### **SUPPLY AGREEMENT**

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This Supply Agreement (the "**Agreement**") effective as of January 1, 2017 (the "**Effective Date**") by and between Ortho-Clinical Diagnostics, Inc., a New York corporation with an address at 1001 US Route 202, Raritan, New Jersey 08869 ("**Ortho**"), and ALBA BIOSCIENCE LIMITED a company with its principal place of business at 5 James Hamilton Way, Biocampus, Bush Loan, Penicuik, Scotland EH26 0BF UK ("**Alba**").

#### **RECITALS**

WHEREAS, Ortho and Alba, as successor in interest to the Scottish National Blood Transfusion Service, entered into an Umbrella Supply Agreement dated December 1, 2004 ("Umbrella Agreement") for the manufacture, supply and sale of certain products contained within the Umbrella Agreement and associated Product Attachments; and

WHEREAS, Ortho develops, manufactures, sells and distributes medical devices and would like to purchase certain products from Alba hereunder to be used as a medical device; and

WHEREAS, Alba has the experience, authorizations, facilities and capacity required to manufacture and sell Product (as defined below), and Ortho would like to purchase Product from Alba pursuant to the terms of this Agreement; and

WHEREAS, Ortho and Alba have entered into a Quality Agreement effective as of October 11, 2016 which allocates certain responsibility for quality standards applicable to the Products; and

WHEREAS, Alba and Ortho entered into Product Attachment No. 5 to the Umbrella Agreement, effective June 1, 2013 for the supply of certain products and other services by Alba to Ortho; and

WHEREAS, upon execution of this Agreement, Alba and Ortho intend to terminate the Umbrella Agreement, together with all Product Attachments thereto and enter into this Supply Agreement.

NOW, THEREFORE, in consideration of the mutual promises, covenants and agreements hereinafter set forth, the parties hereto agree as follows:

# ARTICLE 1 DEFINITIONS

As used throughout this Agreement, each of the following terms shall have the respective meaning set forth below:

- 1.01 "Affiliate" of a party shall mean: (i) when applicable to Alba, any entity that directly or indirectly controls, is controlled by or is under common control with such entity (control with respect to Alba shall mean ownership or interest, direct or indirect, in at least fifty percent (50%) of such Alba, either through the ownership of such Alba's stock, voting power, membership interest or otherwise, or the power to direct the management and policies of such Alba); and (ii) when applicable to Ortho, Ortho-Clinical Diagnostics Bermuda Co. Ltd., a Bermuda exempted limited liability company, and its subsidiaries.
- 1.02 "CPI" shall mean the latest UK Consumer Price Index as defined by the UK Office for National Statistics on 1st October each year.
- 1.02"Exclusive Product(s)" shall mean Products listed on Schedule A-1 that are manufactured and packaged in accordance with the Exclusive Product Specifications (hereinafter defined), along with any Improvements thereto.
- 1.03 "Exclusive Product Specifications" shall mean the specifications for the design, composition, product safety assurance, manufacture, packaging, and/or quality control of the Exclusive Products, as set forth on Schedule B-1 attached hereto.
- 1.04 "Facility" shall mean the facility or facilities of Alba currently located at (i) Ellens Glen Road, Edinburgh, Scotland, (ii) Douglas House, Pentlands Science Park, Bush Loan, Penicuik, Scotland, or (iii) Allan-Robb Campus, 5 James Hamilton Way, Penicuik, Edinburgh, Scotland such locations to be amended if changed during the Term of this Agreement.
- 1.05 "**Improvement**" shall mean any change, improvement, modification or development to Product, the Specifications, the Raw Materials or the method or process of manufacture or production of Product.
- 1.06 "Intellectual Property Rights" shall mean the intellectual property, trade secrets, know-how, technology and information, whether or not protected by patents, that are required in order to make Product.
- 1.07 "Labeling" shall mean all artwork and text associated with the Products, Product packaging and other associated Product documentation, including instructions for use (IFU).
- 1.08 "Non-Exclusive Product(s)" shall mean Products listed on Schedule A-2 that are manufactured by Alba and packaged in accordance with the Non-Exclusive Product Specifications (hereinafter defined), along with any Improvements thereto.
- 1.09 "Non-Exclusive Product Specifications" shall mean Alba's specifications for the design, composition, product safety assurance, manufacture, packaging, and/or quality control of the Non-

- 1.10 "OrthoSera Products" shall mean the so-named subset of Exclusive Products listed on Schedule A-1 whose intended use is for use as blood grouping reagents for extended phenotyping performed in Column Agglutination Technology (CAT).
- 1.12 "Outstanding Development Milestone" shall mean the development milestones set in Section 1 of the Second Milestone Letter (which is set forth hereto as Schedule K), provided that Alba has to seek FDA approval for all rare antisera reagents set forth in Section 1 of the Milestone Letter except for anti-M
- 1.13 "**Product(s)**" shall collectively mean the Exclusive and Non-Exclusive Products as defined herein.
- 1.14 "Quality Agreement" shall mean that certain Quality Agreement effective October 11, 2016 between Ortho and Alba, attached hereto as Schedule J, as may be amended from time to time. The terms of the Quality Agreement are incorporated by reference into this Agreement and are considered terms of this Agreement.
- 1.15 "Raw Materials" shall mean the materials, components, and packaging required to manufacture and package Product in accordance with the applicable Specifications.
- 1.16 "**Regulatory Authority**" means any governmental agency or authority regulating the manufacture, packaging, sale, shipment or storage of Product.
- 1.17 "**Specifications**" shall collectively mean the Exclusive Product Specifications and the Non-Exclusive Product Specifications, as defined herein.
- 1.18 "Term" shall consist of the Initial Term plus any extensions elected in accordance with Section 7.02.
- 1.19 "TPM" means Third Party Manufacturer.
- 1.20 "**Trade Dress**" shall mean packaging, labeling, trademarks, copyrights, slogans, artwork, text, instructions for use and all other intellectual property that appear on or are otherwise used in connection with the sale and use of a Product hereunder.

#### **ARTICLE 2**

#### SUPPLY OF PRODUCT; COMPLETION OF OUTSTANDING DEVELOPMENT MILESTONE

- 2.01 <u>Supply of Product.</u> During the term of this Agreement, Alba shall manufacture and supply to Ortho, and Ortho shall purchase from Alba, those quantities of Product ordered by Ortho in accordance with Article 4. The Parties acknowledge that Ortho is not obligated to buy any minimum or specific amount of Product under this Agreement except for the quantities of Product defined in Schedule A Part I that Ortho orders through binding purchase orders. Without limiting the effect of the foregoing, Ortho acknowledges that it will not place a purchase order for a batch size less than the minimum batch size, if any, set forth on Schedule A-1 and A-2.
- 2.02 <u>Raw Materials</u>. All Raw Materials shall be procured by Alba in accordance with applicable laws and regulations. Alba shall be responsible for the quality of the Raw Materials used in the manufacture of Products and for their conformity with the Exclusive Product Specifications or the Non-Exclusive Product Specifications, whichever are applicable.
- 2.03 Affiliates and TPMs. From time to time during the Term, Ortho may direct Affiliates and TPMs to

purchase Products from Alba for the benefit of Ortho. Alba agrees that it will provide each designated Affiliate or TPM with such Products on the same terms and conditions setforth in this Agreement. Alba and Ortho acknowledge that while Alba is affording the Affiliate or TPM the benefit of terms of this Agreement, the relationship between Alba and TPM is an independent relationship and Ortho is not a party to such relationship or any agreement between such parties. Alba acknowledges and agrees that Ortho is not ensuring that any Affiliate or TPM will, nor is any Affiliate or TPM committed or obligated to, purchase any minimum or specific amount of Product from Alba and Ortho is not obligated to make any payments to Alba on behalf of such Affiliate or TPM.

- 2.04 <u>Manufacturing Facility</u>. All Product made under this Agreement shall be manufactured, packaged and stored only at Alba's Facility. Alba's Facility shall meet or exceed all applicable requirements for development, manufacture, sale and distribution to intended markets, including but not limited to cGMPs as they relate to Product. Alba also agrees to make any changes to its Facility and/or manufacturing processes necessary to comply with its obligations under this Agreement. Any changes made by Alba to its Facilities, processes and equipment shall be made only in accordance Article 6 (Improvements and Change to Process).
- 2.05 <u>Completion of Outstanding Development Milestone</u>. Alba and Ortho executed a so-called milestone letter dated July 21, 2016 (the "**First Milestone Letter**"). The parties hereby agree to replace the First Milestone Letter with the amended and restated milestone letter as attached hereto in <u>Schedule K</u> ("**Second Milestone Letter**").
- 2.06 <u>Termination of Product Attachment # 5</u>. The parties entered into a product attachment # 5 ("**Product Attachment # 5**") effective June 13, 2013 for the supply and purchase of the OrthoSera Products to Ortho. The OrthoSera Products are not yet approved by the FDA for use with Ortho's VISION and VISION MAX instruments. Alba shall validate the OrthoSera Product for use on Ortho's VISION and VISION MAX instruments and make regulatory filings in accordance with <u>Schedule M</u>. With effect as of September 1, 2018, the Parties hereby terminate Product Attachment # 5.

