STATE SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement (the "Agreement") is entered into between the State of North Carolina ("the State") and Alere San Diego, Inc. ("Alere, SD"), collectively, "the Parties."

II. PREAMBLE

As a preamble to this Agreement, the Parties agree to the following:

A. Alere San Diego, Inc. ("Alere SD"), formerly known as Biosite, Inc., is a Delaware corporation that maintains its principal place of business in San Diego, California. Alere SD is a wholly-owned subsidiary of Alere, Inc., formerly known as Inverness Medical Innovations, Inc., a Delaware corporation that maintains its principal place of business in Waltham, Massachusetts. At all relevant times herein, Alere SD developed, manufactured, and sold in vitro diagnostic devices used for rapid point-of-care testing, including the testing devices marketed under the tradename "Triage" listed in Exhibit A to this Agreement (the "Triage Devices").

B. On June 30, 2011, Amanda Wu (the "Relator") filed a *qui tam* action in the United States District Court for the District of Maryland captioned *United States of America, et al., ex rel. Wu v. Alere San Diego, Inc., et al.*, Civil Action No. GLR-11-CV-1808, pursuant to the qui tam provisions of the Federal False Claims Act, 31 U.S.C. § 3730(b) and various Sate False Claims Acts. Relator filed a First Amended Complaint on November 17, 2011. This *qui tam* action will be referred to as the "Civil Action."

C. Alere SD has entered into a separate civil settlement agreement (the "Federal Settlement Agreement") with the "United States of America" as that term is defined in the Federal Settlement Agreement (the "United States").

D. The State contends that Alere SD submitted, or caused claims for payment to be submitted, to the State's Medicaid Program (42 U.S.C. Chapter 7 Subchapter XIX), including managed care entities as defined by 42 U.S.C. § 1396u.

E. The State contends that it has certain civil and administrative causes of action against Alere SD for engaging in the following conduct (the "Covered Conduct"):

> The State contends that, during the period January 1, 2006, through March 31, 2012, Alere SD developed, manufactured, and sold the Triage Devices for use in rapid point-of-care testing to aid in the diagnosis of certain diseases and conditions. The Triage Devices were used primarily at or near the site of patient care, including in the emergency department or patient bedside. The Triage Devices were used to support and aid the clinical decision making relating to patients suspected of acute coronary syndromes, heart failure, drug overdose, and other serious conditions where timely decisions are critical to ensuring proper patient care.
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> Certain Triage Devices were used in aid of diagnosis of cardiac conditions. Triage cardiac devices work by measuring the concentrations of cardiac enzymes or analytes that are recognized biochemical markers associated with cardiac injury ("cardiac markers"). In using these cardiac marker testing devices, clinicians collect a small sample of the patient's blood that is placed on the device, which is then placed into a meter that provides a measurement of the concentrations of the relevant cardiac markers to aid in diagnosing the patient.
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> Other Triage Devices were used for toxicology testing, allowing clinicians to test for the presence of certain metabolites of prescription and non-prescription drugs ("drug markers"). In using these toxicology testing devices, clinicians collect a urine sample that is placed on the device, which is then placed into a meter that provides a qualitative determination regarding the presence of the drug markers.
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> The State alleges that the Triage Devices were marketed and sold with product inserts that made representations regarding the device specifications, including the coefficient of variation ("CV") for each cardiac marker or drug marker measured by the devices. The CV represents a measure of variation for a distribution of test results within a product lot. It is the ratio of the standard deviation to the

statistical mean of the test results. With regard to the cardiac Triage Devices, each product insert denoted the relevant CV for each cardiac marker tested.

The State contends that Alere SD manufactured and sold Triage Devices between January 1, 2006, and March 31, 2012, for which the actual device CV, including the CV at the most relevant level, differed materially from the CV representations contained on the product labeling and the 510(k) submissions, and were not compliant with then Current Good Manufacturing Practices. The State contends that the disparity between the actual CV and the CV representations contained on the product labeling resulted in the certain devices having significantly decreased precision relative to the claims made in the package inserts. The State contends that the decreased precision, in turn, had the potential to create false positives or false negatives that adversely affected clinical decision making.

