

**CORPORATE INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
GENOTOX LABORATORIES LTD.**

**I. PREAMBLE**

Genotox Laboratories Ltd. (Genotox) 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). Contemporaneously with this CIA, Genotox is entering into a Settlement Agreement with the United States.

**II. EFFECTIVE DATE, TERM, AND DEFINITIONS**

A. Effective Date. The “Effective Date” of this CIA shall be the signature date of the final signatory to this CIA.

B. Term. The term of this CIA shall be five years from the Effective Date, except that Sections VII and X shall continue for 120 days after OIG’s receipt of: (1) Genotox’s final Annual Report or (2) any additional documentation relating to the final Annual Report requested by OIG, whichever is later. In addition, if OIG issues a Stipulated Penalties Demand Letter pursuant to Section X.C.1 or a Notice of Material Breach and Intent to Exclude pursuant to Section X.E.2 prior to the expiration of the 120 day period, then Section X shall remain in effect until the Stipulated Penalties Review described in Section X.E.2 or the Exclusion Review described in Section X.E.3 is completed, and Genotox complies with the decision.

C. Definitions.

1. “Arrangements” means:

- a. every arrangement or transaction that involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value and is between Genotox and (i) any actual or potential source of health care business or referrals to Genotox or (ii) any actual or potential recipient of health care business or referrals from Genotox; and
- b. every financial relationship (as defined at 42 C.F.R. § 411.354(a)) that is between Genotox and a physician (or a physician’s immediate family member (as defined at 42 C.F.R. § 411.351)) who makes a referral (as defined at 42 U.S.C. § 1395nn(h)(5)) to

Genotox for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)).

- i. “Source of health care business or referrals” means any individual or entity that refers, recommends, arranges for, orders, leases, or purchases any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program.
- ii. “Recipient of health care business or referrals” means any individual or entity (a) to whom Genotox refers an individual for the furnishing or arranging for the furnishing of any item or service, or (b) from whom Genotox purchases, leases or orders or arranges for or recommends the purchasing, leasing, or ordering of any good, facility, item, or service, for which payment may be made in whole or in part by a Federal health care program.

2. “Certifying Covered Persons” means the following: Chief Executive Officer; Chief Operating Officer; Vice President of Operations; Regional Sales Director; and Controller.

3. “Covered Persons” means: (a) all owners who are natural persons, officers, and employees of Genotox; (b) all contractors who furnish patient care items or services or perform billing or coding functions on behalf of Genotox; and (c) all physicians and other non-physician practitioners who are members of Genotox’s active medical staff.

4. “Disclosure Program” means a program that enables individuals to disclose to the Compliance Officer or some other person who is not in the disclosing individual’s chain of command any potential violations of criminal, civil, or administrative law related to the Federal health care programs or any issues or questions associated with Genotox’s policies, conduct, practices, or procedures.

5. “Exclusion Lists” means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available at <http://www.oig.hhs.gov>) and state Medicaid program exclusion lists that are publicly available.

6. “Ineligible Person” means an individual or entity who: (a) is currently excluded from participation in any Federal health care program or (b) has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a) (mandatory exclusion) but has not yet been excluded from participation in any Federal health care program.

7. “Overpayment” means any funds that Genotox receives or retains under any Federal health care program to which Genotox, after applicable reconciliation, is not entitled under such Federal health care program.

8. “Reportable Event” means: (a) a substantial Overpayment; (b) a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which criminal penalties or civil monetary penalties under Section 1128A or 1128B of the Social Security Act (the “Act”) or exclusion under Section 1128 of the Act may be authorized; (c) the employment of or contracting with or having as a member of the active medical staff a Covered Person who is an Ineligible Person; or (d) the filing of a bankruptcy petition by Genotox.

9. “Reporting Period” means each one-year period during the term of this CIA, beginning with the one-year period following the Effective Date.

10. “Training Plan” means a written plan that outlines the steps Genotox will take to ensure that Covered Persons receive training on a periodic basis during the term of the CIA regarding Genotox’s CIA requirements and compliance program and the applicable Federal health care program requirements, including the requirements of 42 U.S.C. § 1320a-7b(b) (the Anti-Kickback Statute) and 42 U.S.C. § 1395nn (the Stark Law).

11. “Transition Plan” means a plan to address whether and how Genotox’s compliance program will continue to include the compliance program requirements set forth in Section III of the CIA, following the end of the CIA’s term.

### **III. COMPLIANCE PROGRAM REQUIREMENTS**

Genotox shall establish and maintain a compliance program that includes the following elements:

#### **A. Compliance Officer, Compliance Committee, and Management Certifications.**

1. *Compliance Officer.* Within 90 days after the Effective Date, Genotox shall appoint a Compliance Officer who is an employee and a member of senior management of Genotox. The Compliance Officer shall report directly to the Chief Executive Officer of Genotox and shall not be or be subordinate to the General Counsel or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for Genotox. The Compliance Officer shall be responsible for, without limitation:

- a. developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements;
- b. monitoring the day-to-day compliance activities engaged in by Genotox; and
- c. all reporting requirements of this CIA.