# ARTICLE 3 PRICES FOR PRODUCT

3.01 <u>Prices</u>. The price for the Products shipped by Alba until 31st Dec 2020 shall be as set forth in Schedule A-1 and A-2.

#### 3.02 Price Adjustments.

- (a) With effect from January 2021 and every contract year thereafter, the Price of each Product shall increase or decrease (as the case may be) by the same percentage that the UK CPI rate increases or decreases compared to the previous year (as at 1st October); minus three percent (3%).
- 3.03 <u>Payment Terms</u>. Ortho shall pay all undisputed invoices issued by Alba within 60 days after receipt of such invoice. Ortho shall remit payment by electronic bank transfer. All payments shall be in US dollars.

#### 3.04 Taxes.

(a) General: Except as set forth in this Agreement, Ortho shall make all payments to Alba under this Agreement without deduction or withholding for any sales, use, gross receipts, excise, value-added, business, consumption, services, goods and services, withholding, personal property or other taxes (each individually referred to as "Tax"), except to the extent that any such deduction or withholding is required by Law or treaty. Each Party shall be responsible for taxes based on its own income, employment taxes of its own employees and for taxes on any property it owns or leases.

- (b) VAT, GST, Sales, Use and Similar Taxes: If any taxing authority imposes a VAT, GST, sales, use, service, consumption, business or similar Tax upon payments under this Agreement, then Ortho agrees to pay that amount if specified in a valid invoice or supply exemption documentation; provided, however, that applicable Law requires Alba to charge and collect such Tax from Ortho and no valid exemption documentation has been supplied by Ortho to Alba. Alba is solely responsible for identifying, billing and collecting such required Taxes in all relevant federal, state, county, municipal and other taxing jurisdictions and for filing all required Tax returns in a timely manner. To the extent that Alba does not provide Ortho a valid invoice (i.e., an invoice compliant with this Agreement and the rules and regulations of the jurisdictions of both Alba and Ortho, including separate identification of the Tax where legally required), Alba shall assume any and all responsibility for non-compliance, including payment of the Tax and any interest and penalties. To the extent that a Tax is required by Law to be separately identified in Alba's billings to Ortho, Alba shall separately identify the Tax and assume any and all responsibility for non-compliance, including payment of the Tax and any interest and penalties. Each Party shall provide and make available to the other any resale certificates, information regarding out-of-state sales, treaty certification and any other exemption certificates or information requested by a Party.
- 3.05 <u>Cost Improvement Program</u>. Each year during the Term, Alba's intention is to reduce the manufacturing **cost** for Product for each upcoming year by 3 % over the preceding year through Ortho's and Alba's Cost Improvement Program ("**CIP**"). Alba acknowledges that it is familiar with the CIP and is committed toward achieving the targeted reduction each year. Such commitment may be achieved through a number of ways, including but not limited to savings achieved through contract pricing, distribution/storage costs, quality/inspection of Products, waste, overage, Set-up reduction, inventory, design changes, reduction of field service costs, manufacturing tools, manufacturing efficiencies and leveraging from new business opportunities.

# ARTICLE 4 FORECASTS; ORDERS

4.01 <u>Forecasts</u>. At least once a year (or other frequency agreed upon between Alba and Ortho), Ortho shall provide Alba with a twelve (12) month, non-binding forecast of Ortho's expected requirements for Product for the then-current month plus the subsequent eleven (11) months (the "Forecast"). Each Forecast will extend out to a twelve (12) month horizon to facilitate planning on the part of Alba. Ortho and Alba will utilize Ortho's monthly (or other frequency agreed upon between Alba and Ortho), Sales and Operations Planning Process ("S&OP") to review the Forecasts, Ortho's orders, Alba's Product supply plans, Alba's capacity including Committed Capacity and Ortho's market demand changes. Alba will advise Ortho of monthly capacity limitations and reasonably expected capacity issues during the S&OP. Committed Capacity shall mean 150% of Forecast.

#### 4.02 <u>Orders</u>.

- (a) Ortho shall place any binding orders for Product by written or electronic purchase order to Alba ("Purchase Order") for shipment in accordance with lead time indicated for each Product on Schedule A-1 or A-2. Within five (5) days after receipt of a Purchase Order, Alba shall send Ortho a written acknowledgment of the Purchase Order, including specific acknowledgment of a delivery date, quantity and shipping terms.
- (b) The parties acknowledge that Ortho is not obligated to buy any specific amount of Product, and Ortho shall not be responsible for Raw Material inventory beyond its obligations under such binding Purchase Orders.
- 4.03 <u>Adjustments</u>. Ortho may submit Purchase Orders to Alba for quantities of Product less than or in excess of the Forecast amounts up to the Committed Capacity. For adjustments in excess of Committed Capacity, Alba agrees to use commercially reasonable efforts to fill those orders.

4.04 <u>Delivery</u>. Shipment locations for the Products ordered by Ortho are set forth in Schedules sA-1 and A-2 and Alba shall deliver Product to Ortho in accordance with the delivery date (or maximum 5 days early) specified in the Purchase Order. If Alba is unable to meet such any such delivery date, Alba shall so notify Ortho no later than 14 days prior to such delivery date. In the event that Alba is unable to deliver any Product by the desired delivery date and fails to notify Ortho of such inability, Ortho shall have the right to withhold, without penalty, 10% of the total invoice amount for such late delivery. In addition, if Alba is unable to deliver any Product to Ortho in accordance with the schedule of desired delivery dates for 3 consecutive months, then, regardless of whether Alba notified Ortho of such inability, Ortho shall be entitled to, upon 15 days' notice to Alba, either (i) withhold, without penalty, 10% of the total invoice amount for the late delivery that occurred in the last of the 3 consecutive months, and for every late delivery thereafter or (ii) terminate this Agreement. Ortho agrees that it will not exercise its right under clause (ii) above if Alba demonstrates to Ortho's satisfaction, Alba's willingness and ability to deliver Product in accordance with the schedule of desired delivery dates for the rest of the term of this Agreement.

4.05 <u>Shortages</u>. Ortho shall notify Alba in writing of any shortage in any shipment of Product within seven (7) days of Ortho receiving the shipment. Alba shall, at Ortho's option, refund to Ortho the Price paid for the quantity of the shortfall, or make up the shortfall, at no additional cost to Ortho, as soon as possible but no later than within seven (7) days if replacement stock is available, or, if no replacement stock is available, as soon as reasonably practicable after receiving such notice. Alba shall also refund Ortho for the shipping costs incurred by Ortho.

4.06 <u>Conflicts</u>. To the extent of any conflict or inconsistency between this Agreement and any Purchase Order, purchase order release, confirmation, acceptance or any similar document, the terms of this Agreement shall govern, unless the terms of such other agreement signed by the parties specifically indicate the parties' intention that such other agreement shall govern as to the term in conflict.

# ARTICLE 5 ADDITIONAL UNDERSTANDINGS OF THE PARTIES

5.01 Most-Favored Customer. Subject to restrictions in Section 5.02, Alba represents and warrants that the Prices for the Products set forth in Schedule A-1 or A-2 are at least as low as the price charged by Alba to other buyers for the same Products or similar products. If, at any time during the Term, Alba charges any other buyer a lower price for the same Products or similar products, upon execution of the agreement between Alba and such other buyer Alba shall apply that price to the applicable Products or similar products under this Agreement. If Alba fails to meet the lower price, Ortho may, at its option, in addition to all of its other rights under this Agreement or at law, terminate this Agreement without liability with immediate effect. The Parties shall reflect any adjustment to pricing under this Section 5.01 in an amendment to Schedule A-1 or A-2, as applicable; provided, however, that, notwithstanding anything to the contrary contained in Section 5.01, the execution and delivery of any such amendment by each of the Parties will not be a condition to the effectiveness of such Price adjustment. During the term of this Agreement and for three (3) years thereafter, Alba agrees to:

- i) keep written records related to its agreements with third parties, in sufficient detail to allow determination of whether Alba's has complied with Section 5.01; and
- ii) permit a certified public accounting firm of nationally recognized standing selected by Ortho and reasonably acceptable to Alba to periodically examine any such written

must provide Alba with at least 7 days' advance notice of such audit, (ii) any such audit may not occur more than once every year, and (iii) the accounting firm shall only be entitled to disclose to Ortho whether or not Alba has complied with Section 5.01 of this Agreement and the reasoning supporting its conclusion. No other information shall be provided to Ortho. The fees charged by such accounting firm shall be paid by Ortho; provided, however, that if such audit uncovers a breach of Section 5.01, the fees of such accounting firm together with any overpayment uncovered shall be paid by Alba.

