DISTRIBUTION AND DEVELOPMENT AGREEMENT

This Distribution and Development Agreement (this "Agreement") is made and entered into as of May 1, 2016 by and between Sekisui Diagnostics, LLC and its Affiliates, a Delaware limited liability company with principal offices at 4 Hartwell Place, Lexington, Massachusetts 02421 ("Sekisui"), and Qualigen, Inc. and its Affiliates, a Delaware corporation with principal offices at 2042 Corte Del Nogal, Carlsbad, California 92011 ("Qualigen" and together with Sekisui, each a "Party" and together the "Parties").

WHEREAS, Qualigen is engaged in the manufacture, supply and development of certain clinical rapid diagnostic test devices and controls; and

WHEREAS, Qualigen wishes to appoint Sekisui as its exclusive distributor for such products in the Territory (as defined below); and WHEREAS, Sekisui wishes to be appointed as the exclusive distributor of such products and to fund the development of certain future products.

NOW, THEREFORE, in consideration of the mutual covenants hereinafter contained, the parties hereto agree as follows:

1. Definitions

- 1.1. Adverse Event shall mean an incident in which the Product was alleged to have caused or contributed to the death or serious injury of a patient or operator and would require submitting a Medical Devices Report to the FDA (as hereinafter defined) as per 21 CFR 803, or a similar report to a Competent Authority (as hereinafter defined) as per Vigilance Guidance MEDDEV 2.12-1.
- 1.2. Affiliate shall mean, (i) with respect to Qualigen, any corporation or other form of business organization, which directly or indirectly owns, controls, is controlled by, or is under common control with Qualigen, and (ii), with respect to Sekisui, shall mean Sekisui Diagnostics (UK) Ltd., Sekisui Diagnostics PEI, Inc., SEKISUI MEDICAL CO., LTD., and Sekisui Diagnostics GmbH. An entity shall be regarded as being in control of another entity if the former entity has the direct or indirect power to vote more than fifty percent (50%) of the outstanding voting securities (or other ownership interest for a business organization other than a corporation) of that entity, or the direct or indirect ability to direct or cause the direction of the general management and policies of the other entity.
- 1.3. <u>Applicable Markets</u> shall mean the United States, Canada, the European Union, Japan and other additional geographies that are added from time to time at the request of Sekisui, but only to the extent that it is commercially reasonable for Qualigen to expand to such additional geographies.
- 1.4. <u>Available Margin</u> is defined on <u>Exhibit A</u>.
- 1.5. <u>Business Plan</u> shall mean the business plan attached as <u>Exhibit B</u> hereto, which business plan may be amended from time to time by mutual agreement of Qualigen and Sekisui.
- 1.6. <u>COGS</u> is defined on <u>Exhibit A</u>.

- 1.7. <u>Competent Authority</u> shall mean the governmental authority in a member state of the European Union which has competence in relation to the Products.
- 1.8. <u>Development Plan</u> shall mean the development plan attached as <u>Exhibit C</u> hereto, which development plan may be amended from time to time by mutual agreement of Qualigen and Sekisui.
- 1.9. <u>Effective Date</u> shall mean May 1, 2016.
- 1.10. <u>European Union</u> shall mean the countries in Europe that are under the CE mark regulatory regime.
- 1.11. <u>Exclusivity Period</u> shall mean the period from the Effective Date until December 31, 2018.
- 1.12. FDA shall mean the U.S. Food and Drug Administration or any successor agency.
- 1.13. Health Canada shall mean the department of the government of Canada with responsibility for national public health.
- 1.14. Intellectual Property Rights means all intellectual property rights in any jurisdiction worldwide, including, without limitation: (a) Patent Rights; (b) rights associated with works of authorship including copyrights, copyright applications, and copyright registrations; (c) rights relating to the protection of trade secrets, know-how or confidential information; and (d) rights in any trade names, trademarks, service marks, domain names, logos, trade dress and brand features.
- 1.15. <u>Net Revenue</u> is defined on <u>Exhibit A</u>.
- 1.16. Patent Rights means all patents, patent applications and inventions on which patent applications are filed and all patents issuing therefrom worldwide, together with any extensions, registrations, confirmations, reissues, continuations, divisionals, continuations-in-part, re-examination certificates, substitutions or renewals, supplemental protection certificates, term extensions (under applicable patent law or other law), provisional rights and certificates of inventions.
- 1.17. <u>Potentially Serious Complaint</u> shall mean any information coming to the notice of Qualigen or Sekisui which might relate to a Serious Incident (as hereinafter defined), or to a significant lapse in the quality of the Products, or might lead to significant adverse public or media comment, or otherwise significantly, adversely affect the reputation or business of Sekisui or Qualigen.
- 1.18. <u>Products</u> shall mean all of Qualigen's current and future products, including without limitation those listed on <u>Exhibit D</u>, for sale under the trade names listed with such products, including any improvements thereto.
- 1.19. Qualigen Retained Customers shall mean certain of Qualigen's existing direct sales customers, all as listed on Exhibit E.
- 1.20. Regulatory Approval shall mean the approval of the applicable Regulatory Authority required for the promotion, marketing, distribution and/or sale of the Products in any territory in which they are being sold, including any Product registration or license, and any supplement, amendment or variation thereto, required before the commencement of commercial sales of the Products in such territory, and export and import approvals for the Products.

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- 1.21. Regulatory Authorities shall mean the FDA, each Competent Authority, Health Canada and the Japanese Pharmaceuticals and Medical Devices Agency.
- 1.22. Revenue Affiliate shall mean any entity of which Sekisui has the direct or indirect power to vote more than fifty percent (50%) of the outstanding voting securities (or other ownership interest for a business organization other than a corporation) of that entity, or the direct or indirect ability to direct or cause the direction of the general management and policies of that entity.
- 1.23. Sale Transaction shall mean (i) any transaction in which Qualigen, Qualigen's business or control of Qualigen is acquired, (ii) any license, sale, lease, transfer, or other disposition, in a single transaction or series of related transactions, of all or substantially all of Qualigen's assets other than in the ordinary course of business, (iii) any sale of a majority of the outstanding shares of capital stock of Qualigen, (iv) any sale or license of any rights to any Qualigen products, now or hereafter existing, other than in the ordinary course of business, (v) any liquidation or dissolution of Qualigen, (vi) any similar transaction resulting in a change of control of Qualigen, or (vii) any of the foregoing with respect to any now or hereafter existing subsidiary of Qualigen which holds, on a consolidated basis, all or substantially all of Qualigen's assets (i.e., of the assets of Qualigen and all its Affiliates considered together).
- 1.24. <u>Serious Incident</u> shall mean an incident involving the Products, which is reportable to a Competent Authority and as defined in Section 5 of Annex III of the IVD Directive, and the European Commission Medical Devices Vigilance Guidelines 2.12-1 or such other Guidelines as may be issued from time to time.
- 1.25. <u>Territory</u> shall mean worldwide excluding Qualigen Retained Customers.
- 1.26. Third Party shall mean a party other than Sekisui or Qualigen or any Affiliate of Sekisui or Qualigen.

2. Appointment and Term

- 2.1. Appointment. Qualigen hereby appoints Sekisui, and Sekisui accepts the appointment to act on an exclusive basis pursuant to the terms and conditions of this Agreement, as a distributor for the sale of the Products in the Territory. Sekisui shall be permitted to appoint sub-distributors in the Territory (including any current Qualigen distributors) with the approval of Qualigen, not to be unreasonably withheld or delayed. Sekisui shall purchase the Products exclusively from Qualigen, and Qualigen shall supply the Products exclusively to Sekisui, in each case for the Territory. Qualigen shall assign to Sekisui Qualigen's agreements with Qualigen's current distributors (such that such current Qualigen distributors shall become Sekisui subdistributors), each of which is set forth on Schedule 2.1 hereto; if any of such agreements do not allow such assignment and the current distributor declines to consent to such an assignment to Sekisui, Qualigen shall (if Sekisui so requests) act pursuant to such agreement to terminate such agreement.
- 2.2. Term. The initial term of this Agreement shall commence on the Effective Date and shall continue for a period of five (5) years unless earlier terminated pursuant to Section 14 hereof (the "Term"). The initial term of this Agreement and any renewal term thereof shall be automatically extended at the end of the initial term and any renewal term thereof for an additional one (1) year period unless either Party notifies the other Party not less than six (6) months before the end of the then in effect term of its intent to terminate this Agreement. References in this Agreement to "Term" shall be deemed to include the initial five (5) year term as well as a reduction or extension of that time period that may occur as a result of the provision of this Section 0 or the provisions of Section 14.

- 2.3. <u>Customer Product Rentals</u>. All instruments placed with customers under a rental program during the Term shall be owned by Sekisui ("<u>Sekisui Instruments</u>"), while Qualigen shall retain ownership of instruments placed with customers under a rental program before the execution of this Agreement ("<u>Qualigen Instruments</u>") and any instruments (including FastPack® 2.0) placed by Qualigen to the Qualigen Retained Customers.
- 2.4. <u>Qualigen Retained Customers.</u> In addition to the retention of the Qualigen Instruments, Qualigen shall be permitted to continue selling the existing Qualigen products directly to the Qualigen Retained Customers. However, Qualigen shall not engage any distributors (whether exclusive or non-exclusive) other than Sekisui for the Qualigen Retained Customers. Sekisui shall not, and shall cause its subdistributors not to, market, rent or sell any Products to the Qualigen Retained Customers.

3. Supply; Orders

- 3.1. Supply. Qualigen shall supply Sekisui with all of Sekisui's commercial requirements for the Product in the Applicable Markets. All Products supplied by Qualigen to Sekisui shall have on the date of shipment by Qualigen a shelf life of not less than a minimum three (3) month shelf life for products shipped within the United States and not less than a minimum four (4) month shelf life for products shipped outside the United States (or such longer shelf-life as may be mutually agreed by Qualigen and a Sekisui customer with respect to a specific customer order). Qualigen shall use reasonable efforts to assure that the Products, as manufactured by Qualigen, conform to the applicable product specifications and requirements of the Regulatory Authorities in, and are manufactured in accordance with all Regulatory Approvals, laws and regulations applicable to the Products in the Applicable Markets. Qualigen shall maintain the necessary records to comply with all Regulatory Approvals and other applicable rules and regulations in the Applicable Markets.
- 3.2. Forecast. Sekisui shall submit to Qualigen by the fifth day of each calendar month a rolling twelve (12) month (month-by-month) forecast of the quantity of each Product that Sekisui anticipates selling during the following twelve (12) months (the "Forecast"). As to Reagent Kits each respective Forecast shall represent reasonable estimates to be used for planning and inventory stocking purposes as indicated in Exhibit D, and shall not be binding on Sekisui; provided, however, that as to Instruments the quantities for each of the first three months of each respective Forecast shall be deemed to constitute and shall constitute firm, binding orders for such quantities of Instruments in such respective months (but in no event for a lesser quantity for a month than the quantity for such month which, pursuant to an earlier Forecast, had already become a firm, binding order).

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- 3.3. Orders. Orders shall be processed as set forth in Exhibit F. Each purchase order shall be governed by the terms and conditions of this Agreement (regardless of whether such purchase order references the Agreement). Sekisui shall be allowed to, for convenience, document its purchase orders by using Sekisui's standard form of purchase order, but in no event shall anything in such purchase order vary, contradict or augment the terms of this Agreement, and the parties agree that any "preprinted" provisions in the purchase orders shall, if they are inconsistent with or additive to this Agreement, simply be disregarded and shall be deemed inapplicable and/or rejected (regardless of acceptance, performance or apparent acquiescence, none of which shall constitute or be construed to constitute Qualigen's or Sekisui's consent to or recognition of terms, conditions or provisions that are different from or are not contained in this Agreement), unless in a separate and nonboilerplate agreement which expressly identifies and waives this Section 3.3 Qualigen agrees to accept such "preprinted" term. Similarly, Qualigen shall be allowed to, for convenience, document its acknowledgements, confirmations and similar instruments by using Qualigen's standard form of acknowledgement, confirmation and similar instruments, but in no event shall anything in such acknowledgements, confirmations and similar instruments vary, contradict or augment the terms of this Agreement, and the Parties agree that any "preprinted" provisions in the acknowledgements, confirmations and similar instruments shall, if they are inconsistent with or additive to this Agreement, simply be disregarded and be deemed inapplicable and/or rejected (regardless of acceptance, performance or apparent acquiescence, none of which shall constitute or be construed to constitute Qualigen's or Sekisui's consent to or recognition of terms, conditions or provisions that are different from or are not contained in this Agreement), unless in a separate and nonboilerplate agreement which expressly identifies and waives this Section 3.3 Sekisui agrees to accept such "preprinted" term.
- 3.4. Product Records. Qualigen shall test or cause to be tested each lot of Product purchased by Sekisui. Qualigen shall provide Sekisui with copies of any Product test records requested or Sekisui may audit Qualigen to review the Product test records.
- 3.5. No Alterations or Mishandling. Sekisui shall not, and shall also cause its subdistributors not to, alter or modify (or add to or subtract from) in any way any Products delivered by Qualigen hereunder. Sekisui shall, and shall also cause its subdistributors to, handle, store and transport the Products in accordance with Qualigen's guidelines and shall not, and shall also cause its subdistributors not to, subject such Products to abuse, mishandling or unusual physical, thermal, chemical or electrical stress or sell any Product after its expiration date.
- 3.6. Packaging and Labeling. The Products shall be delivered by Qualigen, and Sekisui shall cause the Products to be delivered to end users, in Qualigen packaging and with Qualigen labeling, all as intended to be received by the end user. Such packaging and labeling (and the Products themselves) (and "product inserts," which Qualigen may provide online so long as it is done in compliance with all legal requirements of the applicable jurisdiction) shall include such Qualigen trade names, brand names, trademarks and logos (and patent notices) as Qualigen shall select and with such size, colors, positioning and prominence as Qualigen shall select in its sole discretion, and shall not include any Sekisui trade names, brand names, trademarks or logos (except that, if so required by applicable law, Qualigen shall include a statement that Sekisui is the distributor and/or that Sekisui is the importer). Sekisui shall not imprint or affix any of its (or any non-Qualigen person's) trade names, brand names, trademarks or logos to any Product or its packaging or labeling, and shall also cause its subdistributors not to do so. Sekisui shall not deface, cover, obscure, erase, alter or remove any Qualigen trade names, brand names, trademarks or logos (or patent notices) applied by Qualigen to the Products or to the Products' packaging or labeling, and shall also cause its subdistributors not to do so.

