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 of the Department of Health and Human Services (collectively, the United States); and Alere Inc. (ALR) and Alere San Diego, Inc. (ASD) (collectively, Alere), through their authorized representatives. Collectively, all of the above will be referred to as "the Parties."

RECITALS

A. ALR and ASD are both Delaware corporations. During the period relevant to this Agreement, ALR was headquartered in Waltham, Massachusetts, and ASD was headquartered in San Diego, California. Alere manufactured, marketed, offered for sale, and sold blood coagulation monitoring systems in the United States under the name "INRatio." In October 2017, Abbott Laboratories (Abbott), an Illinois corporation, acquired Alere. All of the conduct in Paragraph C below occurred before the acquisition.

B. The United States contends that Alere 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).

C. The United States contends that it has certain civil claims against Alere arising from the following alleged conduct during the period from July 19, 2008 through July 29, 2016, referred to below as the Covered Conduct:

Alere sold INRatio blood coagulation monitoring systems, comprised of a reusable meter and disposable test strips, for use by patients at home and healthcare providers in the professional setting. Blood coagulation monitoring is essential for many patients who are prescribed anticoagulant drugs that interfere with the formation of blood clots. Too much of an anticoagulant drug can cause major bleeding, and too little of the drug can cause blood clots. To measure blood

coagulation, Alere's INRatio system used a software algorithm to measure blood clotting based on changes in the electrical impedance in a blood sample.

Since at least March 2008, Alere knew that, due to an algorithm defect in the INRatio system, INRatio could produce an incorrect, or discrepant, result for some patients. Alere knew that the INRatio algorithm had a "system limitation" that could not handle certain types of impedance curves generated from patients' blood samples, including convex, or "ski slope," curves. As Alere acknowledged internally, "[t]he INRatio meter software cannot reliably determine PTs [Prothrombin Time values, a measure of how long it takes blood to clot] for certain impedance curve shapes." For such curves, Alere knew that the INRatio algorithm could return a discrepant result to some patients and healthcare providers. Alere further knew that patients and healthcare providers relied on INRatio's results in making healthcare decisions, including changing or maintaining anticoagulant dosages.

Alere received repeated warnings, including from their own personnel, that INRatio's algorithm was flawed and could return discrepant results. For example, the INRatio software developer warned Alere in April 2009 that INRatio's algorithm "has no 'defense'" against the class of ski slope curves. The developer advised Alere that the issue could be "identified & mitigated" by changing the INRatio algorithm, which "[w]ould eliminate many serious errors with [the] current [algorithm]." The developer attempted to fix the algorithm but did not identify an acceptable solution that meaningfully reduced discrepant results. Rather than pursue further work to fix the problem, Alere acknowledged internally to making "a business decision" to close their Corrective and Preventive Action (CAPA) investigation without fixing the INRatio algorithm defect. Alere did not pursue the further software improvement efforts that its software developer warned were "sorely needed" and failed to inform patients, healthcare providers, and insurers of the defect.

After 2009, despite Alere's knowledge from the CAPA investigation, Alere represented to the Food and Drug Administration (FDA) in medical device reports that it had "investigat[ed]" INRatio meters reported to have returned discrepant results and "did not uncover any deficiencies" in the meters. Alere did not correct its prior written and oral statements to the FDA that the "root cause" of the discrepant results was "unknown."

As a result, INRatio remained on the market for years after Alere knew that the INRatio algorithm could cause discrepant results. Alere admitted internally in 2014 that the INRatio algorithm defect was "a design issue that has been part of the INRatio product since the early days," and that they had "[r]ecognition of the issue in 2008." For over eight years, despite knowing of the INRatio defect, Alere continued to distribute and sell INRatio systems. Throughout this time, Alere was aware that INRatio systems were linked to over a dozen deaths and hundreds of injuries, including bleeding requiring surgery, gastrointestinal bleeding, bleeding requiring endoscopic cautery or repair, bleeding requiring a blood transfusion, intra-cerebral hemorrhaging, and cardiovascular events following a bleeding episode. As Alere admitted internally, "[i]n some cases [INRatio's defect] has led to patient harm."

Alere's conduct also resulted in damages to Medicare. Alere knowingly submitted or caused to be submitted false claims to Medicare for the purchase and/or use of Alere's INRatio system. If Alere had properly disclosed INRatio's defect, Medicare would not have paid those claims, which were for the use of an INRatio system that was neither reasonable and necessary, nor safe and effective.

D. This Settlement Agreement is neither an admission of liability by Alere nor a concession by the United States that its claims are not well founded. Alere denies the United States' allegations in Paragraph C.

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. Alere shall pay to the United States Thirty-Eight Million Seven Hundred Fifty Thousand Dollars ($38,750,000.00) plus interest at the rate of one and five-eighths percent (1.625%) per annum, calculated daily, from April 15, 2021 and continuing until and including the day of payment (Settlement Amount), of which Eighteen Million Eight Hundred Thirty-Eight Thousand Dollars ($18,838,000.00) is restitution, no later than fourteen (14) calendar 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. Subject to the exceptions in Paragraph 3 (concerning reserved claims) below, and conditioned upon Alere's full payment to the United States of the Settlement Amount, the United States releases Alere and Alere's current and former parent corporations, including Abbott; direct and indirect subsidiaries; brother or sister corporations; divisions; current or former corporate owners; and the corporate successors, transferees, heirs, and assigns of any of them (collectively, the Released Parties) from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729–33; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801–12; or the common law theories of payment by mistake, unjust enrichment, and fraud.

3. Notwithstanding the releases 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 healthcare 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.

4. Alere waives and shall not assert any defenses they 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. The Released Parties fully and finally release 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 the Released Parties have 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), TRICARE carrier or payer, Federal Employees Health Benefits Program (FEHBP) carrier or payer, or any state payer, related to the Covered Conduct; and Alere agrees not to resubmit to any Medicare contractor, TRICARE carrier or payer, FEHBP carrier or payer, 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. Alere 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 Alere, their 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) Alere'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 Alere 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 FEHBP (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Alere, and Alere 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 Alere or any of their subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

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

paragraph) on Alere or any of their 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 Alere'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 Paragraphs 2 and 9 (waiver for beneficiaries paragraph), below.

9. Alere agrees that they waive and shall not seek payment for any of the healthcare billings covered by this Agreement from any healthcare beneficiaries or their parents, sponsors, legally responsible individuals, or third party payers 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 New Jersey. 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 Alere'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.

[SIGNATURE PAGES FOLLOW]

THE UNITED STATES OF AMERICA

DATED: 7/2/2021 BY: _____

CHRISTOPHER TERRANOVA
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 7/2/2021 BY: _____

DANIEL W. MEYLER
Assistant United States Attorney
United States Attorney's Office
District of New Jersey

APPROVED:

_____

LEE M. CORTES, JR.
Chief, Health Care Fraud Unit
United States Attorney's Office
District of New Jersey

APPROVED:

_____

RACHAEL A. HONIG
Acting United States Attorney
United States Attorney's Office
District of New Jersey

DATED: _____ BY: GREGORY DEMSKE Digitally signed by GREGORY DEMSKE Date: 2021.07.02 08:51:58 -04'00'

GREGORY DEMSKE
Chief Counsel to the Inspector General
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

ALERE

DATED: 7/6/21 BY: _____

DAVID MENDELSON
Abbott Laboratories Divisional Vice President and
Assistant General Counsel, Litigation
For Alere Inc. and Alere San Diego, Inc.

DATED: 7/6/21 BY: _____

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