STATE OF WASHINGTON
Washington State Department of Health
SOLE SOURCE POSTING

August 31,2023

The Washington State Department of Health (DOH) contemplates awarding a sole source contract to Thermo Fisher Scientific to provide one Quantstudio 12k Flex qPCR System combined with one Open Array Accufill liquid handler and an additional Quantstudio 12k Flex qPCR System (no second liquid handler is needed).

The DOH is requesting this sole source posting.

- Thermo Fisher Scientific is a leading provider of DNA and RNA purification and analysis equipment and plasticware.

- It offers a range of spectrophotometers that can measure DNA, RNA and protein quantitation with only 1-2µL of sample in seconds. It has a variety of nucleic acid extraction and purification methods to suit different sample types, throughput levels, and purity requirements. It has a selection of genomic DNA extraction kits that contain all the reagents needed to isolate high-quality genomic DNA from different sample types.

- The NBS program has over ten years working with previous models of PCR instrumentation from Thermo Fisher Scientific. We currently use a Quantstudio 7 system which uses a custom Taqman low density array (TLDA) with 41 unique primers and probes for Cystic Fibrosis variants. We have been using this method since 2018. Long before that, we have used their VIIA7 instruments in our PCR testing of Severe Combined Immunodeficiency and Spinal Muscular Atrophy.

Consequences of not having Sole source:

- If this sole source filing is denied, it would hinder the timeliness of our reporting results for Cystic Fibrosis where early diagnosis is key for health complications. With an expected approximate 800% increase in samples, PHL will not be able to complete testing in a timely manner, risking not meeting turn-around-times (TATs) and tying up key personnel that would otherwise be free to conduct other testing. Our current Quantstudio 7k Flex is only capable of 7 samples per run. The Quantstudio 12k Flex is capable of 48 samples per OpenArray plate. Four OpenArray plates can be run at one time to maximum of 198 samples.

- There is a risk is that the laboratory will be unable to perform basic required testing impacting the lab's overall effectiveness and in rare circumstances the lab's status could be forced to ship its samples to other states for testing, lengthening response times and increasing risk for infants born in Washington, Hawaii, and Idaho.

- More time will be required of staff that could be used performing other tasks. The increased workload would put physical strain while performing the testing. Each run in our current method relies on 45-60 minutes of hand pipetting. The workload is expected to increase from 3 runs per week to 3 runs per day. The Open Array Accufill System component will reduce strain and time to one run per day.

- The addition of multiple instrument types increases complexity, which may increase the chance of errors. Errors may have severe adverse consequences for the newborns tested.

- If this sole source is not approved the cost could be higher overall. Our current Quantstudio 7 PCR system supports Taqman low density array cards (TLDA). The Quantstudio 12 supports TLDA and Open array cards. If we proceed with an alternative, we will need to acquire additional instruments for back up.

The Department of Health will enter into a purchase and maintenance contract with Thermo Fisher Scientific. The purchase order will be issued on or before September 1, 2023, including (1) year of service coverage (1 PM per year) from the instrumentation installation date. The cost of this purchase is approximately $487,371.49, including service contract of approximately $34,720.00.

Offerors contemplating the above requirements are required to submit capability statements detailing their ability to meet the state's requirements within five (5) working days of this announcement. The following information should be included in the capability statements:

Capability statements should address the following state requirements:

- Supports the Washington State Newborn Screening Cystic Fibrosis (CFTR) custom panel of 41 specific CF-causing genetic variants (list of variants can be obtained by contacting the NBS follow-up supervisor at 206-418-5410).

- Supportive of Taqman fluorescence detection chemistry.

- Have a proven track record of DNA analysis equipment within the newborn screening community.

In the absence of other qualified sources, it is the state's intent to make a sole source award of the contract. To submit capability statements or for questions, contact:

Name: Brooke Jensen
Phone: 360.790.8256
Email: Brooke.Jensen@des.wa.gov

NOTE: DOH is posting this sole source notice per DES Policy 140-00. This notice is made available on the DOH web site and via WEBS under commodity codes: 175-23 DNA or RNA Acids (Nucleic, etc.) Including Extraction, Purification, Quantification and Sequencing; 490-77 Pumps, Liquid (Laboratory Type): Metering, Peristaltic, Syringe, etc

Washington State Department of Health

PURCHASE ORDER

L123265

Page Number	Purchase Order Date
1 of 2	AUG/31/2023

Supplier: SWV0098470-01
ACCT # 68885415
LIFE TECHNOLOGIES
12088 COLLECTIONS CENTER DRIVE
CHICAGO, IL 60693
Phone: 800-955-6288
Fax: 760-602-6500

Ship-to: GS1
DEPT OF HEALTH
1610 NE 150TH ST.
SHORELINE, WA 98155

Bill-to: GX4B
WA STATE DEPT OF HEALTH
PURCHASING INVOICES
DOHFSPURCHASING@DOH.WA.GOV

AUTHORITY	F.O.B.	PAYMENT TERMS	REQUESTED BY	REQUISITION #
DES 07215	DEST., PREPAY & ADD	NET 30	OAKES, JOSHUA, 206 418-5410	

