- b. all U.S.-based officers and employees of Quest and members of Quest's boards of directors;
- c. all U.S.-based contractors, subcontractors, agents, and other persons who perform Quality Systems - Related Functions (as defined below) for Quest that are ordinarily performed by employees.

Notwithstanding the above, this term does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year.

4. "Management Covered Persons" means

- a. all Quest officers and director-level employees, other than those who work for or on behalf of an IVD Subsidiary, who are Covered Persons;
- b. all Covered Persons who work for or on behalf of Quest's compliance department; and
- c. all employees who are Covered Persons and provide legal advice to Quest.

5. "IVD-Subsidiary Covered Persons" means

- a. all U.S.-based Covered Persons who are employees of an IVD Subsidiary; and
- b. all U.S.-based contractors, subcontractors, agents and other persons who perform Quality Systems-Related Functions (as defined below) for IVD Subsidiaries that are ordinarily performed by employees.

6. The term "Quality System - Related Functions" means the IVD Subsidiaries' systems for achieving compliance with 21 C.F.R. Part 820 – Subparts A, B, G, I, and J, and §§ 820.186 and 820.198 of Subpart M; and reviewing and approving IVD Product labeling to assure labeling compliance with 21 C.F.R. §§ 809.10(a) and (b).

7. The term "Government-Reimbursed Laboratory Tests" means all laboratory tests using IVD Products manufactured by IVD Subsidiaries that are performed for beneficiaries of a Federal health care program and reimbursed by such a program.

8. The term “IVD Products Compliance Committee” means the compliance committee that supports the Compliance Officer with regard to FDA requirements applicable to IVD Products.

9. The term “Federal Health Care Program Compliance Committee” means the compliance committee that supports the Compliance Officer with regard to the Federal health care program requirements applicable to Quest Diagnostics.

10. The term “Business Unit or Location” means U.S.-based Quest regional laboratories and IVD Subsidiaries.

11. The term “Certifying Employee” means all Quest presidents, chairpersons, chief executive officers, vice presidents, sales directors, and managing directors of Business Units who are Covered Persons.

III. CORPORATE INTEGRITY OBLIGATIONS

Quest shall establish and maintain a Compliance Program that includes the following elements:

A. Compliance Responsibilities of Compliance Officer, Compliance Committees, the Board of Directors, and Management Certifications.

1. *Compliance Officer.* Within 90 days after the Effective Date, Quest shall appoint an individual to serve as its Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be responsible for ensuring the development and implementation of policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements and FDA requirements. The Compliance Officer shall be a member of senior management of Quest Diagnostics, shall report directly to Quest’s CEO, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Quality, Safety, and Compliance Committee (QSC) of the Quest Diagnostics Board of Directors, and shall be authorized to report on such matters to the QSC at any time. The Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Quest as well as for any reporting obligations created under this CIA.

Quest shall not assert a privilege to the OIG with respect to legal advice or counsel Quest obtains after the Effective Date and during the term of the CIA from the Compliance Officer or any employee reporting to the Compliance Officer regarding (i) Federal health care programs, statutes and CMS regulations; and (ii) FDA regulations governing IVD Products manufactured by IVD Subsidiaries, or (iii) compliance with the terms of this CIA. The Compliance Officer or any employee reporting to the Compliance Officer may seek legal advice from internal or external attorneys outside the Compliance Department without waiving any applicable privilege.

Quest shall report to OIG, in writing, any changes in the identity or position description of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

2. *Compliance Committees.* Within 90 days after the Effective Date, Quest shall appoint an IVD Products Compliance Committee and a Federal Health Care Programs Compliance Committee. Each Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management as are necessary and have the expertise and experience to assist in meeting the requirements of this CIA (e.g., senior executives of relevant departments, such as marketing, manufacturing, laboratory testing, clinical trials, healthcare information technology, risk assessment, human resources, internal audit, legal, medical affairs, and operations). The Compliance Officer shall chair each Compliance Committee and each Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

Quest shall report to OIG, in writing, any changes in the composition of either Compliance Committee, or any actions or changes that would affect either Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

3. *Board of Directors.* The Quest Diagnostics' Board of Directors (the Board) shall retain ultimate responsibility for the review and oversight of matters related to compliance with Federal health care program requirements, FDA requirements, and the obligations of the CIA. The Board has established the QSC. The Board shall maintain the QSC during the term of this CIA. The Board shall notify OIG within 30 days of any

changes in the membership. The Board, through its QSC, shall, at a minimum, be responsible for the following:

a. Oversight: The QSC shall meet at least quarterly and shall review and oversee Quest's Compliance Program, including but not limited to the performance of the Compliance Officer, the compliance department, and the Compliance Committees.

b. Compliance Expert Review:

i. Within 120 days of the Effective Date of this CIA, the QSC shall retain an independent and objective individual or entity with expertise in compliance with health care compliance programs (Compliance Expert) to assist the QSC with its responsibilities related to oversight of Quest's Compliance Program.

ii. The QSC shall arrange for the performance of an annual review (Compliance Program Review) for each Reporting Period of the CIA by the Compliance Expert of the effectiveness of Quest's Compliance Program related to the reporting of compliance concerns, the notification of appropriate management personnel responsible for the resolution of the compliance concerns and the subsequent reporting to the Board or senior management of Quest Diagnostics, as appropriate, of those concerns that prove to be significant and material. This process is to be known as the "Compliance Concerns Process." In connection with the Compliance Program Review, the Compliance Expert shall evaluate the involvement of the compliance department, the IVD Products Compliance Committee, and the Federal Health Care Program Compliance Committee in the Compliance Concerns Process. The QSC shall review the results of the Compliance Program Review as part of the review and evaluation of Quest's Compliance Program. Quest shall not assert a privilege to the OIG with respect to any advice, counsel, or work product provided by the Compliance Expert after the Effective Date and during the term of the CIA.

iii. The Compliance Expert shall create a work plan for the Compliance Program Review and shall complete performance of the annual Compliance Program Review. The Compliance Expert shall prepare a written report in connection with the Compliance Program Review (Compliance Program Review Report). The Compliance Program Review Report shall include, at a minimum, a copy of the work plan, the review findings, and the recommendations to the QSC regarding Quest's Compliance Concerns Process.

iv. The Compliance Expert shall perform the Compliance Program Review in a professionally independent and objective fashion, taking into account any other business relationships or engagements that may exist between the Compliance Expert and Quest.

v. The requirements and responsibilities of the Compliance Expert are set forth in Appendix B of this CIA, which is incorporated by reference.

c. Board Resolution: For each Reporting Period of the CIA, the Board shall adopt a resolution, signed by each individual member of the Board, summarizing its review and oversight of Quest's compliance with the requirements of the Federal health care program regulations, the FDA requirements, and the obligations of this CIA.

