



## COMPLIANCE MANUAL – Part 2

# Compliance Program Summary

January 2022

### Introduction

Diax Labs is a CLIA-certified, COLA accredited laboratory that provides a broad range of diagnostic laboratory services. It participates in Federal and State health care programs and is committed to ensuring compliance with all applicable laws, regulations, and program standards. Furthermore, Diax Labs, by virtue of its mission and values, intends to conduct its operations in accordance with the highest standards of organizational and personal integrity.

### Compliance Program

To ensure that it is in full compliance with legal and regulatory requirements, Diax Labs has developed and implemented a comprehensive Compliance Program (CP) in accordance with principles established by the Office of Inspector General (OIG) in the U.S. Department of Health and Human Services.

*The OIG believes a comprehensive compliance program provides a mechanism that addresses the public and private sections' mutual goals of reducing fraud and abuse, enhancing health care provider operational functions; improving the quality of health care services; and reducing the cost of health care.<sup>1</sup>*

The Diax Labs CP is applicable to all stakeholders – employees, contractors, vendors, and providers. As referenced by the OIG, through the implementation of its CP, Diax Labs desires to:

- *Demonstrate its commitment to honest and responsible conduct;*
- *Increase the likelihood of preventing, identifying, and correcting unlawful and/or unethical behavior at an early stage;*
- *Encourage employees and contractors to report potential problems to allow for appropriate internal inquiry and corrective action; and*
- *Through early detection and reporting, minimize any financial loss.<sup>2</sup>*

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<sup>1</sup> OIG Compliance Program Guidance for Clinical Laboratories, 63 Fed. Reg. 45076 (August 24, 1998).

<sup>2</sup> OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4858, 4859 (January 31, 2005).

Consistent with the OIG's Compliance Program Guidance, the core elements of the Diax Labs CP are:

- CP Organizational Structure/Oversight
- Written Compliance Guidance
- Compliance Education and Training
- Lines of Communication
- Disciplinary and Enforcement Standards
- Auditing and Monitoring
- Investigation of Complaints, Response to Detected Offenses, and Corrective Actions

While the seven elements necessary for an effective compliance program have been recommended by the OIG for entities that receive (directly or indirectly) funds through Federal health care programs (e.g., Medicare and Medicaid), Diax Labs believes that these compliance steps are also key to ensuring the integrity and transparency of its operations. Diax Labs is committed to establishing a comprehensive CP to address and mitigate actual and potential risks, implementing the seven core elements as follows:

### **1. Compliance Program Organizational Structure/Oversight**

- The Diax Labs CP is overseen and monitored by the company's Managing Director. They seek to ensure that Diax Labs takes appropriate steps to mitigate risks that can negatively impact its mission, reputation, and operations. They receive regular reports from the Designated Compliance Officer (DCO) and establish the priorities and direction of the CP.
- An Executive Compliance Committee (ECC), comprised of Diax Labs senior executives and managers, meets on a regular basis to review, and discuss risk areas and provide guidance on implementation of the CP.
- The Diax Labs CP is managed by the DCO who is responsible for its operations and responds to issues and risks that may arise.

### **2. Written Compliance Guidance**

- The Diax Labs CP is implemented through core written guidance and policies, including:
  - A Code of Conduct and Ethics
  - Compliance Responsibilities, Duty to Report and Non-Retaliation Policy
  - Sanctions Screening Policy
  - Compliance Education and Training Policy

### **3. Compliance Education and Training**

- General and specialized compliance training programs are provided to DiAx Labs employees and contractors. Special attention is given to sales team members to ensure adherence to applicable laws, regulations, and policies and procedures, including the DiAx Labs Code of Conduct and Ethics, as well as receipt of appropriate compliance training.

### **4. Lines of Communication**

- A Compliance Hotline is maintained by an independent, third-party vendor, through which complaints can be made and issues raised on a confidential (and if desired, anonymous) basis. It can be reached at:

Phone: 1-855-252-7606

Internet: [www.hotline-services.com](http://www.hotline-services.com)

- Awareness and adherence to the PAN “Compliance Responsibility, Duty to Report and Non-Retaliation” policy is encouraged through managers, supervisors, the DCO, or the Compliance Hotline.
- Documents, including compliance policies and procedures, are readily available to DiAx Labs employees through a shared file system.
- Other means of sharing CP information with stakeholders are routinely explored and developed to ensure awareness and adherence to the DiAx Labs CP.

### **5. Disciplinary and Enforcement Standards**

- Guidelines for Appropriate Conduct and a Progressive Disciplinary Policy have been developed and are set forth in the Employee Handbook. They are intended to provide guidance regarding the equitable and uniform application of disciplinary action and enforcement where misconduct is determined to have occurred.
- A protocol between the Compliance Office and the Human Resources Department has been established for coordinating the receipt, investigation, and resolution of misconduct by employees.
- A complaint and resolution tracking system has been established and is maintained to document the handling and resolution of substantiated non-compliance in an equitable, reasonable, and appropriate manner.

## 6. Auditing and Monitoring

- An annual risk assessment is conducted to identify and address high risk areas.
- Based on the results of the annual risk assessment process, an annual audit work plan is established.
- Both external and internal audits are conducted, and audit reports issued with findings, observations, and recommendations for review by management and the ECC. An external, independent, third-party auditor is retained to conduct audits of in certain high-risk areas.
- The Compliance Team maintains an audit tracking system to monitor the conduct of audits, findings and recommendations, management responses and follow-up remedial actions.

## 7. Investigation of Complaints, Response to Detected Offenses and Corrective Actions

- The Compliance Team investigates/reviews all complaints, issues, concerns, or issues that are raised relating to compliance with applicable laws, regulations, Governmental guidance, as well as internal policies and procedures.
- A tracking system, maintained by the Compliance Team, is used to document all investigations/reviews from initiation through resolution and subsequent remedial action, if warranted.
- The DiAx Labs Compliance Team reports to the ECC and senior management on a regular basis on investigations and reviews to ensure strategic direction and guidance is provided for an effective CP.

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DiAx Labs' CP is directed toward ensuring compliance with all applicable laws, regulations, Government guidelines, as well as adherence to the highest ethical principles. It is designed to

*Establish a culture within a clinical laboratory that promotes prevention, detection, and resolution of instances of conduct that do not conform to Federal and State law, and Federal, State, and private payer health care program requirements, as well as the clinical laboratory's ethical and business policies.<sup>3</sup>*

*The compliance program [is intended to] effectively articulate and demonstrate the organization's commitment to the compliance process.<sup>4</sup>*

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<sup>3</sup> OIG Compliance Program Guidance for Clinical Laboratories, 63 Fed. Reg. at 45077 (August 24, 1998).

<sup>4</sup> Id.

Through its CP, DiAx strives to meet its mission, maintain the quality of services, ensure the supporting documentation, and the accuracy claims for payment.