

**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