The Compliance Officer shall not have any noncompliance job responsibilities that, in OIG's discretion, may interfere or conflict with the Compliance Officer's ability to perform the duties outlined in this CIA.

Genotox shall report to OIG, in writing, any changes in the identity, duties, or job responsibilities of the Compliance Officer within five business days after such a change.

2. *Compliance Committee.* Within 90 days after the Effective Date, Genotox shall appoint a Compliance Committee that is chaired by the Compliance Officer. The Compliance Committee shall include, at a minimum, the members of senior management necessary to meet the requirements of this CIA. The Compliance Committee shall be responsible for, among other things, reviewing the policies and procedures required by Section III.B below at least annually, reviewing the training required by Section III.C below at least annually, implementation and oversight of the risk assessment and internal review process required by Section III.E below, and the development and implementation of the Transition Plan required by Section III.J below. The Compliance Committee shall meet at least quarterly.

Genotox shall report to OIG, in writing, any changes to the membership of the Compliance Committee within 15 business days after such a change.

3. *Management Certifications.* The Certifying Covered Persons shall monitor compliance within the divisions or departments for which they are responsible and annually certify that the applicable Genotox division or department is in compliance with applicable Federal health care program requirements and the requirements of this CIA. For each Reporting Period, each Certifying Covered Person shall certify as follows:

“I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of division or department], an area under my supervision. My job responsibilities include ensuring [insert name of division or department]'s compliance with all applicable Federal health care program requirements, requirements of the Corporate Integrity Agreement, and Genotox's policies and procedures. To the best of my knowledge, the [insert name of division or department] is in compliance with all applicable Federal health care program requirements and the requirements of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States.”

If any Certifying Covered Person is unable to provide this certification, the Certifying Covered Person shall provide a written explanation of the reasons why he or she is unable to provide the certification.

Within 90 days after the Effective Date, Genotox shall develop and implement a written process for Certifying Covered Persons to follow for the purpose of completing the certification required by this section (e.g., reports that must be reviewed, assessments that must be completed, sub-certifications that must be obtained, etc. prior to the Certifying Covered Person making the required certification).

B. Written Standards. Within 90 days after the Effective Date, Genotox shall develop and implement written policies and procedures (Policies and Procedures) that address the following: (1) the operation of Genotox’s compliance program, including the compliance program requirements outlined in this CIA; (2) Genotox’s compliance with Federal health care program requirements, including but not limited to compliance with the Anti-Kickback Statute and the Stark Law, and the regulations and other guidance documents related to these statutes; (3) a written review and approval process for Arrangements, the purpose of which is to ensure that all Arrangements do not violate the Anti-Kickback Statute and the Stark Law; and (4) the identification, quantification, and repayment of Overpayments. Genotox shall enforce its Policies and Procedures and make compliance with its Policies and Procedures an element of evaluating the performance of all Covered Persons. The Policies and Procedures shall be made available to all Covered Persons.

The Compliance Committee shall review the Policies and Procedures at least annually and update the Policies and Procedures as necessary. Any new or revised Policies and Procedures shall be made available to all Covered Persons. All Policies and Procedures shall be made available to OIG upon request.

C. Training and Education.

1. *Covered Persons Training.* Within 90 days after the Effective Date, Genotox shall develop a Training Plan that includes the following information: (a) training topics; (b) categories of Covered Persons required to attend each training session; (c) length of the training session(s); (d) schedule for training; and (e) format of the training. The Compliance Committee shall review the Training Plan at least annually and update the Training Plan as necessary.

2. *Training Records.* Genotox shall make available to OIG, upon request, training materials and records verifying that the training described in Sections III.C.1 and III.C.2 has been provided.

D. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, Genotox shall engage an entity (the “Independent Review Organization” or “IRO”) that meets the qualifications and requirements outlined in Appendix A to this CIA, which is incorporated by reference, to perform the reviews described in this Section III.D.

b. *Retention of Records.* The IRO and Genotox shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports exchanged between the IRO and Genotox related to the reviews described in this Section III.D.

- c. *Access to Records and Personnel.* Genotox shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in this Section III.D and that all records furnished to the IRO are accurate and complete.

2. *Claims Review.* The IRO shall review fee-for-service claims submitted by Genotox and reimbursed by the Medicare program, to determine whether the items and services furnished were medically necessary and appropriately documented and whether the claims were correctly coded, submitted, and reimbursed (Claims Review) and shall prepare a Claims Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference.

3. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Genotox a certification that the IRO has (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.D and (b) concluded that it is, in fact, independent and objective, in accordance with the requirements specified in Appendix A to this CIA. The IRO's certification shall include a summary of all current and prior engagements between Genotox and the IRO.

