

## BIORELIANCE® TERMS AND CONDITIONS FOR TESTING SERVICES

Client shall be bound by these Terms and Conditions for Testing Services ("Terms") upon Client's submission to BioReliance of a purchase order or signed quotation for a Study (as defined below). These Terms, together with the Protocol (as defined below), and any applicable Quality Agreement, shall constitute the Agreement.

**1. STANDARD OF PERFORMANCE.** BioReliance Corporation ("BioReliance") will perform all studies (each, a "Study") using due care in accordance with (a) the study protocol ("Protocol"), (b) generally prevailing industry standards, and (c) Good Laboratory Practices and/or other laws and regulations ("Regulations") applicable to the Study being performed, as amended from time to time. BioReliance will make commercially reasonable efforts to start and complete all Studies in a timely fashion and will notify the Client if BioReliance determines that there are likely to be substantial changes in the proposed start or completion dates of a Study.

**2. FEES AND PAYMENT.** Client shall make payment in full for all charges specified, with no right to set-off or reduction, to BioReliance in accordance with the quotation issued to Client for the relevant Study. Unless otherwise agreed in writing by BioReliance, payment terms shall be net thirty (30) days from date of invoice. If BioReliance does not receive payment by the due date, an interest charge may be added at the rate of 1.5% per month (18% per year) or the maximum legal rate, whichever is less, to unpaid invoices from the due date thereof. ANY DISCOUNTS FOR PERFORMANCE OF A STUDY MUST BE EXPRESSLY OFFERED TO CLIENT BY BIORELIANCE IN WRITING. UNDER NO CIRCUMSTANCES WILL BIORELIANCE HONOR ANY DISCOUNTS AUTOMATICALLY TAKEN BY CLIENT FOR ANY REASON, EVEN IF CLIENT HAS INFORMED BIORELIANCE IN WRITING OF THE POSSIBILITY OF SUCH DISCOUNT. BIORELIANCE MAY CHARGE THE INTEREST RATES SET FORTH ABOVE FOR ANY UNPAID AMOUNTS OWED TO BIORELIANCE AS A RESULT OF SUCH UNAUTHORIZED DISCOUNT.

**3. STUDY MATERIALS; DATA AND INFORMATION.** Client will provide BioReliance with sufficient amounts of all compounds, materials, or other substances ("Test Article") with which to perform the Study, as well as all sufficient and comprehensive data and information, including but not limited to material safety and data sheets, concerning the stability of the Test Article, storage and safety requirements (collectively, "Data and Information"). In the event that the information supplied regarding the Test Article on the Data and Information form is missing or in error, the Client agrees to bear all reasonable costs related to such error or missing information, including but not limited to, assay repeats, project management time, and reasonably related costs and expenses. In the event Client becomes aware of any additions, deletions, or modifications to any such requirements during the course of the Study or any retention of any samples of Test Article, it shall immediately notify BioReliance thereof. These additions, deletions and/or modifications may result in an amended quote or statement of work for the project, at BioReliance's sole discretion, and may result in additional charges and expenses to be paid by Client for work and services that are required outside of standard time lines and/or requirements stated in the Study, quotation or Protocol. The Client shall include with the shipped study material the BioReliance submission form with the appropriate disposition box selected instructing BioReliance to either dispose of the Test Article or return it after thirty (30) days. If the disposition box is not checked, BioReliance will dispose of the Test Article. Where regulatory approval is required for BioReliance to work with the Material, BioReliance's obligation to begin performance of the services shall be subject to the receipt of all such approvals. The Client (or, to the extent otherwise agreed in writing between BioReliance and the Client, BioReliance) shall use all commercially reasonable endeavors to ensure that BioReliance receives all such approvals in a timely manner, consistent with any time estimates provided by BioReliance, by diligently applying for, and pursuing receipt of such approvals. Each of BioReliance and the Client will endeavor to provide its reasonable assistance to the other party in such other party's foregoing efforts; provided that the Client shall reimburse BioReliance for all reasonable out-of-pocket costs and expenses incurred by BioReliance in providing such assistance. If there is any delay in the obtaining of any such approvals, then any estimates provided by BioReliance shall be deemed extended by a period equal to the duration of such delay. If such approvals are not, or cannot be, obtained, then the services may be terminated. If BioReliance has agreed to undertake the procurement of any custom or non-standard materials from a third party in connection

