



BIOMÉRIEUX VISION SUITE Data Processing Terms (US)

BUSINESS ASSOCIATE AGREEMENT

1. APPLICABILITY

These BIOMÉRIEUX VISION SUITE Data Processing Terms (US) (“**Data Processing Terms**”) shall govern Processing activities relating to Personal Data that is collected, processed, or hosted by bioMérieux or its Sub-Processors within the United States. These Data Processing Terms shall comprise this Business Associate Agreement (“**BAA**”) and, where applicable, the appended Service Provider Addendum. In the event of a conflict between these Data Processing Terms and the General Terms or the Additional Terms, these Data Processing Terms shall control.

This BAA is intended to ensure that Business Associate will establish and implement appropriate safeguards for the Protected Health Information or PHI under HIPAA that Business Associate may receive, create, maintain, use, or disclose in connection with the bioMérieux Solution. This BAA shall take effect on the date that Business Associate first receives, maintains, creates, uses, or discloses PHI.

2. DEFINITIONS

- 2.1 “**Applicable Laws**” shall have the meaning set forth in the General Terms.
- 2.2 “**Applicable Terms**” shall mean the General Terms and any applicable Additional Terms, or any other applicable underlying agreement.
- 2.3 “**Additional Terms**” shall have the meaning set forth in the General Terms.
- 2.4 “**ARRA**” shall mean the American Recovery and Reinvestment Act of 2009.
- 2.5 “**bioMérieux**” shall have the meaning set forth in the General Terms.
- 2.6 “**Business Associate**” shall have the meaning ascribed to “business associate” under HIPAA and, for purposes of this BAA, shall refer to bioMérieux but only to the extent that bioMérieux creates, receives, maintains or transmits any Protected Health Information under the Applicable Terms.
- 2.7 “**Covered Entity**” shall have the meaning ascribed to “covered entity” under HIPAA and, for purposes of this BAA, shall refer to Customer but only to the extent that Customer permits bioMérieux to create, receive, maintain or transmit Protected Health Information under the Applicable Terms.
- 2.8 “**Customer**” shall have the meaning set forth in the General Terms.
- 2.9 “**De-identified Data**” shall have the meaning set forth in the General Terms.
- 2.10 “**General Terms**” shall mean the BIOMÉRIEUX VISION SUITE General Terms and Conditions.
- 2.11 “**HIPAA**” shall mean the Health Insurance Portability and Accountability Act of 1996, as the same may be amended (including, but not limited to, by ARRA and HITECH Act), modified or supplemented from time to time, and any successor statute thereto, and any and all rules or regulations promulgated from time to time thereunder.
- 2.12 “**HITECH Act**” shall mean the Health Information Technology for Economic and Clinical Health Act of 2009.
- 2.13 “**HHS**” shall mean the United States Department of Health and Human Services.
- 2.14 “**Privacy Rule**” shall mean 45 C.F.R. Part 160 and 45 C.F.R. Part 164, Subparts A and E as interpreted under applicable regulations and guidance of general application published by HHS, including all amendments thereto for which compliance is required, as amended by HIPAA, HITECH Act, and ARRA.
- 2.15 “**Security Rule**” shall mean 45 C.F.R. Part 160 and 45 C.F.R. Part 164, Subparts A and C as interpreted under applicable regulations and guidance of general application published by HHS, including all amendments thereto for which compliance is required, as amended by HIPAA, HITECH Act, and ARRA.
- 2.16 “**bioMérieux Solution**” shall have the meaning set forth in the General Terms.
- 2.17 Unless the context clearly indicates otherwise, the following terms in this BAA shall have the same meaning as ascribed to those terms under HIPAA: “**Breach**”, “**Designated Record Set**”, “**Disclosure**”, “**Electronic Protected Health Information**” or “**ePHI**”, “**Health Care Operations**”, “**Individual**”, “**Notice of Privacy Practices**”, “**Protected Health Information**” or “**PHI**”, “**Required By Law**”, “**Secretary**”, “**Security Incident**”, “**Subcontractor**”, and “**Use**”.

