



**STATE OF WASHINGTON
DEPARTMENT OF HEALTH**

Sole Source Contract Support and Regular Wastewater Testing
for SARS-CoV-2, Monkeypox Virus (mpox), and potentially Polio and other Pathogens

January 25, 2023

The Washington State Department of Health (DOH) contemplates awarding a sole source contract to Biobot Analytics, Inc. to provide support and regular testing for SARS-CoV-2, Monkeypox Virus (mpox), and potentially polio and other pathogens in wastewater. The contractor will onboard and retain Wastewater Treatment Plants (WWTP), manage all logistics of collecting wastewater samples and timely sample delivery, conduct laboratory analysis to obtain pathogen detection, quantity and sequencing in wastewater samples, and securely transfer data results to DOH in a format and timeframe identified by DOH.

DOH monitors community infection levels of pathogens (such as SARS-CoV-2 and mpox) in wastewater samples across the state. Currently, 28 WWTP across 16 counties are collecting and submitting samples for analysis of SARS-CoV-2 and mpox. The Washington State Public Health Laboratory (PHL) analyzes samples from 15 WWTPs while the Center for Disease Control and Prevention (CDC) contracted lab, Biobot, analyzes samples from 13 WWTPs. The CDC's contract with Biobot ends January 28, 2023.

The DOH requires this contract with the existing CDC contractor, Biobot, to ensure continued and standardized wastewater sampling and analysis of SARS-CoV-2, mpox and other pathogens of public health importance for statewide surveillance. Not only does Biobot have the experience and knowledge of the WWTPs and our required data systems, switching vendors causes issues with maintaining consistency of data, continuity of data as well as increases potential of losing sites. When CDC switched vendors previously, we lost two months of sampling data as well as 41% of our WWTP when they dropped out.

It is crucial that we have a wide reaching and robust wastewater epidemiology program that supports sampling throughout the state. For epidemiologists and local health officials to make appropriate and accurate inferences about wastewater results, sampling must occur consistently and for a sustained period. When the CDC's contract ends with Biobot, we could lose 48% of our sampling sites and 26% of our county representation. Not only would it be challenging for the PHL to absorb these WWTP it would leave little to no room for expansion to other sites.

DOH will enter into a one (1) year contract with Biobot Analytics. The contract will be issued on the Date of Execution and will continue for a one (1) year initial term. The cost of this one (1) year contract is \$529,909. DOH may opt to extend the contract for an additional three (3) times in one (1) year increments, subject to the availability funding and if necessary. DOH determines that each optional additional one (1) year extension would result in equal (and/or slightly higher) consideration being added to the total contract value.

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.

Capability statements should address the following state requirements:

- At least one year of experience partnering with a state or federal agency to implement wastewater surveillance for SARS-CoV-2 and proof of partnership.
- Ability to analyze liquid influent wastewater samples for both N1 and N2 genes of SARS-CoV-2, mpox, and polio, and sequence samples for variants of SARS-CoV-2 and polio virus.
- Ability to produce data that is comparable to the PHL by use of digital droplet PCR (ddPCR) for analysis of N1 and N2 genes of SARS-CoV-2, mpox, and polio.
- Onboard and collect wastewater samples from rural/remote populations.
- Provide data analysis results to DOH epidemiologists within 48-hours of collection at the wastewater treatment plant.
- Securely store and share data using established data pipelines.
- Demonstrated competency in working within established data systems and procedures.
- Provide sole ownership of data results and wastewater samples to DOH, only analyzing samples and using the data as approved by DOH.

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: Frank Webley, DOH Contracts Office Consultant

Email: BIDS@doh.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, the DES SSCD, and via WEBS under commodity codes:

- 918-12 – Analytical/Predictive Studies and Surveys (Consulting)
- 989-91 – Water Sampling and Analysis Services
- 961-48 – Laboratory and Field Testing Services (Not Otherwise Classified)
Incl. Hazardous Waste



CONTRACT NUMBER:
PRV27738-0

SUB-RECIPIENT
☐ YES ☒ NO

FFATA FORM REQUIRED
☐ YES ☒ NO

THIS AGREEMENT is made by and between the State of Washington Department of Health, hereinafter referred to as DOH, and the party whose name appears below, hereinafter referred to as Contractor.

CONTRACTOR NAME and ADDRESS:

BioBot Analytics, Inc.
501 Massachusetts Ave
Cambridge, MA 02139

UBI: 604 862 628

PURPOSE: The purpose of this Agreement is to expand the Washington Wastewater-Based Epidemiology (WAWBE) program capacity to monitor pathogens in wastewater across the state. This contract is written in anticipation of reaching testing capacity at the DOH Public Health Lab (PHL). This contract will provide SARS- CoV-2 concentration and sequencing data, monkeypox (mpox) concentration data, and, if and when needed, polio concentration and sequencing data to DOH to support public health action.

IT IS MUTUALLY AGREED THAT:

STATEMENT OF WORK: The Contractor shall provide all the necessary personnel, equipment, materials, goods and services and otherwise do all things necessary for or incidental to the performance of the work as described in Exhibit A, attached hereto and incorporated herein.

PERIOD OF PERFORMANCE: Subject to its other provisions, the period of performance under this contract shall be from *Date of Execution through one year from Date of Execution*, unless sooner terminated as provided herein, and depending on the timing of DES approval. Any work done outside of the period of performance shall be provided at no cost to DOH. **NOTE:** Upon availability of additional funding, DOH reserves the right to amend the agreement annually, for up to three additional one-year terms.

DEPARTMENT OF ENTERPRISE SERVICES APPROVAL: This contract may be required to be filed with the Department of Enterprise Services (DES) for approval under the provisions of Chapter 39.26 RCW. No contract or amendment required to be so filed is effective and no work thereunder shall be commenced nor payment made therefore until ten (10) working days following the date of filing, and, if required, until approved by DES. In the event DES fails to approve the contract or amendment, the contract shall be null and void.

FEDERAL FUNDING ACCOUNTABILITY AND TRANSPARENCY ACT (FFATA): If checked above, this contract is supported by federal funds that require compliance with the Federal Funding Accountability and Transparency Act (FFATA or the Transparency Act). The purpose of the Transparency Act is to make information available online so the public can see how federal funds are spent.

To comply with the act and be eligible to enter into this contract, your organization must have a Unique Entity Identifier (UEI) number. A UEI number provides a method to verify data about your organization. If you do not already have one, you may receive a UEI number free of charge by contacting System for Award Management (SAM) at [SAM.GOV](https://sam.gov).

Information about your organization and this contract will be made available on www.USASpending.gov by DOH as required by P.L. 109-282. DOH's form, Federal Funding Accountability and Transparency Act Data Collection Form, is considered part of this contract and must be completed and returned along with the contract.

CONSIDERATION: The maximum consideration available under this contract shall not exceed **\$529,909.00** without a properly executed written amendment signed by representatives of both parties authorized to do so. Consideration includes but is not limited to all taxes, fees, surcharges, etc.

Source of Funds:

Federal: \$529,909.00 State: \$0.00 Other: \$0.00 TOTAL: \$529,909.00

Contractor agrees to comply with all applicable rules and regulations associated with these funds.

Unless otherwise indicated in this contract, any State funds which are unexpended as of June 30th will not be available for carry over into the next State fiscal year (July – June).

INVOICES AND PAYMENT: Contractor will submit invoices to the DOH Project Manager for all amounts to be paid. Invoices must reference this contract number and provide detailed information as requested. All invoices must be approved by DOH prior to payment; approval will not be unreasonably withheld. DOH will authorize payment only upon satisfactory completion and acceptance of deliverables and for allowable costs as outlined in the statement of work and/or budget. DOH will return all incorrect or incomplete invoices and will not pay for services that occur outside the period of performance. The Contractor will not invoice for services if they are entitled to payment, have been, or will be paid by any other source for that service.

DOH will issue payment within 30 days of receiving a correct and complete invoice and approving the deliverable(s). DOH must receive correct and complete invoices within 60 days of the contract expiration date. Late invoices will be paid at the discretion of DOH and are contingent upon the availability of funds. Failure to submit a properly completed IRS form W-9 may result in delayed payments.

GOVERNANCE: In the event of an inconsistency in this contract, unless otherwise provided herein, the inconsistency shall be resolved by giving precedence in the following order:

- A. Federal statutes and regulations
- B. State statutes and regulations
- C. Contract amendments
- D. The contract (in this order)
 - 1. Primary document (document that includes the signature page)
 - 2. Statement of Work (Exhibit A)
 - 3. Standard/General Terms and Conditions (Exhibit B)
 - 4. Special Terms and Conditions (Exhibit C if used)

UNDERSTANDING: This contract, including referenced exhibits, attachments and documents included herein by reference, contains all the terms and conditions agreed upon by the parties. No other

understandings, oral or otherwise, regarding the subject matter of this contract shall exist or bind any of the parties hereto.

APPROVAL: This contract shall be subject to the written approval of DOH Contracting Officer and shall not be binding until so approved. Only the Contracting Officer or his/her designee, by written delegation made prior to action, shall have the expressed, implied, or apparent authority to alter, amend, modify, or waive any clause or condition of this contract. Furthermore, any alteration, amendment, modification, or waiver of any clause or condition of this contract is not effective or binding unless made in writing and signed by the Contracting Officer.

IN WITNESS WHEREOF: DOH and the Contractor have signed this contract.

CONTRACTOR SIGNATURE	DATE
PRINT OR TYPE NAME	TITLE
DOH CONTRACTING OFFICER SIGNATURE	DATE

This contract has been approved as to form by the attorney general.

EXHIBIT A, DOH CONTRACT PRV27738-0

STATEMENT OF WORK

BioBot Analytics, Inc.

Period of Performance:

Date of Execution through one year from Date of Execution

PURPOSE:

The purpose of this Agreement is to expand the Washington Wastewater-Based Epidemiology (WAWBE) program capacity to monitor pathogens in wastewater across the state. This contract is written in anticipation of reaching testing capacity at the DOH Public Health Lab (PHL).

This contract will provide SARS- CoV-2 concentration and sequencing data, monkeypox (mpox) concentration data, and, if and when needed, polio concentration and sequencing data to DOH to support public health action.

CONTRACT OVERVIEW:

Washington State Department of Health (“DOH”) will enter a one-year contract with Biobot Analytics (“Biobot”, “Contractor”). The cost of this one-year contract is **\$529,909.00**. DOH may opt to extend the contract for an additional three times in one- year increments subject to the availability funding and if necessary. DOH determines that each optional additional one-year extension would result in equal (and/or slightly higher) consideration being added to the total contract value.

The contractor must/will support regular testing for SARS- CoV-2, mpox, and (if and when available, and if and when requested) polio in wastewater.

The contractor will:

- A. Onboard and retain wastewater treatment plants (WWTP) identified by DOH.
- B. Manage all logistics of onboarding wastewater treatment plants, collecting wastewater samples, and sample delivery, in a timely and efficient manner.
- C. Conduct laboratory analysis to obtain detection, quantification, and sequencing results of SARS-CoV- 2, detection, and quantification of monkeypox, and, if and when available, detection, quantification, and sequencing of polio in community wastewater samples.¹
- D. Securely transfer results: quantification results will be transferred in NWSS file format (see Appendix A) initially via email followed by programmatic method (S3 or SFTP transfer) agreed to at a later date; sequencing results will be transferred to NCBI’s SRA in a format and time frame identified by DOH following the execution of this contract.

As wastewater surveillance is an emerging method of detection, WA DOH may request testing of additional, yet to be determined pathogens, based on emerging public health needs. Any request will be submitted as an amendment to this contract, will allow for a reasonable assay development timeline, and must be agreed to by both parties. Any assay developed as part of new pathogen testing reporting will be subject to any CDC reporting/sample-handling guidelines.

All wastewater samples collected through this agreement will be the sole property of DOH. DOH hereby grants contractor a non-exclusive, royalty-free right and license to use the wastewater samples for contractor’s research and development purposes, including publications and data sharing activities, for so long as the wastewater samples remain in contractor’s possession and control. DOH may request the

¹ Polio deliverables must be triggered by an explicit WA DOH request and must allow for a reasonable assay development timeline that will be agreed to by both parties. Any assay developed as part of polio reporting will be subject to any CDC reporting/sample-handling guidelines.

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STATEMENT OF WORK

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return or destruction of the wastewater samples at any time, and the contractor will promptly comply with DOH's request. DOH will be responsible for all costs and expenses associated with the return or destruction of any wastewater samples.

The sample's associated data and reporting, or any other derivative information the contractor uses, maintains, discloses, receives, creates, transmits or otherwise obtains in connection with its performance of the agreement and that contractor delivers to DOH, will be the joint property of DOH and the contractor, and each party shall have all rights to use such associated data and reporting or any other derivative information delivered to DOH for any purpose- upon request, each party shall provide a report detailing use of data.

CONTRACT TASKS:

The contractor shall perform all services and maintain all standards and requirements for services provided under this Agreement in accordance with the below:

- **A. Onboard wastewater facilities identified by DOH**
 - The contractor will meet with WWTP managers to answer questions about the wastewater-based epidemiology and the sampling work they are performing and onboard the wastewater facility to their data collection system.
 - The contractor will work with WWTP managers to establish a point of contact for the WWTP and set collection sample days and delivery pick-up.
 - Before collecting any wastewater samples, the contractor will export all information detailed in Appendix C into a Biobot standard csv file for WADOH to upload into REDCap.
- **B. Collect samples from authorized facilities**
 - The contractor will train onsite staff to collect composite samples from each authorized facility in Washington at least twice per week.
 - Wastewater samples will be collected using 24-hour composite samplers, and collection start times will be set to ensure accurate representation of the population served.
 - Sample volumes must be sufficient to allow all required testing and repeat testing if necessary.
- **C. Safety Training of staff at authorized facilities**
 - The contractor will ensure safe collection practices are identified, following CDC standard practices detailed below.
 - Standard practices associated with wastewater treatment plant operations should be sufficient to protect wastewater workers from SARS-CoV-2, monkeypox, and polio. These standard practices can include engineering and administrative controls, handwashing, specific safe work practices, and personal protective equipment normally required when handling untreated wastewater.
 - Beyond CDC recommendations for how to protect against COVID-19, no additional COVID-19 specific protections are recommended for workers managing wastewater, including those at wastewater treatment facilities.

