

EXHIBIT A

UNITED STATES ATTORNEY'S OFFICE
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

DEFERRED PROSECUTION AGREEMENT

The United States of America, by the undersigned attorneys, and Genotox Laboratories Ltd. ("Genotox") hereby enter into the following Deferred Prosecution Agreement (the "Agreement"):

1. Investigation and Statement of Relevant Facts

1.1. The Investigation

The United States, including the United States Attorney's Office for the Western District of Texas, the United States Attorney's Office for the Southern District of Georgia, the Department of Justice, Civil Division, Commercial Litigation Branch, Fraud Section, the Department of Defense Criminal Investigative Service, and Department of Health and Human Services Office of Inspector General have been investigating Genotox for violations of federal law, in particular the Anti-Kickback Statute (codified at 42 U.S.C. § 1320a-7b), the False Claims Act (codified at 31 U.S.C. §§ 3729-3733), and the Eliminating Kickbacks in Recovery Act (codified at 18 U.S.C. § 220). The criminal and civil investigations have concerned, among other things, Genotox's use of "custom toxicology profiles" for urine drug testing and commission payments to sales representatives who were not in a bona fide employment relationship with Genotox.

The United States' parallel civil and criminal investigations include a criminal investigative component within the purview of the United States Attorney's Office for the Western District Texas and a civil investigative component within the purview of the United States Attorney's Office for the Southern District of Georgia and the Department of Justice, Civil Division, Commercial Litigation Branch, Fraud Section. Genotox has requested a global resolution of the

United States' investigations. This Agreement is intended to resolve the criminal component of the United States' investigation.

1.2. Statement of Relevant Facts

The United States and Genotox agree that the following statements are true and accurate:

Genotox is a Clinical Laboratory Improvement Amendments (CLIA) certified reference laboratory that was established in 2012 and which specializes in urine drug testing, pharmacogenomic testing, and infectious disease testing. Genotox maintains operations in and/or transacts business in, among other places, Austin, Texas, and Georgia. At all times relevant to this Agreement, Genotox sought and received reimbursements for services from, among other payors, Medicare, Medicaid, Tricare, and private insurance.

From approximately 2014 to 2020, Genotox signed contracts with independent sales representatives and marketing firms (referred to collectively as "1099 representatives") to market and promote Genotox to medical providers, including physicians' practices.¹ From approximately 2014 to March 2019, the 1099 representatives were paid almost exclusively on a percentage commission basis. Genotox executed contracts in which it committed to pay a 1099 representative a percentage of total revenue associated with medical provider accounts for which the 1099 representative was responsible. These payments were made on an ongoing basis for the term of the agreement.

The revenue used to calculate the commission payment was the revenue realized from billings to insurers, including Medicare and Tricare, for services provided by Genotox to medical providers and patients, including urine drug testing. That revenue was dependent both upon the

¹ Genotox referred to the independent sales representatives and marketing firms as "1099" representatives because they received IRS Form 1099 as independent contractors, whereas employees received IRS Form W-2 from Genotox.

volume of tests ordered and the type of tests or test panels ordered. The billing codes used included G0480, G0481, G0482, and G0483. The commission rate was often 25% but could vary from contract to contract.

The 1099 representatives were not bona fide employees of Genotox. They facilitated the referral of individuals to Genotox, and arranged for the ordering of, among other things, urine drug testing services from Genotox.

Beginning in or around March 2019, Genotox accelerated its transition of its 1099 representatives from percentage commission payments to fixed-rate marketing services agreements (“MSAs”). Among other reasons, Genotox doubted that percentage-based commissions complied with, among other things, EKRA. This led to an effort to transition 1099 representatives to fixed-rate MSAs.

At times, however, Genotox compared the marketing cost associated with MSAs to the marketing cost associated with the prior percentage commission structure. For example, 1099 representative T.C. was paid on a 30% commission basis through approximately March 2019. Starting in April 2019, T.C. was paid a fixed rate fee pursuant to an MSA, but Genotox tracked the difference between the fixed payment and what Genotox would have paid T.C. under the old 30% commission structure. The analysis was performed in order to assess the economic effect of the MSA on Genotox’s marketing costs and to aid renegotiation of MSAs.