At a minimum, the resolution shall include the following language:

“The Board of Directors has made a reasonable and due inquiry into the operations and effectiveness of Quest's Compliance Program for the period _____, including the performance of the Compliance Officer, the Compliance Committees, and the compliance department. In connection with its inquiry, the Board of Directors has retained an independent and objective Compliance Expert with expertise in health care compliance programs to support the Board of Directors' responsibilities. The Board of Directors has arranged for the Compliance Expert to perform a Compliance Program Review to (i) assess the effectiveness of Quest's Compliance Concerns Process and (ii) provide the Board of Directors with recommendations with respect to the Compliance Concerns Process. The Board of Directors has reviewed the Compliance Program Review Report and has adopted the recommendations of the Compliance Expert set forth in the Compliance Program Review Report. Based on all of these steps, the Board has concluded that, to the best of its knowledge, Quest has implemented an effective Compliance Program.”

If the Board is unable to provide such a conclusion in the resolution, the Board shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Compliance Program at Quest. In addition, if the Board decides not to adopt certain recommendations of the Compliance Expert, the Board shall identify all recommendations it has decided not to adopt in an attachment to its resolution together with a written explanation of the reason(s) why it has decided not to adopt such recommendations.

The Board's resolution and the Compliance Program Review Report shall be provided to the OIG with the Annual Report, as provided in Section V.B below.

4. Management Accountability and Certifications. Quest represents that compliance is a component of each employee's performance evaluation. In addition to the responsibilities set forth in this CIA for all Covered Persons, all Certifying Employees are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify in writing or electronically that, to the best of their knowledge, the applicable area of authority is compliant with applicable Federal health care program and FDA requirements, and the obligations of this CIA.

For each Reporting Period, each Certifying Employee, other than those employed by IVD Subsidiaries, shall certify in writing or electronically that:

"I have been trained on and understand the compliance requirements and responsibilities as they relate to [department or functional area], an area under my supervision. My job responsibilities include ensuring compliance with regard to the _____ [insert name of the department or functional area.] To the best of my knowledge, except as otherwise described herein, the _____ [insert name of the department or functional area] of [Quest/Quest Affiliate] is in material compliance with applicable Federal health care program requirements and the obligations of the CIA."

For each Reporting Period, each IVD Subsidiary Certifying Employee shall certify in writing or electronically that:

"I have been trained on and understand the compliance requirements and responsibilities as they relate to [department or functional area], an area under my supervision. My job responsibilities include ensuring compliance with regard to the _____ [insert name of the department or functional area.] To the best of my knowledge, except as otherwise described herein, the _____ [insert name of the department or functional area] of [IVD Subsidiaries] is in material compliance with applicable FDA requirements and the obligations of the CIA."

If any Certifying Employee is unable to provide such a conclusion in the certification, the Certifying Employee shall include in the certification a written explanation of the reasons why he or she is unable to provide the conclusion and the steps being taking to address the issue(s) identified in the certification.

The certifications shall be made available to the OIG upon request.

B. Written Standards.

1. *Code of Conduct.* Within 120 days after the Effective Date, Quest shall develop, implement, and distribute to all Covered Persons a written Code of Conduct. Quest shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

- a. Quest's commitment to full compliance with all Federal health care program requirements and FDA requirements, as applicable;
- b. Quest's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements, FDA requirements, and with Quest's own Policies and Procedures as implemented pursuant to Section III.B (including the requirements of this CIA), as applicable;
- c. the requirement that all of Quest's Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by Quest, suspected violations of any Federal health care program requirements, FDA requirements, or of Quest's own Policies and Procedures, as applicable;
- d. the possible consequences to both Quest and Covered Persons of failure to comply with Federal health care program requirements, FDA requirements, and with Quest's own Policies and Procedures and the failure to report such noncompliance, as applicable; and
- e. the right of all individuals to use the Disclosure Program described in Section III.E, and Quest's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Within 120 days after the Effective Date, each Covered Person shall certify, in writing or electronically, that he or she has received, read, understood, and shall abide by Quest's Code of Conduct. New Covered Persons shall receive the Code of Conduct and

shall complete the required certification within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later, in accordance with the new Covered Persons training, discussed at Section III.C.1 below.

Quest shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code of Conduct shall be distributed within 30 days after any revisions are finalized. Each Covered Person shall certify, in writing or electronically, that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.

2. *Policies and Procedures.* To the extent not already accomplished, within 120 days after the Effective Date, Quest shall take the following actions:

a. Quest shall implement written policies and procedures regarding the operation of Quest's compliance program and its compliance with Federal health care program requirements. At a minimum, the Quest Policies and Procedures shall address:

i. the subjects relating to the Code of Conduct identified in Section III.B.1; and

ii. the handling of compliance concerns received by Quest, including guidelines for evaluating and investigating compliance concerns and implementing the appropriate corrective action to ensure that problems have been remedied and properly reported;

b. Quest shall ensure implementation at the IVD Subsidiaries of policies and procedures regarding IVD Subsidiaries' Quality Systems-Related Functions.

Within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be made available to all individuals whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), Quest shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date

of any revisions, the relevant portions of any such revised Policies and Procedures shall be made available to all individuals whose job functions relate to those Policies and Procedures.

C. Training and Education.

1. *General Training.* Within 120 days after the Effective Date, Quest shall provide at least one hour of General Training to each Covered Person. This training, at a minimum, shall explain:

- a. Quest's CIA requirements; and
- b. Quest's Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues); and
- c. the duty to report, and the process to follow when reporting, compliance concerns.

New Covered Persons shall receive one hour of training that includes the subjects covered in the General Training within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. *Management Covered Persons Specific Training.* Within 120 days after the Effective Date, each Management Covered Person shall receive at least one hour of Management Covered Persons Specific Training in addition to the General Training required above. In the first Annual Reporting Period, this training shall include a discussion of

- a. the role and responsibilities of Management Covered Persons in implementing and effectuating Quest's Compliance Program;
- b. policies and procedures relating to the Compliance Concerns Process; and

- c. the facts that gave rise to this CIA as a case study, focusing on issue identification, organizational communication, and preventative action.

In subsequent Reporting Periods, Quest shall develop and provide one hour of Management Covered Persons Specific Training based on the findings of the Compliance Expert's Compliance Program Review.