4. Price, Shipment and Payment

- 4.1. Price. The price that Sekisui shall pay for the Products shall be established separately for the Reagent Kits and for the products other than Reagent Kits. The price that Sekisui shall pay for the Reagent Kits Products shall be based upon a formula intended to ensure that Sekisui will receive 90% of the total Available Margin for all Products during the first 12 months of this Agreement, 70% of the total Available Margin for all Products during months 13-24 of this Agreement, and 65% of the total Available Margin for all Products thereafter. Accordingly, the prices (established separately for the Reagent Kits and for the products other than Reagent Kits) to be paid by Sekisui for the Products shall be fixed (subject to a later lookback true up) for each respective prospective six month period in the manner set forth in Exhibit D. The initial prices Sekisui agrees to pay for the respective Products for the first such prospective "six month period" (in this instance actually a five month period: May-September 2016) shall be fixed (subject to a later lookback true up) in the manner set forth in Exhibit D. Thereafter such prices shall be revisited and recalculated (prospectively) every six months in the manner set forth in Exhibit D (i.e., for purposes of such calculations for establishing the new prospective prices for the reagent products, the applicable Net Revenue, COGS and Available Margin shall be the Net Revenue, COGS and Available Margin for the applicable historical 6-month period as defined in Exhibit D). In addition, on a semi-annual basis, such amount shall be reviewed based on the actual Net Revenue, COGS and Available Margin for the 6 months then ended. In the event that such review results in a difference from the intended share of Available Margin between the Parties as contemplated above, the Parties shall make a true up payment between them in order to compensate for such overpayment or shortfall, all as provided in Exhibit D. Any true-up payments shall be paid by the applicable Party within 30 days of the receipt of an invoice for the agreed to true up amount. Sekisui shall set the customer selling prices in good faith and in a commercially reasonable manner.
- 4.2. Shipment. The shipment of orders to Sekisui's customers shall be subject to the ability of Sekisui and Qualigen to obtain all required licenses and permits then in effect. Qualigen agrees (i) to assist Sekisui in obtaining such required licenses or permits, (ii) to comply with all Regulatory Approvals in, including all approvals and licenses necessary to import the Product into, the Applicable Markets, and (iii) to maintain the necessary records to comply with all Regulatory Approvals and other applicable rules and regulations in the Applicable Markets. Qualigen shall not be subject to unreasonable requests for assistance in applying for Regulatory Approvals such as providing original or proprietary documents, submitting free product samples or extensive translations. All Product ordered by Sekisui's customers shall be suitably packed for shipment and storage by Qualigen on behalf of Sekisui in accordance with Qualigen's standard commercial shipping practices. Each order shall be shipped as designated by Sekisui's customers in the order. If the carrier noted on the Sekisui customer's purchase order is not available, or if the purchase order does not designate a carrier, then Sekisui shall select the mode of shipment or, if Sekisui does not select the mode of shipment, Qualigen shall select the mode of shipment. Qualigen's responsibility shall be to deposit the ordered goods with the designated carrier within the shipping periods specified, and Qualigen shall not be liable for late delivery if so accomplished.
- 4.3. <u>Delivery Terms.</u> Qualigen shall deliver Products ordered by Sekisui, FCA (Incoterms 2010) Qualigen's facility in Carlsbad, California. Title to Products ordered by Sekisui shall pass to Sekisui upon delivery to the designated Sekisui storeroom at Qualigen's facility. While held at the Sekisui storeroom, any physical inventory loss will be the responsibility of Qualigen. Sekisui undertakes that all Sekisui inventory of Products shall be kept at such designated Sekisui storeroom at Qualigen's facility, until resale to Sekisui's customers.

- 4.4. <u>Sales Expense</u>; <u>Business Plan</u>. For the avoidance of doubt, Sekisui shall be responsible for all sales and related sales expense except for Qualigen Retained Customers. The Business Plan sets forth Sekisui's plans for the sale and distribution of the Products, including target budget and resource allocations for the marketing and sales of the Products and estimated forecasts of sales to customers. Sekisui shall in good faith use commercially reasonable efforts, in conformance with good commercial practice and standards, government regulations and other applicable requirements, to promote, market and sell the Products, to execute the Business Plan and to achieve its objectives. Except as set forth in <u>Section 3.2</u>, such forecasts and budgets are intended for guidance purposes only and are not binding obligations. Sekisui shall be responsible for bad debt (customer nonpayment) and credit card merchant fees and expenses.
- 4.5. <u>Financing Payments; Development Plan</u>. In addition to the payments for the purchase of Products set forth in <u>Section 4.1</u> above, in connection with this Agreement and in furtherance of the Development Plan, Sekisui shall provide to Qualigen up to \$6,200,000 of financing in accordance with the timing and other provisions of the Development Plan and the achievement of the applicable milestones set forth therein (the "<u>Financing Payments</u>"). All such Financing Payments shall be used in accordance with the Development Plan and shall be non-refundable once paid, other than as set off in connection with a Sale Transaction as further described below. Time is of the essence for the payment by Sekisui of the resulting Financing Payments upon confirmation of achievement by Qualigen of the respective Development Plan milestones as set forth in Section 6.2 and the Development Plan.
- 4.6. Personnel Matters. Sekisui shall offer employment to four Qualigen sales representatives to become employees of Sekisui with primary responsibility for the sale of the Products, and Qualigen hereby consents to and permits such employment. Such offers of employment are subject to Sekisui's employment policies, including the successful completion of customary background checks, and are not a guarantee of ongoing employment. Upon the expiration or termination of the Term (other than in connection with a Sale Transaction in which Sekisui acquires Qualigen), Sekisui shall cooperate in permitting Qualigen to offer to rehire any Sekisui sales representatives who are primarily responsible for selling the Products. A sales person "primarily responsible for selling the Products" is one that spends more than half of his or her time and receives more than half of his or her commission based compensation based on sales of the Products.
- 4.7. <u>Invoice Terms</u>. Sekisui shall pay for each Product sold by Qualigen within 30 days after Sekisui has received the applicable invoice from Qualigen.
- 4.8. Marketing Claims. Sekisui covenants to Qualigen that Sekisui will not make any written or oral representation or marketing claim (either formal or informal) about any Product's capabilities or characteristics other than those representations and claims that are fully and directly supported by factual materials provided by Qualigen to Sekisui. Sekisui shall not make any false or misleading representations to customers or others regarding Qualigen or the Products. Sekisui shall not make any representations, warranties or guarantees with respect to the specifications, features or capabilities of the Products that are not contained within Qualigen's documentation accompanying the Products or Qualigen's literature describing the Products, including Qualigen's standard limited warranty and disclaimers.

- 4.9. Taxes. Qualigen's stated Product prices do not include any foreign, federal, state or local sales taxes that may be applicable to the Products, but in the event that such sales taxes are applicable and Qualigen has the legal obligation to collect such sales taxes (or are sales taxes imposed on a seller), Qualigen shall be entitled to add to its invoice the amount of such sales taxes and Sekisui shall pay such amount unless Sekisui provides Qualigen with a valid tax exemption certificate authorized by the appropriate taxing authority. As between the Parties, all customs duties shall be the responsibility of Sekisui, and all duty expenses will be included as an element of COGS as referenced in Exhibit A and will be included as part of the Actual Margin True-Up as defined in Exhibit D. The parties agree to cooperate with one another and use reasonable efforts to avoid or reduce tax withholding or similar obligations in respect of Financing Payments, Product purchase payments, and other payments made by Sekisui to Qualigen under this Agreement. To the extent Sekisui is required to withhold taxes on any payment to Qualigen, Sekisui shall pay the amounts of such taxes to the proper governmental authority in a timely manner and promptly transmit to Qualigen evidence of such payment and/or an official tax certificate, or such other evidence as Qualigen may reasonably request, to establish that such taxes have been paid. Qualigen shall provide Sekisui any tax forms that may be reasonably necessary in order for Sekisui to not withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by applicable law, of withholding taxes, value added taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or value added tax.
 - 4.9.1. Medical Device Tax. The party responsible for paying any applicable medical device excise tax pursuant to Section 4191 of the U.S. Internal Revenue Code or any successor thereto will be as determined under such tax provisions. If any, such medical device excise tax will be treated as a cost element to be included in COGS as referenced in Exhibit A.
- 4.10. Interest. Accrual and payment of interest shall not be deemed to excuse or cure breaches of contract arising from late payment or nonpayment. Cumulative with and not exclusive of any and all other available remedies, payments that are more than 30 days past due hereunder, and which are not otherwise subject to a good faith dispute, shall accrue interest, from the due date until paid, at an annual rate equal to the prime rate, as reported in The Wall Street Journal, Eastern U.S. Edition, on the date such payment is due, plus an additional 200 basis points (2%).
- 4.11. <u>Currency</u>. All invoices under this Agreement shall be paid in United States dollars.

5. Manufacturing and Quality Assurance

- 5.1. Manufacturing Conformance. Qualigen represents and warrants that it shall manufacture all Products in accordance with the applicable product specifications and all applicable federal, state and local laws, regulations, and guidelines. Qualigen represents and warrants that no Product delivered by Qualigen under this Agreement will be adulterated or misbranded within the meaning of 21 U.S.C. Sections 351-352, or within the meaning of any other applicable law as such laws are constituted and effective at the time of such shipment or delivery. Qualigen shall maintain appropriate certification status and compliance with the FDA's Quality System Regulation, the Directive of 27 October 1998 on In Vitro Diagnostic Medical Devices (IVDD) and/or all other applicable regulations. Upon request, Qualigen shall furnish to Sekisui any such information required to enable Sekisui to comply with all applicable regulations and standards that pertain to distributors for the Products.
- 5.2. <u>Manufacturing Changes</u>. Qualigen shall notify Sekisui in writing no less than 3 months prior to any material changes which affect (i) the form, fit or function of any Products, or (ii) the labeling or regulatory status of the Products in any of the Applicable Markets.
- 5.3. Manufacturing Site. During the Term, Qualigen shall manufacture all Products using Qualigen's facilities located in Carlsbad, California. Qualigen shall give at least six (6) months prior written notice to Sekisui of any proposed relocation of the manufacturing of any Product. Any new facility proposed to be used by Qualigen in manufacturing any Product shall be subject to a new and separate audit by Sekisui personnel in accordance with Quality Systems Regulations (QSR), as well as ISO 13485.

- 5.4. Approved Supplier. It is acknowledged that Qualigen is an "Approved Supplier" as to Products manufactured at Qualigen's Carlsbad, California facility. As part of Sekisui's supplier approval program, Sekisui will have the option to perform an audit (applying Sekisui's standard supplier criteria for qualification as an "Approved Supplier") at Qualigen's Carlsbad, California manufacturing facility annually and at each relocated manufacturing facility at which Qualigen will manufacture the Products within sixty (60) days of Qualigen's notice to Sekisui of the relocation of such manufacturing facility. Within thirty (30) days after the completion of an audit, Sekisui shall inform Qualigen in writing of the results of such audit. If Qualigen does not pass such audit and the reasons for such failure can be remedied within a reasonable period of time (which shall not be less than sixty (60) days), then Sekisui shall provide Qualigen with a list of proposed remedial action items and a proposed timeframe within which to accomplish such action items. If Qualigen does not pass such audit and the reasons for such failure cannot be remedied within a reasonable period of time or Qualigen fails or elects not to complete any remedial actions reasonably suggested by Sekisui, then Sekisui's sole and exclusive remedy shall be to terminate this Agreement in accordance with the provisions of Section 14 of this Agreement, with such termination to be effective upon receipt of a termination notice by Qualigen sent by Sekisui at any time after the sixty day remedy period described in this <u>Section 5.4</u> has passed. As scheduled, Sekisui may perform an audit during reasonable business hours to confirm ongoing compliance with the Quality System Regulations and confirm adequate process controls. Sekisui shall notify Qualigen at least one month in advance of a planned audit and Qualigen shall make reasonable efforts to accommodate the desired schedule. Sekisui further agrees that any information obtained from Qualigen or its Affiliates or agents in connection with any such audit shall be deemed Qualigen Confidential Information and subject to the provisions of Section 13 of this Agreement.
- 5.5. Technical Support. Qualigen shall provide to Sekisui and its customers commercially reasonable technical support (i) for the promotion, sale, after-sale service and support of Products sold in the Territory pursuant to this Agreement; (ii) in connection with any customer inquiries or complaints and (iii) in connection with interactions with the Regulatory Authorities. Qualigen shall be responsible for the management and costs of all such service. Qualigen shall be entitled to charge customers for, and to retain, commercially reasonable fees for service and support of out-of-warranty Instruments.
- 5.6. <u>Trade Compliance</u>. Upon execution of this Agreement, Qualigen, with Sekisui's assistance, shall provide to Sekisui the Export Commodity Control Number (ECCN) and Harmonized Tariff Codes (HTS), Country of Origin (COO), Trade Agreement Act (TAA) and Buy America Act (BAA) determinations or other relevant information for any Product supplied to Sekisui pursuant to this Agreement.

