

## SETTLEMENT AGREEMENT

### I. PARTIES

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 U.S. Department of Health and Human Services ("HHS"); the United Mine Workers of America 1992 Benefit Plan, 1993 Benefit Plan, and Combined Benefit Fund ("UMWA Funds"), by and through the U.S. Department of Labor (collectively, "the United States"); and Great Lakes Medical Laboratory, Inc. ("GLML"), by and through their authorized representatives. All of the aforementioned individuals and entities are collectively referred to herein as "the Parties."

### II. RECITALS

A. At all relevant times, GLML was a corporation organized under the laws of the State of Michigan.

B. At all relevant times, GLML's principal place of business was in Farmington Hills, Michigan. At all relevant times, GLML operated as a medical reference laboratory.

C. The United States contends that GLML submitted or caused to be submitted false claims for payment to Medicare (Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396w-5) and the UMWA Funds.

D. At all relevant times, GLML accepted referrals for laboratory testing for patients who were eligible to receive reimbursement and/or health benefits under the Medicare Program

and the UMWA Funds, both of which were federal health care benefit programs as defined in 18 U.S.C. § 24(b).

E. The United States further contends that it has certain civil claims against GLML for engaging in the following alleged conduct: At all relevant times, the Current Procedural Terminology (“CPT”) Manual included CPT codes 82542 and 83789. CPT Code 82542 is defined as column chromatography, including mass spectrometry, if performed, for non-drug analyte(s) not elsewhere specified, qualitative or quantitative, for each specimen. CPT Code 83789 is defined as mass spectrometry and tandem mass spectrometry, for non-drug analyte(s) not elsewhere specified, qualitative or quantitative, for each specimen. Great Lakes routinely billed these codes with G0482 and G0483. G0482 and G0483 are codes included in the Healthcare Common Procedure Coding System (“HCPCS”). HCPCS Code G0482 was used to seek reimbursement for definitive testing of urine samples for 15 to 21 drug classes. HCPCS Code G0483 was used to seek reimbursement for definitive testing of urine samples for 22 or more drug classes. The descriptions for both of these HCPCS codes specifically include mass spectrometry and chromatography. Billing CPT Code 82542 and 83789 indicated that separate and distinct chromatography and mass spectrometry was performed by GLML. There was no indication on the requisition forms submitted with referrals from medical providers to GLML that separate chromatography or mass spectrometry was ordered. Likewise, there is no evidence in the laboratory results generated by GLML that separate chromatography or mass spectrometry was performed. Billing separately for these services constitutes unbundling and double billing.

In addition, GLML routinely appended modifier -59 in order to bypass Medicare edits that were designed to prevent payment for duplicate services. From on or about January 4, 2016 continuing through on or about May 12, 2017, GLML presented at least 21,732 claims to Medicare and the UMWA Funds which included HCPCS Code G0482 or G0483 and CPT codes 82542 and 83789 with Modifier 59 appended. These false claims resulted in a losses to Medicare and the UMWA Funds in the amount of **\$600,368.82**. The conduct described in this paragraph is hereinafter referred to as the "Covered Conduct".

F. This Agreement is not an admission of liability by GLML, nor is it a concession by the United States that its claims are not well founded.

G. 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 Agreement, the Parties have reached a full and final settlement pursuant to the Terms and Conditions set forth below.

### III. TERMS AND CONDITIONS

1. GLML shall pay to the United States the sum of **\$1,200,737.64** (the "Settlement Amount") as follows:

(a) GLML shall pay the sum of **\$300,000** to the United States by electronic funds transfer ("EFT") pursuant to written instructions to be provided by the Office of the United States Attorney for the Southern District of West Virginia within three (3) business days of the Effective Date of this Agreement.