3. *IVD-Subsidiary Covered Persons Specific Training.* Within 120 days after the Effective Date, each IVD-Subsidiary Covered Person shall receive at least two hours of IVD-Subsidiary Covered Persons Specific Training in addition to the General Training required above. This training shall include a discussion of:

- a. the applicable FDA requirements regarding IVD Products;
- b. policies and procedures applicable to the quality and labeling of IVD Products;
- c. the legal sanctions for violations of the FDA requirements;
- d. disciplinary policies and procedures for violations of Quest's Policies and Procedures, including those policies relating to FDA requirements;
- e. examples of proper and improper practices related to quality and labeling of IVD Products;
- f. the subjects covered in the Management Covered Specific Persons Training tailored for IVD-Subsidiary Covered Persons Specific Training; and
- g. the role, with regard to the IVD Subsidiaries, that Quest's Compliance Officer, IVD Products Compliance Committee, and compliance department each play in the investigation and resolution of compliance concerns that arise in relation to the quality and labeling of IVD Products.

After receiving the IVD-Subsidiary Covered Person Specific Training, each IVD-Subsidiary Covered Person shall receive at least one hour of Specific Training in each subsequent Reporting Period.

New Management Covered Persons and IVD-Subsidiary Covered Persons shall receive Specific Training within 30 days after the beginning of their employment or becoming new Management Covered Persons or IVD Covered Persons, or within 120 days after the Effective Date, whichever is later. A Covered Person who has completed the applicable Specific Training shall review the work of new Covered Persons required to take Specific Training, to the extent that the work relates to Government-Reimbursed Laboratory Tests or other testing services reimbursed by the Federal health care programs, until such time as the new Covered Person completes the applicable Specific Training.

4. *Certification.* Each individual who is required to attend training shall certify, in writing, or in electronic form, if applicable, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials. The certifications and course materials shall be made available to OIG, upon request.

5. *Qualifications of Trainer.* Persons providing the training shall be knowledgeable about the subject area.

6. *Update of Training.* Quest shall review the training annually, and, where appropriate, update the training to reflect changes in Federal health care program and FDA requirements, as applicable, any issues discovered during internal audits, Compliance Program Reviews, or the Independent Review Organization(s) Review, and any other relevant information.

7. *Computer-based Training.* Quest may provide the training required under this CIA through appropriate computer-based training approaches. If Quest chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training. If Quest chooses to provide computer-based training, all applicable requirements to provide a number of "hours" of training in this Section III.C may be met with respect to computer-based training by

providing the required number of “normative” hours as that term is used in the computer-based training industry.

D. Review Procedures.

1. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, Quest shall engage an entity (or entities), such as an accounting, auditing, law, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to assist Quest in evaluating its IVD Subsidiaries’ Quality Systems – Related Functions. The IRO review will be referred to as the IVD Products Review.

The applicable requirements relating to the IRO are outlined in Appendix C to this CIA, which is incorporated by reference. The applicable requirements relating to the IVD Products Review are outlined in Appendix D to this CIA, which is incorporated by reference.

Each IRO engaged by Quest shall have expertise in the applicable FDA requirements as may be appropriate to the specific Review for which it is retained. Each IRO shall assess, along with Quest, whether it can perform the engagement in a professionally independent and objective fashion, as appropriate to the nature of the review, taking into account any other business relationships or other engagement that may exist. Quest shall not assert a privilege to the OIG with respect to any advice, counsel, or work product provided by the IRO during the term of the CIA. The OIG must approve Quest’s selection of each IRO prior to its engagement.

To the extent the scope of IVD Subsidiaries’ operations and corresponding FDA regulatory requirements change, the scope of the IRO’s engagement may be altered to correspond with IVD Subsidiaries’ operational activities and regulatory requirements. Quest must notify the OIG in writing within 30 days of the change, and the OIG must provide written approval of any changes in the IRO engagement.

2. *Frequency of the IVD Products Review.* The Reviews shall be performed annually and shall cover each of the Reporting Periods.

3. *Retention of Records.* The IRO and Quest shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Quest) related to the Reviews.

4. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Quest a certification or sworn affidavit that it has evaluated its professional independence and objectivity, as appropriate to the nature of the engagement, with regard to the IVD Products Review and that it has concluded that it is, in fact, independent and objective.

E. Disclosure Program.

Prior to the Effective Date, Quest established a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the appropriate compliance officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Quest's policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. Quest shall continue to appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall continue to emphasize a nonretribution, nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Quest shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be made available to OIG upon request.

F. Ineligible Persons.

1. *Definitions.* For purposes of this CIA:

- a. an "Ineligible Person" shall include an individual or entity who:
 - i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or
 - ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

- b. "Exclusion Lists" include:
 - i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.oig.hhs.gov>); and
 - ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://www.epls.gov>).

2. *Screening Requirements.* Quest shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

- a. Quest shall continue to screen all prospective and current Covered Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall implement policies within 120 days of the CIA Effective Date requiring such Covered Persons to disclose whether they are Ineligible Persons.

- b. Quest represents that it screened all current U.S.-based employees within the six-month period preceding the Effective Date. Quest

shall continue screening all current Covered Persons on an annual basis thereafter.

c. Within 120 days after the Effective Date, Quest shall implement a policy requiring all Covered Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in this Section affects the responsibility of (or liability for) Quest to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person. Quest understands that items or services furnished by excluded persons are not payable by Federal health care programs and that Quest may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Quest meets the requirements of Section III.F.

3. *Removal Requirement.* If Quest has actual notice that a Covered Person has become an Ineligible Person, Quest shall remove such Covered Person from responsibility for, or involvement with, Quest's business operations related to the Federal health care programs and shall remove such Covered Person from any position for which the Covered Person's compensation or the items or services furnished, ordered, or prescribed by the Covered Person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the Covered Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If Quest has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term, Quest shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of IVD Products used to perform Government Reimbursed Laboratory Tests, testing services, or any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings.

Within 30 days after the Effective Date or discovery by Quest's compliance department or legal department, whichever is later, Quest shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Quest conducted or brought by a

governmental entity or its agents involving an allegation that Quest has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Quest shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

H. Notification of Communications with FDA

Within 30 days after the Effective Date or the date on which Quest receives or submits any written report, correspondence, or communication between an IVD Subsidiary and the FDA that discusses an IVD Subsidiary's alleged material non-compliance with applicable FDA Regulations, whichever is later, Quest shall provide a copy of the report, correspondence, or communication to the OIG. If an IVD Subsidiary receives or is notified of any adverse final determination made by the FDA, Quest shall notify OIG in writing within 15 days after receipt of such notification. Quest shall also provide written notice to the OIG within 30 days after learning of the resolution of any such disclosed matter, and shall provide the OIG with a description of the findings and/or results of the matter, if any.