with the performance of the services, then BioReliance's obligation to procure such materials shall be subject to BioReliance's reaching agreement with such third party on terms and conditions of such procurement which are satisfactory to BioReliance in BioReliance's sole discretion. BioReliance shall not have any obligation to procure any such custom or non-standard materials if such an agreement cannot be reached with such third party. Risk of loss or damage to the material shall remain with the Client. In the event of any loss of, or damage to, the material required for the services, or if additional material is required to enable BioReliance to repeat all or any part of the services, then BioReliance shall carry out the work necessary to perform the services or to repeat the services.

**4. CHANGES.** Client shall have the right to request reasonable changes in or modifications ("Changes") to a Client-specific Protocol of a Study which BioReliance has agreed to conduct and which has not been completed. All such Changes in a Client-Specific Protocol shall be in writing and shall be signed by authorized representatives of BioReliance and Client. If such Changes result in an increase in the cost of the Study, the fee shall be adjusted commensurate with such increase. If such Changes affect the projected completion date of the study, the completion and report due dates shall be adjusted commensurate with such affect.

**5. DATA.** Client shall be the exclusive owner of and shall have title to all documentation, records, raw data, specimens or other work product ("Data") generated during the performance of the Study. Client shall not own or have title to any BioReliance protocols or standard operating procedures ("SOPs"). Unless otherwise agreed to by the parties, BioReliance shall store and maintain all Data in accordance with the Regulations upon completion of the Study for a period of three (3) years. After said three (3) year period, or such shorter period as may be agreed to or as specified in the Regulations, BioReliance shall notify Client regarding the return, disposal or continued storage of all Data. In the event Client elects to have the Data returned or disposed of, BioReliance shall do so at Client's expense. For returns, Client may specify the address to receive the Data if different than its business offices. In the event Client elects to continue storing Data at BioReliance, BioReliance shall charge a fee for such storage in accordance to the price list then in effect for such services. In the event no response is received from Client within thirty (30) days of the notice letter, BioReliance will dispose of the Data at Client's expense. All such services for return, disposal or storage shall be in accordance with all applicable Regulations.

**6. CONFIDENTIALITY.** During performance of the Studies and for ten (10) years thereafter, BioReliance will treat all Data and all information regarding such Data as proprietary and confidential and will not knowingly disclose the same to any person other than Client or its designated representatives.

Notwithstanding any other provisions, BioReliance shall have no liability or obligation to the Client for nor be in any way restricted in, its disclosure of or use of any Data which:

- a) is already lawfully known to BioReliance; or
- b) is or becomes publicly known by any means whatsoever, through no wrongful act of BioReliance; or
- c) is received from a third party without breach of this Agreement; or
- d) is disclosed pursuant to an enforceable order of a court of competent jurisdiction; or
- e) is independently developed by or for BioReliance.

Except as required for regulatory submissions, Client will treat any BioReliance confidential information, including but not limited to protocols, SOPs, and the like, in accordance with the above.

**7. REPORTS.** BioReliance shall deliver a report of findings for each study performed. An estimated delivery date for the report shall be mutually agreed upon and specified in the Protocol. If the Client requests a draft report, the Client shall have thirty (30) days from receipt of the draft report to review the report and provide comments to BioReliance. Within thirty (30) days of receipt of any Client comments, BioReliance will provide Client with the final report. If no

comments are received from Client within thirty (30) days following delivery of the draft report, the draft report shall become the final report, a copy of which shall be delivered to the Client.

