

CLINICAL REFERENCE LABORATORY TERMS & CONDITIONS

In consideration of the terms, conditions, and covenants set forth, and intending to be legally bound hereby, The Children's Hospital of Philadelphia ("CHOP") and the customer placing the Order ("Customer") (CHOP and Customer are each referred to herein as a "Party" and collectively as the "Parties") hereby agree as follows, effective as of the date these Terms and Conditions are received by CHOP electronically with an Order ("Effective Date"):

Services not reflected in an Order signed by a licensed physician will not be provided.

- 1. **PURPOSE:** CHOP operates a highly specialized children's hospital and pediatric health system and also engages in advanced and, in some cases unique, programs of pediatric clinical care, education and research. Among those programs is a highly sophisticated clinical laboratory (the "Clinical Laboratory"), which offers services of a nature and quality that is not generally available from commercial sources and that are available from CHOP because of its unusual clinical, educational and research capabilities, including genetic laboratory services.
- 2. COMPLETE AGREEMENT: These Terms & Conditions ("Terms and Conditions") and the applicable test requisition form(s) (each an "Order" and all Orders with the Terms and Conditions, collectively, this "Agreement") shall constitute the complete and exclusive statement of the agreement between CHOP and Customer with respect to the requested services CHOP is to perform for Customer hereunder pursuant to each Order ("Services"). Each Order submitted by Customer constitutes Customer's acceptance of this Agreement. This Agreement may be modified only pursuant to a written instrument signed by authorized representatives of both Parties. The invalidity in whole or in part of any provision of this Agreement shall not affect the validity of other provisions. To the extent that Customer's terms and conditions contained in a purchase order or other document, whether paper or electronic with or without click through technology, provided by Customer to CHOP, if any, conflict with this Agreement or add additional terms, this Agreement shall control and such different or additional terms are hereby rejected. Either Party's failure to insist upon the performance of any term of this Agreement shall not be construed as a waiver of that Party's present or future right to such performance and each Party's obligations in respect thereto shall continue in full force and effect. The rule of contract law which states that any ambiguity or contradictions between the terms of an agreement will be resolved against the drafter of such agreement is hereby waived and shall not apply to the interpretation of this Agreement. The headings in this Agreement have been inserted solely for convenient reference and shall be of no legal effect.
- 3. CHOP SERVICES: Without limiting the generality of the foregoing, and provided Customer has fully paid all prior invoiced amounts at the time of the receipt for a request for Services, CHOP agrees specifically as follows: (a) Upon receipt in the Clinical Laboratory (not the CHOP loading dock) of a properly completed Order accompanied by properly labelled patient specimens from Customer ("Specimens"), of a type and quantity sufficient to perform the testing requested in the Order and any related information from Customer necessary to perform Services, CHOP will provide testing and results reporting in accordance with CHOP's established procedures for testing of the types specified in the Order; (b) Upon completion of testing and release of results, CHOP shall maintain the Specimens and all related material and data generated from the testing (the "Data") for, at minimum, the period required by the Clinical Laboratory Improvement Amendments of 1988 and the regulations promulgated thereunder (collectively, "CLIA") all of which shall remain the property of CHOP and CHOP shall have the right to use the Data generated from the testing and the Specimens that remain following the testing for all purposes except as prohibited by applicable law; (c) CHOP makes no representation that its testing service procedures and methods satisfy any U.S. Food and Drug Administration, U.S. Department of Health and Human Services, international (IHC), or state law requirements for drug or device studies, clinical trials or research involving human subjects, and the parties agree that through its performance of the Services, CHOP is not "engaged" in research involving human subjects within the meaning of the Federal Policy for the Protection of Human Subjects (the "Common Rule") and the guidance issued thereunder; (d) CHOP represents that it has, and will continue to have for the term of this Agreement (1) appropriate licensure as required by the Commonwealth of Pennsylvania to perform the Services, and (2) such federal certification as is required under CLIA to perform the Services; and (e) CHOP reserves the right to modify its testing protocols used for the Specimens at any time.
- 4. CUSTOMER RESPONSIBILITIES: Customer will properly collect the Specimens and request Services from CHOP from time to time through use of the test requisition form (the Order) supplied by CHOP. Customer will be responsible for properly packaging, shipping, and delivering the Specimens that are necessary to perform the Services requested in each Order. Customer is responsible tracking their shipment of the Specimens, for providing specimen tracking information to CHOP as indicated on the requisition form and posted to www.chop.edu/labs, as well as confirming in