The tracking was performed specifically as to each 1099 representative that was transitioned to an MSA. For example, the 1099 representative N.I. was paid at a 25% commission rate through approximately March 2019 and then pursuant to a fixed-rate MSA afterwards. One way in which Genotox measured N.I.’s performance under the MSA was by comparison to the old 25% commission rate. Therefore, Genotox continued to consider the percentage commission

structure in managing its marketing costs after certain 1099 representatives were transitioned to MSAs starting in or around March 2019.

The percentage commission payments to 1099 representatives did not end in March 2019. At least three 1099 representatives continued to be paid on a percentage commission basis with one arrangement lasting until at least October 2020. L.L., a 1099 marketing representative began receiving commissions from Genotox in or around December 2018. The commission payments continued through at least October 2020. In that time, L.L. received over \$190,000 in commission payments from Genotox. For the period December 2018 through October 2020, approximately \$186,000 (or 97%) of Genotox's payments to L.L. under a percentage commission agreement came after March 2019.

The percentage commission payments and MSA payments totaled at least \$1,140,000 for 2016, \$1,100,000 for 2017, \$1,130,000 for 2018, \$2,757,000 for 2019, and \$1,290,000 for 2020.

The 1099 representatives were responsible for marketing Genotox goods and services to providers in a specified geographic area. And their percentage commissions were tied directly to the revenue generated from—and thus the volume of—testing ordered by each practice or physician within the 1099 representative's purview.

When onboarding a new practice, the 1099 representative would offer the providers at that practice the ability to use in the requisition process forms known as "Custom Toxicology Profiles" or "custom profiles" to order, among other things, urine drug testing. Genotox used custom profiles through approximately January 2022. The custom profiles allowed a provider to pre-select a set of tests for Genotox to perform and bill for, such as presumptive screening for all analytes and categories offered by Genotox, as well as full definitive liquid chromatography tandem mass spectrometry (LC-MS/MS) testing for all analytes and metabolites offered by Genotox.

The form included an acknowledgment by the provider that stated, among other things, that the provider has “deemed that these tests are medically necessary for my patient population” and that “I will use my custom profile for patients only with a documented medical necessity to support the tests included.” Nonetheless, the custom profiles were used by Genotox and certain physicians to perform and bill the same set of tests for all, or nearly all, of a physician’s patients, generally at the highest reimbursement categories (*i.e.*, G0482 and G0483). The marketing accounts for many of these providers were also managed by one or more 1099 representatives.

Genotox’s practice was to require a test order signed by the ordering provider to be submitted with each sample for each date of service. Each test order required the physician to indicate what testing they wanted performed. The individual test order could include any of the following, based on the Provider’s assessment of testing required for that patient that day: only the custom profile, the custom profile with additional or reduced testing, or testing completely different than the custom profile.

The following example illustrates the connection between the 1099 representative commission structure and revenues generated from practices that used custom profiles. Dr. D at a Chicago pain management practice used custom profiles to order tests from Genotox in 2015, 2016, 2017, 2018, and early 2020. Based on orders from Dr. D’s practice, Genotox billed approximately \$890,000 for toxicology services. Approximately \$420,000 of that amount was paid by federal payors for drug testing procedures. Approximately 99% of the toxicology testing for Dr. D was billed using code G0483 (excluding 2015), which had the highest reimbursement rate from federal payors because it included, among other things, testing for 22 or more drug classes.

In 2018, 1099 representative N.I. was responsible for sales and marketing for Dr. D's practice and received commissions on revenue that Genotox derived from testing that Dr. D ordered. In 2018, for example, Genotox's toxicology billings for tests ordered by Dr. D. totaled approximately \$743,000. N.I. received 25% of the revenue realized in commission payments. N.I. received a total of approximately \$196,000 in commissions from Genotox in 2018. Commissions derived from Dr. D's billings constituted approximately 95% of the commission payments N.I. received from Genotox in 2018. N.I.'s commissions were thus tied directly to revenue generated from Dr. D, which in turn depended on the volume of high-reimbursement-rate testing orders that Dr. D placed.

