

DETERMINA DEL DIRIGENTE

Numero della determina N. 527 Prot. n. 65175

Data: 06/05/2020

Oggetto: G021_2020 - Determina di aggiudicazione ex art.63 co 2 lett. b) del D.Lgs 50/2016

Contenuto: Fornitura di un “Sistema Quanterix SR-X per la misurazione ultra-sensibile di biomarcatori per mezzo della tecnologia Simoa”.

CIG 8286169AF7

CUP B12F16001280007 - CUP B14I18000630007

Struttura Esigente: Dipartimento di Neuroscienze, Psicologia, Area del Farmaco e Salute del Bambino - NEUROFARBA

Responsabile Unico del Procedimento: Dott. Francesco Bardazzi

Direttore del Dipartimento: Prof. Patrizio Blandina

Struttura proponente l'atto: Obiettivo Strategico – Centrale Acquisti

Dirigente: Dr. Massimo Benedetti

Conti Economici - Spesa Descrizione Conto

La copertura finanziaria della spesa è assicurata per 69.000 euro dal finanziamento di Ateneo per l'acquisizione di strumenti finalizzati alla ricerca anno 2019 (progetto 58514_strumenti_ricerca_2020) e la quota rimanente per due terzi (euro 20.235,08 + iva)sul progetto58514_BANDOCONGIUNTO_UNIFICRF_SORBI di cui è assegnatario il prof. Sorbi e per un terzo (10.117,54 euro+iva) sul progetto in attività commerciale CONVMAS91.

Allegato N. 1 Relazione del RUP pagg. 3

Allegato N. 2 Offerta Economica pagg. 6

Allegato N. 3 Dichiarazione di Unicità /Scheda Tecnica pagg. 3

Tipologia di pubblicazione

Integrale

IL DIRIGENTE

VISTO la delibera del Consiglio del Dipartimento di Neuroscienze, Psicologia, Area del Farmaco e Salute del Bambino - NEUROFARBA dell'Università degli Studi di Firenze del 16/12/2019 che approva, nell'ambito del finanziamento di Ateneo per l'acquisizione di strumenti finalizzati alla ricerca anno 2019, la richiesta, dei professori Maria Pia Amato, Luca Massacesi e Sandro Sorbi, per l'acquisto della fornitura di un "Sistema Quanterix SR-X per la misurazione ultra-sensibile di biomarcatori per mezzo della tecnologia Simoa" per le esigenze della ricerca;

CIG 8286169AF7

CUP B12F16001280007 - CUP B14I18000630007

IMPORTO APPALTO **euro 86.910,00** oltre IVA 22% e € 0 per oneri della sicurezza da rischi di interferenza;

VISTO la relazione del Dott. Francesco Bardazzi, Responsabile Amministrativo del Dipartimento NEUROFARBA, che in qualità di Responsabile unico del Procedimento (**Allegato "1"** parte integrante e sostanziale del presente atto) ha individuato la Società **Quanterix Corporation, 113 Hartwell Avenue, Lexington, MA, USA** come unico distributore per la fornitura del Sistema Quanterix SR-X, con caratteristiche di esclusività, unicità e infungibilità (**Allegato "1"** parte integrante e sostanziale del presente atto) per l'affidamento del contratto ai sensi dell'art. 63 comma 2 lett. b) del D.lgs n. 50/2016;

PRESO ATTO dell'Avviso Esplorativo prot. 19371 (rep. n. 1023) del 20/02/2020 del Dipartimento di Neuroscienze, Psicologia, Area del Farmaco e Salute del Bambino - NEUROFARBA, pubblicato sulla piattaforma START della Regione Toscana con n.001771/2020 il 20/02/2020, al fine di verificare se vi siano altri operatori che possano effettuare la fornitura con le caratteristiche tecniche richieste;

PRESO ATTO del Verbale del Dipartimento di NEUROFARBA del 03/03/2020 attestante che nessun operatore economico ha manifestato interesse per la fornitura sulla piattaforma START;

VISTO il documento di offerta/ preventivo Quote Number **00013924**, prodotto dalla Società **Quanterix Corporation, 113 Hartwell Avenue, Lexington, MA, USA** (scadenza validità 31/05/2020) in data del 08/04/2020 al Dipartimento di Neuroscienze, Psicologia, Area del Farmaco e Salute del Bambino - NEUROFARBA - Viale G. Pieraccini, Firenze, per l'importo di corrispettivo di **euro 86.910,00 + oltre IVA 22% (Allegato "2" parte integrante e sostanziale del presente atto)**;

PRESO ATTO della dichiarazione di Unicità del sistema Quanterix SR-X, prodotto e distribuito da Quanterix Corporation che misura in modo ultra-sensibile biomarcatori per mezzo della tecnologia Simoa®. Il Sistema è una piattaforma integrata che comprende lo strumento SR-X ed i reagenti Simoa, entrambi coperti da brevetti e non ci sono sistemi o prodotti con licenza offerti da terzi che siano in grado di utilizzare qualsiasi componente o metodo della piattaforma Simoa. (Allegato "3", parte integrante e sostanziale del presente atto);

PRESO ATTO che il Responsabile Unico del Procedimento, in data 27/04/2020 ha restituito la dichiarazione assenza situazioni di conflitto di interesse / incompatibilità e la dichiarazione di congruità dell'offerta (agli atti);

PRESO ATTO della autodichiarazione firmata, inviata al Dipartimento di NEUROFARBA il 06/03/2020 da parte del Legale Rappresentante (Vice Presidente - Senior Legal Counsel) Brine P. Keane della Società **Quanterix Corporation, 113 Hartwell Avenue, Lexington, MA, USA** sul

possesso dei requisiti generali di cui all'art. 80 del D.Lgs 50/2016 in capo alla Società **Quanterix Corporation**;

Il sottoscritto in qualità di Dirigente preposto della Centrale Acquisti, Responsabile del Procedimento, ai sensi e per gli effetti dell'art. 5 della L. 241/90, limitatamente all'endoprocedimento di gara e contratto in oggetto, per le motivazioni espresse nella parte narrativa del presente atto che qui si intendono integralmente richiamate

DETERMINA

1. Di aggiudicare alla Società Quanterix Corporation, 113 Hartwell Avenue, Lexington, MA, USA), ai sensi e per gli effetti dell'art. 63 comma 2 lett. b) del D.lgs n. 50/2016, il contratto di fornitura del "Sistema Quanterix SR-X per la misurazione ultra-sensibile di biomarcatori per mezzo della tecnologia Simoa" di cui al documento di offerta /preventivo allegato, per un importo di corrispettivo complessivo pari ad euro **86.910,00 oltre IVA 22%**;
2. di dare atto che:
 - l'importo complessivo, pari ad **euro 106.030,2** iva compresa, troverà copertura finanziaria sul Budget anno 2020 per euro **69.000,00**, dal finanziamento di Ateneo per l'acquisizione di strumenti finalizzati alla ricerca anno 2019 (progetto 58514_strumenti_ricerca_2020) mentre la quota rimanente per due terzi (**20.235,08 euro oltre IVA**) sul progetto 58514_BANDOCONGIUNTO_UNIFICRF_SORBI di cui è assegnatario il prof. Sorbi e per un terzo (**10.117,54 euro oltre IVA**) sul progetto in attività commerciale CONVMASS91 di cui è assegnatario il prof. Massacesi del Dipartimento Neurofarba dell'Università degli Studi di Firenze;
 - il tempo di esecuzione dell'appalto è fissato in 60 giorni naturali e consecutivi decorrenti dal verbale di attivazione della fornitura;
 - il contratto di appalto sarà stipulato nella forma di Ordine d'Acquisto da parte del Dipartimento NEUROFARBA;
 - di non richiedere, sulla base di quanto indicato dal RUP, la cauzione definitiva di cui all'103 c.11 del D.lgs 50/2016, in considerazione della comprovata solidità dell'impresa affidataria;
 - che il presente decreto è soggetto a pubblicazione sull'albo ufficiale di Ateneo. di procedere alla pubblicazione della presente Determina: all'Albo Ufficiale di Ateneo (<https://www.unifi.it/albo-ufficiale.html>) sul profilo web della Stazione Appaltante, sezione "Amministrazione trasparente"; sul Portale Trasparenza sezione Bandi di Gara ai sensi di legge; sulla Piattaforma SITAT SA REGIONE TOSCANA - Pubblicazione provvedimento ai sensi art. 29 D.lgs 50/2016/MIT, ai sensi dell'Art. 29 D. Lgs 50/2016 e D. Lgs 33/2013

