

## 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”), Genomic Health, Inc. (“GHI” or “Defendant”) and Samuel Caughron and Kirsten Arndt-Hutson (“Relators”) (hereafter collectively referred to as “the Parties”), through their authorized representatives.

### RECITALS

A. GHI is Delaware corporation and headquartered in Redwood City, California. GHI is a provider of genomic-based clinical diagnostic tests. GHI’s principal tests have a proprietary name of Oncotype DX® and have been used for patients diagnosed with breast, colon and prostate cancer. GHI was acquired by Exact Sciences Corp. (“Exact”) on November 11, 2019 and is a wholly-owned subsidiary of Exact.

B. On July 21, 2016, Samuel Caughron, M.D., filed a *qui tam* action in the United States District Court for the Eastern District of New York captioned *United States ex rel. Samuel Caughron, M.D. and Samuel Caughron, M.D., individually v. Genomic Health, Inc.*, Civil Action No. CV-16-4038 (E.D.N.Y.), pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the “Caughron Action”). On March 17, 2017, Kirsten Arndt-Hutson filed a *qui tam* action in the United States District Court for the Eastern District of Wisconsin, which was transferred to the Eastern District of New York, captioned *United States ex rel. Doe v. Genomic Health, Inc., et al.*, Civil Action No. CV-17-4460 (E.D.N.Y.), pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the “Doe Action”, and together with the Caughron Action, the “Civil Actions”).

C. The United States contends that GHI 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”).

D. The United States contends that it has certain civil claims against GHI arising from GHI’s failure to comply with the Date of Service Rule, 42 C.F.R. § 414.510 (“DOS Rule”). Specifically, the United States contends as follows:

(1) During the period from January 1, 2008 through February 29, 2020, GHI knowingly submitted false claims for reimbursement to the Medicare Program on behalf of Medicare beneficiaries for Oncotype DX® tests (hereinafter “tests”). Under the DOS Rule, claims for payment for tests that were ordered within 14 days following a hospital in-patient’s discharge were required to be submitted by the hospital to the Medicare Program. Instead, GHI cancelled, delayed, held or otherwise did not process orders for tests that were subject to the DOS Rule and submitted claims for reimbursement to the Medicare Program with a date of service that resulted in direct reimbursement to GHI. This caused the Medicare Program to incur additional costs beyond what it would have otherwise paid.

(2) During the period from January 1, 2008 through February 29, 2020, GHI knowingly submitted or conspired to submit false claims for reimbursement to the Medicare Program on behalf of Medicare beneficiaries by permitting, failing to discourage, and encouraging providers who initially ordered tests within 14 days following a hospital in-patient’s discharge from the hospital to cancel those orders and reorder the tests at least 14 days following the in-patient’s discharge from the hospital.

(3) During the period from January 1, 2008 through December 31, 2017, GHI knowingly submitted false claims for reimbursement to the Medicare Program for tests ordered within 14 days following a hospital out-patient’s discharge from the hospital. For tests that were

initially ordered within 14 days following a hospital out-patient's discharge, GHI submitted claims to the Medicare Program directly for reimbursement. As a result, the Medicare Program paid GHI for claims that GHI should not have submitted directly to the Medicare Program for reimbursement.

(4) During the period from January 1, 2008 through December 31, 2017, GHI knowingly submitted or conspired to submit false claims for reimbursement to the Medicare Program on behalf of Medicare beneficiaries by permitting, failing to discourage, and encouraging providers who initially ordered tests within 14 days following a hospital out-patient's discharge from the hospital to cancel those orders and reorder the tests at least 14 days following the out-patient's discharge from the hospital.

(5) During the period January 1, 2007 through December 31, 2018, GHI knowingly and willfully paid remuneration to hospitals by deliberately failing to collect payments from those hospitals for tests performed by GHI for the hospital's in-patients and outpatients when the tests were ordered within 14 days following the patient's discharge from the hospital. As a result, GHI violated the Anti-Kickback Statute, 42 U.S.C. 1320a-7b(b) and knowingly caused false claims to be submitted to the Medicare Program.

The conduct set forth in this Paragraph is referred to below as the "Covered Conduct."

E. Relators claim entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relators' reasonable expenses, attorneys' fees and costs.

F. This Settlement Agreement is neither an admission of liability by GHI 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. GHI shall pay to the United States \$32,500,000.00 (“Settlement Amount”) of which \$16,250,000.00 is restitution, and interest on the Settlement Amount at a rate of 3.875% per annum from June 22, 2023, no later than 30 days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney’s Office for the Eastern District of New York.

