SETTLEMENT AGREEMENT

This Settlement Agreement (Agreement) is entered into among (a) the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (OIG-HHS) of the Department of Health and Human Services (HHS), the United States Railroad Retirement Board (RRB), and the Defense Health Agency (DHA), acting on behalf of the TRICARE Program (collectively, the "United States"); (b) Genotox Laboratories Ltd. (Genotox); and (c) relator Alex DiGiacomo (Relator), through their authorized representatives. Collectively, all of the above will be referred to as "the Parties."

RECITALS

- A. Genotox, a Texas limited partnership with its principal place of business in Austin, Texas, is a reference laboratory that was established in 2012 and which specializes in urine drug testing, pharmacogenomic testing, and infectious disease testing.
- B. On September 16, 2020, Relator filed a *qui tam* action in the United States District Court for the Southern District of Georgia captioned *United States ex rel. DiGiacomo v. Genotox Laboratories, Ltd., et al.*, No. 2:20-cv-97 (S.D. Ga.), pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the Civil Action).
- C. On June 30, 2021, the Centers for Medicare & Medicaid Services (CMS) suspended Genotox's Medicare payments pursuant to 42 C.F.R. § 405.371(a)(2). In light of the CMS payment suspension, RRB suspended Genotox's Railroad Retirement Medicare Program payments. The Suspended Amount is the total amount of funds held in suspense of payment to Genotox by CMS and RRB on the Effective Date. As of February 28, 2023, the Suspended Amount was approximately \$4,995,278.85.

- D. The United States contends that Genotox submitted or caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395–1395lll (Medicare), the Railroad Retirement Medicare Program, administered by RRB under the Railroad Retirement Act of 1974, 45 U.S.C. §§ 231–231v (RRMP), and the TRICARE Program, 10 U.S.C. §§ 1071–1110b (TRICARE).
- E. Genotox admits and accepts responsibility for the facts described in Exhibit A hereto.
- F. The United States contends that it has certain civil claims against Genotox arising from the following conduct, by which Genotox knowingly submitted or caused the submission of false or fraudulent claims to Medicare, RRB, and TRICARE: (a) during the period from January 1, 2014 through October 31, 2020, Genotox knowingly and willfully paid commissions to independent contractor sales representatives and marketing firms to arrange for or recommend the ordering of Genotox's urine drug tests (UDT), and Genotox calculated such commissions based on a percentage of the revenue it realized from its UDT billings to insurers, including Medicare, RRB, and TRICARE; and (b) during the period from January 1, 2014 through January 31, 2022, Genotox knowingly submitted UDT claims to Medicare, RRB, and TRICARE for tests that were not covered and/or not reasonable and necessary, including blanket orders of UDT for all patients in a healthcare provider's practice and routine standing orders of UDT for all patients in a provider's practice. The conduct set forth in this Paragraph F is referred to below as the "Covered Conduct."
- G. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relator's reasonable expenses, attorneys' fees, and costs.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

- 1. Genotox shall pay to the United States the sums specified in this Paragraph (collectively, the Settlement Amount), under the terms and conditions specified herein, by electronic funds transfer pursuant to written instructions to be provided by the Civil Division of the United States Department of Justice.
- a. Genotox shall pay to the United States within ten (10) calendar days of the Effective Date the sum of Four Hundred Seventy-Seven Thousand Seven Hundred Seventy-Four Dollars (\$477,774.00) (Initial Payment).
- b. Genotox hereby agrees that the United States shall retain the Suspended Amount forevermore. Genotox expressly relinquishes any and all rights of any kind that it may have with respect to the Suspended Amount, including but not limited to: any and all claims or rights to have an overpayment determined under 42 C.F.R. § 405.372(c); any and all rights to payment of those funds; and any and all rights to appeal, whether formally or informally and whether administratively or judicially, the right of the United States, CMS, and/or RRB to retain those funds; and any other rights Genotox may have to challenge the withholding or the CMS and/or RRB suspensions in any respect.
- c. Genotox shall pay to the United States the sum of Four Hundred Fifteen Thousand Dollars (\$415,000.00), plus interest at four percent (4.0%) per annum, pursuant to the payment schedule attached as Exhibit B (each a Payment Over Time and collectively the Payments Over Time). The Payments Over Time may be prepaid, in whole or in part, without penalty or

premium. Genotox shall execute contemporaneously with this Agreement and provide to the United States a Promissory Note (attached as Exhibit C) in the total amount of the Payments Over Time. Under the terms and conditions specified in the Promissory Note (attached as Exhibit C) and the Security Agreement (attached as Exhibit D), the Payments Over Time shall be fully secured by assets sufficient to pay the Payments Over Time due and owing under this Agreement.

d. If, in any calendar year from 2023 through 2027, Genotox's gross revenue exceeds Thirteen Million Five Hundred Thousand Dollars (\$13,500,000.00) for that calendar year, then Genotox shall pay the United States a sum (hereinafter Revenue Payment) equal to: (i) onehalf of one percent (0.5%) of Genotox's gross revenue for that calendar year between Thirteen Million Five Hundred Thousand Dollars (\$13,500,000.00) and Twenty Million Dollars (\$20,000,000.00); plus (ii) one-sixth of Genotox's gross revenue for that calendar year between Twenty Million Dollars (\$20,000,000.00) and Thirty-Five Million Dollars (\$35,000,000.00); plus (iii) one-third of Genotox's gross revenue for that calendar year between Thirty-Five Million Dollars (\$35,000,000.00) and Fifty Million Dollars (\$50,000,000.00); plus (iv) one-half of Genotox's gross revenue for that calendar year that exceeds Fifty Million Dollars (\$50,000,000.00). Within thirty (30) days following the December 31 close of each calendar year 2023 through 2027 (Submission Date), Genotox shall submit, for itself and any other property, entity, or venture in which Genotox has an ownership interest, annual audited financial statements and any other supporting documentation (Audited Financials) for the purposes of calculating any Revenue Payment. If no annual audited financial statements exist, then Genotox shall submit by the Submission Date unaudited financial statements and any other supporting documentation (Unaudited Financials) for the purposes of calculating any Revenue Payment. In the event Genotox submits an unaudited financial statement, it shall also submit by the Submission Date a signed

written certification subject to 18 U.S.C. § 1001 confirming that the unaudited financial statement is truthful, accurate, and complete (Signed Certification). Such Audited Financials, Unaudited Financials, and Signed Certification shall be submitted to the undersigned counsel for the United States (or anyone else they identify to receive service). Genotox shall pay any Revenue Payment to the United States by electronic funds transfer, pursuant to written instructions by the United States, within sixty (60) days following the December 31 close of the year. For avoidance of doubt, no portion of the Suspended Amount retained by the United States pursuant to subparagraph (b) above shall be considered Genotox's gross revenue for purposes of this subparagraph.

