

BUSINESS ASSOCIATE AGREEMENT

This Business Associate Agreement (Agreement) is entered into by and between San Bernardino County on behalf of Arrowhead Regional Medical Center (hereinafter "Covered Entity" or "CE") and Abbott Rapid Diagnostics Informatics, Inc. ("Business Associate"), located at 915 East High Street, Suite 500, Charlottesville, Virginia, 22902. This Agreement is effective as of the date fully executed.

RECITALS

WHEREAS, Covered Entity and Business Associate entered into a contract with an effective date of September 19, 2023 for RALS™ SOFTWARE SYSTEM LICENSE AND SUPPORT MASTER AGREEMENT ("Contract"); and

WHEREAS, as a result of the services and/or goods provided by BA to CE under the Contract, CE may to disclose to BA certain information, including Protected Health Information ("PHI"); and

WHEREAS, CE and BA intend to protect the privacy and provide for the security of the PHI disclosed to BA pursuant to this Agreement in compliance with the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 (HIPAA), the Health Information Technology for Economic and Clinical Health Act, Public Law 111-005 (HITECH Act), their implementing regulations, and other applicable laws; and

WHEREAS, the Privacy Rule and the Security Rule require CE to enter into a contract containing specific requirements with BA prior to the disclosure of PHI, as set forth in, but not limited to, Title 45, sections 164.314, subdivision (a), 164.502, subdivision (e), and 164.504, subdivision (e) of the Code of Federal Regulations (C.F.R.) and as contained in this Agreement; and

WHEREAS, pursuant to HIPAA and the HITECH Act, BA shall fulfill the responsibilities of this Agreement by being in compliance with the applicable provisions of the HIPAA Standards for Privacy and Security of PHI set forth at 45 C.F.R. sections 164.530 (Administrative Requirements), 164.308 (Administrative Safeguards), 164.310 (Physical Safeguards), 164.312 (Technical Safeguards), 164.316 (Policies and Procedures and Documentation Requirements), and, 164.400, et seq. and 42 United States Code (U.S.C.) section 17932 (Breach Notification Rule), in the same manner as they apply to a CE under HIPAA; and

NOW THEREFORE, in consideration of the mutual promises below and the exchange of information pursuant to this Agreement, the parties agree that the terms and conditions of this Agreement, as further set forth below, shall apply to the services provided by BA under the Contract:

A. Definitions

Unless otherwise specified herein, capitalized terms used in this Agreement shall have the same meanings as given in the Privacy Rule, the Security Rule, the Breach Notification Rule, and HITECH Act, as and when amended from time to time.

1. Breach shall have the same meaning given to such term under the HIPAA Regulations [45 C.F.R. §164.402] and the HITECH Act [42 U.S.C. §§17921 et seq.], and includes the definition set forth in 22 California Code of Regulations (C.C.R.) § 79901(b).
2. Business Associate (BA) shall have the same meaning given to such term under the Privacy Rule, the Security Rule, and the HITECH Act, including but not limited to 42 U.S.C. section 17921 and 45 C.F.R. section 160.103, and includes the definition set forth in 22 C.C.R. § 79901(c).
3. Covered Entity (CE) shall have the same meaning given to such term as under the Privacy Rule and Security Rule, including, but not limited to 45 C.F.R. section 160.103.
4. Designated Record Set shall have the same meaning given to such term under 45 C.F.R. section 164.501.
5. Detect(ed) shall have the same meaning given to such term under 22 C.C.R. § 79901(f).
6. Electronic Protected Health Information (ePHI) means PHI that is maintained in or transmitted by electronic media as defined in the Security Rule, 45 C.F.R. section 164.103.
7. Individual shall have the same meaning given to such term under 45 C.F.R. section 160.103.
8. Medical Information shall have the same meeting given to such term under 22 C.C.R. § 79901(l).
9. Privacy Rule means the regulations promulgated under HIPAA by the United States Department of Health and Human Services (HHS) to protect the privacy of Protected Health Information, including, but not limited to, 45 C.F.R. Parts 160 and 164, subparts A and E.
10. Protected Health Information (PHI) shall have the same meaning given to such term under 45 C.F.R. section 160.103, limited to the information received from, or created or received by Business Associate from or on behalf of, CE, and includes Medical Information.
11. Security Rule means the regulations promulgated under HIPAA by HHS to protect the security of ePHI, including, but not limited to, 45 C.F.R. Part 160 and 45 C.F.R. Part 164, subparts A and C.
12. Unsecured PHI shall have the same meaning given to such term under the HITECH Act and any guidance issued pursuant to such Act, including, but not limited to 42 U.S.C. section 17932, subdivision (h).