IL DIRIGENTE
Centrale Acquisti
Dott. Massimo Benedetti
Firmato Digitalmente



UNIVERSITÀ
DEGLI STUDI
FIRENZE

Dipartimento di Neuroscienze, Psicologia, Area del Farmaco e Salute del Bambino -
NEUROFARBA

ACQUISTO DI UN “Sistema Quanterix SR-X per la misurazione ultra-sensibile di biomarcatori per mezzo della tecnologia Simoa”

CIG 8286169AF7

CUP B12F16001280007, B14I18000630007

RELAZIONE

Responsabile Unico del Procedimento

La presente relazione è rilasciata dal sottoscritto dott. Francesco Bardazzi, responsabile amministrativo del Dipartimento di Neuroscienze, Psicologia, Area del Farmaco e Salute del Bambino – NEUROFARBA, viale Pieraccini 6, 50134 Firenze, in qualità di Responsabile del Procedimento ai sensi dell’art. 31 del D.L.gs. 50/2016, incaricato con delibera del Consiglio di Dipartimento del 16 dicembre 2019.

Come da richiesta dai professori Maria Pia Amato, Luca Massacesi e Sandro Sorbi ed approvata dal Consiglio di dipartimento del 16/12/2019, nell’ambito del finanziamento di Ateneo per l’acquisizione di strumenti finalizzati alla ricerca anno 2019, si rende necessario acquistare:

- un “Sistema Quanterix SR-X per la misurazione ultra-sensibile di biomarcatori per mezzo della tecnologia Simoa” di cui è stato predisposto il Progetto da porre a base di gara, ai sensi e per gli effetti dell’art. 63 c.3 lett.b) d.lgs 50/2016 che si compone dei seguenti elaborati:
 - ✓ il Capitolato di appalto (normativo e prestazionale);
 - ✓ Dichiarazione di Unicità.

La **quota prevalente** è costituita dalla fornitura di “Sistema Quanterix SR-X per la misurazione ultra-sensibile di biomarcatori per mezzo della tecnologia Simoa”, mentre le rimanenti prestazioni, non prevalenti, sono da intendersi complementari alla scadenza della garanzia di legge post-vendita al prezzo offerto ed alle condizioni presentate;

La fornitura è stata inserita nella programmazione biennale di beni e servizi 2020/2021 ai sensi dell’art.21 D.lgs n..50/2016 con il codice **CUI 0127968048020200000 017**;

Inoltre è stato verificato che la suddetta strumentazione non è acquistabile mediante canali CONSIP;

Il RUP dott. Francesco Bardazzi ha individuato la società Quanterix Corporation, 113 Hartwell Avenue, Lexington, MA, USA come unico fornitore del servizio con caratteristiche di esclusività, unicità e infungibilità in relazione alla fornitura sopra indicata.

Il sottoscritto RUP dott. Francesco Bardazzi preso atto di quanto sopra dichiarato che si è pervenuti alla determinazione dell'importo pari a Euro 86.910,00 + Iva da porre a base di negoziazione, di cui € 0 per oneri della sicurezza/interferenza.

Si dichiara che per le attività oggetto del contratto non sussistono rischi da interferenza, pertanto gli oneri relativi alla sicurezza risultano pari a zero. Il contratto di appalto è “a corpo”.

La copertura finanziaria della spesa è assicurata sul budget anno 2020 per 69.000 euro dal finanziamento di Ateneo per l'acquisizione di strumenti finalizzati alla ricerca anno 2019 (progetto 58514_strumenti_ricerca_2020) e la quota rimanente per due terzi (euro 20.235,08 + iva) sul progetto 58514_BANDOCONGIUNTO_UNIFICRF_SORBI di cui è assegnatario il prof. Sorbi e per un terzo (10.117,54 euro+iva) sul progetto in attività commerciale CONVMAS91 di cui è assegnatario il prof. Massacesi del Dipartimento Neurofarba ed è autorizzata dal Consiglio di Dipartimento del 16 dicembre 2019.

Verificato che non sussistono situazioni di conflitto di interessi;

La fornitura è acquisibile esclusivamente in “UNICITÀ” per le motivazioni di seguito dettagliate:

Caratteristiche di unicità per Sistema Quanterix SR-X per la misurazione ultra-sensibile di biomarcatori per mezzo della tecnologia Simoa®

Il Sistema Quanterix SR-X per la misurazione ultra-sensibile di biomarcatori per mezzo della tecnologia Simoa presenta le seguenti caratteristiche esclusive che lo rendono uno strumento unico sul mercato:

È una piattaforma integrata che comprende lo strumento SR-X ed i reagenti Simoa, entrambi coperti da brevetti. Non ci sono sistemi o prodotti con licenza offerti da terzi che siano in grado di utilizzare qualsiasi componente o metodo della piattaforma Simoa.

Quanterix SR-X - Caratteristiche

- Misura singole molecole immobilizzate sulla superficie di particelle magnetiche da 2,7 micron. Ogni particella magnetica è incapsulata in un pozzetto di 50 femtolitri all'interno di una matrice di 239.000 pozzetti. Gli analiti sono etichettati con un enzima e il prodotto dell'enzima viene rilevato mediante imaging.
- È in grado di misurare le concentrazioni di biomarcatori in matrici di campioni quali siero, plasma, liquido cerebrospinale, urina e saliva.
- È compatibile con un menu di oltre 80 immunodosaggi Simoa con limiti di rilevazione in media 100 volte inferiori rispetto ai metodi ELISA basati su piastra e CV inferiori al 10%.
- Consente l'uso simultaneo di misurazioni digitali (conteggio di singole molecole) e analogiche (intensità di fluorescenza) con un intervallo dinamico di 4 ordini di grandezza.
- Supporta l'uso di saggi Homebrew Simoa che consentono agli utenti di creare analisi personalizzate per il rilevamento di proteine e acidi nucleici.
- Supporta misurazioni multiplex fino a un massimo di 6 analiti per reazione.

Secondo l'art. 103, comma 11, del D. Lgs. n. 50/2016, in considerazione della comprovata solidità del fornitore, leader a livello mondiale nella produzione di sistemi per la misurazione ultra-sensibile di biomarcatori e della natura speciale della fornitura, l'amministrazione non richiede una garanzia definitiva.

Dato l'esito dell'avviso esplorativo, pubblicato sulla piattaforma START dal 03/02/2020 al 29/02/2020, per la verifica dell'unicità del fornitore per affidamento ex art.63 c.3 lett.b) D.Lgs.50/2016, il RUP dichiara che non vi sono altri operatori economici che possono effettuare la fornitura dello strumento sopra descritto.