- e. During calendar years 2023 through 2027, Genotox shall provide thirty (30) calendar days' advance, written notice to the United States of any sale, transfer, merger, or liquidation of any Qualifying Asset (defined below) that individually or collectively has a fair market value of at least Fifty Thousand Dollars (\$50,000.00) (Sale Event). As referred to herein, a Qualifying Asset is any asset or assets owned or controlled by Genotox, or any other property, entity, or venture in which Genotox has an ownership interest. Within fourteen (14) calendar days of the closing of each Sale Event, Genotox shall pay to the United States fifty percent (50%) of the following amount: (i) the greater of the total proceeds from the Sale Event and the fair market value of the Qualifying Assets, less (ii) any associated federal, state, and local tax payments and transaction fees directly incurred by Genotox in effectuating the Sale Event (Sale Event Payment).
- f. All payments by Genotox under subparagraphs (a)–(e) up to Twenty-Nine Million Ninety-Six Thousand Seven Hundred Thirty-Three Dollars (\$29,096,733.00) are restitution to the United States.
- 2. Conditioned upon the United States receiving the payments in Paragraph 1(a)–(e) above, the United States agrees that it shall pay to Relator by electronic funds transfer seventeen

percent (17.0%) of each such payment under this Agreement (Relator's Share) as soon as feasible after receipt of the payment.

- 3. Pursuant to 31 U.S.C. § 3730(d)(2), Genotox shall pay Two Hundred Twenty-Five Thousand Dollars (\$225,000.00) (Relator's Fees) to Relator's counsel for Relator's reasonable expenses, attorneys' fees, and costs within ten (10) calendar days of the Effective Date, pursuant to written instructions to be provided by Relator's counsel.
- 4. Subject to the exceptions in Paragraph 7 (concerning reserved claims) below, and subject to Paragraph 10 (concerning disclosure of assets), Paragraph 19 (concerning default), and Paragraph 20 (concerning bankruptcy) below, and upon the United States' receipt of the Settlement Amount, the United States releases Genotox from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729–3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801–3812; or the common law theories of payment by mistake, unjust enrichment, and fraud.
- 5. Subject to the exceptions in Paragraph 7 below, and subject to Paragraph 10 (concerning disclosure of assets), Paragraph 19 (concerning default), and Paragraph 20 (concerning bankruptcy) below, and upon the United States' receipt of the Settlement Amount and Relator's counsel's receipt of the Relator's Fees, Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, releases Genotox and its current and former parent corporations; current and former direct and indirect subsidiaries; current and former brother or sister corporations and divisions; and its current or former owners, officers, directors, employees, and affiliates (collectively, "Genotox Releasees"), from any and all claims and potential claims, including but not limited to all claims included in Relator's *qui tam* complaint filed in the Civil

Action, any other claims the Relator has on behalf of the United States under the False Claims Act, 31 U.S.C. §§ 3729–3733, and for any and all claims for relief, actions, rights, causes of action, suits, debts, obligations, liabilities, demands, losses, damages (including treble damages and any civil penalties), punitive damages, costs and expenses of any kind, character, or nature whatsoever, known or unknown, fixed or contingent, in law or in equity, in contract or in tort, or under any federal or state statute or regulations, or otherwise that Relator has standing to bring which Relator may now have or claim to have against the Genotox Releasees, arising in any way out of or connected in any way with the facts, claims, and circumstances alleged in the Civil Action, or from any other past activities and actions of the Genotox Releasees.

6. In consideration of the obligations of Genotox in this Agreement and the Corporate Integrity Agreement (CIA), entered into between OIG-HHS and Genotox, and upon the United States' receipt of full payment of the Settlement Amount, OIG-HHS shall release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Genotox under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in this paragraph and in Paragraph 7 below (concerning reserved claims). OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Genotox from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this paragraph precludes OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 7 below.

- 7. Notwithstanding the releases given in Paragraphs 4 and 6 of this Agreement, or any other term of this Agreement, the following claims and rights of the United States are specifically reserved and are not released:
 - a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
 - b. Any criminal liability;
 - Except as explicitly stated in this Agreement, any administrative liability or enforcement right, including mandatory exclusion from Federal health care programs;
 - d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
 - e. Any liability based upon obligations created by this Agreement;
 - f. Any liability of individuals;
 - g. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
 - h. Any liability for failure to deliver goods or services due; and
 - i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.
- 8. Relator and his heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). Conditioned upon Relator's receipt of the Relator's Share, Relator and his heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States, its agencies, officers, agents,

employees, and servants, from any claims arising from the filing of the Civil Action or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the Civil Action.

- 9. Relator, for himself, and for his heirs, successors, attorneys, agents, and assigns, releases Genotox from any liability to Relator arising from the filing of the Civil Action, or under 31 U.S.C. § 3730(d) for expenses or attorneys' fees and costs.
- 10. Genotox has provided sworn financial disclosures and supporting documents (together "Financial Disclosures") to the United States, and the United States has relied on the accuracy and completeness of those Financial Disclosures in reaching this Agreement. Genotox warrants that the Financial Disclosures are complete, accurate, and current as of the Effective Date of this Agreement. If the United States learns of asset(s) in which Genotox had an interest of any kind as of the Effective Date of this Agreement (including, but not limited to, promises by insurers or other third parties to satisfy Genotox's obligations under this Agreement) that were not disclosed in the Financial Disclosures, or if the United States learns of any false statement or misrepresentation by Genotox on, or in connection with, the Financial Disclosures, and if such nondisclosure, false statement, or misrepresentation changes the estimated net worth set forth in the Financial Disclosures by Fifty Thousand Dollars (\$50,000.00) or more, the United States may at its option: (a) rescind this Agreement and reinstate its suit or file suit based on the Covered Conduct; or (b) collect the full Settlement Amount in accordance with the Agreement plus one hundred percent (100%) of the net value of Genotox's previously undisclosed assets. Genotox agrees not to contest any collection action undertaken by the United States pursuant to this provision, and agrees that it will immediately pay the United States the greater of (i) a ten percent (10%) surcharge of the amount collected in the collection action, as allowed by 28 U.S.C.