I. Notice to Customers

Within 90 days after the Effective Date, Quest shall send, by postage prepaid first class mail, Certificate of Mailing requested, an exact copy of the notice attached hereto as Attachment A, showing the date of the mailing, to each U.S.-based person or entity to which Nichols Institute Diagnostics (NID) sold NID's Advantage Intact and Bio-Intact PTH test kits between October 1, 2004 and April 1, 2006.

This mailing shall notify the recipients of the terms of the settlement with the United States, including an explanation of the conduct to which NID, a wholly-owned subsidiary of Quest, pled guilty and the conduct resolved by the civil settlement, including the identification of the specific diagnostic products at issue, as set forth in Attachment A. The mailing shall also notify such person or entity that they (it) may report any concerns or questions regarding an IVD Product manufactured by NID to a compliance telephone number or e-mail address established by Quest or the FDA.

The Compliance Officer (or a designee) shall maintain a log of all calls and messages received through the Quest compliance telephone number listed in the notice.

The log shall include a record and summary of each call and message received (whether anonymous or not), the status of the call or message, and any corrective action taken in response to the call or message. As part of the Implementation Report and each Annual Report, Quest shall provide to the OIG a summary of the calls and messages received.

The Notice Log shall be made available to the OIG upon request.

J. Reporting.

1. *Overpayments*.

a. *Definition of Overpayments*. For purposes of this CIA, an “Overpayment” shall mean the amount of money Quest has received in excess of the amount due and payable under any Federal health care program requirements.

b. *Reporting of Overpayments*. If, at any time, Quest identifies or learns of any Overpayment, Quest shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days after identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. Also, within 30 days after identification of the Overpayment, Quest shall repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified, within 30 days after identification, Quest shall notify the payor of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor’s policies, and, for Medicare contractors, shall include the information contained on the Overpayment Refund Form, provided as Appendix E to this CIA. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

2. Reportable Events.

a. *Definition of Reportable Event.* For purposes of this CIA, a “Reportable Event” means anything that involves:

- i. a substantial Overpayment;
- ii. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program or FDA requirement regarding the Quality Systems – Related Functions for which penalties or exclusion may be authorized; or
- iii. the filing of a bankruptcy petition by Quest.

A Reportable Event may be the result of an isolated event or a series of occurrences.

b. *Reporting of Reportable Events.* If Quest determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Quest shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:

i. If the Reportable Event results in an Overpayment, the report to OIG shall be made at the same time as the notification to the payor required in Section III.J.1, and shall include all of the information on the Overpayment Refund Form, as well as:

(A) the payor’s name, address, and contact person to whom the Overpayment was sent; and

(B) the date of the check and identification number (or electronic transaction number) by which the Overpayment was repaid/refunded;

- ii. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
- iii. a description of Quest's actions taken to correct the Reportable Event; and
- iv. any further steps Quest plans to take to address the Reportable Event and prevent it from recurring.
- v. If the Reportable Event involves the filing of a bankruptcy petition, the report to the OIG shall include documentation of the filing and a description of any Federal health care program authorities implicated.

IV. CHANGES TO BUSINESS UNITS OR LOCATIONS

A. Change or Closure of Business Unit or Location. In the event that, after the Effective Date, Quest changes Locations or closes a Business Unit or Location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Quest shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change or closure of the Location.

B. Purchase or Establishment of New Business Unit or Location. In the event that, after the Effective Date, Quest purchases or establishes a new Business Unit or Location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Quest shall notify OIG at least 30 days prior to such purchase or the operation of the new Business Unit or Location. This notification shall include the address of the new Business Unit or Location, phone number, fax number, Medicare provider number and/or supplier number, if applicable, and the name and address of the contractor that issued each number, if applicable. Each new Business Unit or Location and all Covered Persons at each new Business Unit or Location shall be subject to the applicable requirements of this CIA.

C. Sale of Unit or Location. In the event that, after the Effective Date, Quest proposes to sell any or all of its Business Units or Locations that are subject to this CIA, Quest shall notify OIG of the proposed sale at least 30 days prior to the sale of such Business Unit or Location. This notification shall include a description of the Business

Unit or Location to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This CIA shall be binding on the purchaser of such Business Unit or Location, unless otherwise determined and agreed to in writing by the OIG.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 150 days after the Effective Date, Quest shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;

2. the names and positions of the members of the Compliance Committees required by Section III.A.2;

3. the names and positions of the Certifying Employees as required by Section III A.4;

4. a copy of Quest's Code of Conduct required by Section III.B.1;

5. a copy of all Policies and Procedures required by Section III.B.2;

6. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

7. the following information regarding each type of training required by Section III.C:

a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions;

- b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request;

8. a description of the Disclosure Program required by Section III.E;
9. the following information regarding the Compliance Expert: (a) identity, address, and phone number; (b) a copy of the engagement letter; and (c) a summary and description of any and all current and prior engagements and agreements between Quest, Board members, and the Compliance Expert;
10. certification from the Compliance Expert regarding their or its professional independence and objectivity with respect to Quest and Board members;
11. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; and (c) a summary and description of any and all current and prior engagements and agreements between Quest and the IRO;
12. a certification from the IRO regarding its professional independence and objectivity with respect to Quest;
13. a description of the process by which Quest fulfills the requirements of Section III.F regarding Ineligible Persons;
14. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken in response to the screening and removal obligations set forth in Section III.F; and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services furnished, ordered or prescribed by an Ineligible Person;
15. a summary of the calls and messages received in response to the mailing sent to NID Customers as set forth in Section III.I;
16. a list of all of Quest's Business Units or Locations (including locations and mailing addresses); the corresponding name under which each Location is doing

business; the corresponding phone numbers and fax numbers; each Location's Medicare provider number and/or supplier number(s) if applicable; and the name and address of each Medicare contractor to which Quest currently submits claims, if applicable;

17. a description of Quest's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

18. the certifications required by Section V.C.