The State contends that Alere SD personnel were aware of this disparity and aware that it put the company at considerable regulatory and financial risk given the company's inability to set specifications correctly and the resulting potential for decreased precision when using the products. The State alleges that Alere SD was also aware of customer complaints regarding tests that produced false positives and false negatives that could have been related to the disparity in CV and resulting decreased precision for certain cardiac Triage Devices. The State contends that, despite customer complaints regarding false positives and false negatives, Alere failed to take appropriate corrective or preventive actions.

The U.S. Food and Drug Administration ("FDA") conducted inspections of Alere SD facilities in the spring of 2012, and the State contends that FDA personnel identified (i) statistically significant disparities between the actual cardiac Triage Device CV specifications and the CV specifications marketed to clinicians on the product labeling; (ii) an unacceptably high degree of variability when conducting quality control testing of the cardiac Triage Devices; and (iii) changes to the manufacturing and release specifications for toxicology Triage Devices that resulted in the release to market of certain products lots containing products that potentially had significantly decreased precision.

On May 22, 2012, Alere SD sent an "Urgent Medical Device Recall" to its customers to notify them that the company was initiating a "voluntary recall" of certain lots of the Triage Devices. The notification explained that "these lots may have significantly decreased precision relative to the package insert, which could result in an increased frequency of false positive or false negative results." The company further advised that "there have been reports of patients receiving inappropriate clinical management which may have been due to such erroneous results." Customers were instructed to discontinue use of the affected products subject to the recall. On June 11, 2012, Alere SD sent a second "Urgent Medical Device Recall" to its customers to notify them that the "voluntary recall" of Triage Devices included additional product lots. A third recall letter was issued

on June 12, 2012, expanding the recall to include several additional lots of Triage Devices.

As a result of the foregoing conduct, the State alleges that between January 1, 2006, and June 12, 2012, Alere SD knowingly submitted or caused the submission of false or fraudulent claims for the Triage Devices to be submitted to, or caused purchases by, Medicaid.

F. Alere SD denies the State's allegations set forth in Paragraph E.

G. This Agreement is neither an admission of facts or liability by Alere SD, nor a concession by the State that its allegations are not well founded.

H. The Parties mutually desire to reach a full and final settlement as set forth below.

III. TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants and obligations set forth in this Agreement, and for good and valuable consideration as stated herein, the Parties agree as follows:

1. Alere SD agrees to pay to the United States and the Medicaid Participating States (as defined in Sub-paragraph (c) below), collectively, the sum of $33,239,672.00 plus accrued interest on that amount of 2.25% per annum commencing on April 1, 2017 and continuing to and including the day payment is made under this Agreement (the "Settlement Amount"). The Settlement Amount shall constitute a debt immediately due and owing to the United States and the Medicaid Participating States on the "Effective Date" of the Federal Settlement Agreement, as defined therein and subject to the terms of this Agreement. The debt shall forever be discharged by payments to the

United States and the Medicaid Participating States under the following terms and conditions:

(a) Alere SD shall pay to the United States the sum of $28,378,892.62 plus accrued interest on that amount at the rate of 2.25 % per annum commencing on April 1, 2017 (the "Federal Settlement Amount"). The Federal Settlement Amount shall be paid pursuant to the terms of the Federal Settlement Agreement.

(b) Alere SD shall pay to the Medicaid Participating States the sum of $4,860,779.38 plus accrued interest (the "Medicaid State Settlement Amount"), subject to the non-participating state deduction provision of Sub-paragraph (d) below (the "Medicaid Participating State Settlement Amount"), no later than seven (7) business days after the expiration of the 60-day opt-in period for Medicaid Participating States described in Sub-paragraph (c) below. The Medicaid Participating State Settlement Amount shall be paid by electronic funds transfer to the New York State Attorney General's National Global Settlement Account pursuant to written instructions from the state negotiating team (the "State Team"), which written instructions shall be delivered to counsel for Alere SD.