5.7. REACH and RoHS Compliance. If any Product supplied by Qualigen is manufactured in or imported into the European Union, Qualigen shall, at its sole cost and expense, comply with applicable requirements under Regulation (EC) 1907/2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals ("REACH"), and Directive 2011/65/EC concerning the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment ("RoHS"), each as may be amended from time to time. Upon reasonable request, Qualigen shall provide reasonable proof of compliance with REACH and RoHS, including any registration, communication, safety data sheet, chemical report, or technical or other supporting documentation. Qualigen represents and certifies that it has gathered, or will gather, the compliance documentation information with appropriate methods to ensure its accuracy and that such information is true, correct and complete to the best of its knowledge and belief as of the date that Qualigen provides its declaration. Qualigen acknowledges that Sekisui will rely on this certification in determining the compliance of the Products with REACH and RoHS. Sekisui acknowledges that Qualigen may have relied on information provided by Third Parties in completing its compliance review, and that Qualigen may not have independently verified such information, provided that Qualigen has conducted appropriate due diligence and its reliance on such Third Parties is reasonable and that Qualigen has no reason to question the reliability of such Third Parties' information and certifications. Qualigen-controlled manufacturing processes shall be in compliance with REACH and RoHS in that they do not add any substances to the resultant Product to the extent currently prohibited by REACH and RoHS. Based upon the information supplied by Third Parties along with Qualigen's knowledge of its own manufacturing processes, Qualigen will certify that, to the best of its knowledge, each of the Products identified in any certification is in compliance with the substance restrictions of REACH and RoHS or is exempt from REACH and RoHS, unless Qualigen has advised Sekisui in advance that any Product or any material incorporated into, or used to produce, any Product ("Material") do not comply with REACH or RoHS. Qualigen has processes in place to ensure proper control of Materials declarations, and segregation of ROHScompliant and non-compliant Material within Qualigen's manufacturing processes. Qualigen shall maintain REACH and RoHS records and compliance documentation for the amount of time required under REACH or RoHS. Qualigen and Sekisui agree to promptly notify each other if either learns of any developments relating to REACH or RoHS that might impact Sekisui's ability to use any Product or place it on the market in the European Union. Qualigen agrees to notify Sekisui promptly: (1) if there are changes to the REACH registration relevant to the Product; (2) if any of the substances, preparations, or substances in articles purchased by Sekisui meet the criteria referred to in Art. 57 of REACH or are on the candidate list for eventual inclusion in Annex XIV of REACH; (3) if a REACH registration has been rejected by the European Chemicals Agency (ECHA); or (4) of any other development relating to any Product's status under REACH or RoHS where such development might affect Sekisui's ability to use any Product or to place it on the market in the European Union.

6. <u>Management Committee</u>

6.1. Management Committee. Each Party shall, within five (5) business days after the Effective Date, designate four (4) representatives, at least one of whom shall have sufficient authority to enable him or her to make decisions on behalf of the Party he or she represents, to comprise the management committee (the "Management Committee") overseeing the implementation and revision of the Business Plan and Development Plan. Each Party shall (A) promptly notify the other Party in writing of any change in its appointed representatives; and (B) be solely responsible for all travel-related costs and expenses for its respective representatives to attend meetings or to otherwise participate in, or carry out its obligations under, the Management Committee. The Qualigen representatives on the Management Committee shall initially be Paul Rosinack, Michael Poirier, Chris Lotz and Shishir Sinha. The Sekisui representatives on the Management Committee shall initially be Bob Schruender, Lee Lipski, Alan Bauer and Tom Cummins.

- 6.2. Meetings. The Management Committee shall be responsible for: (A) meeting quarterly unless otherwise specified in writing by the Parties (in person or via phone/webmeeting) to monitor, review, and discuss the progress under the Business Plan and Development Plan; (B) resolving disputes or disagreements between the Parties with respect to the implementation of the Business Plan and Development Plan; (C) coordinating the exchange of information between the Parties in connection with the activities contemplated by the Business Plan, the Development Plan and this Agreement; (D) confirming the achievement of any milestones resulting in an additional payment under the Development Plan, and (E) carrying out any other responsibilities as are set forth in this Agreement, or that are assigned to it by the Parties. Each Party may invite other representatives of such Party to join any management committee meeting if it would be useful to have their input for a particular agenda topic. For the avoidance of doubt, the Management Committee shall not have the power to amend this Agreement or to waive a Party's compliance with the terms and conditions contained in this Agreement.
- 6.3. <u>R&D Subcommittee</u>. The Management Committee shall also organize research and development review meetings, which may include members of the Management Committee as well as other representatives of either Party, meeting monthly unless otherwise specified in writing by the Parties (in person or via phone/webmeeting) to monitor, review, and discuss the progress of the development of future Products and manufacturing capability in accordance with the Development Plan, including a review of all applicable data and an assessment of resources.
- 6.4. Quality Subcommittee. The Management Committee may also organize quality review meetings, which may include members of the Management Committee as well as other representatives of either Party, meeting quarterly unless otherwise specified in writing by the Parties (in person or via phone/webmeeting) to monitor, review, and discuss various aspects of Qualigen's quality assurance programs, including a one day Quality program management review and one day of internal auditing of quality matters.
- 6.5. Other Subcommittees. The Management Committee may establish other subcommittees from time to time as it deems appropriate.

7. Information Rights

- 7.1. <u>Development Plan.</u> Qualigen shall maintain complete and accurate records and data regarding the work completed under the Development Plan. Representatives of Sekisui may, upon reasonable advance notice, (a) visit the facilities where the Development Plan activities are being performed, and (b) consult with any such Qualigen personnel performing such activities.
- 7.2. <u>Delivery of Financial Statements and Other Information</u>. Qualigen shall deliver to Sekisui:
 - 7.2.1. as soon as practicable, but in any event within one-hundred eighty (180) days after the end of each fiscal year of Qualigen (i) a balance sheet as of the end of such year, (ii) a statement of income for such year, and (iii) a comparison between (x) the actual amounts as of and for such fiscal year and (y) the comparable amounts for the prior year and as included in Qualigen's budget for such year, with an explanation of any material differences between such amounts, all such financial statements in the form of a compilation prepared by independent public accountants;
 - 7.2.2. as soon as practicable, but in any event within thirty (30) days after the end of each quarter of each fiscal year of Qualigen, an unaudited statement of income for such fiscal quarter, and an unaudited balance sheet as of the end of such fiscal quarter, all prepared in accordance with GAAP (except that such financial statements may (i) be subject to normal year-end audit adjustments; and (ii) not contain all notes thereto that may be required in accordance with GAAP);

- 7.2.3. as soon as practicable, but in any event within thirty (30) days of the end of each month, an unaudited income statement for such month, and an unaudited balance sheet as of the end of such month, all prepared in accordance with GAAP (except that such financial statements may (i) be subject to normal year-end audit adjustments and (ii) not contain all notes thereto that may be required in accordance with GAAP);
- 7.2.4. as soon as practicable, but in any event within forty five (45) days after the end of each quarter of each fiscal year of Qualigen, a progress report setting forth Qualigen's business results and progress against the Development Plan; and
- 7.2.5. as soon as practicable, but in any event no later than sixty (60) days before the end of each fiscal year, a budget and business plan for the next fiscal year, prepared on a monthly basis, including balance sheets and income statements.

8. <u>Intellectual Property Rights</u>

- 8.1. <u>Background Intellectual Property Rights</u>. Each Party shall own and retain all right, title and interest in and to all of its Intellectual Property Rights created before or independently from the Development Plan and this Agreement ("<u>Qualigen Background IP</u>" and "<u>Sekisui Background IP</u>," respectively).
- 8.2. Development Plan Intellectual Property Rights. Except as set forth in this Section, Qualigen shall own all right, title and interest in and to all Intellectual Property Rights (if any) resulting from Qualigen's activities under the Development Plan ("Development IP"), but excluding all Sekisui Background IP. In the event that any Development IP is jointly invented by the Parties in accordance with applicable intellectual property laws, then the ownership of such Development IP that has been jointly invented shall be co-owned by the Parties in accordance with such applicable intellectual property laws; provided, however, that neither Party shall have any duty or obligation to account to the other for any use or exploitation of such jointly invented Development IP and as between the Parties, each Party shall be entitled to retain any and all benefit, financial or otherwise, derived by such Party from such jointly invented Development IP.
- 8.3. Prosecution and Enforcement of Development IP. Except as set forth below, Qualigen shall have the sole right to prepare, file applications on and registrations for, prosecute, obtain, maintain, defend and enforce all Intellectual Property Rights in the Development IP in such manner as Qualigen deems appropriate in its sole discretion, including incurring and paying all expenses required for such purposes. Notwithstanding the foregoing, Qualigen shall use commercially reasonable efforts to preserve, obtain and maintain in the Applicable Markets all material Development IP and Qualigen Background IP related to or used in connection with the development and manufacturing of the Products as well as any improvements or alternative embodiments thereof, and shall consult Sekisui before determining not to pursue in any Applicable Market any particular Intellectual Property Rights related to any product development efforts covered by the Development Plan. In the event that Qualigen elects not to prosecute or maintain in a particular Applicable Market country any Patent Rights in the jointly developed Development IP (the "Abandoned Joint IP"), Sekisui may elect to prosecute such Abandoned Joint IP in such particular Applicable Market country, in which case the Patent Rights for such Abandoned Joint IP in such particular in Applicable Market country shall be owned solely by Sekisui.

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8.4. Marks. During and after the Term, neither Party shall register, use or claim ownership or other rights in any logo, trade name, brand name or trademark of the other Party in existence during the Term (nor any logo, trade name, brand name or trademark confusingly similar to any logo, trade name, brand name or trademark of the other Party in existence during the Term), nor assist anyone else to do so, nor make or assist in any challenge to any logo, trade name, brand name or trademark of the other Party in existence during the Term.

9. <u>Sale Transaction</u>

- 9.1. Exclusivity Period. The parties anticipate that they will entertain a potential acquisition of Qualigen by Sekisui during 2018 on terms to be mutually agreed. Accordingly, Qualigen hereby agrees that during the Exclusivity Period, Qualigen shall not, directly or indirectly, through its affiliates, agents, stockholders, officers, directors or otherwise solicit, initiate, participate in discussions or negotiations or otherwise cooperate in any way with, or provide any information to any person, entity or group other than Sekisui concerning a Sale Transaction. In the event that Qualigen nonetheless receives an unsolicited offer to engage in a Sale Transaction during such Exclusivity Period, Qualigen may engage with such party to the extent legally required to comply with its fiduciary duties, so long as Qualigen (i) promptly communicates to Sekisui the material terms of any proposal or offer or request for information which it may receive in respect of any such proposed Sale Transaction, including the purchase price, form and timing of consideration and the identity of the acquirer, and (ii) complies with Sekisui's Right of First Refusal (as defined below).
- 9.2. Negotiation Period. No later than July 1, 2018 (and sooner upon Sekisui's written request at any time before July 1, 2018), the parties shall engage in good faith negotiations for a period of up to 6 months (the "Negotiation Period") with respect to a potential acquisition by Sekisui of Qualigen. During the Negotiation Period, Qualigen shall provide to Sekisui all due diligence information reasonably requested by Sekisui so that it may make an informed offer to acquire Qualigen. Any Financing Payments made by Sekisui will be credited against any such Sale Transaction agreed to between Sekisui and Qualigen. If the parties do not mutually agree to the terms of such potential acquisition within the Negotiation Period then the Exclusivity Period shall end and, subject to Sekisui's Right of First Refusal, Qualigen shall be free to negotiate the terms of a Sale Transaction with any Third Party.
- 9.3. Right of First Refusal. During the Term, Sekisui shall have a right of first refusal to match the terms of any arms length, bona fide proposed Sale Transaction with a Third Party ("Sekisui's Right of First Refusal"). Qualigen shall provide Sekisui with at least 30 days prior written notice and access to all due diligence materials provided to any potential acquirer, such 30 day period to commence upon the notification to Sekisui that Qualigen's board of directors has approved such Proposed Sale Transaction (as set forth in a term sheet or draft definitive agreement provided to Sekisui), subject to Sekisui's Right of First Refusal. At any time during such 30 day period, Sekisui may elect to match the terms of such proposal. Sekisui will be credited in any such proposal by the cumulative amount of all Financing Payments made to date. For example, if a Third Party offers to acquire Qualigen for \$50,000,000 and Sekisui has funded the full \$6,200,000 of Financing Payments, Sekisui's Right of First Refusal to match the proposed transaction would be a price of \$43,800,000. In the event that Sekisui elects not to move forward with such proposal for a Sale Transaction, Qualigen shall have a period of 120 days to consummate a Sale Transaction on the same terms as provided to Sekisui. If a Sale Transaction has not been consummated within such 120 days period, any Sale Transaction must once again comply with the provisions of this Section 9.3.

- 9.4. Penalty for Breach. In the event of any breach of Sections 9.1 through 9.3, including without limitation, any actions by stockholders of Qualigen that result in a Sale Transaction without complying with Sections 9.1 through 9.3 above, or otherwise hinder the intent and purpose of the provisions of Sections 9.1 through 9.3 above, in addition to any other remedies available to Sekisui under the terms of this Agreement, including the right to specific performance and other equitable remedies, Sekisui shall be entitled to liquidated damages in the amount of three times any and all Financing Payments made to date. For the avoidance of doubt, this clause does not apply to a failure of the stockholders of Qualigen to approve a Sale Transaction proposed by Sekisui, so long as such stockholders did not approve a Sale Transaction on the same terms with a Third Party during the Term.
- 9.5. Molecular Clinical Diagnostics. In furtherance of the foregoing, during the Exclusivity Period, Qualigen shall, in consultation with Sekisui, take commercially reasonable steps to seek to regain any rights in any Qualigen molecular clinical diagnostic product technology that Qualigen has previously granted to Gen-Probe, Hologic, or any of their affiliates.