B. Annual Reports. Quest shall submit to OIG annually a report with respect to the status of, and findings regarding, Quest's compliance activities for each of the 5 Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer, and any change in the membership of the Compliance Committees or the QSC as described in Section III.A;
2. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B.2 and the reasons for such changes (e.g., change in payor policy);
3. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
4. the following information regarding each type of training required by Section III.C:
 - a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions;
 - b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions. A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request;

5. a complete copy of all reports prepared pursuant to Section III.A.3, along with a copy of the Compliance Expert's engagement letter (if applicable);
6. the Board's resolution adopted pursuant to Section III.A.3;
7. a summary and description of any and all current and prior engagements and agreements between Quest, Board members, and the Compliance Expert;
8. certification from the Compliance Expert regarding their or its professional independence and objectivity with respect to Quest and Board members, if different from what was submitted as part of the Implementation Report;
9. the steps being taken to address issues identified in the certifications of Certifying Employees pursuant to Section III.A.4;
10. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letter (if applicable);
11. Quest's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.D;
12. a summary and description of any and all current and prior engagements and agreements between Quest and the IRO, if different from what was submitted as part of the Implementation Report;
13. a certification from the IRO regarding its professional independence and objectivity with respect to Quest;
14. a summary of the calls and messages received in response to the letter sent to NID customers as set forth in Section III.I;
15. a summary of Reportable Events (as defined in Section III.J) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;
16. a report of the aggregate Overpayments returned to the Federal health care programs. Overpayment amounts shall be broken down into the following

categories: Medicare, Medicaid (report each applicable state separately, if applicable), and other Federal health care programs. Overpayment amounts that are routinely reconciled or adjusted pursuant to policies and procedures established by the payor do not need to be included in this aggregate Overpayment report;

17. a summary of the disclosures in the disclosure log required by Section III.E that relate to Federal health care program or FDA requirements;

18. any changes to the process by which Quest fulfills the requirements of Section III.F regarding Ineligible Persons;

19. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken by Quest in response to the screening and removal obligations set forth in Section III.F; and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services furnished, ordered or prescribed by an Ineligible Person;

20. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

21. a description of all changes to the most recently provided list of Quest's Business Units and Locations (including addresses) as required by Section V.A.16; the corresponding name under which each Business Unit or Location is doing business; the corresponding phone numbers and fax numbers if applicable; each Business Unit or Location's Medicare provider number(s) and/or supplier number(s) if applicable; and the name and address of each Medicare contractor to which the Business Unit or Location currently submits claims if applicable; and

22. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that:

1. to the best of his or her knowledge, except as otherwise described in the applicable report, Quest is in compliance with all of the requirements of this CIA;

2. he or she has reviewed the certifications of each Certifying Employee;

3. he or she has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information in the Report is accurate and truthful; and

4. to the best of his or her knowledge, Quest has complied with its obligations under the Settlement Agreement: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs;

D. Designation of Information. Quest shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Quest shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: 202.619.2078
Facsimile: 202.205.0604

Quest:

Timothy U. Sharpe
Vice President, Compliance
1201 S. Collegeville Rd.
Collegeville, PA 19426
Telephone: 610.454.6500
Facsimile:

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt. Upon request by OIG, Quest may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), either instead of or in addition to, a paper copy.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Quest's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Quest's locations for the purpose of verifying and evaluating: (a)

Quest's compliance with the terms of this CIA; and (b) Quest's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Quest to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Quest's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Quest shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Quest's employees may elect to be interviewed with or without a representative of Quest present.

VIII. DOCUMENT AND RECORD RETENTION

Quest shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CIA, for 6 years (or longer if otherwise required by law) from the Effective Date.

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Quest prior to any release by OIG of information submitted by Quest pursuant to its obligations under this CIA and identified upon submission by Quest as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Quest shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

Quest is expected to fully and timely comply with all of its CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Quest and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Quest fails to establish and implement any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. a written Code of Conduct;
- d. written Policies and Procedures;
- e. the training of Covered Persons, Management Covered Persons, and IVD Subsidiary Covered Persons;
- f. a Disclosure Program;
- g. Ineligible Persons screening and removal requirements;
- h. notice to NID customers; and
- i. notification of Government investigations or legal proceedings.

2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day the Board fails to engage a Compliance Expert, as required in Section III.A.3 and Appendix B; or Quest fails to engage an IRO, as required in Section III.D and Appendix C.

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Quest fails to submit the Implementation Report or any Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Quest fails to submit any Compliance Program Review Report or Board Resolution in accordance with the requirements of Section III.A.3 and Appendix B, or any IVD Products Review Report in accordance with the requirements of Section III.D and Appendix D.

5. A Stipulated Penalty of \$1,500 for each day Quest fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Quest fails to grant access.)

6. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Quest as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of \$1,000 for each day Quest fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Quest stating the specific grounds for its determination that Quest has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Quest shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Quest receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-6 of this Section.

B. Timely Written Requests for Extensions. Quest may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Quest fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Quest receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that Quest has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Quest of: (a) Quest's failure to comply; and (b) OIG's

exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Quest shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Quest elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Quest cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Quest has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

1. *Definition of Material Breach.* A material breach of this CIA means:

- a. a failure by Quest to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Section III.J;
- b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C;
- d. a failure to engage and use a Compliance Expert in accordance with Section III.A.3 and Appendix B; or

d. a failure to engage and use an IRO in accordance with Section III.D and Appendix C.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Quest constitutes an independent basis for Quest's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Quest has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Quest of: (a) Quest's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* Quest shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

a. Quest is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;

b. the alleged material breach has been cured; or

c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Quest has begun to take action to cure the material breach; (ii) Quest is pursuing such action with due diligence; and (iii) Quest has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Quest fails to satisfy the requirements of Section X.D.3, OIG may exclude Quest from participation in the Federal health care programs. OIG shall notify Quest in writing of its determination to exclude Quest (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Quest's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Quest may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to Quest of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Quest shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Quest was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Quest shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Quest to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Quest requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

- a. whether Quest was in material breach of this CIA;
- b. whether such breach was continuing on the date of the Exclusion

Letter; and

c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Quest had begun to take action to cure the material breach within that period; (ii) Quest has pursued and is pursuing such action with due diligence; and (iii) Quest provided to OIG within that period a reasonable timetable for curing the material breach and Quest has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Quest, only after a DAB decision in favor of OIG. Quest's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Quest upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Quest may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Quest shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Quest, Quest shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

XI. EFFECTIVE AND BINDING AGREEMENT

Quest and OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns, and transferees of Quest;
- B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;
- C. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA;
- D. OIG may agree to a suspension of Quest's obligations under the CIA in the event of Quest's cessation of participation in Federal health care programs. If Quest

ceases participating in Federal health care programs and is relieved of its CIA obligations by OIG, Quest shall notify OIG at least 30 days in advance of Quest's intent to resume participating as a provider or supplier with any Federal health care program. Upon receipt of such notification, OIG shall evaluate whether the CIA should be reactivated or modified.

E. The undersigned Quest signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

F. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

ON BEHALF OF QUEST

/Michael E. Prevoznik/

MICHAEL E. PREVOZNIK
Senior Vice President and General Counsel
Quest Diagnostics Incorporated

4/9/09
DATE

/Hope S. Foster/

HOPE S. FOSTER
Mintz, Levin, Cohn, Ferris, Glovsky,
and Popeo, P.C.
Counsel for Quest Diagnostics Incorporated

4/9/09
DATE

**ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**

/Gregory E. Demske/

4/14/09

GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

DATE

Attachment A

Dear NID Customer:

As you may be aware Quest Diagnostics Incorporated and its wholly-owned subsidiary, Nichols Institute Diagnostics (NID) recently entered into a global civil, criminal, and administrative settlement with the United States and individual states in connection with the labeling and marketing of certain NID in vitro diagnostic test kits, namely NID's Advantage Intact and Bio-Intact PTH test kits. Quest Diagnostics, Incorporated voluntarily closed NID in April 2006.