Per tali motivazioni e per quanto sopra esposto il sottoscritto

DETERMINA

Visto l'esito negativo dell'avviso per verifica unicità del fornitore per affidamento ex art.63 c.2 lett. b) d.lgs. 50/2016, di procedere all'affidamento diretto ai sensi dell'ex art.63 comma 2 lett. b) del D.lgs.50/2016 e di trasmettere la pratica alla Centrale Acquisti dell'Ateneo per l'espletamento della procedura di appalto e la contrattualizzazione.

Responsabile del Procedimento
Dott. Francesco Bardazzi

Quanterix

high definition diagnostics

900 Middlesex Turnpike
Billerica, MA 01821
+1 (617) 301-9400

www.quanterix.com

Contact Name Benedetta Nacmias
Contact Title Associate Professor of Neurology
Account Name University of Florence

Quanterix Corporation is pleased to provide you with this requested quotation for a Simoa instrument and/or associated assay kits and services. The Simoa technology at the heart of this platform enables the detection and quantification of biomarkers previously difficult or impossible to measure, opening up new applications to address significant unmet needs in life science research. The ultrasensitivity of Simoa assays sets it apart from all other immunoassays available today, offering PCR-like limits of detection with both existing and novel protein biomarkers. A robust menu of ultrasensitive assays are available for proteins important in a variety of applications including inflammation, metabolism, neurology, oncology and cardiovascular disease, in addition to offering homebrew capabilities for the development of assays of specific interest to your laboratory.

If you are a European Customer, please send purchase orders to Quanterix Europe Customer Service at europescustomerservice@quantex.com. If you are from the USA or any other region, please send purchase orders to Quanterix Customer Service at customerservice@quantex.com.

Bill To Name University of Florence Ship To Name University of Florence
Bill To Azienda Ospedaliero-Universitaria Careggi Ship To Florence
Viale Pieraccini, 6 - CUBO 3, pad 27 b Italy
Florence, 50139 Italy

Product Code	Product	Product Description	List Price	Quantity	Discount	Total Price
102917	Quanterix SR-X	The Quanterix SR-X is digital immunoassay instrument capable of analyzing samples using the proprietary single-molecule array (Simoa) technology and delivering ultra-sensitive measurements of proteins of interest over a wide dynamic range and with low CV's. Includes instrument and software with one full year of service and warranty coverage.	EUR 80,000.00	1.00	10.00%	EUR 67,500.00
103082	Installation Kit for SR-X	This kit includes Simoa plate magnet, labware and reagents required for installation and SAT for SR-X instrument.	EUR 0.00	1.00		EUR 0.00
103050	Simoa Microplate Shaker (230V)	(230V EU) Incubating microplate shaker for Simoa reagent mixing and assay incubations. Digital programming and control of shake speed (100 to 1200 rpm) and incubation temperature (ambient +5°C to 65°C). Includes 5 year warranty. 230 V.	EUR 3,000.00	1.00	10.00%	EUR 2,700.00
102897	Simoa Microplate Washer	The Simoa Microplate Washer features 96-well plate washing for sample prep of Simoa assays. Includes one year warranty.	EUR 17,000.00	1.00	10.00%	EUR 15,300.00
103165	Quanterix SR-X/SP-X Bundle Shipping	Shipping Charges - Quanterix SR-X or Quanterix SP-X, Simoa Microplate Washer and Simoa Microplate Shaker using economy shipping.	EUR 1,410.00	1.00		EUR 1,410.00

Subtotal EUR 96,410.00
Total Price EUR 86,910.00
Shipping and Handling EUR 0.00
Grand Total EUR 86,910.00

Prepared By Sabrina Ghelima

Created Date 4/8/2020

Email sghelima@quanterix.com

Quote Number 00013924

Expiration Date 05/31/2020

Payment Terms: 30 Days Net.

Shipping Terms: FOB Destination for instruments

Shipping Terms: FOB Ship Point for all other products

Estimated Ship Date for Instruments: 90 Days

QUANTERIX CORPORATION TERMS AND CONDITIONS

1. AGREEMENT

A. THE SALE BY QUANTERIX CORPORATION ("QUANTERIX") TO THE INITIAL PURCHASER ("BUYER") OF THE PRODUCTS AND/OR SERVICES DESCRIBED HEREIN IS GOVERNED EXCLUSIVELY BY THE TERMS AND CONDITIONS OF THE FOLLOWING DOCUMENTS (COLLECTIVELY REFERRED TO HEREIN AS THE "AGREEMENT"): (A) THESE QUANTERIX CORPORATION TERMS AND CONDITIONS, ("TERMS AND CONDITIONS"); AND (B) THE SALES QUOTATION, PROPOSAL, OR STATEMENT OF WORK ("SOW") ISSUED BY QUANTERIX OR ITS AUTHORIZED REPRESENTATIVE TO WHICH THESE TERMS AND CONDITIONS ARE ATTACHED (THE "SALES QUOTE"). THESE TERMS AND CONDITIONS TAKE PRECEDENCE OVER BUYER'S ADDITIONAL OR DIFFERENT TERMS AND CONDITIONS, TO WHICH NOTICE OF OBJECTION IS HEREBY GIVEN. BUYER'S ENTITLEMENT TO THE PRODUCTS OR SERVICES IS CONTINGENT UPON BUYER'S ACCEPTANCE OF THESE TERMS AND CONDITIONS, ANY CHANGES TO WHICH MUST SPECIFICALLY BE AGREED TO IN A WRITING EXECUTED BY QUANTERIX AND BUYER BEFORE BECOMING BINDING ON EITHER PARTY. Buyer acknowledges that Quanterix's sales representatives and other agents have no authority to make any representation or warranty not included in this Agreement or to modify or waive any provision of this Agreement. In the event of any inconsistency or conflict between these Terms and Conditions and the provisions of the Sales Quote, these Terms and Conditions shall control, except to the extent expressly set forth in the Sales Quote and signed by an authorized officer of Quanterix.

B. For purposes of the Agreement: "System" shall mean, collectively, the instrument, as described in the Sales Quote, the Software (defined below), and any related hardware, peripherals or other non consumable components; "Consumables" shall mean the reagents and consumables sold by Quanterix including those in Quanterix's standard product catalog as may be updated from time to time by Quanterix; "Product(s)" shall mean the System and/or any Consumable(s); "Accelerator Services" shall mean agreed upon research services by the parties to be performed by Quanterix's Accelerator Laboratory; "Field Service" shall mean services performed by Quanterix field service or field applications personnel; "Service" shall mean Accelerator Services or Field Service, as the case may be. and "Deliverables" shall mean all inventions, discoveries, improvements, ideas, processes, formulations, products, works of authorship, databases, trade secrets, know-how, information, data, documentation, reports, research, creations and all other products and/or materials arising from or made in the performance of Accelerator Services.

C. The parties agree, and Buyer represents and warrants, that all Products sold hereunder shall only be used in or for the following field: research use only and not for in vitro diagnostics.

2. PURCHASE ORDERS

A. Buyer may order a System by submitting a written purchase order (signed by Buyer's authorized representative) to Quanterix by fax, mail, or electronically, to which Buyer shall attach a copy of the Sales Quote that has been signed by an authorized representative of Buyer. Buyer may order Consumables through Quanterix's website or by submitting a written purchase order (signed by Buyer's authorized representative) to Quanterix by fax, mail, or electronically, which purchase order shall specify (i) the Sales Quote reference number set forth on the Sales Quote, if any, or (ii) the specific Consumables to be purchased, quantity, shipping instructions, requested delivery dates and bill-to and ship-to addresses. "Buyer may order Services by submitting a written purchase order (signed by Buyer's authorized representative) to Quanterix by fax, mail, or electronically, to which Buyer shall attach a copy of the Sales Quote, or Proposal or SOW that has been signed by an authorized representative of Buyer."