LINE NO.	ITEM NUMBER	DESCRIPTION	QUANTITY	UNIT PRICE	TOTAL COST
1	A53970	QUANTSTUDIO 12K FLEX OPEN ARRAY W/LIQUID HANDLER GTSQS12KOADT,AB PLAT,IQOQ,TRN EACH	1 EA	253,230.34	253,230.34
2	4472380GTS	QUANTSTUDIO 12K FLEX OPEN ARRAY GTS QS 12K FLEX,OA INST EACH	1 EA	186,700.00	186,700.00
3	*	SHIPPING QUOTE S5134956 CAPITAL ASSET TAG: H208885 & H208886 DES FILING REQUIREMENT: The provisions of Chapter 39.26 RCW require the agency to file this sole source contract with the Department of Enterprise Services (DES) for approval. The effective date of this contract is upon DES approval of the contract, the tenth (10th) working day after it is filed with DES, or as agreed between the parties, whichever is later. Continued on next page...	1 EA	2,128.32	2,128.32

1. Show PO# on all invoices and shipping documents.
2. Unless otherwise noted, Washington State sales tax applies to this order.

AGENCY APPROVAL	DATE
Nancy Lander	AUG/31/2023

PREPARED BY	DATE	T.I.N.	RECEIVED BY	DATE
NANCY LANDER	AUG/31/2023	330373077		

DOC. DATE	PMT DUE DATE	CURRENT DOC. NO.	REF. DOC. NO.	VENDOR MESSAGE

REF DOC SUF	TRANS CODE	MOD	FUND	APPN INDEX	PROGRAM INDEX	SUB OBJ	SUB SUB OBJECT	ORG INDEX	ALLOC	BUDGET UNIT	MOS	PROJECT	SUB PROJ	AMOUNT	INVOICE NUMBER
							DETAILS PROVIDED ON SEPARATE PAGE								

ACCOUNTING APPROVAL FOR PAYMENT	DATE	WARRANT TOTAL	WARRANT NUMBER

☐ Vendor Copy ☐ Accounting Copy ☐ Program Copy - Receiving Report

Washington State Department of Health

PURCHASE ORDER

L123265

Page Number	Purchase Order Date
2 of 2	AUG/31/2023

Supplier: SWV0098470-01
ACCT # 68885415
LIFE TECHNOLOGIES
12088 COLLECTIONS CENTER DRIVE
CHICAGO, IL 60693
Phone: 800-955-6288
Fax: 760-602-6500

Ship-to: GS1
DEPT OF HEALTH
1610 NE 150TH ST.
SHORELINE, WA 98155

Bill-to: GX4B
WA STATE DEPT OF HEALTH
PURCHASING INVOICES
DOHFSPURCHASING@DOH.WA.GOV

AUTHORITY	F.O.B.	PAYMENT TERMS	REQUESTED BY	REQUISITION #
DES 07215	DEST., PREPAY & ADD	NET 30	OAKES, JOSHUA, 206 418-5410	

LINE NO.	ITEM NUMBER	DESCRIPTION	QUANTITY	UNIT PRICE	TOTAL COST
				Tax:	45,532.05
				Total:	487,590.71

1. Show PO# on all invoices and shipping documents.
2. Unless otherwise noted, Washington State sales tax applies to this order.

AGENCY APPROVAL	DATE
Nancy Lander	AUG/31/2023

PREPARED BY	DATE	T.I.N.	RECEIVED BY	DATE
NANCY LANDER	AUG/31/2023	330373077		

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Washington State Department of Health Purchase Order (PO) Terms and Conditions

THE PURCHASE ORDER CONTRACT INCLUDES THE FOLLOWING ADDITIONAL TERMS AND CONDITIONS AND INCLUDES, BUT IS NOT LIMITED TO, THE INVITATION TO BID, REQUEST FOR QUOTATIONS, SPECIFICATIONS, PLANS AND PUBLISHED RULES AND REGULATIONS OF THE WASHINGTON STATE DEPARTMENT OF ENTERPRISE SERVICES AND THE LAWS OF **THE STATE OF WASHINGTON WHICH ARE HERBY INCORPORATED BY REFERENCE.**