2. Acceptance of Responsibility

Genotox has reviewed the attached criminal Information and acknowledges that the United States Attorney's Office for the Western District of Texas will file it in the United States District Court for the Western District of Texas, charging the company with violations of the AKS. Genotox (a) knowingly waives any right it may have to indictment on these charges, as well as all rights to a speedy trial pursuant to the Sixth Amendment to the United States Constitution, Title 18, United States Code, Section 3161, and Federal Rule of Criminal Procedure 48(b); (b) knowingly waives any objection with respect to venue to any charges arising out of the conduct described in the Statement of Relevant Facts above and consents to the filing of the Information, as provided under the terms of this Agreement, in the United States District Court for the Western District of Texas; and (c) agrees that the charges in the Information and any charges arising from the conduct described in the Statement of Relevant Facts are not time-barred by the applicable statute of limitations on the date of the signing of this Agreement. The United States Attorney's

Office for the Western District of Texas agrees to defer prosecution of Genotox pursuant to the terms and conditions described below.

Genotox admits, accepts, and acknowledges that it is responsible under United States law for the acts as set forth in the Statement of Relevant Facts, and that the facts in the Statement of Relevant Facts are true and accurate. Genotox agrees that, effective as of the date Genotox signs this Agreement, in any prosecution that is deferred by this Agreement, it will not dispute the Statement of Relevant Facts set forth in this Agreement, and, in any such prosecution, the Statement of Relevant Facts shall be admissible as: (a) substantive evidence offered by the government in its case-in-chief and rebuttal case; (b) impeachment evidence offered by the government on cross-examination; and (c) evidence at any sentencing hearing or other hearing. In addition, in connection therewith, Genotox agrees not to assert under the United States Constitution, Rule 410 of the Federal Rules of Evidence, Rule 11(f) of the Federal Rules of Criminal Procedure, Section 1B1.1(a) of the United States Sentencing Guidelines, or any other federal statute or rule that the Statement of Relevant Facts should be suppressed or is otherwise inadmissible as evidence in any form.

3. Cooperation

Genotox shall cooperate fully with the United States Attorney's Office for the Western District of Texas in any and all matters relating to the conduct described in the Statement of Relevant Facts until the end of the term of this Agreement. At the request of the United States Attorney's Office for the Western District of Texas, Genotox shall also cooperate fully with other domestic or foreign law enforcement and regulatory authorities and agencies in any investigation of Genotox or its affiliates, or any of its present or former officers, directors, employees, agents, and consultants, or any other party, in any and all matters relating to the conduct described in the

Statement of Relevant Facts. Genotox's cooperation pursuant to this Paragraph is subject to applicable law and regulations, including data privacy and national security laws, as well as valid claims of attorney-client privilege or attorney work product protection; however, Genotox must provide to the United States Attorney's Office for the Western District of Texas a log of any information or cooperation that is not provided based on an assertion of law, regulation, or privilege, and Genotox bears the burden of establishing the validity of any such assertion. Genotox agrees that its cooperation pursuant to this paragraph shall include, but not be limited to, the following:

a) Genotox represents that it has truthfully disclosed all factual information with respect to its activities, those of its affiliates, and those of its present and former directors, officers, employees, agents, and consultants relating to the conduct described in the Statement of Relevant Facts, as well as any other conduct that Genotox knows to be under investigation by the United States Attorney's Office for the Western District of Texas. Genotox further agrees that, during the term of this Agreement, it shall promptly and truthfully disclose all factual information that it may gain, or about which the United States Attorney's Office for the Western District of Texas may inquire, with respect to its activities, those of its affiliates, and those of its present and former directors, officers, employees, agents, and consultants relating to the conduct described in the Statement of Relevant Facts. This obligation of truthful disclosure includes, but is not limited to, the obligation of Genotox to provide, upon request, any document, record, or other tangible evidence about which the United States Attorney's Office for the Western District of Texas may inquire, including evidence that is responsive to any requests made prior to the execution of this Agreement.