writing with the Clinical Laboratory that the Clinical Laboratory is in receipt of the Specimen. Customer understands and agrees that (a) the science and technology related to the Services are constantly evolving, and that the test results and Data are based on CHOP's best interpretation of the testing results as of the date such results and data are interpreted, and that after providing Customer the results and Data CHOP has no ongoing obligation to update, revisit, or later evaluate such results or Data; (b) the test results and data contained therein are not guaranteed to be error free; (c) Customer is solely responsible for any clinical diagnoses or treatment decisions related to use of the test results and Data as well as for any actions that it or its personnel take with regards thereto including use of such data for research or other purposes; (d) Customer agrees that it shall in all instances obtain and maintain all necessary and legally required informed consents, authorizations, approvals, and permissions required by applicable federal and state law for CHOP to perform the Services, including but not limited to any consents required for the performance of genetic testing under state law in the state in which Customer and the patient are located, and that Customer's transfer of the Specimens to CHOP is performed in compliance with all applicable laws, including to the extent applicable, laws governing the crossborder transfers of personal data and human tissue; and (e) Customer shall ensure that the ordering physician whose name appears on the Order holds all licenses required by applicable law for the ordering of the Services, completes all documentation required by applicable law, and maintains documentation necessary to make determinations regarding the medical necessity of all laboratory tests ordered under this Agreement. Notwithstanding anything to the contrary contained in this Agreement, Customer shall bear the risk of loss of, or damage to, all Specimens until they are accepted by the Clinical Laboratory as set forth in Section 3 of this Agreement. If applicable, if the Parties mutually agree in writing that CHOP will return the Specimen to Customer, Customer shall bear the risk of loss, or damage to, all Specimens upon release by Clinical Laboratory.

- 5. FEES: (a) Upon completion of each test or set of tests as requested by Customer, or at other intervals agreed in the Order, CHOP will invoice Customer at the fee rates set forth in the fee schedule that is in effect on the date of the Order and; (b) The fees established in this Agreement, including the Order, cover the CHOP testing and results reporting Services requested. If Customer subsequently requests any other services other than as specifically described in an Order, a new Order must be submitted to CHOP as a precondition of completing such additional services and additional fees will apply. Customer agrees to reimburse CHOP for its reasonable out-of-pocket expenses in the event of any Customer or third party audits or inspections, reviews, subpoenas, depositions, trial or other litigation requests or appearances, and any other requests by Customer or any third party in connection with the Services provided by CHOP under this Agreement, provided the foregoing will not apply where any such request is based on allegations of CHOP's failure to properly perform the Services under this Agreement; (c) Customer agrees to pay CHOP within thirty (30) days from the date of any invoice for its Services; CHOP reserves the right to refuse further Services if payment on any invoice to Customer is more than thirty (30) days overdue and until all undisputed outstanding balances are paid in full, regardless of whether Customer submits a request or provides a specimen to CHOP; (d) All payments shall be mailed to: The Children's Hospital of Philadelphia, Lock Box #780310, PO Box 780310, Philadelphia, PA 19178-0310. (e) The Department of Pathology and Laboratory Medicine at CHOP does not bill third party insurances or Medicaid for client testing and it is explicitly understood by Customer that CHOP shall invoice the Customer and does not provide any billing services on behalf of patients or third parties. Notwithstanding the above, rates may be increased by CHOP to be effective the first day of each fiscal year (July 1). Payments not received within the time specified will accrue interest at the rate of twelve percent (12%) per annum.
- 6. FAIR MARKET VALUE; NO INDUCEMENTS: Each Party acknowledges that this Agreement is non-exclusive and that neither Party is restricted from referring any service to, or otherwise generating any business for, or contracting with, any other entity of its choosing for the same, similar or any other services. The Parties further acknowledge that the compensation provided hereunder represents the fair market value of the Services to be performed, has been negotiated in an arm's-length transaction, and has not been determined in any manner that takes into account the value or volume of any business or referrals generated between the parties and is not intended to induce or pay for referrals from one Party to the other.
- 7. HAZARDOUS AND REGULATED MATERIAL: Customer shall package, label, transport and ship hazardous materials, items containing hazardous materials and any other regulated materials, including all Specimens, in accordance with all applicable federal, state, and local laws, rules, ordinances and regulations, and in the case of transportation by air, the International Air Transport Association Dangerous Goods Regulations, and Customer shall furnish to CHOP any appropriate documentation showing compliance with same. All materials sent to CHOP shall be free of any agents or toxins prohibited by sections 351A(b) and (c) of the Public Health Services Act or 42 C.F.R. Part 73, as in effect on the date Specimens are sent. Prior to each shipment of any hazardous or regulated materials, Customer

shall notify CHOP of the nature of such shipment by such means of communication as will allow for the proper preparation for acceptance of the delivery and shall identify same on all shipping documents. Customer shall be solely responsible for notifying carriers and other handlers of any risks inherent in any such shipments.