This letter provides you with additional information about the settlement, explains Quest's commitments going forward, and provides you with access to information about those commitments. In general terms, the Government alleged that at certain times before NID closed it sold products that failed to meet certain claims made in the directional inserts and other statements and materials of NID and caused clinical laboratories using those kits to submit false claims for those tests and for follow-on treatments and medical services performed as a result of NID's Advantage Intact and Bio-Intact PTH test kits. To resolve these matters, NID pled guilty to a criminal misbranding violation and Quest and NID agreed to pay a total of \$302 million to the Federal Government. Additional information about the settlements may be found at the following websites **[include a link to the USAO and Quest]**.

As part of the federal settlement, Quest also entered a five-year corporate integrity agreement with the Office of Inspector General of the U.S. Department of Health and Human Services. The corporate integrity agreement is available at <http://oig.hhs.gov/fraud/cia/index.html>. Under this agreement, Quest agreed to undertake certain obligations designed to promote compliance with Federal health care program and FDA requirements. We also agreed to notify NID customers who purchased Advantage Intact and Bio-Intact PTH test kits about the settlement and inform them that they can report any questionable practices regarding these test kits to Quest's Compliance Department or the FDA.

Please call or email Quest at **1-800-TBD** or **[email address]** if you have questions about the settlement referenced above or to report any instances in which you believe that improper conduct occurred. Alternatively, you may report any such instances to the FDA's Office of In Vitro Device Evaluations and Safety at 301-240-0443. You should direct medical questions or concerns about the products to Quest's Compliance Department.

We appreciate your time and attention. We are dedicated to ensuring that we bring you the scientific and medical information you need to make well-informed decisions.

Sincerely,
Timothy U. Sharpe, Vice President, Compliance
Quest Diagnostics Incorporated

Quest Diagnostics Incorporated

APPENDIX A
QUEST AFFILIATES

Subsidiaries

Quest Diagnostics Holdings Incorporated (DE)
Quest Diagnostics Clinical Laboratories, Inc. (DE)

Quest Diagnostics Incorporated (MD)
Diagnostic Reference Services Inc. (MD)
Pathology Building Partnership (MD) (gen. ptrshp.)

Quest Diagnostics Incorporated (MI)

Quest Diagnostics Investments Incorporated (DE)
Quest Diagnostics Finance Incorporated (DE)

Quest Diagnostics LLC (IL)

Quest Diagnostics LLC (MA)

Quest Diagnostics LLC (CT)

Quest Diagnostics Nichols Institute (f/k/a Quest Diagnostics Incorporated) (CA)

Quest Diagnostics of Pennsylvania Inc. (DE)

Quest Diagnostics of Puerto Rico, Inc. (PR)

Quest Diagnostics Receivables Inc. (DE)

Quest Diagnostics Ventures LLC (DE)

American Medical Laboratories, Incorporated (DE)
Quest Diagnostics Nichols Institute, Inc. (VA)
Quest Diagnostics Incorporated (NV)
APL Properties Limited Liability Company (NV)

DPD Holdings, Inc. (DE)
MetWest Inc. (DE)
Diagnostic Path Lab, Inc. (TX)
Quest Diagnostics Provider Network, LLC (CO)

Enterix Inc. (DE)
Enterix (Australia) Pty Limited (Australia)
Enterix Pty Limited (Australia)
Enterix UK Limited (UK)

Focus GmbH (Germany)

Focus Technologies Holding Company (DE)
Focus Diagnostics, Inc. (DE)

HemoCue, Inc. (CA)
QDI Acquisition AB (Sweden)
 POCT Holding AB (Sweden)
 HemoCue Holding AB (Sweden)
 HemoCue AB (Sweden)
 HemoCue Oy (Finland)
 HemoCue GmbH (Germany)
 HemoCue AG (Switzerland)
 Biotest Medizintechnik GmbH (Germany)
 HemoCue Diagnostics B.V. (The Netherlands)
 HC Diagnostics, Limited (UK)

Lab Portal, Inc. (DE)

LabOne, Inc. (MO)
 ExamOne World Wide, Inc. (PA)
 ExamOne World Wide of NJ, Inc. (NJ)
 LabOne, L.L.C. (KS)
 Central Plains Holdings, Inc. (KS)
 Lab One Canada, Inc. (Ontario)
 ExamOne Canada, Inc. (Ontario)
 Rapid-Med Plus Franchise Corporation (Ontario)
 LabOne of Ohio, Inc. (DE)
 Osborn Group Inc. (DE)

Lifepoint Medical Corporation (DE)
 C&S Clinical Laboratory, Inc. (d/b/a Clinical Diagnostic Services) (NJ)

MedPlus, Inc. (OH)
 Valcor Associates Inc. (PA)

Unilab Corporation (DE)

Nichols Institute Diagnostics (CA)
Nichols Institute Diagnostics Limited (UK)
Nichols Institute Diagnostika GmbH (Germany)
Nichols Institute International Holding B.V. (Netherlands)
 Nichols Institute Diagnostics B.V. (Netherlands)
 Nichols Institute Diagnostics SARL (France)

Nomad Massachusetts, Inc. (MA)
 Laboratorio de Analisis Biomedicos, S.A. (Mexico)

Quest Diagnostics Mexico, S.A. de C.V. (f/k/a Laboratorios Clinicos de Mexico, S.A. de C.V.) (Mexico)

Quest Diagnostics do Brasil Ltda. (Brazil)

Quest Diagnostics India Private Limited (India)

Quest Diagnostics Limited (UK)
 The Pathology Partnership plc (UK)

AmeriPath Group Holdings, Inc. (DE)
 AmeriPath Holdings, Inc. (DE)
 AmeriPath Intermediate Holdings, Inc. (DE)
 AmeriPath, Inc. (DE)