3. BUSINESS ASSOCIATE OBLIGATIONS

- 3.1 **Limitation on Uses and Disclosures.** Business Associate shall not to use or disclose PHI, other than as permitted or required by this BAA or as Required By Law, or if such use or disclosure does not otherwise cause a Breach of Unsecured PHI.
- 3.2 **Safeguards.** Business Associate shall use appropriate safeguards and comply with 45 C.F.R. Part 164, Subpart C with respect to ePHI, to prevent use or disclosure of PHI other than as provided for by the BAA.
- 3.3 **Mitigation of Impermissible Uses and Disclosures.** Business Associate shall mitigate, to the extent practicable, any harmful effect that is known to Business Associate as a result of a use or disclosure of PHI by Business Associate or Business Associate’s Subcontractor in violation of this BAA’s requirements or that would otherwise cause a Breach of Unsecured PHI.
- 3.4 **Reporting of Security Incidents.** Business Associate shall report to Covered Entity any Breach of Unsecured PHI not provided for by this BAA of which it becomes aware without unreasonable delay. Business Associate also shall provide any available additional information reasonably requested by Covered Entity for purposes of investigating the Breach and any other available information that Covered Entity is required to include to the individual under 45 C.F.R. Part 164.404(c) at the time of notification or promptly thereafter as information becomes available. Business Associate’s notification of a Breach of Unsecured PHI under this Section shall comply in all respects with each applicable provision of Section 13400 of Subtitle D (Privacy) of ARRA, HIPAA, and related guidance issued by the Secretary or the delegate of the Secretary from time to time.
- 3.5 **Limitations on Reporting.** For relevant reporting obligations under this Schedule, Business Associate and Covered Entity acknowledge that because the PHI is hosted in an encrypted format by Business Associate’s cloud service provider, it may not be possible for Business Associate to provide information about the identities of individuals who may be affected, or a description of the type of information that may have been subject to a Security Incident, Impermissible Use or Disclosure, or Breach.



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3.6 Subcontractors. Business Associate shall, in accordance with 45 C.F.R. Parts 164.502(e)(1)(ii) and 164.308(b)(2), if applicable, require that any Subcontractors, including its cloud service provider, that create, receive, maintain, or transmit PHI on behalf of Business Associate agree to the same restrictions, conditions, and requirements that apply to Business Associate under this Agreement.

3.7 Access to PHI. Provided that PHI is maintained in a Designated Record Set, Business Associate shall make available PHI in a Designated Record Set to Covered Entity as necessary to satisfy Covered Entity's obligations under 45 C.F.R. Part 164.524.

3.8 Amendment of PHI. Provided that PHI is maintained in a Designated Record Set, Business Associate shall make any amendments to PHI in a Designated Record Set as directed or agreed to by Covered Entity pursuant to 45 C.F.R. Part 164.526, or to take other measures as necessary to satisfy Covered Entity's obligations under 45 C.F.R. § 164.526.

3.9 Accounting of Disclosures. Business Associate, in cooperation with its cloud service provider, shall make available to Covered Entity information required to provide an accounting of disclosures in accordance with 45 C.F.R. Part 164.528 of which Business Associate is aware of.

3.10 Internal Records. Business Associate agrees to make its internal practices, books, and records, including policies and procedures regarding PHI, relating to the use and disclosure of PHI and Breach of any Unsecured PHI received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity, available to Covered Entity (or the Secretary) for the purpose of Covered Entity or the Secretary determining compliance with the Privacy Rule.

3.11 Non-Performance of Covered Entity's Obligations. Business Associate and Covered Entity acknowledge that the Service is a software as a service offering to be used by Covered Entity and, thus, Business Associate shall not be deemed to carry out any of Covered Entity's obligation(s) under Subpart E of 45 C.F.R. Part 164 by virtue of making the Service available to Covered Entity.

3.12 No Sale of PHI. Business Associate agrees to comply with the "Prohibition on Sale of Electronic Health Records or Protected Health Information," as provided in Section 13405(d) of Subtitle D (Privacy) of ARRA, and the "Conditions on Certain Contacts as Part of Health Care Operations," as provided in Section 13406 of Subtitle D (Privacy) of ARRA and related guidance issued by the Secretary from time to time.

3.13 Liability. Business Associate acknowledges that it shall be liable under the civil and criminal enforcement provisions set forth at 42 U.S.C. § 1320d-5 and 1320d-6, as amended, for failure to comply with any of the use and disclosure requirements of this BAA and any guidance issued by the Secretary from time to time with respect to such use and disclosure requirements.

4. BUSINESS ASSOCIATE PERMITTED USE

4.1 General Uses and Disclosures. Business Associate agrees to receive, create, use, or disclose PHI only in a manner that is consistent with this BAA, the Privacy Rule, or Security Rule, and only in connection with providing services to Covered Entity; provided that the use or disclosure would not violate the Privacy Rule, including 45 C.F.R. § 164.504(e), if the use or disclosure would be done by Covered Entity.

4.2 Disclosures Required By Law. Business Associate may use or disclose PHI only as Required By Law.

4.3 De-Identification of PHI. Covered Entity permits Business Associate to de-identify PHI in order to generate De-identified Data and shall do so in a manner that is consistent with the Privacy Rule and in connection with providing services to Covered Entity pursuant to Applicable Terms.