10. Representations and Warranties

- 10.1. <u>By Qualigen</u>. Qualigen hereby represents, warrants and covenants that:
 - (a) Qualigen has the full right, power and corporate authority to enter into this Agreement, and to make the promises set forth in this Agreement, and to grant the rights herein, and that there are no outstanding agreements, assignments or encumbrances in existence inconsistent with the provisions of this Agreement and that this Agreement is enforceable against Qualigen.
 - (b) The Products supplied to Sekisui under this Agreement shall conform to the applicable product specifications and shall not infringe upon the patents or proprietary rights of any Third Party. To the extent any Third Party owns any patents or proprietary rights relating to the use, sale, or manufacture of a Product in the Territory, Qualigen represents and warrants that it has sufficient valid rights from such Third Party under which (1) Qualigen may manufacture and sell such Product to Sekisui, and (2) Sekisui may use and sell such Products royalty free in the Territory.
 - (c) As of the Effective Date, Qualigen has not been notified with respect to, and to Qualigen's best knowledge there is no patent infringement action pending before any court or governmental agency or other tribunal relating to any Product.
 - (d) As of the Effective Date, Qualigen has not been notified with respect to, and to Qualigen's best knowledge no material actions are pending before any court or governmental agency or other tribunal relating to any Product.
 - (e) All Product delivered to Sekisui or Sekisui's customers pursuant to this Agreement, at the time of such delivery, shall not be adulterated or misbranded within the meaning of any applicable law, regulation or guideline effective at the time of delivery and shall not be an article which may not be introduced into interstate commerce under any applicable law, regulation or guideline.

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(f) The manufacturing facilities and processes utilized for the manufacture of each Product shall comply with applicable FDA regulations including, without limitation, applicable current Good Manufacturing Practices as described in 21 CFR 820.

Qualigen does not represent, warrant or covenant that the Development Plan will be successfully accomplished, that the Development Plan will produce any particular results or any favorable results, that the Development Plan will result in any Development IP (or in any valuable Development IP), that the Products (if any) arising from the Development Plan can ever receive Regulatory Approvals or be successfully or profitably commercialized, or that any other current or future Products can be successfully or profitably commercialized by Sekisui. Moreover, Sekisui acknowledges and accepts the risks inherent in attempting to develop and commercialize any medical product. There is no implied representation that any Products can be successfully developed or commercialized.

Qualigen shall provide to Sekisui and for the benefit of Sekisui's customers of Products a standard commercial written warranty that the Products will be free of defects in materials or workmanship starting from the date the Product has been received by Sekisui's customer and ending after the length of time stated for the applicable Product on Exhibit D hereto (the "User Warranty"). The User Warranty is contingent upon proper use of a Product in the application for which such Product was intended and does not cover Products that were altered or modified (or added to or subtracted from), that were used after the expiration date thereon or that were subjected by the carrier, distributor or the customer to abuse, mishandling or unusual physical, thermal, chemical or electrical stress.

- 10.2. <u>By Sekisui</u>. Sekisui represents, warrants and covenants that:
 - (a) Sekisui has the full right, power and corporate authority to enter into this Agreement and to make the promises set forth in this Agreement and that there are no outstanding agreements, assignments or encumbrances in existence inconsistent with the provisions of this Agreement and that this Agreement is enforceable against Sekisui.
 - (b) As of the Effective Date, Sekisui has not been notified in writing with respect to, nor is there, to Sekisui's best knowledge, any patent infringement action pending before any court or governmental agency or other tribunal relating to Sekisui's sale or distribution of the Products.
 - (c) As of the Effective Date, Sekisui has not been notified in writing with respect to, nor is there, to Sekisui's best knowledge, any action pending preventing Sekisui from selling and distributing the Products in the Territory.
 - (d) Sekisui shall use its commercially reasonable efforts to obtain before distribution of each Product, all licenses, registrations and permits required to enable Sekisui to act as a distributor of such Product in the Territory.
 - (e) Sekisui shall not make, or advise its customers to make, any alterations or modifications to, or any additions to or subtractions from, any Product.
 - (f) Sekisui shall make no attempt to reverse-engineer any Product nor encourage or assist anyone else to do so.

10.3. No Implied Warranties. The express warranties set forth in this Section 10 and elsewhere in this Agreement are provided in lieu of, and EACH PARTY HEREBY DISCLAIMS, all other warranties, express and implied, relating to the subject matter of this Agreement. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY OTHER WARRANTY, EXPRESS, IMPLIED OR STATUTORY, TO THE OTHER PARTY WITH RESPECT TO THE PRODUCTS OR THE OTHER SUBJECT MATTER OF THIS AGREEMENT. THE PARTIES EXPRESSLY EXCLUDE ANY IMPLIED WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. Each Party's representations, warranties and/or covenants under this Agreement are solely for the benefit of the other Party and may be asserted only by the other Party and not by anyone else (including without limitation any customer of the other Party; provide, however, that end user customers may assert the User Warranty against Qualigen).

11. <u>Indemnities</u>

- 11.1. Indemnification by Sekisui. Sekisui shall indemnify, defend and hold harmless Qualigen, and its directors, officers, employees, agents and representatives (collectively, the "Qualigen Indemnitees") from and against any and all claims, suits and proceedings by a Third Party (individually and collectively, "Claims"), and any and all losses, obligations, damages, deficiencies, costs, penalties, liabilities, assessments, judgments, amounts paid in settlement, fines and expenses (including court costs and reasonable fees and expenses of attorneys), incurred in the investigation, defense and/or settlement of any Claims (individually and collectively, "Losses"; it being expressly understood, however, that incidental, special, indirect and consequential damages and lost profits, lost savings and interruptions of business are expressly excluded therefrom and from such defined term): (a) arising out of the negligence or willful misconduct of Sekisui or its directors, officers, employees, agents or representatives in the performance of Sekisui's obligations under this Agreement; or (b) arising out of or in connection with a breach or violation by Sekisui or its subdistributor of any applicable law or a material breach by Sekisui of any of its obligations under this Agreement, including any representations or warranties set forth herein; provided, however, that Sekisui shall have no liability or obligation to any Qualigen Indemnitee for any Claims or Losses to the extent that such Claims or Losses are primarily caused by a Qualigen Indemnitee's breach of applicable law, breach of this Agreement, negligence or willful misconduct.
- 11.2. Indemnification by Qualigen. Qualigen shall indemnify, defend and hold harmless Sekisui and its directors, officers, employees, agents and representatives (collectively, the "Sekisui Indemnitees") from and against any and all Losses incurred in the investigation, defense and/ or settlement of any Claims: (a) related to bodily injury, death or property damage directly caused by any Product which has not been altered or modified (or added to or subtracted from) in any way, has been handled, stored, transported and used in accordance with Qualigen's guidelines and has not been used after its expiration date or subjected to abuse, mishandling or unusual physical, thermal, chemical or electrical stress; (b) arising out of the negligence or willful misconduct of Qualigen or its directors, officers, employees, agents or representatives; (c) arising out of a breach or violation by Qualigen of any applicable law or a material breach by Qualigen of any of its obligations under this Agreement, including any representations or warranties set forth herein; or (d) arising out of any claim that any of the manufacture, marketing, import, offer for sale, sale, or use of any Product infringes upon any patent, proprietary, or intellectual property right of any Third Party in the Territory; provided, however, that Qualigen shall have no liability or obligation to any Sekisui Indemnitee for any Claims or Losses to the extent that such Claims or Losses are primarily caused by a Sekisui Indemnitee's (or any other entity or person within the Sekisui corporate family's) breach of applicable law, breach of this Agreement, negligence or willful misconduct.

- 11.3. Patent Indemnity. Qualigen and Sekisui shall notify each other promptly in writing of any action (and all prior claims relating to such action) brought against Qualigen or Sekisui alleging that the manufacture, marketing, import, offer for sale, sale or use of a Product constitute infringement of the intellectual property rights of a Third Party, and (provided that such a Claim does not arise from Sekisui's noncompliance with Sections 3.6, 8.4, 10.2(b), 10.2(c), 10.2(e) or 10.2(f) of this Agreement (e.g., Sekisui has altered a Product or has used a Sekisui trademark in connection with a Product)) Qualigen agrees to defend Sekisui in such action at its expense and shall pay any costs or damages finally awarded against Sekisui in any such action; provided, that Qualigen shall have had sole control of the defense of any such action and all negotiations for its settlement or compromise and provided further that no settlement or compromise shall be binding on a Party hereto without its prior written consent, which consent shall not be unreasonably withheld. In the event a lawsuit is filed against Sekisui or Qualigen alleging that the manufacture, marketing, import, offer for sale, sale or use of a Product constitute infringement of the intellectual property rights of a Third Party, or Qualigen files an action for declaratory judgment because of a serious threat of such a lawsuit, or if in Qualigen's reasonable business judgment a Product is likely to become the subject of a claim of infringement of a patent or other intellectual property right; then Qualigen may, at its expense, and may request Sekisui's assistance to, attempt to obtain a license to such patent or other intellectual property right.
- 11.4. Indemnification Procedures. The Party or other Indemnitee intending to claim indemnification under this Section 11 (an "Indemnified Party") shall promptly notify the other Party (the "Indemnifying Party") of any Claim in respect of which the Indemnified Party intends to claim such indemnification (provided, that no delay or deficiency on the part of the Indemnified Party in so notifying the Indemnifying Party will relieve the Indemnifying Party of any liability or obligation under this Agreement except to the extent the Indemnifying Party has suffered actual prejudice directly caused by the delay or other deficiency), and the Indemnifying Party shall assume the defense thereof (with counsel selected by the Indemnifying Party and reasonably satisfactory to the Indemnified Party) whether or not such Claim is rightfully brought; provided, however, that an Indemnified Party shall have the right to retain its own counsel and participate in the defense thereof, with the fees and expenses to be paid by the Indemnified Party, unless the Indemnifying Party does not assume the defense or unless a representation of both the Indemnified Party and the Indemnifying Party by the same counsel would be inappropriate due to the actual or potential differing interests between them, in which case the reasonable fees and expenses of counsel retained by the Indemnified Party shall be paid by the Indemnifying Party. Notwithstanding the previous sentence, in no event shall the Indemnifying Party be required to pay for more than one separate counsel no matter the number or circumstances of all Indemnified Parties. If the Indemnifying Party shall fail to timely assume the defense of and reasonably defend such Claim, the Indemnified Party shall have the right to retain or assume control of such defense and the Indemnifying Party shall pay (as incurred and on demand) the fees and expenses of counsel retained by the Indemnified Party and all other expenses of investigation and litigation. The Indemnified Party, and its directors, officers, advisers, agents and employees, shall cooperate fully with the Indemnifying Party and its legal representatives in the investigations of any Claim. The Indemnifying Party shall not be liable for the indemnification of any Claim settled (or resolved by consent to the entry of judgment) without the written consent of the Indemnifying Party. Also, if the Indemnifying Party shall control the defense of any such Claim, the Indemnifying Party shall have the right to settle such Claim; provided, that the Indemnifying Party shall obtain the prior written consent (which shall not be unreasonably withheld or delayed) of the Indemnified Party before entering into any settlement of (or resolving by consent to the entry of judgment upon) such Claim unless (A) there is no finding or admission of any violation of law or any violation of the rights of any person or entity by an Indemnified Party, no requirement that the Indemnified Party admit fault or culpability, and no adverse effect on any other claims that may be made by or against the Indemnified Party and (B) the sole relief provided is monetary damages that are paid in full by the Indemnifying Party and such settlement does not require the Indemnified Party to take (or refrain from taking) any action.

Regardless of who controls the defense, the other Party hereto shall reasonably cooperate in the defense as may be requested. Without limitation, the Party hereto which is not the Indemnifying Party and (if different) the Indemnified Party, and their respective directors, officers, advisers, agents and employees, shall cooperate fully with the Indemnifying Party and its legal representatives in the investigation and defense of any Claim.

- 11.5. Expenses of Enforcement. As the Parties intend complete indemnification, all costs and expenses of enforcing any provision of this Section 11 shall also be reimbursed by the Indemnifying Party except as otherwise set forth in Section 11.4.
- 11.6. <u>Insurance</u>. Qualigen, at its own expense, shall procure and maintain during the Term, insurance policies with the minimum coverages set forth below ("<u>Insurance</u>"). Sekisui shall be named as an additional insured with respect to the Insurance. The Insurance shall be primary for all purposes to other insurance coverage, whether such other insurance is stated to be primary, contributory, excess, contingent or otherwise, without recourse to or contribution from any Sekisui-owned coverage.
 - (a) Commercial General Liability Insurance Combined single limit for bodily and property damage of not less than \$1,000,000 for each occurrence and \$2,000,000 annual aggregate providing:
 - Assault and Battery coverage,
 - Broad form property damage coverage,
 - Broad form contractual liability coverage,
 - Products and completed operations coverage, and
 - Personal and advertising injury coverage.
 - (b) Workers' Compensation and Employer's Liability Insurance With limits of liability for:
 - Workers' compensation as required by statute;
 - Employer's liability for bodily injury by accident: \$500,000 each accident; bodily injury by disease: \$500,000 policy limit; and bodily injury by disease: \$500,000 each employee.

All Qualigen's Insurance shall be placed with an insurer that (a) has an A.M. Best rating of A- or better or (b) is a qualified self-insurance program that is approved by Sekisui. Qualigen shall provide Sekisui, upon request, with written evidence of the Insurance, including where it is provided through qualified self-insurance. Nothing in this Section shall be deemed to limit Qualigen's responsibility to the amounts stated above or to any limits of Qualigen's insurance policies.

12. Regulatory Matters

12.1. Regulatory Approval. Qualigen shall be responsible for maintaining, at its sole cost, the Regulatory Approvals required for the marketing and sale of the Products in the Applicable Markets. Qualigen shall hold in its name all Regulatory Approvals required for the marketing and sale of the Products in a country or region and shall (to the extent commercially reasonable to do so) maintain in good standing all existing Regulatory Approvals. Qualigen and Sekisui shall provide reasonable advice and assistance to each other as may be necessary to maintain required Regulatory Approvals. In addition, Qualigen shall use commercially reasonable efforts to obtain Regulatory Approval for any additional territories upon Sekisui's commercially reasonable request.