- 5.02 Exclusive Rights. During the Initial Term of this Agreement, or any extension hereof, and for one (1) year thereafter, (other than its manufacture of OrthoSera exclusively for Ortho) Alba shall not manufacture, promote, market, distribute, sell (directly or indirectly) by itself or through any third party or other intermediary any anti-sera product for use in column agglutination technology unless approved in writing by Ortho.
- 5.03 <u>Equipment</u>. In the event that Ortho has made, or will make, available certain equipment, tools or dies for Alba to use in manufacturing or otherwise producing Product, Alba shall use and maintain such equipment in accordance with the terms set forth in Schedule G.
- 5.04 <u>Competing/Similar Products</u>. Both Alba and Ortho recognize and acknowledge that Alba and Ortho and their Affiliates have been, and will continue to be, actively involved in the field of Transfusion Diagnostics. Each party acknowledges that, subject to any express limitations set forth in this Agreement, including in particular the prohibition on manufacture for third parties of OrthoSera Product or similar products, each party and its Affiliates may market, sell and distribute products which compete directly or indirectly with the Products and which may contain similar ingredients or technology as a Product, and may continue to market, sell and distribute these and other competing or similar products throughout the term of this Agreement. Alba acknowledges that Ortho and its Affiliates may have such products manufactured internally or by a third party.
- 5.05 <u>Business Review Meetings.</u> Representatives of Ortho and Alba shall hold regularly scheduled business review meetings ("**BRM**") to (a) review new and existing business initiatives and the quality systems used to manufacture Product, (b) discuss productivity improvements, opportunities to improve profitability, quality issues relating to Product, corrective action plans, complaint and support activities and market outlook; (c) review the established BCP; and (d) identify new business opportunities. The BRM shall be held at least once per calendar year; <u>provided</u>, that both parties agree to meet on an ad hoc basis if business reasons warrant. Alba understands and acknowledges that Ortho intends to measure Alba's overall performance under this Agreement. If Alba's performance rating is not satisfactory to Ortho, Alba and Ortho will discuss any concerns that Ortho raises regarding Alba's performance at the BRM.
- 5.06 <u>Financial Collaboration Program; Audit.</u> In an effort to protect the integrity of its supply chain, Ortho requires financial health monitoring of its suppliers. Accordingly, Alba shall comply with the following:
- (i) Alba shall provide the following information as directed by Ortho to senior Finance management of Ortho on the following schedule: (a) audited financial statements a minimum of once per fiscal year; (b) Alba's management-approved financial statements quarterly, upon request of Ortho; and (c) details of debt structure, maturity schedule and renewal options upon request.

- (ii) Once every twelve (12) months, Ortho shall have the right upon reasonable notice to, or to cause a third party to, audit the financial books and records of Alba specifically for purposes of evaluating the financial stability of the Alba. Alba shall provide reasonable cooperation and assistance to Ortho, at Ortho's cost and expense, in connection with such audit.
- 5.07 <u>Business Continuity Plan/Back-up Supply</u>. Alba agrees to establish and maintain a Business Continuity Plan ("**BCP**") that clearly defines a process to minimize or eliminate interruption in manufacturing operations in the event of a business interruption at Alba's Facility and/or at the facilities of Materials suppliers for Product. Alba understands that the BCP Program documents a consistent process for evaluating business continuity risk, self-assessing risk mitigation procedures, and prioritizing risks and mitigation activities at such facilities. The goal of the BCP is to quickly restore supply of Product following a disruption.

## ARTICLE 6 IMPROVEMENTS AND CHANGES TO PRODUCT

- 6.01 Improvements; Control Process. (a) From time to time during the term of this Agreement, Alba or Ortho may submit to the other written proposals for the adoption, implementation or development of any improvement to a Product (each, an "Improvement"). In no event shall any such Improvement be implemented or made without the prior written approval of the Ortho. If the parties agree on any such Improvement and implementation date, they shall modify the Specifications to reflect the same and shall review the Price to be charged for such Product. In the event Alba is unable to supply Product that meets any changes to the Specifications proposed by Ortho and agreed by Alba, then Ortho shall be free to terminate this Agreement upon 180 days prior written notice, without payment of any fees, charges or other amounts, except for those amounts due and owing to Alba at such time for binding Purchase Orders.
- (b) In the event an Improvement is necessary due to applicable laws, regulations or guidelines, Alba agrees that Improvements to the method or process of manufacture or production of Product shall be made at Alba's sole cost and expense. Alba further agrees that no improvements, changes or modifications to the method or process of manufacture or production of the Products or Raw Materials shall be made without prior written notification to and approval of Ortho and any such improvement, change or modification shall be made at Alba's sole cost and expense.
- (c) In the event of any change to a Product, Alba shall establish an appropriate qualification protocol which will be reviewed and approved by Ortho. Ortho and Alba shall determine an appropriate inventory level for the pre-change Product in order to cover on-going requirements during the qualification process.
- (d) Alba shall notify Ortho, in writing, at least ninety (90) days in advance and obtain approval from Ortho prior to making any changes to the Specifications, Raw Materials, the production process, production equipment or location(s) involved in the fulfillment of this Agreement.
- 6.02 Ortho Initiated. Ortho may at any time suggest Improvements, which may be implemented by the Alba as soon as reasonably possible; provided, that (a) none of such Improvements give rise to any claim of infringement of any third party patent or other proprietary right and (b) it is reasonably feasible for Alba to make such Improvements without requiring any capital investment on the part of Alba. If any such Improvement, as suggested by Ortho and implemented by Alba, causes a decrease in Alba's cost of producing a Product, all such cost savings shall be passed on to Ortho in the form of lower Price for such Product after deduction of any costs incurred by Alba in implementing such Improvement.
- 6.03 <u>Product Life Cycle Management</u>. In addition to the Improvements outlined in 6.01 and 6.02 above, Alba and Ortho agree to establish a Life Cycle Management Team to review and suggest additional Improvements to existing Products covered by this Agreement and, where agreed by both

parties, to develop new products, which may be added to this Agreement, The parties shall manage and allocate costs associated with projects relating to any Improvements (or prospective new products) identified for review by the Life Cycle Management Team as outlined in Schedule M.

### ARTICLE 7 TERM

- 7.01 <u>Initial Term</u>. The initial term of this Agreement (the "**Initial Term**") shall commence on the Effective Date and remain in effect for ten (10) years unless sooner terminated as expressly provided under the term of this Agreement.
- 7.02 Optional Extension. Ortho, at its sole option, may extend this Agreement for up to three additional one-year terms after the expiration of the Initial Term by giving Alba at least 180 days' prior written notice for each such additional term.
- 7.03 <u>Purchase Orders -- Survival</u>. The terms of this Agreement shall survive for binding Purchase Orders, blanket purchase orders and repair purchase orders issued prior to the expiration of this Agreement and such Purchase Orders shall continue to be subject to this Agreement until such Purchase Orders are completed, terminated or modified by mutual agreement of the parties in accordance with this Agreement.

### ARTICLE 8 TERMINATION

- 8.01 <u>Termination by Ortho Without Cause</u>. Notwithstanding anything to the contrary in this Agreement, Ortho may terminate this Agreement without cause at any time during the Term upon twelve (12) months prior written notice.
- 8.02 <u>Termination for Breach</u>. This Agreement may be terminated, prior to the expiration of its Term, by either party by giving written notice of its intent to terminate and stating the grounds therefor if the other party shall materially breach or materially fail in the observance or performance of any representation, warranty, guarantee, covenant or obligation under this Agreement. The party receiving the notice shall have ninety (90) days from the date of receipt thereof to cure the breach or failure. In the event such breach or failure is cured, the notice shall be of no effect.
- 8.03 <u>Insolvency.</u> This Agreement may be terminated, prior to the expiration of its term, upon fifteen (15) days written notice by either party: (i) in the event that the other party hereto shall (1) apply for, take any step towards or consent to the appointment of, or the taking of possession by, a receiver, custodian, administrator, trustee or liquidator of itself or of all or a substantial part of its property, (2) make a general assignment for the benefit of its creditors. (3) commence a voluntary case under the United States Bankruptcy Code, as now or hereafter in effect (the "Bankruptcy Code") or analogous proceeding in any other jurisdiction, (4) file a petition seeking to take advantage of any law (the "Bankruptcy Laws") relating to bankruptcy, administration, insolvency, reorganization, winding-up, or composition or readjustment of debts in any jurisdiction, (5) fail to controvert in a timely and appropriate manner, or acquiesce in writing to, any petition filed against it in any involuntary case under the Bankruptcy Code or analogous proceeding in any other jurisdiction, or (6) take any corporate action for the purpose of effecting any of the foregoing; or (ii) if a proceeding or case shall be commenced against the other party hereto in any court of competent jurisdiction, seeking (1) its liquidation, administration, reorganization, dissolution or winding-up, or the composition or readjustment of its debts, (2) the appointment of a trustee, receiver, custodian, administrator, liquidator or the like of the party or of all or any substantial part of its assets, or (3) similar relief under any Bankruptcy Laws, or an order, judgment or decree approving any of the foregoing shall be entered and continue unstayed for a period of 60 days; or an order for relief against the other party hereto shall be entered in an involuntary case under the Bankruptcy Code or analogous laws in any other jurisdiction.

