

	<i>The American Association for Laboratory Accreditation</i>	
	F611 – HIPAA BUSINESS ASSOCIATE AGREEMENT	Document Revised: January 21, 2010
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In order to comply with the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and implementing regulations, 45 C.F.R. Parts 160 and 164, the American Association for Laboratory Accreditation (“A2LA”) and _____ (“Covered Entity”) agree as follows:

1. **Permitted Uses and Disclosures For Accreditation Purposes.** To the extent that, in the course of inspecting the laboratory facilities at Covered Entity, A2LA gains access to “protected health information” as defined in 45 C.F.R. § 164.501, A2LA may use and disclose such Protected Health Information (“PHI”) as necessary to evaluate the Covered Entity for accreditation purposes.
2. **Permitted Uses and Disclosures For Other Purposes.** A2LA may use PHI as necessary for the proper management and administration of A2LA or to carry out A2LA’s legal responsibilities. A2LA may disclose such information to third parties for these purposes only if (A) the disclosure is required by law; or (B) A2LA obtains reasonable assurances from the recipient of the PHI that (1) the information will be held in confidence and used or further disclosed only as required by law or for the purpose for which it was disclosed to the person; and (2) the recipient will notify A2LA of any breach in the confidentiality of the information.
3. **Prohibited Uses and Disclosures.** A2LA shall not use or disclose such PHI except as the Covered Entity itself may. A2LA shall use and disclose PHI only to the extent necessary for a permitted purpose.
4. **Compliance with Privacy Standards.** A2LA shall not use or disclose PHI other than as permitted or required by this Agreement or as required by law.
5. **Safeguards** A2LA shall use appropriate safeguards to prevent use or disclosure of PHI other than as provided for by this Agreement.
6. **Reporting** A2LA shall report to the Covered Entity any use or disclosure of PHI which is not provided for by this Agreement of which A2LA becomes aware.
7. **Subcontractors** A2LA shall ensure that any agents, including any subcontractors, to whom it provides PHI shall agree to the same restrictions and conditions that apply to A2LA with respect to the PHI.
8. **Patient’s Right to Access.** A2LA shall allow individuals who are the subjects of the PHI to inspect and copy their information in the possession of A2LA if Covered Entity does not also maintain such information.

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9. **Amendment of PHI.** A2LA shall make available the PHI for amendment and shall incorporate amendments to the PHI upon notification by Covered Entity that such information requires amendment.

10. **Accountings of Disclosures.** If A2LA discloses the PHI to any third party, A2LA shall make available to Covered Entity the information that is necessary for the Covered Entity to provide an accounting of disclosures to a requesting individual.

11. **Access by Department of Health and Human Services.** A2LA shall make its internal practices, books, documents and records relating to the use and disclosure of the PHI available to the Secretary of the Department of Health and Human Services for purposes of determining the Covered Entity’s compliance with the HIPAA privacy regulations.

12. **Termination.** This Agreement shall terminate when Covered Entity no longer utilizes A2LA to inspect its laboratory facilities. Covered Entity may terminate its relationship with A2LA if it determines that A2LA has violated a material term of this Agreement. The rights and responsibilities of A2LA under this Agreement shall survive termination.

13. **Return or Destruction of Information.** Upon termination of its relationship with Covered Entity, A2LA shall, if feasible, return or destroy all of the PHI that A2LA still maintains in any form and shall retain no copies of such information. If such return or destruction is not feasible, A2LA shall extend the protections of this Agreement to the PHI and shall limit further uses and disclosures to those purposes that make the return or destruction of the information infeasible.

14. **Amendment.** The parties shall modify this Agreement to bring it into compliance with any changes in HIPAA or the HIPAA privacy regulations that are made after the date of execution of this Agreement.

15. **Interpretation.** Any ambiguity in this Agreement shall be resolved in a manner that brings the Agreement into compliance with the then most current version of HIPAA and the HIPAA privacy regulations.



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IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement as of this ____ day of _____, 20__.

Covered Entity

American Association for Laboratory Accreditation

CLIA Certificate # _____

By: _____

By: _____

Name: _____

Name: _____

Title: _____

Title: _____

List the # (s) for which the agreement applies:

Mail agreements to:

Name: _____

Institution: _____

Address: _____

Phone # _____