(c) Alere SD shall execute a State Settlement Agreement with any State that executes such an Agreement in the form to which Alere SD and the State Team have agreed, or in a form otherwise agreed to by Alere SD and an individual State. The State shall constitute a Medicaid Participating State provided this Agreement is fully executed by the State and delivered to Alere SD's attorneys within 60 days of receiving this Agreement. If this condition is not satisfied within 60 days, Alere SD's offer to resolve

this matter with the State shall become null and void absent written agreement between counsel for Alere SD and the State Team to extend the 60-day period.

(d) The total portion of the amount paid by Alere SD in settlement for the Covered Conduct for the State is $456,326.37, consisting of a portion paid to the State under this Agreement and another portion paid to the United States as part of the Federal Settlement Agreement. The amount allocated to the State under this Agreement is the sum of $144,141.20 plus applicable interest (the "State Amount"). If the State does not execute this Agreement within 60 days of receiving this Agreement, the State Amount shall be deducted from the Medicaid State Settlement Amount and shall not be paid by Alere SD absent written agreement between counsel for Alere SD and the State Team to extend the time period for executing this Agreement.

2. Contingent upon receipt of the State Amount, the State agrees to dismiss with prejudice any state law claims which the State has the authority to dismiss currently pending against Alere SD in State or Federal Courts for the Covered Conduct, including any supplemental state law claims asserted in the Civil Action. Contingent upon receipt of the State Amount, the State, if served with the Civil Action and otherwise liable to pay a relator's share, agrees to pay the Relator(s) the amount of $28,828.24 plus applicable interest. This amount is to be paid through the State Team and has been addressed via a side letter with the Relator in the Civil Action.

3. Subject to the exceptions in Paragraph 4 below, in consideration of the obligations of Alere SD set forth in this Agreement, and conditioned upon receipt by the State of the State Amount, the State agrees to release Alere SD, its predecessors and current and former parents, divisions, subsidiaries, affiliates, successors, transferees,

heirs, and assigns (collectively, the "Alere SD Released Entities"), from any civil or administrative monetary cause of action that the State has for any claims submitted or caused to be submitted to the State's Medicaid Program as a result of the Covered Conduct.

4. Notwithstanding the releases given in Paragraph 3 of this Agreement, or any other term of this Agreement, the following claims of the State are specifically reserved and are not released:

(a) any criminal, civil, or administrative liability arising under state revenue codes;

(b) any criminal liability;

(c) any civil or administrative liability that any person or entity, including the Alere SD Released Entities, has or may have to the State or to individual consumers or state program payors under any statute, regulation, or rule not expressly covered by the release in Paragraph 3 above, including, but not limited to, any and all of the following claims: (i) State or federal antitrust violations; and (ii) claims involving unfair and/or deceptive acts and practices and/or violations of consumer protection laws;

(d) any liability to the State for any conduct other than the Covered Conduct;

(e) any liability based upon obligations created by this Agreement;

(f) except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusions from the State's Medicaid Program;

(g) any liability for expressed or implied warranty claims or other claims for defective or deficient products and services, including quality of goods and services;

(h) any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct;

(i) any liability for failure to deliver goods or services due; or

(j) any liability of individuals.

5. Alere SD waives and shall not assert any defenses it may have to criminal prosecution or administrative action for the Covered Conduct, which defenses may be based in whole or in part on a contention, under the Double Jeopardy Clause of the Fifth Amendment of the U.S. Constitution or the Excessive Fines Clause of the Eighth Amendment of the U.S. Constitution, that this Agreement bars a remedy sought in such criminal prosecution or administrative action.

6. In consideration of the obligations of the State set forth in this Agreement, the Alere SD Released Entities waive and discharge the State and any of its agencies, departments, and personnel including, but not limited to, officials, employees, and agents, whether current or former in their official and individual capacities from any causes of action (including attorneys' fees, costs, and expenses of every kind and however denominated) which the Alere SD Released Entities have against the State and any of its agencies, departments, and personnel as previously referenced arising from the State's investigation and prosecution of the Covered Conduct.

