

## 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”), the United States Department of Veterans Affairs (“VA”), which administers the Veterans Health Administration (“VHA”), and the Office of Personnel Management (“OPM”), which administers the Federal Employees Health Benefits Program (“FEHBP”) (collectively, the “United States”); Miraca Life Sciences, Inc., now known as Inform Diagnostics, Inc. (“Inform”); and Relator Christopher Wallace (“Relator”) (hereafter collectively referred to as “the Parties”), through their authorized representatives.

### RECITALS

A. Inform is a Delaware corporation with its headquarters in Irving, Texas. Inform provides anatomic pathology services to physician practices throughout the United States. Throughout the period referenced in this Agreement, certain of Inform’s anatomic pathology services were reimbursed by federal health care programs, including Medicare, the VHA, and the FEHBP. On November 20, 2017, following a change in Miraca’s ownership, the company became known as Inform. On April 27, 2022, Fulgent Genetics purchased Inform and the company is now a wholly owned subsidiary of Fulgent. Inform continues to perform anatomic pathology and other services and remains headquartered in Irving, Texas.

B. On January 15, 2019, Relator filed a qui tam action in the United States District Court for the District of Massachusetts captioned *United States ex rel. Christopher Wallace, M.D. v. Inform Diagnostics, Inc.*, 19-cv-10091, pursuant to the qui tam provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the “Civil Action”). Relator alleges that Inform violated the federal False Claims Act by submitting false claims to Medicare and other federally funded

healthcare programs for non-payable, nonallowable laboratory services conducted without a treating physician's order as part of an improper upfront, preorder testing scheme. Relator alleges that, rather than perform only the test(s) ordered by the treating physician, Inform automatically and systematically ran additional tests, including special stains, without the treating physician's knowledge, consent, or order, and without a pathologist's determination of medical necessity.

C. The United States contends that Inform 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 VHA, 38 U.S.C. Chapter 17, and the FEHBP, 5 U.S.C. §§ 8901-8914.

D. Inform admits, acknowledges, and accepts responsibility for the following facts. From January 1, 2013 through January 31, 2018, Inform routinely and automatically conducted up-front periodic acid-Schiff-Alcian Blue and immunohistochemical stains on gastrointestinal biopsy specimens prior to a pathologist's: (i) review of the routine stain, and (ii) an individualized determination regarding whether the aforementioned additional stains were medically necessary. In addition, from January 1, 2013 through December 31, 2018, Inform routinely and automatically conducted up-front periodic acid-Schiff stains on dermatological biopsy specimens prior to a pathologist's: (i) review of the routine stain, and (ii) an individualized determination regarding whether the aforementioned additional stain was medically necessary. This conduct is referred to below as the "Covered Conduct."

E. 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.

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

## TERMS AND CONDITIONS

1. Inform shall pay to the United States \$16,000,000.00 (“Settlement Amount”), of which \$8,000,000.00 is restitution, and interest on the Settlement Amount at a rate of 1.5% per annum from January 28, 2022, no later than 10 days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney for the District of Massachusetts.

2. Conditioned upon the United States receiving the Settlement Amount and as soon as feasible after receipt, the United States shall pay \$2,720,000 to Relator by electronic funds transfer (“Relator’s Share”).

3. Inform shall pay to Relator the amount of \$61,567, as full satisfaction of Relator’s claims against Inform for Relator’s attorneys’ fees, expenses, and costs pursuant to 31 U.S.C. § 3730(d). The terms and releases related to the settlement of Relator’s attorneys’ fees, expenses, and costs pursuant to 31 U.S.C. § 3730(d) are not provided for herein but are instead the subject of a separate agreement between Inform and Relator.

4. Subject to the exceptions in Paragraph 6 (concerning reserved claims) below, and upon the United States’ receipt of the Settlement Amount plus interest due under Paragraph 1, the United States releases Inform, its predecessors, its current and former parents, divisions, subsidiaries, successors, and assigns (collectively, the “Defendant Releasees”) 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 6 below, and conditioned upon the United States’ receipt of the Settlement Amount plus interest due under Paragraph 1 and Relator’s

receipt of the payment for attorneys' fees, expenses, and costs referred to in Paragraph 3, Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, releases the Defendant from any civil monetary claim the Relator has on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733 and from any liability to Relator arising from the filing of the Civil Action including, but not limited to, any employment-related claims associated with the Covered Conduct.

6. Notwithstanding the releases given in Paragraph 4 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 failure to deliver goods or services due; and
- h. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

7. 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.

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

10. Inform fully and finally releases Relator, his heirs, successors, attorneys, agents, and assigns, from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Inform has asserted, could have asserted, or may assert in the future against Relator, his heirs, successors, attorneys, agents, and assigns related to the Covered Conduct or the Civil Action.