(b) GLML shall pay the sum of **\$900,737.64** to the United States within ninety (90) days of the Effective Date of this Agreement, plus interest at the Treasury Constant Maturity Rate of 1.57% per annum (accruing from the Effective Date of this Agreement) by electronic funds transfer ("EFT") pursuant to written instructions to be provided by the Office of the United States Attorney for the Southern District of West Virginia.

(c) GLML further agrees to execute a Stipulation for Consent Judgment whereby it stipulates to, among other things, the entry of a consent judgment if there is a default by GLML in payment of the Settlement Amount and a failure to timely cure that default within five (5) days of receiving written notice of default from the United States. GLML agrees to the entry of a consent judgment against it for the remaining unpaid balance of the Settlement Amount plus court costs, expenses and attorney's fees equal to fifteen percent (15%) of the entire amount due at the time of the default. The Stipulation for Consent Judgment will be executed by GLML at the same time that the Settlement Agreement is executed and may be submitted to the District Court for entry as a miscellaneous action without adjudication or further demonstration of assent by GLML.

(d) The Parties agree that the payment by GLML of the Settlement Amount to the United States includes an amount of \$600,368.82 that shall constitute restitution within the meaning of Section 162(f) of the Internal Revenue Code of 1986, as amended (the "Code") with respect to the payments GLML received from Medicare and the UMWA Funds as described in the Covered Conduct (the "Restitution Amount"). The Parties agree to make any returns or filings in respect of the Settlement Amount as may be required by the Code and any regulations thereunder.

2. Subject to the exceptions in Paragraph 4 below (concerning excluded claims), and conditioned upon full payment of the Settlement Amount by GLML, and subject to Paragraph 13 below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment under this Agreement), the United States releases GLML; direct and indirect subsidiaries; brother or sister corporations; divisions; current or former corporate owners; and the corporate successors and assigns of any of them, from any civil or administrative monetary claims 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; and the common law theories of payment by mistake, unjust enrichment, and fraud.

3. In consideration of the obligations of GLML in this Agreement and the Integrity Agreement (“IA”), entered into between OIG-HHS and GLML, and conditioned upon GLML’s full payment of the Settlement Amount, the OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against GLML under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in this Paragraph and in Paragraph 4 (concerning excluded claims), below. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude GLML from Medicare, Medicaid and other Federal health care programs under 42 U.S.C.

§ 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 4, below.

4. Notwithstanding the release given in Paragraph 2 and of this Agreement, or any 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 provided in this Agreement, any administrative liability, including mandatory 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 for personal injury or property damage or for other consequential damages arising from the Covered Conduct; and
- g. Any liability of individuals not specifically released herein.

5. GLML waives and shall not assert any defenses it may have to any criminal prosecution or administrative action relating to the Covered Conduct which is based, in whole or in part, on the contention that, under the Double Jeopardy Clause of the Fifth Amendment to the Constitution of the United States of America, or under the Excessive Fines Clause of the Eighth

Amendment to the Constitution of the United States of America, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

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

7. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by Medicare, any other federal health care benefit program, or any state payer, related to the Covered Conduct; and GLML agrees not to resubmit to Medicare, any other federal health care benefit program, or any state payer any previously denied claims related to the Covered Conduct, and agrees not to appeal denials of any such claims, and to withdraw any such pending appeals.

8. GLML further agrees to the following:

a. Unallowable Costs Defined: That 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), if any, incurred by or on behalf of GLML in connection with the following shall be "Unallowable Costs" for government contracting purposes with the United States and under the Medicare program, Medicaid program, TRICARE program and FEHBP:

1. Matters covered by this Agreement and any related plea agreement;
2. Audit(s) and civil and any criminal investigation(s) by the United States of the matters covered by this Agreement;
3. Investigation, defense, and corrective actions undertaken by GLML 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 any plea agreement;
5. The payment(s) GLML makes to the United States pursuant to this Agreement, including any costs and attorney's fees; and
6. the negotiation of, and obligations undertaken pursuant to the IA to:  
(i) retain an independent review organization to perform quarterly reviews as described in Section III of the IA; and (ii) prepare and submit reports to the OIG-HHS, are unallowable, including any costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employee Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs). However, nothing in paragraph 8.a.6 that may apply to the obligations undertaken pursuant to the IA affects the status of costs that are not allowable based on any other authority applicable to GLML.