- 12.2. <u>Distribution Approvals</u>. Sekisui shall be responsible for seeking, obtaining and maintaining (i) all licenses, registrations and permits (excluding patents) required to be obtained by Sekisui to enable Sekisui to act as a distributor of the Product pursuant to this Agreement, and (ii) all approvals from the Regulatory Authorities regarding marketing and advertising materials to be used by Sekisui to promote the Product. Qualigen shall cooperate with Sekisui in making and maintaining all filings that may be necessary or desirable in connection with obtaining and maintaining any regulatory approvals necessary for Sekisui to act as a distributor of the Product in the Applicable Markets.
- 12.3. <u>Communication With Agencies</u>. In the Applicable Markets, Qualigen shall have responsibility for communications with the Regulatory Authorities concerning any required Regulatory Approvals, approval of Product related marketing and advertising materials, and Product quality matters.
- 12.4. Governmental Warnings. Each Party shall advise the other Party promptly (but in any event within no more than 48 hours) of any warning (including any FDA Form 483), citation, indictment, claim, lawsuit, or proceeding issued or instituted by any federal, state or local governmental entity or agency against the Party, or of any revocation of any license or permit if, and only to the extent that, the manufacture, storage, or handling of the Product, or the marketing, selling, promotion or distribution of the Product, is affected.
- 12.5. Adverse Events, Recalls and Field Corrections. Qualigen shall have responsibility to determine whether any Adverse Events, Recalls or Field Corrections information must be reported to the FDA (under United States law) or any other Regulatory Authorities and Qualigen shall have responsibility to prepare and submit notification of Adverse Events, Recalls and/or Field Corrections to respective Regulatory Authorities for the Products. Qualigen shall provide prompt notice to Sekisui of any Adverse Events, Recalls or Field Corrections, which notice shall in any event be delivered within no more than 3 business days from Qualigen learning of such occurrence.
- 12.6. Complaints. Qualigen shall receive, investigate in a timely manner, and as appropriate, resolve customer complaints in the Territory. If an investigation is needed in response to a complaint or inquiry related to the Product, Qualigen shall perform the investigation and shall bear the cost of such investigation. The documentation of such investigation shall include, but not be limited to, investigation results, cause analysis, corrective and preventative action and health hazard/medical assessment, as appropriate. In the event a Product is returned by a customer for investigation, Qualigen shall ship a replacement Product to the customer. (Provided, that if a request for a return of Product is due to a change of mind over using the Product or the Sekisui customer has overstocked the product, rather than due to a warranty issue, Qualigen need not accept the return or provide any replacement or substitute.) Qualigen shall retain records of all Product related complaints, or Adverse Events for a period of not less than five (5) years beyond the expiration date of the Product or for such longer period as may be required by applicable law. Qualigen shall use commercially reasonable efforts to ensure that all complaints are appropriately closed within 90 days or less from the receipt of such complaint.

- 12.7. Product Recalls. In the event that (i) any Applicable Market governmental agency or authority issues a request or directive or orders that the Products be recalled or retrieved, (ii) an Applicable Market court of competent jurisdiction orders that the Products be recalled or retrieved, or (iii) Qualigen and Sekisui reasonably determine, after mutual consultation, that the Products should be recalled, corrected or retrieved in any particular country or countries, Qualigen and/or Sekisui shall conduct such activity and the parties shall take all appropriate corrective actions and shall execute the steps detailed in the recall strategy. Qualigen shall be responsible for the content of any communication to the customers regarding any Recall or Field Correction. In the event such action results from Sekisui's gross negligence or willful misconduct, Sekisui shall be responsible for the expenses thereof. Otherwise, Qualigen shall be responsible for the expenses of the action. Sekisui and Qualigen shall cooperate fully with one another in conducting any such action. Sekisui shall destroy units of Products lawfully recalled only upon Qualigen's (or any governmental authority's) written instruction to destroy such units of Products, and only then in accordance with Qualigen's procedures and instructions. Otherwise, Sekisui shall return the recalled units of Product to Qualigen in accordance with Qualigen's procedures and instructions after completion of the action.
- 12.8. European Union Vigilance and Canada Mandatory Problem Reporting. In the event that Qualigen receives any Potentially Serious Complaints regarding the Products from a customer located in the European Union or Canada, then Qualigen shall notify Sekisui promptly, but in any event within no more than (3) business days. If Qualigen receives a complaint from any Competent Authority or Health Canada with regard to the Products, Qualigen shall notify Sekisui promptly, but in any event within no more than 48 hours. Qualigen shall have the responsibility to correspond with the Competent Authority or Health Canada, as the Authorized Representative or Regulatory Correspondent, regarding any such complaints. If corrective actions are required, the cost of the corrective action shall be borne by Qualigen up to the extent such complaint is related to the manufacturing of the Products by Qualigen, or some other cause or event attributable to Qualigen, and shall be borne by Sekisui up to the extent such complaint is due to some other cause or event attributable to Sekisui.

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13. Confidential Information; Audit Rights

- 13.1. Confidentiality Obligation. It is contemplated that in the course of the performance of this Agreement each Party may, from time to time, disclose proprietary and confidential information to the other ("Confidential Information"). Except to the extent expressly authorized by this Agreement or otherwise agreed to in writing, during the Term and for a period of five (5) years following the expiration or termination of this Agreement, the receiving Party shall disclose the other Party's Confidential Information only to its own (or its Affiliates') officers, employees, consultants, Third Party service providers, attorneys, accountants, agents, bankers, lenders, prospective lenders and prospective equity investors, and in each case only if and to the extent necessary to carry out their respective responsibilities under this Agreement or in accordance with the exercise of their rights under this Agreement or in accordance with customary permitted practice (such as to seek or maintain financing or credit), and such disclosure shall be limited to the maximum extent possible consistent with such responsibilities and rights. Except as set forth in the foregoing sentence, neither Party shall disclose Confidential Information of the other to any Third Party without the other's prior written consent. In all events, however, any and all disclosure to a Third Party (or to any such Affiliate) shall be pursuant to the terms of a non-disclosure/nonuse agreement no less restrictive than this Section 13 (or, in the case of attorneys, to a duty and obligation of nondisclosure/nonuse pursuant to the applicable rules of the profession). The Party which disclosed Confidential Information of the other to any Third Party (or to any such Affiliate) shall be responsible and liable for any disclosure or use by such Third Party or Affiliate (or its disclosees) which would have violated this Agreement if committed by the Party itself. Neither Party shall use Confidential Information of the other except as expressly allowed by and for the purposes of this Agreement or in accordance with the exercise of their rights under this Agreement or in accordance with customary permitted practice (such as to seek or maintain financing or credit) or and, after the Term, by Qualigen only to the extent required to continue to offer and provide goods and services to former Sekisui customers of Products. Each Party shall take such action to preserve the confidentiality of each other's Confidential Information as it would customarily take to preserve the confidentiality of its own Confidential Information (but in no event less than a reasonable standard of care). Upon expiration or termination of this Agreement, each Party, upon the other's request, promptly shall return or destroy all the Confidential Information disclosed to the other Party pursuant to this Agreement, including all copies, reflections, analyses and extracts of documents, except for one archival copy (and such electronic copies that exist as part of the Party's computer systems, network storage systems and electronic backup systems) of such materials solely to be able to monitor its obligations that survive under this Agreement. The non-use and non-disclosure obligations set forth in this Section 13 shall not apply to any Confidential Information, or portion thereof, that the receiving Party can demonstrate:
 - (a) is at the time of disclosure in the public domain;

- (b) after disclosure, becomes part of the public domain, by publication or otherwise, through no fault of and or without violation of any duty of confidentiality of the receiving Party or its disclosees;
- (c) at the time of disclosure is already in the receiving Party's possession with no duty of confidentiality, and such prior possession can be demonstrated by the receiving Party by written proof (provided that this subsection shall not apply to Confidential Information exchanged between the Parties before the execution of this Agreement that was subject to a confidentiality obligation at the time of such disclosure);
- (d) is rightfully received by the receiving Party on a non-confidential basis from an independent Third Party without obligation of confidentiality; provided, however, that to the receiving Party's best knowledge, such information was not obtained by said Third Party, directly or indirectly, from the disclosing Party; or
- (e) is independently developed by or expressly for the receiving Party, in either case solely by personnel without any access to or use of the disclosing Party's Confidential Information, as shown by receiving Party's contemporaneous written records.

In the event either Party must disclose the other Party's Confidential Information in order to comply with applicable governmental regulations or as otherwise required by law or judicial process, such Party shall give reasonable advance notice to the other Party of such proposed disclosure in order that the non-disclosing Party may intercede and oppose such process, and shall use its best efforts to secure a protective order or confidential-treatment order preventing or limiting (to the greatest possible extent and for the longest possible period) the disclosure and/or requiring that the Confidential Information so disclosed be used only for the purposes for which the law or regulation required, or for which the order was issued.

The Parties acknowledge that the defined term "Confidential Information" shall include not only a disclosing Party's own Confidential Information but also Confidential Information of an Affiliate or of a Third Party which is in the possession of a disclosing Party. However, both Parties agree not to disclose to the other Party any Confidential Information of a Third Party which is in the possession of such Party, unless the other Party has given an express prior written consent (which specifies the owner of such Confidential Information) to receive such particular Confidential Information.

Notwithstanding anything to the contrary in this Agreement or any other agreement between Sekisui and Qualigen, nothing in this Agreement or any other agreement between the Parties prohibits, or is intended in any manner to prohibit, either Sekisui or Qualigen from reporting possible violations of federal law or regulation to any governmental agency or entity, including but not limited to the Department of Justice, the Securities and Exchange Commission, the Congress, and any agency Inspector General, or making other disclosures that are protected under the whistleblower provisions of federal law or regulation. Sekisui and Qualigen do not need the prior authorization of anyone at the other Party or the other Party's legal counsel to make any such reports or disclosures and they are not required to notify the other Party that it has made such reports or disclosures.

- 13.2. <u>Use of Names</u>. During the Term, Sekisui is hereby permitted to use the Qualigen name and any Qualigen content (including the content of any existing sales collateral and marketing materials) in any sales collateral, marketing materials or other communications used in connection with the marketing and sales of the Product with the prior written consent of Qualigen, which consent shall not be reasonably withheld or delayed. Other than as provided in the foregoing sentence or to the extent such use is based on a public disclosure previously made by the other Party, during the Term neither Qualigen nor Sekisui shall use the name of the other in any verbal or written communications with any Third Party, except as allowed or contemplated herein, without the prior written consent of the other Party.
- 13.3. Press Releases. Neither Party shall make any press release or other similar public announcement concerning this Agreement without the prior written consent of the other Party, which consent shall not be unreasonably withheld. Notwithstanding the foregoing, in the event such disclosure or public announcement is required to be made on a more immediate basis to comply with applicable laws, then approval will be deemed granted if no response is received from the non-disclosing Party within the time frames required by law; provided, however, that the disclosing Party provides the non-disclosing Party with notice of the legally required time frame for the approval of the disclosure. Neither Party shall use the trademark or logo of the other Party, its Affiliates or their respective employee(s) in any publicity, promotion, news release or public disclosure relating to this Agreement or its subject matter, except as may be required by law or except with the prior express written permission of such other Party, such permission not to be unreasonably withheld or delayed, or except in Sekisui's advertisement, promotion and sale of the Products in compliance with this Agreement in the ordinary course of business. Notwithstanding the above, once a public disclosure has been made, either Party shall be free to disclose to Third Parties any information contained in said public disclosure, without further pre-review or pre-approval.
- 13.4. Audit Rights. Each Party shall keep accurate books and records in sufficient detail to comply with applicable laws, rules and regulations and this Agreement and enable the other Party to determine the correctness of any report made under this Agreement and monitor compliance with applicable laws, rules and regulations and this Agreement through the process below. Upon reasonable written notice (and no more often than once every 150 days), the auditing Party shall have the right, during normal business hours, to audit the books and records maintained by the audited Party pursuant to this Agreement to ensure the accuracy of all reports and payments made hereunder.

14. Termination

- 14.1. <u>Termination by Either Party</u>. Either Party may terminate this Agreement (i) immediately upon written notice in the event of the closing of a Sale Transaction; or (ii) immediately upon written notice if the other files a voluntary bankruptcy petition or makes a general assignment for the benefit of creditors or becomes subject to any order for relief or involuntary bankruptcy petition under any bankruptcy, liquidation, insolvency or similar law which is not dismissed within 60 days.
- 14.2. <u>Termination by Qualigen.</u> Qualigen may terminate this Agreement (i) upon thirty (30) days prior written notice in the event of any failure of Sekisui to make a Financing Payment that is determined to be due, which failure is not cured within such 30 day period, or (ii) upon sixty (60) days prior written notice in the event of any material breach of the diligence obligations (which is understood not to include failing to meet forecasts for sales to customers) set forth in the Business Plan (as it may be amended by the Parties from time to time), which breach is not cured within such 60 day period.
- 14.3. <u>Termination by Sekisui</u>. Sekisui may terminate this Agreement upon prior written notice (i) in the event of any failure of Qualigen to meet a milestone set forth in the Development Plan (as it may be amended by the Parties from time to time), or (ii) at any other time upon ninety (90) days' prior written notice of impending termination.
- 14.4. Effect of Termination. Sections 4.6, 5.5, 8.1, 8.2, 11.1-11.4, 13, 14.4 and 15 shall survive the later of the expiration or termination of the Term. In addition, all provisions that survive termination, that are irrevocable or that arise due to termination shall survive in accordance with their terms. Any other provisions of this Agreement contemplated by their terms to pertain to a period of time following termination or expiration of this Agreement shall survive only for the specified period of time. Upon the expiration or termination of the Term, (i) Sekisui shall cooperate in permitting Qualigen to offer to rehire any Sekisui sales representatives who are primarily responsible for selling the Products as set forth in Section 4.6, (ii) Sekisui shall transfer to Qualigen the ownership of any Sekisui Instruments (subject to reimbursement from Qualigen for the book value (original cost less depreciation) of such Sekisui Instruments), (iii) Qualigen shall reimburse Sekisui for a prorated portion of all prepaid distribution fees paid by Sekisui during the final year of this Agreement to subdistributors, (iv) Sekisui shall assign to Qualigen each subdistributor agreement which Qualigen requests be assigned to Qualigen, and (v) each Party shall remain liable for its obligations accrued before the effective date of such expiration or termination (and for avoidance of doubt: upon expiration or termination Sekisui shall remain liable to pay Qualigen all Financing Payments then due under the Development Plan based upon the milestones that Qualigen has completed by the date of such expiration or termination). In the event there are unfulfilled orders for Products outstanding as of termination of this Agreement, Sekisui may, at its option, cancel such orders upon notice to Qualigen (in which case Qualigen agrees to fill such orders to Sekisui's end customers directly unless such customer chooses to cancel such order) or cause Qualigen to fulfill such orders and invoice Sekisui for amounts owed with respect thereto. If either Party is aware of an impending expiration or termination of the Term, it shall conduct its business with respect to the subject matter of this Agreement in the ordinary course (and not otherwise than in the ordinary course) for the duration of the Term.