1. CHANGES: No alteration in any of the terms, conditions, delivery, price, quality, quantities or specifications of this order will be effective without prior written approval of the Washington State Department of Health (DOH).
2. ADD-ONS: By mutual written agreement, additional quantities of items may be purchased within 12 months of the date of award provided the original purchase price, terms, conditions and specifications remain the same. Add-on purchases shall be submitted to the supplier using a DOH Purchase Order and shall reference the original contract or purchase order. Initial and subsequent licenses should span ten years or less.
3. HANDLING: No charges will be allowed for handling, including but not limited to, packing, wrapping, bags, containers, or reels unless otherwise stated herein.
4. DELIVERY: With respect to delivery under this order, time is of the essence, and the order is subject to termination to deliver as specified. Acceptance by DOH of late performance wi or without objection or reservation shall not waive the right to claim damage for such breach nor construe a waiver of the requirements for the timely performance of any obligation remaining to be performed by supplier.
    a. Deliver Exceptions: Any Supplier exceptions to the delivery date, as specified in the order, the supplier shall give prior written notification and obtain written approval thereto from DOH.
5. PAYMENTS AND ASSIGNMENTS: Invoices will not be processed for payment until items invoiced are received. DOH will not honor drafts nor accept goods on a sight draft basis. Furthermore, the provisions or monies due under this contract shall only be assignable with prior written approval from DOH.
6. SHIPPING INSTRUCTIONS: Unless otherwise specified, all goods are to be shipped prepaid, FOB Destination. Where shipping addresses indicate room numbers, supplier shall make delivery to that location at no additional charge. Where specific authorization is granted to ship goods FOB Shipping point, supplier agrees to prepay all shipping charges and route as instructed, or if instructions are not provided, route by cheapest common carrier and bill DOH as a separate item on the invoice for said charges. Each invoice for shipping charges shall contain the original or a copy of the bill indicating that the payment for shipping has been made. It is also agreed that DOH reserves the right to refuse COD shipments.
7. REJECTION: All goods or materials purchased herein are subject to written approval by DOH. Any rejection of goods or materials resulting because of non-conformity to the terms and specifications of this order, whether held by DOH or returned will be at the supplier's risk and expense.
8. IDENTIFICATION: All invoices, packing lists, packages, shipping notices, instruction manuals, and other written documents affecting this order shall contain the applicable purchase order number. Packing lists shall be included with each shipment pursuant to this order, indicating the contents of each package therein.
9. INFRINGEMENTS: Supplier agrees to protect and save harmless DOH against all claims, suits, or proceedings for patent, trademark, copyright or franchise infringement arising from the purchase, installation, or use of goods and materials ordered and to assume all expenses and damages arising from such claims, suits, or proceedings.
10. NONWAIVER BY ACCEPTANCE OF VARIATION: No provision of this order or the right to receive timely performance of any act called for by the terms shall be deemed waived by DOH of a breach thereof as to any particular transaction or occurrence.
11. WARRANTIES: Supplier warrants that items supplied under this order conform to specifications herein and are fit for the purpose for which such goods are ordinarily employed, except that if a particular purpose is stated, the material must then be fit for the particular purpose.
12. CASH DISCOUNT: In the event DOH is entitled to a cash discount, the period of computations will commence on the date of delivery or receipt of a correctly completed invoice, whichever is later. If an adjustment in payment is necessary due to damage, the cash discount period shall commence on the date final approval for payment is authorized. If a discount is made part of the contract but the invoice does not reflect the existence of a cash discount, DOH is entitled to a cash discount with the period commencing on the date it is determined by DOH that a cash discount applies.
13. TAXES: unless otherwise indicated, DOH agrees to pay all State of Washington sales or use tax. No charge by supplier shall be made for Federal Excise taxes, and DOH agrees to furnish supplier with acceptance of items supplied under this order with an exemption certificate.
14. LIENS, CLAIMS, AND ENCUMBRANCES: Supplier warrants and represents that all goods and materials ordered herein are free and clear of all liens, claims or encumbrances of any kind.
15. RISK OF LOSS: Regardless of FOB Point, supplier agrees to bear all risks of loss, injury, or destruction of goods and materials ordered herein which occur prior to delivery. Such loss, injury, or destruction shall not release supplier form any obligation hereunder.
16. SAVE HARMLESS: Supplier shall protect, indemnify, and save DOH harmless from and against any damage, cost, or liability for any injuries to person or property arising from acts or omissions of supplier, his employees, agents, or subcontractors, howsoever caused.
17. PRICES: If price is not stated on this order, it is agreed that the goods shall be billed at the price last quoted or paid, or the prevailing market price, whichever is lower.
18. TERMINATION: in the event of a breach by supplier of any of the provisions of this contract, DOH reserves the right to cancel and terminate this contract forthwith upon giving oral or written notice to supplier. Supplier shall be liable for damages suffered by DOH resulting from supplier's breach of contract.
19. NONDISCRIMAINATION AND AFFIRMATIVE ACTION: The supplier agrees not to discriminate against any client, employee, or applicant for employment or services because of race, creed, color, national origin, sex, marital status, age, or the presence of any sensory, mental or physical handicap with regard to, but not limited to, the following: employment upgrading, demotion or transfer, recruitment or recruitment advertising, lay-offs, or termination, rates of pay or other forms of compensation, selection for training, rendition for services. It is further understood that any supplier who is in violation of this clause shall be barred forthwith from receiving awards of any purchase order form the state unless supplier demonstrates to DOH's satisfaction that the discriminatory practices have terminated and that a recurrence of such acts is unlikely.
20. ANIT-TRUST: Supplier and DOH recognize that in actual economic practice, overcharges resulting from anti-trust violations are in fact borne by DOH. Therefore, supplier herby assigns to DOH any and all claims for such overcharges.
21. DEFAULT: DOH may terminate this contract, without penalty or further liability, upon not less than thirty (30) days prior written notice to supplier, if supplier defaults on any provision of this contract and fails to cure such default within that thirty (30) day period, or such longer period, as may be reasonably determined by DOH.
22. ATTORNEY FEES: In the event of controversy, claim, or dispute arising out of this contract for which the supplier is adjudged by a court of competent jurisdiction to be at fault, supplier shall pay DOH all attorney fees, costs and expenses incurred by DOH in connection therewith.
23. GIFTS: The supplier shall comply with all applicable sections of the State Ethics law, RCW 42.52, which regulates gifts to state officers and employee's. Under that statute, any state officer or employee who has or will participate with the supplier regarding any aspect of the contract involving the purchase of goods or services is prohibited from seeking or accepting any gift, gratuity, favor or any of economic value from the supplier. Neither the supplier nor any agent or representative shall offer anything of economic value as a gift, gratuity or favor directly or indirectly to any such officer or employee.
24. ACCEPTANCE: This order expressly limits acceptance to the terms and conditions stated in the purchase order and these additional terms and conditions. Any terms proposed by supplier are objected to and herby rejected, unless otherwise provided in writing by DOH.
25. FORCE MAJEURE: Vendor will not be responsible for delays in delivery due to acts of God, firm, strikes, epidemics, war, riot, delay in transportation or railcar transport shortages, provided vendor notifies DOH immediately in writing of such pending or actual delay. Normally in the event or any such delays (acts of God, etc.) the date of delivery will be extended for a period equal to the time lost due to the reason for delay. However, DOH reserves the right to cancel the order and find a different source of supply if the delay is in DOH's opinion lengthy and the materials or services are needed quickly
26. PUBLIC DISCLOSURE: PO and all contents and attachments shall be deemed a public record as defined in RCW 42.56 "Public Records."
27. SEVERABILITY: If a court of competent jurisdiction declares any provision of the PO to be invalid, the other provisions and rights and obligations of the parties remain in effect.
28. CLICK-THROUGH AGREEMENTS: ANY CLICK-THROUGH, CLICK-WRAP, BROWSE-WRAP OR OTHER ONLINE AGREEMENTS "ONLINE AGREEMENTS" MADE IN ORDER TO ACCOMPLISH PAYMENT SHALL BE NULL AND VOID AND SHALL BE EXPRESSLY PROHIBITED FROM MODIFYING THE TERMS AND CONDITIONS OF THIS AGREEMENT EVEN IF SUBSEQUENTLY MADE. THIS AGREEMENT SHALL GOVERN ALL LICENSES PURCHASED BY CUSTOMER UNDER EITHER A SINGLE OR MULTIPLE PURCHASE ORDERS AND ANY SUBSEQUENT ONLINE AGREEMENTS SHALL CONTINUE TO BE NULL AND VOID UNLESS OR UNTIL THIS AGREEMENT IS TERMINATED.