4.4 Impermissible Disclosures. Business Associate may not use or disclose PHI in a manner that would violate 45 C.F.R. Part 164, Subpart E if done by Covered Entity.

5. COVERED ENTITY OBLIGATIONS

5.1 Obligations. Covered Entity shall:

- (a) Provide Business Associate with the Notice of Privacy Practices it publishes in accordance with the Privacy Rule, and any changes or limitations to such notice under 45 C.F.R. Part 164.520, to the extent that such changes or limitations may affect Business Associate's use or disclosure of PHI.
- (b) Notify Business Associate of any restriction on the use or disclosure of PHI that Covered Entity has agreed to or is required to comply with under 45 C.F.R. Part 164.522, to the extent that such restriction may affect Business Associate's use or disclosure of PHI under this BAA.
- (c) Notify Business Associate of any changes in or revocation of permission by an individual to use or disclose PHI, if such change or revocation may affect Business Associate's permitted or required uses and disclosures of PHI under this BAA.
- (d) Be solely responsible to implement adequate Administrative, Physical, and Technical Safeguards on its networks or systems as required by 45 C.F.R. Part 164, Subpart C. Accordingly, Business Associate shall not be liable for any Breach, Security Incident and/or unauthorized disclosure of PHI resulting from Covered Entity's failure or inability to implement such safeguards, or any other failure or omission by Covered Entity.

5.2 Prohibited Requests. Covered Entity shall not request Business Associate to use or disclose PHI in any manner that would not be permissible under the Privacy and Security Rule if done by Covered Entity.

5.3 Necessary Consents. Covered Entity warrants that it has obtained any necessary authorizations, consents, and other permissions that may be required under Applicable Laws prior to utilizing the Service to process or host PHI.

6. TERM, TERMINATION

6.1 Term. This BAA shall terminate on the earlier of:

- (a) the date that either party terminates for cause as authorized under Section 6.2.
- (b) the date that all of the PHI received from Covered Entity, or created or received by Business Associate or its cloud service provider, is destroyed or returned to Covered Entity. If it is not feasible to return or destroy PHI, protections are extended in accordance with Section 6.3.

6.2 Cure. Upon either party's knowledge of material breach by the other party, the non-breaching party shall provide an opportunity for the breaching party to cure the breach or end the violation, or terminate the BAA. If the breaching party does not cure the breach or end the violation within a reasonable timeframe not to exceed 30 days from the notification of the breach, or if a material term of the BAA has been breached and a cure is not possible, the non-breaching party may terminate this BAA and the Applicable Terms, upon written notice to the other party.



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6.3 Effect of Termination. Upon termination of this BAA for any reason, Business Associate and its cloud service provider, with respect to PHI received from Covered Entity, or created, maintained, or received by Business Associate on behalf of Covered Entity, shall:

- (a) Retain only that PHI that is necessary for Business Associate or its cloud service provider to continue its proper management and administration or to carry out its legal responsibilities.
- (b) Return or destroy the remaining PHI that Business Associate still retains in any form.
- (c) Continue to use appropriate safeguards and comply with Subpart C of 45 C.F.R. Part 164 with respect to retained PHI to prevent use or disclosure of the same, other than as provided for in this Section 6, for as long as Business Associate retains the PHI.
- (d) Not use or disclose the PHI retained by Business Associate other than for the purposes for which such PHI was retained and subject to the same conditions set out at Section 3 and Section 4 as applied prior to termination.
- (e) Return or destroy any PHI retained by Business Associate when it is no longer needed by Business Associate for its proper management and administration or to carry out its legal responsibilities.

6.4 Survival. The respective rights and obligations of parties under Section 6.3 of this BAA shall survive the termination of this BAA.

7. MISCELLANEOUS

7.1 Amendment to Comply with Law. The parties agree to take such action as is necessary to amend this BAA to comply with the requirements of the Privacy Rule, the Security Rule, HIPAA, ARRA, HITECH Act, the Consolidated Appropriations Act of 2021, and any other Applicable Laws.

7.2 Interpretation. This BAA shall be interpreted in the following manner:

- (a) Any ambiguity shall be resolved in favor of a meaning that permits Covered Entity to comply with HIPAA.
- (b) Any inconsistency between the BAA's provisions and HIPAA, including all amendments, as interpreted by the HHS, a court, or another regulatory agency with authority over the Parties, shall be interpreted according to the interpretation of the HHS, the court, or the regulatory agency.
- (c) Any provision of this BAA that differs from those required by HIPAA, but is nonetheless permitted by HIPAA, shall be adhered to as stated in this BAA.