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- **D. Transport collected samples from the authorized facilities to the contractor**
 - When sending samples to laboratories, samples will be packed with cold packs (4°C) and shipped via same-day or overnight shipping. Package and ship samples as Category B infectious substance (UN 3373), in accordance with the U.S. Department of Transportation's Hazardous Materials Regulations and the International Air Transport Association Dangerous Goods Regulations. Additional details can be found here if considering FedEx: <https://www.fedex.com/en-us/service-guide/dangerous-goods.html>
 - The samples must arrive at the laboratory within 24 hours of collection, barring delays out of the control of the contractor.
- **E. Process samples**
 - Process the samples received at the laboratory:
 - SARS-CoV-2: qPCR (quantification) assay within one business day of receipt of the samples on all samples collected
 - SARS-CoV-2: COVID NGS (sequencing) assay within 5 business days on 50% of samples collected, unless otherwise specified by DOH.
 - Mpox: qPCR (quantification) assay within 3 business days on 50% of samples, unless otherwise specified by DOH.
 - If and when the contractor develops an assay for the detection of poliovirus in wastewater, the contractor shall conduct laboratory analysis and sequencing for polio virus when/if requested by DOH, on a frequency identified by DOH.
 - All testing protocols must include measurement of recovery efficiency, matrix inhibition evaluation, and human fecal normalization that meet specifications put forward by CDC. Specifications can be found here: <https://www.cdc.gov/healthywater/surveillance/wastewater-surveillance/testing-methods.html>
 - Required QA/QC controls include extraction blanks, negative controls, positive controls, standard curves (if using RT-qPCR), and data management policies.
- **F. Submit results**
 - Reporting details are outlined in section **DELIVERABLES AND REPORTING**.

DELIVERABLES AND REPORTING

The contractor understands that the reports are due within the timeframes established and that the DOH will not make associated payment installments under this agreement until such reports are received, reviewed, and accepted.

EXHIBIT A, DOH CONTRACT PRV27738-0**STATEMENT OF WORK****BioBot Analytics, Inc.***Period of Performance:**Date of Execution through one year from Date of Execution***Onboarding Deliverables:**

Report/Activity Name	Recipient	Reporting Cadence	Format	Details
Onboarding Status Report	DOH	Weekly until all sites are onboarded	Email	Information to be included: facility names, WWTP point of contact, onboarding status
WWTP Onboarding Support	DOH	Once for each onboarded facility	Contractor can facilitate WWTP operators entering this data	Information to be included: this is found in Appendix C.

Laboratory and Reporting Deliverables:

Pathogen	Assay	Sampling Cadence	Recipient	Turnaround Time	Deliverable	Start Date**
SARS-CoV-2	qPCR	2x/week	WWTP, LHJ and DOH	1 business day from sample receipt	PDF report of SARS-CoV-2 raw and effective concentration	DOE
			DOH	2 business days from sample receipt	NWSS-formatted CSV, raw and effective concentration	DOE
SARS-CoV-2	NGS	1x/week	DOH	2 weeks from sample receipt	Raw read data deposited into NCBI's SRA	DOE
		1x/week	DOH	18 days from sample receipt	Variant percentage Excel table	1/1/23
Pathogen	Assay	Sampling Cadence	Recipient	Turnaround Time	Deliverable	Start Date**
MPOX	qPCR	1x/week *	DOH	3 business days from sample receipt	NWSS-formatted CSV, raw and effective	1/1/23

EXHIBIT A, DOH CONTRACT PRV27738-0**STATEMENT OF WORK****BioBot Analytics, Inc.***Period of Performance:**Date of Execution through one year from Date of Execution*

					concentration	
Polio ***	TBD*	TBD*	DOH	TBD**	NWSS-formatted CSV, raw and effective concentration	TBD**
Polio***	NGS	1x/week	DOH	TBD**	Raw read data deposited into NCBI's SRA	TBD**
Other Pathogens ****	TBD	TBD	DOH	TBD	TBD	TBD

* unless otherwise requested by DOH **Start dates are targets for Contractor readiness. Precise launch dates are dependent on successful onboarding.
 Polio testing must be triggered by an explicit WA DOH request. Assay must be validated within four weeks of contract signature. Any assay developed as part of polio reporting will be subject to any CDC reporting/sample handling guidelines. *Additional pathogen deliverables must be triggered by an explicit WA DOH request. Precise details regarding sampling cadence and reporting turnaround times are dependent on the specific assay that is chosen or developed, but Contractor will make all reasonable efforts to deliver results in a timely manner.

COMPENSATION

A. DOH will enter into a one-year contract with Biobot Analytics.

- The contract's period of performance will be from ***Date of Execution through "one year from Date of Execution"***, unless sooner terminated as provided herein, and depending on the timing of DES approval. **NOTE:** Upon availability of additional funding, DOH reserves the right to amend the agreement annually, for up to three (3) additional one-year terms.
- DOH determines that each optional additional one-year extension would result in equal (and/or slightly higher) consideration being added to the total contract value.

B. Payment will be based on the number of samples collected and analyzed for the invoicing period agreed to by the contractor and DOH.

C. The target budget of this project is **\$529,909.00**. Payment will be contingent upon receipt of data results with billing based on the number of samples analyzed per pathogen.

Type of Sample	Cost (per sample)
COVID analysis	\$350
COVID sequencing	\$250
MPV analysis	\$150

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STATEMENT OF WORK

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Additional pathogen analysis	TBD
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- D.** Payment for satisfactory performance of the work shall not exceed this amount unless the parties mutually agree to a higher amount in a written Amendment to this Agreement executed by both parties.
- E.** Contractor will submit invoices on an agreed-to basis for approval and payment, as identified by DOH following the execution of this contract.
- F.** DOH will notify the contractor within three business days if there are any issues with the invoice.
- G.** Invoices will be submitted for payment within 7 business days of receipt and approval.
- H.** DOH will not provide compensation for sample analysis provided past the agreed upon one business day turnaround period from sample receipt in contractor laboratory for SARS-CoV-2 quantification, three business day turnaround period from sample receipt in contractor laboratory for mpox, and two-week turnaround period from sample receipt in the contractor laboratory for SARS-CoV-2 variant detection. Turnaround time for any polio report will be determined in conjunction with WADOH upon addition to contract. The contractor is expected to provide results regardless of if they meet the above deadlines and will flag any samples that were analyzed outside of the deadline for invoicing quality assurance.

ROLES AND RESPONSIBILITIES

- A.** The contractor and DOH will identify and appoint a point of contact for coordinating and communicating items covered in this agreement.
- B.** The contractor is responsible for maintaining an adequate supply of testing kits and shipping materials to support the continuous flow of testing throughout the contract period.
- C.** The contractor will communicate with WWTPs and delivery couriers if any sample collections are missed and will notify the DOH project coordinator if a facility misses two consecutive sample collections and provide a resolution or next steps if the issue cannot be resolved.
- D.** The contractor will notify DOH if there are any delays to sample submission within 24 hours of identifying the problem and will update the project coordinator on steps towards the problems resolution.

EXHIBIT A, DOH CONTRACT PRV27738-0**STATEMENT OF WORK****BioBot Analytics, Inc.***Period of Performance:**Date of Execution through one year from Date of Execution*

- E.** The contractor shall implement administrative, physical, and technical safeguards that reasonably and appropriately protect the samples and the resultant data.
- F.** The contractor will secure all equipment necessary to perform the services required under this agreement.
- G.** The contractor has all appropriate licenses or waivers in place to perform all wastewater surveillance testing.

Appendix A: Data needed for submission to DOH

Please find further description of these fields here:

<https://www.cdc.gov/healthywater/surveillance/wastewater-surveillance/data-reporting-analytics.html#data-dictionary>

Column	NWSS Required?
sample_id	Required
wwtp_name	Required
sample_collect_date	Required
sample_collect_time	Required
analysis_version	Not applicable
effective_sarscov2_concentration_copies_per_liter	Not applicable
kit_detection_status	Not applicable
kit_id	Not applicable
protocol_version	Not applicable
raw_sarscov2_concentration_copies_per_liter	Not applicable
sampling_end_date	Not applicable
capacity_mgd	Required
concentration_method	Required
county_names	Required

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epaid	Not required
extraction_method	Required
flow_rate	Required
hum_frac_mic_conc	Not required
hum_frac_mic_unit	Not required
hum_frac_target_mic	Not required
hum_frac_target_mic_ref	Not required
inhibition_adjust	Required
inhibition_detect	Required
inhibition_method	Required
institution_type	Required
lab_id	Required
lod_ref	Required
lod_sewage	Required
major_lab_method	Not required
ntc_amplify	Required
num_no_target_control	Required
pasteurized	Not required
pcr_gene_target	Required
pcr_gene_target_ref	Required
pcr_target	Required
pcr_target_avg_conc	Required

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pcr_target_below_lod	Not required
pcr_target_std_error	Not required
pcr_target_units	Required
pcr_type	Required
population_served	Required
quant_stan_type	Required
rec_eff_percent	Required
rec_eff_spike_conc	Required
rec_eff_spike_matrix	Required
rec_eff_target_name	Required
reporting_jurisdiction	Required
sample_location	Required
sample_matrix	Required
sample_type	Required
stan_ref	Required
test_result_date	Required
time_zone	Not required
wwtp_jurisdiction	Required
zipcode	Required

Appendix B: Sequencing data to be submitted into NCBI's SRA

Wastewater Data Element Names	Description
*sample_name	Concise and unique name for the sample, consistent within the lab. (Biobot uses

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	anonymized sample_names). Same as internal kit ID on Biobot reports (e.g., weekly variant reports).
bioproject_accession	The accession number of the BioProject(s) to which the BioSample belongs.
*organism	The most descriptive organism name for this sample (to the species, if possible).
*collection_date	The date on which the sample was collected; must be in Coordinated Universal Time (UTC).
*geo_loc_name	Geographical origin of the sample. Country separated from more location details by colon, e.g., Country: State
*isolation_source	Describes the physical, environmental and/or local geographical source of the biological sample from which the sample was derived.
collected_by	Name of persons or institute who collected the sample.
purpose_of_ww_sampling	The reason the sample was collected.
ww_sample_site	The type of site where the wastewater sample was collected.
*ww_population	Number of persons contributing wastewater to this sample collection site.
ww_surv_jurisdiction	A jurisdiction identifier that can be used to support linking the sample to a public health surveillance system.
*ww_sample_matrix	The wastewater matrix that was sampled.
*ww_sample_type	Type of wastewater sample collected
*ww_sample_duration	Duration of composite sample collected, in units of hours.
ww_surv_system_sample_id	The sample ID used for submission to a public health surveillance system. Same as internal kit ID on Biobot reports (e.g., weekly variant reports).
ww_processing_protocol	The protocol used to process the wastewater sample.

EXHIBIT A, DOH CONTRACT PRV27738-0**STATEMENT OF WORK****BioBot Analytics, Inc.***Period of Performance:**Date of Execution through one year from Date of Execution*

concentration_method	The method used to concentrate a target organism, nucleic acid, organelle, etc. within a sample.
extraction_method	The protocol used to extract nucleic acids (DNA or RNA) from a sample
*ww_surv_target_1	Taxonomic name of the surveillance target. For the COVID-19 response, 'SARS-CoV-2' is used.
*ww_surv_target_1_known_present	Is genetic material of the surveillance target(s) known to the submitter to be present in this wastewater sample? (Yes/No).
Sequenced_by	The name of the agency that generated the sequence.

* Fields are mandatory for NCBI. Submission will fail if any mandatory fields are not completed. If information is unavailable for any mandatory field, it is possible to enter 'not collected', 'not applicable' or 'missing' as appropriate.

Appendix C: Onboarding Data

The contractor will prepare an Excel file for bulk upload that includes the following data fields and will work with WA DOH to determine appropriate format for each.