B. All purchase orders from Buyer are subject to approval and acceptance by Quanterix. Quanterix may accept a purchase order by countersigning or acknowledging such purchase order, or Quanterix shall be deemed to have accepted a purchase order if Quanterix ships Products pursuant to such purchase order. For Services, Quanterix shall be deemed to have accepted purchase order if Quanterix commences performance of the Services (including

procuring materials necessary for the Services). Any terms or conditions in any purchase order, acknowledgment, confirmation or other document provided by Buyer to Quanterix that are different from or in addition to those set forth in the Agreement are expressly rejected by Quanterix and shall be of no effect.

C. Purchase orders for Products accepted by Quanterix are generally not subject to cancellation by Buyer. Buyer may only cancel an order with the written consent of an authorized officer of Quanterix, and only upon payment by Buyer of reasonable cancellation charges that shall take into account the expenses, if any, already incurred by Quanterix or any third parties and commitments made by Quanterix or third parties in anticipation of filling such cancelled purchase order.

D. Purchase orders for Accelerator Services accepted by Quanterix are generally not subject to cancellation by Buyer. Buyer may only cancel an order with the written consent of an authorized officer of Quanterix, and only upon payment of costs plus reasonable margin by Buyer for all Services as outlined in PO performed to date prior to termination and all non-cancellable out-of-pocket expenses actually and reasonably incurred prior to the date of termination, including any third party commitments.

E. Purchase orders for Field Service accepted by Quanterix are non-cancellable.

3. PRICES

A. The prices in the Sales Quote are valid solely during the period set forth in the Sales Quote. After expiration of such period, Quanterix shall have the right to change such prices. Such prices (i) are based upon manufacture of the quantity and type of Product ordered for shipment and end use within the United States only (unless expressly stated otherwise in the Sales Quote), (ii) are subject to revision when interruption, engineering changes or changes in quantity or quality are caused or requested by Buyer, and (iii) do not include warranty service or installation outside the United States (unless expressly stated otherwise in the Sales Quote).

B. Unless expressly stated otherwise in the Sales Quote, the prices for Consumables ordered hereunder shall be Quanterix's list prices in effect at the time of submission of the applicable purchase order.

C. Unless expressly stated otherwise in the sales quote, the prices for Services ordered hereunder are valid solely during the period set forth in the Sales Quote or SOW. After expiration of such period, Quanterix shall have the right to change such prices. Such prices (i) are based upon the Services agreed upon by parties, and (ii) are subject to revision when changes in Services are caused or requested by Buyer.

D. Unless expressly stated otherwise in the Sales Quote, the prices of Products or Services are exclusive of insurance, freight, and all excise, sales, use, transfer, and other taxes and duties imposed by any federal, state, municipal, or other government authority with respect to the sale, purchase, delivery, storage, use, consumption or transportation of Products or Deliverables, all of which taxes and duties are the sole obligation of, and shall be paid by, Buyer. Clerical errors made by Quanterix in the Sales Quote are subject to correction.

4. PAYMENT TERMS

A. Products: Buyer will be invoiced at the time of shipment of each Product. Accelerator Services: Buyer will be invoiced for Services at the time of completion of Services or, if outlined in a separate SOW, payment terms will be dictated by SOW. Field Service: Buyer will be invoiced (i) for service contracts, the first day of service coverage under the contract; or (ii) for demand service, the date on which service is performed. Payments for Products or Services are due in full within thirty (30) days of the date of the applicable invoice from Quanterix, except as specifically stated otherwise in the Sales Quote. All payments shall be made in immediately available U.S. Dollars. If payment in full is not received by the due date, interest may accrue on all unpaid amounts at the rate of 1.5% per month or the maximum legal rate, whichever is less, together with all costs and expenses (including, without limitation, reasonable attorneys' fees and disbursements and court costs) incurred by Quanterix in collecting such overdue amounts or otherwise enforcing Quanterix's rights hereunder.

B. Any credit terms extended to Buyer may be changed or withdrawn by Quanterix at any time upon notice, and Quanterix reserves the right to require alternative payment terms, including, without limitation, a letter of credit or full or partial payment in advance. All purchase orders are accepted, and the obligation of Quanterix to make deliveries or perform Services is, subject to Quanterix's right to require Buyer to pay all or any part of the purchase price in advance of delivery, or to make shipment C.O.D. If Buyer fails to make advance payment when requested to do so by Quanterix or if Buyer is or becomes delinquent in the payment of any sum due Quanterix or refuses to accept C.O.D. shipments, then Quanterix shall have the right, in addition to any other remedy to which it may be entitled in law or in equity, to cancel Buyer's purchase order and terminate the Agreement, refuse to make further deliveries, refuse to provide further Services and declare immediately due and payable all unpaid amounts for Products

previously delivered to Buyer or Services previously performed for Buyer.

5. SPECIFICATIONS The specifications of Products set forth in sales literature are not guaranteed unless certified in writing by Quanterix. Quanterix reserves the right to make changes to the specifications of any Product delivered under the Agreement from time to time, at Quanterix's discretion.

6. SHIPMENTS/DELIVERY

A. Unless otherwise specified in the Sales Quote, Quanterix will ship Products to Buyer FCA (Incoterms 2010) Quanterix's shipping point, warehouse, or service center, via a carrier specified by Quanterix (unless other requested by Buyer and approved by Quanterix). Delivery will be deemed complete upon delivery via the carrier set forth above. Buyer will pay for all shipping charges, and shall instruct Quanterix to: (i) prepay the carrier and add such charges to Buyer's invoice or (ii) if Buyer has an account with the carrier, charge such account. The carrier shall be deemed the Buyer's agent, and any claims for damages in shipment must be filed with the carrier. Risk of loss of and damage to the Products will pass to Buyer at the time Products are delivered to the carrier. Buyer will be responsible for deciding whether to purchase loss/damage insurance or not to insure, and for paying all insurance costs. Title to the System shall pass to Buyer upon receipt at Buyer's designated ship-to address. Notwithstanding the foregoing and unless otherwise specified in the Sales Quote, Products shipped from the United States to France, Germany, The Netherlands, Sweden, Switzerland or the United Kingdom shall be shipped by Quanterix DDP excluding VAT (Incoterms 2010) destination point, Buyer's designated ship-to address, via a carrier specified by Quanterix. In such cases, (i) delivery will be deemed complete and title and risk of loss of and damage to the Products will pass to Buyer upon receipt at Buyer's designated ship-to address, and (ii) Quanterix will pay for all shipping charges, provided, however VAT responsibility remains with the Buyer.

B. Unless otherwise specified by Sales Quote or separate SOW, Quanterix will deliver Deliverables electronically.

C. Quanterix reserves the right to delay the fulfillment of a purchase order or partially fulfill a purchase order if Quanterix determines, in its sole discretion that the Products manufactured for Quanterix do not meet Quanterix quality standards or if there is a failure of a Quanterix supplier or their suppliers in supplying a Product to Quanterix. The scheduled shipping or delivery date, if provided to Buyer by Quanterix, is Quanterix's reasonable estimate of the time the Products will be shipped or deliverables will be Delivered and Quanterix assumes no liability for loss, general damages, or special or consequential damages due to delays. Unless expressly stated otherwise in the Sales Quote, Quanterix may make delivery in installments and may render a separate invoice for each installment. Each installment delivery shall be considered a separate independent transaction, and payment therefor shall be made accordingly.

7. INSTALLATION; SERVICE AND MAINTENANCE

A. Buyer shall be responsible for the procurement at its expense of any special permits required for the installation or operation of the System. Quanterix and the Buyer will cooperate with each other to coordinate such installation. The cost of the installation of the System is included in the price(s) for the System as set forth in the Sales Quote.