§ 3011(a), or (ii) the United States' reasonable attorneys' fees and expenses incurred in such an action. In the event that the United States, pursuant to this Paragraph rescinds this Agreement, Genotox waives and agrees not to plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims that (a) are filed by the United States within one hundred twenty (120) calendar days of written notification to Genotox that this Agreement has been rescinded, and (b) relate to the Covered Conduct, except to the extent these defenses were available on the Effective Date.

- 11. Genotox waives and shall not assert any defenses Genotox may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.
- 12. Genotox fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Genotox has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct or the United States' investigation or prosecution thereof.
- 13. Genotox fully and finally releases the Relator from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Genotox has asserted, could have asserted, or may assert in the future against the Relator, related to the Covered Conduct and the Relator's investigation and prosecution thereof.

14. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by HHS, any Medicare contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, or carrier), RRB, TRICARE, or any state payer, related to the Covered Conduct; and Genotox agrees not to resubmit to HHS, any Medicare contractor, RRB, TRICARE, or any state payer any previously denied claims related to the Covered Conduct, agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals.

15. Genotox agrees to the following:

- a. <u>Unallowable Costs Defined</u>: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395–1395lll and 1396–1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Genotox, its present or former officers, directors, employees, shareholders, and agents in connection with:
 - (1) the matters covered by this Agreement and any related deferred prosecution agreement;
 - (2) the United States' audit(s) and civil and criminal investigation(s) of the matters covered by this Agreement;
 - (3) Genotox's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and criminal investigation(s) in connection with the matters covered by this Agreement (including attorneys' fees);
 - (4) the negotiation and performance of this Agreement and any deferred prosecution agreement;

- (5) the payments Genotox makes to the United States pursuant to this

 Agreement and any payments that Genotox may make to Relator, including
 costs and attorneys' fees; and
- (6) the negotiation of, and obligations undertaken pursuant to the CIA to:(i) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and (ii) prepare and submit reports to OIG-HHS,

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, RRMP, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs). However, nothing in Paragraph 15(a)(6) above that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to Genotox.

- b. <u>Future Treatment of Unallowable Costs</u>: Unallowable Costs shall be separately determined and accounted for by Genotox, and Genotox shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Genotox or any of its subsidiaries or affiliates to the Medicare, Medicaid, RRMP, TRICARE, or FEHBP Programs.
- c. <u>Treatment of Unallowable Costs Previously Submitted for Payment:</u>
 Genotox further agrees that within ninety (90) days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program,

including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Genotox or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. Genotox agrees that the United States, at a minimum, shall be entitled to recoup from Genotox any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Genotox or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Genotox or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

- d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Genotox's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.
- 16. Genotox agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Genotox shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. Genotox further agrees to furnish to the United States, upon

request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf.

- 17. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraphs 5 and 12 above and Paragraph 18 (waiver for beneficiaries paragraph), below.
- 18. Genotox agrees that it waives and shall not seek payment for any of the healthcare billings covered by this Agreement from any healthcare beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.
- 19. The Settlement Amount represents the amount the United States is willing to accept in compromise of its civil claims arising from the Covered Conduct due solely to Genotox's financial condition as reflected in the Financial Disclosures referenced in Paragraph 10 above.
- a. In the event that Genotox fails to pay the Settlement Amount as provided in the payment schedule set forth in Paragraph 1 above and Exhibit B hereto, Genotox shall be in Default of Genotox's payment obligations (Default). The United States will provide a written Notice of Default, and Genotox shall have an opportunity to cure such Default within seven (7) calendar days from the date of receipt of the Notice of Default by making the payment due under the payment schedule and paying any additional interest accruing under the Settlement Agreement up to the date of payment. Notice of Default will be delivered to Genotox, or to such other representative as Genotox shall designate in advance in writing. If Genotox fails to cure the Default within seven (7) calendar days of receiving the Notice of Default and in the absence of an agreement with the United States to a modified payment schedule (Uncured Default), the

remaining unpaid balance of the Settlement Amount shall become immediately due and payable, and interest on the remaining unpaid balance shall thereafter accrue at the rate of twelve percent (12%) per annum, compounded daily from the date of Default, on the remaining unpaid total (principal and interest balance).

b. In the event of Uncured Default, Genotox agrees that the United States, at its sole discretion, may (i) retain any payments previously made, rescind this Agreement, and pursue the Civil Action or bring any civil and/or administrative claim, action, or proceeding against Genotox for the claims that would otherwise be covered by the releases provided in Paragraphs 4 and 6 above, with any recovery reduced by the amount of any payments previously made by Genotox to the United States under this Agreement; (ii) take any action to enforce this Agreement in a new action or by reinstating the Civil Action; (iii) offset the remaining unpaid balance from any amounts due and owing to Genotox and/or any of its subsidiaries or affiliates by any department, agency, or agent of the United States at the time of Default or subsequently; and/or (iv) exercise any other right granted by law, or under the terms of this Agreement, or recognizable at common law or in equity. The United States shall be entitled to any other rights granted by law or in equity by reason of Default, including referral of this matter for private collection. In the event the United States pursues a collection action, Genotox agrees immediately to pay the United States the greater of (i) a ten percent (10%) surcharge of the amount collected, as allowed by 28 U.S.C. § 3011(a), or (ii) the United States' reasonable attorneys' fees and expenses incurred in such an action. In the event that the United States opts to rescind this Agreement pursuant to this Paragraph, Genotox waives and agrees not to plead, argue, or otherwise raise any defenses of statute of limitations, laches, estoppel or similar theories, to any civil or administrative claims that (i) are filed by the United States against Genotox within one hundred twenty (120) days of written

notification that this Agreement has been rescinded, and (ii) relate to the Covered Conduct, except to the extent these defenses were available on the Effective Date. Genotox agrees not to contest any offset, recoupment, and /or collection action undertaken by the United States pursuant to this Paragraph, either administratively or in any state or federal court, except on the grounds of actual payment to the United States.