B. Obligations and Activities of BA

1. Permitted Uses and Disclosures

- i. CE shall disclose PHI to BA for the following purposes: RALS Plus Software Interface and remote support.
- ii. BA may disclose PHI: (i) for the proper management and administration of BA; (ii) to carry out the legal responsibilities of BA; (iii) for purposes of Treatment, Payment and Operations (TPO); (iv) as required by law; or (v) for Data Aggregation purposes for the Health Care Operations of CE. Prior to making

any other disclosures, BA must obtain a written authorization from the Individual.

- iii. If BA discloses PHI to a third party, BA must obtain, prior to making any such disclosure, (i) reasonable written assurances from such third party that such PHI will be held confidential as provided pursuant to this Agreement and only disclosed as required by law or for the purposes for which it was disclosed to such third party, and (ii) a written agreement from such third party to immediately notify BA of any breaches of confidentiality of the PHI, to the extent it has obtained knowledge of such breach. [42 U.S.C. section 17932; 45 C.F.R. sections 164.504(e)(2)(i), 164.504(e)(2)(i)(B), 164.504(e)(2)(ii)(A) and 164.504(e)(4)(ii)]

2. Prohibited Uses and Disclosures

- i. BA shall not use, access or further disclose PHI other than as permitted or required by this Agreement or as required by law. Further, BA shall not use PHI in any manner that would constitute a violation of the Privacy Rule or the HITECH Act. BA shall disclose to its employees, subcontractors, agents, or other third parties, and request from CE, only the minimum PHI necessary to perform or fulfill a specific function required or permitted hereunder.
- ii. BA shall not use or disclose PHI for fundraising or marketing purposes.
- iii. BA shall not disclose PHI to a health plan for payment or health care operations purposes if the patient has requested this special restriction, and has paid out of pocket in full for the health care item or service to which the PHI solely relates. (42 U.S.C. section 17935(a) and 45 C.F.R. section 164.522(a)(1)(i)(A).)
- iv. BA shall not directly or indirectly receive remuneration in exchange for PHI, except with the prior written consent of CE and as permitted by the HITECH Act (42 U.S.C. section 17935(d)(2); and 45 C.F.R. section 164.508); however, this prohibition shall not affect payment by CE to BA for services provided pursuant to this Agreement.

3. Appropriate Safeguards

- i. BA shall implement appropriate safeguards to prevent the unauthorized use or disclosure of PHI, including, but not limited to, administrative, physical and technical safeguards that reasonably protect the confidentiality, integrity and availability of the PHI BA creates, receives, maintains, or transmits on behalf of the CE, in accordance with 45 C.F.R. sections 164.308, 164.310, 164.312 and 164.316. [45 C.F.R. sections 164.504(e)(2)(ii)(b) and 164.308(b).]
- ii. In accordance with 45 C.F.R. section 164.316, BA shall maintain reasonable and appropriate written policies and procedures for its privacy and security program in order to comply with the standards, implementation specifications, or any other requirements of the Privacy Rule and applicable provisions of the Security Rule. These policies and procedures should be made available within a reasonable timeframe to the CE upon request.
- iii. BA shall provide appropriate training for its workforce on the requirements of the Privacy Rule and Security Rule as those regulations affect the proper handling, use confidentiality and disclosure of the CE's PHI. These trainings and/or evidence of

completion of such trainings should be made available to the CE within a reasonable timeframe upon request.

Such training will include specific guidance relating to sanctions against workforce members who fail to comply with privacy and security policies and procedures and the obligations of the BA under this Agreement.

4. Subcontractors

BA shall enter into written agreements with agents and subcontractors to whom BA provides CE's PHI that impose the same restrictions and conditions on such agents and subcontractors that apply to BA with respect to such PHI, and that require compliance with all appropriate safeguards as found in this Agreement.