15. Miscellaneous

- 15.1. <u>Independent Contractor</u>. For the purpose of the Agreement each Party shall be, and shall be deemed to be, an independent contractor and not an agent, partner, joint venturer or employee of the other Party. Neither Party shall have authority to make any statements, representations or commitments of any kind, or to take any action which shall be binding on the other Party (except as may be explicitly provided for herein or authorized in writing), and each Party agrees not to purport to do so.
- 15.2. <u>Assignment</u>. The Agreement shall not be assigned and is not assignable or delegable by either Party without the written consent of the other, which consent shall not be unreasonably withheld; provided, that Sekisui and Qualigen each may assign this Agreement without the consent of the other to a successor in connection with the merger, consolidation or sale of such Party or of all or substantially all of its assets or the portion of its business to which this Agreement relates.
- 15.3. No Waiver. Failure of either Party to enforce (or reasonable delay in enforcing) a right under this Agreement shall not act as a waiver of that right or the ability to later assert that right relative to the particular situation involved or to terminate this Agreement arising out of any subsequent default or breach. A waiver by a Party of any of the terms and conditions of this Agreement in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any other term or condition hereof.
- 15.4. Severability. This Agreement is divisible and separable. If any provision of this Agreement is determined by a final and binding court judgment (for which no further appeal is possible) to be invalid, illegal or unenforceable to any extent, such provision shall not be not affected or impaired up to the limits of such invalidity, illegality or unenforceability; the validity, legality and enforceability of the remaining provisions of this Agreement shall not be affected or impaired in any way; and the affected provision shall (if at all possible) be construed as if it had been written in such a way as to both be valid, legal and enforceable and to achieve, to the greatest lawful extent, the evident economic, business and other purposes of such invalid, illegal or unenforceable provision (or portion of provision).
- 15.5. Notices. All notices required or permitted under this Agreement shall be in writing and shall be deemed given and made (i) if by personal delivery, on the date of such delivery, (ii) if by recognized overnight courier specifying next-business-day delivery, on the next business day after the date of deposit with such courier (by the courier's stated time for enabling next-business-day delivery), (iii) if by email, on the date sent by email if sent during normal business hours of the recipient, and on the next business day if sent after normal business hours of the recipient, and (iv) if by US registered mail, on the fifth business day following such mailing in the US, in each case addressed at the address shown below for, or such other address as may be designated by 10 days' advance written notice hereunder by, such Party.

If to Sekisui: Sekisui Diagnostics, LLC 4 Hartwell Place Lexington, MA 02421 Attn: President

Email: bob.schruender@sekisuidiagnostics.com

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With copies (which shall not constitute notice) to:

Sekisui Diagnostics LLC

4 Hartwell Place

Lexington, MA 02421

Attn: Vice President, Legal Affairs

Email: elizabeth.mcevoy@sekisuidiagnostics.com

Foley Hoag LLP Seaport West

155 Seaport Boulevard Boston, MA 02210

Boston, MA 02210

Attn: Mark A. Haddad

Email: mhaddad@foleyhoag.com

If to Qualigen: Qualigen, Inc. 2042 Corte Del Nogal Carlsbad, CA 92011 Attn: President

Email: prosinack@qualigeninc.com

With a copy (which shall not constitute notice) to:

Stradling Yocca Carlson & Rauth, P.C. 4365 Executive Drive, Suite 1500

San Diego, CA 92121 Attn: Hayden Trubitt Email: htrubitt@sycr.com

- 15.6. Entire Agreement and Modification. The Agreement, including the Exhibits thereto, constitutes the entire understanding between the parties with respect to the subject matter hereof and supersedes and cancels any previous or contemporaneous agreements or understandings, whether oral, written or implied, heretofore in effect, including any letter of intent, and sets forth the entire agreement between Sekisui and Qualigen with respect to the subject matter hereof (provided, that any and all previous nondisclosure/nonuse obligations, including the July 7, 2015 Confidential Disclosure Agreement) are not superseded and remain in full force and effect for all disclosures made prior to the date of this Agreement). Each Party acknowledges that it has not relied, in deciding whether to enter into this Agreement on this Agreement's expressly stated terms and conditions, on any representations, warranties, agreements, commitments or promises which are not expressly set forth within this Agreement. No agreements amending, altering, supplementing or waiving the terms hereof may be made except by the express terms of a written document signed by duly authorized representatives of the Parties.
- 15.7. Governing Law. This Agreement shall be governed by, and construed and interpreted in accordance with, the laws of the State of Delaware, without reference to its conflicts of laws principles. The parties agree that the United Nations Convention on Contracts for the International Sale of Goods shall be inapplicable to this Agreement.
- 15.8. <u>Attorney Fees</u>. If litigation becomes necessary to enforce the provisions of this Agreement, the successful Party shall be entitled to recover from the other Party reasonable expenses, including attorneys' and other professional fees, in addition to any other available remodies.

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- 15.9. <u>Headings</u>. The headings contained in this Agreement are for reference purposes only and are in no way intended to describe, interpret, define or limit the scope, extent or intent of this Agreement or any provision hereof.
- 15.10. Counterparts; Delivery. 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. Signatures to this Agreement may be delivered by email attachment or other electronic transmission, and such signatures and such delivery shall be fully effective and binding on the Party sending the same.
- 15.11. <u>Further Assurances</u>. Each Party covenants and agrees to, without the necessity of any further consideration, execute, acknowledge and deliver any and all such further or other documents and instruments and take any such further or other action as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.
- 15.12. Force Majeure. No Party shall be liable to any other Party or be deemed to have breached or defaulted under this Agreement for failure or delay in the performance of any of its obligations under this Agreement (other than obligations for the payment of money) for the time and to the extent such failure or delay is caused by or results from acts of God, earthquake, riot, civil commotion, terrorism, war, strikes or other labor disputes, fire, flood, failure or delay of transportation, omissions or delays in acting by a governmental authority, acts of a government or an agency thereof or judicial orders or decrees or restrictions or any other like reason which is beyond the control of the respective Party. The Party affected by force majeure shall provide the other Party with full particulars thereof as soon as it becomes aware of the same (including its best estimate of the likely extent and duration of the interference with its activities), and shall use commercially reasonable efforts to overcome the difficulties created thereby and to resume performance of its obligations hereunder as soon as practicable, and the time for performance shall be extended for a number of days equal to the duration of the force majeure.
- 15.13. Equitable Relief. Each Party recognizes that the covenants and agreements herein and their continued performance as set forth in this Agreement are necessary and critical to protect the legitimate interests of the other Party, that the other Party would not have entered into this Agreement in the absence of such covenants and agreements and the assurance of continued performance as set forth in this Agreement, and that a Party's breach or threatened breach of such covenants and agreements will cause the opposed Party irreparable harm and significant injury, the amount of which will be extremely difficult to estimate and ascertain, thus making any remedy at law or in damages inadequate. Therefore, each Party agrees that an opposed Party shall be entitled to specific performance, an order restraining any breach or threatened breach of Section 13 and all other provisions of this Agreement, and any other equitable relief (including but not limited to temporary, preliminary and/or permanent injunctive relief), without the necessity of posting of any bond or security. This right shall be in addition to and not exclusive of any other remedy available to such other Party at law or in equity.
- 15.14. Rights and Remedies are Cumulative. Except to the extent as may be expressly set forth herein, all rights, remedies, undertakings, obligations and agreements contained in or available upon violation of this Agreement shall be cumulative and none of them shall be in limitation of any other remedy or right authorized in law or in equity, or any undertaking, obligation or agreement of the applicable Party.

- 15.15. Third Party Beneficiaries. Except as expressly set forth in Section 11, the terms and provisions of this Agreement are intended solely for the benefit of each Party hereto and their respective successors or permitted assigns and it is not the intention of the Parties to confer third-party beneficiary rights upon any other person.
- 15.16. No Implied License. No right or license is granted to Sekisui by implication, estoppel, or otherwise to any know-how, patent or other intellectual property right owned or controlled by Qualigen.
- 15.17. Exhibits. The Exhibits referred to in the Agreement are deemed incorporated by reference at each place in the Agreement when reference is made thereto.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed by their duly authorized representatives as of the date first above written.

SEKISUI DIAGNOSTICS, LLC	QUALIGEN, INC.
By: /s/Robert T. Schruender	By: /s/ Paul A. Rosinack
Name: Robert T. Schruender	Name: Paul A. Rosinack
Title: President and COO	Title: President and CEO
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Exhibit A Revenue, Cost and Available Margin April 28, 2016

Revenue

<u>Actual Gross Revenue</u> – Consistent with GAAP revenue recognition, Gross Revenue reflects amounts invoiced or otherwise charged by Sekisui Diagnostics, LLC and its Affiliates to unrelated Third Parties for Products sold to customers, including amounts for any shipping, handling, freight, postage, insurance and transportation charges, to the extent included as a separate line item in the gross amount invoiced.

Actual Gross Revenue does not include the following:

- any sales or value added taxes imposed on the sale, delivery or use of the Products.
- Reagent Rental Early Termination Fees. Any such fees collected shall belong exclusively to Qualigen.
- Warranty Agreement Revenue and other Service Contract Revenue. Any such revenue shall belong exclusively to Qualigen.

Notwithstanding the foregoing, amounts invoiced by Sekisui and its Affiliates for sales of Products among Sekisui and its Affiliates ('Sekisui Intercompany Sales') for resale shall not be included in the computation of Net Revenue.

Actual 'Gross to Net' (GTN) Adjustments – consist of:

- a) discounts, refunds, rebates, sub distributor "channel" fees, chargebacks, retroactive price adjustments, and any other allowances given and taken which effectively reduce the net selling price (other than such which have already diminished the gross amount invoiced), including, without limitation, volume discounts.
- b) Product returns and allowances

Net Revenue – Actual Gross Revenue less Actual GTN Adjustments

Cost of Goods Sold (COGS)

Components of COGS include:

Actual Material Costs -

Consists of:

- Qualigen Bill of Material (BOM) Standard Costs (for instrument, reagent kit and related consumable products sold by Sekisui):
 - o raw materials
 - o component materials
 - o packaging materials
- Allocated standard shipping material costs, including envirocoolers, shipping boxes and filler materials
- Actual cost of ice packs
- Actual outbound freight expense (as applicable based on shipping terms) for sales and rentals of instruments, and sales of reagents and related consumables.

Exhibit A-1

(Note: Qualigen records costs of raw material, component, packaging and shipping materials (excluding ice packs) at standard, and records manufacturing variances including purchase price and material usage variances as part of Labor & Overhead. If Qualigen's manufacturing variances exceed 3% of its total production costs in any True-Up Period referenced in Exhibit D, such variances are to be allocated between inventory and COGS based on total inventory turns for the applicable True-Up Period)

Actual Labor & Overhead Costs -

Consists of:

Instrument and Reagent Manufacturing Cost Center Expenses – Including direct instrument and reagent manufacturing-related wages and related taxes and benefits, direct Property Plant & Equipment depreciation, direct production supplies, direct production-related repairs & maintenance expenses, inbound freight expenses, material variances and allocated manufacturing-related occupancy expenses for expenses such as rent, utilities, janitorial services, telephone expense, supplies and depreciation. Reagent manufacturing also includes an allocation of R&D department expenses relating to formulation oversight. In Qualigen's FY 2016 financial data, this allocation represented approximately \$60k. Workers' comp insurance is included as part of the occupancy allocation in Qualigen's FY2016 financial results. Beginning with Qualigen's FY 2017 financial reporting, Workers' comp insurance will be included as a direct allocation to the Instrument and Reagent Manufacturing cost centers based on salary amounts.

Quality Cost Center Expenses - Including wages and related taxes and benefits, equipment repairs and maintenance expenses, professional consulting services, supplies, dues & subscriptions, filing fees, depreciation and allocated Quality occupancy expenses. Wages include expenses for VP – Operations. The Quality Cost Center is responsible for:

- Regulatory filings
- Quality System Management
- Complaint review
- Batch record review
- Document Control
- Quality Control (QC), including:
 - > Test incoming raw materials, WIP, and FG items
 - Complaint testing confirmation
 - Product troubleshooting

Exhibit A-2

Materials Management Cost Center Expenses - Including wages and related taxes and benefits, professional consulting services, supplies, depreciation and allocated Material Management occupancy expenses. The Materials Management Cost Center is responsible for:

- Production planning
- Scheduling
- Purchasing
- Shipping & Receiving

Occupancy allocations to Instrument and Reagent manufacturing, Quality and Materials Management departments are based on applicable square footage percentages.

Actual Labor & Overhead Costs also include the standard cost of FastPacks consumed for QC testing, retainage, scrap, and obsolete inventory write-downs.

Actual Labor & Overhead Costs do not include instrument repair costs. Such costs shall be the responsibility of Qualigen with respect to instruments under warranty that are repaired or replaced, and shall be included in the instrument transfer prices with respect to refurbished instruments sold to Sekisui.