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), the VA, or OPM related to the Covered

Conduct; and Inform agrees not to resubmit to any Medicare contractor, the VA, or OPM 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. Inform 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 Inform, 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) Inform's 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 attorneys' fees);
  - (4) the negotiation and performance of this Agreement; and
  - (5) the payment Inform makes to the United States pursuant to this Agreement and any payments that Inform may make to Relator, including costs and attorneys' fees

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and FEHBP (hereinafter referred to as Unallowable Costs).

- b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Inform, and Inform 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 Inform or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.
- c. Treatment of Unallowable Costs Previously Submitted for Payment: Inform 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 Inform 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. Inform agrees that the United States, at a minimum, shall be

entitled to recoup from Inform 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 Inform or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on Inform 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 Inform's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.

13. 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 14 (waiver for beneficiaries paragraph), below.

14. Inform 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.

15. Upon receipt of the payment described in Paragraph 1, above, and the payment of attorneys' fees and costs outlined in the separate settlement agreement between Inform and



Relator, the United States and the Relator shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal of the Civil Action pursuant to Rule 41(a)(1). With respect to the United States, the dismissal shall be with prejudice as to the Covered Conduct and without prejudice as to any other conduct or causes of action.

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, except that nothing in this paragraph shall release, waive or affect any claim of the Relator against Inform for attorneys' fees, expenses, and costs under 31 U.S.C § 3730(d). Such claims for fees, costs, and expenses have been resolved by the separate agreement referred to in Paragraph 3.

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 jurisdiction and 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.

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 Inform's successors, transferees, heirs, and assigns.


23. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.

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

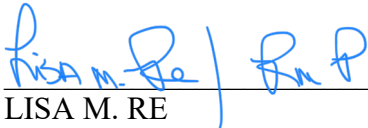
25. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

**THE UNITED STATES OF AMERICA**

DATED: 7/20/22

BY:   
\_\_\_\_\_  
ALEXANDRA BRAZIER  
LINDSEY ROSS  
Assistant United States Attorneys  
District of Massachusetts

DATED: 7/13/2022

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: \_\_\_\_\_

BY: \_\_\_\_\_  
EDWARD M. DEHARDE  
Deputy Associate Director of Federal Employee  
Insurance Operations, Healthcare and Insurance  
United States Office of Personnel Management

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
PAUL ST. HILLAIRE  
Assistant Inspector General  
for Legal & Legislative Affairs  
Office of the Inspector General  
United States Office of Personnel Management

**THE UNITED STATES OF AMERICA**

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

ALEXANDRA BRAZIER  
LINDSEY ROSS  
Assistant United States Attorneys  
District of Massachusetts

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

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

**EDWARD DEHARDE** Digitally signed by EDWARD DEHARDE  
Date: 2022.07.19 16:07:05 -04'00'  
EDWARD M. DEHARDE  
Deputy Associate Director of Federal Employee  
Insurance Operations, Healthcare and Insurance  
United States Office of Personnel Management

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

**PAUL ST HILLAIRE** Digitally signed by PAUL ST HILLAIRE  
DN: c=US, o=U.S. Government, ou=Office of  
Personnel Management, cn=PAUL ST HILLAIRE,  
0.9.2342.19200300.100.1.1=24001000034787  
Date: 2022.07.19 16:12:42 -04'00'  
PAUL ST. HILLAIRE  
Assistant Inspector General  
for Legal & Legislative Affairs  
Office of the Inspector General  
United States Office of Personnel Management

**INFORM DIAGNOSTICS, INC. - DEFENDANT**

DATED: 7/9/22

BY: 

DARRYL GOSS  
Inform Diagnostics, Inc.

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

AMY LERMAN  
CLAY LEE  
Epstein Becker & Green, P.C.  
Counsel for Inform Diagnostics, Inc.

**INFORM DIAGNOSTICS, INC. - DEFENDANT**

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

DARRYL GOSS  
Inform Diagnostics, Inc.

DATED: 7/8/22

BY:  \_\_\_\_\_

AMY LERMAN  
CLAY LEE  
Epstein Becker & Green, P.C.  
Counsel for Inform Diagnostics, Inc.

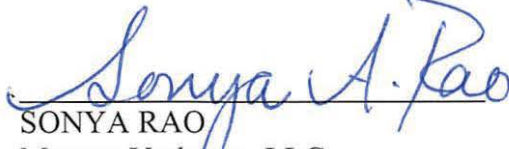
**CHRISTOPHER WALLACE - RELATOR**

DATED: 07/07/2022 BY: Chryh Walk  
CHRISTOPHER WALLACE

DATED: \_\_\_\_\_ BY: \_\_\_\_\_  
SONYA RAO  
Morgan Verkamp, LLC  
Counsel for Christopher Wallace

**CHRISTOPHER WALLACE - RELATOR**

DATED: \_\_\_\_\_ BY: \_\_\_\_\_  
CHRISTOPHER WALLACE

DATED: 07/07/2022 BY:   
SONYA RAO  
Morgan Verkamp, LLC  
Counsel for Christopher Wallace