b. Future Treatment of Unallowable Costs: If applicable, these Unallowable Costs shall be separately determined and accounted for by GLML. GLML 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 GLML to the Medicare, Medicaid, TRICARE, FEHBP, or other federal health care benefit programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: If applicable, GLML further agrees that within 60 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 GLML, or on behalf of GLML by any medical practice or entity through which GLML provided medical services, 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. GLML agrees that the United States, at a minimum, shall be entitled to recoup from it 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 GLML, or on behalf of GLML by any medical practice or entity through which GLML provided medical services, on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on GLML's cost reports or the cost reports of any medical practice or entity through which GLML provided medical services, 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 the books and records of GLML to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

9. 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 10 directly below.

10. GLML 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 payers based upon the claims included in and defined as Covered Conduct.

11. In the event the United States opts to rescind this Agreement following a breach by GLML, then GLML agrees that it shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims that (a) are filed by the United States within 30 calendar days of written notification to GLML that this Agreement has been rescinded; and (b) relate to the Covered Conduct, except to

the extent these defenses were available on the Effective Date of this Agreement.

12. GLML warrants that it has reviewed its financial situation and that it is currently solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and shall remain solvent following the payment to the United States of the Settlement Amount. Further, the Parties warrant that, in evaluating whether to execute this Agreement, they (a) intended that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to GLML, within the meaning of 11 U.S.C. § 547(c)(1); and (b) conclude that these mutual promises, covenants, and obligations shall, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any person or entity to which GLML is or becomes indebted on or after the date of this transfer, all within the meaning of 11 U.S.C. § 548(a)(1).

13. If, within 91 days of the Effective Date of this Agreement or any payment made under this Agreement, GLML or a third party commences any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors: (a) seeking to have an order for relief of GLML's debts, or seeking to adjudicate GLML as bankrupt or insolvent; or (b) seeking appointment of a receiver, trustee, custodian, or other similar official for GLML or for all or any substantial part of GLML's assets, then GLML agrees as follows:

a. GLML's obligations under this Agreement may not be avoided pursuant to 11 U.S.C. §§ 547 or 548, and GLML shall not argue or otherwise take the position in any such

case, proceeding, or action that: (i) its obligations under this Agreement may be avoided under 11 U.S.C. §§ 547 or 548; (ii) it was insolvent at the time this Agreement was entered into, or became insolvent as a result of any payment made to the United States hereunder; or (iii) the mutual promises, covenants, and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to GLML.

b. If GLML's obligations under this Agreement are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, then the United States, at its sole option, may rescind and/or void this Agreement and any releases herein, and may bring any civil and/or administrative claim, action, or proceeding against GLML for the claims that would otherwise be covered by the release provided in Paragraph 2 hereof. GLML agrees that: (i) any such claims, actions, or proceedings brought by the United States (including any proceedings to exclude GLML from participation in Medicare, TRICARE or other Federal health care benefit programs) are not subject to an automatic stay imposed pursuant to 11 U.S.C. § 362(a) as a result of the action, case, or proceedings described in the first clause of this Paragraph, and that GLML shall not argue or otherwise contend that the claims, actions, or proceedings of the United States are subject to an automatic stay; (ii) GLML shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claims, actions, or proceedings that are brought by the United States within 30 calendar days of written notification to GLML that this Agreement and the releases herein have been rescinded pursuant to this

Paragraph, except to the extent such defenses were available on the Effective Date of this Agreement; and (iii) the United States has a valid claim against GLML in the amount of **\$25,500,000**, and the United States may pursue its claim in the case, action, or proceeding referenced in the first clause of this Paragraph as well as in any other case, action, or proceeding.

c. GLML acknowledges that its agreement in this Paragraph is provided in exchange for valuable consideration provided in accordance with this Agreement.