For BioReliance® Genetic Toxicology and Mammalian Toxicology Services:

If the Client requests a draft report, the Client shall have ninety (90) days for Genetic Toxicology reports and one hundred eighty (180) days for Mammalian Toxicology reports from receipt of the respective draft report, to review the report and provide comments to BioReliance.

**8. FACILITY VISITS.** Upon reasonable advance notice, BioReliance will permit Client representatives to visit BioReliance's facilities during normal working hours and with reasonable frequency, to observe Study progress, discuss the Study with appropriate officials of BioReliance, and inspect and copy records and Data relevant to the Study. Facility visits shall also be permitted during the Data retention period described in Section 5 above. During facility visits, Client may inspect, but shall not be permitted to copy or remove, in whole or in part, any of BioReliance's SOPs. While on BioReliance's premises, Client shall adhere to any and all safety, security, and confidentiality measures required by BioReliance.

**9. USE OF NAMES.** Client shall not use BioReliance's name or the names of BioReliance's employees in any advertising or sales promotional material or in any publication without prior written consent of BioReliance. BioReliance will not use Client's name or the names of Client's employees in any advertising or sales promotional material or in any publication without prior written consent of Client. Notwithstanding the above, Client shall be permitted to use BioReliance's name in any regulatory submission associated with the Project without prior written consent of BioReliance, and BioReliance shall be permitted to use Client's name to the extent necessary to comply with regulatory requirements without prior written consent of Client.

**10. INVENTIONS AND PATENTS.** Client shall become the exclusive owner of and BioReliance hereby assigns to Client all concepts, inventions, improvements, designs, programs, formulas, know-how, methods, processes and writings, whether or not copyrightable or patentable, relating exclusively to the Test Article and discovered exclusively as a result of performing Client's Study (collectively, the "Inventions"). If requested by Client, BioReliance shall, at Client's expense, do all things reasonably necessary to obtain patents or copyrights on any Inventions discovered exclusively as a result of performing Client's Study to the extent the same may be patented or copyrighted.

Notwithstanding the foregoing, "Inventions" shall not include, and BioReliance is and shall continue to be the sole owner of, all concepts, inventions, improvements, designs, programs, formulas, know-how, methods, processes, and writings utilized or developed in conducting the Project to the extent relating solely and generally to the business, processes, practices, or services performed by BioReliance for its customers.

**11. CLIENT'S WARRANTY.** Client represents and warrants that it will comply with all applicable laws and regulations governing use of Test Articles and any products related thereto, and agrees to use Test Articles and any products related thereto solely for the purposes set forth in, and in accordance with, any approved uses therefor. Client represents and warrants that it owns or possesses, has access to, or is licensed under all patents, patent applications, inventions, improvements, trademarks, trade names, copyrights, licenses, information, proprietary rights, processes and know-how necessary for the Test Article, and the performance of the Study will not result in any infringement, misappropriation, violation of any agreement, or conversion of or conflict with the rights of third parties. Client has not received, nor has any knowledge of, any conflict with the asserted rights of other individuals or entities with respect to any intellectual property rights used or to be used in connection with the Test Article. Client represents and warrants that it is sufficiently self-insured or possesses sufficient insurance coverage against any liability arising under this Agreement.

**12. LIMITED WARRANTY; REMEDY; DAMAGES.** The undertaking of BioReliance to perform the Study is a contract for services only. The sole warranty with respect to its services is that it will perform the Study with due care in accordance with the Protocol, generally prevailing industry standards, and the Regulations. Any claim by the Client for a breach of such warranty shall be made in writing to BioReliance on or before the first