Currently, the Medical Device Excise Tax provision of the Affordable Care Act is repealed (from Jan. 2016 through December 2017). However, should this provision be re-enacted, or similar such provision enacted, the cost of such excise taxes will be included as a cost element included in Actual Cost of Goods. The margin share and true-up process will reflect this cost.

Any duty expenses incurred by Sekisui Diagnostics to enable sales of Products will be included as a cost element included in Actual Cost of Goods. The margin share and true-up process will reflect this cost.

Actual 'Reagent Rental' Instrument Depreciation Costs -

Reflects depreciation expenses for all Product-related instruments placed in service before and after execution of the DISTRIBUTION AND DEVELOPMENT AGREEMENT. Assets placed in service before April 2015 reflect a 5 year useful life. Assets placed in service beginning April 2015 reflect a 3 year useful life. Sekisui Diagnostics has a \$5,000 Asset Capitalization Threshold (ACT) and all capitalized instruments will utilize a 3 year life for all Reagent Rental units it owns. (all instruments purchased at costs < \$5,000 will be expensed, with the expense included as part of COGS in the Margin Sharing True-Up process.) All depreciation expenses reflect straight-line depreciation.

Available Margin

<u>Available Margin is defined and calculated as:</u> Net Revenue less Cost of Goods Sold (COGS)

Exhibit A-3

- EXHIBIT 6 Devices Plan Agril 19, 2016
 Assumptions
 1. Subh expense have been updated
 2. Sel. 716 is antigned as 75% 50, 25% Qualque (per the current split in 2015)
 3. Model summer MAVS is started to [11 months of Ft]
 4. With 5 months earlier introduction of 2.0, revenue for 2.0 is palled forward 6 months
 5. FFP pathers in scaled back starting m 21 PM 71 retreated of origins join in 11 FT 18
 6. \$150K of Marketing Promo accelerated into 2117 land removed from 11018) due to faster learch of 2.0
 7. Field Sales costs and Michaelon program fees increase at 75 per page.
 8. Model assumes Oct 1 2017 launch of 2.0 e,VXI D with remainder of measure-label for sale by end of PT18

080 \$000	300000000000000000000000000000000000000	3.00 mm		FY2016				
	2015 9Mo Apr-Dec Annualizd	(May/Jun) FCS7	Q2 PCST	Q3 PCST	O4 FCST	FY2016 (11 mo) FCST	FY2017 FCST	FY2018 FGST
Domestic	Secretary Control		1000		1000			
FPIP Instrument Sales-Direct FPIP Reagent Sales-Direct		\$30 \$270	\$70 \$680	\$70 \$750	\$70 \$850	\$240 \$2,550	\$262 \$2,782	\$260 \$2,780
Total Sales-Direct	\$2,840	\$300	\$750	\$820	\$920	\$2,790	\$3,044	\$3,044
FPIP Instrument Sales-MMS FPIP Reagent/Misc Sales-MMS 2.0 Instrument Sales-Distribution 2.0 Reagent/Misc Sales-Distrib*		\$30 \$400	\$90 \$700	\$90 \$800	\$90 \$1,022	\$300 \$3,002	\$458 \$4,989 \$101 \$263	\$317 \$5,075 \$743 \$3,795
Total Sales-Distribution	\$3,342	\$430	\$790	\$970	\$1,112	\$3,302	\$5,811	\$9,934
Total Domestic Sales	\$6,181	\$730	\$1,540	\$1,790	\$2,032	\$6,092	\$8,854	\$12,977
International								
FPIP Instrument Sales FPIP Reagent Sales Total International Sales	5624	\$25 \$60 \$85	\$35 \$100 \$135	\$35 \$145 \$180	\$35 \$170 \$205	\$130 \$475 \$805	\$145 \$518 \$663	\$217 \$556 \$813
TOTAL INTERIORISE STATES	3024	20.0	9133	3100	\$203	4000	\$00.5	241.
Total Revenues	\$6,005	\$815	\$1,675	\$1,970	25,557	\$6,697	\$9,517	\$13,790
A STATE OF CASE OF COLUMN STATE OF CASE OF CAS	-	12%	25%	29%	33%	100%		
EPIP Instrument Placements 2.0 Instrument Placements **	100	24	39	42	42	147	127 90	GEC
-Field Sales Personnel		111	200	200	200	753	E24	840
-McKesson Program -Marketing / Promo ***		43	65	65	50	238 183	265	276
Operating SBM Expenses		\$2101	\$3151	\$3151	\$3151	\$1,155	\$1,5421	\$2,550

^{*} Assumes minimal impact to existing business w/only/VitD on 2.0 in FY17
** Assumes Oct 1 2017 Start w/Vit D
*** Includes demo units, Ad-Promo, etc

Exhibit B-1

Project/Activity	Esti	mated Cost	Timeframe
I-Pad App	\$	25,000	March, 2106 - May, 2016
Direct Mail Campaigns	\$	24,000	May - Sept, 2016
Pocket Brochure & Assay Cards	\$	12,000	July, 2016
Advertising Campaign	\$	40,000	July, 2016 - March, 2017
Assay Webinars	\$	15,000	August-November, 2016
MDSI Distributor Campaign (3)	\$	19,500	June, 2016 - Jan, 2017
Value Proof Tool	\$	20,000	April-July, 2016 (For AACC)
AACC Campaigns	\$	7,500	July, 2016
Miscellaneous Web Activities	\$	5,000	April, 2016 - March, 2017
TOTAL	\$	168,000	

Exhibit B-2

Exhibit C Development Plan April 28, 2016

FY 2016			
Target Review Month	April 2016	August 2016	December 2016
Payment (\$000)	\$1,000	\$1,000	\$1,000
Payment Due Date	May 1, 2016	September 1, 2016	January 1, 2017
Criteria for Payment			
Milestones Completed	Execution of Definitive	 FP2.0 Analyzer Validated Software 	 Vitamin D-Clinical Studies 11/18
(Dates shown are	Agreement	8/15	
projected Completion dates)		 Delivery of first 5 FP2.0 Analyzer Prototypes 8/8 	• Vitamin D-510k Submission 12/16
		• Vitamin D- Design Verification 8/12	 Testosterone-Feasibility 12/16 FP2.0 Analyzer Production - Order Production Tooling 10/24
Milestones in progress and on schedule		 Vitamin D- Design Transfer/ Design Validation (8/22 - 10/21) 	• Vitamin D-CE Mark (12/19 - 1/13)
(Dates shown are projected start and		• Testosterone-Feasibility (7/11 - 12/16)	 Vitamin D-CLIA Waiver Study (12/12 - 3/10)
completion dates)		• FP2.0 Analyzer Production - Order	 Testosterone- Design Verification
r		Production Tooling (7/19 - 10/24)	(12/19 - 3/10)
		Pouch Production Line, Issuance	• TSH-Feasibility (1/9 - 6/16)
		of Purchase Order to Manufacturer (\$600K on 10/28/16)	• FP2.0 Analyzer Production - Draft Production Documents (10/25- 12/19)
			Pouch Production Line - Concept Output Description: (10/21, 1/6) Pouch Production Line - Concept
			Design (10/31 - 1/6)
			 Pouch Production Line – Engineering Drawings (\$600K on 3/17/17)
		Exhibit C-1	·

Exhibit C Development Plan April 28, 2016

FY	201	7

Target Review Month	April 2017	August 2017	January 2018
Payment (\$000)	\$1,300	\$800	\$375
Payment Due Date Criteria for Payment	May 1 and June 1, 2017 May be split ½ May 1 and ½ June 1 if underlined milestones not completed by May 1.	September 1, 2017	February 1, 2018
Milestones Completed (Dates shown are projected Completion dates)	 Vitamin D-CE Mark 1/13 Vitamin D-CLIA Waiver Study 3/10 Vitamin D-510k Clearance 5/19 	 Vitamin D-510k Clearance 5/19 Vitamin D-CLIA Waiver Submission 5/22 Testosterone-CE Mark 8/18 	 Vitamin D-Commercialized 10/30 Testosterone-510k Clearance 12/22 Testosterone-CLIA Waiver Study 10/13
	 Vitamin D-CLIA Submission 5/22 Testosterone- Design Verification Review 3/24 FP2.0 Analyzer Production - Setup Production Line/Training/QC Documents 3/6 	 Testosterone-510k Submission 7/21 TSH-Feasibility 6/16 FP2.0 Analyzer Pilot Builds 1 through 3 8/14 	 Testosterone-CLIA Waiver Submission 12/25 TSH- Design Transfer/Design Validation 9/25, 10/30 PSA-Feasibility 12/15
	Pouch Production Line – Hardware/Software Design 1/9	 Pouch Production Line - Acceptance Review 7/7 Pouch Production Line Installation 8/18 	 FT4-Feasibility 12/15 Pouch Production Line in service 10/20 (\$200K)
Milestones in progress and on schedule (Dates shown are	 Testosterone-Design Transfer/Design Validation (3/27 - 5/26) 	• Testosterone-CLIA Waiver Study (7/17 - 10/13)	• TSH-Clinical Studies (11/27 - 12/29)
projected start and completion dates)	 TSH-Feasibility (1/9 - 6/16) FP2.0 Analyzer Production – 	 TSH- Design Verification (6/19 - 9/22) TSH- Design Transfer/ Design 	 PSA-Design Verification (12/18 - 3/23) FT4-Design Verification (12/18 -
	Order Parts (3/7 - 7/24) • Pouch Production Line Fabrication (3/6 - 5/12)	Validation (9/25 – 11/24) • PSA-Feasibility (7/10 - 12/15)	3/23)
	Pouch Production Machine Acceptance Test (\$600K on 7/17/17)	• FT4-Feasibility (7/10 - 12/15)	
		• Pouch Production Line Training (8/21 - 9/1) Exhibit C-2	

Exhibit C Development Plan April 28, 2016

FY 2018 Target Review Month

Target Review Month	April 2018	August 2018	January 2019
Payment (\$000)	\$365	\$232	\$100
Payment Due Date	May 1, 2018	September 1, 2018	February 1, 2019
Criteria for Payment	•	-	-
Milestones Completed	 TSH-510k Submission 1/19 	 Testosterone-Commercialized 6/4 	 TSH-Commercialized 12/3
(Dates shown are	 TSH-CE Mark 2/16 	 TSH-510k Clearance 6/22 	 PSA-CLIA Waiver Study 9/14
projected Completion dates)	• TSH-CLIA Waiver Study 4/13	 TSH-CLIA Waiver Submission 6/25 	• PSA-510k Clearance 12/21
,	 PSA- Design Verification 3/9 	 PSA-CE mark 7/23 	 PSA-CLIA Submission 12/24
	• FT4- Design Verification 3/9	• FT4-CE mark 7/23	 FT4-CLIA Waiver Study 9/14 FT4-510 Clearance 12/21 FT4-CLIA Submission 12/24
Milestones in progress and on schedule Dates shown are	 Testosterone CLIA Waiver Submission under review (12- 26 - 4/30) 	• TSH-CLIA Waiver Submission under review (6/26 - 10/29)	
projected start and completion dates)	• PSA- Design Transfer/ Design Validation (3/26 – 5/25)	• PSA-CLIA Waiver Study (7/16 - 9/14)	
	• FT4- Design Transfer/ Design Validation (3/26 – 5/25)	• FT4-CLIA Waiver Study (7/16 - 9/14)	

- Payments made based on progress against the Development Plan as evidenced by completion of milestones indicated and progress against milestones yet to be completed. Target review month is estimated timing only.
- Completion of milestones will be based upon the completion of the deliverables, to Sekisui's satisfaction, in accordance with Qualigen's standard product development practices as defined in Qualigen's Quality System Procedure Document #91000002 Rev018. Key terms, such as Feasibility, Verification, Validation and Transfer, are also defined in Qualigen's Quality System Procedure Document #91000002 Rev018.