Field	Description
Sample Site Name	The name of the facility or location of sampling
Contact Name	Name for the main contact for the sampling site
Contact Phone	Phone number for the main contact
Shipping Address	Shipping address of the sampling site
Reporting Jurisdiction	Washington
County Names	Names of all counties served by this sampling site. If there are cities/jurisdictions served that are not within a county (e.g., independent cities), list those in Other Jurisdiction
ZIP code	Zip code for sampling location
Population Served	Estimated population served by the wastewater flow through the sampling site
Sample Location	Location type of sample
Sample Location, please specify	Comment if needed describing location of sample
Institution Type	Type of institution for sampling site
NPDES Permit Number	National Pollutant Discharge Elimination System (NPDES) permit for wastewater facilities
Name of Wastewater Treatment Plant	Name of the wastewater treatment plant that services sample site
Wastewater Treatment Plant	Jurisdiction for the treatment plant

EXHIBIT A, DOH CONTRACT PRV27738-0**STATEMENT OF WORK****BioBot Analytics, Inc.***Period of Performance:**Date of Execution through one year from Date of Execution*

Jurisdiction	
Design Capacity	The capacity in MGD for the wastewater facility
Stormwater Input	Does the WWTP treat water from a combined sewer system (i.e., a sewer system that collects both sewage and stormwater, or is significantly impacted by I&I)?
Type of Sample Collected	Flow weighted, time weighted, or manual composites
Composite Frequency	Frequency of sub-sample collection (for composite samples only): for flow-weighted, the number of sub-samples collected per million gallons of flow; for time-weighted, the number of sub-samples per hour. Flow-weighted example: a value of 5 would indicate 5 sub-samples per million gallons, or 1 sub-sample per 200,000 gallons
Sample Matrix	Responses include raw wastewater, primary and secondary effluent, and primary and secondary sludge
Sample Notes	Additional information such as time interval represented by composite sample (e.g., 6am-9am)
WWTP Average Daily Flow for previous 12 months	Million gallons per day – MGD

Appendix D**DOH and Biobot Analytics, Inc. points of contact:**Biobot Analytics, Inc. Point of Contact

Name: Jennings Heussner

Title: Director, Government Business

Phone: (859) 331-7150

Email: jennings@biobot.ioDOH Point of Contact

Name: Anneke Jansen

Title: Healthy Homes and Communities Section Manager

Phone: (360) 789-8738

Email: Anneke.Jansen@doh.wa.gov

EXHIBIT B, DOH CONTRACT PRV27738-0 GENERAL TERMS AND CONDITIONS

I. DEFINITIONS

As used throughout this contract, the following terms shall have the meanings set forth below:

1. "Allowable Cost" shall mean an expenditure which meets the test of the Uniform Guidance (2CFR 200) (see "I. Federal Compliance"). The most significant factors affecting allowability of cost are; 1) they must be necessary and reasonable, 2) they must be allocable, 3) they must be authorized or not prohibited under State or local laws and regulations, and 4) they must be adequately documented. For more specifics see Selected Items of Cost 2 CFR 200.420).
2. "Client" shall mean an agency, firm, organization, individual or other entity applying for or receiving services under this contract.
3. "Cognizant State Agency" shall mean the State agency from whom the sub-recipient receives federal financial assistance. If funds are received from more than one State agency, the cognizant State agency shall be the agency who contributes the largest portion of federal financial assistance to the sub-recipient, unless a cognizant State agency has been designated by OFM.
4. "Confidential Information " shall mean information that is exempt from disclosure under chapter 42.56 RCW, and other State or Federal statutes and regulations.
5. "Contractor" shall mean that agency, firm, provider, organization, individual or other entity performing services under this contract. It shall include any subcontractor retained by the prime Contractor as permitted under the terms of this contract.

A contract is for the purpose of obtaining goods and services for the non-Federal entity's own use and creates a procurement relationship with the Contractor. See §200.22 Contract. Characteristics indicative of a procurement relationship between the non-Federal entity and a Contractor are when the non-Federal entity receiving the Federal funds:

- A. Provides the goods and services within normal business operations;
 - B. Provides similar goods or services to many different purchasers;
 - C. Normally operates in a competitive environment;
 - D. Provides goods or services that are ancillary to the operation of the Federal program; and
 - E. Is not subject to compliance requirements of the Federal program as a result of the agreement, though similar requirements may apply for other reasons.
6. "Contracting Officer" shall mean that individual(s) of the Contracts and Procurement Office of DOH and his/her delegates within that office authorized to execute this contract on behalf of DOH.
 7. "Department" shall mean the Department of Health (DOH) of the State of Washington, any division, section, office, unit or other entity of the department, or any of the officers or other officials lawfully representing DOH.
 8. "Equipment" shall mean an article of non-expendable, tangible property having a useful life of more than one year and an acquisition cost of \$5,000 or more.

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9. "Noncompliance" shall mean if a non-Federal entity fails to comply with Federal statutes, regulations or the terms and conditions of a Federal award, the Federal awarding agency or pass-through entity may impose additional conditions, as described in §200.207 Specific conditions. If the Federal awarding agency or pass-through entity determines that noncompliance cannot be remedied by imposing additional conditions, the Federal awarding agency or pass-through entity may take one or more of the following actions, as appropriate in the circumstances:
- A. Temporarily withhold cash payments pending correction of the deficiency by the non-Federal entity or more severe enforcement action by the Federal awarding agency or pass-through entity.
 - B. Disallow (that is, deny both use of funds and any applicable matching credit for) all or part of the cost of the activity or action not in compliance.
 - C. Wholly or partly suspend or terminate the Federal award.
 - D. Initiate suspension or debarment proceedings as authorized under 2 CFR part 180 and Federal awarding agency regulations (or in the case of a pass-through entity, recommend such a proceeding be initiated by a Federal awarding agency).
 - E. Withhold further Federal awards for the project or program.
 - F. Take other remedies that may be legally available.
10. "Personal Information" shall mean information identifiable to any person, including, but not limited to, information that relates to a person's name, health, finances, education, business, use or receipt of governmental services or other activities, addresses, telephone numbers, social security numbers, driver license numbers, other identifying numbers, and any financial identifiers. Personal information includes "protected health information" as set forth in 45 CFR § 164.50 as currently drafted and subsequently amended or revised and any other information that may be exempt from disclosure to the public or other unauthorized persons under either chapter 42.56 RCW or other State and Federal statutes.
11. "Reimbursement" shall mean that DOH will repay the Contractor for allowable costs incurred under the terms of this contract.
12. "Sensitive Data" shall mean data that is held confidentially, and if compromised, may cause harm to individual citizens or create a liability for the State.
13. "Specific Conditions"
- A. The Federal awarding agency or pass-through entity may impose additional specific award conditions as needed, in accordance with paragraphs (b) and (c) of this section, under the following circumstances:
 - 1) Based on the criteria set forth in §200.205 Federal awarding agency review of risk posed by applicants;
 - 2) When an applicant or recipient has a history of failure to comply with the general or specific terms and conditions of a Federal award;
 - 3) When an applicant or recipient fails to meet expected performance goals as described in §200.210 Information contained in a Federal award; or
 - 4) When an applicant or recipient is not otherwise responsible.

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B. These additional Federal award conditions may include items such as the following:

- 1) Requiring payments as reimbursements rather than advance payments;
- 2) Withholding authority to proceed to the next phase until receipt of evidence of acceptable performance within a given period of performance;
- 3) Requiring additional, more detailed financial reports;
- 4) Requiring additional project monitoring;
- 5) Requiring the non-Federal entity to obtain technical or management assistance; or
- 6) Establishing additional prior approvals.

C. The Federal awarding agency or pass-through entity must notify the applicant or non-Federal entity as to:

- 1) The nature of the additional requirements;
- 2) The reason why the additional requirements are being imposed;
- 3) The nature of the action needed to remove the additional requirement, if applicable;
- 4) The time allowed for completing the actions if applicable, and
- 5) The method for requesting reconsideration of the additional requirements imposed.

D. Any specific conditions must be promptly removed once the conditions that prompted them have been corrected.

14. “Subcontractor” shall mean a person, partnership, or company, not in the employ of or owned by the Contractor, who is performing all or part of those services under a separate contract with or on behalf of the Contractor. The terms “subcontractor” and “subcontractors” mean subcontractor(s) in any tier

15. “Subrecipient” shall mean a non-Federal entity that received a subaward from a pass-through entity to carry out part of a Federal program; but does not include an individual that is a beneficiary of such program. A subrecipient may also be a recipient of other Federal awards directly from a Federal awarding agency. (2 CFR 200.93)

Characteristics which support the classification of the non-Federal entity as a subrecipient include when the non-Federal entity:

- A. Determines who is eligible to receive what Federal assistance;
- B. Has its performance measured in relation to whether objectives of a Federal program were met;
- C. Has responsibility for programmatic decision making;
- D. Is responsible for adherence to applicable Federal program requirements specified in the Federal award; and
- E. In accordance with its contract, uses the Federal funds to carry out a program for a public purpose specified in authorizing statute, as opposed to providing goods or services for the benefit of a pass-through entity.

16. “Successor” shall mean any entity which, through amalgamation, consolidation, or other legal succession becomes invested with rights and assumes burdens of the first Contractor/Vendor.

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II. GENERAL CONDITIONS

1. **ACCESS TO DATA** – In compliance with chapter 39.26 RCW, the Contractor shall provide access to data generated under this contract to DOH, the Joint Legislative Audit and Review Committee, and the State Auditor at no additional cost. This includes access to all information that supports the findings, conclusions, and recommendations of the Contractor's reports, including computer models and methodology for those models. The Contractor agrees to make personal information covered under this contract available to DOH for inspection or to amend the personal information, as directed by DOH. Contractor shall, as directed by DOH, incorporate any amendments to the personal information into all copies of such personal information maintained by the Contractor or its subcontractors.
2. **ADVANCE PAYMENTS PROHIBITED** – No payment in advance or in anticipation of services or supplies to be provided under this contract shall be made by DOH.
3. **AMENDMENTS** – This contract may be amended by mutual written contract of the parties. Such amendments shall not be binding unless they are in writing and signed by personnel authorized to bind each of the parties.
4. **AMERICANS WITH DISABILITIES ACT (ADA) OF 1990, PUBLIC LAW 101-336, also referred to as the "ADA" 28 CFR Part 35** – The Contractor must comply with the ADA, which provides comprehensive civil rights protection to individuals with disabilities in the areas of employment, public accommodations, State and local government services, and telecommunications.
5. **ASSIGNABILITY** – Neither this contract nor any claim arising under this contract shall be transferred or assigned by the Contractor without prior written consent of DOH.
6. **ATTORNEYS' FEES** – In the event of litigation or other action brought to enforce contract terms, each party agrees to bear its own attorney's fees and costs.
7. **CHANGE IN STATUS** - In the event of substantive change in the legal status, organizational structure, or fiscal reporting responsibility of the Contractor, Contractor agrees to notify DOH of the change. Contractor shall provide notice as soon as practicable, but no later than thirty days after such a change takes effect.
8. **CONFIDENTIALITY/SAFEGUARDING OF INFORMATION** – The use or disclosure by any party, either verbally or in writing, of any Confidential Information shall be subject to Chapter 42.56 RCW and Chapter 70.02 RCW, as well as other applicable Federal and State laws and administrative rules governing confidentiality. Specifically, the Contractor agrees to limit access to Confidential Information to the minimum amount of information necessary, to the fewest number of people, for the least amount of time required to do the work. The obligations set forth in this clause shall survive completion, cancellation, expiration, or termination of this contract.

A. Notification of Confidentiality Breach

Upon a breach or suspected breach of confidentiality, the Contractor shall immediately notify the DOH Chief Information Security Officer at security@doh.wa.gov. For the purposes of this contract, "immediately" shall mean within one business day.

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The Contractor will take steps necessary to mitigate any known harmful effects of such unauthorized access including, but not limited to sanctioning employees, notifying subjects, and taking steps necessary to stop further unauthorized access. The Contractor agrees to indemnify and hold harmless DOH for any damages related to unauthorized use or disclosure by the Contractor, its officers, directors, employees, subcontractors, or agents.

Any breach of this clause may result in termination of the contract and the demand for return of all Information.

B. Subsequent Disclosure

The Contractor will not release, divulge, publish, transfer, sell, disclose, or otherwise make the Confidential Information known to any other entity or person without the express prior written consent of the Secretary of Health, or as required by law.

If responding to public record disclosure requests under RCW 42.56, the Contractor agrees to notify and discuss with the DOH Chief Information Security Officer requests for all information that are part of this contract, prior to disclosing the information. The Contractor further agrees to provide DOH a minimum of two calendar weeks to initiate legal action to secure a protective order under RCW 42.56.540.

9. **CONFLICT OF INTEREST** – Notwithstanding any determination by the Executive Ethics Board or other tribunal, DOH may, in its sole discretion, by written notice to the Contractor, terminate this contract if it is found, after due notice and examination by DOH that there is a violation of the ethics in public service act, chapter 42.52 RCW, or any similar statute involving the Contractor in the procurement of, or performance of this contract.

In the event this contract is terminated as provided above, DOH shall be entitled to pursue the same remedies against the Contractor as it could pursue in the event of a breach of the contract by the Contractor. The rights and remedies of DOH provided for in this section shall not be exclusive are in addition to any other rights and remedies provided by law. The existence of facts upon which DOH makes a determination under this section shall be an issue and may be reviewed as provided in the “disputes” section of this contract.

10. **COVENANT AGAINST CONTINGENT FEES** – The Contractor warrants that no person or selling agent has been employed or retained to solicit or secure this contract upon an agreement or understanding for a commission, percentage, brokerage or contingent fee, excepting bona fide employees or bona fide established agents maintained by the Contractor for the purpose of securing business. DOH shall have the right, in the event of breach of this clause by the Contractor, to annul this contract without liability, or in its discretion, to deduct from the contract price or consideration or recover by other means the full amount of such commission, percentage, brokerage or contingent fee.
11. **DEBARMENT** – The Contractor, by signature to this contract, certifies that the Contractor is not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded in any Federal department or agency from participating in transactions. The Contractor agrees to include the above requirement in all subcontracts into which it enters to complete this contract.
12. **DISPUTES** – The parties shall use their best, good faith efforts to cooperatively resolve disputes and problems that arise in connection with this contract. Both parties will continue without delay

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to carry out their respective responsibilities under this contract while attempting to resolve the dispute under this section. When a genuine dispute arises between DOH and the Contractor regarding the terms of this agreement or the responsibilities imposed herein which cannot be resolved, either party may submit a request for non-binding mediation to the other party through the DOH Contracts Unit and the DOH Contracts Unit will notify the other party of the request for non-binding mediation. DOH Contracts will act as the initial coordination point and manage the non-binding mediation communication to and from the parties.

Each party agrees that the DOH will identify three mediators who are neutral to both parties. Each party agrees that Contractor will identify one of the three mediators to engage in this process. Each party agrees that it will be responsible for one-half (1/2) the cost of the mediator. Each party agrees that the non-binding mediation will occur at a time and place convenient to all parties, including the mediator and that preference is for the mediation to occur in Olympia or Tumwater, Washington. Each party agrees the mediation is non-binding.