E. Risk Assessment and Internal Review Process. Within 90 days after the Effective Date, Genotox shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with Genotox's participation in the Federal health care programs, including but not limited to the risks associated with the submission of claims for items and services furnished to Medicare and Medicaid program beneficiaries and the Anti-Kickback Statute and Stark Law risks associated with Arrangements. The Compliance Committee shall be responsible for implementation and oversight of the risk assessment and internal review process. The risk assessment and internal review process shall be conducted at least annually and shall require Genotox to: (1) identify and prioritize risks, (2) develop work plans or audit plans (as appropriate) related to the identified risk areas, (3) implement the work plans and audit plans, (4) develop corrective action plans in response to the results of any internal audits performed, and (5) track the implementation of the work plans and any corrective action plans and assess the effectiveness of such plans.

F. Disclosure Program. Within 90 days after the Effective Date, Genotox shall establish a Disclosure Program. Genotox shall appropriately publicize the existence of the Disclosure Program (e.g., via periodic e-mails to employees or by posting the information in prominent common areas). The Disclosure Program shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. The Disclosure Program shall prohibit retaliation against Covered Persons relating to use of the Disclosure Program and Genotox shall not retaliate against Covered Persons for use of the Disclosure Program. The Compliance Officer (or designee) shall conduct a review of each disclosure received through the Disclosure Program, including gathering all relevant information from the disclosing individual, and ensure that appropriate follow-up is conducted.

The Compliance Officer (or designee) shall record all disclosures (whether or not related to a potential violation of criminal, civil, or administrative law related to the Federal health care programs) in a written disclosure log within two business days of receipt of the disclosure. The disclosure log shall include the following information: (1) a summary of each disclosure received

(whether anonymous or not), (2) the date the disclosure was received, (3) the individual or department responsible for reviewing the disclosure, (4) the status of the review, (5) any corrective action taken in response to the review, and (6) the date the disclosure was resolved.

G. Ineligible Persons.

1. *Screening Requirements.* Genotox shall:

- a. screen all prospective Covered Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, or medical staff credentialing process, shall require such Covered Persons to disclose whether they are Ineligible Persons;
- b. screen all Covered Persons against the Exclusion Lists within 90 days after the Effective Date and on a monthly basis thereafter; and
- c. require all Covered Persons to disclose immediately to the Compliance Officer (or designee) if they become an Ineligible Person.

2. *Removal Requirement.* If Genotox has actual notice that a Covered Person has become an Ineligible Person, Genotox 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 for in whole or part, directly or indirectly, by any Federal health care program(s) from which the Covered Person has been excluded, at least until such time as the Covered Person is reinstated into participation in such Federal health care program(s). Items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and Genotox may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Genotox meets the requirements of Section III.G.

H. Notification of Government Investigation or Legal Proceeding. Genotox shall notify OIG, in writing, of any ongoing investigation or legal proceeding by a governmental entity or its agents involving an allegation that Genotox has committed a crime or has engaged in fraudulent activities, within 30 days of Genotox receiving notice of such investigation or legal proceeding. This notification shall include a description of the allegation(s), the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Within 30 days after resolution of the matter, Genotox shall notify OIG, in writing, of the resolution of the investigation or legal proceeding.

I. Reportable Events. Genotox shall notify OIG, in writing, within 30 days after determining that a Reportable Event exists, as follows:

1. *Substantial Overpayment.* The report to OIG shall include:

- a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions, or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of individuals and entities believed to be implicated, including an explanation of their roles in the Reportable Event;
- b. the Federal health care programs affected by the Reportable Event;
- c. a description of the steps taken by Genotox to identify and quantify the Overpayment; and
- d. a description of Genotox's actions taken to correct the Reportable Event and prevent it from recurring.

Within 60 days of identification of the substantial Overpayment, Genotox shall repay the Overpayment, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and any applicable regulations and Centers for Medicare and Medicaid Services (CMS) guidance, and provide OIG with documentation of the repayment.

2. *Probable Violation of Law.* The report to OIG shall include:

- a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of individuals and entities believed to be implicated, including an explanation of their roles in the Reportable Event;
- b. a statement of the Federal criminal, civil or administrative laws that are probably violated by the Reportable Event;
- c. the Federal health care programs affected by the Reportable Event;
- d. a description of the steps taken by Genotox to identify and quantify any Overpayments; and
- e. a description of Genotox's actions taken to correct the Reportable Event and prevent it from recurring.

If the Reportable Event involves an Overpayment, within 60 days of identification of the Overpayment, Genotox shall repay the Overpayment, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and any applicable regulations and CMS guidance, and provide OIG with documentation of the repayment.

3. *Ineligible Person.* The report to OIG shall include:

- a. the identity of the Ineligible Person and the job duties performed by that individual;
- b. the dates of the Ineligible Person's employment or contractual relationship or medical staff membership;
- c. a description of the Exclusion Lists screening that Genotox completed before and/or during the Ineligible Person's employment or contract or medical staff membership and any flaw or breakdown in the screening process that led to the hiring or contracting with or credentialing the Ineligible Person;
- d. a description of how the Ineligible Person was identified; and
- e. a description of any corrective action implemented to prevent future employment or contracting with or credentialing an Ineligible Person.