Quotation: S5134956
July 31, 2023

Life Technologies Corporation
5781 Van Allen Way
Carlsbad, CA 92008
Fax No.: 1-800-331-2286 USA
To Order: 1-800-955-6288 USA
www.thermofisher.com

To place an order from this quote, sign in to your account at thermofisher.com

Alternatively, you can email your order to
NAInstrumentOrders@thermofisher.com
or Fax it to 877-680-2537.

To ensure you receive your discount pricing, please clearly reference your quotation number on your purchase order. Please issue your **Purchase Order to: Life Technologies Corporation.**

We now offer highly competitive financing options with low monthly payments. Please contact your local sales representative, or click here for more information on how we can meet your financing needs.

Valid From	:	07/05/2023
Valid To	:	09/29/2023
Freight Terms	:	FOB FACTORY - FRT QUOTED
Payment Terms	:	Net 30

WASHINGTON STATE DEPT OF HEALTH

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1610 NE 150TH ST

SHORELINE, WA 98155 US

ATTN:

WE ARE PLEASED TO QUOTE ON YOUR REQUIREMENT AS FOLLOWS

Item No	SKU	Description	Min Qty	List Price	Package Price	Net Price	Extended Price
1	A53970	GTSQS12KOADT,AB PLAT,IQOQ,TRN EACH This package solution includes the following: GTS QS 12KFLEX,OPEN ARRAY DSTP, GTS QS12K OA ACCUFILL SYSTEM, AB Platinum warranty enhnacement for QS12K OA and AccuFill, IQOQ and 1 day basic training (TRN00076 is only basic instrument and software training; additional workflow training required to be selected based on application needs) You have saved $0.00 per package Each individual package contains:	1	$316,070.00	$253,230.34	$253,230.34	$253,230.34