7.3 Integration. This BAA constitutes the entire agreement between the parties related to the subject matter of this BAA. This BAA supersedes all prior negotiations, discussions, representations, or proposals, whether oral or written. This BAA may not be modified unless done so in writing and signed by a duly authorized representative of both parties. If any provision of this BAA, or part thereof, is found to be invalid, the remaining provisions shall remain in effect.



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SERVICE PROVIDER ADDENDUM

1. APPLICABILITY

This Service Provider Addendum (“SPA”) to the Data Processing Terms is intended to ensure that Service Provider will establish and implement appropriate safeguards for Personal Information (as defined pursuant to CCPA) collected from or about residents of California that Service Provider may receive, create, maintain, use, or disclose in connection with the bioMérieux Solution. This SPA shall take effect on the date that Service Provider first receives, maintains, creates, uses, or discloses Personal Information.

2. DEFINITIONS

- 2.1 “Additional Terms” shall have the meaning set forth in the General Terms.
- 2.2 “Applicable Laws” shall have the meaning set forth in the General Terms.
- 2.3 “Applicable Terms” shall mean the General Terms and any applicable Additional Terms, or any other applicable underlying agreement.
- 2.4 “CCPA” shall mean the California Consumer Privacy Act of 2018, as the same may be amended (including by the California Privacy Right Act of 2020), modified or supplemented from time to time, and any successor statute thereto, and any and all rules or regulations promulgated from time to time thereunder.
- 2.5 “bioMérieux” shall have the meaning set forth in the General Terms.
- 2.6 “Customer” shall have the meaning set forth in the General Terms.
- 2.7 “General Terms” shall mean the BIOMÉRIEUX VISION SUITE General Terms and Conditions.
- 2.8 “Service Provider” shall have the meaning ascribed to it under CCPA and, for purposes of the SPA, shall refer to bioMérieux but only to the extent that bioMérieux creates, receives, maintains or transmits any Personal Information under the Applicable Terms.
- 2.9 Unless the context clearly indicates otherwise, the following terms in this SPA shall have the same meaning as ascribed to those terms under CCPA: “Business Purpose”, “Collects”, “Contractor”, “Personal Information”, “Sell” or “Sale”, and “Service Provider”.

3. SERVICE PROVIDER OBLIGATIONS

- 3.1 **Limitations on Uses and Disclosures.** Service Provider shall:
 - (a) only collect, use, retain, or disclose Personal Information for the Business Purposes.
 - (b) not collect, use, retain, disclose, sell, or otherwise make Personal Information available for Service Provider's own commercial purposes or in a way that does not comply with CCPA. If a law, court order, or validly served process requires Service Provider to disclose Personal Information for a purpose unrelated to the Business Purpose, Service Provider must first inform Customer of the legal requirement and give Customer an opportunity to object or challenge the requirement, unless the law prohibits such notice.
 - (c) limit Personal Information collection, use, retention, and disclosure to activities reasonably necessary and proportionate to achieve the Business Purposes or another compatible operational purpose.
- 3.2 **Customer Instructions.** Service Provider shall promptly comply with any Customer request or instruction requiring Service Provider to provide, amend, transfer, or delete Personal Information, or to stop, mitigate, or remedy any unauthorized processing.
- 3.3 **Notice at Collection.** If the Business Purposes require the collection of Personal Information from individuals on the Customer's behalf, Service Provider shall provide a CCPA-compliant notice at collection.
- 3.4 **Cooperation.** Service Provider shall reasonably cooperate with and assist Customer in meeting its CCPA compliance obligations and responding to CCPA-related inquiries, including responding to verifiable requests, taking into account the nature of Service Provider's processing and the information available to Service Provider.
- 3.5 **Notices or Complaints.** Service Provider shall notify Customer immediately if it receives any complaint, notice, or communication that directly or indirectly relates either party's compliance with CCPA in relation to any Business Purpose.
- 3.6 **Personal Information Retention.** If Service Provider is required by any Applicable Laws to retain Personal Information upon termination of the Applicable Terms, Service Provider shall securely isolate and protect such Personal Information from any further processing, except to the required by Applicable Laws.

4. SUBCONTRACTORS

- 4.1 **Use of Contractors.** Service Provider may use a Contractor to provide fulfill the Business Purposes, but only if the Contractor qualifies as a service provider under CCPA. Service Provider shall not make any disclosures to the Contractor that CCPA would treat as a sale.
- 4.2 **Liability.** Service Provider remains fully liable to Customer for each Contractor's performance of its obligations to Service Provider pertaining to the Business Purposes.