B. Quanterix will not be obligated to perform service or maintenance of any System, which in its sole judgment: (i) has been repaired by other than an authorized Quanterix representative; (ii) has been altered or damaged as a result of additions or changes made to the System by the Buyer or anyone else not authorized by Quanterix; (iii) has been damaged by environmental conditions at the Buyer's site; (iv) has been damaged due to operator error or failure to perform standard operating procedures and routine maintenance as prescribed in any operators manual provided by Quanterix; (v) has been damaged as a result of the Buyer moving the System from its installed location; (vi) has unauthorized software installed; or (vii) has been used in breach of any term or condition of the Agreement.

C. Certain Systems include remote access and/or performance monitoring functionality (the "Remote Functionality") that allows Quanterix to acquire and collect data (the "Data") pertaining to performance, sample processing reliability and/or data yield. This functionality does not collect personally identifiable patient information or information regarding samples. Quanterix may use the Data for purposes including, but not limited to, assistance with product repairs, diagnostics, research, and analytics to improve functionality or optimize customer usage, product development and quality control/improvement, and may require access to the Remote Functionality and the Data to provide service support

8. ACCEPTANCE

A. Subject to the limited warranty below, Buyer shall be deemed to have accepted the System when Quanterix has completed installation of the System.

B. Subject to the limited warranty below, Buyer shall be deemed to have accepted Consumables (i) upon delivery to the common carrier for Consumables shipped FCA (Incoterms 2010) Quanterix's shipping point, as contemplated by

Section 6 above, or (ii) upon receipt at Buyer's designated ship-to address for Consumables shipped DDP (Incoterms 2010) destination point, as contemplated by Section 6 above. Buyer shall inspect all Consumables within five (5) business days after deemed acceptance (the "Inspection Period"). Buyer shall notify Quanterix within the Inspection Period of any missing quantity or components of Consumables, any delivery of Consumables not ordered, and/or any damage to the delivered Consumables that is or should be obvious upon a visual and physical inspection thereof. As soon as practicable upon receipt of any such notice pursuant to this Section 8B, Quanterix shall use commercially reasonable efforts to provide replacement Consumables for missing and/or damaged Consumables (unless any such damage is attributable to an act or omission of Buyer or the carrier). Quanterix shall bear the expenses for such replacement Consumables to the extent Buyer previously paid for any corresponding damaged Consumables and/or incomplete shipments. Replacement shipments shall also be subject to the terms set forth in Section 6 (Shipments). The replacement of any missing and/or damaged Consumables pursuant to this Section 8B is Buyer's sole and exclusive remedy with respect to such missing or damaged Consumables. Buyer hereby waives any claims it may have related to the Consumables not reported within the Inspection Period.

9. WARRANTY

A. Subject to the exclusions set forth in 9B below, Quanterix warrants that: (i) the System (including Quanterix-supplied components and accessories, but excluding Software) sold under the Agreement shall be free from material defects in workmanship and materials for one (1) year after delivery of the System in accordance with Section 6; provided, however, that: (a) components or accessories of the System which by their nature are not intended to, and will not, function for one (1) year are warranted only to give reasonable service for a reasonable time; and (b) the warranty for the System, or its components or accessories purchased by Quanterix from a third party manufacturer and sold to Buyer, including as part of or as a replacement part for a System, shall be limited to those warranties, if any, offered by such third party manufacturer on a pass-through basis to Buyer; and (ii) the Consumables sold under the Agreement shall be free from material defects in workmanship and materials until the expiration date indicated on such Consumables by Quanterix, unless stated otherwise in the Sales Quote (collectively each relevant period of time shall be referred to as the "Warranty Period"); and (iii) that (a) it possesses the necessary expertise to perform Services consistent with professional standards of the industry, and (b) Services will be performed in a professional and workmanlike manner consistent with professional standards of the industry. Quanterix shall re-perform any Services not in compliance with this warranty brought to its attention within a reasonable time after those Services are performed." Notwithstanding anything to the contrary herein, Quanterix's Returned Goods Authorization shall apply with respect to all warranties hereunder (as defined in 9.C below).

B. The foregoing limited warranties in Section 9A shall be void if: (i) the System is moved from the location within Buyer's facility where the System was installed by Quanterix; (ii) the System, any component thereof, or any Consumable is used in breach of these Terms and Conditions (including the License); (iii) the System, any component thereof, or any Consumable is not used in compliance with the accompanying documentation (including but not limited to operators manual or other labeling provided with the Products or Deliverables) provided by Quanterix; (iv) the System, any component thereof, or any Consumable is used with: (a) software, hardware or machinery not authorized by Quanterix (v) the System, any component thereof, or any Consumable has been subjected to: physical abuse, misuse, abnormal use, tampering, or unusual physical stress; use by inadequately trained or untrained operators; use after defect or malfunction has been detected; improper storage or failure to continually provide a suitable operating environment; modification, accessorization and/or servicing (including installation) by anyone other than Quanterix or a third party designated by Quanterix, unless pre approved by Quanterix; acts of God; negligence or accidents; (vi) the System, any component thereof, or any Consumable is returned in improper packaging or (iv) the failure of Services to meet any specified acceptance criteria is due to the negligence or misconduct of Buyer or due to materials provided by Buyer and used in the Services. If the System is used with any reagent or consumable not supplied by Quanterix, the System may not work in accordance with the specifications set forth in the product specifications provided in the System Brochure. Furthermore, in such a case, any repairs or service required as a direct result of use usage of consumables or reagents not provided by Quanterix, will be not covered by Quanterix' warranty and service contract.

C. If Quanterix's investigation and inspection discloses that a Product or component defect developed within the applicable Warranty Period under normal and proper use in accordance with the Agreement and Quanterix's operating instructions, Quanterix agrees, at its option, either (i) to correct by repair, or by replacement with an equivalent product or component, any such defective Product or component, or (ii) to refund the purchase price paid by Buyer for such defective Product. Any Product or component repaired or replaced by Quanterix shall be owned by

Quanterix and at Quanterix's request shall be returned to Quanterix. Any Product repaired or replaced will also be warranted for the remainder of the applicable original Warranty Period or for sixty (60) calendar days, whichever is the longer. No Products shall be returned to Quanterix for repair or refund without the prior written authorization of Quanterix, including, where required by Quanterix, an applicable return authorization number ("Quanterix's Returned Goods Authorization"). Buyer shall follow Quanterix's instructions regarding any return of defective Product or component. Failure to follow Quanterix's instructions or return of a Product without authorization will void the warranty set forth in Section 9A above. The repair or replacement of any Product or component, or the refund to Buyer of the purchase price paid for such Product or component, is Buyer's sole and exclusive remedy with respect to the failure of any Product to be free from material defects in workmanship and materials (in accordance with the limited warranties in this Section 9).

D. EXCEPT FOR THE EXPRESS LIMITED WARRANTIES SET FORTH IN THIS SECTION 9, THE PRODUCTS, SERVICES AND DELIVERABLES ARE PROVIDED "AS IS" AND QUANTERIX MAKES NO WARRANTY, EXPRESS, STATUTORY OR OTHERWISE, WITH RESPECT TO THE PRODUCTS OR SERVICES OR OTHERWISE IN CONNECTION WITH THESE TERMS AND CONDITIONS, AND QUANTERIX HEREBY EXPRESSLY DISCLAIMS ALL OTHER WARRANTIES RELATING TO THE PRODUCTS OR SERVICES, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF NON-INFRINGEMENT, FITNESS FOR A PARTICULAR PURPOSE OR MERCHANTABILITY. QUANTERIX DOES NOT WARRANT THAT THE USE OF THE PRODUCTS OR PROVISION OF SERVICES OR THEIR RESULTS OR DELIVERABLES SHALL BE UNINTERRUPTED OR ERROR-FREE.