A party's request for a non-binding mediation must:

- Be in writing,
- Clearly state the disputed issues,
- State the relative positions of the parties, state the Contractor's name, address, and his/her contact number, the DOH Program Contract Manager.
- Be mailed to ATTN: DOH Contracts and Procurement Director, P.O. Box 47905, Olympia, WA 98504-7905 within 30 day (30) calendar days after the party could have reasonably be expected to have knowledge of the issue which he/she now disputes, or
- Be emailed to DOHCon.Mgmt@doh.wa.gov with the subject line clearly displaying the contract number and the word "DISPUTE."

The non-binding mediation process constitutes the sole administrative remedy available under this contract. The parties agree that this resolution process shall precede any action in a judicial and quasi-judicial tribunal. Both parties have a duty and responsibility to timely pursue and engage in non-binding mediation. However, the requesting party may pursue judicial or quasi-judicial action prior to the completion of non-binding mediation if the subject party unnecessarily delays or intentionally frustrates the mediation process.

13. **EFFECTIVE DATE** – Unless otherwise specified under period of performance, the effective date of this contract and subsequent amendments, if any, is the date of execution. The date of execution is the last date of signature of the parties to the contract. Contractor assumes all liability for any expenses incurred prior to the date of execution or in the event the contract/amendment is not executed.
14. **EXECUTIVE ORDER 18-03 – WORKERS' RIGHTS (MANDATORY INDIVIDUAL ARBITRATION)**. This clause applies ONLY to those entities who have submitted a bid as part of a competitive procurement AND have certified that a mandatory individual arbitration and/or class or collective action waiver regarding employee disputes is not required as a condition of employment. Contractor represents and warrants, as previously certified in Contractor's bid submission, that Contractor does NOT require its employees, as a condition of employment, to sign or agree to mandatory individual arbitration clauses or class or collective action waivers. Contractor further represents and warrants that, during the term of this Contract, Contractor shall not, as a condition of employment, require its employees to sign or agree to mandatory individual arbitration clauses or class or collective action waivers.

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15. **GOVERNING LAW** – This contract shall be governed by the laws of the State of Washington and applicable federal laws and regulations. The venue of any legal action or suit concerning this contract shall be the Thurston County Superior Court and all actions or suits thereon shall be brought therein.

16. **INDEMNIFICATION** – To the fullest extent permitted by law, Contractor shall indemnify, defend and hold harmless the State of Washington, DOH, agencies of the State and all officials, and employees of the State, from and against all claims arising out of or resulting from the performance of the contract. “Claim” as used in this contract means any financial loss, claim, suit, action, damage, or expense, including but not limited to attorney’s fees, attributable for bodily injury, sickness, disease or death, or injury to or destruction of tangible property including loss of use resulting therefrom. Contractor's obligation to indemnify, defend, and hold harmless includes any claim by Contractors’ agents, employees, representatives, or any subcontractor or its employees.

Contractor expressly agrees to indemnify, defend, and hold harmless the State for any claim arising out of or incident to Contractor’s or any subcontractor’s performance or failure to perform the contract. Contractor’s obligation to indemnify, defend, and hold harmless the State shall not be eliminated or reduced by any actual or alleged concurrent negligence of State or its agencies, employees and officials.

Contractor waives its immunity under Title 51 RCW to the extent it is required to indemnify, defend and hold harmless State and its agencies, officials, agents or employees.

17. **INDEPENDENT CAPACITY OF THE CONTRACTOR** – The parties intend that an independent contractor relationship will be created by this contract. The Contractor and his or her employees or agents performing under the contract are not employees of DOH. The contractor shall not hold himself/herself out as nor claim to be an officer or employee of DOH or of the State of Washington by reason hereof, nor will the Contractor make any claim of right, privilege or benefit which would accrue to such employee under law. Conduct and control of the work will be solely with the Contractor.

18. **INDUSTRIAL INSURANCE COVERAGE** – The Contractor shall comply with the provisions of Title 51 RCW, Industrial Insurance. Prior to performing work under this contract, the Contractor shall provide or purchase industrial insurance coverage for the Contractor’s employees, as may be required of an “employer” as defined in Title 51 RCW, and shall maintain full compliance with Title 51 RCW during the course of this contract. If the Contractor fails to provide industrial insurance coverage or fails to pay premiums or penalties on behalf of its employees as may be required by law, DOH may collect from the Contractor the full amount payable to the Industrial Insurance accident fund. DOH may deduct the amount owed by the Contractor to the accident fund from the amount payable to the Contractor by DOH under this contract, and transmit the deducted amount to the Department of Labor and Industries, Division of Insurance Services. This provision does not waive any of the Department of Labor and Industries rights to collect from the Contractor.

Industrial insurance coverage through the Department of Labor & Industries is optional for sole proprietors, partners, corporate officers and others, per RCW 51.12.020.

19. **INSURANCE** – The Contractor shall provide insurance coverage as set out in this section. The intent of the required insurance is to protect the State should there be any claims, suits, actions,

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costs, damages or expenses arising from any negligent or intentional act or omission of the Contractor or subcontractor, or agents of either, while performing under the terms of this contract. The Contractor shall provide insurance coverage which shall be maintained in full force and effect during the term of this Contract, as follows:

- A. **Commercial General Liability Insurance Policy** - Provide a commercial general liability insurance policy, including contractual liability, in adequate quantity to protect against legal liability arising out of contract activity but no less than \$1,000,000 per occurrence. Additionally, the Contractor is responsible for ensuring that any subcontractors provide adequate insurance coverage for the activities arising out of subcontracts.
- B. **Automobile Liability** - In the event that services delivered pursuant to this contract involve the use of vehicles, either owned or unowned by the Contractor, automobile liability insurance shall be required. The minimum limit for automobile liability is:
 - 1) \$1,000,000 per occurrence, using a combined single limit for bodily injury and property damage
- C. The insurance required shall be issued by an insurance company/ies authorized to do business within the State of Washington, and shall name the State of Washington, and its employees as additional insureds under the insurance policy/ies. All policies shall be primary to any other valid and collectable insurance. Contractor shall instruct the insurers to give DOH 30 days advance notice of any insurance cancellation.

Upon request, Contractor shall submit to DOH, a certificate of insurance which outlines the coverage and limits defined in the Insurance section. If a certificate of insurance is requested, Contractor shall submit renewal certificates as appropriate during the term of the contract.

- 20. **LICENSING, ACCREDITATION AND REGISTRATION** – The Contractor shall comply with all applicable local, State, and Federal licensing, accreditation and registration requirements/standards, necessary for the performance of this contract.
- 21. **LIMITATION OF AUTHORITY** – Only the Contracting Officer or his/her delegate by writing (delegation to be made prior to action) shall have the express, implied, or apparent authority to alter, amend, modify, or waive any clause or condition of this contract on behalf of DOH. No alteration, modification, or waiver of any clause or condition of this contract is effective or binding unless made in writing and signed by the Contracting Officer.
- 22. **MATERIAL BREACH** – Contract may be terminated for cause by DOH, at the sole discretion of the Contract Administrator, for failing to perform a contractual requirement or for a material breach of any term or condition. Material breach of a term or condition of the Contract may include but is not limited to:
 - A. Contractor failure to perform services or deliver materials, supplies, or equipment by the date required or by an alternate date as mutually agreed in a written amendment to the Contract;
 - B. Contractor failure to carry out any warranty or fails to perform or comply with any mandatory provision of the contract;
 - C. Contractor becomes insolvent or in an unsound financial condition so as to endanger performance hereunder;

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- D. Contractor becomes the subject of any proceeding under any law relating to bankruptcy, insolvency or reorganization, or relief from creditors and/or debtors that endangers the Contractor's proper performance hereunder;
 - E. Appointment of any receiver, trustee, or similar official for Contractor or any of the Contractor's property and such appointment endangers the Contractor's proper performance hereunder;
 - F. A determination that the Contractor is in violation of federal, state, or local laws or regulations and that such determination renders the Contractor unable to perform any aspect of the Contract.

23. **NONDISCRIMINATION** – During the performance of this contract, the Contractor shall comply with all Federal and State nondiscrimination laws, regulations and policies.

24. **NONDISCRIMINATION LAWS NONCOMPLIANCE** – In the event of the Contractor's noncompliance or refusal to comply with any nondiscrimination law, regulation, or policy, this contract may be rescinded, canceled or terminated in whole or in part, and the Contractor may be declared ineligible for further contracts with DOH. The Contractor shall, however, be given a reasonable time in which to cure this noncompliance. Any dispute may be resolved in accordance with the disputes procedure set forth herein.

25. **OPPORTUNITY TO CURE** – In the event Contractor fails to perform a contractual requirement or materially breaches any term or condition, DOH may issue a written cure notice. The Contractor may have a period of time in which to cure. DOH is not required to allow the Contractor to cure defects if the opportunity for cure is not feasible as determined solely within the discretion of DOH. Time allowed for cure shall not diminish or eliminate Contractor's liability for liquidated or other damages, or otherwise affect any other remedies available against Contractor under the contract or by law.

If the breach remains after Contractor has been provided the opportunity to cure, DOH may do any one or more of the following:

- a) Exercise any remedy provided by law;
- b) Terminate this contract and any related contracts or portions thereof;
- c) Procure replacements and impose damages as set forth elsewhere in this contract;
- d) Impose actual or liquidated damages;
- e) Request that DES suspend or bar Contractor from receiving future solicitations or other opportunities;
- f) Require Contractor to reimburse the state for any loss or additional expense incurred as a result of default or failure to satisfactorily perform the terms of the contract.

26. **OVERPAYMENTS AND ASSERTION OF LIEN** – In the event that DOH establishes overpayments or erroneous payments made to the Contractor under this contract, DOH may secure repayment, plus interest, if any, through the filing of a lien against the Contractor's real property, or by requiring the posting of a bond, assignment or deposit, or some other form of security acceptable to DOH, or by doing both.

27. **PRIVACY** – Personal information including, but not limited to “protected health information” collected, used or acquired in connection with this contract shall be used solely for the purposes of this contract. Contractor and its subcontractors agree not to release, divulge, publish, transfer, sell or otherwise make known to unauthorized persons personal information without the express written

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consent of DOH or as provided by law. Contractor agrees to implement physical, electronic and managerial safeguards to prevent unauthorized access to personal information.

DOH reserves the right to monitor, audit, or investigate the use of personal information collected, used or acquired by the contractor through this contract. The monitoring, auditing, or investigating may include but is not limited to "salting" by DOH. Contractor shall certify the return or destruction of all personal information upon expiration of this contract. Salting is the act of placing a record containing unique but false information in a database that can be used later to identify inappropriate disclosure of data contained in the database.

Any breach of this provision may result in termination of the contract and the demand for return of all personal information. The Contractor agrees to indemnify and hold harmless DOH for any damages related to the Contractor's unauthorized use of personal information.

For the purposes of this provision, personal information includes but is not limited to information identifiable to an individual that relates to a natural person's health, finances, education, business, use or receipt of governmental services, or other activities, names, addresses, telephone numbers, social security numbers, driver license numbers, financial profiles, credit card numbers, financial identifiers and other identifying numbers.

28. **PUBLICITY** – The Contractor agrees to submit to DOH all advertising and publicity matters relating to this contract wherein DOH's name is mentioned or language used from which the connection of DOH's name may, in DOH's judgment, be inferred or implied. The Contractor agrees not to publish or use such advertising and publicity matters without the prior written consent of DOH.

29. **RECORDS, DOCUMENTS, AND REPORTS** –The Contractor shall maintain books, records, documents, data and other evidence relating to this contract and performance of the services described herein, including but not limited to accounting procedures and practices which sufficiently and properly reflect all direct and indirect costs of any nature expended in the performance of this contract. Contractor shall retain such records for a period of six (6) years following the date of final payment. At no additional cost, these records, including materials generated under the contract, shall be subject at all reasonable times to inspection, review or audit by DOH, personnel duly authorized by DOH, the Office of the State Auditor, and Federal and State officials so authorized by law, regulation or agreement.

If the contract reimburses the Contractor for costs incurred in performance, the Contractor shall in addition maintain books, records, documents and other evidence of procedures and practices which sufficiently and properly reflect all direct and indirect costs of any nature expended in the performance of this contract.

If any litigation, claim or audit is started before the expiration of the six (6) year period, the records shall be retained until all litigation, claims, or audit findings involving the records have been resolved.

30. **REGISTRATION WITH DEPARTMENT OF REVENUE** – The Contractor shall complete registration with the Washington State Department of Revenue, if applicable, and be responsible for payment of all taxes due on payments made under this contract.

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31. **REMEDIES** – If Contractor is in breach under any provision of this Contract, DOH shall have all of the remedies listed in this section in addition to all other remedies set forth in other sections of this Contract following the notice and cure period set forth. DOH in its sole discretion, may exercise any or all of the remedies available to it, concurrently or consecutively, including one or more of the following remedies:
- A. **Suspend Performance** – Suspend Contractor’s performance with respect to all or any portion of this Contract pending necessary corrective action as specified by the State without entitling Contractor to an adjustment in price/cost or performance schedule. Contractor shall promptly cease performance and incurring costs in accordance with the State’s directive and the State shall not be liable for costs incurred by Contractor after the suspension of performance under this provision.
 - B. **Withhold Payment** – Withhold payment to Contractor until corrections in Contractor’s performance are satisfactorily made and completed.
 - C. **Deny Payment** – Deny payment for those obligations not performed, that due to Contractor’s actions or inactions, cannot be performed or, if performed, would be of no value to the State; provided, that any denial of payment shall be reasonably related to the value to the State of the obligations not performed.
 - D. **Removal** – Notwithstanding any other provision herein, the State may demand immediate removal of any of Contractor’s employees, agents, or Subcontractors whom the State deems incompetent, careless, insubordinate, unsuitable, or otherwise unacceptable, or whose continued relation to this Contract is deemed to be contrary to the public interest or the State’s best interest.
32. **RIGHT OF INSPECTION** – The Contractor shall provide right of access to its facilities to DOH, or any of its officers, or to any other authorized employee or official of the State of Washington or the federal government, at all reasonable times, in order to monitor and evaluate performance, compliance, and/or quality assurance under this contract. The Contractor shall make available information necessary for DOH to comply with the client's right to access, amend, and receive an accounting of disclosures of their Personal Information according to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) or any regulations enacted or revised pursuant to the HIPAA provisions and applicable provisions of Washington State law. The Contractor’s internal policies and procedures, books, and records relating to the safeguarding, use, and disclosure of personal information obtained or used as a result of this contract shall be made available to DOH and the U.S. Secretary of the Department of Health & Human Services, upon request.
33. **RIGHTS IN DATA/COPYRIGHT** – Unless otherwise provided, all materials produced exclusively under this contract shall be considered "works for hire" as defined by the U.S. Copyright Act and shall be owned by DOH. DOH shall be considered the author of such Materials. In the event the Materials are not considered “works for hire” under the U.S. Copyright laws, Contractor hereby irrevocably assigns all right, title, and interest in Materials, including all intellectual property rights, to DOH effective from the moment of creation of such materials.