Exhibit C-3

Exhibit D Product List 26-Apr-16

Part ID	Description	Initial Transfer Price	Min Order & Lead Time	Warranty
Instruments	& Accessories			
	FastPack IP Analyzer	\$6,692.00	3 Month Forecast	1 year
	FastPack IP Analyzer, Refurb	\$6,113.00	3 Month Forecast	1 year
	FastPack IP Analyzer - Upgrade	\$3,314.00	3 Month Forecast	1 year
	External Printer Kit	\$281.00	3 Month Forecast	1 year
	External Printer Kit, Refurb	\$21.00	3 Month Forecast	1 year
	100 μL Pipette IP	\$259.00	3 Month Forecast	1 year
	100 µL Pipette IP, Refurbished	\$38.00	3 Month Forecast	1 year
	25 µL Pipette IP	\$259.00	3 Month Forecast	1 year
	25 uL Pipette IP, Refurbished	\$38.00	3 Month Forecast	1 year
17000490	시아 병교에 하게 하게 되는 사람이 가다지가 되었다면 하지만 하게 하다.	\$91.40	3 Month Forecast	1 year
	Desktop Power Supply, 12VDC, 150W, Refur	\$0.00	3 Month Forecast	1 year
17000015		\$1.96	3 Month Forecast	1 year
	Eurpoean power cord	\$4.11	3 Month Forecast	1 year
65000159	IP Procedure Manual - English	\$4.77	3 Month Forecast	1 year
65000160	Quality Assurance Manual	\$23.64	3 Month Forecast	1 year
65000161	Quality Assurance Log	\$23.76	3 Month Forecast	1 year
17000474		\$25.88	5 Week Forecast	1 year
17000378		\$3.32	5 Week Forecast	1 year
20000037		\$43.24	5 Week Forecast	1 year
	Tips, Stat-Pet Pipet	\$3.45	5 Week Forecast	1 year
17000336	nps, state et ripet	45,45	5 Week Forecast	1 year
Reagent Kits	3 (3 (2)) (3)	4.000	Em 20	
	FastPack Kit PSA, 50 Test	\$184.00	5 Week Forecast	Through Expiration Date
25000009	Fastpack Kit, Testosterone, 50 Test	\$188.00	5 Week Forecast	Through Expiration Date
25000015	Fastpack Kit, Free T4, 50 Test	\$163.00	5 Week Forecast	Through Expiration Date
	Fastpack Kit, TSH, 50 Test	\$169.00	5 Week Forecast	Through Expiration Date
25000040		\$111.00	5 Week Forecast	Through Expiration Date
25000041		\$113.00	5 Week Forecast	Through Expiration Date
25000042		\$101.00	5 Week Forecast	Through Expiration Date
25000043		\$98.00	5 Week Forecast	Through Expiration Date
	FastPack® IP hCG Kit	\$104.00	5 Week Forecast	Through Expiration Date
25000045	HITT THE TOTAL CONTRACTOR OF THE PARTY OF TH	\$104.00	5 Week Forecast	Through Expiration Date
25000068	20 (10 (10 (10 (10 (10 (10 (10 (10 (10 (1	\$144.00	5 Week Forecast	Through Expiration Date
	TPSA 50 Test kit 25s	\$184.00	5 Week Forecast	Through Expiration Date
25000076	TPSA IP kit 25s	\$111.00	5 Week Forecast	Through Expiration Date
Calibrators/C	ontrols/Verifiers			
25000002	Kit, Calibrator, FastPack PSA	\$4.62	5 Week Forecast	Through Expiration Date
25000003	Kit, Control PSA	\$5.20	5 Week Forecast	Through Expiration Date
25000008	Kit, Calibrator, Free PSA	\$5.46	5 Week Forecast	Through Expiration Date
25000014	Kit, Calibrator, Testosterone	\$4.34	5 Week Forecast	Through Expiration Date
25000016	Kit, Calibrator, Free T4	\$4.34	5 Week Forecast	Through Expiration Date
25000017	Method Verification Kit - PSA	\$4.72	5 Week Forecast	Through Expiration Date
25000024	Kit, Calibrator, TSH	\$4.62	5 Week Forecast	Through Expiration Date
25000029	Method Verification Kit - Testo	\$4.88	5 Week Forecast	Through Expiration Date
25000030	Method Verification Kit - TSH	\$4.86	5 Week Forecast	Through Expiration Date
25000031	Method Verification Kit - FT4	\$4.86	5 Week Forecast	Through Expiration Date
	hCG Method Verification Kit	\$5.72	5 Week Forecast	Through Expiration Date
25000035	hCG Calibrator Kit	\$4.97	5 Week Forecast	Through Expiration Date
25000036		\$9.05	5 Week Forecast	Through Expiration Date
25000056	FastPack® System Control Kit	\$8.07	5 Week Forecast	Through Expiration Date
25000064	Method Verification Kit – Vitamin D	\$5.39	5 Week Forecast	Through Expiration Date
25000065	FastPack® System Control Kit-INT	\$7.95	5 Week Forecast	Through Expiration Date
	TPSA Calibrator 25s kit	\$4.44	5 Week Forecast	Through Expiration Date

Exhibit D-1

Exhibit D Transfer Price and True-Up Process April 22, 2016

Transfer Prices

Initial Transfer Prices for all Products in aggregate are based on Qualigen's actual April 2015 – December 2015 COGS plus an amount estimated to represent Qualigen's 10% share of the actual April 2015 – December 2015 Available Margin as defined in Exhibit A and summarized in Table C. Going forward, transfer prices for Products other than reagent kits will be set as of each October 1 and April 1 for the prospective 6-month period based on Qualigen's standard unit cost in effect on the first day of the month prior to the date the new transfer prices are agreed upon (either September 1 and March 1) for the prospective 6-month period.

Going forward, transfer prices for <u>reagent kits</u> will be set as of each October 1 and April 1 for the prospective 6-month period based on historical COGS for the earliest 6 months of the 9-month period ended the day before such date plus an amount that is estimated to represent Qualigen's applicable share of Available Margin with regard to the retrospective 6-month period as noted in Table A below.

 $Table\ A\ below\ provides\ time frames\ for\ the\ contract\ term.\ Both\ companies'\ fiscal\ years\ run\ from\ April\ 1^{st}\ to\ March\ 31^{st}.$

Table A

	Transfer Price Basis:
Transfer Price Effective	Retrospective Periods
5/1/2016 - 9/30/2016	4/1/2015 - 12/31/2015
10/1/2016 - 3/31/2017	1/1/2016 - 6/30/2016
4/1/2017 - 9/30/2017	7/1/2016 - 12/31/2016
10/1/2017 - 3/31/2018	1/1/2017 - 6/30/2017
4/1/2018 - 9/30/2018	7/1/2017 - 12/31/2017
10/1/2018 - 3/31/2019	1/1/2018 - 6/30/2018
4/1/2019 - 9/30/2019	7/1/2018 - 12/31/2018
10/1/2019 - 3/31/2020	1/1/2019 - 6/30/2019
4/1/2020 - 9/30/2020	7/1/2019 - 12/31/2019
10/1/2020 - 3/31/2021	1/1/2020 - 6/30/2020
	Exhibit D-2

True-Up Process

Per Table B below, for each "True-Up Period", an all-Products true-up will be prepared to ensure each party receives their contractual margin share of the actual Available Margin. The true-up process will result in a payment due from either party, depending on which party has received excess Available Margin for the True-Up Period. True-ups will be determined every six months. The first true-up will be based on a stub period consisting of results from the first day of this Agreement to September 30, 2016.

Table B below provides the true-up periods and Available Margin shares.

Table B

True-Up Period	True-up Completed	Available Margin Split Sekisui/Qualigen
5/1/2016 - 9/30/2016	10/5/2016	90% / 10%
10/1/2016 - 3/31/2017	4/5/2017	90% / 10%
4/1/2017 - 9/30/2017	10/4/2017	90% Apr, 70% May - Sep / 10% Apr, 30% May - Sep
10/1/2017 - 3/31/2018	4/4/2018	70% / 30%
4/1/2018 - 9/30/2018	10/3/2018	70% Apr, 65% May - Sep / 30% Apr, 35% May - Sep
10/1/2018 - 3/31/2019	4/3/2019	65% / 35%
4/1/2019 - 9/30/2019	10/3/2019	65% / 35%
10/1/2019 - 3/31/2020	4/4/2020	65% / 35%
4/1/2020 - 9/30/2020	10/3/2020	65% / 35%
10/1/2020 - 3/31/2021	4/3/2021	65% / 35%

Sekisui and Qualigen jointly have the responsibility to review and approve each true-up calculation. The process follows the following steps:

- 1) Qualigen provides Qualigen-incurred COGS information to Sekisui (see Table C)
- 2) Sekisui adds its Net Revenue information and Sekisui-incurred COGS information (see Table C) to the Qualigen-incurred COGS information and develops the first draft of the true-up calculation
- 3) Qualigen and Sekisui review and agree on the calculation. Both parties will use best efforts to complete the review and approval process in a timely manner.

Note: to ensure the True-up calculation is available for recording in September or March results, both Qualigen and Sekisui need to be diligent in providing their data on a timely basis according to the dates set forth in Table B above.

Exhibit D-3

Table C Available Margin

Element	Oualigen	Sekisui	Notes
Net Revenue	C B.	X	Sales to customer (e.g. McKesson, Direct or EMEA), less deductions expressly allowed by the Exhibit A definition
Material cost within COGS	х	Х	Sekisui cost is for outbound freight and expensed Sekisui Instruments after 5/1/2016 (instruments sold to customers by Sekisui, and provided to customers through the reagent rental program when instrument cost is less than Sekisui's capitalization threshold)
Labor & Overhead within COGS	х		Qualigen's manufacturing variances will be charged to COGS in the period unless such variances exceed 3% of its total production costs, in which case the variances are to be allocated between inventory and COGS based on total inventory turns for the True-Up Period
Instrument Depreciation	X	X	Sekisui's cost is for Sekisui Instruments purchased after 5/1/2016 and provided to customers through the reagent rental program (when instrument cost is greater than Sekisui's capitalization threshold).

All Available Margin Elements referenced above shall not include any of Qualigen's sales to Sekisui that have not been sold at the end of the True-Up Period by Sekisui to its customers.

Exhibit D-4

EXHIBIT E Qualigen Retained Customers

Acct #	Name	City	State
11436	Low T Centers, Inc. and Affiliates	Southlake	TX
08260	Chicago Prostate Cancer Center	Westmont	IL
02217	Elias Tawil, MD	Pittsburg	KS
03268	Lake Success Urological	Lake Success	NY
01815	Mason City Clinic	Mason City	IA
02358	Surgical Assoc. Northwest PC	Federal Way	WA
03197	Surgical Assoc. Northwest, PC	Auburn	WA
02845	Urological Assoc. Grand Island	Grand Island	NE
02575	Urology Care, Inc Jefferson	Jefferson City	MO
01343	Warren L. Lowry, M.D., S.C	Rockford	IL
00051	Iowa Clinic	West Des Moines	IA
	Exhibit E-1		

Exhibit F

Qualigen Financial Process flow overview: Requirements for Purchasing/OTC/Finance reporting Updated 4/15/16

All customer and inventory transactions will be recorded at SD at a summary level. Qualigen would maintain all supporting detail on their accounting system.

Procure to Pay

- 1) Qualigen to provide SD purchasing an SD inventory report by SKU on the first work day of the month.
- 2) SD and Qualigen to prepare and agree to a monthly rolling 12 month product forecast by SKU to be provided to Qualigen by SD purchasing the fifth work day of the month.
- 3) SD Purchasing will coordinate with Qualigen to determine safety stock levels and re-order timing based on current SD inventory levels and lead times.
- 4) SD Purchasing will submit a purchase order for inventory to Qualigen monthly.
- 5) Qualigen will invoice SD for inventory purchased according to the SD Purchase order.
- 6) SD A/P to pay invoice from Qualigen per agreed upon terms of payment.

Order to Cash

- 1) SD customer to submit Purchase order to Qualigen for Qualigen products.
- 2) Sales order entered into Qualigen ERP system by Qualigen customer service on behalf of SD.
- 3) Credit card customers provide credit card information to Qualigen customer service via SD credit card form. Qualigen customer service provides to SD finance credit card information for verification prior to shipment.
- 4) Order fulfilled and shipped to SD customer by Qualigen.
- 5) Qualigen generates SD invoice to customer at full commercial value on behalf of SD.
- 6) Freight charges should be managed as freight collect on Customer account or SD account.
- 7) Invoice sent to SD customer by Qualigen on behalf of SD.
- 8) Customer remits to SD lock box
- 9) Qualigen manages the cash applications for SD accounts receivable.
- 10) Customer relationship for management of debt collections to be managed by SD.

Exhibit F-1

Finance month end reporting

- 1) Qualigen to provide no later than work day 2 the following information for SD related data to SD Finance:
 - a. A/R balances by Customer
 - b. Inventory Balances by SKU quantity, and SD cost (transfer price)
 - c. Units Sold in the month by SKU and cost (transfer price, if available)
 - d. Summary Invoiced Revenue by Customer by SKU
 - e. Prompt pay, channel fees, chargebacks information
 - f. Fixed Asset information, e.g. instrument by customer, location, serial #, etc.
- 2) SD Finance will create journal entries to record Sales, A/R, COGS, Inventory and any related reserve or revenue adjustments using monthly reports with information provided by Qualigen.
- 3) SD Finance will coordinate with Qualigen to conduct an annual physical count of inventory at their location.
- 4) SD finance and Qualigen finance will schedule routine meetings to discuss monthly reports or discrepancies.
- 5) SD finance reconciles margin split, per the agreement terms, with Qualigen.

Qualigen will have custodial responsibility for Sekisui inventory held at Qualigen. Any inventory shrinkage or damage to Sekisui inventory while at Qualigen will be Qualigen's responsibility.

Exhibit F-2

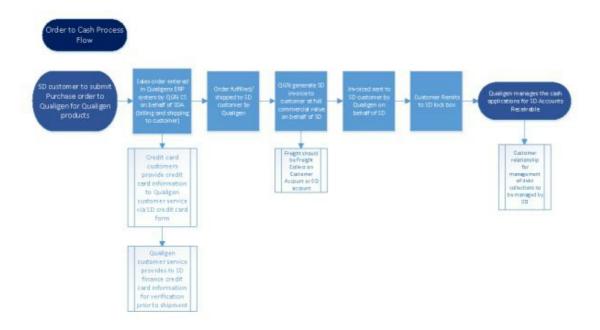


Exhibit F-3



Exhibit F-4

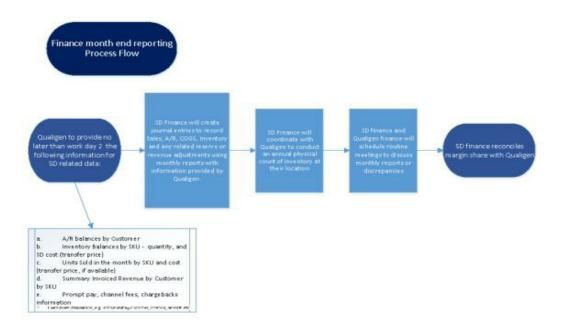


Exhibit F-5

SCHEDULE 2.1

Qualigen Distribution Agreements

- 1. McKesson Distribution Agreement effective April 20, 2010 as amended August 12, 2013 and April 20, 2015
- 2. McKesson Marketing Service Agreement effective July 1, 2014
- 3. Woongbee MeDiTech Inc. Distribution Agreement dated November 12, 2002
- 4. Nanova Co., Ltd. Distribution Agreement dated October 29, 2014
- 5. Axon Lab A.G. Distribution Agreement effective September 22, 2015

The following Distribution Agreements also shall be assigned upon Sekisui's request.

- A. Alpha Diagnostics Sp. Z o.o Distribution Agreement dated November 15, 2010
- B. Cariad Technologies Ltd. distribution Agreement dated April 15, 2005, as amended May 30, 2005
- C. CliniLine, S.A. Distribution Agreement dated February 5, 2003, as amended October 27, 2004

Schedule 2.1