14. In the event that GLML fails to pay any amount as provided in Paragraph 1 hereof on the date on which such payment is due, then GLML shall be in breach of the terms of this Agreement ("Default" or "Breach").

15. Notwithstanding any other provision set forth herein, in the event of Default as defined in Paragraph 14 above, OIG-HHS may exclude GLML from participating in all federal health care programs until GLML pays the Settlement Amount and reasonable costs. OIG-HHS will provide written notice of any such exclusion to GLML. GLML waives any further notice of 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 participate in federal health care programs is not automatic. If at the end of any period of exclusion GLML 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. GLML will not be reinstated unless and until OIG-HHS approves such request for reinstatement.

16. Each Party to this Agreement shall bear its own legal and other costs incurred

in connection with this matter, including the preparation and performance of this Agreement.

17. GLML represents that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever and with the benefit of legal counsel of its choosing.

18. This Agreement is governed by the laws of the United States. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties relating to this Agreement shall be in the United States District Court for the Southern District of West Virginia.

19. For purposes of construction, 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 dispute or legal proceeding.

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

21. All persons signing this Agreement on behalf of the United States represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement. The individuals signing this Agreement on behalf of GLML represent and warrant that they are authorized to execute this Agreement on behalf of GLML.

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

23. This Agreement is binding on (a) GLML; (b) the successors, transferees, heirs, and

assigns of GLML; and (c) The United States.

24. All Parties consent to disclosure by the United States of this Agreement, and information about this Agreement, the Covered Conduct, and the settlement of the government's claims, to the public. The Parties further agree that the United States may file this Settlement Agreement in the United States District Court for the Southern District of West Virginia as a miscellaneous action and may take all actions necessary to do so.

25. This Agreement is effective on the date of the 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.

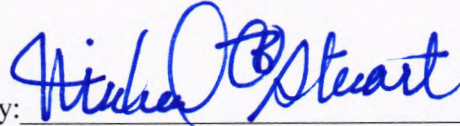
**[SIGNATURES APPEAR ON THE FOLLOWING PAGES]**

THE UNITED STATES OF AMERICA

Dated: \_\_\_\_\_

10/21/2020

By: \_\_\_\_\_



MICHAEL B. STUART  
United States Attorney  
U.S. Attorney's Office  
Southern District of West Virginia

Dated: \_\_\_\_\_

10/21/2020

By: \_\_\_\_\_



LISA M. RE  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the Inspector General  
Office of Inspector General  
U.S. Dept. of Health and Human Services



**GREAT LAKES MEDICAL LABORATORY, INC.**

Dated: 10/5/2020

Nabil Ahmed, President  
Great Lakes Medical Laboratory, Inc.

Dated: 10/6/2020

Andrew L. Sparks  
ANDREW L. SPARKS  
Counsel for Great Lakes Medical Laboratory

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

**UNITED STATES OF AMERICA,**

**Plaintiff,**

**v.**

**GREAT LAKES MEDICAL  
LABORATORY, INC.**

**Defendant.**

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**MISC. ACTION No. \_\_\_\_\_**

**STIPULATION FOR CONSENT JUDGMENT**

The Plaintiff, United States of America, by Alan G. McGonigal and Jennifer M. Mankins, Assistant United States Attorneys for the Southern District of West Virginia, and the Defendant, Great Lakes Medical Laboratory, Inc. ("GLML"), by its counsel, Andrew L. Sparks, hereby represented that they have achieved a compromise and settlement of all the False Claims Act claims the United States can assert as a result of the Covered Conduct of GLML, as more fully described in the Settlement Agreement entered into by the parties. Said compromise and settlement calls for the payment of the debt owed to the United States by the Defendant pursuant to the following terms and conditions:

I. GLML concedes that the United States District Court for the Southern District of West Virginia has jurisdiction over the matters set forth in the Settlement Agreement and over GLML. The Settlement Agreement entered into by the parties (the "Settlement Agreement") is attached to and made a part of this Stipulation for Consent Judgment.