Item No	SKU	Description	Min Qty	List Price	Package Price	Net Price	Extended Price
1.1	4471090GTS	GTS QS 12KFLEX,OPEN ARRAY EACH	1				
1.2	ZGP1SCQSTUDIO12KOA	AB PLATINUM 1PM1OQ, QS12KOA CONTRACT	1				
1.3	ZGP1SCACUFILQS12K	AB PLATINUM 1PM, ACCUFILLQS12K CONTRACT	1				
1.4	TRN00076	TRN, QPCR FAS, 1 DAY Customer Site Please open a training call.	1				
1.5	4472009	IQOQ,SVC QUANTSTUDIO OPEN ARRAY RUO	1				
2	4469602	QS 12K FLEX OPENARRAY RNASEP KIT	1	$1,592.00	$0.00	$0.00	$0.00
3	4469620	QS 12K FLEX OPENARRAY PRACTICE KIT	1	$2,215.00	$0.00	$0.00	$0.00
4	4471227	QS OA LOADING PLATE EACH	2	$646.00	$0.00	$0.00	$0.00
5	4478601	QS 12K FLEX OA CALIBRATION KIT EACH	1	$1,350.00	$0.00	$0.00	$0.00
6	4475956	QS OPEN ARRAY TRN, CUST SITE SITE	1	$3,480.00	$0.00	$0.00	$0.00
7	4472380GTS	GTS QS 12K FLEX,OA INST EACH	1	$186,700.00		$186,700.00	$186,700.00
8	4469602	QS 12K FLEX OPENARRAY RNASEP KIT	1	$1,592.00	$0.00	$0.00	$0.00
9	4469620	QS 12K FLEX OPENARRAY PRACTICE KIT	1	$2,215.00	$0.00	$0.00	$0.00
10	4471227	QS OA LOADING PLATE EACH	2	$646.00	$0.00	$0.00	$0.00
11	4478601	QS 12K FLEX OA CALIBRATION KIT EACH	1	$1,350.00	$0.00	$0.00	$0.00

Item No	SKU	Description	Min Qty	List Price	Package Price	Net Price	Extended Price
12	4472009	IQOQ,SVC QUANTSTUDIO OPEN ARRAY RUO	1	$14,690.00	$0.00	$0.00	$0.00
13	4475956	QS OPEN ARRAY TRN, CUST SITE SITE	1	$3,480.00	$0.00	$0.00	$0.00
14	ZGP1SCQ STUDIO12 KOA	AB PLATINUM 1PM1OQ, QS12KOA CONTRACT	1	$34,720.00	$0.00	$0.00	$0.00

Estimated Shipping & Handling : $2,128.32

Total: $442,058.66

This quotation, and Life Technologies' **GENERAL TERMS AND CONDITIONS OF SALE** (which are incorporated by reference into this quotation and any resulting contract), set out the terms on which Life Technologies is offering to sell the product(s) or service(s) listed in this quotation. By issuing a purchase order or otherwise ordering or accepting product(s) or services, you expressly confirm that you intend to be bound by and agree to the terms of this quotation and Life Technologies' General Terms and Conditions of Sale to the exclusion of all other terms not expressly agreed to in writing by an authorized representative of Life Technologies, and that the purchase and sale transaction between you and Life Technologies is subject to and will be governed by this quotation and Life Technologies' General Terms and Conditions of Sale.

Customers may be required to evaluate as a discount, for cost-reporting purposes, the value of any Product listed as $0.00 on any invoice. The Product listed as $0.00 represents an in-kind discount and is included in the total fair market value price for the instrument product.

Life Technologies' General Terms and Conditions of Sale can be found on Life Technologies' website at http://www.thermofisher.com/termsandconditions under the "terms and conditions" link at the bottom of the webpage.

NOTE: Customer MUST reference quotation number when ordering to receive discounts

ADDITIONAL TERMS AND CONDITIONS OF QUOTATION

1. This quotation shall apply only to direct order purchases. In order to receive quoted prices, the quotation number must be referenced at time of order. Credits will not be issued for orders not referencing quotation numbers.

2. The effective dates of this quotation appear on the first page unless otherwise noted.

3. Percentage discounts in this quotation will be calculated from our current price for the applicable product. Discounts will be calculated from single unit catalog price. We reserve the right to change our prices at any time. Any increase or decrease to the price of a product would result in a change to your discounted price. Certain discounts are based on categories of products (e.g., "Pricing Product Line" or "PPL" discounts) that might change over time. We reserve the right to re-align products within a category or add or remove products to or from a specific category at any time. Such realignment, addition or removal may result in a change to your discounted price for a particular product.

4. We may terminate this quotation upon written notice.

5. This quotation contains our confidential pricing information which if disclosed to third parties could cause competitive harm to us. Subject to overriding obligations to third party funding agencies or governmental entities, the customer agrees to keep all pricing information contained herein confidential.

Christy Simbeya
christy.simbeya@thermofisher.com
Sales Representative

Washington State Department of
Enterprise Services
Contracts & Procurement

Sole Source CONTRACT Filing Justification Template

DOH Contract Number:
L123265

Use the following justification template for preparing to file sole source contracts in the Sole Source Contracts Database (SSCD). Once completed, copy and paste the answers into the corresponding SSCD question and answer fields. You will also need to include a copy of this completed form in the documents you post to your agency website and in WEBS.
***NOTE:** All proposed sole source vendors will need to be registered in WEBS. Vendors must do this themselves. Further, DOH will need the WEBS commodity codes from this vendor for those services the vendor has registered in WEBS. List the vendor commodity codes in the sole source notice form.*

What is a sole source contract?