5. Reporting of Improper Access, Use or Disclosure or Breach

Every suspected and actual Breach shall be reported immediately, but no later than five (5) business days upon discovery, to CE's Office of Compliance. Upon discovery of a Breach or suspected Breach, BA shall complete the following actions:

- i. Provide CE's Office of Compliance with the following information to include but not limited to:
 - a) Name and address of the facility where the breach occurred;
 - b) Date and time the Breach or suspected Breach occurred;
 - c) Date and time the Breach or suspected Breach was discovered or Detected;
 - d) Number of staff, employees, subcontractors, agents or other third parties and the names and titles of each person allegedly involved, including the person who performed the Breach, witnessed the Breach, used the PHI, or the person to whom the disclosure was made;
 - e) Name of patient(s) affected;
 - f) Number of potentially affected Individual(s) with contact information;
 - g) Description of how the Breach or suspected Breach allegedly occurred; and
 - h) Description of the PHI that was Breached, including the nature and extent of the PHI involved, including the types of individually identifiable information and the likelihood of re-identification.
- ii. Conduct and document a risk assessment by investigating without unreasonable delay and in no case later than five (5) calendar days of discovery of the Breach or suspected Breach to determine the following:
 - a) The nature and extent of the PHI involved, including the types of identifiers and likelihood of re-identification;
 - b) The unauthorized person who had access to the PHI;
 - c) Whether the PHI was actually acquired or viewed; and
 - d) The extent to which the risk to PHI has been mitigated.
- iii. Provide a completed risk assessment and investigation documentation to CE's Office of Compliance within ten (10) calendar days of discovery of the Breach or

suspected Breach with a determination as to whether a Breach has occurred. At the discretion of CE, additional information may be requested.

- a) If BA and CE agree that a Breach has not occurred, notification to Individual(s) is not required.
 - b) If a Breach has occurred, notification to the Individual(s) is required and BA must provide CE with affected Individual(s) name and contact information so that CE can provide notification.
 - c) The risk assessment and investigation documentation provided by BA to CE shall, at a minimum, include a description of any corrective or mitigation actions taken by BA.
- iv. Make available to governing State and Federal agencies in a time and manner designated by CE or governing State and Federal agencies, any policies, procedures, internal practices and records relating to a Breach or suspected Breach for the purposes of audit.

6. Access to PHI

To the extent BA maintains a Designated Record Set on behalf of CE, BA shall make PHI maintained by BA or its agents or subcontractors in Designated Record Sets available to CE for inspection and copying within ten (10) days of a request by CE to enable CE to fulfill its obligations under the Privacy Rule. If BA maintains ePHI, BA shall provide such information in electronic format to enable CE to fulfill its obligations under the HITECH Act. If BA receives a request from an Individual for access to PHI, BA shall immediately forward such request to CE.

7. Amendment of PHI

If BA maintains a Designated Record Set on behalf of the CE, BA shall make any amendment(s) to PHI in a Designated Record Set that the CE directs or agrees to, pursuant to 45 C.F.R. section 164.526, or take other measures as necessary to satisfy CE's obligations under 45 C.F.R. section 164.526, in the time and manner designated by the CE.

8. Access to Records

BA shall make internal practices, books, and records, including policies and procedures, relating to the use, access and disclosure of PHI received from, or created or received by BA on behalf of, CE available to the Secretary of HHS, in a time and manner designated by the Secretary, for purposes of the Secretary determining CE's compliance with the Privacy Rule and Security Rule and patient confidentiality regulations. Any documentation provided to the Secretary shall also be provided to the CE upon request.

9. Accounting for Disclosures

BA, its agents and subcontractors shall document disclosures of PHI and information related to such disclosures as required by HIPAA. This requirement does not apply to disclosures made for purposes of TPO. BA shall provide an accounting of disclosures to CE or an Individual, in the time and manner designated by the CE. BA agrees to implement a process that allows for an accounting to be collected and maintained by BA and its agents or subcontractors for at least six (6) years prior to the request. At a

minimum, the information collected and maintained shall include: (i) the date of disclosure; (ii) the name of the entity or person who received PHI and, if known, the address of the entity or person; (iii) a brief description of PHI disclosed; and (iv) a brief statement of purpose of the disclosure that reasonably informs the individual of the basis for the disclosure, or a copy of the Individual's authorization, or a copy of the written request for disclosure.