4. *Bankruptcy.* The report to OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program requirements implicated.

5. *Reportable Events Involving the Stark Law.* Any Reportable Event that involves solely a probable violation of the Stark Law should be submitted by Genotox to CMS through the self-referral disclosure protocol (SRDP), with a copy to OIG. However, if Genotox identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then Genotox is not required by this Section III.I to submit the Reportable Event to CMS through the SRDP, but shall provide OIG with a copy of the repayment documentation.

J. Transition Plan. Prior to the end of the fourth Reporting Period, Genotox shall develop a Transition Plan that is reviewed and approved by the Chief Executive Officer. The Transition Plan shall be implemented following the end of the CIA's term. A copy of Genotox's approved Transition Plan shall be included in Genotox's fourth Annual Report.

#### **IV. SUCCESSOR LIABILITY**

If, after the Effective Date, Genotox proposes to (a) sell any or all of its business, business units, or locations (whether through a sale of assets, sale of stock, or other type of transaction) relating to the furnishing of items or services that may be reimbursed by a Federal health care program; or (b) purchase or establish a new business, business unit, or location relating to the furnishing of items or services that may be reimbursed by a Federal health care program, the CIA shall be binding on the purchaser of any business, business unit, or location and any new business, business unit, or location (and all Covered Persons at each new business, business unit, or location) shall be subject to the requirements of this CIA, unless otherwise determined and agreed to in writing by OIG. Genotox shall notify OIG, in writing, of such sale or purchase within 30 days following the closing of the transaction and shall notify OIG, in writing, within 30 days of establishing such new business, business unit, or location.

If Genotox wishes to obtain a determination by OIG that a proposed purchaser or proposed acquisition will not be subject to the CIA requirements, Genotox must notify OIG in writing at least 30 days in advance of the proposed sale or purchase. This notification shall include a description of the business, business unit, or location to be sold or purchased, a brief description of the terms of the transaction and, in the case of a proposed sale, the name and contact information of the prospective purchaser.

## **V. IMPLEMENTATION REPORT AND ANNUAL REPORTS**

A. Implementation Report. Within 120 days after the Effective Date, Genotox shall submit a written report (Implementation Report) to OIG that includes, at a minimum, the following information:

1. the name, business address, business phone number, and position description of the Compliance Officer required by Section III.A.1, and a detailed description of any noncompliance job responsibilities;
2. the names and positions of the members of the Compliance Committee required by Section III.A.2;
3. the names and positions of the Certifying Covered Persons required by Section III.A.3 and a copy of the written process for Certifying Covered Persons to follow in order to complete the certification required by Section III.A.3;
4. a list of the Policies and Procedures required by Section III.B;
5. the Training Plan required by Section III.C.1;
6. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this CIA; and (d) a certification from the IRO regarding its professional independence and objectivity with respect to Genotox that includes a summary of all current and prior engagements between Genotox and the IRO;
7. a description of the risk assessment and internal review process required by Section III.E;
8. a description of the Disclosure Program required by Section III.F;
9. a description of the Ineligible Persons screening and removal process required by Section III.G;
10. a description of Genotox's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business;

11. a list of all of Genotox's locations (including mailing addresses), the corresponding name under which each location is doing business, and the location's Medicare and state Medicaid program provider number and/or supplier number(s); and

12. a certification by the Compliance Officer, Chief Executive Officer, and Chief Operating Officer that:

- a. to the best of his or her knowledge, except as otherwise described in the report, Genotox has implemented and is in compliance with all of the requirements of this CIA;
- b. 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
- c. he or she understands that the certification is being provided to and relied upon by the United States.

B. Annual Reports. Genotox shall submit to OIG a written report (Annual Report) for each of the five Reporting Periods that includes, at a minimum, the following information:

1. any change in the identity, position description, or noncompliance job responsibilities of the Compliance Officer; a current list of the Compliance Committee members, and a current list of the Certifying Covered Persons, along with the identification of any changes made during the Reporting Period to the Compliance Committee, or Certifying Covered Persons;

2. the dates of each meeting of the Compliance Committee (copies of the meeting minutes shall be made available to OIG upon request);

3. a description of any changes to the written process for Certifying Covered Persons to follow in order to complete the certification required by Section III.A.3;

4. the certifications of Certifying Covered Persons required by Section III.A.3;

5. a list of any new or revised Policies and Procedures required by Section III.B. developed during the Reporting Period;

6. a description of any changes to the Training Plan required by Section III.C, and a summary of all training furnished to Covered Persons during the Reporting Period;

7. a complete copy of all reports prepared pursuant to Section III.D and Genotox's response to the reports, along with corrective action plan(s) related to any issues raised by the report, and documentation of Genotox's refund of the Estimated Overpayment (as defined in Appendix B to this CIA);