10. LIMITATION OF LIABILITY

A. QUANTERIX SHALL NOT BE LIABLE FOR ANY LOSS, DAMAGE, OR INJURY RESULTING FROM BUYER'S OR THIRD PARTIES' NEGLIGENCE, LACK OF TRAINING, USE OR MISUSE, OR MISAPPLICATION OF THE PRODUCTS OR DELIVERABLES. IN NO EVENT SHALL QUANTERIX (OR ITS SUPPLIERS OR LICENSORS) BE LIABLE TO BUYER OR ANY THIRD PARTIES FOR ANY CONSEQUENTIAL, INCIDENTAL, PUNITIVE, CONTINGENT, STATUTORY OR ANY OTHER SPECIAL DAMAGES (INCLUDING WITHOUT LIMITATION LOSS OF PROFITS OR LOSS OF DATA) ARISING OUT OF OR RELATED TO THE AGREEMENT OR THE MANUFACTURE, USE (OR INABILITY TO USE), SALE, HANDLING, SUPPLY OR FAILURE OR DELAY IN SUPPLYING THE PRODUCTS, PROVIDING THE SERVICES, DELIVERING THE DELIVERABLES, OR REPAIR, MAINTENANCE OR REPLACEMENT OF ANY PRODUCT, WHETHER IN CONTRACT, TORT, OR OTHERWISE, EVEN IF QUANTERIX WAS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. BUYER ASSUMES SOLE AND EXCLUSIVE RESPONSIBILITY AND LIABILITY FOR ITS USE OF THE PRODUCTS AND DELIVERABLES.

B. QUANTERIX'S (AND ITS SUPPLIERS' AND LICENSORS') LIABILITY FOR DAMAGES ON ACCOUNT OF A CLAIMED DEFECT IN ANY PRODUCT, OR ARISING OUT OF THE MANUFACTURE, SALE, SUPPLY OR FAILURE OR DELAY IN SUPPLYING THE PRODUCTS, OR SERVICES RELATED THERETO, PROVIDING THE SERVICES, OR DELIVERING THE DELIVERABLES, WHETHER BASED UPON WARRANTY, CONTRACT, TORT, STRICT LIABILITY OR OTHERWISE, SHALL IN NO EVENT EXCEED THE APPLICABLE PURCHASE PRICE PAID BY BUYER WITH RESPECT TO THE PRODUCT, SERVICE OR DELIVERABLE ON WHICH THE CLAIM IS BASED. FURTHER, WITH RESPECT TO ANY CONSUMABLE, QUANTERIX'S LIABILITY HEREUNDER SHALL BE LIMITED AND SUBJECT TO BUYER'S CLAIM BROUGHT WITHIN ONE YEAR OF DELIVERY OF SUCH CONSUMABLE TO BUYER. QUANTERIX SHALL NOT BE LIABLE FOR DAMAGES RELATING TO ANY NON QUANTERIX INSTRUMENT, EQUIPMENT, OR APPARATUS WITH WHICH ANY PRODUCT IS USED. NO ACTION RELATING TO THE PRODUCTS OR SERVICES MAY BE BROUGHT BY BUYER MORE THAN ONE YEAR AFTER SHIPMENT OF A PRODUCT OR DELIVERY OF A DELIVERABLE. SELLER DISCLAIMS ALL LIABILITY OF ANY KIND OF SELLER'S SUPPLIERS AND LICENSORS.

11. INTELLECTUAL PROPERTY

A. Buyer acknowledges that: (i) all right, title, and interest in and to all patents, copyrights, trademarks, trade secrets, and all other intellectual property and proprietary rights subsisting in or related to the Products or Services ("IP Rights") belong to Quanterix; (ii) no transfer of ownership, title, or any other rights in the IP Rights is made by the sale of any Product or Service to Buyer, except for the right to use the Products or Services in compliance with all applicable terms and conditions of the Agreement; and (iii) such right to use the Products or Services explicitly does not include the right to modify, enhance, or improve the IP Rights or Products or to transfer IP Rights or Products or Services to any third party. Buyer shall not engage in any act or omission that would impair any IP Rights of Quanterix or its suppliers or licensors.

B. Accelerator Services: Subject to 9.C below, (i) Buyer will own all rights to Deliverables and (ii) Quanterix will assign and does assign to Buyer all right, title and interest in and to all Deliverables.

C. Notwithstanding anything to the contrary contained herein, any (i) technology improvements, processes or process improvements developed by Quanterix related to Quanterix's pre-existing technology, and (ii) pre-existing patents, trade secrets, know-how or other technology or information owned or controlled by Quanterix and that are incorporated into or embodied in any Deliverables provided hereunder will be owned by Quanterix. Quanterix hereby grants to Buyer a perpetual, irrevocable, non-exclusive, worldwide, royalty-free, non-transferable, fully paid-up license for research use only under Quanterix's intellectual property rights that are incorporated into or embodied in any Deliverables solely to the extent necessary for Buyer to utilize the Deliverables for research use only purposes.

D. Certain Systems include remote access and/or performance monitoring functionality that allows Quanterix to acquire and collect data (the "Data") pertaining to Product performance, sample processing reliability and/or data yield, and to potentially allow Quanterix to develop proactive service programs to maintain optimal instrument performance over time. This functionality does not collect personally identifiable patient information or information regarding samples. By enabling the remote access functionality, you consent to the acquisition of collection of the Data.

12. COMPLIANCE WITH APPLICABLE LAWS

Buyer shall use the Products or Deliverables in strict accordance with all applicable local, state and federal laws, regulations and guidelines, including without limitation all safety precautions accompanying the Products or Deliverables. Without limiting the foregoing, Buyer shall strictly comply with all applicable export laws, controls and regulations, and Buyer shall not export, divert, transfer or disclose, directly or indirectly, any Product, Deliverable or related technical data, materials or documents to any country (or any national or resident thereof) which the U.S. Government determines from time to time is a country (or end-user) to which such export, re-export, diversion, transfer or disclosure is restricted, without obtaining the prior written authorization of Quanterix and the applicable U.S. Government agency. Buyer shall use prudence and reasonable care in the use, handling, storage, transportation, disposition, and containment of the Products or Deliverables. Quanterix shall have no responsibility or liability for the use of any Product or Deliverable in violation of this Section 12.

13. RESTRICTIONS

Buyer shall not, and shall not attempt or purport to: (i) modify, reverse engineer, decompile or disassemble any Product or component thereof; or (ii) rent, lease, loan, sell, sublicense, distribute, transmit or otherwise transfer any Product, or any of Buyer's rights to use any Product, to any third party.

14. U.S. GOVERNMENT CONTRACTS

If the Products or Deliverables to be furnished under the Agreement are to be used in the performance of a U.S. Government contract or subcontract, and a U.S. Government contract number shall appear on Buyer's purchase order, those clauses of the applicable U.S. Government procurement regulation which are required by Federal Statutes to be included in U.S. Government subcontracts shall be incorporated herein by reference, including, without limitation, the Fair Labor Standards Act of 1938, as amended. The Products or Deliverables (including each of the components that constitute Software and its related documentation) are a "commercial item" as that term is defined at 48 C.F.R. 2.101. As it relates to any Software, the Software is "commercial computer software" and "commercial computer software documentation" as such terms are used in 48 C.F.R. 12.212. Consistent with 48 C.F.R. 12.212 and 48 C.F.R. 227.7202-1 through 227.7202-4, all U.S. Government end users acquire the components of Software and any documentation provided with Software with only those rights set forth in this Agreement.