- 8. TERMINATION: (a) CHOP may terminate this Agreement at any time, in whole or in part, by written notice to Customer. Either Party may terminate this Agreement at any time, with or without cause, upon thirty (30) days prior written notice to the other Party, or immediately if this Agreement is deemed in good faith by one Party to be in violation of applicable law or regulations or any third party legal rights, and upon consultation of the Parties the notifying Party determines in its sole discretion that the Agreement cannot be modified to avoid any such violation. Termination of this Agreement shall not affect the rights and obligations of the Parties accrued prior to termination hereof. (b) In the event of termination, CHOP shall return all testing results for which payment has been received. Upon termination, Customer shall pay all amounts owing to CHOP for Services rendered prior to the effective date of termination of the Agreement in accordance with this this Agreement, including the Order.
- **9. FORCE MAJEURE:** CHOP shall not be liable to Customer for failure to perform hereunder to the extent that CHOP's failure to perform arises out of causes beyond the control and without the fault or negligence of CHOP. Such causes include acts of God, acts of Customer, acts of a government in either its sovereign or contractual capacity, fires, floods, epidemics, pandemics, quarantine restrictions, supply or material shortages, strikes or freight embargoes.
- 10. INDEPENDENT CONTRACTOR: It is understood that CHOP and Customer are independent contractors engaged in the operation of their own respective businesses. Neither Party is, or is to be considered as, the agent, representative, partner or employee of the other Party for any purposes whatsoever and neither Party shall make any statement to the contrary. No employee of CHOP may be listed by Customer as an investigator or co-investigator under this Agreement on any research protocol conducted by Customer or in any grant, research contract or publication without the express written approval of CHOP.
- 11. INDEMNIFICATION: Customer shall defend, indemnify and hold harmless CHOP, its officers, employees, trustees, medical and research staffs, agents and representatives (the "CHOP Indemnitees") from and against any and all claims, demands, damages, liabilities, expenses, losses of every nature and kind, including but not limited to attorney's fees and costs, (collectively, "Claims") sustained or alleged to have been sustained in connection with or arising out of the Services, the Agreement, or the performance hereunder of CHOP, its agents, employees, subcontractors and consultants, even in the event CHOP is alleged or found to be partially negligent. However, Customer shall not be obligated to so indemnify CHOP in the event CHOP is proven to be solely negligent.
- 12. CONFIDENTIAL INFORMATION: (a) Any non-medical information provided by Customer to CHOP under this Agreement which is marked as confidential will be kept confidential, and CHOP will not disclose such information to third parties (except for disclosures required by law, information that was already in its possession, information that becomes publicly available through no fault of CHOP, or information which is lawfully disclosed to a CHOP by a third party which does not have a confidentiality obligation to Customer) without the express written approval of Customer, (b) While performing their respective duties and obligations under this Agreement, CHOP and Customer each shall, and shall cause their respective officers, directors, employees, physicians, residents, agents, and contractors to, comply with all laws and regulations that apply to the confidentiality and security of patient information, including the federal Health Insurance Portability and Accountability Act of 1996 as amended HIPAA"), 42 U.S.C. § 1171 et seq. and regulations issued under it, which are now in force or which may subsequently be in force, (c) Customer shall treat as confidential all non-public information disclosed by CHOP in connection with this Agreement, including but not limited to written or oral communications, personal data, plans, specifications, and other data (collectively, "Confidential Information"). The terms and conditions of this Agreement shall also be deemed Confidential Information. Customer shall not disclose Confidential Information to any third party except as CHOP authorizes, and shall only disclose it to those within Customer's organization who need to use it in performance of this Agreement. Upon completion or termination of this Agreement, Customer shall return or destroy all such Confidential Information (except for this Agreement), or otherwise dispose of it as CHOP may approve.
- 13. USE OF NAME OR MARKS AND INTELLECTUAL PROPERTY: Neither Party may use the other's name(s), logos trademark(s), service mark(s) or any other identifying terms or marks, images, likenesses or quotes of any employee of the other in any communication or public disclosure in any medium or in any form of publicity in connection with or alluding to performance under this Agreement, or for any other purpose except as specifically authorized in writing in advance by the other Party in each instance of use. In the case of CHOP, such approval must be



obtained in advance in writing from CHOP's Chief Marketing Officer. All CHOP Intellectual Property (as hereinafter defined) is and shall remain the sole and exclusive property of CHOP and CHOP grants Customer no express or implied intellectual property rights in any CHOP Intellectual Property. "CHOP Intellectual Property" means (i) any invention (whether or not patentable), know-how, works of authorship, technology, software, techniques, developments, ideas, concepts, discoveries designs, algorithms, models, formulations, improvements, protocols, data and proprietary information, and (ii) any patents, copyrights, trademarks, service marks, trade secrets or other intellectual property rights in or associated with the foregoing, in each case (i) or (ii) that was owned or controlled by CHOP prior to, or created, invented or generated by CHOP during or after, the term of this Agreement. The provisions of this Paragraph 13 shall survive the expiration or termination of this Agreement.