8. a certification from the IRO regarding its professional independence and objectivity with respect to Genotox, including a summary of all current and prior engagements between Genotox and the IRO;
9. a description of any changes to the risk assessment and internal review process required by Section III.E, including the reason(s) for such changes;
10. a summary of the following components of the risk assessment and internal review process during the Reporting Period: (a) risk areas identified, (b) work plans and internal audit plans developed, (c) internal audits performed, (d) corrective action plans developed in response to internal audits, and (e) steps taken to track the implementation of the work plans and corrective action plans. Copies of any work plans, internal audit reports, and corrective action plans shall be made available to OIG upon request;
11. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs, including at least the following information: (a) a description of the disclosure, (b) the date the disclosure was received, (c) the resolution of the disclosure, and (d) the date the disclosure was resolved. The complete disclosure log shall be made available to OIG upon request;
12. a description of any changes to the Ineligible Persons screening and removal process required by Section III.G, including the reason(s) for such changes;
13. a summary of any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H that includes a description of the allegation(s), the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;
14. a summary of all Reportable Events required to have been reported pursuant to Section III.I during the Reporting Period;
15. (in the fourth Annual Report), a copy of the Transition Plan required by Section III.J;
16. a summary of any audits conducted during the applicable Reporting Period by any Medicare or state Medicaid program contractor or any government entity or contractor, involving a review of Federal health care program claims, and Genotox's response and corrective action plan (including information regarding any Federal health care program refunds) relating to the audit findings;
17. a description of all changes to the most recently provided list of Genotox's locations (including addresses) as required by Section V.A.11;
18. a description of any changes to Genotox's corporate structure, including any parent and sister companies, subsidiaries, and their respective lines of business; and

19. a certification by the Compliance Officer, Chief Executive Officer, and Chief Operating Officer that:

- a. to the best of his or her knowledge, except as otherwise described in the report, Genotox has implemented and is in compliance with all of the requirements of this CIA;
- b. 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
- c. he or she understands that the certification is being provided to and relied upon by the United States.

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. Designation of Information. Genotox 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. Genotox 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**

All notifications and reports required under this CIA shall be submitted using the following contact information:

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  
Email Address: [officeofcounsel@oig.hhs.gov](mailto:officeofcounsel@oig.hhs.gov)

Genotox:

Matthew McCarty, M.D.; Nick Laude  
Chief Executive Officer; Chief Compliance Officer  
Genotox Laboratories Ltd.  
2170 Woodward Street, Suite 100  
Auston, TX 78744  
Telephone: 512-600-6601  
Email Address: mmccarty@genotoxlabs.com;  
nlaude@genotoxlabs.com

Unless otherwise requested by OIG, all notifications and reports required by this CIA shall be submitted electronically. OIG shall notify Genotox in writing of any changes to the OIG contact information listed above. Genotox shall notify OIG in writing within two business days of any changes to the Genotox contact information listed above.

**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 conduct interviews, examine and/or request copies of or copy Genotox's books, records, and other documents and supporting materials, and conduct on-site reviews of any of Genotox's locations, for the purpose of evaluating: (a) Genotox's compliance with the requirements of this CIA and (b) Genotox's compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by Genotox to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. For purposes of this provision, OIG or its duly authorized representative(s) may interview any of Genotox's owners, employees, and contractors 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. Genotox shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Genotox's owners, employees, and contractors may elect to be interviewed with or without a representative of Genotox present.

**VIII. DOCUMENT AND RECORD RETENTION**

Genotox shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this CIA for six 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 Genotox prior to any release by OIG of information submitted by Genotox pursuant to this CIA and identified upon submission by Genotox as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Genotox shall have the rights set forth at 45 C.F.R. § 5.42(a).

**X. BREACH AND DEFAULT PROVISIONS**

A. Stipulated Penalties. OIG may assess:

1. A Stipulated Penalty of up to \$2,500 for each day Genotox fails to comply with Section III.A;
2. A Stipulated Penalty of up to \$2,500 for each day Genotox fails to comply with Section III.B;
3. A Stipulated Penalty of up to \$2,500 for each day Genotox fails to comply with Section III.C;
4. A Stipulated Penalty of up to \$2,500 for each day Genotox fails to comply with Section III.D;
5. A Stipulated Penalty of up to \$2,500 for each day Genotox fails to comply with Section III.E;
6. A Stipulated Penalty of up to \$2,500 for each day Genotox fails to comply with Section III.F;
7. A Stipulated Penalty of up to \$2,500 for each day Genotox fails to comply with Section III.G;
8. A Stipulated Penalty of up to \$2,500 for each day Genotox fails to comply with Section III.H;
9. A Stipulated Penalty of up to \$2,500 for each day Genotox fails to comply with Section III.I;
10. A Stipulated Penalty of up to \$2,500 for each day Genotox fails to comply with Section III.J;
11. A Stipulated Penalty of up to \$2,500 for each day Genotox fails to comply with Section IV;
12. A Stipulated Penalty of up to \$2,500 for each day Genotox fails to comply with Section V;
13. A Stipulated Penalty of up to \$2,500 for each day Genotox fails to comply with Section VII;
14. A Stipulated Penalty of up to \$2,500 for each day Genotox fails to comply with Section VIII; or

15. A Stipulated Penalty of up to \$50,000 for each false certification or false statement made to OIG by or on behalf of Genotox under this CIA.