7. The amount that Alere SD must pay to the State pursuant to Paragraph III.1. above will not be decreased as a result of the denial of any claims for payment now being withheld from payment by the State's Medicaid Program, or any other state program payor, for the Covered Conduct; and Alere SD agrees not to resubmit to the State's Medicaid Program or any other state program payor, any previously denied

claims, which denials were based on the Covered Conduct, and agrees to withdraw the appeal of, or not to appeal or cause the appeal of, any such denials of claims.

8. Alere SD shall not seek payment for any claims for reimbursement to the State's Medicaid Program covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors.

9. Alere SD expressly warrants that it has reviewed its financial condition 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 payment of the Settlement Amount and compliance with this Agreement.

10. The Parties each represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

11. Except as expressly provided to the contrary in this Agreement, 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.

12. Except as otherwise stated in this Agreement, this Agreement is intended to be for the benefit of the Parties only, and the Parties do not release any liability as to any other person or entity.

13. In addition to all other payments and responsibilities under this Agreement, Alere SD agrees to pay the State Team's reasonable expenses and fees, including travel costs, consultant expenses, and administrative fees. Alere SD will pay this amount by separate check made payable to the National Association of Medicaid Fraud Control Units, after the Medicaid Participating States execute their respective Agreements, or as otherwise agreed by the Parties.

14. This Agreement is governed by the laws of the State and venue for addressing and resolving any and all disputes relating to this Agreement shall be the state courts of appropriate jurisdiction of the State.

15. The undersigned Alere SD signatories represent and warrant that they are authorized as a result of appropriate corporate action to execute this Agreement. The undersigned State signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement on behalf of the State through their respective agencies and departments.

16. The Effective Date of this Agreement shall be the date of signature of the last signatory to this Agreement. Facsimiles of signatures shall constitute acceptable binding signatures for purposes of this Agreement.

17. This Agreement shall be binding on all successors, transferees, heirs, and assigns of the Parties.

18. This Agreement constitutes the complete agreement between the Parties with respect to this matter and shall not be amended except by written consent of the Parties.

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

STATE OF NORTH CAROLINA

By: _____ Dated: 4/30/2018

CHARLES H. HOBGOOD
Director, Medicaid Investigations Division
Office of the Attorney General

By: _____ Dated: 4/16/2018

DAVE RICHARD
Deputy Secretary for Medical Assistance
Division of Medical Assistance

ALERE SAN DIEGO, INC.

By: _____ Dated: 6/15/16

David Mendelsohn
Name

Assoc. General Counsel
Title

Alere San Diego, Inc.

By: _____ Dated: _____

Counsel to

(May need multiple blocks)

EXHIBIT A

Product Number	Product Description
94000	Triage TOX Panel
94100	Triage TOX Panel DS PCP&THC
94200	Triage TOX Panel DS APAP&THC
94400	Triage TOX Panel DS – MTD/APAP/THC/PCP
94400M	Triage TOX Panel DS-MTD/APAP/THC/PCP+MDMA
94400P	Triage TOX Panel DS-MTD/APAP/THC/PCP+PPX
94400X	Triage TOX Panel DS-MTD/APAP/THC/PCP+OXY
94400XM	Triage TOX DS-MTD/APAP/THC/PCP+OXY+MDMA
94400XMB	Triage TOX-MTD/APAP/THC/PCP+OXY+MDMA+BUP
94400XMP	Triage TOX-MTD/APAP/THC/PCP+OXY+MDMA+PPX
94400XP	Triage TOX DS-MTD/APAP/THC/PCP+OXY+PPX
97000	Triage Cardiac Panel
97100	Triage Cardio ProfilER Panel
97100CP	Triage Cardio ProfilER Panel w/ XR BNP
97300	Triage Cardio ProfilER S.O.B. Panel
98000	Triage BNP Panel

Alere San Diego, Inc.
Case # ALERE-212 (f/k/a 13-12-01)