SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into among 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), VitalAxis Inc., and (hereafter collectively referred to as "the Parties"), through their authorized representatives.

RECITALS

- A. VitalAxis provides front-end and back-end services to health care providers, including diagnostic laboratories. One service they provide, VitalDx, allows a laboratory's clients to order tests and view the results of those tests on a cloud-based platform. VitalAxis also offers a service that automates the billing of tests submitted through VitalDx to health insurance programs.
- B.
- C. VitalAxis has been credited in this settlement under the Department of Justice's Guidelines for Taking Voluntary Disclosure, Cooperation, and Remediation into Account in False Claims Act Matters, Justice Manual § 4-4.112. The cooperation VitalAxis provided included performing and disclosing the results of an internal investigation, disclosing relevant facts and material not known to the government but relevant to its investigation, providing information relevant to potential misconduct by other individuals and entities, and admitting liability.

D. The United States contends that it has certain civil claims against VitalAxis for causing the submission of false claims to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395111 ("Medicare"). Specifically, the United States contends that, between May 7, 2020, and November 26, 2020, VitalAxis included the wrong National Provider Identifier ("NPI") number in claims that it submitted on behalf of for Respiratory Pathogen Panels ("RPPs") that were billed with COVID-19 tests and that were purportedly ordered by Dr. . Dr. did not order RPPs, nor did he have an active NPI number, rendering him ineligible to bill Medicare. The physician whose NPI number VitalAxis included in the claims that it submitted on behalf of also had not ordered RPPs, although he did have an active NPI number. As a result, Medicare paid for medically unnecessary RPPs. VitalAxis therefore caused the submission of false claims to Medicare in violation of the False Claims Act, 31 U.S.C. § 3729. That conduct is referred to below as the "Covered Conduct."

D.

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. VitalAxis shall pay to the United States \$300,479.58 ("Settlement Amount"), of which \$171,702.62 is restitution, no later than 14 days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the Civil Division of the United States Department of Justice.

2.

3. Subject to the exceptions in Paragraph 3 (concerning reserved claims) below, and upon the United States' receipt of the Settlement Amount plus interest due under Paragraph 1, the United States releases VitalAxis 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.

4.

- 5. Notwithstanding the release given in Paragraph 2 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;
 - c. Except as explicitly stated in this Agreement, any administrative liability or enforcement right, including mandatory and 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;

 6.

 7.

8. VitalAxis waives and shall not assert any defenses VitalAxis 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.

- 9. VitalAxis 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 VitalAxis 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.
 - 10.

- 11. 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) related to the Covered Conduct; and VitalAxis agrees not to resubmit to any Medicare contractor 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.
 - 12. VitalAxis 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 VitalAxis, its present or former officers, directors, employees, shareholders, and agents in connection with:
 - (1) the matters covered by this Agreement;

- (2) the United States' audit(s) and civil investigation(s) of the matters covered by this Agreement;
- (3) VitalAxis's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in connection with the matters covered by this Agreement (including attorneys' fees);
- (4) the negotiation and performance of this Agreement;
- (5) the payment VitalAxis 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. <u>Future Treatment of Unallowable Costs</u>: Unallowable Costs shall be separately determined and accounted for by VitalAxis, and VitalAxis 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 VitalAxis or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.
- c. <u>Treatment of Unallowable Costs Previously Submitted for Payment:</u>

 VitalAxis further agrees that within 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 VitalAxis 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. VitalAxis agrees that the United States, at a minimum, shall be entitled to recoup from VitalAxis 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 VitalAxis or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on VitalAxis 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 VitalAxis's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.
- 13. VitalAxis agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, VitalAxis 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. VitalAxis 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.

- 14. 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 15 (waiver for beneficiaries paragraph), below.
- 15. VitalAxis agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.
- 16. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.
- 17. Each Party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.
- 18. 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 Northern 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.
- 19. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.
- 20. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

- 21. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.
- 22. This Agreement is binding on VitalAxis's successors, transferees, heirs, and assigns.
 - 23.
- 24. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.
- 25. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: June 16, 2023	BY:	PAUL R. PERKINS Deputy Director Commercial Litigation Branch Civil Division United States Department of Justice
DATED:	BY:	NEELI BEN DAVID Assistant United States Attorney United States Attorney's Office for the Northern District of Georgia
DATED:	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
	<u>VIT</u>	ALAXIS INC DEFENDANT
DATED:	BY:	ARUN TUMATI Executive Vice President, VitalAxis Inc.

THE UNITED STATES OF AMERICA

DATED:	BY:	PAUL R. PERKINS Deputy Director Commercial Litigation Branch Civil Division United States Department of Justice
DATED:	BY:	NEELI BEN-DAVID Assistant United States Attorney United States Attorney's Office for the Northern District of Georgia
DATED: <u>06/13/23</u>	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
	<u>VIT</u>	ALAXIS INC DEFENDANT
DATED:	BY:	ARUN TUMATI Executive Vice President, VitalAxis Inc.

THE UNITED STATES OF AMERICA

DATED:	BY:	PAUL R. PERKINS Deputy Director Commercial Litigation Branch Civil Division United States Department of Justice
DATED:	BY:	NEELI BEN-DAVID Assistant United States Attorney United States Attorney's Office for the Northern District of Georgia
DATED:	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
	<u>VITA</u>	LAXIS INC DEFENDANT
DATED: 6/15/2023	BY:	ARUN TUMATI Executive Vice President, Vital Axis Inc.