b) Upon request of the United States Attorney's Office for the Western District of Texas, Genotox shall designate knowledgeable employees, agents, or attorneys to provide the information and materials described above on behalf of Genotox. It is further understood that Genotox must at all times provide complete, truthful, and accurate information.

c) Genotox shall use its best efforts to make available for interviews or testimony, as requested by the United States Attorney's Office for the Western District of Texas, present or former officers, directors, employees, agents, and consultants of Genotox. This obligation includes, but is not limited to, sworn testimony before a federal grand jury or in federal trials, as well as interviews with domestic or foreign law enforcement and regulatory authorities. Cooperation under this Paragraph shall include identification of witnesses who, to the knowledge of Genotox, may have material information regarding matters under investigation. This provision does not abridge or diminish the rights of such individuals, such as the right to invoke the Fifth Amendment protection against self-incrimination, nor will the valid assertion of such rights by such individuals constitute a breach of this Agreement by Genotox.

d) With respect to any information, testimony, documents, records, or other tangible evidence provided to the United States Attorney's Office for the Western District of Texas pursuant to this Agreement, Genotox consents to any and all disclosures, subject to applicable laws and regulations, to other governmental authorities, including United States authorities and those of a foreign government, as the United States Attorney's Office for the Western District of Texas, in its sole discretion, shall deem appropriate.

4. Agreement to Defer Prosecution

In entering into this Agreement, Genotox agrees to: (i) accept responsibility for the conduct described in the Statement of Relevant Facts above; and (ii) otherwise comply with the terms of this Agreement.

In consideration of Genotox entering into this Agreement, the United States agrees not to criminally prosecute Genotox for a period of eighteen months or thereafter for any crime related to the conduct described in the Statement of Relevant facts. The United States and Genotox intend for this Agreement to resolve the United States' criminal investigation of Genotox relating to the conduct described in the Statement of Relevant Facts.

The Agreement does not preclude or limit the United States from investigating or prosecuting Genotox for any crime not related to the conduct described in the Statement of Relevant Facts. Nothing in this Agreement shall preclude or limit the United States from bringing a criminal prosecution against Genotox, its subsidiaries, or its current or former officers, directors, employees, and agents for false statements, obstruction of justice, perjury, subornation of perjury, or aiding and abetting or conspiring to commit such an offense based on Genotox's conduct in performing its obligations under this Agreement.

5. Term of Agreement

This Agreement shall have a term of eighteen months from the date of on which the Information is filed, except as specifically provided below. It is understood that for the eighteen-month term of this Agreement, Genotox shall: (i) not violate any United States laws; (ii) truthfully and completely disclose non-privileged information concerning all matters about which the United States inquires, which information can be used for any purpose, except as otherwise limited in this Agreement; (iii) bring to the United States' attention all potentially criminal conduct by Genotox, its subsidiaries, or its current or former officers, directors, employees, agents, or consultants,

discovered after this Agreement is signed; and (iv) bring to the United States' attention all criminal or regulatory investigations, administrative proceedings, or civil actions brought by any governmental authority in the United States against Genotox.

If the United States determines, in its sole discretion, that Genotox has committed any violation of federal or state law subsequent to the date of this Agreement, or that Genotox has given false, incomplete, or misleading information at any time, or that Genotox has otherwise violated any provision of this Agreement, Genotox shall thereafter be subject to prosecution for any federal violation of which the United States has knowledge, including perjury and obstruction of justice, and the United States may refer any violation of law not within federal criminal jurisdiction to competent authorities. Any such prosecution that is not barred by the applicable statute of limitations on the date of the signing of this Agreement may be commenced against Genotox, notwithstanding the expiration of the statute of limitations between the signing of this Agreement and the expiration of the term of the Agreement plus one year. Thus, by signing this Agreement, Genotox agrees that the statute of limitations with respect to any prosecution that is not time-barred on the date that this Agreement is signed shall be tolled for the term of this Agreement plus one year.