- c. In the event of Uncured Default, OIG-HHS may exclude Genotox from participating in all Federal health care programs until Genotox pays the Settlement Amount, with interest, as set forth above (Exclusion for Default). OIG-HHS will provide written notice of any such exclusion to Genotox. Genotox waives any further notice of the exclusion under 42 U.S.C. § 1320a-7(b)(7), and agrees not to contest such exclusion either administratively or in any state or federal court. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, Genotox wishes to apply for reinstatement, it must submit a written request for reinstatement to OIG-HHS in accordance with the provisions of 42 C.F.R. §§ 1001.3001–.3005. Genotox will not be reinstated unless and until OIG-HHS approves such request for reinstatement. The option for Exclusion for Default is in addition to, and not in lieu of, the options identified in this Agreement or otherwise available.
- 20. In exchange for valuable consideration provided in this Agreement, Genotox and Relator acknowledge the following:
- a. Genotox has reviewed its financial situation and warrants that it is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I) and shall remain solvent following payment to the United States of the Settlement Amount.
- b. In evaluating whether to execute this Agreement, the Parties intend that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous

exchange for new value given to Genotox, within the meaning of 11 U.S.C. § 547(c)(1), and the Parties conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange.

- c. The mutual promises, covenants, and obligations set forth herein are intended by the Parties to, and do in fact, constitute a reasonably equivalent exchange of value.
- d. The Parties do not intend to hinder, delay, or defraud any entity to which Genotox was or became indebted to on or after the date of any transfer contemplated in this Agreement, within the meaning of 11 U.S.C. § 548(a)(1).
- e. If any of Genotox's payments or obligations under this Agreement are avoided for any reason (including but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code) or if, before the Settlement Amount is paid in full, Genotox or a third party commences a case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors seeking any order for relief of Genotox's debts, or to adjudicate Genotox as bankrupt or insolvent; or seeking appointment of a receiver, trustee, custodian, or other similar official for Genotox or for all or any substantial part of Genotox's assets:
- (i) The United States may rescind the releases in this Agreement and bring any civil and/or administrative claim, action, or proceeding against Genotox for the claims that would otherwise be covered by the releases provided in Paragraphs 4 and 6 above;
- (ii) The United States has an undisputed, noncontingent, and liquidated allowed claim against Genotox in the amount of Eighty-Seven Million Two Hundred Ninety Thousand One Hundred Ninety-Nine Dollars (\$87,290,199.00), less any payments received pursuant to Paragraph 1 of this Agreement, provided, however, that such payments are not

otherwise avoided and recovered from the United States by Genotox, a receiver, trustee, custodian, or other similar official for Genotox;

- (iii) If any payments are avoided and recovered by a receiver, trustee, creditor, custodian, or similar official, the United States shall not be responsible for the return of any amounts already paid by the United States to the Relator; and
- (iv) If, notwithstanding subparagraph (iii), any amounts already paid by the United States to the Relator pursuant to Paragraph 2 above are recovered from the United States in an action or proceeding filed by a receiver, trustee, creditor, custodian, or similar official in or in connection with a bankruptcy case that is filed within two years of the Effective Date of this Agreement or of any payment made under Paragraph 1 of this Agreement, Relator shall, within thirty (30) days of written notice from the United States to the undersigned Relator's counsel, return to the United States all amounts recovered from the United States.
- f. Genotox agrees that any civil and/or administrative claim, action, or proceeding brought by the United States under Paragraph 20(e) is not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) because it would be an exercise of the United States' police and regulatory power. Genotox shall not argue or otherwise contend that the United States' claim, action, or proceeding is subject to an automatic stay and, to the extent necessary, consents to relief from the automatic stay for cause under 11 U.S.C. § 362(d)(1). Genotox waives and shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claim, action, or proceeding brought by the United States within one hundred twenty (120) days of written notification to Genotox that the releases have been rescinded pursuant to this Paragraph, except to the extent such defenses were available on the Effective Date.

- 21. Upon receipt of the Initial Payment described in Paragraph 1(a) above, the Parties shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal of the Claims Against Genotox in the Civil Action pursuant to Rule 41(a)(1). The Joint Stipulation of Dismissal shall be with prejudice as to the United States' and the Relator's claims in the Civil Action against Genotox as to the Covered Conduct and consistent with the terms and conditions of this Agreement. The Joint Stipulation of Dismissal shall be without prejudice to the United States and with prejudice to the Relator as to all other claims against Genotox in the Civil Action.
- 22. Except as provided in Paragraph 3 above, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.
- 23. Each Party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.
- 24. This Agreement is governed by the laws of the United States. The exclusive venue for any dispute relating to this Agreement is the United States District Court for the Southern District of Georgia. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.
- 25. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties. Forbearance by the United States from pursuing any remedy or relief available to it under this Agreement shall not constitute a waiver of rights under this Agreement.
- 26. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

- 27. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.
 - 28. This Agreement is binding on Genotox's successors, transferees, heirs, and assigns.
 - 29. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.
- 30. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.
- 31. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

[SIGNATURE PAGE(S) FOLLOW]

THE UNITED STATES OF AMERICA

DATED: 3/30/2023	BY:	DOUGLAS ROSENTHAL CHRISTOPHER TERRANOVA Trial Attorneys Commercial Litigation Branch Civil Division United States Department of Justice
DATED: 3/30/2013	BY:	BRADFORD C. PATRICK Assistant United States Attorney United States Attorney's Office Southern District of Georgia
DATED: <u>3/29/2</u> 023	BY:	LISA M. RE Assistant Inspector General for Legal Affairs Office of Counsel to the Inspector General Office of Inspector General United States Department of Health and Human Services
DATED: <u>03/19/2023</u>	BY:	BLEY.PAUL.NICHO Digitally signed by BLEY.PAUL.NICHOLAS.1099873821 Date: 2023.03.19 14:17:05-0400' SALVATORE M. MAIDA General Counsel

Defense Health Agency United States Department of Defense

GENOTOX

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DATED: 3	111	11.57.7	
DATED. 7	1 30	1000	
DAILD.			

BY:

MATTHEW MCCARTY, M.D.

Chief Executive Officer Genotox Laboratories Ltd.

DATED: 3-20-23

BY:

MATTHEW DIGGS

ALEXANDER PORTER Davis Wright Tremaine LLP

Counsel for Genotox Laboratories Ltd.

DATED: 3/16/23 BY:

AZEX DIGIACOMO

ATED: BY

ROBERT H. SNYDER, JR. Cannella Snyder LLC

Counsel for Alex DiGiacomo

EXHIBIT A

Genotox admits and accepts responsibility for the following conduct:

1. Genotox is a Clinical Laboratory Improvement Amendments (CLIA) certified reference laboratory that was established in 2012 and which specializes in urine drug testing (UDT), 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, TRICARE, and RRB.