B. Timely Written Requests for Extensions. Genotox 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. 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 Genotox fails to meet the revised deadline set by OIG. 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 Genotox 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.* If OIG determines that a basis for Stipulated Penalties under Section X.A exists, OIG shall notify Genotox of: (a) Genotox's failure to comply and (b) OIG's demand for payment of Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter.* Within 15 business days after the date of the Demand Letter, Genotox shall either: (a) 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.

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.

D. Exclusion for Material Breach.

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

- a. failure to comply with any of the requirements of this CIA for which OIG has previously issued a demand for Stipulated Penalties under Section X.C, unless such Stipulated Penalty was overturned by an ALJ on appeal pursuant to the procedures described in Section X.E below;
- b. failure to comply with Section III.A.1;
- c. failure to comply with Section III.D;
- d. failure to comply with Section III.I;
- e. failure to comply with Section V;

- f. failure to respond to a Demand Letter in accordance with Section X.C;
- g. a false statement or false certification made to OIG by or on behalf of Genotox under this CIA;
- h. failure to pay Stipulated Penalties within 20 days after an ALJ issues a decision ordering Genotox to pay the Stipulated Penalties or within 20 days after the HHS Departmental Appeals Board (DAB) issues a decision upholding the determination of OIG; or
- i. failure to come into compliance with a requirement of this CIA for which OIG has demanded Stipulated Penalties, pursuant to the deadlines listed in Section X.E.2.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Genotox constitutes an independent basis for Genotox’s exclusion from participation in the Federal health care programs. The length of the exclusion shall be in the OIG’s discretion, but not more than five years for each material breach. Upon a preliminary determination by OIG that Genotox has materially breached this CIA, OIG shall notify Genotox of: (a) Genotox’s material breach and (b) OIG’s intent to exclude Genotox. (This notification shall be referred to as the “Notice of Material Breach and Intent to Exclude.”)

3. *Response to Notice.* Genotox shall have 30 days from the date of the Notice of Material Breach and Intent to Exclude to submit any information and documentation for OIG to consider before it makes a final determination regarding exclusion.

4. *Exclusion Letter.* If OIG determines that exclusion is warranted, OIG shall notify Genotox in writing of its determination to exclude Genotox. (This letter shall be referred to 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 the Exclusion Letter. The effect of the exclusion shall be that no Federal health care program payment may be made for any items or services furnished, ordered, or prescribed by Genotox, including administrative and management services, except as stated in regulations found at 42 C.F.R. §1001.1901(c). The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, Genotox 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 issuing a Demand Letter or Exclusion Letter to Genotox, and as an agreed-upon remedy for the resolution of disputes arising under this CIA, Genotox 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. 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 DAB, in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21, but only to the extent this CIA does not provide otherwise. Notwithstanding

the language in 42 C.F.R. § 1005: (a) the request for a hearing involving Stipulated Penalties shall be made within 15 business days after the date of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after the date of the Exclusion Letter and (b) no discovery shall be available to the parties. The procedures relating to the filing of a request for a hearing can be found at <http://www.hhs.gov/dab/divisions/civil/procedures/divisionprocedures.html>

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 Genotox was in full and timely compliance with the requirements of this CIA for which OIG demands payment and (b) the period of noncompliance. Genotox shall have the burden of proving its full and timely compliance. If the ALJ upholds the OIG's determination that Genotox has breached this CIA and orders Genotox to pay Stipulated Penalties, Genotox must (a) come into compliance with the requirement(s) that resulted in the OIG imposing Stipulated Penalties and (b) pay the Stipulated Penalties within 20 days after the ALJ issues a decision, unless Genotox properly and timely requests review of the ALJ decision by the DAB. If the ALJ decision is properly and timely appealed to the DAB and the DAB upholds the determination of OIG, Genotox must (a) come into compliance with the requirement(s) that resulted in the OIG imposing Stipulated Penalties and (b) pay the Stipulated Penalties within 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 whether Genotox was in material breach of this CIA. If the ALJ sustains the OIG's determination of material breach, the exclusion shall take effect 20 days after the ALJ issues the decision. 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. Genotox 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 Genotox, Genotox 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. 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 and Genotox agrees not to seek additional review of the DAB's decision (or the ALJ's decision if not appealed) in any judicial forum.

## **XI. EFFECTIVE AND BINDING AGREEMENT**

Genotox and OIG agree as follows:

A. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA.