"Sole source" means a contractor providing goods or services of such a unique nature or sole availability at the location required that the contractor is clearly and justifiably the only practicable source to provide the goods or services. (RCW 39.26.010)

Unique qualifications or services are those which are highly specialized or one-of-a-kind.

Other factors which may be considered include past performance, cost-effectiveness (learning curve), and/or follow-up nature of the required goods and/or services. Past performance alone does not provide adequate justification for a sole source contract. Time constraints may be considered as a contributing factor in a sole source justification however will not be on its own a sufficient justification.

Why is a sole source justification required?

The State of Washington, by policy and law, believes competition is the best strategy to obtain the best value for the goods and services it purchases, and to ensure that all interested vendors have a fair and transparent opportunity to sell goods and services to the state.

A sole source contract does not benefit from competition. Thus the state, through RCW 39.26.010, has determined it is important to evaluate whether the conditions, costs and risks related to the proposal of a sole source contract truly outweigh forgoing the benefits of a competitive contract.

Providing compelling answers to the following questions will facilitate the evaluation.

DES Sole Source Question	DOH Program Manager Response
Specific Problem or Need	
1. What is the business need or problem that requires this contract?	**Response:** Newborn screening in Washington State is a collaborative effort involving the State Department of Health (DOH), and numerous providers of newborn and related child health services throughout the state. It is the stated policy of the state of Washington "...to make every effort to detect as early as feasible and to prevent where possible...preventable heritable disorders leading to developmental disabilities or physical defects" (Chapter 70.83 RCW and Chapter 246-650 WAC). To achieve this, the law directs the Department of Health to "…require

DES Sole Source Question	DOH Program Manager Response
	screening tests of all newborn infants before they are discharged from the hospital..." for disorders "... and perform rapid, efficient screening as defined by the state board of health." The Newborn Screening (NBS) Program assures that all infants born in Washington with rare but treatable disorders, approved by the State Board of Health are diagnosed and referred for treatment as early as possible. The DOH has contracts with Hawaii Department of Health and Idaho Department of Health and Welfare to perform newborn screening for their babies. The NBS program tests for congenital disorders needing prompt medical intervention to prevent disability and death. Cystic Fibrosis is an autosomal recessive disorder affecting primarily the lungs due to mucus buildup and persistent infection that restricts breathing over time. Newborns are identified by immunoreactive trypsinogen (IRT) from Revvity (formally Perkin Elmer) Autodelfia. A DNA test is used as a second method to confirm the results of the first test. The method was designed and validated in the NBS laboratory to improve sensitivity of the IRT method using a Thermo Fisher Scientific Quantstudio RT-PCR system which can screen for 41 variants of DNA that cause Cystic Fibrosis. This current request is to add increased testing capacity from one Quantstudio 12k Flex qPCR System combined with one Open Array Accufill liquid handler and an additional Quantstudio 12k Flex qPCR System (no second liquid handler is needed). Starting in July 2023, The WA Newborn screening laboratory increased testing for Cystic Fibrosis. This was done by lowering cut-off values for IRT which we expect to cause an approximate 800% increase in samples for the confirmatory DNA testing. An important way to ensure the integrity of NBS results is by having all instruments from the same instrumentation supplier. This standardization is desirable because having harmonized standard operating procedures (SOPs) reduces the likelihood of human error. Using Thermo Fisher Scientific and non-Thermo Fisher Scientific PCR instruments in the same laboratory would be dangerous because different instruments and protocols introduces a higher likelihood of making an error. There is an added benefit in decreases in staff time and maintenance costs. Overall DOH seeks for standardization among instruments because errors in NBS can cause death and permanent disability.

DES Sole Source Question	DOH Program Manager Response
ole Source Criteria *(Describe how this vendor is "a contractor providing goods or services of such a unique nature or sole availability at the location required that the contractor is clearly and justifiably the only practicable source to provide the goods or services."*	
2. Describe the unique features, qualifications, abilities or expertise of the contractor proposed for this sole source contract.	**Response:** Thermo Fisher Scientific is a leading provider of DNA and RNA purification and analysis equipment and plasticware. Some of the unique qualifications of Thermo Fisher Scientific for DNA equipment are: It offers a range of spectrophotometers that can measure DNA, RNA and protein quantitation with only 1-2µL of sample in seconds. It has a variety of nucleic acid extraction and purification methods to suit different sample types, throughput levels, and purity requirements. It has a selection of genomic DNA extraction kits that contain all the reagents needed to isolate high-quality genomic DNA from different sample types. The NBS program has over ten years of experience working with previous models of PCR instruments from Thermo Fisher Scientific. We currently use Quantstudio 7 system, which uses a custom Taqman low density array (TLDA) consisting of 41 unique primers and probes for Cystic Fibrosis variants that was validated in the NBS laboratory. We have been using this method since 2018. Long before that, we have used their VIIA7 instruments in our PCR testing of Severe Combined Immunodefiency and Spinal Muscular Atrophy. The Thermo Fisher Scientific Quantstudio 12K Flex is a real-time PCR system that can run up to four 3,072-reaction OpenArray plates in about four hours. It is designed for the highest flexibility and supports a broad range of genomic applications. It also has five-interchangeable block formats including: OpenArray plate, TaqMan Array card, 384-well, and 96-well (0.1 and 0.2 mL) designed for the highest flexibility and supports a broad range of genomic applications. This new format of plate design allows to screen upwards for 48 samples for cystic fibrosis using a CF panel that the lab has been using since 2018. This will also include a unique liquid handler known as an Open Array Accufill System that can deliver small volumes less than 5 ul. This is a required component for OpenArray.