AmeriPath 5.01(a) Corporation (TX)
AmeriPath Cincinnati, Inc. (OH)
AmeriPath Cleveland, Inc. (OH)
AmeriPath Consolidated Labs, Inc. (FL)
AmeriPath Florida, LLC (DE)
AmeriPath Hospital Services Florida, LLC (DE)
AmeriPath Indemnity, Ltd. (Cayman Islands)
AmeriPath Indiana, LLC (IN)
AmeriPath, LLC (DE)
 AmeriPath Texas, LP
AmeriPath Kentucky, Inc. (KY)
AmeriPath Lubbock 5.01(a) Corporation (TX)
AmeriPath Lubbock Outpatient 5.01(a) Corporation (TX)
AmeriPath Marketing USA, Inc (FL)
AmeriPath Michigan, Inc. (MI)
AmeriPath Mississippi, Inc. (MS)
AmeriPath New York, LLC (DE)
AmeriPath North Carolina, Inc. (NC)
AmeriPath Ohio, Inc. (DE)
 AmeriPath Youngstown Labs, Inc. (OH)
AmeriPath PAT 5.01(a) Corporation (TX)
AmeriPath Pennsylvania, LLC (PA)
AmeriPath Philadelphia, Inc. (NJ)
AmeriPath San Antonio 5.01(a) Corporation (TX)
AmeriPath SC, Inc. (SC)
AmeriPath Severance 5.01(a) Corporation (TX)
AmeriPath Texarkana 5.01(a) Corporation (TX)
AmeriPath Wisconsin, LLC (WI)
AmeriPath Youngstown, Inc. (OH)
Anatomic Pathology Services, Inc. (OK)
API No. 2, LLC (DE)
Arlington Pathology Association 5.01(a) Corporation (TX)
Dermatopathology Services, Inc. (AL)
DFW 5.01(a) Corporation (TX)
Diagnostic Pathology Management Services, LLC (OK)
Kailash B. Sharma, M.D., Inc. (GA)
NAPA 5.01(a) Corporation (TX)
Nuclear Medicine and Pathology Associates (GA)
Ocmulgee Medical Pathology Association, Inc. (GA)
O'Quinn Medical Pathology Association, LLC (GA)
PCA of Denver, Inc. (TN)
PCA of Nashville, Inc. (TN)
Peter G. Klacsmann, M.D., Inc. (GA)
Sharon G. Daspit, M.D., Inc. (GA)
Shoals Pathology Associates, Inc. (AL)
Specialty Laboratories, Inc. (CA)
Strigen, Inc. (UT)
 Arizona Pathology Group, Inc. (AZ)
 Regional Pathology Consultants, LLC (UT)
 Rocky Mountain Pathology, LLC (UT)
TID Acquisition Corp. (DE)
TXAR 5.01(a) Corporation (TX)

APPENDIX B

COMPLIANCE EXPERT

This Appendix contains the requirements relating to the Compliance Expert required by Section III.A.3 of the CIA.

A. Compliance Expert Engagement.

The Compliance Expert engaged by the QSC shall possess the qualifications set forth in Paragraph B, below, to perform the responsibilities in Section III.A.3 of the CIA and Paragraph C below. The Compliance Expert shall conduct the Compliance Program Review in a professionally independent and objective fashion, as set forth in Section III.A.3 of the CIA and Paragraph C below. Within 30 days after OIG receives written notice of the identity of a selected Compliance Expert, OIG will notify Quest if the Compliance Expert is unacceptable. Absent notification from OIG that the Compliance Expert is unacceptable, the QSC may continue to engage the Compliance Expert.

If the QSC engages a new Compliance Expert during the term of the CIA, this Compliance Expert shall also meet the requirements of this Appendix and Section III.A.3 of the CIA. If a new Compliance Expert is engaged, Quest shall submit the information identified in Section V.A.9 of the CIA to OIG within 30 days of engagement of the Compliance Expert. Within 30 days after OIG receives written notice of the identity of the selected Compliance Expert, OIG will notify Quest if the Compliance Expert is unacceptable. Absent notification from OIG that the Compliance Expert is unacceptable, the QSC may continue to engage the Compliance Expert.

B. Compliance Expert Qualifications.

Each Compliance Expert engaged to perform the Compliance Program Review shall be knowledgeable in health care compliance programs and the requirements of this CIA, and shall perform the Compliance Program Review on a timely basis.

C. Compliance Expert Responsibilities.

Within 150 days after the Effective Date the Compliance Expert shall develop the proposed work plan for the Compliance Program Review for the first Reporting Period and shall deliver the proposed work plan to the OIG for review. The Compliance Expert may provide the proposed work plans to Quest Diagnostics for review and comment. Within 30 days of the beginning of each of the remaining Reporting Periods, the Compliance Expert shall deliver to OIG a proposed work plan for that Reporting Period. Within 30 days after OIG receives the proposed work plan, OIG will notify Quest if the work plan is unacceptable. Absent notification from OIG that the work plan is

unacceptable, the Compliance Expert may conduct the Compliance Program Review for the applicable Reporting Period using the Work Plan.

The Compliance Expert shall conduct the Compliance Program Review in accordance with the requirements of Section III.A.3, and shall also

1. prepare timely, clear, well-written Compliance Program Review Reports (as defined in Section III.A.3.b of the CIA); and
2. respond to all OIG inquiries in a prompt, objective, and factual manner.

D. Compliance Expert - Independence and Objectivity.

Each Compliance Expert must perform each Compliance Program Review in a professionally independent and objective fashion, taking into account any other business relationships or engagements that may exist between the Compliance Expert and Quest and individual Board members. The Compliance Expert shall include in the Compliance Program Review Report a certification or sworn affidavit that the Compliance Program Expert has evaluated his, her, or its professional independence and objectivity, as appropriate to the nature of the engagement, with regard to the Compliance Program Review and has concluded that the Compliance Expert is, in fact, independent and objective.

E. Compliance Expert Removal/Termination.

1. *Provider.* If the QSC terminates any Compliance Expert during the course of the Compliance Expert's engagement, Quest must submit a notice explaining the QSC's reasons to OIG no later than 30 days after termination. The QSC must engage a new Compliance Expert in accordance with Paragraph A of this Appendix.

2. *OIG Removal of Compliance Expert* In the event OIG has reason to believe that any Compliance Expert does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out the responsibilities as described in Section III.A.3 of the CIA and Paragraph C above, OIG may, at its sole discretion, require the QSC to engage a new Compliance Expert in accordance with Paragraph A of this Appendix.

Prior to requiring the QSC to engage a new Compliance Expert, OIG shall notify Quest of OIG's intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, Quest may request a meeting with OIG to discuss any aspect of the Compliance Expert's qualifications, independence or performance of his, her, or its responsibilities and to present additional information regarding these matters. Quest shall provide any additional information as

may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the Compliance Expert with Quest prior to requiring the QSC to terminate the Compliance Expert. However, the final determination as to whether or not to require the QSC to engage a new Compliance Expert shall be made at the sole discretion of OIG.

APPENDIX C

INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.D of the CIA.

A. IRO Engagement.

Quest shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Quest if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Quest may continue to engage the IRO.