8.04 Effect of Termination. Notwithstanding the termination of this Agreement for any reason, each party hereto shall be entitled to recover any and all damages or losses that such party shall have sustained by reason of the breach by the other party hereto of any of the terms of this Agreement. Termination of this Agreement for any reason shall not release either party hereto from any liability which at such time has already accrued or which thereafter accrues from a breach or default prior to such expiration or termination, nor affect in any way the survival of any other right, duty or obligation of either party hereto which is expressly stated elsewhere in this Agreement to survive such termination. In the case of a termination under Section 8.03 above, the non-defaulting party may pursue any remedy available in law or in equity with respect to such breach.

8.05 Transitional Support. If this Agreement expires or terminates, Alba shall provide Ortho with such exit assistance (e.g., knowledge transfer, bid assistance, cooperation) as reasonably requested by Ortho in writing (the "Exit Assistance Services"). Ortho shall reimburse Alba for its actual and reasonable out of pocket costs incurred in performing the Exit Assistance Services requested by Ortho. At least 90 days prior to the effective date of termination (excluding in the event of immediate termination) or expiration, Alba shall propose to Ortho a plan for the provision of the Exit Assistance Services describing how and when it will perform the Exit Assistance Services and the estimated charges for the performance of the Exit Assistance Services. The Parties will use commercially reasonable efforts to agree on a final plan for performance of the Exit Assistance Services as soon as possible.

If this Agreement expires or terminates, Ortho may elect to have Alba continue to supply Products under the terms of this Agreement for up to twenty-four (24) months after the effective date of expiration or termination ("Run-Off Period").

# ARTICLE 9 DELIVERY; INVENTORY

9.01 <u>Delivery</u>. All shipments must be accompanied by (a) a packing slip which describes the articles, states the Purchase Order number and shows the shipment's destination and (b) all documents required by the Quality Agreement. Alba agrees to promptly forward the original bill of lading or other shipping receipt for each shipment in accordance with Ortho's instructions. Alba further agrees to promptly render, after delivery of goods or performance of services, correct and complete invoices to Ortho.

9.02 <u>Pallet Policy</u>. Alba agrees that it shall comply with Ortho's Policy for Wood Pallets, set forth in <u>Schedule E</u>. Ortho has the right to reject any Product or materials that fail to comply with this policy.

9.03 <u>Shipment</u>. Delivery shall be <u>EX WORKS</u> (Incoterms 2010). Alba will pack all Product ordered hereunder in accordance with the Specifications, and in a manner suitable for shipment and sufficient to enable Product to withstand the effects of shipping.

9.04 <u>Inventory/ Shelf life</u>. Product must adhere to <u>Schedules A-1 and A-2</u> for shelf life remaining on the date it is delivered to Ortho at its facilities or such other location as shall be designated by Ortho as a point of delivery. Alba and Ortho agree to cooperate to improve the process for ordering Product with the mutual objectives of expediting the supply process to a just-in-time process and reducing inventory cost and/ or distribution cost. If requested by Ortho, Alba shall inform Ortho as to its raw material inventory levels.

9.05 Safety Stock. Alba shall use reasonable commercial efforts to maintain a three (3) month reserve of all critical raw materials ("Safety Stock"), based on each OrthoSera Product forecast at all times throughout the term of this Supply Agreement. Such Safety Stock shall be reviewed and modified periodically with Ortho input.

#### INSPECTION AND AUDIT

Ortho shall have the right, upon reasonable notice to Alba and during regular business hours, to inspect and audit Alba's premises, including the Alba Facilities or facilities being used by any supplier of Alba for production and storage of Product (1) to assure compliance by Alba (and its suppliers) with applicable law and regulation, including current Good Manufacturing Practice regulations ("cGMP") as defined by the United States Food, Drug & Cosmetic Act, as amended (the "Act"), the US Drug Enforcement Administration regulations, the Occupational Safety and Health Administration regulations and the US Environmental Protection Agency regulations and applicable United States Food and Drug Administration ("FDA") regulations, (2) to assure compliance with the provisions of this Agreement and (3) to determine Alba's costs in connection with Product to the extent these costs are passed on to Ortho. Alba shall (within 15 days for Critical observations and 30 days for Major and Minor observations) remedy or cause the remedy of any deficiencies which may be noted in any such audit or, if any such deficiencies cannot reasonably be remedied within such period, present to Ortho a written plan to remedy such deficiencies as soon as possible. The failure by Alba to remedy or cause the remedy of any such deficiencies within such period or to present such a plan within such period and then use its best efforts to remedy or cause the remedy of such deficiencies in accordance with such written plan, as the case may be, shall be deemed a material breach of this Agreement. Ortho shall also have the right to conduct annual audit loss prevention site visits through its insurance company representatives with prior notice to Alba and an annual cycle count of any inventory Ortho may have on site with Alba. Time of such inspections shall be mutually agreed upon by both parties. Alba acknowledges that the provisions of this Article 10 granting Ortho certain audit rights shall in no way relieve Alba of any of its obligations under this Agreement, nor shall such provisions require Ortho to conduct any such audits.

# ARTICLE 11 QUALITY/DEFECTIVE PRODUCT/REGULATORY INSPECTIONS/TESTING

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11.01 Quality. Alba warrants that any Product sold to Ortho hereunder shall conform to the Specifications for such Product, comply with applicable law and regulations and the terms of this Agreement (including the Quality Agreement) and be free from defects in design, material and workmanship ("Product Requirements"). Any Product failing to meet the foregoing Product Requirements shall be considered "Defective Product". Delivery of any Product by Alba to Ortho shall constitute a certification by Alba that the Product conforms to the foregoing requirements. Manufacturing and testing shall be performed as per applicable cGMPs. Mutual quality roles and responsibilities shall be defined in the Quality Agreement and each party shall fulfill such responsibilities. Alba represents and warrants to Ortho that neither Alba nor any of its employees have been "debarred" by the FDA, nor has Alba received notice that debarment proceedings have been commenced against Alba or any of its employees. Alba will immediately notify Ortho in writing if any such proceedings have commenced or if Alba or any of its employees are debarred by the FDA. Ortho may terminate this Agreement immediately upon receipt of any such notice from Alba.

#### 11.02 Disposition of Defective Product.

(a) Delivery of Products shall not be deemed in itself as constituting acceptance of the Products by Ortho. Ortho shall notify Alba of the existence and nature of any non-compliance or defect and Alba shall have a reasonable opportunity to inspect such Defective Product and provide Ortho with detailed written instructions to return or dispose of such Defective Product. At the request and expense of Alba, Ortho shall return the Defective Product, or a representative sample thereof to Alba for testing.

