

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”) (collectively, the “United States”) and Laboratory Corporation of America Holdings (“Labcorp”) (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. Labcorp, based in Burlington, North Carolina, is a clinical diagnostics company that conducts business nationwide. Through its toxicology business unit, Labcorp performs presumptive and definitive urine drug testing (“UDT”) for medical drug monitoring. Presumptive testing, which is primarily immunoassay-based testing, generally detects the presence or absence of substances within drug classes and reports qualitative results, subject to certain testing thresholds. Definitive testing involves use of more sophisticated testing methods and equipment capable of performing mass spectrometry, identifying individual substances and metabolites, and reporting their relative concentrations when applicable. Labcorp offers definitive testing via mass spectrometry methods, including liquid chromatography/tandem mass spectrometry (“LC-MSMS”) and gas chromatography/mass spectrometry (“GC-MS”). Labcorp performs UDT and submits claims for payment for UDT to the Medicare Part B Program (“Medicare”). 42 U.S.C. §§ 1395j-1395w-6.

B. During the relevant period, Medicare payment for UDT was based on bundled payment rates associated with the various Current Procedure Terminology (“CPT”) or Healthcare Common Procedure Coding System (“HCPCS”) codes applicable to the type and amount of testing in question. For presumptive testing performed by a clinical diagnostic laboratory, regardless of the number of drug classes for which a laboratory tested and billed,

Medicare paid a flat rate for the service per patient as described by CPT code 80307. For definitive testing, Medicare paid bundled rates depending on the number of drug classes for which a laboratory tested and billed as follows: HCPCS Codes G0480 (1-7 drug classes); G0481 (8-14 drug classes); G0482 (15-21 drug classes); and G0483 (22 or more drug classes). In general, among the bundled rates described above, Medicare paid the highest amount for G0483 and did not pay more for additional drug classes tested beyond 22.

C. The United States contends that it has certain civil claims against Labcorp for submitting false claims for medically unnecessary UDT to Medicare.

D. Labcorp admits, acknowledges, and accepts responsibility for the following facts. From January 1, 2018 through November 22, 2023, Labcorp routinely submitted claims for presumptive and definitive UDT to Medicare. During this timeframe, some of the presumptive and definitive UDT performed by Labcorp for Medicare patients was pursuant to a testing panel marketed by Labcorp as “ToxAssure Comprehensive.” ToxAssure Comprehensive consisted of a preselected combination of presumptive UDT for certain substances and direct to definitive UDT (*i.e.*, with no prior presumptive test) for other substances. Labcorp ran many of these tests simultaneously for the same patient, on the same date of service, using the same urine sample and billed Medicare with CPT code 80307 for the presumptive UDT and HCPCS code G0483 for the definitive UDT. In other words, Labcorp billed Medicare for both the all-inclusive presumptive CPT code and the highest-tier definitive HCPCS code each time the ToxAssure Comprehensive was performed. For several of the substances tested on a direct-to-definitive basis, a presumptive testing option existed but Labcorp performed its definitive tests without first performing a presumptive test to inform the necessity of definitive testing for that substance. The foregoing conduct in Paragraph D is hereinafter referred to as the “Covered Conduct.”

E. The United States alleges that the full ToxAssure Comprehensive Test billed as described above resulted in the submission of medically unnecessary claims to Medicare for some of the patients for whom the Test was performed.

F. Labcorp has ceased billing to Medicare the combination of G0483 and 80307 for beneficiaries tested using ToxAssure Comprehensive.

In consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Labcorp shall pay to the United States \$14,500,000 (“Settlement Amount”) plus interest accruing at a rate of 4.5 percent per annum beginning on May 14, 2025, of which \$8,286,000 is restitution, no later than 30 days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by United States Attorney’s Office for the District of Massachusetts.

2. 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 Labcorp, its predecessors, its current and former parents, divisions, subsidiaries, successors, and assigns, 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 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 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 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.

4. Labcorp waives and shall not assert any defenses Labcorp 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. Labcorp 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 Labcorp 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 Labcorp agrees not to resubmit to any Medicare 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.

7. Labcorp 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. §§ 1395-1395lll and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Labcorp, 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 and any criminal investigation(s) of the matters covered by this Agreement;
- (3) Labcorp'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

- (5) the payment Labcorp 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 Labcorp, and Labcorp 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 Labcorp or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

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

8. 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 9 (waiver for beneficiaries paragraph), below.

9. Labcorp 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.

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

11. Each Party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

12. 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 Massachusetts. 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.

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

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

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

16. This Agreement is binding on Labcorp's successors, transferees, heirs, and assigns.

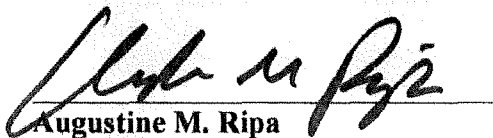
17. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

18. 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: 7/14/26

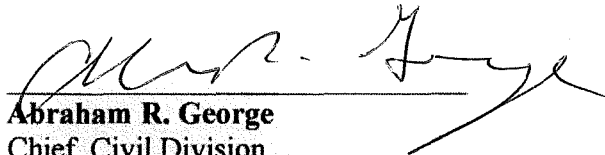
BY:



Augustine M. Ripa
Senior Counsel for Health Care Fraud
Commercial Litigation Branch
Civil Division

DATED: 7/15/26

BY:



Abraham R. George
Chief, Civil Division
Assistant United States Attorney
District of Massachusetts

DATED: _____

BY:

Susan E. Gillin
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

THE UNITED STATES OF AMERICA

DATED: _____

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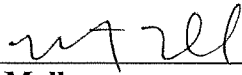
DATED: 7/10/26

BY: _____


Susan E. Gillin
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

LABORATORY CORPORATION OF AMERICA HOLDINGS

DATED: July 6 2026

BY: 
Matthew Mall
Senior Vice-President and General Counsel
Laboratory Corporation of America Holdings

DATED: July 6, 2026

BY: 
Gregory F. Noonan
Hogan Lovells Cadwalader US LLP
Counsel for Labcorp