10. Termination

This Agreement is effective as of the date fully executed and until the earlier of (1) it is terminated by either party or (2) expiration or termination of the Contract. Either party may terminate this Agreement with at least thirty (30) days written notice to the other party. Notwithstanding anything in the foregoing, this Agreement may not be terminated by either party if the Contract is in effect and federal law requires this Agreement for the provision of the services by BA under the Contract. CE may also immediately terminate this agreement, and any related agreements, if CE determines that BA has breached a material term of this Agreement. CE may, at its sole discretion, provide BA an opportunity to cure the breach or end the violation within the time specified by the CE.

11. Effect of Termination

Upon termination of this Agreement, BA shall either destroy or return all PHI required to be retained by the BA or its subcontractors, employees or agents. If BA determines that returning the PHI is not feasible, BA shall provide the CE with written notification of the conditions that make return not feasible. Additionally, the BA must follow established policies and procedures to ensure PHI is safeguarded and disposed of adequately in accordance with 45 C.F.R. section 164.310, and must submit to the CE a certification of destruction of PHI. For destruction of ePHI, the National Institute of Standards and Technology (NIST) guidelines must be followed. BA further agrees to extend any and all protections, limitations, and restrictions contained in this Agreement, to any PHI retained by BA or its subcontractors, employees or agents after the termination of this Agreement, and to limit any further use, access or disclosures.

12. Breach by the CE

Pursuant to 42 U.S.C. section 17934, subdivision (b), if the BA is aware of any activity or practice by the CE that constitutes a material Breach or violation of the CE's obligations under this Agreement, the BA must take reasonable steps to address the Breach and/or end eliminate the continued violation, if the BA has the capability of mitigating said violation. If the BA is unsuccessful in eliminating the violation and the CE continues with non-compliant activity, the BA must terminate the Agreement (if feasible) and report the violation to the Secretary of HHS.

13. Mitigation

BA shall have procedures in place to mitigate, to the extent practicable, any harmful effect that is known to BA of a use, access or disclosure of PHI by BA, its agents or subcontractors in violation of the requirements of this Agreement.

14. Costs Associated to Breach

BA shall be responsible for reasonable costs associated with a Breach. Costs shall be based upon the required notification type as deemed appropriate and necessary by the CE and shall not be reimbursable under the Agreement at any time. CE shall determine

the method to invoice the BA for said costs. Costs shall incur at the current rates and may include, but are not limited to the following:

- Postage;
- Alternative means of notice;
- Media notification; and
- Credit monitoring services.

15. Direct Liability

BA may be held directly liable under HIPAA and California law for impermissible uses and disclosures of PHI; failure to provide breach notification to CE; failure to provide access to a copy of PHI or ePHI to CE or individual; failure to disclose PHI to the Secretary of HHS when investigating BA's compliance with HIPAA; failure to provide an accounting of disclosures; and, failure to enter into a business associate agreement with subcontractors.

16. Indemnification

17. Each party ("Indemnifying Party") shall indemnify, defend and hold harmless the other party, its officers, directors, employees, agents, successors and assigns (collectively, "Indemnified Party") from and against any losses claims, actions, demands, liabilities, damages, judgements, costs and expenses ("Claims") arising from a Breach of Unsecured Protected Health Information caused by the Indemnifying Party, subject to any limitation of liability or damage disclaimer set forth in the underlying agreement between the parties. Notwithstanding the foregoing, the Indemnifying Party shall have no obligation of indemnification to the extent that any Claims arise out of the Indemnified Party's violation of applicable law, negligence, recklessness, willful misconduct or breach of this BAA. If the Indemnifying Party assumes the defense of any Claim, the Indemnified party shall cooperate with the Indemnifying Party, as reasonably requested, in the investigation and defense of the Claim. Judicial or Administrative Proceedings

CE may terminate the Contract, effective immediately, if (i) BA is named as a defendant in a criminal proceeding for a violation of HIPAA, the HITECH Act, the Privacy Rule, Security Rule or other security or privacy laws or (ii) a finding or stipulation is made in any administrative or civil proceeding in which the BA has been joined that the BA has violated any standard or requirement of HIPAA, the HITECH Act, the Privacy Rule, Security Rule or other security or privacy laws.