anniversary of the date that the final report is delivered to the Client. The sole remedy of the Client for breach of such warranty shall be to require BioReliance to re-perform the Study (or such portions thereof as may reasonably be required to be re-performed), and, in such event BioReliance shall diligently pursue the re-performance of the Study or portions thereof until completion. THE WARRANTY SET FORTH IN THIS PARAGRAPH IS IN LIEU OF ANY AND ALL OTHER WARRANTIES RELATING TO THE SERVICES TO BE PERFORMED, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. UNDER NO CIRCUMSTANCES SHALL BIORELIANCE BE LIABLE TO THE CLIENT OR ANY THIRD PARTY CLAIMING BY OR THROUGH THE CLIENT FOR ANY LOST PROFITS, INCIDENTAL, INDIRECT, CONSEQUENTIAL, SPECIAL, OR OTHER DAMAGES. BIORELIANCE'S LIABILITY TO THE CLIENT FOR THE BREACH OF ANY TERMS AND CONDITIONS OF THE PROTOCOL OR THIS AGREEMENT (OTHER THAN ANY BREACH OF THE WARRANTY, WHICH SHALL BE GOVERNED BY THE EXCLUSIVE REMEDY CONTAINED IN THIS PARAGRAPH) SHALL BE LIMITED TO DIRECT DAMAGES IN AN AMOUNT NOT TO EXCEED THE FEE PAID OR TO BE PAID BY THE CLIENT TO BIORELIANCE IN CONNECTION WITH THE STUDY.

**13. INDEMNIFICATION; INSURANCE.** Except where proximately caused by the gross negligence or willful misconduct of BioReliance, the Client shall indemnify, defend and hold harmless BioReliance, its parents, subsidiaries, and affiliates and their respective officers, directors, employees, and agents from and against any and all expenses (including, but not limited to, reasonable attorney's fees), damages, judgments, and losses incurred or suffered by any such indemnified party as a result of or in connection with any claim, demand, or cause of action asserted or brought by a third party (including, but not limited to, officers, employees, and agents of the Client) for (i) physical injury to or death of persons or physical damage to property arising out of or based upon the manufacture, sale, or use of any quantity of the Test Article, or any derivative thereof or product related thereto, by or on behalf of the Client, whether such manufacture, sale, or use took place prior to conclusion of the Study or thereafter and whether or not such manufacture, sale, or use took place in reliance, in whole or in part, on the Study or any portion thereof, or (ii) physical injury to or death of persons or physical damage to property arising out of BioReliance's use of any quantity of the Test Article in accordance with the Protocol, Regulations, and/or other written or verbal instructions issued by Client; or (iii) infringement, unlawful disclosure or misappropriation of copyright, patent, trade secret or other intellectual property by reason of the performance of the Study on the Test Article. Client shall maintain adequate commercial general liability and product liability insurance in such amounts and with such scope of coverage as is customary in the life sciences industry with regard to the manufacture and sale of the products and deliverables hereunder.

**14. NO SOLICITATION.** During the term of this Agreement and for a period of one (1) year from the date the final report is delivered to the Client, the Client shall not directly solicit or recruit for employment, without prior written approval of BioReliance, any personnel employed by BioReliance who has in any manner been associated with the Project. The foregoing restriction shall not apply in the case of such employee being interviewed, offered employment, and/or hired following that employee's response to a publicly posted position of the Client.

**15. FORCE MAJEURE.** It is mutually understood and agreed that BioReliance shall not be responsible for failure or delay in performance of its obligations under or in connection with this Agreement due to causes beyond its reasonable control, including but not limited to, acts of God, governmental actions, fire, labor difficulty, shortages, civil disturbances, transportation problems, interruptions of power or of communications, failure of suppliers or subcontractors, or natural disasters. This paragraph shall not apply to Client's obligation to make any payment to BioReliance.

**16. ASSIGNMENT.** BioReliance will not assign its rights or delegate its responsibilities hereunder without the prior written consent of

Client. In the event Client assigns its rights or delegates its responsibilities hereunder to a third party, Client shall provide BioReliance with written notice of such assignment as soon as possible after such assignment or delegation is made.

**17. INDEPENDENT PARTIES.** Nothing in this Agreement shall be construed as to create any relationship between BioReliance and Client other than that of independent contracting parties. Neither party shall have any right, power or authority to assume, create or incur any expense, liability or obligation, express or implied, on behalf of the other.