Payments to "1099 Representatives"

- 2. 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. 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. From approximately 2014 to March 2019, Genotox paid 1099 representatives almost exclusively on a percentage commission basis. Genotox executed contracts in which it committed to pay 1099 representatives a percentage of total revenue associated with medical provider accounts for which each 1099 representative was responsible. These payments were made on an ongoing basis for the term of the agreement.
- 3. The revenue used to calculate the commission payment was the revenue realized from billings to insurers, including Medicare, TRICARE, and RRB, for services Genotox provided to healthcare providers and patients, including UDT. That revenue was dependent both upon the 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.

- 4. 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, UDT from Genotox.
- 5. 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, the Eliminating Kickbacks in Recovery Act (EKRA), 18 U.S.C. § 220. Genotox then began an effort to transition 1099 representatives to fixed-rate MSAs.
- 6. However, 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.
- 7. In addition, at times after March 2019, 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.

- 8. The tracking was performed specifically as to each 1099 representative that was transitioned to an MSA. For example, 1099 representative N.I. was paid 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.
- 9. The 1099 representatives were responsible for marketing Genotox UDT to providers in a specified geographic area. Genotox tied the 1099 representatives' percentage commissions directly to the revenue generated from—and thus the volume of—testing ordered by each practice or physician for which the 1099 representative was responsible. Genotox's percentage commission 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.

Use of "Custom Toxicology Profiles"

10. 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.

- 11. 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 healthcare provider'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.
- 12. 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.
- 13. 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.

EXHIBIT B

Calendar Year	Payment Due Date	Payment Due	4.0% Interest	Principal	Balance
					\$415,000.00
2023	12/31/2023	\$96,600.00	\$16,600.00	\$80,000.00	\$335,000.00
2024	12/31/2024	\$93,400.00	\$13,400.00	\$80,000.00	\$255,000.00
2025	12/31/2025	\$92,200.00	\$10,200.00	\$82,000.00	\$173,000.00
2026	12/31/2026	\$91,920.00	\$6,920.00	\$85,000.00	\$88,000.00
2027	12/31/2027	\$91,520.00	\$3,520.00	\$88,000.00	
	Total	\$465,640.00	\$50,640.00	\$415,000.00	

EXHIBIT C

Promissory Note

- 1. For value received, and pursuant to the Settlement Agreement executed on <u>May ch</u> 30 2023 (Settlement Agreement), the terms and definitions of which are incorporated by reference herein, debtor Genotox Laboratories Ltd. (Debtor), for itself and its successors and assigns, promises to pay to the United States of America (United States), or its assignee, the full principal sum of Four Hundred Fifteen Thousand Dollars (\$415,000.00), plus interest at four percent (4.0%) per annum, pursuant to the payment schedule in Exhibit B of the Settlement Agreement, herein incorporated by reference. This Note matures on the date of last payment on the Payment Schedule in Exhibit B, which is December 31, 2027, if at that time, the full debt amount has not been satisfied. Debtor has an address of 2170 Woodward Street, Suite 100, Austin, TX 78744. The United States has an address of the United States Attorney's Office for the Southern District of Georgia, 22 Barnard Street, Suite 300, Savannah, GA 31401.
- 2. Payments shall be made by electronic funds transfer pursuant to written instructions to be provided by the Civil Division of the United States Department of Justice. If there is any change in the method or instructions of payment, the United States shall inform Debtor at least five (5) business days before the next Payment Over Time is due.
- 3. This Note may be prepaid, in whole or in part, without penalty or premium. Partial prepayment does not alter the interest rate applicable each year as reflected in Paragraph 1 of this Note.
- 4. Pursuant to the Settlement Agreement, and to secure the Payments Over Time and this Note, Debtor will execute, contemporaneous with the Settlement Agreement, a Security Agreement (Security Agreement) in favor of the United States, in the form of Exhibit D, in which Debtor will grant the United States a first priority security interest in the Debtor's assets identified on Exhibit E (collectively, Collateral). This Collateral is for the full principal sum of Four Hundred Fifteen Thousand Dollars (\$415,000.00), plus interest at four percent (4.0%) per annum, pursuant to the payment schedule in Exhibit B of the Settlement Agreement.
- 5. Debtor is in default of this Note on the date of occurrence of any of the following events (Events of Default).
 - A. Debtor fails to pay any amount provided for in this Note within seven (7) calendar days from the date of Debtor's receipt of a Notice of Default pursuant to Paragraph 19(a) of the Settlement Agreement.
 - B. If prior to making the full payment of the amount due under this Note, any case, proceeding, or other action is instituted:
 - under any law relating to bankruptcy, insolvency, reorganization, or relief of Debtor, seeking to have any order for relief entered against Debtor, or seeking to adjudicate Debtor as bankrupt or insolvent; or

M.M 3/29/23

- ii. seeking appointment of a receiver, trustee, custodian or other similar official for Debtor or for all or any substantial part of Debtor's assets.
- C. Debtor's failure to pay the sums specified in Paragraph 1(c) of the Settlement Agreement within seven (7) calendar days from the date of Debtor's receipt of a Notice of Default pursuant to Paragraph 19(a) of the Settlement Agreement.
- 6. Debtor shall provide the United States written notice of an Event of Default specified in Paragraph 5(B) of this Note within five (5) business days of such event by overnight mail, delivered to the United States Attorney's Office for the Southern District of Georgia, 22 Barnard Street, Suite 300, Savannah, GA 31401.
- 7. Upon the occurrence of an Event of Default, without further notice or presentment and demand by the United States:
 - A. The remaining unpaid balance of the Payments Over Time, which is secured by the Security Agreement (Exhibit D), shall become immediately due and payable (Default Amount). Interest shall accrue on the Default Amount from the date of the Event of Default at twelve percent (12%) per annum, compounded daily.
 - B. The United States may take any action necessary to execute upon the Collateral and/or Security Agreement to secure its remaining debt.
 - C. The United States retains any and all other rights and remedies it has or may have under law and equity, and may exercise those rights or remedies.
 - D. No failure or delay on the part of the United States to exercise any right or remedy shall operate as a waiver of the United States' rights. No partial or single exercise by the United States of any right or remedy shall operate as a waiver of the United States' rights.
 - E. Debtor will pay the United States all reasonable costs of collection, including reasonable attorneys' fees and expenses.
- 8. Except as provided by law or regulation, Debtor shall not lease, assign, sell, transfer, or encumber, voluntarily or otherwise, the Collateral without the written consent of the United States, which shall not be unreasonably withheld. The United States may grant consents, partial releases, subordinations, and satisfactions in accordance with regulations.
- 9. Waiver by the United States of any default by Debtor or their successors or assigns will not constitute a waiver of a subsequent default. Failure by the United States to exercise any right, power, or privilege which it may have by reason of default will not preclude the exercise of such right, power, or privilege so long as Debtor remains in Uncured Default of the Settlement Agreement as defined in Paragraph 19(a) of the Settlement Agreement or if a subsequent default occurs.