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	Thermo Fisher Scientific is covered by the NASPO contract for lab supplies but the laboratory equipment needed exceeds $75,000.
3. What kind of market research did the agency conduct to conclude that alternative sources were inappropriate or unavailable? Provide a narrative description of the agency's due diligence in determining the basis for the sole source contract, including methods used by the agency to conduct a review of available sources such as researching trade publications, industry newsletters and the internet; contacting similar service providers; and reviewing statewide pricing trends and/or agreements. Include a list of businesses contacted (if you state that no other businesses were contacted, explain why not), date of contact, method of contact (telephone, mail, e-mail, other), and documentation demonstrating an explanation of why those businesses could not or would not, under any circumstances, perform the contract; or an explanation of why the agency has determined that no businesses other than the prospective contractor can perform the contract.	**Response:** Laboratory staff read published articles about existing tests and prospective tests to see which systems are viable options. APHL contains a user reported list of instrumentation used by other state newborn screening laboratories for cystic fibrosis testing. Alternatives: Agilent provides AriaMx Realtime PCR which isusable with many fluorescence detection chemistries, including SYBR Green and EvaGreen dyes, and fluorogenic probe systems such as TaqMan. It supports 96 well plates, strip tubes and 0.2 ml tubes. While the system does have compatible probes, it will be unable to support the volume demanded to screen for Cystic Fibrosis. Luminex xTAG60 is a technology that allows performing multiplexed nucleic acid assays using Luminex instruments. Multiplexing is the simultaneous detection of multiple analytes in a single sample, which can save time, cost, and resources. Some of the benefits of Luminex xTAG60 are that it can detect up to 60 targets per reaction using universal tag-sets. It can be used for a variety of applications, such as infectious disease testing, genetic testing, and pharmacogenomics. It can provide accurate and reliable results with high sensitivity and specificity. It can be customized to meet specific needs and preferences using open-source software. The Luminex system is not compatible with the current Quantstudio CFDNA materials and supplies, (cartridges, DNA primers, etc.). Two Luminex instruments would be needed for redundancy. MiseqDX Cystic Fibrosis is a FDA regulated product line from Illumina that offers two types of assays for cystic fibrosis testing using next-generation sequencing (NGS) on the MiseqDX instrument. Some of the benefits of MiseqDX Cystic Fibrosis are: It can provide accurate and reliable detection of CFTR variants with high sensitivity

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	and specificity. It can offer two assays in one product: the 139-Variant Assay and the Clinical Sequencing Assay. The 139-Variant Assay can detect 139 CFTR variants defined in the CFTR2 database as of August 2013, which covers more than 90% of cystic fibrosis cases in the US. The Clinical Sequencing Assay can sequence all protein coding regions and intron/exon boundaries of the CFTR gene, including two large deletions, two deep intronic mutations, and indels in homopolymeric regions. It can provide fast and easy workflow with a single PCR step, multiplexing capability, and on-board data analysis and report generation. Each kit is purchasable to scale of laboratory run up to 48 samples at a time but across 6 runs. Working with regional pulmonologists, our program has selected 41 variant panel for cystic fibrosis and Sequencing DNA is not a testing option for our laboratory. The assay's duration is 48 hours compared to 4 hours with proposed equipment; this length of time is far too long for a high-throughput newborn screening laboratory.
4. What considerations were given to providing opportunities in this contract for small business, including but not limited to unbundling the goods and/or services acquired.	**Response:** We are unaware of any small businesses selling this type of specialized systems. Small businesses tend not to make laboratory equipment, or they do not have a track record of reliability or service. Resellers, if available are not an appropriate option for clinical testing; the instruments must be new and under a full manufacture warrantee.
5. Provide a detailed and compelling description that includes quantification of the costs and risks mitigated by contracting with this contractor (i.e. learning curve, follow-up nature).	**Response:** The main reason the NBS laboratory is seeking sole source justification is to provide instrument redundancy and standardization with Thermo Fisher Scientific products. All NBS DNA tests will be performed on the same type of PCR instruments. We expect to see an approximate 800% increase in samples. We will use the Quantstudio 12 system as a DNA testing method for a possible sample volume maximum of 48 samples per OpenArray plate. Four OpenArray plates can be run at one time to maximum of 198 samples. Both this system and our current Quantstudio system can support the same Taqman low density array cards (TLDA). They both use