**18. WAIVER.** No waiver by either party of any breach of any provision hereof shall constitute a waiver of any other breach of that or any other provision hereof.

**19. SEVERABILITY.** If any part, term or provision of this Agreement is determined to be invalid or unenforceable, the remainder of this Agreement shall not be affected, and this Agreement shall otherwise remain in full force and effect.

**20. CANCELLATION.** Cancellation of a Study in progress will result in partial charge commensurate with percentage of work completed at time of cancellation, and payment of actual noncancellable costs incurred by BioReliance in performance of the Study prior to cancellation.

**21. ENTIRE AGREEMENT.** This Agreement, including the quotation of fees and charges, the Protocol and appendices, exhibits or other schedules, constitutes the entire agreement between the Parties with respect to the subject matter of this Agreement, and supercedes any conflicting terms that may be set forth on Client's purchase order, BioReliance's invoice, or any other documentation of either party, unless agreed to in writing by authorized representatives of both parties. This Agreement is not intended to confer upon any person other than the BioReliance and Client any rights or remedies hereunder. There are no representations, warranties, understandings or agreements relating to this Agreement which are not fully expressed herein. No amendment, modification, waiver or discharge of any provision of this Agreement will be valid unless in writing and signed by an authorized representative of the party against which such amendment, modification, waiver or discharge is sought to be enforced.

**22. GOVERNING LAW.** The Services shall be governed by and construed in accordance with the laws of the state in which the BioReliance facility or affiliate performing the Services is a resident, or if such affiliate is outside the United States, then with the laws of the territory in which such affiliate is located, in each case without reference to any rules of conflict of laws, and except that matters pertaining to intellectual property rights and patents shall be governed by the laws of the jurisdiction in which such intellectual property rights or patents exist. Both parties consent to the exclusive jurisdiction of such courts and expressly waive any objections or defenses based on lack of personal jurisdiction or venue.

**23. TERMINATION.** Either party may terminate this Study in the event of a material breach of these Terms and Conditions by the other party, provided such breach is not cured within thirty (30) days after receipt of written notice from the non-breaching party specifying the details regarding such breach. Either party may terminate the Study or related services immediately by written notice to the other party if the other party abandons its operations, becomes insolvent, becomes the subject of voluntary or involuntary bankruptcy, arrangement, composition or other like proceeding, which is not dismissed within thirty (30) days of commencement thereof, makes an assignment for the benefit of its creditors, or consents to the appointment of a trustee, receiver or other fiduciary for all or a substantial part of its assets. BioReliance may terminate the Study or related services at any time with or without cause by giving Client at least thirty (30) days written notice.

#### **ADDITIONAL TERMS AND CONDITIONS AS APPLICABLE**

**For BioReliance® Cell Banking Services:** BioReliance shall deliver the cell bank(s) and a Certificate of Analysis for each Study/Project performed.

**CANCELLATION.** In the event Client cancels a Study/Project prior to commencement of the Project ("Service Commencement"), Client shall pay a Cancellation Fee based on the effective date of such cancellation, as follows:

<u>Days before Project Commencement:</u>	<u>Percentage</u>
<u>Due:</u>	
30 days or less, or after Project Commencement	100%
31-90 days	15%
More than 90 days	0%

The percentage shall be calculated based on the remaining balance of the Project Fee as modified by any Changes. Additionally, Client shall be responsible for all non-cancelable expenses BioReliance has incurred in performance or anticipation of future portions of the Project. Under no circumstances shall the Cancellation Fees and expenses set forth herein be greater than the total Project Fee, as it may be modified by any Change.

**For BioReliance® Technical Transfer Services:** For any unpaid and undisputed invoice past due, BioReliance reserves the right to suspend work and/or withhold delivery of any Data or Report not yet delivered to Client (in each case any estimated time periods for performance shall be extended for a commercially reasonable time period in the discretion of BioReliance).