- 10. This Note shall be governed and construed according to the laws of the United States of America.
- 11. Debtor acknowledges that it is entering into this Note, freely, voluntarily and with no degree of compulsion whatsoever.

IN WITNESS THEREOF, Matthew McCarty, M.D., as an authorized signatory of Genotox Laboratories, Ltd., appearing personally in Austin, TX, and intending to hereby legally bind Genotox Laboratories, Ltd. and its successors and assigns, has caused this Note to be executed, duly attested this <u>ite</u> day of <u>March</u>, 2023.

Date: 3/16/2023

Matthew McCarty, M.D., Authorized Signatory

HEATHER BETTES ID #129105653 My Commission Expires

GENOTOX LABORATORIES, LTD.

On ______, 2023, before me the undersigned officer, personally came Matthew McCarty, M.D., to me known who, being duly sworn, did depose and state that (1) he resides in Texas, (2) he is the Chief Executive Officer of Genotox Laboratories Ltd., the company described in and which executed the above instrument, and (3) being authorized to do so, he signed on behalf of Genotox Laboratories Ltd. as its authorized signatory.

Notary Public State of Texas

My Commission Expires: 09/04/2024

EXHIBIT D

Security Agreement

- M.M. 3/29/23 THIS SECURITY AGREEMENT executed on March 16 2023, for value received, is made between the United States of America (United States) and Genotox Laboratories Ltd. (Genotox), a Texas limited partnership whose principal place of business is 2170 Woodward Street, Suite 100, Austin, TX 78744.
- WHEREAS Genotox is justly indebted to the United States as evidenced by the Settlement Agreement, Promissory Note (Note) (Exhibit C), or other instruments, and in the future may incur additional indebtedness to the United States, which may also be evidenced by one or more promissory notes or other instruments, which have been executed by Genotox and which are payable to the order of the United States, and authorize acceleration of the entire indebtedness at the option of the United States upon any Uncured Default of the Settlement Agreement as defined in Paragraph 19(a) of the Settlement Agreement or any Event of Default as defined in Paragraph 5 of the Note by Genotox (collectively, Indebtedness); and it is the purpose and intent of this Security Agreement to secure prompt payment and the timely performance of all debts, liabilities, obligations and covenants of Genotox to the United States hereunder without limitation (hereafter called Obligations) contained therein.

NOW THEREFORE, in consideration of said Obligations and (1) to secure the prompt payment of all existing and future Indebtedness and liabilities of Genotox to the United States and of all renewals, modifications, and extensions of such Indebtedness, all with interest; (2) in any event and at all times to secure the prompt payment of all advances and expenditures made by the United States, with interest, as described in this Security Agreement; and (3) the timely performance of every covenant and agreement of Genotox contained in this Security Agreement or in any supplementary agreement:

GENOTOX GRANTS TO the United States a first priority security interest in the Debtor's assets identified on Exhibit E (collectively, Collateral).

GENOTOX WARRANTS, COVENANTS, AND AGREES THAT: 3.

- Genotox is the absolute and exclusive owner of the Collateral, and such Collateral is free from all liens, encumbrances, security and other interests except any existing liens, encumbrances, security or other interests in favor of the United States which shall remain in full force and effect. Genotox will defend the Collateral against the claims and demands of all other persons.
- Genotox will (1) care for and maintain Collateral in a good and reasonable manner; (b) (2) insure the Collateral in such amounts and manner as may be reasonably required by the United States, and if it fails to do so, the United States, at its option, may procure such insurance; (3) permit the United States to inspect the Collateral at any reasonable time; (4) not abandon the Collateral or encumber, conceal, remove, sell or otherwise dispose of it or of any interest in the Collateral, or permit others to do so, outside the ordinary course of business or without the prior written consent of the United States; (5) not permit the Collateral to be levied upon, injured or destroyed, or its value to be impaired; and (6) maintain accurate records of the Collateral, furnish

the United States any requested information related to the Collateral and allow the United States to inspect and copy all records relating to the Collateral.

- (c) Genotox will pay promptly when due all: rents, taxes, insurance premiums, levies, assessments, liens, and other encumbrances, and costs of maintenance and other charges now or later attaching to, levied on, or otherwise pertaining to the Collateral or this security interest.
- (d) The United States is authorized to file financing statements describing the Collateral, to file amendments to the financing statements, and to file continuation statements.
- (e) Genotox will immediately notify the United States of: any material change in the Collateral or in the Collateral's location; change in their names, address, or location; change in any warranty or representation in this Security Agreement; change that may affect this security interest or its perfection; and any event of default.
- (f) The United States may at any time pay any other amounts required in this Security Agreement to be paid by Genotox and not paid when due, including any costs and expenses for the preservation or protection of the Collateral or this security interest, as advances for the account of Genotox. All such advances shall bear interest at the rate borne by the Note.
- (g) In order to secure or better secure the above-mentioned Obligations or Indebtedness, Genotox agrees to execute any further documents and to take any further actions reasonably requested by the United States to evidence or perfect the security interest granted herein or to effectuate the rights granted to the United States herein.