B. All requirements and remedies set forth in this CIA are in addition to and do not affect (1) Genotox's responsibility to follow all applicable Federal health care program

requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable Federal health care program requirements.

C. The undersigned Genotox signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacities and that they are authorized to execute this CIA.

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

**ON BEHALF OF GENOTOX**

/Matthew McCarty/  
Matthew McCarty, M.D.  
Chief Executive Officer  
Genotox Laboratories Ltd.

3/20/2023  
DATE

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

/Lisa M. Re/  
LISA M. RE  
Assistant Inspector General for Legal Affairs  
Office of Inspector General  
U.S. Department of Health and Human Services

3/29/2023  
DATE

/Candace Ashford/  
Candace Ashford  
Senior Counsel  
Office of Inspector General  
U.S. Department of Health and Human Services

2023.03.30  
DATE

## APPENDIX A

### 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

1. Genotox 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 E. Within 30 days after OIG receives the information identified in Section V.A.6 of the CIA or any additional information submitted by Genotox in response to a request by OIG, whichever is later, OIG will notify Genotox if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Genotox may continue to engage the IRO.

2. If Genotox engages a new IRO during the term of the CIA, that IRO must also meet the requirements of this Appendix. If a new IRO is engaged, Genotox shall submit the information identified in Section V.A.6 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by Genotox at the request of OIG, whichever is later, OIG will notify Genotox if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Genotox may continue to engage the IRO.

#### B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Claims Review who have expertise in the Federal health care program requirements applicable to the claims being reviewed;
2. assign individuals to design and select the Claims Review sample who are knowledgeable about the appropriate statistical sampling techniques;
3. assign individuals to conduct the coding review portions of the Claims Review who have a nationally recognized coding certification and who have maintained this certification (e.g., completed applicable continuing education requirements);
4. assign licensed nurses or physicians with relevant education, training and specialized expertise (or other licensed health care professionals acting within their scope of practice and specialized expertise) to make the medical necessity determinations required by the Claims Review; and
5. 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 Claims Review in accordance with the specific requirements of the CIA;
2. follow all applicable Federal health care program rules and reimbursement guidelines in making assessments in the Claims Review;
3. request clarification from the applicable Federal health care program if in doubt of the application of a particular program policy or regulation;
4. respond to all OIG inquires in a prompt, objective, and factual manner; and
5. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. Genotox Responsibilities

Genotox shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in III.D of this CIA and that all records furnished to the IRO are accurate and complete.

E. IRO Independence and Objectivity

The IRO must perform the Claims Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the U.S. Government Accountability Office.

F. IRO Removal/Termination

1. *Genotox and IRO.* If Genotox terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Genotox must submit a notice explaining (a) its reasons for termination of the IRO or (b) the IRO's reasons for its withdrawal to OIG, no later than 30 days after termination or withdrawal. Genotox must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. *OIG Removal of IRO.* In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph E, or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify Genotox in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. Genotox shall have 30 days from the date of OIG's written notice to provide information regarding the IRO's qualifications, independence or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's

review of any information provided by Genotox regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify Genotox in writing that Genotox shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. Genotox must engage a new IRO within 60 days of its receipt of OIG's written notice. The final determination as to whether or not to require Genotox to engage a new IRO shall be made at the sole discretion of OIG.

## APPENDIX B

### CLAIMS REVIEW

A. Claims Review. The IRO shall perform the Claims Review for each of the five Reporting Periods.

1. *Definitions*.

- a. “Paid Claim” means a fee-for-service claim submitted by Genotox and for which Genotox has received reimbursement from the Medicare program.
- b. “Population” means all Paid Claims during the 12-month period covered by the Claims Review. In OIG’s discretion, OIG may limit the Population to one or more subset(s) of Paid Claims to be reviewed and shall notify Genotox and the IRO of its selection of the Population at least 30 days prior to the end of each Reporting Period. Genotox, or its IRO on behalf of Genotox, may submit proposals identifying suggestions for the subset(s) of Paid Claims to be reviewed at least 120 days prior to the end of each Reporting Period. In connection with limiting the Population, OIG may consider (1) proposals submitted by Genotox or its IRO, (2) information furnished to OIG regarding the results of Genotox’s internal risk assessment and internal auditing, or (3) other information obtained by OIG. The determination of whether, and in what manner, to limit the Population shall be made at the sole discretion of OIG.
- c. “Overpayment” means the amount of money Genotox has received in excess of the amount due and payable under Medicare program requirements, as determined by the IRO in connection with the Claims Review performed under this Appendix.
- d. “Error Rate” means the percentage of net Overpayments identified in the Claims Review Sample. The net Overpayment shall be calculated by subtracting all underpayments identified in the Claims Review Sample from all Overpayments identified in the Claims Review Sample. The Error Rate is calculated by dividing the net Overpayment by the total dollar amount associated with the Paid Claims in the Claims Review Sample.