18. Insurance

During the term of this Agreement, BA shall maintain Cyber Liability Insurance with limits of no less than \$1,000,000 for each occurrence or event with an annual aggregate of \$2,000,000 covering privacy violations, information theft, damage to or destruction of electronic information, intentional and/or unintentional release of private information, alteration of electronic information, extortion and network security. The policy shall protect the CE and cover Breach response cost as well as regulatory fines and penalties. The policy shall also cover any and all claims, causes of action, and demands whatsoever made for loss, damage, or injury to any person arising from the breach of the security, privacy, or confidentiality obligations of BA, its agents or employees, under this Agreement and under HIPAA 45 C.F.R. Parts 160 and 164, Subparts A and E.

19. Assistance in Litigation or Administrative Proceedings

BA shall make itself, and any subcontractors, employees, or agents assisting BA in the performance of its obligations under the Agreement, available to CE, at no cost to CE, to testify as witnesses, or otherwise, in the event of litigation or administrative proceedings being commenced against CE, its directors, officers, or employees based upon a claimed violation of HIPAA, the HITECH Act, the Privacy Rule, the Security Rule, or other laws relating to security and privacy, except where BA or its subcontractor, employee or agent is a named adverse party.

C. Obligations of CE

1. CE shall notify BA of any of the following, to the extent that such may affect BA's use, access, maintenance or disclosure of PHI:
 - i. Any limitation(s) in CE's notice of privacy practices in accordance with 45 C.F.R. section 164.520.
 - ii. Any changes in, or revocation of, permission by an individual to use, access or disclose PHI.
 - iii. Any restriction to the use, access or disclosure of PHI that CE has agreed to in accordance with 45 C.F.R. section 164.522.

D. General Provisions

1. Remedies

BA agrees that CE shall be entitled to seek immediate injunctive relief as well as to exercise all other rights and remedies which CE may have at law or in equity in the event of an unauthorized use, access or disclosure of PHI by BA or any agent or subcontractor of BA that received PHI from BA.

2. Ownership

The PHI shall be and remain the property of the CE. BA agrees that it acquires no title or rights to the PHI.

3. Regulatory References

A reference in this Agreement to a section in the Privacy Rule and Security Rule and patient confidentiality regulations means the section as in effect or as amended.

4. No Third-Party Beneficiaries

Nothing express or implied in the Contract or this Agreement is intended to confer, nor shall anything herein confer, upon any person other than CE, BA and their respective successors or assigns, any rights, remedies, obligations or liabilities whatsoever.

5. Amendment

The parties acknowledge that state and federal laws related to privacy and security of PHI are rapidly evolving and that amendment of the Contract or this Agreement may be required to ensure compliance with such developments. The parties shall negotiate in good faith to amend this Agreement when and as necessary to comply with applicable laws. If either party does not agree to so amend this Agreement within 30 days after receiving a request for amendment from the other, either party may terminate the Agreement upon written notice. To the extent an amendment to this Agreement is

required by law and this Agreement has not been so amended to comply with the applicable law in a timely manner, the amendment required by law shall be deemed to be incorporated into this Agreement automatically and without further action required by either of the parties. Subject to the foregoing, this Agreement may not be modified, nor shall any provision hereof be waived or amended, except in a writing duly signed and agreed to by BA and CE.

6. Interpretation

Any ambiguity in this Agreement shall be resolved to permit CE to comply with the Privacy and Security Rules, the HITECH Act, and all applicable patient confidentiality regulations.

7. Compliance with State Law

In addition to HIPAA and all applicable HIPAA Regulations, BA acknowledges that BA and CE may have confidentiality, privacy, and breach notification obligations under State law, including, but not limited to, the California Confidentiality of Medical Information Act (Cal. Civil Code §56, et seq. ("CMIA")), and 22 C.C.R. § 79001 et seq. If any provisions of this Agreement or HIPAA Regulations or the HITECH Act conflict with CMIA or any other California State law regarding the degree of protection provided for PHI and patient medical records, then BA shall comply with the more restrictive requirements.