Materials means all items in any format and includes, but is not limited to, data, reports, documents, pamphlets, advertisements, books, magazines, surveys, studies, computer programs, films, tapes, and/or sound reproductions that derive exclusively from the Contractor’s work under this contract. Ownership includes the right to copyright, patent, register and the ability to transfer these rights.

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For materials that are delivered under the contract, but that incorporate pre-existing materials not produced under the contract, Contractor hereby grants to DOH a nonexclusive, royalty-free, irrevocable license (with rights to sublicense others) in such materials to translate, reproduce, distribute, prepare derivative works, publicly perform, and publicly display. The Contractor warrants and represents that Contractor has all rights and permissions, including intellectual property rights, moral rights and rights of publicity, necessary to grant such a license to DOH.

The Contractor shall exert all reasonable effort to advise DOH, at the time of delivery of materials furnished under this contract, of all known or potential invasions of privacy contained therein and of any portion of such document which was not produced in the performance of this contract. DOH shall receive prompt written notice of each notice or claim of copyright infringement received by the Contractor with respect to any data delivered under this contract. DOH shall have the right to modify or remove any restrictive markings placed upon the data by the Contractor.

34. SECURITY OF INFORMATION – Unless otherwise specifically authorized by the DOH Chief Information Security Officer, Contractor receiving confidential information under this contract assures that:

- Encryption is selected and applied using industry standard algorithms validated by the National Institute of Standards and Technology (NIST) Cryptographic Algorithm Validation Program against all information stored locally and off-site. Information must be encrypted both in-transit and at rest and applied in such a way that it renders data unusable to anyone but authorized personnel, and the confidential process, encryption key or other means to decipher the information is protected from unauthorized access.
- It is compliant with the applicable provisions of the Washington State Office of the Chief Information Officer (OCIO) policy 141, Securing Information Technology Assets, available at: <https://ocio.wa.gov/policy/securing-information-technology-assets>.
- It will provide DOH copies of its IT security policies, practices and procedures upon the request of the DOH Chief Information Security Officer.
- DOH may at any time conduct an audit of the Contractor's security practices and/or infrastructure to assure compliance with the security requirements of this contract.
- It has implemented physical, electronic and administrative safeguards that are consistent with OCIO security standard 141.10 and ISB IT guidelines to prevent unauthorized access, use, modification or disclosure of DOH Confidential Information in any form. This includes, but is not limited to, restricting access to specifically authorized individuals and services through the use of:
 - Documented access authorization and change control procedures;
 - Card key systems that restrict, monitor and log access;
 - Locked racks for the storage of servers that contain Confidential Information or use AES encryption (key lengths of 256 bits or greater) to protect confidential data at rest, standard algorithms validated by the National Institute of Standards and Technology (NIST) Cryptographic Algorithm Validation Program (CMVP);
 - Documented patch management practices that assure all network systems are running critical security updates within 6 days of release when the exploit is in the wild, and within 30 days of release for all others;
 - Documented anti-virus strategies that assure all systems are running the most current anti-virus signatures within 1 day of release;

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- Complex passwords that are systematically enforced and password expiration not to exceed 120 days, dependent user authentication types as defined in OCIO security standards;
 - Strong multi-factor authentication mechanisms that assure the identity of individuals who access Confidential Information;
 - Account lock-out after 5 failed authentication attempts for a minimum of 15 minutes, or for Confidential Information, until administrator reset;
 - AES encryption (using key lengths 128 bits or greater) session for all data transmissions, standard algorithms validated by NIST CMVP;
 - Firewall rules and network address translation that isolate database servers from web servers and public networks;
 - Regular review of firewall rules and configurations to assure compliance with authorization and change control procedures;
 - Log management and intrusion detection/prevention systems;
 - A documented and tested incident response plan

Any breach of this clause may result in termination of the contract and the demand for return of all personal information.

35. **SEVERABILITY** – If any provision of this contract or any provision of any document incorporated by reference shall be held invalid, such invalidity shall not affect the other provisions of this contract which can be given effect without the invalid provision, and to this end the provisions of this contract are declared to be severable.
36. **SITE SECURITY** – While on DOH premises, Contractor, its agents, employees, or subcontractors shall conform in all respects with physical, fire or other security policies or regulations. Failure to comply with these regulations may be grounds for revoking or suspending security access to these facilities. DOH reserves the right and authority to immediately revoke security access to Contractor staff for any real or threatened breach of this provision. Upon reassignment or termination of any Contractor staff, Contractor agrees to promptly notify DOH.
37. **SUBCONTRACTING** – Neither the Contractor, nor any subcontractors, shall enter into subcontracts for any of the work contemplated under this contract without prior written approval of DOH. In no event shall the existence of the subcontract operate to release or reduce the liability of the Contractor to DOH for any breach in the performance of the Contractor's duties. This clause does not apply to Hospitals and/or Medical Clinics that must contract with specialty physicians (e.g., anesthesiologists, radiologists, physicians groups, independent practitioners, etc.) nor does it include contracts of employment between the Contractor and personnel assigned to work under this contract.

Additionally, the Contractor is responsible for ensuring that all terms, conditions, assurances and certifications set forth in this contract are carried forward to any subcontracts. Contractor and its subcontractors agree not to release, divulge, publish, transfer, sell or otherwise make known to unauthorized persons personal information without the express written consent of DOH or as provided by law.

If, at any time during the progress of the work, DOH determines in its sole judgment that any subcontractor is incompetent or undesirable, DOH shall notify the Contractor, and the Contractor shall take immediate steps to terminate the subcontractor's involvement in the work.

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The rejection or approval by DOH of any subcontractor or the termination of a subcontractor shall not relieve the Contractor of any of its responsibilities under the contract, nor be the basis for additional charges to DOH.

DOH has no contractual obligations to any subcontractor or vendor under contract to the Contractor. The Contractor is fully responsible for all contractual obligations, financial or otherwise, to their subcontractors.

38. **SURVIVABILITY** – The terms and conditions contained in this contract which by their sense and context, are intended to survive the completion, cancellation, termination, or expiration of the contract shall survive,

39. **SUSPENSION OF PERFORMANCE AND RESUMPTION OF PERFORMANCE** – In the event contract funding from State, Federal, or other sources is withdrawn, reduced, or limited in any way after the effective date of this contract and prior to normal completion, DOH may give notice to Contractor to suspend performance as an alternative to termination. DOH may elect to give written notice to Contractor to suspend performance when DOH determines that there is a reasonable likelihood that the funding insufficiency may be resolved in a timeframe that would allow performance to be resumed prior to the end date of this contract. Notice may include notice by facsimile or email to Contractor's representative. Contractor shall suspend performance on the date stated in the written notice to suspend. During the period of suspension of performance each party may inform the other of any conditions that may reasonably affect the potential for resumption of performance.

When DOH determines that the funding insufficiency is resolved, DOH may give Contractor written notice to resume performance and a proposed date to resume performance. Upon receipt of written notice to resume performance, Contractor will give written notice to DOH as to whether it can resume performance, and, if so, the date upon which it agrees to resume performance. If Contractor gives notice to DOH that it cannot resume performance, the parties agree that the contract will be terminated retroactive to the original date of termination. If the date Contractor gives notice it can resume performance is not acceptable to DOH, the parties agree to discuss an alternative acceptable date. If an alternative date is not acceptable to DOH, the parties agree that the contract will be terminated retroactive to the original date of termination.

40. **TAXES** – All payments accrued on account of payroll taxes, unemployment contributions, any other taxes, insurance or other expenses for the Contractor or its staff shall be the sole responsibility of the Contractor.
41. **TERMINATION FOR CONVENIENCE** – Except as otherwise provided in this contract, the Contracting Officer may, by TEN (10) calendar days written notice, beginning on the second day after the mailing, terminate this contract in whole or in part when it is in the best interests of DOH.

If this contract is so terminated, DOH shall be liable only for payment in accordance with the terms of this contract for services rendered prior to the effective date of termination.

42. **TERMINATION FOR DEFAULT** – In the event DOH determines the contractor has failed to comply with the conditions of this contract in a timely manner, DOH has the right to suspend or terminate this contract. Further, DOH may terminate this contract for default, in whole or in part, if DOH has a reasonable basis to believe that the Contractor has:

EXHIBIT B, DOH CONTRACT PRV27738-0
GENERAL TERMS AND CONDITIONS

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- A. Failed to meet or maintain any requirement for contracting with DOH;
 - B. Failed to ensure the health or safety of any client for whom services are being provided under this contract;
 - C. Failed to perform under, or otherwise breached, any term or condition of this contract; and/or
 - D. Violated any applicable law or regulation.

Before suspending or terminating the contract, DOH shall notify the Contractor in writing of the need to take corrective action. If corrective action is not taken within fourteen (14) days, the contract may be terminated or suspended. In the event of termination or suspension, the Contractor shall be liable for damages as authorized by law including, but not limited to, any cost difference between the original contract and the replacement or cover contract and all administrative costs directly related to the replacement contract, e.g., cost of the competitive bidding, mailing, advertising and staff time. DOH reserves the right to suspend all or part of the contract, withhold further payments, or prohibit the Contractor from incurring additional obligations of funds during investigation of the alleged compliance breach and pending corrective action by the Contractor or a decision by DOH to terminate the contract. A termination shall be deemed to be a "termination for convenience" if it is determined that the Contractor: (1) was not in default; or (2) failure to perform was outside of his or her control, fault or negligence. The rights and remedies of DOH provided in this contract are not exclusive and are in addition to any other rights and remedies provided by law.

43. **TERMINATION PROCEDURE** – Upon termination of this contract DOH may require the Contractor to deliver to DOH any property specifically produced or acquired for the performance of such part of this contract as has been terminated.

DOH shall pay to the Contractor the agreed upon price, if separately stated, for completed work and services accepted by DOH. In addition DOH shall pay the amount agreed upon by the Contractor and the Contracting Officer for (a) completed work and services for which no separate price is stated, (b) partially completed work and services, (c) other property or services which are accepted by DOH, and (d) the protection and preservation of the property. If the termination is for default, the Contracting Officer shall determine the extent of the liability of DOH. Failure to agree with such determination shall be a dispute within the meaning of the Disputes clause of this contract.

DOH may withhold from any amounts due the Contractor for such completed work or services such sum as the Contracting Officer determines to be necessary to protect DOH against potential loss or liability.

The rights and remedies of DOH provided in this section shall not be exclusive and are in addition to any other rights and remedies provided by law or under this contract.

After receipt of a notice of termination, and except as otherwise directed by the Contracting Officer, the Contractor shall:

- Stop work under the contract on the date and to the extent specified in the notice;
- Place no further orders or subcontracts for materials, services, facilities except as necessary to complete such portion of the work not terminated;

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GENERAL TERMS AND CONDITIONS

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- Assign to DOH, to the extent directed by the Contracting Officer, all of the rights, titles, and interest of the Contractor under the orders and subcontracts in which case DOH has the right, at its discretion, to settle or pay any or all claims arising out of the termination of such orders and subcontracts.
 - Settle all outstanding liabilities and all claims arising out of orders or subcontracts, with the approval or ratification of the Contracting Officer to the extent he/she may require, which approval or ratification shall be final for all the purposes of this clause;
 - Transfer title to DOH and deliver, as directed by the Contracting Officer, any property which, if the contract had been completed, would have been required to be furnished to DOH;
 - Complete performance of such part of the work not terminated by the Contracting Officer; and,
 - Take such action as may be necessary, or as the Contracting Officer may direct, for the protection and preservation of the property related to this contract which is in the possession of the Contractor and in which DOH has or may acquire an interest.

44. **WAIVER OF DEFAULT** – Waiver of any default or breach shall not be deemed to be a waiver of any subsequent default or breach. Any waiver shall not be construed to be a modification of the terms of this contract unless stated to be such in writing and signed by authorized representative of DOH.

DOH Contract Number:
PRV27738- 0

Sole Source CONTRACT Filing Justification Template

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.