2. *Claims Review Sample*. The IRO shall select a random sample of 100 Paid Claims (Claims Review Sample). The IRO shall review the Paid Claims based on Genotox’s documentation and the applicable Medicare program requirements to determine whether the items and services furnished were medically necessary and appropriately documented, and whether the claim was correctly coded, submitted, and reimbursed.

3. *Other Requirements*.

- a. Supplemental Materials. The IRO shall request all documentation required for its review of the Paid Claims in the Claims Review Sample and Genotox shall furnish such documentation to the IRO prior to the IRO initiating its review of the Claims Review Sample. If the IRO accepts any supplemental documentation from Genotox after the IRO has completed its initial review of the Claims Review Sample (Supplemental Materials), the IRO shall include the following in the Claims Review Report: (i) a description of the Supplemental Materials, (ii) the date the Supplemental Materials were accepted, (iii) the IRO's reason(s) for accepting the Supplemental Materials, and (iv) the relative weight the IRO gave to the Supplemental Materials in its review.
- b. Paid Claims without Supporting Documentation. Any Paid Claim for which Genotox cannot produce documentation shall be considered an error and the total reimbursement received by Genotox for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims without documentation is not permitted.
- c. Use of First Sample Drawn. The first set of Paid Claims selected shall be used for the Claims Review Sample (i.e., it is not permissible to generate more than one list of random samples and then select one for use).

4. *Repayment of Estimated Overpayment.* The findings of the Claims Review Sample shall be used by the IRO to estimate the actual Overpayment in the Population with the point estimate and a two-sided 90% confidence interval. Within 60 days of receipt of the Claims Review Report, Genotox shall repay the lower limit of the two-sided 90% confidence interval (Estimated Overpayment) to the Centers for Medicare and Medicaid Services (CMS). Documentation of Genotox's refund of the Estimated Overpayment to CMS shall be submitted to OIG with Genotox's Annual Report. OIG, in its sole discretion, may refer the findings of the Claims Review Sample to CMS for appropriate follow up.

B. Claims Review Report. The IRO shall prepare a Claims Review Report for each Claims Review that includes the following information:

1. *Claims Review Methodology.*
  - a. Claims Review Objective. A statement of the objective intended to be achieved by the Claims Review.
  - b. Claims Review Population. A description of the Population subject to the Claims Review.
  - c. Source of Data. A description of (1) the process used to identify Paid Claims in the Population and (2) the specific documentation and other information sources relied on by the IRO when performing the Claims Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies (including title

and policy number), CMS program memoranda (including title and issuance number), Medicare carrier or intermediary manual or bulletins (including issue and date), other policies, regulations, or directives).

- d. Review Protocol. A narrative description of how the Claims Review was conducted and what was evaluated.
- e. Supplemental Materials. The information regarding any Supplemental Materials required by A.3.a., above.

2. *Statistical Sampling Documentation.*

- a. A copy of the printout of the random numbers generated by the “Random Numbers” function of the statistical sampling software used by the IRO.
- b. A description or identification of the statistical sampling software package used by the IRO.

3. *Claims Review Findings.*

a. Narrative Results.

- i. A description of Genotox’s billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.
- ii. A description of controls in place at Genotox to ensure that all items and services furnished by Genotox are correctly coded, appropriately documented, and medically necessary.
- iii. A narrative explanation of the results of the IRO’s review of the Claims Review Sample, including an explanation of all errors identified by the IRO.

b. Quantitative Results.

- i. Total number and percentage of instances in which the IRO determined that the coding of the Paid Claims submitted by Genotox differed from what should have been the correct coding.
- ii. Total number and percentage of instances in which the IRO determined that a Paid Claim was not appropriately documented.
- iii. Total number and percentage of instances in which the IRO determined that a Paid Claim was for items or services that were not medically necessary.

- iv. Total dollar amount of Paid Claims included in the Claims Review Sample and the net Overpayment associated with the Claims Review Sample.
- v. Error Rate in the Claims Review Sample.
- vii. An estimate of the actual Overpayment in the Population with the point estimate and a two-sided 90% confidence interval.
- viii. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim:
  - 1. Federal health care program billed;
  - 2. Beneficiary health insurance claim number;
  - 3. Date of service;
  - 4. Code submitted (e.g., DRG, CPT code, etc.);
  - 5. Code reimbursed;
  - 6. Allowed amount reimbursed by payor;
  - 7. Correct code (as determined by the IRO);
  - 8. Correct allowed amount (as determined by the IRO);
  - 9. Whether the item or service was medically necessary;
  - 10. Whether the item or service was appropriately documented; and
  - 11. The dollar difference between allowed amount reimbursed by payor and the correct allowed amount.

- c. Recommendations. The IRO's report shall include any recommendations for improvements to Genotox's billing and coding system or to Genotox's controls for ensuring that all items and services billed to the Medicare program by Genotox are correctly coded, appropriately documented, and medically necessary, based on the findings of the Claims Review.

4. *Credentials*. The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Claims Review and (2) performed the Claims Review.