4. IT IS FURTHER AGREED THAT:

- (a) Until default, Genotox may retain possession of the Collateral and continue to operate the laboratory equipment in the ordinary course of business.
- (b) Default shall exist under this Security Agreement if Genotox fails to perform or discharge any obligation or to pay promptly any Indebtedness secured by this Security Agreement or to observe or perform any covenants or agreements in this Security Agreement or in any supplementary agreement contained, or if any of Genotox's representations or warranties herein prove false or misleading, or upon the dissolution or winding up, or their equivalent, of Genotox or upon its bankruptcy or insolvency. Upon any Uncured Default of the Settlement Agreement as defined in Paragraph 19(a) of the Settlement Agreement or any Event of Default as defined in Paragraph 5 of the Note by Genotox:
 - (1) The United States, at its option, with or without notice as permitted by law may (a) declare the unpaid balance on the Obligations and any Indebtedness secured by this Security Agreement immediately due and payable; (b) enter upon the premises and take possession of, repair, improve, use, and operate the Collateral or make equipment usable, for the purpose of protecting or preserving the Collateral or this lien, or preparing or processing the Collateral for sale, and (c) exercise any sale or other rights accorded by law. The United States may disclaim all warranties relating to title, possession, quiet enjoyment, merchantability, fitness or the like in any disposition of the Collateral;

- (2) Genotox (a) agrees to assemble the Collateral and make it available to the United States at such times and places as designated by the United States; and (b) waives all notices, exemptions, compulsory disposition and redemption rights;
- (3) A default shall exist under any other security instrument held by the United States and executed or assumed by Genotox on real property or personal property related thereto. Likewise, default under such other security instrument shall constitute default under this Security Agreement.
- (c) Proceeds from disposition of Collateral shall be applied first on expenses of retaking, holding, preparing for sale, processing, selling and the like and for payment of reasonable attorneys' fees and legal expenses incurred by the United States, second to the satisfaction of prior security interests or liens to the extent required by law, third to the satisfaction of Indebtedness secured by this Security Agreement, fourth to the satisfaction of subordinate security interests to the extent required by law, and fifth to any obligations of Genotox owing to the United States. Any proceeds collected under insurance policies shall be applied first on advances and expenditures made by the United States, with interest, as provided above, second on the debt evidenced by the Settlement Agreement and Note, unless the United States consents in writing to their use by Genotox under the United States' direction for repair or replacement of the Collateral, third on any other obligation of Genotox owing to the United States, and any balance shall be paid to Genotox unless otherwise provided in the insurance policies.
- (d) It is the intent of Genotox and the United States that to the extent permitted by law and for the purpose of this Security Agreement, no Collateral covered by this Security Agreement is or shall become realty or accessioned to other goods.
- (e) Genotox agrees that the United States will not be bound by any present or future State exemption laws. Genotox expressly WAIVES the benefit of any such State laws.
- (f) The United States may comply with any applicable State or Federal law requirements in connection with the disposition of the Collateral and compliance will not be considered to adversely affect the commercial reasonableness of any sale of the Collateral.
- (g) If any provision of this Security Agreement is held invalid or unenforceable, it shall not affect any other provisions, but this Security Agreement shall be construed as if it had never contained such invalid or unenforceable provision.
- (h) The rights and privileges of the United States under this Security Agreement shall accrue to the benefit of its successors and assigns. All covenants, warranties, representations, and agreements of Genotox contained in this Security Agreement shall bind personal representatives, heirs, successors, and assigns.
- (i) Failure of the United States to exercise any right, whether once or often, shall not be construed as a waiver of any covenant or condition or of the breach of such covenant or condition. Such failure shall also not affect the exercise of such right without notice upon any subsequent breach of the same or any other covenant or condition.

- (j) THE UNITED STATES HAS INFORMED GENOTOX THAT DISPOSAL OF PROPERTY COVERED BY THIS SECURITY AGREEMENT WITHOUT THE CONSENT OF THE UNITED STATES, OR MAKING ANY FALSE STATEMENT IN THIS SECURITY AGREEMENT OR ANY RELATED DOCUMENT, MAY CONSTITUTE A VIOLATION OF FEDERAL CRIMINAL LAW.
- 5. This Security Agreement shall be governed and construed according to the laws of the United States of America.
- 6. Genotox acknowledges that it is entering into this Security Agreement, freely, voluntarily and with no degree of compulsion whatsoever.
- 7. Genotox certifies that the signing party below is fully authorized to bind the entity and sign on its behalf.

IN WITNESS THEREOF, Matthew McCarty, M.D., as an authorized signatory of Genotox Laboratories, Ltd., appearing personally in Austin, TX, and intending to hereby legally bind Genotox Laboratories, Ltd. and its successors and assigns, has caused this Security Interest to be executed, duly attested this <u>lee</u> day of <u>March</u>, 2023.

Date: 3/16/2023

GENOTOX LABORATORIES, LTD.

Matthew McCarty, M.D., Authorized Signatory

ID #129105653 My Commission Expires September 04, 2024

On March 16, 2023, before me the undersigned officer, personally came Matthew McCarty, M.D., to me known who, being duly sworn, did depose and state that (1) he resides in Texas, (2) he is the Chief Executive Officer of Genotox Laboratories Ltd., the company described in and which executed the above instrument, and, (3) being authorized to do so, he signed on behalf of Genotox Laboratories Ltd. as its authorized signatory.

Notary Public State of Texas

My Commission Expires: 09/04/2024

EXHIBIT E – COLLATERAL

GENETICS

Manufacturer	Model	Catalog #	Serial #	Location	Description
Eppendorf	5810	5810 R	5811BQ268453	LAB B	Centrifuge
Eppendorf	5810	5810	5810FI665153	LAB B	Centrifuge
					Extraction
Applied Biosystems	MagMAX-96	710	710-1247	LAB B	Instrument
	Tr' D'1 El oc	5400600	511 00654	TADD	Extraction
Thermo Scientific	KingFisher Flex -96	5400630	711-82674	LAB B	Instrument
Thermo Scientific	KingFisher Flex -96	5400630	711-83922	LAB C	Extraction Instrument
Thermo Scientific	Kiligrisher Flex -90	3400030	/11-03922	LADC	Extraction
Thermo Scientific	KingFisher Flex -96	5400630	711-83880	LAB C	Instrument
	QuantStudio 12K				RT-PCR Instrument
Applied Biosystems	Flex	4470661	285880365	LAB C	#1
	QuantStudio 12K				RT-PCR Instrument
Applied Biosystems	Flex	4470661	285880761	LAB C	#2
			250002150	T AD G	RT-PCR Instrument
Applied Biosystems	ViiA 7 MassArray	4453552	278882170 PX16081291/	LAB C	#3
Agena Bioscience	Analyzer & CPM	160000	CP2008422	LAB C	MassArray Instrument #1
Agena Dioscience	MassArray	100000	PX19041582/	LADC	MassArray
Agena Bioscience	Analyzer & CPM	160000	CP1908329	LAB C	Instrument #2
Agena Bioscience	Veriti-96	4375305	2990232965	LAB C	PCR Instrument #5
Agena Bioscience	Veriti-96	4375305	2990234547	LAB C	PCR Instrument #7
Agena Bioscience	Veriti-96	4375305	2990238897	LAB C	PCR Instrument #8
Agena Bioscience	Veriti-96	4375305	2990239243	LAB C	PCR Instrument #10
Agena Bioscience	Veriti-96	4375305	2990238891	LAB C	PCR Instrument #9
Agena Bioscience	Pro Veriti-96	4484075	2739421080139	LAB C	PCR Instrument #11
Labconco	302411100	302411100	1410999594B	LAB B	Biological Safety Cabinet #1
Labconco	302519101	302519101	200593916A	LAB C	Biological Safety Cabinet #2
Labconco	302519101	302519101	200593917A	LAB C	Biological Safety Cabinet #3
Labconco	302519101	302519101	200898793A	LAB B	Biological Safety Cabinet #4
Labconco	302519101	302519101	200898789	LAB B	Biological Safety Cabinet #5
Mott Manufacturing	7421000	7421000	692902	LAB C	Chemical Fume Hood