2. Conditioned upon the United States receiving the Settlement Amount and as soon as feasible after receipt, the United States shall pay \$5,687,500.00 to Relator Samuel Caughron by electronic funds transfer (“Relator’s Share”).

3. Subject to the exceptions in Paragraph 5 (concerning reserved claims) below, and upon the United States’ receipt of the Settlement Amount, plus interest due under Paragraph 1, the United States releases GHI, together with its current and former parent corporations, direct and indirect subsidiaries, brother and sister corporations, divisions, current and former corporate owners, and the corporate successors and assigns of any of them, 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. Subject to the terms and exceptions in Paragraph 7 below, and upon the United States’ receipt of the Settlement Amount, plus interest due under Paragraph 1, Relators, for themselves, their heirs, successors, attorneys, agents, and assigns, release GHI together with its current and former parent corporations, direct and indirect subsidiaries, brother and sister corporations, divisions, current and former corporate owners, and the corporate successors and assigns of any of them, and their respective current and former officers, directors, employees,

attorneys, servants and agents from any civil claim the Relators have on behalf of themselves and the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733, and all conduct and claims arising from, or alleged in, any complaint filed in the Civil Actions.

5. Notwithstanding the releases given in Paragraph 3 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.

6. Relators and their 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

Samuel Caughron's receipt of the Relator's Share, Relators and their 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 Actions or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the Civil Actions.

7. Notwithstanding the releases given in Paragraphs 4 and 6 of this Agreement, or any other term of this Agreement, Relators' claims against GHI under 31 U.S.C. § 3730(d) for attorney's fees, costs and expenses are specifically reserved and are not released.

8. GHI waives and shall not assert any defenses GHI 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. GHI 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 GHI 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. GHI fully and finally releases the Relators from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that GHI has asserted, could have asserted, or may assert in the future against the Relators, related to the Covered Conduct and the Relators' investigation and prosecution thereof.

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); and GHI agrees not to resubmit to any Medicare contractor 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.

12. GHI 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 GHI, 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) GHI'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 GHI makes to the United States pursuant to this Agreement and any payments that GHI may make to Relators, including costs and attorney's fees

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 GHI, and GHI 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 GHI or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: GHI 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 GHI or any of their 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. GHI agrees that the United States, at a minimum, shall be entitled to recoup from GHI 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 GHI or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this

paragraph) on GHI 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 GHI'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 Paragraphs 3 and 4 above and Paragraph 14 (waiver for beneficiaries paragraph), below.

14. GHI 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, the Relators and the United States shall promptly sign and file in each of the Civil Actions Joint Stipulations of Dismissal pursuant to Rule 41(a)(1) as described below.

The Joint Stipulation of Dismissal in the Caughron Action shall: (1) dismiss with prejudice all monetary claims asserted by Relator Caughron on behalf of the United States against GHI for the Covered Conduct as defined in Recitals Paragraph D of the Settlement Agreement; (2) dismiss without prejudice to the United States and with prejudice to Relator Caughron all other claims asserted by Relator Caughron on behalf of the United States set forth in Relator Caughron's Complaint; and (3) reserving Relator Caughron's claims on behalf of Relator Caughron against GHI under 31 U.S.C. § 3730(d) for attorney's fees, costs and expenses.

The Joint Stipulation of Dismissal in the Doe Action shall: 1) dismiss with prejudice all monetary claims asserted by Relator Doe on behalf of the United States against GHI for the

Covered Conduct as defined in Recitals Paragraph D of the Settlement Agreement; (2) dismiss without prejudice to the United States and with prejudice to Relator Doe the claims asserted by Relator Doe against GHI on behalf of the United States set forth in Relator Doe's Complaint; (3) dismiss without prejudice to the United States and without prejudice to Relator Doe all other claims asserted by Relator Doe against all remaining Defendants except GHI on behalf of the United States set forth in Relator Doe's Complaint; and (4) reserve Relator Doe's claims on behalf of Relator Doe against GHI under 31 U.S.C. § 3730(d) for attorney's fees, costs and expenses.

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 jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the Eastern District of New York. 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 GHI's successors, transferees, heirs, and assigns.