Upon completion of the Technical Transfer Services, any remaining Test Articles or materials will be destroyed within four (4) months of issuance of the Report and/or Data to Client unless otherwise agreed upon in writing.

In the event that it is agreed between the parties that BioReliance will release to the Client any product produced by BioReliance as a result of the Technical Transfer Services (Product), then the following conditions shall apply: The Product is not GMP compliant and it is an essential condition of release that neither the Client nor any third party shall use the Product for clinical trials or for any other use on humans. The Client shall not use the Product in breach of any applicable rules or regulations and shall take all proper and reasonable precautions to protect the Product from any improper use. The Client accepts all risks associated with the use of the Product and shall free and indemnify BioReliance against any claims by third parties resulting from Client's use of the Product. The Product is experimental in nature and BioReliance provides no warranties relating to the description or quality of the Product or its fitness for a particular purpose or use under any conditions whether or not known to BioReliance except as may be specified in the Contract and/or Technical Transfer Specification, and the Client shall fully indemnify, and keep indemnified and hold harmless, BioReliance against any and all claims, actions, costs, expenses or other liabilities whatsoever in respect of any liability under the Consumer Protection Act 1987; any negligent or willful act or omission of the Client in relation to the use, processing, transport or storage of the Product. The Client acknowledges that the Product may have characteristics which are unknown or difficult to determine and which may prove potential hazards and risks either in their transport, handling, delivery, use, disposal and overall treatment and possession. The Client shall not pass the Product to any third party without BioReliance's prior written consent which consent shall not be unreasonably withheld.

**For BioReliance® Production Services:** Production Services include but are not limited to; clinical bulk manufacture and final filling of clinical bulk material. Where estimates of quantities of the Product are provided by BioReliance the Client acknowledges that these are estimates only and any failure by BioReliance to produce the estimated quantity of the Product shall not be deemed to be a breach of the contract and BioReliance shall not be liable for any loss, damage, costs or expenses of any nature, whether direct or consequential, resulting from a failure to produce any specific quantity of the Product save where such a failure is due to BioReliance's non-compliance with these terms. BioReliance is not responsible for, and makes no warranty whatsoever with regard to, genetic alterations, including the formation of replication competent viruses (such as replication competent adenovirus or replication competent retrovirus) which occurs during the production of the Product. Under no circumstances shall such genetic alterations be the basis for a claim by the Client. BioReliance provides no warranties relating to the description or quality of the Product or its fitness for a particular purpose or use under any conditions whether

or not known to BioReliance except as may be specified in the contract, and the Client shall fully indemnify, and keep indemnified and hold harmless, BioReliance against any and all claims, actions, costs, expenses or other liabilities whatsoever in respect of any liability under the Consumer Protection Act 1987.