TOXICOLOGY

Manufacturer	Model	System Handle	Serial #	Description	Instr. #
Agilent	G1316C	Louann	DEBAC05110	Thermostatted Col Comp	1
Agilent	G4220A	Louann	DEBAA03240	1290 Binary Pump	1
Agilent	G6460A	Louann	SG12437205	QQQ LC/MSD-6460A	1
Agilent	G4226A	Louann	DEBAP06866	1290 Infinity Autosampler	1
Agilent	MPS	Louann		Grestel Autosampler	1
Agilent	G1316C	Lucky	DEBAC05576	Thermostatted Col Comp	2
Agilent	G4220A	Lucky	DEBAA03245	1290 Binary Pump	2
Agilent	G6460A	Lucky	SG12527211	QQQ LC/MSD-6460A	2
Agilent	G4226A	Lucky	DEBAP06898	1290 Infinity Autosampler	2
Agilent	MPS	Lucky	MPS 380138	Grestel Autosampler	2
Agilent	G1316C	Rori	DEBAC08786	Thermostatted Col Comp	3
Agilent	G4220A	Rori	DEBAA04484	1290 Binary Pump	3
Agilent	G6460A	Rori	SQ14147307	QQQ LC/MSD-6460C	3
Agilent	G4226A	Rori	DEBAP06897	1290 Infinity Autosampler	3
Agilent	K1316C	Garth	DEEAH00193	1290 TCC Clinical ed.	4
Agilent	K1330B	Garth	DEEAJ00173	1290 Thermostat Clinical ed.	4
Agilent	G4220A	Garth	DEBAA05439	1290 Infinity Binary Pump	4
Agilent	G4226A	Garth	DEBAP06778	1290 Infinity Autosampler	4
Agilent	G6460C	Garth	SG14507302	6400 Series QQQ LC/MS	4
Agilent	K1316C	Roxanne	DEEAH00181	1290 TCC Clinical ed.	5
Agilent	K1330B	Roxanne	DEEAJ00182	1290 Thermostat Clinical ed.	5
Agilent	G4220A	Roxanne	DEBAA05449	1290 Infinity Binary Pump	5
Agilent	G4226A	Roxanne	DEBAP06774	1290 Infinity Autosampler	5
Agilent	G6460C	Roxanne	SG14507310	6400 Series QQQ LC/MS	5
Agilent	K1316C	Alex	DEEAH00182	1290 TCC Clinical ed.	6
Agilent	K1330B	Alex	DEEAJ00181	1290 Thermostat Clinical ed.	6
Agilent	G4220A	Alex	DEBAA05434	1290 Infinity Binary Pump	6
Agilent	G4226A	Alex	DEBAP06762	1290 Infinity Autosampler	6
Agilent	G6460C	Alex	SG14517309	6400 Series QQQ LC/MS	6
Tecan	EVO 100	Tecan	1505003527	8-Channel Liquid handle robot	2
Hamilton	Starlet		D654	8-Channel Liquid handle robot	
Hamilton	Starlet		G997	8-Channel Liquid handle robot	
Beckmen	DX700		2018110580	Chemistry Analyzer	
Beckmen	AU680	AU680	2012061516	AU Au680	
Millipore	CLX7040	Millipore	F5HA09530C	Millipore Water purifier	
Peak	Infinity 5050	Peak	A15-01-060	Nitrogen generator	
SPX Hankison	HPR35	SPX Hankison	H035A1151409011	Compressed Air Dryer	
Powerex	SET150720HPAJ	Powerex	(H) 12/16/14- 5729913-540	Air Compressor	
ThermoFisher Scientific	VF-A10-A	IonTrap 1	8302934	Vanquish Autosampler	1

Manufacturer	Model	System Handle	Serial #	Description	Instr. #
ThermoFisher Scientific	VF-P10-A, Rev 01	IonTrap 1	Trap 1 8302818 Vanquish Binary Pump F		1
ThermoFisher Scientific	VH-C10-A	IonTrap 1	6301162	Vanquish Col. Compartment H	1
ThermoFisher Scientific	LTQ XL	IonTrap 1	LTQ21839	Mass Spectrometer System	1
ThermoFisher Scientific	ABCDEF8000- 22	IonTrap 1	2208078R- 1710005	UPS part # 22080-78R	1
ThermoFisher Scientific	VF-A10-A	IonTrap 2	8308362	Vanquish Autosampler	2
ThermoFisher Scientific	VF-P10-A, Rev 01	IonTrap 2	8308629	Vanquish Binary Pump F	2
ThermoFisher Scientific	VH-C10-A	IonTrap 2	6501863	Vanquish Col. Compartment H	2
ThermoFisher Scientific	LTQ VELOS	IonTrap 2	LTQ40673	Mass Spectrometer System	2
ThermoFisher Scientific	ABCDEF8000- 22	IonTrap 2	220878R-1840010	UPS part # 22080-78R	2
Grenova	TipNovus Mini		TM2007	Tip Washer	
Grenova	TipLumus		Tl2016	Tip Dryer	
ThermoFisher Scientific	Miltiskan GO Microplate Reader	Synscan	1510-04699	UV-Vis Plate reader	