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	the current primers and probes, which are also supplied by Thermo Fisher Scientific. After the initial investment, the move from TLDA on Quantstudio 7 to OpenArray on Quantstudio 12 will see an approximate annual savings of $80,000. It would be dangerous for newborns to have two different types of instruments for screening babies, with separate SOPs, handling instructions, maintenance requirements, etc. The chances for error are greatly increased with separate procedures and the consequences of laboratory testing mistakes could be the difference between life and death.
6. Is the agency proposing this sole source contract because of special circumstances such as confidential investigations, copyright restrictions, etc.? If so, please describe.	**Response:** N/A
7. Is the agency proposing this sole source contract because of unavoidable, critical time delays or issues that prevented the agency from completing this acquisition using a competitive process? If so, please describe. For example, if time constraints are applicable, identify when the agency was on notice of the need for the goods and/or service, the entity that imposed the constraints, explain the authority of that entity to impose them, and provide the timelines within which work must be accomplished.	**Response:** No.
8. Is the agency proposing this sole source contract because of a geographic limitation? If the proposed contractor is the only source available in the geographical area, state the basis for this conclusion and the rationale for limiting the size of the geographical area selected.	**Response:** N/A
9. What are the consequences of not having this sole source filing approved? Describe in detail the impact to the agency and to services it provides if this sole source filing is not approved.	**Response:** Additional instruments are required to maintain NBS operations to meet the expanded testing for cystic fibrosis. Operating with only one instrument would be risky.

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	If this sole source filing is denied, it would hinder the timeliness of our reporting results for Cystic Fibrosis where early diagnosis is key for health complications. With an expectant approximate 800% increase in samples, PHL will not be able to complete testing in a timely manner, risking not meeting turn-around-times (TATs) and tying up key personnel that would otherwise be free to conduct other testing. Our current Quantstudio 7k Flex is only capable of 7 samples per run. The Quantstudio 12k Flex is capable of 48 samples per OpenArray plate. Four OpenArray plates can be run at one time to maximum of 198 samples. Other considerations are: • There is a risk that the laboratory will be unable to perform basic required testing impacting the lab's overall effectiveness and in rare circumstances the lab's status could be forced to ship its samples to other states for testing, lengthening response times and increasing risk for infants born in Washington, Hawaii, and Idaho. • More time will be required of staff that could be used performing other tasks. The increased workload would put physical strain while performing the testing. Each run in our current method relies on 45-60 minutes of hand pipetting. The workload is increasing from 3 runs per week to 3 runs per day. The Open Array Accufill System component will reduce strain and time to one run per day. • The addition of multiple instrument types increases complexity, which may increase the chance of errors. Errors may have severe adverse consequences for the newborns tested. • If this sole source is not approved the cost could be higher overall. The QuantStudio 12 is compatible with Taqman low density array cards (TLDA) (current) and Open array cards. If we proceed with an alternative, we will need to acquire an additional instrument for back up. Our current Quantstudio 7 supports TLDA.

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Sole Source Posting	
10. Provide the date in which the sole source posting, the draft contract, and a copy of the Sole Source Contract Justification Template were published in WEBS.	**Contracts Office Use Only:**
a. If exempt from posting in WEBS, please provide which exemption.	**Contracts Office Use Only:**
b. If failed to post, please explain why.	**Contracts Office Use Only:**
11. Were responses received to the sole source posting in WEBS?	**Contracts Office Use Only:**
a. If one or more responses are received, list name of entities responding and explain how the agency concluded the contract is appropriate for sole source award.	**Contracts Office Use Only:**
Reasonableness of Cost	
12. Since competition was not used as the means for procurement, how did the agency conclude that the costs, fees, or rates negotiated are fair and reasonable? Please make a comparison with comparable contracts, use the results of a market survey, or employ some other appropriate means calculated to make such a determination.	**Response:** An alternative would be to purchase an additional Quantstudio 7 Flex instrument. The cost is approximately $166,780 (including tax). As mentioned above, this alternative is more costly per sample (about $80,000/year difference). This request is for a bundled package of one Quantstudio 12K Flex and one Open Array Accufill liquid handler, plus an additional Quantstudio 12K Flex. The Quantstudio instruments cost approximately $186,000 each. This is slightly higher compared to the lower capacity Quantstudio 7 Flex instrument. The increased specimen processing capacity provides cost savings over time ($20/sample compared to $80/sample) The Open Array Accufill liquid handler is a reasonable price at approximately $66,530. A similar liquid handling instrument (Biomek i5) was recently purchased by our laboratory for approximately $175,000. The Biomek 5 instrument is not capable of performing the liquid handling for the CF DNA testing required. The Quantstudio 12k Flex greatly increases testing capacity from 8 samples to 48 samples. It is also backwards compatible with all other DNA Newborn Screening tests.

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	The total purchase price after tax is $487,371.49. This is a reasonable price for this package (we received package discount and adjusted for inflation)

Note: *The DOH Program's contract manager must complete the attached and include with the completed Sole Source Legal Notice as part of your CPAR package, which should be processed through your division's standard process. Contact the Contracts Group Mailbox at DOHCON.Mgmt@doh.wa.gov for assistance.*

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