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- (b) Alba shall replace at its own cost and expense (including reimbursement of freight, Raw Materials and disposition costs) all Defective Product. Without limiting the generality of the foregoing, in such case Ortho reserves the right to (i) have Alba manufacture and supply Product on an expedited basis to replace the Defective Product; (ii) have Alba credit Ortho for the amount and value of Defective Product; or (iii) purchase Product or similar product from another manufacturer or supplier. If Alba fails to so inspect such Defective Product, Ortho may dispose of the Defective Product as it sees fit and Alba shall promptly (i) reimburse Ortho for all direct, out-of-pocket costs incurred by Ortho in connection with the Defective Product, including without limitation, shipping of the Product and disposition and (ii) replace the Defective Product at its own cost and expense or, at Ortho's option, issue a credit as provided herein. Ortho shall have no obligation to pay for any Product that is subject to such a claim of noncompliance or defect and Alba shall reimburse Ortho for all direct, out-of-pocket costs incurred by Ortho in connection with such Product, including, without limitation, shipping of Product and disposition costs. Ortho will control the disposition process. Alba shall be liable for any direct losses arising from damage or defect to any product into which such non-compliant or defective Product may be incorporated by Ortho, its Affiliates or any other third party manufacturer of Ortho. The foregoing shall be without prejudice to Ortho's other rights and remedies.
- 11.03 <u>Independent Testing</u>. If, after Alba's inspections of such Product, the parties disagree as to whether the Product meets the Product Requirements, either party may deliver the Product to an independent third-party laboratory, mutually and reasonably acceptable to both parties, for analytical testing to confirm the Product's conformance with the Product Requirements. All costs associated with such third-party testing shall be at Ortho's expense unless the tested Product is deemed by such third-party to be Defective Product, in which case all such costs, including reimbursement of freight and disposition costs, shall be promptly paid by Alba. No inspection or testing of, or payment for Product by Ortho's or any third-party agent of Ortho's shall constitute acceptance by Ortho thereof, nor shall any such inspection or testing be in lieu or substitution of any obligation of Alba for testing, inspection and quality control as provided in this Agreement (including in the Specifications and Quality Agreement) or under applicable local, state, or federal laws, rules, regulations, standards, codes or statutes.
- 11.04 <u>Reports</u>. Upon Ortho's written request, Alba shall promptly provide Ortho's written reports relating to any aspects of Product that are identified in the Specifications. Notwithstanding the immediately preceding sentence, Alba shall provide Ortho (without a written request) with those reports identified in the Quality Agreement, which Alba is obligated thereunder to provide to Ortho.
- 11.05 <u>Customer Complaints</u>. In the event that Alba or Ortho receives any customer complaint regarding the Products, or any component thereof, manufactured by Alba and distributed by Ortho, then that party shall inform the other as described in the Quality Agreement. The complaint or notice shall then be evaluated and investigated by the party receiving the complaint at their own cost. Either party may request the other party to conduct failure investigations, using the process defined in the Quality Agreement. Alba shall assist Ortho in follow-up correction of Product complaints within the timeframe required by Ortho's procedures. If corrective actions are required, the cost of or part of the corrective action shall be borne by Alba up to the extent such complaint is attributable to a breach by Alba of any of its warranties, guarantees, representations, obligations or covenants contained herein, and shall be borne by Ortho up to the extent such complaint is related to some cause or event attributable to Ortho.
- 11.06 <u>Corrective Action</u>. Alba shall notify Ortho in writing as soon as possible, but no later than within one (1) business day, of any situation of which it becomes aware that could lead to a recall, field alert, Product withdrawal or field correction of any Product provided under this Agreement. The final decision to recall or withdraw Product resides solely with Alba, subject to written approval from Ortho, after joint

discussions and evaluation by Alba and Ortho on the classification of events prior to regulatory notification. In the event any governmental agency having jurisdiction shall request or order, any corrective action with respect to any Product including any recall, corrective action or market action, and the cause or basis of such recall or action is attributable to a breach by Alba of any of its warranties, guarantees, representations, obligations or covenants contained herein, then Alba shall be liable, and shall reimburse Ortho for the reasonable costs of such action including the cost of any Product which is affected thereby whether or not such particular Product shall be established to be in breach of any warranty by Alba hereunder. In the event that such recall or corrective action results from any cause or event attributable to Ortho, including, without limitation, storage of Products by Ortho, Ortho shall be responsible for all costs and expenses of such recall or corrective action. Should such recall or corrective action result from the fault of both parties, the parties shall share such costs and expenses proportionately. The parties agree to reasonably cooperate with each other in the resolution of any such recall or correction action, regardless of fault, in accordance with the timeframe specified under Ortho's procedure for handling these matters. Alba shall provide all cooperation and assistance to Ortho in connection with any such recall or action, including but not limited to, providing (a) requested documentation to demonstrate corrective and preventative action(s) and documentation to update and/or close the recall required by the Regulatory authority, (b) information related to, but not limited to, manufacturing and quality information such as incoming inspection data, batch record / manufacturing data, and product dispositions and release data and (c) information related to, but not limited to, product(s) inventory levels and lot / batch # information, locations and amounts.

11.07 Regulatory Inspections. In the event the Facilities are the subject of an inspection by any Regulatory Authority or any other duly authorized agency of any national, state or local government directly relating to the manufacturing, packaging or warehousing of Product (including any Product complaint), Alba shall notify Ortho as soon as possible but no later than within twenty-four (24) hours of learning of such inspection, and shall, if reasonably possible given the circumstances, afford Ortho the opportunity to be present at such inspection although Ortho shall have no obligation to attend. If any samples of Product are taken, Alba shall collect duplicate samples from the same lot and location. If documents related to Product are taken, Alba shall collect duplicate copies of such documents. These duplicate samples and copies of documents will be sent to Ortho as soon as possible but no later than within forty-eight (48) hours at Ortho's expense. Alba shall supply Ortho with copies of any correspondence or portions of correspondence to the extent relating to the Products. In the event Alba receives any regulatory letter or written comments from any Regulatory Authority in connection with manufacturing and packaging of Products hereunder thereof, it shall provide Ortho with a copy of each such communication as soon as possible but no later than within forty-eight (48) hours. To the extent Alba is required to submit any correspondence to a Regulatory Authority that relates to the manufacture, packaging or warehousing of the Product, Alba shall provide Ortho with a copy of such correspondence as far in advance of its submission to such Regulatory Authority as possible and Ortho shall have the opportunity to review and comment upon such correspondence. Any written observation from a Regulatory Authority shall be shared with Ortho within one (1) day of receipt of the observation by Alba.

### ARTICLE 12 FAILURE TO SUPPLY

12.01 <u>Force Majeure Events</u>. If either party is prevented from performing any of its obligations hereunder due to any cause which is beyond the non-performing party's reasonable control, including fire, explosion, flood, or other acts of God; acts, regulations, or laws of any government; war or civil commotion; strike, lock-out or labor disturbances; or failure of public utilities or common carriers (a "**Force Majeure Event**"), such non-performing party shall not be liable for breach of this Agreement with respect to such non-performance to the extent any such non-performance is due to a Force Majeure Event. The non-performing party is required to provide immediate, and in no case later than within 24 hours, written notice to the other party of the Force Majeure Event. Such non-performance will be excused for three

months or as long as such event shall be continuing (whichever occurs sooner). Such non-performing party shall exercise all reasonable efforts to eliminate the Force Majeure Event and to resume performance of its affected obligations as soon as practicable. Alba recognizes the impact to society of Ortho's inability to serve the medical industry as a result of Alba's failure to supply Product. Therefore, Alba agrees to prioritize Ortho's Product as it allocates any inventory, recovery efforts and production capability. If Alba has a Force Majeure Event that remains unresolved after ninety (90) days, then Ortho may choose, but shall not be obligated, to terminate upon 30 days prior written notice the Agreement without payment of any penalty.

- 12.02 <u>Failure to Supply</u>. Notwithstanding the provisions of Section 12.01, in the event that any of the following occur:
- (a) Alba notifies Ortho (pursuant to Section 12.01 or otherwise) that Alba will not be able to fulfill Ortho's Purchase Order;
- (b) Ortho has sent Alba a notice of termination in accordance with Section 8.02 following Alba's failure to cure the breach;
- (c) Alba does not supply the OrthoSera Product within one hundred and eighty (180) days or any Products other than the OrthoSera Products within ninety (90) days of the scheduled delivery date as set forth in any Purchase order (whether due to the occurrence of a Force Majeure Event, any event listed in Section 8.03 above, or following the commencement of a case by or against Alba under Section 365(n) of Title 11 of the U.S. Code ("Title 11") or otherwise)
- (each of (a) through (c) are referred to as a "Failure to Supply"), then immediately following such Failure to Supply and through and until such time as Alba fully resumes its supply obligations pursuant to this Agreement,
  - (i) Ortho may, in addition to any other rights and remedies hereunder, use, sell make and have made Product and any Raw Materials pursuant to the license granted in Section 12.03;
  - (ii) Ortho may designate a third party manufacturer of the Products or manufacture such Product for itself (with no obligation or liability to Alba);
  - (iii) Alba shall provide Ortho and such other manufacturer with assistance, as reasonably requested, in connection with such manufacturer's or Ortho's efforts to supply Product to Ortho, including:
    - (I) Alba shall use commercially reasonable efforts to allow to (a) facilitate conversations between Ortho and the owner of the Facility (in which the Products are made at the time of the Failure to Supply) to grant Ortho access to the Facility and its software, plant, machinery and know how to assist with the manufacture of the Products and grant Ortho access to the process for the manufacture of the Products, and (b) facilitate conversations between Alba's employees and staff and Ortho and, to the extent permissible by applicable law, grant Ortho the opportunity to participate in efforts to re-establish and maintain supply of the Products and liaise with such employees and staff;

- (II) Alba shall use its reasonable endeavors to ensure any contract counterparty, including suppliers of Raw Materials, to provide their services or any part of their services directly to Ortho;
- (III) Alba shall make such filings with such regulators as are necessary and appropriate;
- (IV) for sake of clarity, Ortho shall pay the Price (as adjusted) for any Product supplied by Alba, less all reasonable costs incurred by Ortho in connection with the activities set forth in this clauses;
- (iv) Alba shall make available to Ortho or its designee access to all technical and proprietary materials, information, techniques and Intellectual Property Rights of Alba for Ortho to procure required Raw Materials or produce or arrange an alternative supplier of Raw Materials or Product. Notwithstanding anything to the contrary contained in this Agreement, in the event that Ortho shall make or have made the Product, pursuant to this Section 12.02, Ortho shall be permitted to disclose to any third party any Confidential Information as is reasonably necessary in connection with such activities (subject to such third party agreeing in writing to be bound by the terms of Article 15 hereof). In the event that Ortho shall purchase Product from another manufacturer or manufacture Product for itself pursuant to this Section 12.02 (other than as a result of a Force Majeure Event), Alba shall be liable for all reasonable costs incurred by Ortho in connection with the activities set forth in clauses (i) through (v) above, including without limitation, costs for technical transfer, qualification, validation and transfer of equipment and Raw Materials and costs of cover until the time when Alba can resume supply The foregoing shall be without prejudice to the Ortho's other rights and remedies, including, without limitation, the right to claim all direct damages and losses incurred (except for consequential damages). Notwithstanding the foregoing, if such inability, unwillingness or failure to supply Products which conform with the applicable Specifications within the delivery periods set forth herein occurs more than two (2) times in any calendar quarter (unless due to a Force Majeure Event), such inability, unwillingness or failure shall be deemed a material breach of this Agreement.