2. Without admitting liability, GLML stipulates to the entry of a consent judgment in the event of a default under the terms of the Settlement Agreement, in accordance with this Stipulation and the Settlement Agreement, for the sum of **\$1,200,737.64**, plus interest at the Treasury Constant Maturity Rate of 1.57% per annum (the "Consent Judgment Amount"), less all sums paid by GLML to the United States pursuant to the Settlement Agreement.

3. Pursuant to the Settlement Agreement, the Settlement Amount shall be paid as follows:

(a) GLML shall pay the sum of **\$300,000** to the United States by electronic funds transfer ("EFT") pursuant to written instructions to be provided by the Office of the United States Attorney for the Southern District of West Virginia within three (3) business days of the Effective Date of this Agreement.

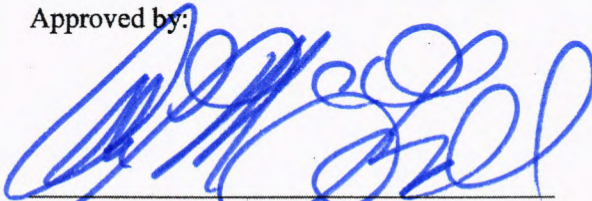
(b) GLML shall pay the sum of **\$900,737.64** to the United States within ninety (90) days of the Effective Date of this Agreement, plus interest at the Treasury Constant Maturity Rate of 1.57% per annum (accruing from the Effective Date of this Agreement) by electronic funds transfer ("EFT") pursuant to written instructions to be provided by the Office of the United States Attorney for the Southern District of West Virginia.

4. The United States shall not seek the entry of a consent judgment so long as GLML performs the terms and conditions of this Stipulation for Consent Judgment and the aforementioned Settlement Agreement. Any failure on the part of GLML to make any payment required by this Stipulation for Consent Judgment and/or the Settlement Agreement that is not cured in accordance with the terms of the Settlement Agreement or to fulfill any other term or condition in this Stipulation for Consent Judgment and/or the Settlement Agreement shall entitle

the United States to immediate entry of a Consent Judgment consistent with this Stipulation and the Settlement Agreement and to immediate enforcement to collect the remaining unpaid balance owed by any and all lawful means, or to such other relief as is specified in the Settlement Agreement.

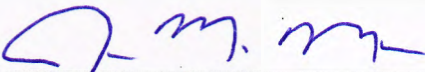
5. In order to signify their agreement to and acceptance of the terms and conditions set forth in this Stipulation for Consent Judgment, the United States, by and through Alan G. McGonigal and Jennifer M. Mankins, Assistant United States Attorneys, and the authorized representatives of GLML and Counsel for GLML have signed this Stipulation and agree to the entry of a consent judgment for the Consent Judgment Amount in the United States District Court for the Southern District of West Virginia consistent with this Stipulation and the Settlement Agreement.

Approved by:



ALAN G. MCGONIGAL  
Assistant United States Attorney  
Counsel for United States

Date: 10/21/20

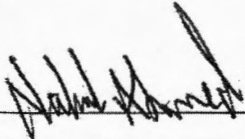


JENNIFER M. MANKINS  
Assistant United States Attorney  
Counsel for United States

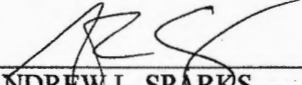
Date: 10/21/20

Approved by:

GREAT LAKES MEDICAL LABORATORY, INC.

By: , PRESIDENT

Date: 10/5/2020

By:   
ANDREW L. SPARKS  
Counsel for Great Lakes Medical Laboratory, Inc.

Date: 10/6/2020