

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) (collectively, the United States); and (b) Genesis Reference Laboratories LLC (Genesis), through their authorized representatives. Collectively, all of the above will be referred to as the Parties.

RECITALS

A. Genesis is a clinical laboratory in Orlando, Florida that provided laboratory testing for patients referred by physicians and other healthcare providers.

B. The United States contends that Genesis submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll (Medicare).

C. The United States contends that it has certain civil claims against Genesis arising from the following alleged conduct from January 1, 2019 to October 31, 2021: Genesis paid marketing companies Corum Group LLC, Provisional Medical Consultants LLC, and RMC Medical LLC (collectively, Marketers) to arrange for and recommend that healthcare providers order clinical laboratory services from Genesis. The Marketers used purported management services organizations (MSOs) to pay thousands of dollars in kickbacks to healthcare providers Chad Shelton, M.D., Michael Boedefeld, M.D., Gregory Stynowick, M.D., Imran Chishti, M.D., Shamim Badiyan, M.D., Stanley Librach, M.D., and Psych Care Consultants LLC (all collectively, Paid HCPs) that were disguised as investment returns but were actually offered to induce the Paid HCPs' referrals to Genesis for urine drug testing (UDT). Genesis knew that the Marketers were paying MSO kickbacks to the Paid HCPs to induce their UDT referrals to Genesis and that the Paid HCPs subsequently referred Medicare patients to Genesis for UDT. Nevertheless, Genesis

submitted to Medicare the claims for UDT ordered by the Paid HCPs. The conduct set forth in this Paragraph C is referred to below as the “Covered Conduct.”

D. This Settlement Agreement is neither an admission of liability by Genesis, nor a concession by the United States that its claims are not well founded.

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. Under the terms and conditions specified herein, Genesis shall pay to the United States a total of One Million One Hundred Ninety-Five Thousand Eight Hundred Forty-Five Dollars and Eighty-Two Cents (\$1,195,845.82), plus interest at four and three-fourths percent (4.75%) per annum (collectively, Settlement Amount), pursuant to the payment schedule attached as Exhibit A, of which Five Hundred Ninety-Seven Thousand Nine Hundred Twenty-Two Dollars and Ninety-One Cents (\$597,922.91) is restitution, by electronic funds transfer pursuant to written instructions to be provided by the Civil Division of the United States Department of Justice. The payments specified in Exhibit A may be prepaid, in whole or in part, without penalty or premium.

2. Subject to the exceptions in Paragraph 3 (concerning reserved claims) below, subject to Paragraph 9 (concerning default) below, and conditioned upon Genesis’ full payment of the Settlement Amount to the United States, the United States releases Genesis 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.

3. Notwithstanding the release given in Paragraph 2 of this Agreement, or any other term of this Agreement, the following claims 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;
- c. Except as explicitly stated in this Agreement, any administrative liability or enforcement right, including mandatory or permissive 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 of corporate entities other than Genesis;
- h. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- i. Any liability for failure to deliver goods or services due; and
- j. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

4. Genesis waives and shall not assert any defenses it 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.

5. Genesis fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Genesis has asserted, could have asserted, or may assert in the future against the United States, and its agencies, officers, agents, employees, and servants related to the Covered Conduct and the United States' investigation and prosecution thereof.

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

7. Genesis agrees to the following:

a. Unallowable Costs Defined: 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. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Genesis in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States' audit(s) and civil and criminal investigation(s) of the matters covered by this Agreement;
- (3) Genesis' investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);
- (4) the negotiation and performance of this Agreement; and

(5) the payment Genesis makes to the United States pursuant to this Agreement, are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Genesis, and Genesis 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 Genesis or any of Genesis' subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Genesis 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 Genesis or any of Genesis' subsidiaries or affiliates, and shall request, and agrees, 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. Genesis agrees that the United States, at a minimum, shall be entitled to recoup from Genesis 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 Genesis or any of Genesis' subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Genesis or any of Genesis' 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 Genesis' books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

8. Genesis agrees to cooperate fully, truthfully, completely, and forthrightly with the United States' investigation(s) of, and/or legal proceeding(s) against, individuals and entities not released in this Agreement. Genesis agrees to encourage, and not impair, the cooperation of Genesis' directors, officers, and employees, and to use their best efforts to make available, and encourage, the cooperation of Genesis' former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. Genesis 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 their possession, custody, or control relating to the Marketers, Paid Physicians, MSOs, any other management services organization, or any agent of the foregoing entities.