0DES Sole Source Question	1DOH Program Manager Response
2Specific Problem or Need	
1. What is the business need or problem that requires this contract?	<p>High-Level Summary:</p> <p>The Washington Wastewater Based Epidemiology (WAWBE) program monitors community infection levels of SARS-CoV-2 and Monkey Pox Virus (mpox) in wastewater samples across Washington (WA) state. We expect to expand to monitor for additional pathogens in the future as public health determines the need. Sampling the same community over time creates data trends that inform</p>

0DES Sole Source Question	1DOH Program Manager Response
	<p>health officials about changes in infection level and potential outbreaks. It is crucial that we have a wide reaching and robust wastewater epidemiology program that supports sampling across several different types of communities throughout the state. For epidemiologists and local health officials to make appropriate and accurate inferences about wastewater results, sampling must occur consistently and for a sustained period.</p> <p>Currently, 28 Wastewater Treatment Plants (WWTP) across 16 counties are collecting and submitting samples for analysis of COVID-19. This is accomplished by samples being analyzed by two labs: The CDC's contracted private lab, Biobot Analytics, Inc., currently analyzes samples from 13 WWTPs and the WA state public health lab (PHL) analyzes samples from 15 WWTPs.</p> <p>In September, the CDC announced that they would be ending their contract with Biobot Analytics, Inc. during the 2023 calendar year. The current contract ends on January 28, 2023, and while there has been mention about a possible 3 to 9 month extension, no contract amendments have been finalized. When the CDC's contract ends with Biobot Analytics, Inc., we will lose 48% of our sampling sites and 26% of our county representation. Absorbing all WWTP's samples analyzed by Biobot Analytics, Inc. would quickly exceed current PHL capacity, leaving limited room for additional expansion.</p> <p>This contract is necessary for the maintenance and expansion of disease monitoring across the state as it relates to SARS-CoV-2, mpox, and potentially, polio virus.</p> <p>Overview of the Washington wastewater-based epidemiology (WAWBE) program:</p> <p>The WAWBE program monitors community infection levels of SARS-CoV-2 and mpox in wastewater samples across Washington state. Wastewater-based epidemiology uses a pooled sample of wastewater collected at WWTPs to test for pathogens, such as SARS-CoV-2, to obtain infection levels for those served by the plant. Since everyone contributes to the wastewater system, wastewater samples can provide infection and transmission information for the community served.</p> <p>By sampling the same community over time, epidemiologists can create data trends that inform health officials about changes in infection level and potential outbreaks. Washington has diverse communities across the state with differences among population size, demographics, COVID-19 and mpox knowledge and practices, and health care access. Given the association between many of these factors and disease outcomes, it is crucial that we have a robust wastewater epidemiology program that supports sampling across several different types of communities. For epidemiologists and local health officials to make appropriate</p>

0DES Sole Source Question	1DOH Program Manager Response
	<p>and accurate inferences about wastewater results, sampling must occur consistently and for a sustained period. Normal sampling frequency for SARS-CoV-2 for Washington sites is 2 times per week for one year minimum, allowing partners to identify weekly and seasonal trends.</p> <p>Current state of what is happening:</p> <p>Sites monitoring:</p> <p>Starting in October 2021, Wastewater Treatment Plants (WWTPs) across the state began collecting and submitting samples for analysis of SARS-CoV-2. Currently, 28 WWTPs spanning 16 counties are actively participating in the monitoring program. Collection and analysis of wastewater samples from these sites is comprised of two groups:</p> <ul style="list-style-type: none"> • Those sites submitting to the CDC’s contracted private lab, Biobot Analytics, Inc., which currently analyzes samples from 13 WWTPs. • Those sites submitting to the PHL, which currently analyzes samples from 15 WWTPs. <p>Pathogens included:</p> <p>Because SARS-CoV-2, Monkeypox (mpox) and polio viruses can be shed in feces, wastewater-based epidemiology can be used to monitor the presence and amount of these pathogens in a community, thus informing DOH and local health officers about the spread of these viruses across Washington state.</p> <p><u>COVID-19</u></p> <p>As the COVID-19 surveillance efforts shift away from case-based monitoring due to the availability of at home tests and overall lower testing rates of communities, wastewater-based epidemiology is becoming a more valuable and cost-effective tool for monitoring community health trends.</p> <p><u>Monkeypox (mpox)</u></p> <p>As part of the mpox response, wastewater-based epidemiology was identified as a key surveillance strategy by the incident management team. Of the 22 counties that had confirmed mpox cases:</p> <ul style="list-style-type: none"> • 9 counties are monitored by the PHL (12 WWTPs) • 4 counties are monitored by the CDC contractor (13 WWTPs). • Both the CDC and PHL are testing wastewater for mpox across their sites starting October 24th. <p>Figure 1. Counties sampling for COVID-19 and mpox in wastewater through the CDC and PHL sampling analysis labs.</p>

0DES Sole Source Question	1DOH Program Manager Response
	<div data-bbox="467 380 743 569"> <p>PHL sampling site</p> <p>Documented monkeypox case</p> <p>PHL sampling site and documented monkeypox case</p> <p>CDC sampling site and documented monkeypox case</p> </div> <p>Polio</p> <p>With heightened concern around polio virus and recent cases of wild-type polio detected in New York, we have started working with the Vaccine Preventable Disease Program to begin exploring incorporating polio testing into our wastewater monitoring efforts. Snohomish and Clark counties were identified by epidemiologists as counties at increased risk for polio emergence. All participating WWTPs in these counties are currently managed under the CDC contractor.</p> <p>DOH leadership has determined that wastewater-based epidemiology needs to be used as soon as a confirmed polio case is identified within the state of Washington. It currently takes the PHL approximately 4-6 months to develop a test and start testing for a new pathogen. This contract is necessary for providing a rapid response and monitoring of polio in the case of an outbreak.</p> <p>Situation:</p> <p>In September, the CDC announced that they would be ending their contract with Biobot Analytics, Inc. during the 2023 calendar year. The current contract ends on January 28, 2023, and while there has been mention about a possible 3 to 9 month extension, no contract amendments have been finalized. When the CDC's contract ends with Biobot Analytics, Inc., we will lose 48% of our sampling sites and 26% of our county representation. Absorbing all WWTP's samples analyzed by Biobot Analytics, Inc. would quickly exceed current PHL capacity, leaving limited room for additional expansion.</p> <p>The sites currently analyzed by CDC's contractor include treatment plants that serve the Muckleshoot Tribal nation, urban centers, and communities at potential increased risk of high COVID-19 transmission. DOH worked closely with the</p>

0DES Sole Source Question	1DOH Program Manager Response
	<p>CDC to create a relationship with the Muckleshoot Tribe for monitoring COVID-19 and mpox in their wastewater. This work is part of an overarching effort to be more equitable in how we gather and use community-level data and support tribal partners.</p> <p>The data from these sites help both DOH and local health officers understand temporal changes in community health. With this additional information, public health professionals can make more evidence-based decisions about topics such as resource allocation (i.e., resources allocated to vaccine education), mandates (i.e., mask wearing), and how to prepare health care facilities for potential surges.</p> <p>It is currently unknown when the CDC contract with Biobot Analytics, Inc. will end, leaving us with the risk of losing these sites if this sole source contract is not in place. At their current capacity, the PHL only has availability to onboard five new facilities, which would mean losing 9 wastewater treatment plants. This loss of sampling sites will drastically limit the ability of the state and local health jurisdictions to track trends of COVID-19 and other health concerns within their communities.</p> <p>Closing statements:</p> <p>This sole source contract is necessary for the maintenance and expansion of disease monitoring across the state as it relates to SARS-CoV-2, mpox, and potentially, polio virus. It is critical that we are able to absorb current CDC sites via a 3rd party commercial contractor. Without this contract, our ability to monitor public health trends across the state will suffer for COVID-19, mpox, and polio responses.</p>
3Sole Source Criteria	
4(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.”	
<p>2. Describe the unique features, qualifications, abilities or expertise of the contractor proposed for this sole source contract.</p>	<p>Unique features of contracting with Biobot Analytics, Inc.:</p> <ol style="list-style-type: none"> 1) They are the current CDC contractor. This means that using them would: <ol style="list-style-type: none"> a. Reduce the risk of information gaps caused by contractor transitions <ol style="list-style-type: none"> i. Biobot Analytics, Inc. could continue collecting and analyzing samples from sites as they transition from the CDC contract to a DOH contract. This would remove the risk of missing sampling days and associated data while the contractor onboards former CDC sites. ii. In July 2022, CDC sites did not collect samples or obtain results for two months when the CDC transitioned from their LuminUltra contract to the current Biobot Analytics, Inc.

0DES Sole Source Question	1DOH Program Manager Response
	<p>contract. This situation already created one break in data trends for these sites, we would like to avoid another. Additionally, we also lost 41% (n=7) of the participating WWTPs in WA during the transition due to plant operators being unwilling or unable to go through another new onboarding process.</p> <ul style="list-style-type: none"> b. Remove the risk of differences in data quality <ul style="list-style-type: none"> i. Many contractors have their own testing techniques for these pathogens, making comparison between labs difficult. ii. If another contractor was chosen, we would need to invest resources in researching the limitations of a new laboratory method and analyze the differences in interpretability across the several methods. iii. Biobot Analytics, Inc. is the leading laboratory for most wastewater based-epidemiology work and has consistent, verified, and well-researched methods for testing. c. Ensure that testing methods align with current CDC standards. <ul style="list-style-type: none"> i. As the current CDC contractor, Biobot Analytics, Inc.'s analysis techniques for SARS-CoV-2, mpox, and polio are all in compliance and alignment with CDC guidelines. ii. Using Biobot Analytics, Inc. as our contractor also ensures that we would be able to compare data collected under the CDC contract with data collected under our contract. <p>2) Biobot Analytics, Inc. is also one of the few companies capable of COVID-19 and mpox testing and is currently developing a polio protocol. Using them would allow testing for both pathogens to be done at the same facility saving both time and money associated with shipping samples to different labs.</p> <ul style="list-style-type: none"> a. Shipping samples from 14 WWTPs to the PHL costs approximately \$142,417 a year. b. Because we need to monitor wastewater samples for SARS-CoV-2, mpox, and potentially, polio virus, using different labs and contracts to monitor for these pathogens would be cost prohibitive in shipping fees alone. c. Biobot Analytics, Inc. includes the cost of shipping in their base fee for SARS-CoV-2 testing. <p>Unique qualification of using Biobot Analytics, Inc.:</p> <ul style="list-style-type: none"> 1) Biobot Analytics, Inc. was one of the first companies to offer wastewater-based epidemiology testing, and therefore has the experience and infrastructure in place to support our program. <ul style="list-style-type: none"> a. Lower costs due to not paying for start-up fees for establishing testing sites and protocols.

0DES Sole Source Question	1DOH Program Manager Response						
	<p>b. They have the infrastructure to support wastewater sampling and wouldn't need time/resources to set up labs, courier services, and other logistics since they are already in place.</p> <p>c. They have streamlined their sampling collection and analysis protocols so that their testing costs no longer reflect start-up expenses.</p> <p>2) Biobot Analytics, Inc. has worked with multiple states to perform similar testing as what is needed for the WAWBE program, and they come highly recommended.</p> <p>a. Have gone through state and federal contracting and are familiar with challenges around wastewater surveillance</p> <p>3) Experience working with a wide variety of data processes and systems including REDCap and DCIPHER.</p> <p>The following table is the basic abilities and expertise that the contractor must provide.</p> <p>Table 1. Abilities and expertise required for contractor</p> <table> <tr> <th data-bbox="456 1010 727 1146">Qualification/ Expertise required</th><th data-bbox="727 1010 1511 1146">Rational/ Why this requirement is necessary</th></tr> <tr> <td data-bbox="456 1146 727 1776">At least one year of experience partnering with a state or federal agency to implement wastewater surveillance for SARS-CoV-2</td><td data-bbox="727 1146 1511 1776"> <ul style="list-style-type: none"> • Has infrastructure in place to support rapid growth and onboarding of new facilities with little to no delay. • Wouldn't need time/resources to set up labs, courier services, and other logistics since they are already in place. • Have streamlined their sampling collection and analysis protocols so that their testing costs no longer reflect start-up expenses. • Lower costs due to not paying for start-up fees for establishing testing sites and protocols. • Have gone through multiple contracts and programs integrating lessons learned from other states performing similar testing. • Familiarity with data security and integrity needs associated with state and federal public health efforts. </td></tr> <tr> <th data-bbox="456 1776 727 1829">Ability required</th><th data-bbox="727 1776 1511 1829">Rational/ Why this requirement is necessary</th></tr> </table>	Qualification/ Expertise required	Rational/ Why this requirement is necessary	At least one year of experience partnering with a state or federal agency to implement wastewater surveillance for SARS-CoV-2	<ul style="list-style-type: none"> • Has infrastructure in place to support rapid growth and onboarding of new facilities with little to no delay. • Wouldn't need time/resources to set up labs, courier services, and other logistics since they are already in place. • Have streamlined their sampling collection and analysis protocols so that their testing costs no longer reflect start-up expenses. • Lower costs due to not paying for start-up fees for establishing testing sites and protocols. • Have gone through multiple contracts and programs integrating lessons learned from other states performing similar testing. • Familiarity with data security and integrity needs associated with state and federal public health efforts. 	Ability required	Rational/ Why this requirement is necessary
Qualification/ Expertise required	Rational/ Why this requirement is necessary						
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Ability required	Rational/ Why this requirement is necessary						

0DES Sole Source Question	1DOH Program Manager Response	
	Analysis of both N1 and N2 SARS-CoV-2 genes	<ul style="list-style-type: none"> There are two genes that can be targeted when analyzing wastewater samples for SARS-CoV-2, and these are the N1 and N2 genes. Research conducted by the PHL shows that analysis of both N1 and N2 genes is necessary to ensure the highest rate of detection for SARS-CoV-2 in wastewater. The N1 gene is starting to mutate and may no longer be viable for monitoring COVID-19 in wastewater. This necessitates the ability to analyze for both the N1 and N2 genes to account for possible mutations and ensure data consistency and quality.
	Sequencing capability	<ul style="list-style-type: none"> We must be able to identify and track new SARS-CoV-2 genetic mutations to make appropriate inferences about wastewater data. Different strains of the SARS-CoV-2 cause varying degrees of symptoms and severity of illness. Therefore, changes in prevalence of different strains circulating in a community will impact health care utilization, vaccination education efforts, and resource allocation considerations. Due to the high sequence diversity in the poliovirus capsid region (which “defines” a poliovirus), sequencing is necessary for monitoring polio virus, since it is the only way to tell if polio in wastewater is derived from a vaccine or if there has been a true outbreak.
	Analysis of mpox	<p>The contractor needs to analyze for the presence/absence and quantity of mpox in wastewater so we can:</p> <ul style="list-style-type: none"> Ensure standardization of pathogen testing data across the state; Understand the presence and spread of mpox across different communities within WA state; Inform health officers about surges and trends with this new health concern; and Aid in decisions about geographic mpox allocation, targeted educational efforts, and training of health care providers.