In the event that the United States determines to institute a criminal prosecution against Genotox after a breach of this Agreement, then:

a) All statements made by or on behalf of Genotox to the United States, including the Statement of Relevant Facts, shall be admissible in evidence in any and all criminal proceedings brought by the United States (for all purposes, including sentencing, connected with a criminal proceeding) against Genotox, and Genotox hereby agrees and stipulates to the authenticity and admissibility of the Statement of Relevant Facts as an admission by Genotox, and

shall be precluded from offering any evidence or argument that contradicts the facts set forth therein or that suggests those facts are untrue or misleading;

b) Genotox shall not assert under the United States Constitution, Rule 11(f) of the Federal Rules of Criminal Procedure, Rule 410 of the Federal Rules of Evidence, Section 1B1.1(a) of the United States Sentencing Guidelines, or any other federal rule that any such statements made by or on behalf of Genotox prior or subsequent to this Agreement should be suppressed or are otherwise inadmissible;

c) The United States shall immediately be free to use the waiver of indictment provided by Genotox and to prosecute Genotox by way of Information for any federal offense arising out of the facts set forth in the Statement of Relevant Facts; and

d) Genotox acknowledges that the United States has made no representations, assurances, or promises concerning what sentence may be imposed by a Court, including as to financial penalties such as restitution, forfeiture, and fine, if Genotox breaches this Agreement and any criminal prosecution instituted thereafter proceeds to judgment. Genotox further acknowledges that any such sentence would be solely within the discretion of the Court, and that nothing in this Agreement binds or restricts the Court in the exercise of such discretion.

If Genotox fully complies with all of its obligations under this Agreement, the United States Attorney's Office for the Western District of Texas will seek dismissal of the Information within ten calendar days of the expiration of the term of this Agreement.

6. Relevant Considerations

The United States Attorney's Office for the Western District of Texas enters into this Agreement based on the individual facts and circumstances presented by this case and Genotox, including:

a. Genotox did not receive voluntary disclosure credit because it did not voluntarily and timely disclose to the United States the conduct described in the Statement of Relevant Facts;

b. Genotox received full credit for its cooperation with the criminal investigation, including making factual presentations, voluntarily making employees and senior executives available for interviews, producing documents regularly, and collecting, analyzing, and organizing voluminous evidence and information for the United States Attorney's Office for the Western District of Texas;

c. Genotox provided all relevant facts known to it, including information about the individuals involved in the conduct described in the Statement of Relevant Facts and conduct disclosed to the United States prior to the Agreement;

d. Genotox engaged in remedial measures, including ending the use of custom profiles and ending commission payments to 1099 representatives for marketing and sales;

e. Genotox has enhanced and has committed to continuing to enhance its compliance program and internal controls;

g. based on Genotox's remediation, the state of its compliance program, and Genotox's operation in a regulated industry, the United States Attorney's Office for the Western District of Texas determined that an independent compliance monitor is unnecessary;

h. the nature and seriousness of the offense conduct;

i. Genotox has no prior criminal history; and

j. Genotox has agreed to continue to cooperate with the United States Attorney's Office for the Western District of Texas in any ongoing investigation of the conduct of

Genotox, and its present or former officers, directors, employees, agents, and consultants relating to violations of federal law.

7. Scope and Interaction of Agreements

This Agreement is binding only on the United States Attorney's Office for the Western District of Texas and cannot bind any other federal, state, or local prosecuting authorities or government agencies, although the United States Attorney's Office for the Western District of Texas will bring Genotox's cooperation and compliance with its obligations under this Agreement to the attention of other prosecuting officers and government agencies, if requested.

Simultaneously, Genotox and the United States Attorney's Office for the Southern District of Georgia and the Department of Justice Commercial Litigation Branch Fraud Section are entering into a Civil Settlement Agreement to settle civil claims in connection with conduct that is the subject of this Agreement and the Information. The United States Attorney's Office for the Western District of Texas in its sole discretion may, but need not necessarily, determine that failure by Genotox to comply fully with those material terms of the Civil Settlement Agreement scheduled to occur during the effective period of this Agreement constitutes a breach of this Agreement.