9. The Settlement Amount represents the amount the United States is willing to accept in compromise of its civil claims against Genesis arising from the Covered Conduct pursuant to the terms and conditions in this Agreement.

a. Genesis shall be in default of this Agreement (Default) if it fails to pay the Settlement Amount as provided in Paragraph 1 above and Exhibit A hereto, or if it fails to comply

materially with any other term or condition of this Agreement, including Paragraph 8 above (concerning cooperation).

b. If Genesis fails to pay the Settlement Amount as provided in Paragraph 1 above and Exhibit A hereto, the United States will provide a written Notice of Default, and Genesis 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 and paying any additional interest accruing under the Settlement Agreement up to the date of payment. Notice of Default will be delivered to Genesis or to such other representative as Genesis shall designate in advance in writing. If Genesis 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).

c. In the event of Uncured Default, or a failure to comply materially with Paragraph 8 above (concerning cooperation), Genesis agrees that the United States, at its sole discretion, may (i) retain any payments previously made, rescind this Agreement, and bring any civil and/or administrative claim, action, or proceeding against Genesis for the claims that would otherwise be covered by the releases provided in Paragraph 2 above, with any recovery reduced by the amount of any payments previously made by Genesis to the United States under this Agreement; (ii) take any action to enforce this Agreement in a new action; (iii) offset the remaining unpaid balance from any amounts due and owing to Genesis and/or affiliated companies 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, Genesis 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, Genesis 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 Genesis 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. Genesis 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.

d. In the event of Uncured Default, or a failure to comply materially with Paragraph 8 above (concerning cooperation), OIG-HHS may exclude Genesis from participating in all Federal healthcare programs (Exclusion for Default). OIG-HHS will provide written notice of any such exclusion to Genesis. Genesis 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, Genesis 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. Genesis 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.

10. 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 Paragraph 11 (waiver for beneficiaries Paragraph), below.

11. Genesis 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.

12. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

13. The Parties and signatories to this Agreement represent that they freely and voluntarily enter into this Agreement without any degree of duress or compulsion.

14. 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 District of New Jersey. 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.

15. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

16. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

17. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

18. This Agreement is binding on Genesis' successors, transferees, heirs, and assigns.

19. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

20. 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: 11/02/2023

BY:



CHRISTOPHER TERRANOVA
Senior Trial Counsel
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 11/01/2023

BY:



KRUTI DHARIA
Assistant United States Attorney
United States Attorney's Office
District of New Jersey

DATED: 11/01/2023

BY:

LISA RE


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RE
Date: 2023.11.01
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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

GENESIS REFERENCE LABORATORIES LLC

DATED: 10/31/2023

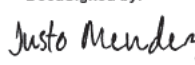
BY:

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Phil Freitas
Member
Genesis Reference Laboratories LLC

DATED: 10/31/2023

BY:

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JUSTO A. MENDEZ
Greenspoon Marder LLP
Counsel for Genesis Reference Laboratories LLC

EXHIBIT A

Payment Due Date	Payment Due	4.75% Interest	Principal	Balance
				\$1,195,845.82
Within 30 calendar days of the Effective Date	\$102,200.00	\$4,668.71	\$97,531.29	\$1,098,314.53
Within 60 calendar days of the Effective Date	\$102,200.00	\$4,287.94	\$97,912.06	\$1,000,402.47
Within 90 calendar days of the Effective Date	\$102,200.00	\$3,905.68	\$98,294.32	\$902,108.15
Within 120 calendar days of the Effective Date	\$102,200.00	\$3,521.93	\$98,678.07	\$803,430.08
Within 150 calendar days of the Effective Date	\$102,200.00	\$3,136.68	\$99,063.32	\$704,366.76
Within 180 calendar days of the Effective Date	\$102,200.00	\$2,749.93	\$99,450.07	\$604,916.69
Within 210 calendar days of the Effective Date	\$102,200.00	\$2,361.66	\$99,838.34	\$505,078.35
Within 240 calendar days of the Effective Date	\$102,200.00	\$1,971.88	\$100,228.12	\$404,850.23
Within 270 calendar days of the Effective Date	\$102,200.00	\$1,580.58	\$100,619.42	\$304,230.81
Within 300 calendar days of the Effective Date	\$102,200.00	\$1,187.75	\$101,012.25	\$203,218.56
Within 330 calendar days of the Effective Date	\$102,200.00	\$793.39	\$101,406.61	\$101,811.95
Within 360 calendar days of the Effective Date	\$102,209.44	\$397.49	\$101,811.95	--
Total	\$1,226,409.44	\$30,563.62	\$1,195,845.82	

DS
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