12.03 <u>License</u>. Alba hereby grants to Ortho a fully paid up exclusive worldwide license, with the right to grant sub-licenses to its Affiliates, to use, sell, make and have made products employing and utilizing the Intellectual Property Rights. Such license shall become effective immediately upon the occurrence and for the duration of a Failure to Supply for all Products, and remain in force until Alba is in a position to resume supply of the Products. Alba shall provide within thirty (30) days of the Effective Date to Ortho a description of Alba's process for the manufacture of the OrthoSera Products and the Fetal Screening Products (including any required formulations and raw materials used for the manufacture of the OrthoSera Products and the Fetal Screening Products) in sufficiently clear and detailed terms that it can be readily followed and carried out by a trained scientist or engineer to make the OrthoSera Product in the manner Alba considers most efficient. Furthermore, should Alba alter, modify or change its process for manufacturing the OrthoSera Product, Alba shall provide to Ortho details of such alteration, modification or change. "Fetal Screening Products" shall mean the fetal screening products described in Schedule A1 as such of this Agreement. "

12.04 <u>Rights Upon Insolvency</u>. All rights and licenses to Intellectual Property Rights granted under this Agreement by Alba to Ortho are, for all purposes of Title 11, licenses of rights to intellectual property as defined in Title 11. Alba agrees during the term of this Agreement to create and maintain current copies

or, if not amenable to copying, detailed descriptions or other appropriate embodiments, of all such Intellectual Property Rights. If a case is commenced by or against Alba under Title 11, then, unless and until this Agreement is rejected as provided in Title 11, Alba (in any capacity, including debtor-inpossession) and its successors and assigns (including, without limitation, a Title 11 trustee) shall either perform all of the obligations provided in this Agreement to be performed by Alba or license to Ortho all such Intellectual Property Rights (including all embodiments thereof) held by Alba and such successors and assigns, as Ortho may elect in a written request, immediately upon such request. If a Title 11 case is commenced by or against Alba, this Agreement is rejected as provided in Title 11 and Ortho elects to retain its rights hereunder as provided in Title 11, then Alba (in any capacity, including debtor-inpossession) and its successors and assigns (including, without limitation, a Title 11 trustee) shall provide to Ortho all such Intellectual Property Rights (including all embodiments thereof) held by Alba and such successors and assigns immediately upon Ortho's written request therefor. All rights, powers and remedies of Ortho, as a licensee hereunder, provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including, without limitation, Title 11) in the event of the commencement of a Title 11 case by or against Alba. Ortho, in addition to the rights, powers and remedies expressly provided herein, shall be entitled to exercise all other such rights and powers and resort to all other such remedies as may now or hereafter exist at law or in equity (including Title 11) in such event. In this Section, all references to Title 11 include any analogous law in any other jurisdiction, and the remaining terminology should be interpreted to give like effect.

12.05 The parties acknowledge, notwithstanding Title 11 and that this Agreement is governed by the laws of the State of New York, that Alba is a company incorporated pursuant to the laws of Scotland, and accordingly, Alba shall only be able to perform its obligations under this Section 12 in so far as is permitted by the insolvency laws of Scotland or any analogous relevant jurisdiction

# ARTICLE 13 INSURANCE

Alba agrees to procure and maintain in full force and effect during the term of this Agreement valid and collectible insurance policies in connection with its activities as contemplated hereby which policies shall be in compliance with the requirements set forth in <u>Schedule C</u>. Upon Ortho's request, Alba shall provide to Ortho a certificate of coverage or other written evidence reasonably satisfactory to Ortho of such insurance coverage.

## ARTICLE 14 TRADE DRESS, LABELING; ARTWORK; PROPRIETARY RIGHTS; TRADEMARKS

14.01 Ortho Trade Dress. For Exclusive Products to be distributed or sold with Ortho Trade Dress (as indicated on Schedule B-1), the label and package insert copy for each Exclusive Product or Orthobranded finished products using, made with or containing any other Product shall: (a) conform to Ortho's standard labeling requirements, (b) comply with all applicable US and EU regulations, standards and requirements, (c) be reviewed by Ortho and be subject to Ortho's approval and (d) contain all other information agreed to by the parties including any requirements set forth in that Exclusive Product's Specifications set forth on Schedule B-1 hereto.

14.02 Alba Trade Dress. For Products to be distributed or sold under Alba Trade Dress (as indicated on Schedules B-1 and B-2), the label and package insert copy for each Product shall: (a) conform to Alba standard labeling requirements and (b) comply with all applicable US and EU regulations, standards and requirements and that Product's Specifications as applicable.

<u>14.03 Labeling.</u> The process for creating and updating documentation and Labeling for the Exclusive Products, shall be as set forth in Schedule I attached hereto.

14.04 <u>Intellectual Property</u>. Alba acknowledges that Ortho is the exclusive owner of and has all rights to the trademarks, trade dress, copyrights, slogans, artwork, text, and all other intellectual property that appear on or are otherwise used in connection with the sale and use of Exclusive Products or Orthobranded finished products, ("**Ortho Background IP**"). For clarity, in spite of its inclusion on Schedule A-1, Alba® Q-Check is a trademark Alba and is not Ortho Background IP. Ortho grants Alba a limited license to use the Ortho Background IP solely in its performance of this Agreement for the benefit of Ortho. Alba grants to Ortho a worldwide, royalty free, non-exclusive license with the right to grant sublicenses, for any invention or development, whether patentable or not, or whether fully completed or not, made by Alba to improve Exclusive Product or the manufacture thereof, including any method or any use or any combination product relating hereto, created while this Agreement is in effect.

14.05 Alba <u>Trademark.</u> Ortho shall not be entitled to make use of Alba' trademark(s), or name in any way either in respect of this Agreement or any other agreement to which Ortho is a party, without written consent from Alba.

14.06 Ortho Trademark. Alba shall use Ortho's name, trade name, and trademarks only in connection with the manufacture of the Exclusive Products under this Agreement and only insofar as necessary to package and label. Alba shall not acquire any right, title or interest to or in Ortho's name, trademarks or Labeling under this Agreement.

### ARTICLE 15 CONFIDENTIALITY

As used herein, "Confidential Information" shall include all confidential or proprietary information given to one party by the other party, or otherwise acquired by such party in its performance of this Agreement, relating to the other party or any of its Affiliates, including information regarding any of the products of such other party or any of its Affiliates, information regarding its advertising, distribution, marketing or strategic plans or information regarding its costs, productivity or technological advances. During the term of this Agreement, and for a period of 5 years thereafter, neither party shall use or disclose to third parties any Confidential Information of the other party. Notwithstanding the foregoing, the receiving party may disclose Confidential Information of the other party to the extent required by law or requested by a governmental authority; provided, that the receiving party shall, to the extent not prohibited, promptly notify the disclosing party of such requirement or request prior to any disclosure. Upon the disclosing party's request at any time, the receiving party shall return to the disclosing party or destroy all material and documents containing or derived from Confidential Information of the other party. Confidential Information shall not include information that (i) was already known to the receiving party at the time of its receipt thereof or is independently developed by receiving party without use of any Confidential Information, (ii) is received from a third party who does not have, to the receiving party's knowledge, any duty of confidentiality to the other party hereunder with respect to such information, or (iii) is or becomes part of the public domain through no breach of this agreement by the receiving party.

## ARTICLE 16 PUBLIC ANNOUNCEMENTS

16.01 <u>Publicity</u>. Neither party shall, except as provided below, make, issue or release any public announcement, press release, statement or acknowledgment of the existence of, or reveal publicly the terms, conditions and status of, the transactions contemplated herein, without the prior written consent of the other party as to the content and time of release of and the media in which such statement or announcement is to be made; provided, however, that in the case of announcements, statements,

acknowledgments or revelations which either party is required by law to make, issue or release, the making, issuing or releasing of any such announcement, statement, acknowledgment or revelation by the party so required to do so by law shall not constitute a breach of this Agreement if such party shall have given, to the extent reasonably possible, not less than two (2) calendar days prior notice to the other party, and shall have attempted, to the extent reasonably possible, to clear such announcement, statement, acknowledgment or revelation with the other party. Alba shall not use the name of Ortho or any of its Affiliates for advertising or promotional purposes without the prior written consent of Ortho. In furtherance of the foregoing, Alba shall not originate any publicity or other announcement, written or oral, whether to the public, the press, the trade, Ortho's or Alba's customers or otherwise, relating to this Agreement or the existence of an arrangement between the parties, without the prior written approval of Ortho.