23. This Agreement is binding on Relators' 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 September 12, 2023

BREON PEACE  
UNITED STATES ATTORNEY  
Eastern District of New York  
271 Cadman Plaza East  
Brooklyn, New York 11201

BY: *Anjna Kapoor*  
ANJNA KAPOOR  
Assistant U.S. Attorney  
(718) 254-6190

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

BY: \_\_\_\_\_  
SANJAY M. BHAMBHANI  
Senior Trial Counsel  
Commercial Litigation Branch  
Civil Division  
United States Department of Justice

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

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**THE UNITED STATES OF AMERICA**

DATED: \_\_\_\_\_ 2023

BREON PEACE  
UNITED STATES ATTORNEY  
Eastern District of New York  
271 Cadman Plaza East  
Brooklyn, New York 11201

BY: \_\_\_\_\_  
ANJNA KAPOOR  
Assistant U.S. Attorney  
(718) 254-6190

DATED: 9/12/2023

BY:   
SANJAY M. BHAMBHANI  
Senior Trial Counsel  
Commercial Litigation Branch  
Civil Division  
United States Department of Justice

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

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**THE UNITED STATES OF AMERICA**

DATED: \_\_\_\_\_ 2023

BREON PEACE  
UNITED STATES ATTORNEY  
Eastern District of New York  
271 Cadman Plaza East  
Brooklyn, New York 11201

BY: \_\_\_\_\_  
ANJNA KAPOOR  
Assistant U.S. Attorney  
(718) 254-6190

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

BY: \_\_\_\_\_  
SANJAY M. BHAMBHANI  
Senior Trial Counsel  
Commercial Litigation Branch  
Civil Division  
United States Department of Justice

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

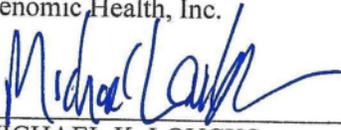
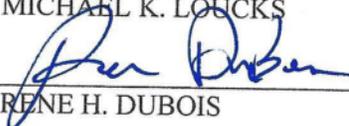
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LISA M. RE  
Assistant Inspector General for Legal  
Affairs  
Office of Counsel to the Inspector General  
Office of Inspector General  
United States Department of Health and  
Human Services

**GENOMIC HEALTH, INC. - DEFENDANT**

DATED: Sept. 7, 2023

BY:   
JAMES HERRIOTT  
Secretary  
Genomic Health, Inc.

DATED: 9/8/23

BY:   
MICHAEL K. LOUCKS  
  
RENE H. DUBOIS

Skadden, Arps, Slate, Meagher & Flom LLP  
Counsel for Genomic Health, Inc.

**SAMUEL CAUGHRON - RELATOR**

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

BY: \_\_\_\_\_  
SAMUEL CAUGHRON

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

BY: \_\_\_\_\_  
PATRICK S. ALMONRODE  
JASON T. BROWN  
Brown, LLC  
111 Town Square Place, Suite 400  
Jersey City, New Jersey 07310  
Counsel for Relator Samuel Caughron, M.D.

**GENOMIC HEALTH, INC. – DEFENDANT**

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

BY: \_\_\_\_\_  
JAMES HERRIOTT  
Secretary  
Genomic Health, Inc.

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

BY: \_\_\_\_\_  
MICHAEL K. LOUCKS

\_\_\_\_\_  
RENE H. DUBOIS

Skadden, Arps, Slate, Meagher & Flom LLP  
Counsel for Genomic Health, Inc.

**SAMUEL CAUGHRON - RELATOR**

DATED: 9/5/23

BY:   
\_\_\_\_\_  
SAMUEL CAUGHRON

DATED: 9/5/23

BY:   
\_\_\_\_\_  
PATRICK S. ALMONRODE  
JASON T. BROWN  
Brown, LLC  
111 Town Square Place, Suite 400  
Jersey City, New Jersey 07310  
Counsel for Relator Samuel Caughron, M.D.

**KIRSTEN ARNDT-HUTSON- RELATOR DOE**

DATED: 9/6/23

BY:   
KIRSTEN ARNDT-HUTSON

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

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

ERIKA A. KELTON  
PETER P. BUDETI  
JOHN W. TREMBLAY  
Phillips & Cohen LLP  
2000 Massachusetts Avenue NW  
Washington, D.C. 20036  
Counsel for Relator Kirsten Arndt-Hutson

**KIRSTEN ARNDT-HUTSON- RELATOR DOE**

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

BY: \_\_\_\_\_  
KIRSTEN ARNDT-HUTSON

DATED: September 8, 2023

BY:   
\_\_\_\_\_  
ERIKA A. KELTON  
PETER P. BUDETI  
JOHN W. TREMBLAY  
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2000 Massachusetts Avenue NW  
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Counsel for Relator Kirsten Arndt-Hutson