Genotox is also simultaneously entering into a Corporate Integrity Agreement with the United States Department of Health and Human Services, Office of Inspector General, in connection with conduct that is the subject of this Agreement and the Information, to implement certain compliance measures. The United States Attorney's Office for the Western District of Texas in its sole discretion may, but need not necessarily, determine that a breach of the Corporate Integrity Agreement during the effective period of this Agreement constitutes a breach of this Agreement.

Within 10 days after the date on which this Agreement is fully executed, Genotox shall make a payment of Four Hundred Seventy-Seven Thousand Seven Hundred Seventy-Four Dollars (\$477,774.00) pursuant to the Civil Settlement Agreement. In light of the Civil Settlement Agreement, no criminal restitution, criminal forfeiture, or criminal fine shall be paid by Genotox, provided it complies with its obligations under this Agreement.

8. Discretion as to Violations of Agreement

Genotox acknowledges and agrees that the United States Attorney's Office for the Western District of Texas has sole discretion to determine whether a violation of this Agreement has occurred. Genotox understands and agrees that the exercise of such discretion is not reviewable by any court. In its discretion, the United States may provide Genotox with notice of a determination that Genotox has violated this Agreement and provide Genotox with an opportunity to explain the nature and circumstances of any alleged violation, including whether Genotox believes a violation has occurred, whether such violation was material, and whether such violation was committed knowingly or willfully, and to document any actions taken to address and cure the violation. In its discretion, the United States may consider such explanation in determining whether any violation has occurred and whether to pursue criminal charges or to take other legal action against Genotox.

9. Public Statements

The parties agree that either party may, in its discretion, make public this Agreement or any and all facts, promises, and representations contained in this Agreement.

10. Entire Agreement

This Agreement sets forth all the terms agreed between Genotox and the United States Attorney's Office for the Western District of Texas. No modifications or additions to this

Agreement shall be valid unless they are in writing and signed by an attorney for the United States, Genotox's attorney, and Genotox.

On Behalf of the United States Attorney's Office for the Western District of Texas:

JAIME ESPARZA
United States Attorney



DATE 03-21-2023

By:

G. Karthik Srinivasan
Alan Buie
Assistant United States Attorneys

On Behalf of Genotox:

I, Dr. Matthew McCarty, have read this Agreement and carefully reviewed every part of it with counsel for Genotox. I understand the terms of this Agreement and voluntarily agree, on behalf of Genotox, to each of its terms. Before signing this Agreement, I consulted counsel for Genotox. Counsel fully advised me of the rights of Genotox, of possible defenses, of federal sentencing law, and of the consequences of entering into this Agreement. No promises or inducements have been made other than those contained in this Agreement. Furthermore, no one has threatened or forced me, or to my knowledge any person authorizing this Agreement on behalf of Genotox, in any way to enter into this Agreement. I am also satisfied with counsel's representation in this matter. I certify that I am duly authorized to enter into and execute this Agreement on behalf of Genotox.

DATE

3-16-23


By:


Dr. Matthew McCarty

We are counsel for Genotox in the matter covered by this Agreement. In connection with such representation, we have examined relevant Genotox documents and discussed the terms of this Agreement with authorized representatives of Genotox. Having done so, we are of the opinion that Dr. Matthew McCarty has been duly authorized to enter into this Agreement on behalf of Genotox and that this Agreement has been duly and validly authorized, executed, and delivered on behalf of Genotox and is a valid and binding obligation of Genotox. I have fully advised authorized representatives of Genotox of the rights of Genotox, of possible defenses, of federal sentencing law, and of the consequences of entering into this Agreement. To our knowledge, the decision of Genotox to enter into this Agreement is informed and voluntary.

DATE 3-20-23

By:


Matthew Diggs, Esq.
Alex Porter, Esq.
Counsel to Genotox