### ARTICLE 17 REPRESENTATIONS AND WARRANTIES

17.01 Products. Alba represents and warrants to Ortho that all Product supplied in connection with this Agreement shall (a) conform to the Specifications for such Product, (b) comply with applicable law and regulations, (c) comply with the terms of this Agreement (including the Quality Agreement), and (d) be of merchantable quality, fit for the purpose intended by this Agreement and free from defects in design, material and workmanship. Alba further represents and warrants that it shall comply with, all current and future statutes, laws, ordinances and regulations, including, without limitation, those enforced by the United States Food and Drug Administration (including compliance with good manufacturing practices), the states and International Standards Organization Rules 9,000 et seq. Alba represents and warrants that it will hold all licenses, permits and similar governmental authorizations necessary or required for Alba to conduct its operations and business and manufacture Product throughout the Term. Alba represents and warrants that any Products that have been stored until delivery or Raw Materials stored until use, shall have been stored under appropriate and secure conditions and in accordance with cGMPs. Alba represents and warrants that Product supplied in connection with this Agreement will not contain any Raw Materials that have not been used or stored in accordance with the Specifications, any other quality assurance standards instructed by Ortho or any supplier of Raw Materials and all applicable governmental standards. Alba represents and warrants that it will maintain all equipment used in connection with the manufacturing, packaging and supplying of Product hereunder in good working condition and in accordance with all applicable laws, rules and regulations.

17.02 Execution and Performance of Agreement. Alba and Ortho each represents to the other that it has full right, power and authority to enter into and perform its obligations under this Agreement. Alba and Ortho each further represents and warrants to the other that the performance of its obligations under this Agreement will not result in a violation or breach of, and will not conflict with or constitute a default under any agreement, contract, commitment or obligation to which such party or any of its Affiliates is a party or by which it is bound.

### ARTICLE 18 COMPLIANCE

18.01 Compliance with Laws. Alba agrees to comply with the applicable provisions of any Federal or state law and all executive orders, rules and regulations issued thereunder, including Executive Order 11246, as amended, Chapter 60 of Title 41 of the Code of Federal Regulations, as amended, prohibiting discrimination against any employee or applicant for employment because of race, color, religion, sex or national origin; Section 60-741.1 of Chapter 60 of 41 Code of Federal Regulations, as amended, prohibiting discrimination against any qualified employee or applicant for employment with disabilities; Section 60.250.1 of Chapter 60 of 41 Code of Federal Regulations, as amended, providing for the employment of qualified special disabled veterans, veterans of the Vietnam era, recently separated veterans and other protected veterans; Chapter 1 of Title 48 of the Code of Federal Regulations, as

Amended, Federal Acquisition Regulations; Sections 206, 207 and 212 of the Fair Labor Standards Act, as amended, and the regulations and orders of the United States Department of Labor promulgated in connection therewith; Section 1502 of the Dodd Frank Wall Street Reform and Consumer Protection Act of 2010, Rule 13(p)-1 regarding Conflict Minerals, as further outlined in <u>Schedule H</u> and any provisions, representations or agreements required thereby to be included in this Agreement are hereby incorporated by reference. If any Product is ordered by Ortho under U.S. government contracts, Alba agrees that all applicable federal statutes and regulations applying to Ortho as a contractor are accepted and binding upon Alba insofar as Alba may be deemed a subcontractor.

18.02 Compliance with Policy on Ortho's Code of Conduct. Alba and its officers have read and understand Ortho's Code of Conduct attached hereto as Schedule D, and as such may be amended (the "Policy"). Alba shall permit representatives of Ortho to enter Alba's premises at any reasonable time, and Alba shall use best endeavors to ensure that representatives of Ortho shall be permitted to enter the premises of any subcontractor involved in the manufacture or supply of any Products (or component thereof) at any reasonable time, in order to inspect relevant employment, health and safety records and to observe the manufacturing process. Alba (and its subcontractors) shall maintain the records necessary to demonstrate compliance with the Policy and shall provide to Ortho a written certification of such compliance annually during the term of this Agreement. If Alba shall fail to comply with this Section, then Ortho shall have the right to terminate this Agreement forthwith, effective upon 10 days' prior written notice, and without payment of any penalty or termination fee.

18.03 Environmental, Health and Safety Standards. With respect to all environmental, safety and industrial hygiene matters related to Alba's activities under this Agreement, Alba shall (a) certify compliance with all applicable laws and regulations issued by national, state and local authorities, (b) inform Ortho promptly of any significant adverse event (e.g., fires, explosions, accidental discharges), (c) inform Ortho promptly of any allegations or findings of violations of applicable laws or regulations, (d) any material community complaint against Alba, and (d) allow Ortho to inspect Alba's facilities if notified of adverse event, such inspections to be at reasonable times and upon reasonable notice. If Alba shall fail to comply with any of the conditions in this section, then Ortho shall have the right to terminate this Agreement forthwith, effective upon 10 days' prior written notice, and without payment of any penalty or termination fee.

18.04 <u>Anti-Corruption Compliance Provision.</u> Neither party shall perform any actions that are prohibited by local and other anti-corruption laws (including the U.S. Foreign Corrupt Practices Act, collectively "**Anti-Corruption Laws**") that may be applicable to one or both parties to the Agreement. Without limiting the foregoing, neither party shall make any payments, or offer or transfer anything of value, to any government official or government employee, to any political party official or candidate for political office or to any other third party related to the transaction in a manner that would violate Anti-Corruption Laws.

18.05 <u>Record Retention</u>. Alba (and its subcontractors and agents) shall use all paper or electronic records, files, documents, work papers and other information in any form, whether marked "confidential" or not (the "Files and Work Papers") relating to the supply of Product, only as permitted by Ortho's Records Management Policy (the "Records Policy") set forth on <u>Schedule F</u>. Alba (and its subcontractors and agents) shall maintain the records necessary to demonstrate compliance with the Records Policy and shall provide to Ortho a written certification of such compliance annually during the term of the Supply Agreement. Alba's failure to comply with this Section 18.05 shall be considered a material breach of the Supply Agreement and Ortho shall have the right to terminate the Supply Agreement forthwith, effective upon 10 days' prior written notice, and without payment of any penalty or termination fee.

18.06 <u>Compliance with REACH Regulation</u>. Alba Bioscience agrees to comply with the European Community Regulation EC 1907/2006 for Registration, Evaluation, Authorization and Restriction of Chemical Substances (REACH Regulation), as applicable to the Products

18.07 Compliance with Product Identification. Alba Bioscience agrees to comply with: (i) unique identification / pedigree bar coding regulations when mandated by US and other local law, (ii) evolving bar code regulations such as the FDA requirement for Unique Device Identifier (UDI) and (iii) GS1 standard.

## ARTICLE 19 INDEMNIFICATION AND LIMITATION OF LIABILITY

19.01 <u>Indemnification by Alba</u>. Alba shall indemnify and hold harmless Ortho (and its Affiliates) from and against any and all third party damages, liabilities, claims, costs, charges, judgments and expenses (including reasonable attorney's fees) (collectively "**Damages**") that may be sustained, suffered or incurred by Ortho (or its Affiliates), arising from or by reason of (a) the breach by Alba of any warranty, representation, covenant or agreement made by Alba in this Agreement; (b) actual or alleged injury to property or person or death occurring to any of Alba's employees, subcontractors, invitees, agents or individuals on Alba's premises; (c) any Product that does not conform to the Specifications or any of the requirements of this Agreement or is otherwise defective; (d) Alba's manufacture, packaging or supply of Products under this Agreement, including any actual or alleged infringement or violation of any patent, trade secret or other proprietary rights of any third party; or (e) Alba's negligence or willful misconduct; <u>provided</u>, that the foregoing shall not apply to the extent arising from Ortho's negligence or willful misconduct.

19.02 <u>Indemnification by Ortho</u>. Ortho shall indemnify and hold harmless Alba from and against any and all third party Damages, that may be sustained, suffered or incurred by Alba arising from or by reason of (a) the breach by Ortho of any warranty, representation, covenant or agreement made by Ortho in this Agreement; or (b) Ortho's negligence of willful misconduct; <u>provided</u>, that the foregoing shall not apply to the extent arising from Alba's negligence or willful misconduct or from Product not meeting Specifications or any of the requirements set forth in this Agreement or otherwise being defective.