15. SOFTWARE LICENSE

A. Products or Deliverables to be furnished under the Agreement may include Software. As used herein, "Software" shall mean any and all software included with or imbedded in the System, including without limitation any modified, updated or enhanced versions of such software generally made available by Quanterix to its customers at no additional charge. To the extent any Products or Deliverables include any Software, use of such Products or Deliverables and Software shall be subject to the terms of the License (defined below).

B. Subject to the terms and conditions of this Agreement, Quanterix grants to Buyer a limited, non-exclusive, nontransferable, non-sublicensable license (the "License"), to execute and use the Software solely for the purpose of operating the System ordered and paid for under the terms of this Agreement. Buyer is not entitled to make a copy of the Software. Quanterix and Buyer intend and agree that all Software provided hereunder is being licensed and not sold; that the words "purchase," "sell," or similar or derivative words are understood and agreed to mean "license";

and that the word "Buyer" or similar or derivative words are understood to mean "licensee." Notwithstanding anything to the contrary contained herein, Quanterix or its licensor(s), as the case may be, retains ownership of and all rights, title and interest in and to the Software. Buyer shall use all Software provided hereunder in accordance with the License and any user documentation provided by Quanterix. For purposes of Section 117 of the Copyright Act of 1976, as amended, and for all other purposes, Quanterix will be considered the owner of the Software and related documentation provided hereunder and any copies thereof, and of all copyright, trade secret, patent, trademark and other intellectual property rights therein. Buyer agrees not to copy, sell, transfer, license, loan, or otherwise make available to third parties any Software or related documentation provided hereunder. Buyer shall not modify, adapt, translate, create derivative works from, enhance, or otherwise change or supplement any Software provided hereunder. The source code for the Software will not be disclosed to the Buyer, and Buyer shall not disassemble, decompile, reverse engineer or otherwise attempt to derive the source code for any Software supplied hereunder. C. Certain Software or portions thereof provided by Quanterix may be owned by one or more third parties and may be licensed to Quanterix. Quanterix and Buyer intend and agree that such Software or portions thereof owned by third parties and provided hereunder are being sub-licensed to Buyer, that such third parties retain ownership of and title to the same, and that such third parties may directly enforce Buyer's obligations hereunder in order to protect their respective interests in such Software or portions thereof. The warranty provisions set forth herein shall not apply to Software or portions thereof owned by third parties and provided hereunder.

16. ASSIGNMENT

This Agreement and Buyer's rights and obligations hereunder may not be assigned by Buyer without the prior written consent of Quanterix, except that Buyer may, without Quanterix's prior consent, assign this Agreement in whole to an affiliate or its successor in interest to all or substantially all of its assets to which this Agreement relates.

17. FORCE MAJEURE

Quanterix shall not be liable for failure to perform any of its obligations under the Agreement, including any loss or damage resulting therefrom, if: (i) any Product covered by the Agreement is purchased for end use outside the United States (unless stated otherwise in the Sales Quote), or (ii) such performance of obligations is in any way adversely affected by the occurrence of any contingency or any cause or causes beyond the control of Quanterix, including, without limitation, acts or forces of nature, any law, rule, regulation of or any act or request of any government authority or agency, failure of any contractor or supplier, manufacturer or distributor product recall, fire, storm, explosion, accidents, war, embargo, riot, acts of terrorism, labor dispute, labor or material shortage, and/or delays in transportation.

18. MISCELLANEOUS

Nothing in the Agreement shall constitute or create a joint venture, partnership, or any other similar arrangement between the parties. Neither party is authorized to act as agent for the other party. Buyer acknowledges and agrees that one or more of the Products or Deliverables may be subject to restrictions and controls imposed by the United States Export Administration Act and the regulations thereunder. This Agreement is made in, governed by, and shall be construed in accordance with the laws of the Commonwealth of Massachusetts, without regard to the conflicts of law principles thereof. Neither the United Nations Convention of Contracts for the International Sale of Goods nor the Uniform Computer Information Transactions Act shall apply to the Agreement. The Agreement constitutes the entire agreement between Quanterix and Buyer pertaining to the sale of the Products or Services by Quanterix to Buyer, and any prior understandings, agreements and representations, oral or written, are superseded by the Agreement. If any provision of the Agreement, or the application thereof to any person or circumstance, is held invalid, illegal or unenforceable, the remaining terms and conditions of the Agreement, and/or the application of such provision to other persons or circumstances (as applicable), shall not be affected thereby, and to such end the provisions of the Agreement are agreed to be severable. Unless otherwise expressly set forth herein, the remedies contained herein are cumulative in addition to any other remedies at law or in equity. Waiver by a party of any provision of the Agreement or of any breach by the other party of any provision of the Agreement shall not be deemed a waiver of future compliance with the Agreement, and such provision, as well as all other provisions of the Agreement, shall remain in full force and effect. No waiver by a party of any provision or breach of the Agreement shall be effective unless in writing and signed by such party. The headings of clauses contained in the Agreement are inserted solely for convenience and ease of reference only and shall not constitute any part of the Agreement, or have any effect on its interpretation or construction.

Certificate of exclusivity

The SiMoA SR-X Digital Benchtop Analyzer is a next generation disruptive technology that is differentiated in many ways:

- The SiMoA system has the ability to measure biomarkers (proteins/cytokines/metabolites) in biological samples at concentrations that are a 1000 fold (femtogram/ml) improvement over current methods (Meso Scale Discovery and Luminex).
- Capable of analyzing biological samples using single-molecule digital ELISA array technology.
- Utilizing magnetic beads to form immunocomplex's. This allows the enzyme bound to the capture antibody to produce sufficient fluorescence in each well to be detectable, even when just a single molecule is present.
- Discs with twenty four channels are used to load, seal, and image the proteins of interest. Each array contains approximately 239,000 wells for maximum sensitivity.
- The increase in sensitivity will allow for less sample to be used for sample processing. Sample volumes as low as 1ul.
- The SR-X system is semi-automated that requires only 1h30 to 2 hours hands-on work on the bench compared to 4 hours for others platforms.
- The SiMoA system has the capability of running Multiplex panels with up to 6 markers.
- Ability to measure DNA and miRNA in semi-automated fashion with little purification and no amplification.
- Digital signal which allows for greater sensitivity and reproducibility.
- Analytical reagents must include the use of paramagnetic beads of 2.7 microns in diameter to allow for high bead to sample molecule ratio (~10:1). Paramagnetic bead size must not exceed an average of 2.7 microns.
- The SiMoA system is an open platform (Homebrew Kit) which will allow for the adoption and development of markers that might be of commercial interest and not currently available.
- System must have open platform assay kits that allow end users to modify and develop and adapt unique, lab specific biomarkers, like the "homebrew" from Quanterix. Open assay kits must be available for purchase and must contain paramagnetic beads and buffers required for conjugation.
- System must be able to detect biomarkers, proteins and DNA in urine, blood, plasma, serum, stool, cell lysates, tissue homogenates, CSF and environmental water.
- System must not utilize glass slides, glass coverslips or lasers.

- Reaction volumes must be very small, equaling 50x10⁻¹⁵ L and must number equal to or greater than 5 million per testing array.
- Throughput must equal at least 68 tests per hour with results between 30 and 60 mins, run in batches or individually.
- Analytical precision must have a CV of less than 10% and a dynamic range of 4 to 5 logs.

The Simoa HD-1 Analyzer is covered by the following patents:

- Four issued US patents on core Simoa assay technology, 8222047, 8236574, 8415171, 8846415
- Four issued or allowed patents on core Simoa technology in Japan, EU, Canada and China, JP 5363663, CA 2791655, CA 2791654, JP 5551798
- Three divisional and continuation applications pending on core technology
- Nine other cases pending US and Worldwide

The Simoa HD-1 analyzer allows researchers to analyze proteins at levels never seen before to dramatically increase the speed of research that will lead to new discoveries. Some of the advantages are dramatic increases in sensitivity (up to 3000x), greatly reduced sample size, the ability to detect DNA, full automation, single molecule detection and a dynamic range up to five logs.