8. Survival

The respective rights and obligations and rights of CE and BA relating to protecting the confidentiality or a patient's PHI shall survive the termination of the Contract or this Agreement.

9. Dispute Resolution

CE and BA agree they will establish mutually satisfactory methods for problem resolution at the lowest possible level as the optimum, with a procedure to escalate problem resolution through the appropriate chain-of-command, as deemed necessary.

10. Notices

All written notices provided for in this Agreement or which either party desires to give to the other shall be deemed fully given, when made in writing and either served personally, or deposited in the United States mail, postage prepaid, and addressed to the other party as follows:

*Arrowhead Regional Medical Center
400 N. Pepper Avenue
Colton, CA 92324
Attn: ARMC Chief Executive Officer*

Notices to Business Associate:

Abbott Laboratories
Privacy Officer

100 Abbott Park Road, Dept. O36X Bldg.
AP06A
Abbott Park, Illinois 60064-3500
Email: ARDx_PrivacyOfficer@Abbott.com

and

Abbott Laboratories
Legal Regulatory & Compliance
Dept. 32RA, Bldg. AP6A-2
100 Abbott Park Road
Abbott Park, Illinois 60064
Attn: Counsel for Global Privacy

Privacy Steward – ARDx Informatics
Abbott Rapid Diagnostics Informatics, Inc.
915 East High Street, Suite 500
Charlottesville, VA 22902
Email: Boni.Boutelle@abbott.com

Notice shall be deemed communicated two (2) County working days from the time of mailing if mailed as provided in this paragraph.

11. Governing Law and Venue

Except where preempted by federal law, this Agreement shall be governed by and construed in all aspects in accordance with the laws of the State of California without regard to principles of conflicts of laws. The Parties agree that any action arising hereunder shall be venued exclusively in the San Bernardino County Superior Court, San Bernardino District.

12. Assignment

Without the prior written consent of CE, this Agreement is not assignable by BA either in whole or in part.

13. Addendum

If Business Associate is using hosted cloud computing services for any part of the services hereunder, the terms of the Business Associate Addendum for Cloud Services, attached as Exhibit A, shall apply and are hereby incorporated as though fully set forth herein.

14. Entire Agreement

This Agreement, including all Exhibits and other attachments, which are attached hereto and incorporated by reference, and other documents incorporated herein, represents the final, complete and exclusive agreement between the parties hereto. Any prior agreement, promises, negotiations or representations relating to the subject matter of this Agreement not expressly set forth herein are of no force or effect. This Agreement

is executed without reliance upon any promise, warranty or representation by any party or any representative of any party other than those expressly contained herein. Each party has carefully read this Agreement and signs the same of its own free will.

15. Counterparts

This Agreement may be executed in any number of counterparts, each of which so executed shall be deemed to be an original, and such counterparts shall together constitute one and the same Agreement. The parties shall be entitled to sign and transmit an electronic signature of this Agreement (whether by facsimile, PDF or other mail transmission), which signature shall be binding on the party whose name is contained therein. Each party providing an electronic signature agrees to promptly execute and deliver to the other party an original signed Agreement upon request.

The undersigned affirms that he/she is a duly authorized representative of the Business Associate for which he/she is signing and has authority to execute this Agreement on behalf of the Business Associate.

SAN BERNARDINO COUNTY

►

Dawn Rowe, Chair, Board of Supervisors

Dated: _____
SIGNED AND CERTIFIED THAT A COPY OF THIS DOCUMENT HAS BEEN DELIVERED TO THE CHAIRMAN OF THE BOARD

Lynna Monell
Clerk of the Board of Supervisors
San Bernardino County

By _____
Deputy

Abbott Rapid Diagnostics

(Print or type name of corporation, company, contractor, etc.)

By ► _____
(Authorized signature - sign in blue ink)

Name Jessica Bishop

(Print or type name of person signing contract)

Title Supervisor, Revenue Accounting

(Print or Type)

Dated: _____

Address _____

By ► _____
(Authorized signature - sign in blue ink)

Name Nicholas Gargiulo

(Print or type name of person signing contract)

Title Sr Commercial Manager

(Print or Type)

Dated: _____

Address: _____