If Quest engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Quest shall submit the information identified in Section V.A.11 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Quest if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Quest may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the IVD Products Review engagement who have expertise in the applicable FDA requirements related to the IVD Subsidiaries.
2. assign qualified individuals to conduct the Review; and
3. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities.

The IRO shall:

1. perform each Review in accordance with the specific requirements of the CIA;

2. evaluate the effectiveness of the IVD Subsidiaries' systems for achieving compliance with 21 C.F.R. Part 820 – Subparts A, B, G, I, and J, and §§ 820.186 and 820.198 of Subpart M, and the effectiveness of IVD Subsidiaries' systems for reviewing and approving IVD Product labeling to assure labeling compliance with 21 C.F.R. §§ 809.10(a) and (b);

3. if in doubt about the applicability of a particular FDA requirement, policy or regulation, request clarification from the appropriate authority;

4. respond to all OIG inquiries in a prompt, objective, and factual manner; and

5. prepare timely, clear, well-written reports that include all the information required by Appendix D to the CIA.

D. IRO Independence and Objectivity.

The IRO must perform the Review in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and Quest.

E. IRO Removal/Termination.

1. *Provider.* If Quest terminates its IRO during the course of the engagement, Quest must submit a notice explaining its reasons to OIG no later than 30 days after termination. Quest must engage a new IRO in accordance with Paragraph A of this Appendix.

2. *OIG Removal of IRO.* In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and/or objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require Quest to engage a new IRO in accordance with Paragraph A of this Appendix.

Prior to requiring Quest to engage a new IRO, OIG shall notify Quest of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, Quest may request a meeting with OIG to discuss any aspect of the IRO's qualifications, independence or performance of its responsibilities and to present additional information regarding these matters. Quest shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO with Quest prior to requiring Quest to terminate the IRO. However, the final

determination as to whether or not to require Quest to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX D

IVD PRODUCTS REVIEW

A. Description of the IVD Products Review

Quest shall retain a Independent Review Organization (IRO) to perform a review to assist Quest in evaluating its IVD Subsidiaries' quality systems, processes, policies, and procedures regarding the IVD Products. The purpose of the review is to evaluate whether the IVD Subsidiaries have effective systems in place to achieve compliance with 21 C.F.R. Part 820 – Subparts A, B, G, I, and J, and §§ 820.186 and 820.198 of Subpart M, and to evaluate the systems in place for reviewing and approving IVD Product labeling to ensure labeling compliance with 21 C.F.R. §§ 809.10(a) and (b).

B. Review Work Plan

The IRO shall develop a work plan for performing the review described in Paragraph A above. The work plan shall include a record sampling plan for validating the effectiveness and implementation of the IVD Subsidiaries' policies and procedures, consistent with FDA Quality System Inspection Technique (QSIT) guidance. The IRO may provide its draft work plans to Quest Diagnostics for review and comment.

Within 150 days after the Effective Date, the IRO shall deliver the proposed work plan for the first Reporting Period to the OIG for review. Within 30 days of the beginning of each of the remaining Reporting Periods, the IRO shall deliver to OIG a proposed work plan for that Reporting Period. Within 30 days after OIG receives the proposed work plan and in consultation with the FDA, OIG will notify Quest if the work plan is unacceptable. Absent notification from OIG that the work plan is unacceptable, the IRO may conduct the review for the applicable Reporting Period using the Work Plan.

C. Report of the IRO Review

Within 30 days after the completion of the IVD Products Review, the IRO shall prepare a report based upon the IVD Products Review performed. The IVD Products Review Report shall include the IRO's findings and supporting rationale regarding:

1. the IVD Subsidiaries' compliance with senior management's responsibility to establish its policy and objectives for, and

commitment to, quality. Senior management shall ensure that the quality policy is understood, implemented, and maintained at all levels of the organization;

2. the effectiveness of the IVD Subsidiaries' systems for achieving compliance with 21 C.F.R. Part 820 – Subparts A, B, G, I, and J, and §§ 820.186 and 820.198 of Subpart M, and the effectiveness of the IVD Subsidiaries' systems for reviewing and approving IVD Product labeling to assure labeling compliance with 21 C.F.R. §§ 809.10(a) and (b);

3. the IRO's recommendations on improving the systems to achieve compliance with the regulations identified in Paragraph C.2 above;

4. the name and credentials of people performing the review;

and

5. the work plan that the IRO used to perform the review.

APPENDIX E

OVERPAYMENT REFUND

TO BE COMPLETED BY MEDICARE CONTRACTOR

Date: _____
 Contractor Deposit Control # _____ Date of Deposit: _____
 Contractor Contact Name: _____ Phone # _____
 Contractor Address: _____
 Contractor Fax: _____

TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER

Please complete and forward to Medicare Contractor. This form, or a similar document containing the following information, should accompany every voluntary refund so that receipt of check is properly recorded and applied.

PROVIDER/PHYSICIAN/SUPPLIER NAME _____
 ADDRESS _____
 PROVIDER/PHYSICIAN/SUPPLIER # _____ CHECK NUMBER# _____
 CONTACT PERSON: _____ PHONE # _____ AMOUNT OF CHECK
 \$ _____ CHECK DATE _____

REFUND INFORMATION

For each Claim, provide the following:

Patient Name _____ HIC # _____
 Medicare Claim Number _____ Claim Amount Refunded \$ _____
 Reason Code for Claim Adjustment: _____ (Select reason code from list below. Use one reason per claim)

(Please list all claim numbers involved. Attach separate sheet, if necessary)

Note: If Specific Patient/HIC/Claim #/Claim Amount data not available for all claims due to Statistical Sampling, please indicate methodology and formula used to determine amount and reason for overpayment: _____

For Institutional Facilities Only:

Cost Report Year(s) _____
 (If multiple cost report years are involved, provide a breakdown by amount and corresponding cost report year.)

For OIG Reporting Requirements:

Do you have a Corporate Integrity Agreement with OIG? Yes No

Reason Codes:

<u>Billing/Clerical Error</u>	<u>MSP/Other Payer Involvement</u>	<u>Miscellaneous</u>
01 - Corrected Date of Service	08 - MSP Group Health Plan Insurance	13 - Insufficient Documentation
02 - Duplicate	09 - MSP No Fault Insurance	14 - Patient Enrolled in an HMO
03 - Corrected CPT Code	10 - MSP Liability Insurance	15 - Services Not Rendered
04 - Not Our Patient(s)	11 - MSP, Workers Comp.(Including	16 - Medical Necessity
05 - Modifier Added/Removed	Black Lung	17 - Other (Please Specify)
06 - Billed in Error	12 - Veterans Administration	
07 - Corrected CPT Code		