- 14. CONFLICTS AND ETHICAL STANDARDS OF CONDUCT: Customer affirms that, to the best of Customer's knowledge, there exist no conflicts of interests between Customer and CHOP or its employees. Customer hereby represents that neither Customer nor any of its employees, representatives or agents has solicited, received, offered or given any gifts, gratuities or anything of more than nominal value to any member of the CHOP community, nor participated in any other unethical conduct in connection with this Agreement. If, at any time, CHOP determines that Customer is in violation of any representation under this Paragraph, CHOP may cancel this Agreement upon written notice to Customer, and CHOP shall have no further obligation to Customer.
- 15. EQUAL OPPORTUNITY EMPLOYER: CHOP is an Equal Opportunity Employer. If applicable, CHOP and Customer shall abide by the requirements of 41 CFR 60-300.5(a). This regulation prohibits discrimination against qualified protected veterans, and requires affirmative action by covered prime contractors and Customers to employ and advance in employment qualified protected veterans. If applicable, CHOP and Customer shall abide by the requirements of 41 CFR 60-741.5(a). This regulation prohibits discrimination against qualified individuals on the basis of disability, and requires affirmative action by covered prime contractors and Customers to employ and advance in employment qualified individuals with disabilities Customer warrants that it will not discriminate in the performance of this Agreement or employment against any person because of age, race, color, religion, national or ethnic origin, sex, sexual orientation, gender identity, marital status, veteran status, or disability. Customer also warrants that it will comply with all applicable executive orders, and federal, state, and local laws, regulations, and rules, relating to nondiscrimination, equal employment opportunity, and affirmative action.
- **16. APPLICABLE LAW/VENUE:** All disputes regarding the construction, interpretation and the parties' obligations under this Agreement shall be governed by the laws of the Commonwealth of Pennsylvania, notwithstanding any of that state's laws to the contrary. The exclusive venue and jurisdiction for the resolution of any such disputes shall be Philadelphia, Pennsylvania.
- 17. COMPLIANCE WITH LAWS AND POLICIES: Without limiting the provisions of Paragraph 15 below (a) CHOP represents that it complies with all applicable federal, state and local statutes laws and regulations, including standards promulgated by the Joint Commission, relating to the Services and CHOP will perform its obligations under this Agreement in accordance with such laws, (b) Customer represents that it complies with all applicable federal, state and local laws and regulations applicable to this Agreement, including without limitation its obligations to obtain any consent, informed consent, or authorizations appropriate to activities it will be conducting and care it will be rendering relating to the Specimens being tested pursuant to this Agreement and the Services to be performed by CHOP.
- 18. ASSIGNMENTS AND SUBCONTRACTING: This Agreement is not assignable in whole or in part by either party without the prior written consent of the other; provided, however, CHOP may assign all or part of the obligations under this Agreement to one of its affiliates. This Agreement shall be binding upon, and shall inure to the benefit of, the parties, and their respective successors and permitted assigns.
- 19. BOOKS AND RECORDS ACCESS: To the extent this Agreement is subject to Section 1861(v)(I)(I) of the Social Security Act, CHOP agrees to make available upon written request of the Secretary of Health and Human Services or the United States Comptroller General or any of their duly authorized representatives, this Agreement, and any books, documents, and records of CHOP that are necessary to certify the nature and extent of costs incurred by Customer under this Agreement until the expiration of four (4) years after the last date Services are performed under this Agreement. CHOP agrees that if CHOP carries out any of the duties or obligations contemplated by this Agreement through a contract or subcontract with a value of Ten Thousand Dollars (\$10,000) or more over a twelve (12) month period, such



contract or subcontract shall require this same access to the books, documents, and records of such contractor or subcontractor.