0DES Sole Source Question	1DOH Program Manager Response	
	Analysis of polio available upon request	<p>Wastewater analysis for polio virus needs to be available soon after the start of the contract period to allow DOH health officers to activate a rapid and surveillance response in the event of a documented case of polio virus in Washington state.</p> <ul style="list-style-type: none"> • Immediate integration of polio testing will help local and state epidemiologists understand the prevalence and spread of polio across WA state. • The public health lab would need 4-6 months to develop a sample analysis protocol for polio virus, making them unable to immediately start testing on an “as needed” basis.
	Uses liquid influent wastewater samples (as opposed to solids)	<ul style="list-style-type: none"> • The results produced by the contractor must be comparable to the PHL and current CDC analysis, who both use this method. • Using liquid influent has been identified by both the CDC and PHL as a best practice for monitoring for pathogens in wastewater
	Uses Digital or digital droplet PCR (ddPCR) to analyze wastewater samples	<ul style="list-style-type: none"> • The results produced by the contractor must be comparable to the PHL and current CDC analysis. • ddPCR is a specific laboratory analysis tool that is known for its high accuracy and is currently used by the PHL and CDC. <p>ddPCR is advantageous in low level detection and exact quantification of targets in wastewater because it is more precise and sensitive than standard or quantitative PCR methods.</p>
	2-day turnaround time for SARS-CoV-2 quantification results	<ul style="list-style-type: none"> • Wastewater-based epidemiology is used by public health as an early warning tool against disease spikes in communities. • Depending on the disease and variant, infected people can start shedding a virus in their stool 2-7 days before they are symptomatic. This lead time allows health officials to gather resources and rapidly respond to an increase in community infection levels. • Since it takes at least two consecutive sampling periods of increased disease levels to identify a sustained increase in community infection levels, minimizing the turnaround time is crucial for effective public health response. • Currently the PHL has a 24-hour turnaround time for producing results but given shipping restrictions we will grant the contractor a 2-day turnaround.

0DES Sole Source Question	1DOH Program Manager Response	
	Experience with RedCAP & DCIPHER Systems	<ul style="list-style-type: none"> • DOH does not have the capacity to build a unique data infrastructure to ingest the contractor result data. • We need to ensure that internal and external partners continue to receive data in a timely fashion. • Contactor must provide results (including all required data fields) in a format that can that does not require changes to DOH's current infrastructure. • The time required to train and monitor their data entry quality is prohibitive to our current FTE capacity and would take away from work currently being done by the Epi team. • Biobot Analytics, Inc. was the only company that has experience with both REDCap, and DCIPHER platforms.
	Can serve rural populations and communities	<ul style="list-style-type: none"> • One key benefits of wastewater-based epidemiology is that is helps health officials monitor disease levels in communities with reduced resources. • Since many rural communities don't have easy access to clinical testing and health care facility capacity is minimal it is required that the contractor collect samples from these communities.
	Data security	<ul style="list-style-type: none"> • We require full ownership of the wastewater data to protect our sampling partners and their communities. • Because we partner with tribal nations and are working to honor their data sovereignty, we need control over who has access to the data, where it is shared, and how it is stored.
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	<p>DOH conducted extensive research to determine that Biobot Analytics, Inc. is the only contractor that can fulfill all the requirements and qualifications that we need for this contractual work.</p> <ul style="list-style-type: none"> • We contacted all DES master contractors that do laboratory testing and found that none analyze wastewater for pathogens. • We then reached out to 12 different companies associated with wastewater testing for SARS-CoV-2. <ul style="list-style-type: none"> ○ The companies we contacted were either featured on the Wastewater Environment Federation (WEF) website or presented at their national conference in March discussing wastewater testing for COVID-19. ○ WEF is a nationally recognized professional group that is comprised of individuals working in wastewater and wastewater- 	

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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.	<p>based epidemiology. They conduct market research on wastewater-based epidemiology equipment and lab contractors.</p> <ul style="list-style-type: none">○ Table 2 shows all companies that we contacted, what method of communication was used, when we first contacted them, and what disqualified them from further review. <p>Of the 12 companies we contacted, three only sell equipment and don’t perform testing, three don’t currently work in the United States, and one didn’t have the ability to test for MPOX. We then met with the remaining five to see if they could fulfill the requirements (Table 3) necessary for this project. As the following table shows, Biobot Analytics, Inc. was the only company that meets all requirements.</p> <p>Table 1. Contractors Contacted</p> <table><tr><th>Company</th><th>Contact name</th><th>Contact method</th><th>Date of contact</th><th>Disqualification for further review</th></tr><tr><td>Exact scientific</td><td>Kent Oostra</td><td>phone</td><td>9/26/2022</td><td>N/A</td></tr><tr><td>Biobot Analytics, Inc.</td><td>Jennings Heussner</td><td>phone</td><td>9/22/2022</td><td>N/A</td></tr><tr><td>LuminUltra</td><td>Scott Harding</td><td>email</td><td>9/23/2022</td><td>N/A</td></tr><tr><td>Shield T3</td><td>Miguel Molina</td><td>phone</td><td>9/16/2022</td><td>N/A</td></tr><tr><td>Ginko Bioworks</td><td>Jamila Gordon</td><td>email</td><td>9/27/2022</td><td>N/A</td></tr><tr><td>Verily</td><td>Melissa Miao</td><td>email</td><td>9/23/2022</td><td>N/A</td></tr><tr><td>Promega</td><td>Alicia Hodnik</td><td>phone</td><td>9/16/2022</td><td>Only sells equipment</td></tr><tr><td>Deep Verge</td><td>Paul Ryan</td><td>phone</td><td>9/16/2022</td><td>Based out of UK</td></tr><tr><td>Sartorius</td><td>US number</td><td>phone</td><td>9/16/2022</td><td>Based out of Germany</td></tr><tr><td>Endress + Hauser</td><td>US number</td><td>phone</td><td>9/16/2022</td><td>Based out of Switzerland</td></tr><tr><td>Hach</td><td>US number</td><td>phone</td><td>9/16/2022</td><td>Only sells equipment</td></tr><tr><td>Illumina</td><td>Customer Support</td><td>phone</td><td>9/16/2022</td><td>Only sells equipment</td></tr></table>	Company	Contact name	Contact method	Date of contact	Disqualification for further review	Exact scientific	Kent Oostra	phone	9/26/2022	N/A	Biobot Analytics, Inc.	Jennings Heussner	phone	9/22/2022	N/A	LuminUltra	Scott Harding	email	9/23/2022	N/A	Shield T3	Miguel Molina	phone	9/16/2022	N/A	Ginko Bioworks	Jamila Gordon	email	9/27/2022	N/A	Verily	Melissa Miao	email	9/23/2022	N/A	Promega	Alicia Hodnik	phone	9/16/2022	Only sells equipment	Deep Verge	Paul Ryan	phone	9/16/2022	Based out of UK	Sartorius	US number	phone	9/16/2022	Based out of Germany	Endress + Hauser	US number	phone	9/16/2022	Based out of Switzerland	Hach	US number	phone	9/16/2022	Only sells equipment	Illumina	Customer Support	phone	9/16/2022	Only sells equipment
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	<p>Table 2. Contractor requirements and the rational for why we need these requirements for our program.</p> <table><tr><th>Qualification/</th><th>Rational/ Why this requirement is necessary</th></tr></table>	Qualification/	Rational/ Why this requirement is necessary																																																															
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0DES Sole Source Question	1DOH Program Manager Response	
	Expertise required	
	At least one year of experience partnering with a state or federal agency to implement wastewater surveillance for SARS-CoV-2	<ul style="list-style-type: none"> • Has infrastructure in place to support rapid growth and onboarding of new facilities with little to no delay. • Wouldn't need time/resources to set up labs, courier services, and other logistics since they are already in place. • Have streamlined their sampling collection and analysis protocols so that their testing costs no longer reflect start-up expenses. • Lower costs due to not paying for start-up fees for establishing testing sites and protocols. • Have gone through multiple contracts and programs integrating lessons learned from other states performing similar testing. • Familiarity with data security and integrity needs associated with state and federal public health efforts.
	Ability required	Rational/ Why this requirement is necessary
	Analysis of both N1 and N2 SARS-CoV-2 genes	<ul style="list-style-type: none"> • There are two genes that can be targeted when analyzing wastewater samples for SARS-CoV-2, and these are the N1 and N2 genes. Research conducted by the PHL shows that analysis of both N1 and N2 genes is necessary to ensure the highest rate of detection for SARS-CoV-2 in wastewater. • The N1 gene is starting to mutate and may no longer be viable for monitoring COVID-19 in wastewater. This necessitates the ability to analyze for both the N1 and N2 genes to account for possible mutations and ensure data consistency and quality.
	Sequencing capability	<ul style="list-style-type: none"> • We must be able to identify and track new SARS-CoV-2 genetic mutations to make appropriate inferences about wastewater data. • Different strains of the SARS-CoV-2 cause varying degrees of symptoms and severity of illness. Therefore, changes in prevalence of different strains circulating in a community will impact health care utilization, vaccination education efforts, and resource allocation considerations. • Due to the high sequence diversity in the poliovirus capsid region (which "defines" a poliovirus),

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		sequencing is necessary for monitoring polio virus, since it is the only way to tell if polio in wastewater is derived from a vaccine or if there has been a true outbreak.
	Analysis of mpox	<p>The contractor needs to analyze for the presence/absence and quantity of mpox in wastewater so we can:</p> <ul style="list-style-type: none"> • Ensure standardization of pathogen testing data across the state; • Understand the presence and spread of mpox across different communities within WA state; • Inform health officers about surges and trends with this new health concern; and • Aid in decisions about geographic mpox allocation, targeted educational efforts, and training of health care providers.
	Analysis of polio available upon request	<p>Wastewater analysis for polio virus needs to be available soon after the start of the contract period to allow DOH health officers to activate a rapid and surveillance response in the event of a documented case of polio virus in Washington state.</p> <ul style="list-style-type: none"> • Immediate integration of polio testing will help local and state epidemiologists understand the prevalence and spread of polio across WA state. • The public health lab would need 4-6 months to develop a sample analysis protocol for polio virus, making them unable to immediately start testing on an “as needed” basis.
	Uses liquid influent wastewater samples (as opposed to solids)	<ul style="list-style-type: none"> • The results produced by the contractor must be comparable to the PHL and current CDC analysis, who both use this method. • Using liquid influent has been identified by both the CDC and PHL as a best practice for monitoring for pathogens in wastewater

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	Uses Digital or digital droplet PCR (ddPCR) to analyze wastewater samples	<ul style="list-style-type: none"> The results produced by the contractor must be comparable to the PHL and current CDC analysis. ddPCR is a specific laboratory analysis tool that is known for its high accuracy and is currently used by the PHL and CDC. <p>ddPCR is advantageous in low level detection and exact quantification of targets in wastewater because it is more precise and sensitive than standard or quantitative PCR methods.</p>
	2-day turnaround time for SARS-CoV-2 quantification results	<ul style="list-style-type: none"> Wastewater-based epidemiology is used by public health as an early warning tool against disease spikes in communities. Depending on the disease and variant, infected people can start shedding a virus in their stool 2-7 days before they are symptomatic. This lead time allows health officials to gather resources and rapidly respond to an increase in community infection levels. Since it takes at least two consecutive sampling periods of increased disease levels to identify a sustained increase in community infection levels, minimizing the turnaround time is crucial for effective public health response. Currently the PHL has a 24-hour turnaround time for producing results but given shipping restrictions we will grant the contractor a 2-day turnaround.
	Experience with RedCAP & DCIPHER Systems	<ul style="list-style-type: none"> DOH does not have the capacity to build a unique data infrastructure to ingest the contractor result data. We need to ensure that internal and external partners continue to receive data in a timely fashion. Contractor must provide results (including all required data fields) in a format that does not require changes to DOH's current infrastructure. The time required to train and monitor their data entry quality is prohibitive to our current FTE capacity and would take away from work currently being done by the Epi team. Biobot Analytics, Inc. was the only company that has experience with both REDCap, and DCIPHER platforms.