Quanterix was recently named (Feb. 2015) as a 2015 award finalist by the internationally renowned Edison Awards™, alongside past diagnostic winners, such as Thermo Scientific and GE Healthcare. The distinguished awards, inspired by Thomas Edison's persistence and inventiveness, recognize innovation, creativity and ingenuity in the global economy.

Sincerely yours,

Mark Roskey
VP and GM, Sales & Marketing
Quanterix Corporation

113 Hartwell Avenue, Lexington, MA 02421-3125

Tel: 617-301-9495 | Mobile: 508-494 0497 | Fax: 781-862-38

Quanterix™

The Science of Precision Health

DESCRIZIONE STRUMENTO

Il sistema Quanterix SR-X, prodotto e distribuito da Quanterix Corporation, misura in modo ultrasensibile biomarcatori per mezzo della tecnologia Simoa®. È una piattaforma integrata che comprende lo strumento SR-X ed i reagenti Simoa, entrambi coperti da brevetti. Non ci sono sistemi o prodotti con licenza offerti da terzi che siano in grado di utilizzare qualsiasi componente o metodo della piattaforma Simoa.

Quanterix SR-X - Caratteristiche

- Misura singole singole molecole immobilizzate sulla superficie di particelle magnetiche da 2,7 micron. Ogni particella magnetica è incapsulata in un pozzetto di 50 femtolitri all'interno di una matrice di 239.000 pozzetti. Gli analiti sono etichettati con un enzima e il prodotto dell'enzima viene rilevato mediante *imaging*.
- È in grado di misurare le concentrazioni di biomarcatori in matrici di campioni quali siero, plasma, liquido cerebrospinale, urina e saliva.
- È compatibile con un menu di oltre 80 immunodosaggi Simoa con limiti di rilevazione in media 100 volte inferiori rispetto ai metodi ELISA basati su piastra e CV inferiori al 10%.
- Consente l'uso simultaneo di misurazioni digitali (conteggio di singole molecole) e analogiche (intensità di fluorescenza) con un intervallo dinamico di 4 ordini di grandezza.
- Supporta l'uso di saggi *Homebrew* Simoa che consentono agli utenti di creare analisi personalizzate per il rilevamento di proteine e acidi nucleici.
- Supporta misurazioni *multiplex* fino a un massimo di 6 analiti per reazione.

DESCRIZIONE DEL GRADO DI INNOVATIVITÀ DELLO STRUMENTO RICHiesto

Quanterix e le piattaforme ultrasensitive per la detezione di singole molecole (Simoa) permettono il monitoraggio di numerosi biomarcatori proteici tra cui ad esempio NF-L, GFAP, TNF-alpha e varie citochine infiammatorie in sangue. Simoa consente ai ricercatori di analizzare i biomarcatori a livelli mai visti prima e di conseguenza aumenta drasticamente la velocità della ricerca che porterà a nuove scoperte.

L'analizzatore da banco Simoa SR-X è una tecnologia rivoluzionaria che consente di misurare biomarcatori (proteine/citochine/metaboliti) in campioni biologici a concentrazioni di femtogrammi/ml. L'aumento della sensibilità consente di utilizzare meno volumi (a partire da 1 microlitro) per il campione da analizzare. Il sistema SR-X è semi automatico e richiede solo 2 ore di lavoro sul banco rispetto alle 4 ore delle altre piattaforme. La piattaforma è aperta e consente l'adozione e lo sviluppo di biomarcatori che potrebbero essere di interesse commerciale e non attualmente disponibili.

Il sistema Quanterix SR-X e i reagenti Simoa sono coperti dai seguenti brevetti:

- Brevetto USPTO n. 8.236.574 B2 Rilevazione ultra-sensibile di molecole o particelle mediante sfere o altri oggetti di cattura
- Brevetto USPTO n. 8.222.047B2 Rilevazione ultra-sensibile di molecole su matrici di singole molecole
- brevetto USPTO n. 8.415.171B2 Metodi e sistemi per estendere la gamma dinamica nei saggi per il rilevamento di molecole o particelle

Nel Febbraio 2015 Quanterix è stata nominata come finalista del premio Edison Awards™, insieme a Thermo Scientific e GE Healthcare. I premi, ispirati dalla persistenza e inventiva di Thomas Edison, riconoscono l'innovazione, la creatività e l'ingegno nell'economia globale.

Quanterix SR-X - Specifiche

- Larghezza: 56 cm, Profondità: 74 cm, Altezza: 56 cm, Peso: 68 kg.
- Alimentazione: 100/240 VAC, 50/60 Hz.
- Braccio robotizzato con movimento completo X, Y, Z per operazioni fluidiche.
- Sensori di blocco della porta per la sicurezza dell'operatore.
- Controllo automatico della messa a fuoco per l'analisi delle immagini.
- Controllo touch screen.
- Alloggiamento di piastre da 96 pozzetti per i campioni.
- Controllo della temperatura di imaging e rilevamento dei dischi Simoa (30° C).
- Scanner di codici a barre integrato per la registrazione dei dettagli di reagenti e campioni.
- Sistema integrato di verifica delle impostazioni.
- Il sistema automatico di rilevamento degli errori interni supporta l'avvertimento dell'utente e riduce al minimo lo spreco di campioni e reagenti.
- Software di assistenza remota per supporto tecnico, risoluzione dei problemi e diagnostica in consultazione con il servizio di assistenza e il personale di assistenza Quanterix.
- Recipienti di reagenti e rifiuti integrati con sistemi sonori per rilevare e richiedere all'utente di sostituire o svuotare i serbatoi secondo necessità.
- Progettato per soddisfare gli standard di sicurezza internazionali.

Quanterix SR-X - Software

- Il software SR-X controlla lo strumento, automatizza il caricamento e l'imaging dei campioni nei dischi Simoa e coordina tutte le fasi operative.
- Il software presenta un'interfaccia utente intuitiva e una configurazione semplificata del protocollo per supportare gli utenti di tutti i livelli.
- L'analisi avanzata dei dati e gli algoritmi di adattamento delle curve forniscono risultati in una serie di formati definiti dall'utente.
- Il software può essere installato su PC Windows offline per consentire agli utenti di creare mappe, definire protocolli e analizzare i risultati.
- Supporto 21CFR.

Lavatore di piastre Simoa

- Il lavatore di piastre Simoa è prodotto esclusivamente per Quanterix.
- La configurazione del dispositivo è ottimizzata per l'automazione delle fasi di lavaggio del dosaggio Simoa e del flusso di lavoro per il sistema SR-X.
- Include impostazioni di sistema pre-programmate, protocolli e calibrazione per i test Simoa.
- Il lavatore di piastre Simoa è l'unica piastra di lavaggio automatica qualificata per offrire prestazioni di dosaggio coerenti ed è l'unica piastra di lavaggio automatica supportata dal Servizio Tecnico e Scientifico di Quanterix.

Agitatore di piastre Simoa

- L'agitatore di piastre Simoa è prodotto esclusivamente per Quanterix.
- La configurazione del dispositivo è ottimizzata per automatizzare le fasi di risospensione e di incubazione di un immunodosaggio Simoa.
- L'agitatore di piastre Simoa è l'unico agitatore per piastre qualificato per offrire prestazioni di dosaggio coerenti ed è l'unico agitatore supportato dal Servizio Tecnico e Scientifico di Quanterix.