**QUALIFIED PERSON.** Where required under any applicable Regulations, BioReliance shall provide the services of a Qualified Person (as defined in the Regulations) who shall have responsibility for releasing the Product to the Client and certifying that the Product has been manufactured in accordance with the terms of the Specifications and in compliance with the principles of the Regulations. Such certification shall, for the avoidance of doubt, relate solely to the Production Services being provided by BioReliance to the Client and with respect to the release of the Product by BioReliance to the Client, and it is acknowledged and accepted by the Client that neither BioReliance nor their Qualified Person shall have any responsibilities for the final release of the Product for the purposes of clinical trials nor for ensuring compliance with any authorisation that may be required by Client or any third party for use of the Product in clinical trials, and the Client shall release and hold harmless both BioReliance and the Qualified Person of any and all liability in respect of such matters. For the purposes of enabling the Qualified Person to perform his/her responsibilities as defined in this Section it is an essential condition that the Client shall provide to BioReliance to the extent reasonably required by BioReliance to comply with the Regulations (i) all relevant information from any applicable marketing or other authorisations relating to the Product and (ii) information on the material and on the Client's process and other relevant information. It shall be the responsibility of the Client to satisfy itself that all relevant requirements of such marketing or other authorisations, insofar as same relate to the services, have been incorporated within the Specifications. Neither BioReliance nor the Qualified Person shall have any responsibility for checking the terms of any such marketing or other authorisations or other related documentation. It shall be the responsibility of the Client, either directly or through any person appointed by the Client with overall responsibility for certification of the finished product batch for release for the purposes of use in clinical trials, to satisfy itself that the Qualified Person appointed by BioReliance for the Production Services, and the role of the Qualified Person as described in this Section is sufficient for its purposes. In undertaking such responsibilities the Qualified Person shall ensure that the following requirements have been met: The Product and its manufacture comply with the terms of the Specifications; manufacture and testing has been carried out in accordance with the Regulations; The principal manufacturing equipment and testing processes comprised within the Production Services have been validated; Any deviations or planned changes in production or quality control have been authorised by the persons responsible in accordance with the procedures defined in the Specifications and any other relevant documentation; All appropriate checks and tests have been performed, including any additional sampling, inspection, tests or checks initiated as a result of deviations or planned changes; All necessary production and quality control documentation has been completed and endorsed by the members of staff authorised to do so in accordance with BioReliance's internal procedures; and all audits have been carried out as required by BioReliance's quality assurance system.

**DELIVERY OF MATERIAL AND PRODUCT.** The Client shall make delivery of Material to the Facility and shall be entirely responsible for any and all costs associated with such delivery. BioReliance shall make delivery of the Product to the Client ex-works at the Facility (Incoterms 2010) at which time all right and title in the Product shall pass to the Client and the Client shall at that time be responsible for the whole risk of loss or damage to the Product from the point of delivery BioReliance shall have no responsibility for the packaging of the Product unless agreed otherwise in writing by BioReliance and the Client. The Client shall be responsible for all charges associated with the packaging and carriage of the Material and/or Product.

**APPROVAL OF PRODUCT.** The Client shall have a period of three (3) months from receipt of the latest of the Product or the Final Report in which to notify BioReliance in writing of any failure of the Product to meet the agreed specification as detailed in the Specifications. In the event that no written notification is received within the said three (3) month period, the Client shall be deemed to have accepted the Product as meeting specification. In the event of BioReliance's receipt of a notice. In the event of BioReliance receives notice from the Client for non-conformance of Product, the Client shall make available to BioReliance the failed Product for inspection at the Facility and neither BioReliance nor the Client shall take any steps to manipulate or otherwise interfere

with the Product until a final resolution is mutually agreed upon in good faith. In the event of a dispute arising as to whether the Product has failed to meet the agreed specification or as to whether any failure to meet the agreed specification is as a result of any act or omission of the Client or any party acting on behalf of the Client or with the authority of the Client or any third party following upon delivery of the Product to the Client, the dispute shall be referred to an independent expert. The independent expert (acting as an expert and not an arbiter) shall be appointed by agreement between BioReliance and the Client or in the absence of agreement within a period of twenty (20) days of the request for referral having been notified by either BioReliance or the Client to the other party. The decision of the expert on the matter under referral, including the award of expenses, shall be final and binding on the parties in the absence of manifest error. Should it be a condition of the contract, or should the Client request and BioReliance consent to the Product being released to the Client prior to the completion of the Quality Assurance Audit or prior to the completion of any tests (including mycoplasma and sterility) forming part of the Production Services or services relating thereto and release of the results thereof, the Client warrants that the Product shall not be used by it, prior to such completion and release of results, for the purposes of clinical trials and the Client further acknowledges that any use of the Product prior to acceptance by it shall be at the Client's risk, and in respect of any such use of the Product prior to such acceptance the Client undertakes to indemnify BioReliance against any and all loss suffered, or any and all claims made against BioReliance, by the Client, or any third party as a result of such use of the Product by the Client, or any third party.

**BIORELIANCE®**