- 20. HIPAA COMPLIANCE: With respect to the performance of their respective duties and obligations under this Agreement and related protected health information, CHOP and Customer each shall, and shall cause their respective officers, directors, employees, physicians, residents, agents, and contractors to, comply with all laws and regulations that apply to the confidentiality and security of patient information, including, without limitation, the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act (Title XIII of the American Recovery and Reinvestment Act of 2009, Public Law No. 111-50), and the regulations promulgated thereunder, including but not limited to 45 C.F.R. Part 160 and 45 C.F.R. Part 164, as from time to time amended (collectively, "HIPAA"). The Parties agree to execute additional mutually agreed upon documents as required under HIPAA to assure the safeguarding of protected health information. In the event such documentation is not agreed upon and executed, either party may terminate this Agreement.
- 21. SANCTIONED PERSONS: CHOP and Customer each hereby affirms and attests that neither it nor any of its affiliates, subcontractors nor any of its corporate officers and directors nor any employees or contractor rendering services under this Agreement (collectively a "CHOP Person" or "Customer Person") have been debarred, suspended or excluded from participation in Medicare, Medicaid, CHAMPUS/TRICARE or any other federal or state health care, procurement or reimbursement program and have not been convicted of any crimes under any federal or state healthcare program or involving fraud or misrepresentation or been subjected to civil monetary penalties related to Medicare, Medicaid, CHAMPUS/TRICARE or any other federal or state health care procurement or reimbursement program. CHOP and Customer will each advise the other immediately upon any CHOP's or Customer's, as the case may be, receipt of a notice of exclusion from participation in Medicare, Medicaid, CHAMPUS/TRICARE, or any other federal or state health care program and/or of an investigation that could result in such a notice.
- 22. THIRD PARTIES: Nothing contained in this Agreement shall be construed to create any rights or benefits in a third party, including Customer patients whose Specimens are being tested by CHOP under this Agreement.
- 23. DISCLAIMER OF WARRANTIES; LIMITATION OF LIABILITY: (a) TO THE MAXIMUM EXTENT ALLOWED BY APPLICABLE LAW, CHOP DOES NOT WARRANT AND MAKES NO REPRESENTATIONS OF ANY KIND, EITHER EXPRESS OR IMPLIED, WITH RESPECT TO ANY PARTICULAR RESULT FROM THE TESTING OF A SPECIMEN OR USE BY CUSTOMER OF ANY TEST RESULTS PROVIDED UNDER THIS AGREEMENT, (b) WITHOUT LIMITING ANY OTHER SUBSECTION OF THIS CLAUSE 19, CHOP SHALL HAVE NO LIABILITY FOR ANY LOSS, DAMAGE, COST OR EXPENSE ARISING OUT OF CUSTOMER'S USE OF THE TEST RESULTS PROVIDED UNDER THIS AGREEMENT, (c) IN ANY DISPUTE ARISING FROM OR RELATED TO THIS AGREEMENT, NEITHER PARTY NOR ITS RESPECTIVE OFFICERS, TRUSTEES, DIRECTORS, EMPLOYEES, AGENTS OR AFFILIATES SHALL BE LIABLE FOR ANY SPECIAL, EXEMPLARY, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, WHETHER IN CONTRACT, WARRANTY, TORT, STRICT LIABILITY OR OTHERWISE. THESE LIMITATIONS SHALL APPLY EVEN IF A PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF RECOVERING THESE DAMAGES AND NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY AND SHALL SURVIVE TERMINATION OF THIS AGREEMENT. THESE LIMITATIONS SHALL NOT APPLY TO OR LIMIT CLAIMS FOR FRAUD, WILLFUL MISCONDUCT OR INDEMNITY OR CONTRIBUTION BETWEEN THE PARTIES FOR DAMAGES CLAIMED BY THIRD PARTIES, (d) TO THE MAXIMUM EXTENT ALLOWED BY APPLICABLE LAW, CHOP'SENTIRE LIABILITY UNDER THIS AGREEMENT SHALL NOT EXCEED THE VALUE OF FEES PAID, OR TO BE PAID, TO CHOP FOR SERVICES RENDERED UNDER THIS AGREEMENT.
- 24. RELEASE OF CLAIMS: Customer on behalf of itself and its present and former officers, directors, employees, agents, attorneys and representatives, successors and assigns ("Customer Releasers") hereby knowingly and voluntarily releases, waives, acquits and forever discharges, to the fullest extent permitted by law, the CHOP Indemnitees from any and all Claims, in any jurisdiction, known or unknown, suspected or claimed, fixed or contingent, specifically mentioned herein or not, that Customer has or may have or claim to have now, or that may hereafter arise, related to the Agreement or the Specimens.
- **25. SURVIVAL:** This Paragraph and Paragraphs 2, 5, 6, 8, 10, 11, 12, 13, 16, 19, 20, 22, 23, and 24 hereunder shall survive the termination of this Agreement for any reason.