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	Can serve rural populations and communities	<ul style="list-style-type: none">One key benefits of wastewater-based epidemiology is that is helps health officials monitor disease levels in communities with reduced resources.Since many rural communities don't have easy access to clinical testing and health care facility capacity is minimal it is required that the contractor collect samples from these communities.				
	Data security	<ul style="list-style-type: none">We require full ownership of the wastewater data to protect our sampling partners and their communities.Because we partner with tribal nations and are working to honor their data sovereignty, we need control over who has access to the data, where it is shared, and how it is stored.				
Table 3. Requirement comparison of viable companies						
	Requirement	Biobot Analytics, Inc.	Ginkgo Bioworks	Verily	LuminUltra	Exact Scientific
1.	At least one year of experience monitoring SARS-CoV-2 in wastewater for a state or federal agency	YES	NO	NO	YES	NO
2.	Analysis of both N1 and N2 SARS-CoV-2 genes	YES	YES	YES	NO	YES
3.	Sequencing capability	YES	YES	YES	YES	YES
4.	Analysis of MPOX	YES	YES	YES	YES	NO
5.	Analysis of polio available upon request	YES	YES	YES	YES	YES
6.	Uses liquid influent	YES	YES	NO	YES	YES

0DES Sole Source Question	1DOH Program Manager Response					
	wastewater samples					
	7. Uses ddPCR to analyze wastewater samples	YES	YES	YES	YES	NO
	8. 2-day turnaround time	YES	YES	YES	NO	NO
	9. Experience with RedCAP and DCIPHER systems	YES	NO	NO	NO	NO
	10. Can serve rural populations and communities	YES	YES	NO	YES	YES
	11. Data Security	YES	YES	NO	YES	YES
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.	Exact Scientific was considered since it is a small private lab based out of Washington State. Unfortunately, they don't have experience testing wastewater for SARS-CoV-2 or mpox. While they could learn our analysis protocols, the time and FTE resources necessary to train and regulate their work is prohibitive to our current program capacity. Coupled with the fact that they couldn't guarantee a 2-day sample analysis turnaround time, we had to rule them out as a possible contractor.					
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).	<p>Contracting with Biobot Analytics, Inc. will mitigate risk and reduce costs in a variety of ways.</p> <ul style="list-style-type: none"> Biobot Analytics, Inc. is one of the most established companies monitoring pathogens in wastewater. They have been analyzing wastewater samples for SARS-CoV-2 since March 2020 and have worked with several states and government agencies. This experience means that: <ul style="list-style-type: none"> They have the infrastructure to support wastewater sampling and wouldn't need time/resources to set up labs, courier services, and other logistics since they are already in place. They have streamlined their sampling collection and analysis protocols so that their testing costs no longer reflect start-up expenses. They have gone through multiple contracts and programs integrating lessons learned from other states performing similar testing. 					

0DES Sole Source Question	1DOH Program Manager Response
	<ul style="list-style-type: none"> • Biobot Analytics, Inc. is the current contractor for the CDC and responsible for sample analysis of 13 WWTPs in Washington. <ul style="list-style-type: none"> • This ensures that they follow CDC guidelines through development of methods for mpox and polio testing. <ul style="list-style-type: none"> ○ By using the current CDC vendor, we are guaranteeing that our data is comparable to a national standard and can assess public health trends. ○ This is especially true in the case of mpox where standards for mpox are in development. The lack of a standardized protocol makes comparison of test results from different labs difficult for epidemiologists to discern infection trends. • They are currently providing the exact services we are wanting to contract, guaranteeing a consistent product and with little to no learning curve. • The transition time and impact moving current CDC sites to the WAWBE program will be negligible. <ul style="list-style-type: none"> ○ Transitioning from commercial contractors took approximately two months when the CDC changed from LuminUltra to Biobot Analytics, Inc. in August of 2022. The contract was in place by the end of the LuminUltra contract, but onboarding of facilities to the new contract was delayed due to logistics and communication issues. ○ During this transition period, 7 WWTPs dropped out of the program due to frustration over the transition. <ul style="list-style-type: none"> ▪ Because WWTPs aren't compensated for participation in these programs, the risk of losing site participation caused by increasing administrative burden to them during transitional phases is high. ▪ Working with Biobot Analytics, Inc. would remove this barrier since these sites are already onboarded to the Biobot Analytics, Inc. sampling system. ○ The gaps in testing during the contractor change caused a gap in data for CDC sites. We are unable to provide health officials with accurate up to date information for this time period. • Because Biobot Analytics, Inc. currently uploads data from the sites of interest to the CDC DCIPHER platform, they have shown to have the capacity and expertise required to format data to existing data infrastructure systems. This will reduce the amount of time it takes to share results with our partners.

0DES Sole Source Question	1DOH Program Manager Response																												
	<ul style="list-style-type: none">Biobot Analytics, Inc. is one of the most affordable contractors for the services we require. While sequencing results are cheaper for LuminUltra than Biobot Analytics, Inc., they were unable to provide a cost estimate for shipping. Given this unknown, it is likely that Biobot Analytics, Inc. is either comparable or cheaper than LuminUltra. While most contractors, including Biobot Analytics, Inc. don't have price estimates for polio testing, they were the most affordable overall.<ul style="list-style-type: none">The following table shows a summary of the per sample price estimates for each contractor. "Unknown" reflects that contractor's inability to provide a cost estimate.<ul style="list-style-type: none">Verily was omitted from the table as they were unable to provide any cost estimates.Exact Scientific was omitted from the table as they were unable to provide cost estimates for all but the COVID analysis (and not the sequencing, or mpox analysis).Pricing uses SARS-CoV-2 testing as the base cost with additional costs for sequencing samples for SARS-CoV-2 variants, analysis of mpox, analysis of polio, and shipping.Biobot Analytics, Inc. is the only contractor that includes shipping into their base SARS-CoV-2 testing cost. <p>Table 1. Cost estimate comparison of contractors. Note: The current estimated cost for analyzing samples for SARS-CoV-2 at the DOH public health lab is approximately \$250 per sample without shipping or FTE.</p> <table><tr><th>Cost (per sample)</th><th>Biobot Analytics, Inc.</th><th>Gingko Bioworks</th><th>LuminUltra</th></tr><tr><td>COVID analysis</td><td>\$350</td><td>\$346</td><td>\$365</td></tr><tr><td>COVID sequencing</td><td>\$250</td><td>\$127</td><td>\$150</td></tr><tr><td>MPOX analysis</td><td>\$150</td><td>\$127</td><td>\$150</td></tr><tr><td>Polio analysis</td><td>Unknown</td><td>\$127</td><td>Unknown</td></tr><tr><td>Shipping</td><td>Included in COVID analysis</td><td>\$311</td><td>Unknown</td></tr><tr><td>Minimum total cost per sample</td><td>\$750</td><td>\$1,038</td><td>\$665</td></tr></table>	Cost (per sample)	Biobot Analytics, Inc.	Gingko Bioworks	LuminUltra	COVID analysis	\$350	\$346	\$365	COVID sequencing	\$250	\$127	\$150	MPOX analysis	\$150	\$127	\$150	Polio analysis	Unknown	\$127	Unknown	Shipping	Included in COVID analysis	\$311	Unknown	Minimum total cost per sample	\$750	\$1,038	\$665
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<p>6. Is the agency proposing this sole source contract because of special circumstances such as confidential investigations, copyright restrictions, etc.? If so, please describe.</p>	<p>We are proposing this sole source contract due to five specific reasons:</p> <ol style="list-style-type: none"> 1. The public health lab is quickly reaching testing capacity for new wastewater treatment plants. 2. The CDC is dropping its contract with Biobot Analytics, Inc. and the PHL does not have capacity to expand to include all current CDC sites. It is currently unknown when the CDC contract with Biobot Analytics, Inc. will end, leaving us with the risk of losing these sites if this sole source contract isn't in place. At their current capacity, the PHL only has availability to onboard five new facilities, which would mean losing 9 wastewater treatment plants. This loss of sampling sites will drastically limit the ability of the state and local health jurisdictions to track trends of COVID-19 and other health concerns within their communities. 3. Wastewater-based monitoring is the long-term plan for monitoring mpox virus to ensure that health officials can mobilize resources quickly in the event of a resurgence or outbreak. While the public health lab is working to create a testing method for mpox in wastewater, their test won't be available until April. Access to mpox testing results from these sites would allow us to monitor the pathogen in counties with the highest case rates, while supporting current PHL capacity. 4. DOH leadership has determined that wastewater-based epidemiology needs to be used as soon as a confirmed polio case is identified within the state of Washington. It currently takes the PHL approximately four months to start testing a new pathogen. This contract is necessary for providing a rapid response and monitoring of polio if there is a confirmed case of paralytic polio in Washington state. Being able to monitor high risk communities will help the polio epidemiologists respond to any potential outbreaks and target resources in near-real time. 5. The necessity of a single contract/contractor to conduct testing for SARS-CoV-2, mpox, and polio at the same time. Because we need to monitor wastewater samples for SARS-CoV-2, mpox, and polio, using different labs and contracts to monitor for these pathogens would be cost prohibitive, and place a higher burden on wastewater treatment operators since they would need to collect multiple samples to ship to the different contractors.
<p>7. Is the agency proposing this sole source contract because of unavoidable, critical time delays or issues that prevented the agency from completing this</p>	<p>We are proposing this sole source contract for two unavoidable reasons:</p> <ol style="list-style-type: none"> 1) The CDC has announced that they will be ending their contract to sample wastewater for SARS-CoV-2 and mpox sometime in 2023. It is currently unknown when the CDC contract with Biobot Analytics, Inc. will end, leaving us with the risk of losing these sites if this sole source contract isn't in place. At their current capacity, the PHL only has availability to onboard five new facilities, which would mean losing 9 wastewater treatment plants.

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<p>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.</p>	<p>This contract needs to be in place to assure that if/when the CDC contract ends, we will be able to cover these sites and continue our expansion of the WAWBE program.</p> <p>2) Wastewater-based epidemiology was identified as a key surveillance tool in the mpox response. As of October 24, Biobot Analytics, Inc. is analyzing wastewater samples for mpox and providing results to CDC. While the PHL is working on a method for testing for mpox in wastewater, they aren't scheduled to complete the validation of their test until April. The counties and treatment plants currently served by Biobot Analytics, Inc. via the CDC contract include King and Snohomish counties which have some of the highest confirmed cases of mpox in Washington. Even if the PHL assumed some testing, there would be missing data for these sites.</p>
<p>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.</p>	<p>N/A</p>
<p>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.</p>	<p>We need this sole source contract in place as soon as possible since we don't know when the CDC contract will end, and we don't have the capacity to onboard those facilities through the PHL. Not having this contract in place limits our ability to inform public health officials on community infection levels and impacts their ability to make evidence-based decisions about resources allocations, staffing, and other important areas.</p> <p>Given changes in testing rates for COVID-19, including increase in at-home-testing and decrease in reported testing, local and state public health agencies use wastewater results to obtain accurate and timely information about community infection trends. Without these results, local health jurisdictions would lose a tool to understand what is going on in their communities as there are limited comparable surveillance options that allow insight into community infection trends.</p> <p>Delays in this contract hurts DOH ability to inform public health recommendations and limits our ability to maintain and expand the program.</p>

0DES Sole Source Question	1DOH Program Manager Response
	<ul style="list-style-type: none"> • 48% of our current sampling sites and 26% of our county representation due to the CDC contract ending. • The PHL can only onboard 5 more additional sites, and will not be able to cover all former CDC sites when the contract ends. • Without this contract we will not have the lab capacity to expand our program and respond to emerging public health threats. <p>Being unable to cover sampling at these sites when the CDC contract ends not only limits our ability to monitor disease levels, but it negatively impacts current DOH equity efforts.</p> <ul style="list-style-type: none"> • Current CDC sites include areas of high mpox case rates, high polio risk areas, and the Muckleshoot Tribe. • DOH worked closely with the CDC to create a relationship with the Muckleshoot Tribe for monitoring COVID-19 and mpox in their wastewater. • Mpox has been shown to have higher rates of infection in LGBTQIA+ populations. Since the Public health lab won't have an analysis for mpox or polio ready until April, it is crucial that we partner with a company that is able to provide that data.
5Sole 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	Contracts Office Use Only:

0DES Sole Source Question	1DOH Program Manager Response																									
agency concluded the contract is appropriate for sole source award.																										
6Reasonableness 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.	<p>We requested price estimates from all potential contractors when meeting with them to discuss our program needs. Biobot Analytics, Inc. is one of the most affordable contractors for the services we require. While sequencing results are cheaper for LuminUltra than Biobot Analytics, Inc., they were unable to provide a cost estimate for shipping Given this unknown, it is likely that Biobot Analytics, Inc. is either comparable or cheaper than LuminUltra.</p> <ul style="list-style-type: none">• While most contractors, including Biobot Analytics, Inc. don't have price estimates for polio testing, they were the most affordable overall.• Table 6 shows a summary of the per sample price estimates for each contractor. Blank cells reflect that contractors inability to provide a cost estimate. Verily was omitted from the table as they were unable to provide any cost estimates.• Pricing uses COVID-19 testing as the base cost with additional costs for sequencing samples for SARS-CoV-2 variants, analysis of MPOX, analysis of polio, and shipping.• Biobot Analytics, Inc. is the only contractor that includes shipping into their base COVID-19 testing cost. <p>Table 6. Cost estimate comparison of contractors. Note: The current estimated cost for analyzing samples for SARS-CoV-2 at the DOH public health lab is approximately \$250 per sample without shipping or FTE.</p> <table><tr><th>Cost (per sample)</th><th>Biobot Analytics, Inc.</th><th>Gingko Bioworks</th><th>LuminUltra</th><th>Exact Scientific</th></tr><tr><td>COVID analysis</td><td>\$350</td><td>\$346</td><td>\$365</td><td>\$270</td></tr><tr><td>COVID sequencing</td><td>\$250</td><td>\$127</td><td>\$150</td><td>Unknown</td></tr><tr><td>MPV analysis</td><td>\$150</td><td>\$127</td><td>\$150</td><td>Unknown</td></tr><tr><td>Polio analysis</td><td>Unknown</td><td>\$127</td><td>Unknown</td><td>Unknown</td></tr></table>	Cost (per sample)	Biobot Analytics, Inc.	Gingko Bioworks	LuminUltra	Exact Scientific	COVID analysis	\$350	\$346	\$365	\$270	COVID sequencing	\$250	\$127	\$150	Unknown	MPV analysis	\$150	\$127	\$150	Unknown	Polio analysis	Unknown	\$127	Unknown	Unknown
Cost (per sample)	Biobot Analytics, Inc.	Gingko Bioworks	LuminUltra	Exact Scientific																						
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Polio analysis	Unknown	\$127	Unknown	Unknown																						

0DES Sole Source Question	1DOH Program Manager Response				
	Shipping	Included in COVID analysis	\$311	Unknown	Unknown
	Minimum total cost per sample	\$750	\$1,038	\$665	\$270

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.

From: [DES Procedure PRO-DES-140-00A](#).