19.03 <u>Claims</u>. The party entitled to indemnification under this Article 19 (the "**Indemnified Party**") shall give prompt written notice of any third party claim or suit and shall permit the other party (the "**Indemnifying Party**") to undertake the defense at the Indemnifying Party's expense. The Indemnified Party shall cooperate in such defense, to the extent reasonably requested by the Indemnifying Party, at the Indemnifying Party's expense. The Indemnified Party shall have the right to participate in such defense at its own expense. In any claim made or suit brought for which the Indemnified Party seeks indemnification under this Article 19, the Indemnified Party shall not settle or offer to settle such claim or suit, or admit liability or damages, without the prior written consent of the Indemnifying Party. The Indemnifying Party shall not settle any claim or suit in such a manner as would create an obligation on the part of the Indemnified Party to any third party without the prior written consent of the Indemnified Party.

19.04 <u>Limitation of Liability</u>. Nothing in this Agreement shall operate to exclude either party's liability to the other for:

- (a) death or personal injury caused by its negligence; or
- (b) any fraudulent misrepresentations

Subject to the foregoing:

- (i) neither Party shall have any liability to the other party, whether in contract, tort (including negligence), breach of statutory duty, or otherwise, for any indirect and consequential loss arising under or in connection with this Agreement; and
- (ii) during each contract year each party's maximum aggregate liability to the other party whether in

contract, tort (including negligence), breach of statutory duty, or otherwise, arising under or in connection with this Agreement shall be not exceed one hundred percent (100%) of the aggregate revenues actually received by Alba under this Agreement in the twelve months prior to the time the claim was made.

### ARTICLE 20 MISCELLANEOUS

20.01 <u>Dispute Resolution</u>. (a) This Agreement shall be governed and construed by the laws of the State of New York, excluding any choice of law rules that may direct the application of the laws of another jurisdiction.

- (b) <u>Mediation</u>. Any controversy or claim arising out of or relating to this Agreement, including any such controversy or claim involving the parent company, subsidiaries, or affiliates under common control of any party (a "**Dispute**"), shall first be submitted to mediation according to the *Commercial Mediation Procedures* of the American Arbitration Association ("AAA") (see www.adr.org). Such mediation shall be attended on behalf of each party for at least one session by a senior business person with authority to resolve the Dispute. Any period of limitations that would otherwise expire between the initiation of a mediation and its conclusion shall be extended until 20 days after the conclusion of the mediation.
- (c) <u>Arbitration</u>. (i) Any Dispute that cannot be resolved by mediation within 45 days of notice by one party to the other of the existence of a Dispute (unless the parties agree to extend that period) shall be resolved by arbitration in accordance with the *Commercial Arbitration Rules* of the AAA ("AAA Rules"; see www.adr.org) and the Federal Arbitration Act, 9 U.S.C. §1 et seq.. The arbitration shall be conducted in New Jersey, by one arbitrator appointed in accordance with the AAA Rules. (ii) The arbitrator shall follow the *ICDR Guidelines for Arbitrators Concerning Exchanges of Information* in managing and ruling on requests for discovery. The arbitrator, by accepting appointment, undertakes to exert her or his best efforts to conduct the process so as to issue an award within eight months of her or his appointment, but failure to meet that timetable shall not affect the validity of the award. (iii) The arbitrator shall decide the Dispute in accordance with the substantive law of New York. The arbitrator may not award punitive or exemplary damages, or attorneys fees or costs, and each party hereby irrevocably waives any right to seek such damages, nor may the arbitrator apply any multiplier to any award of actual damages, except as may be required by statute. The award of the arbitrator may be entered in any court of competent jurisdiction
- 20.02. <u>Relationship of the Parties</u>. The relationship of Ortho and Alba established by this Agreement is that of independent contractors, and nothing contained herein shall be construed to (i) give either party any right or authority to create or assume any obligation of any kind on behalf of the other or (ii) constitute the parties as partners, joint venturers, co-owners or otherwise as participants in a joint or common undertaking.
- 20.03 Entire Agreement. It is the mutual desire and intent of the parties to provide certainty as to their respective future rights and remedies against each other by defining the extent of their mutual undertakings as provided herein. The parties have, in this Agreement, incorporated all representations, warranties, covenants, commitments and understandings on which they have relied in entering into this Agreement, and, except as provided for herein, neither party makes any covenant or other commitment to the other concerning its future action. Accordingly, this Agreement (i) constitutes the entire agreement and understanding between the parties with respect to the subject matter hereof and there are no promises, representations, conditions, provisions or terms related thereto other than those set forth in this Agreement and (ii) supersedes all previous understandings, agreements and representations between the parties, written or oral. No modification, change or amendment to this Agreement shall be effective unless in writing signed by each of the parties hereto.

20.04 Headings. The Article and Section headings contained in this Agreement are for reference purposes

only and shall not affect in any way the meaning and interpretation of this Agreement.

20.05 <u>Notices</u>. All notices and other communications hereunder shall be in writing. All notices hereunder of an Indemnity Claim, a Force Majeure Event, default or breach hereunder, or, if applicable, termination or renewal of the term hereof, or any other notice of any event or development material to this Agreement taken as a whole, shall be delivered personally, or sent by national overnight delivery service or postage pre-paid registered or certified U.S. mail, and shall be deemed given: when delivered, if by personal delivery or overnight delivery service; or if so sent by U.S. mail, three business days after deposit in the mail, and shall be addressed:

If to Alba:Alba Bioscience Limited 5 James Hamilton Way, Biocampus, Bush Loan, Penicuik, Scotland EH26 0BF UK

If to Ortho:Ortho-Clinical Diagnostics, Inc. 1001 US Route 202 Raritan, New Jersey 08869 Attn; Chad Dale, Head of Operations

With a copy to:Ortho-Clinical Diagnostics, Inc. 1001 US Route 202 Raritan, New Jersey 08869 General Counsel

or to such other place as either party may designate by written notice to the other in accordance with the terms hereof.

20.06 <u>Failure to Exercise</u>. The failure of either party to enforce at any time for any period any provision hereof shall not be construed to be a waiver of such provision or of the right of such party thereafter to enforce each such provision, nor shall any single or partial exercise of any right or remedy hereunder preclude any other or further exercise thereof or the exercise of any other right or remedy. Remedies provided herein are cumulative and not exclusive of any remedies provided at law.

20.07 <u>Assignment</u>. This Agreement may not be assigned by Ortho without the prior written consent of the Alba, except that Ortho may assign its rights and/or obligations hereunder to (i) any of its Affiliates, (ii) a successor to its business and (iii) with respect to any Product, to a third party that acquires greater than 50% of Ortho's rights to such Product (whether by sale, license, merger, Change of Control or otherwise). Alba acknowledges that Ortho has entered into this Agreement after consideration of the unique talent, experience and particular attributes of Alba to manufacture and supply Product. Therefore, this Agreement and all rights and obligations hereunder are personal to Alba and may not be assigned or transferred by Alba without the express written consent of Ortho, which consent may be withheld or given in Ortho's sole discretion. Any such assignment or attempted assignment or transfer in the absence of the prior written consent of Ortho shall be void and without effect at the option of the Ortho. Subject to the foregoing sentence, this Agreement shall bind and inure to the benefit of the parties hereto and their respective successors and assigns. Alba shall not subcontract any part of the manufacturing, packaging or supplying of Product, testing procedures or any of its other obligations hereunder to a third party.

20.08 <u>Severability</u>. In the event that any one or more of the provisions (or any part thereof) contained in this Agreement or in any other instrument referred to herein, shall, for any reason, be held to be invalid, illegal or unenforceable in any respect, then to the maximum extent permitted by law, such invalidity,

illegality or unenforceability shall not affect any other provision of this Agreement or any other such instrument. Any term or provision of this Agreement which is invalid, illegal or unenforceable in any jurisdiction shall, to the extent the economic benefits conferred by this Agreement to both parties remain substantially unimpaired, not affect the validity, legality or enforceability of any of the terms or provisions of this Agreement in any other jurisdiction.

- 20.09 <u>Further Assurances</u>. Upon reasonable request from Ortho therefor, Alba shall provide to OCD, promptly, any product samples, manufacturing information and other information as is necessary for Ortho to complete or obtain U.S. or foreign registration (including reimbursement arrangements) or approval in any territory where Ortho is allowed to sell product or use technology.
- 20.10 <u>Counterparts</u>. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.
- 20.11 Expenses. Each party shall pay all of its own fees and expenses (including all legal, accounting and other advisory fees) incurred in connection with the negotiation and execution of this Agreement and the arrangements contemplated hereby.
- 20.12 <u>Survival</u>. Sections 8.04, 20.01 and 20.11 and Articles 14, 15, 16 and 19 shall survive the termination of this Agreement in accordance with the respective terms thereof.

LEGAL ADDRESSES AND BANKING DETAILS OF THE PARTIES	