



**COUNTY OF HENRICO
DEPARTMENT OF FINANCE
PURCHASING DIVISION
CONTRACT EXTRACT
NOTICE OF RENEWAL**

DATE:	November 1, 2023
CONTRACT COMMODITY/SERVICE: <i>(include contracting entity if cooperative)</i>	Onsite Infectious Disease Testing Services
CONTRACT NUMBER:	2356B
COMMODITY CODE:	907.83
CONTRACT PERIOD:	November 1, 2023 through October 31, 2024
RENEWAL OPTIONS:	Three (3) one-year renewal options through 2027
USER DEPARTMENT:	Emergency Management and Workplace Safety
Contact Name:	Rob Rowley
Phone Number:	804.316.3563
Email Address:	row08@henrico.us
HENRICO COOPERATIVE TERMS INCLUDED:	Yes
SUPPLIER: Name:	Next Bio-Research Services, LLC
Address:	11601 Iron Bridge Road, Suite101
City, State:	Chester, VA 23831
Contact Name:	Robert Harris, Ph.D.
Phone Number:	804.977.6603
Email address:	rharris@nextmolecular.com
ORACLE SUPPLIER NUMBER:	584901
BUSINESS CATEGORY:	Small Business
PAYMENT TERMS:	Net 45
DELIVERY:	As Required
FOB:	Destination
BUYER: Name:	Oscar Knott
Title:	Purchasing Director
Phone:	804.501.5649
Email:	kno008@henrico.us

This contract is the result of a competitive solicitation issued by the Department of Finance, Purchasing Division. A requisition must be generated for all purchases made against this contract and the requisition must reference the contract number.



COMMONWEALTH OF VIRGINIA

County of Henrico

**Non-Professional Services Contract
Contract No. 2356B**

This Non-Professional Services Contract (this “Contract”) entered into this 24th day of October 2022, by Next Bio-Research Services, LLC (the “Contractor”) and the County of Henrico, Virginia (the “County”).

WHEREAS the County has awarded the Contractor this Contract pursuant to Request for Proposals No. 22-2356-5JOK (the “Request for Proposals”), for onsite infectious disease testing services.

WITNESSETH that the Contractor and the County, in consideration of the mutual covenants, promises and agreements herein contained, agree as follows:

SCOPE OF CONTRACT: The Contractor shall provide the services to the County as set forth in the Contract Documents.

COMPENSATION: The compensation the County will pay to the Contractor under this Contract shall be pursuant to Exhibit A.

CONTRACT TERM: The Contract term shall be for a period of one year beginning November 1, 2022 and ending October 31, 2023. The County may renew the Contract for up to four one-year terms giving 30 days’ written notice before the end of the term unless Contractor has given the County written notice that it does not wish to renew at least 90 days before the end of the term.

CONTRACT DOCUMENTS: This Contract hereby incorporates by reference the documents listed below (the “Contract Documents”) which shall control in the following descending order:

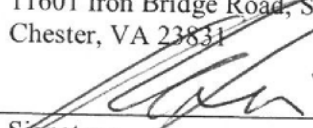
1. This Non-Professional Services Contract between the County and Contractor.
2. The General Contract Terms and Conditions included in the Request for Proposals.
3. Contractor’s Best and Final Offer (Exhibit A).
4. Contractor’s Original Proposal dated June 16, 2022 (Exhibit B).
5. The Scope of Services included in the Request for Proposals.

INDEMNIFICATION: The Contractor agrees to indemnify, defend, and hold harmless the County (including Henrico County Public Schools), and the County’s officers, agents, and employees (“Indemnified Parties”) from any damages, liabilities, and costs, including attorneys’ fees, arising from any claims, demands, actions, or proceedings made or brought against one or more of the Indemnified Parties by any person, including any employee of the Contractor, related to the provision of any services, the failure to provide any services, or the use of any services or materials furnished (or made available) by the Contractor, provided that such liability is not attributable to the sole negligence of the County.

IN WITNESS WHEREOF, the parties have caused this Contract to be duly executed intending to be bound hereby.

[Remainder of page intentionally left blank; signature page to follow]

Next Bio-Research Services, LLC
11601 Iron Bridge Road, Suite 101
Chester, VA 23831



Signature

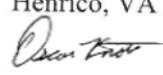
ROBERT B. HARRIS, CFO/CSO

Printed Name and Title

10/24/22

Date

County of Henrico, Virginia
P.O. Box 90775
Henrico, VA 23273-0775



Signature

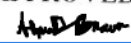
Oscar Knott, CPP, CPPO, VCO

Purchasing Director

11/01/2022

Date

APPROVED AS TO FORM:



Alyssa Brown (Oct 26, 2022 11:19 EDT)

Assistant County Attorney

Date

10/26/2022

Date

Exhibit A

Best and Final Offer (“BAFO”)

RE: RFP 22-2356-5JOK – Onsite Infection Disease Testing Services



NEXT Bio-Research Services, LLC dba



11601 Ironbridge Rd, STE 101
Chester, VA, 23831
Toll Free: 844-812-7415
Direct: 804-977-6603
Fax: 804-977-6630
Email: rharris@nextmolecular.com
www.nextmolecular.com

Robert B. Harris, Ph.D.
CSO, CFO/Co-Founder

9/14/22

Mr. Oscar Knott, CPP, CPPO, VCO
County of Henrico
Department of Finance
8600 Staples Mill Rd
Henrico, VA 23273
Email; kno008@henrico.us

by email

RE: Best and Final Offer ("BAFO") RFP 22-2356-5JOK – Onsite Infection Disease Testing Services

Dear Mr. Knott:

Thank you for your letter of September 8 and thank you and the Henrico team for your time on the phone. Herein, we are pleased to present our Best and Final Offer ("BAFO") in response to RFP 22-2356-5JOK, "On-site Infectious Disease Testing Services." Our BAFO addresses all requested elements of the RFP.

To recap our RFP response, it is noteworthy that the collective research experience and expertise resident at NEXT enabled our lab to be among the first in Virginia (and in the country) to be approved by the CDC for performance of the CoV-2 PCR test. It is this expertise in molecular genetics, next gen sequence analysis and immunoassays that will allow us to respond rapidly and efficiently to whatever is the next infectious disease issue that might emerge in the future. While no one can predict the next pandemic and the infectious agent, NEXT has the tools necessary to implement and validate molecular and or immuno assays to detect and confirm the infectious agent. For example, we have completed validation of a sensitive molecular assay for monkeypox and will be able to rapidly implement this assay for clinical samples (in the event that the CDC, the FDA, and CMS expand testing beyond the Laboratory Response Network to commercial laboratories). This same flexibility and expertise allowed us to implement and validate a comprehensive panel of antibody assays (under Emergency Use Authorization from the FDA)

which provides a detailed picture of a patient's antibody status (and response to vaccine treatment) against SARS CoV-2.

With respect to the particulars of the RFP:

1. NEXT will provide all labor, supervision, materials, equipment, and PPE necessary to provide turnkey on-site infectious disease screening and diagnostic testing, as specified by Henrico County. Testing may be done at multiple locations, seven days per week, 12 hours per day Monday through Sunday. NEXT has its own contracted staff of certified and accredited NPs, RNs, ALS, LPNs, BLS, and EMTs who travel to collection sites throughout the Commonwealth. In addition, NEXT contracts with different professional agencies to provide qualified and licensed personnel to collect test samples. All samples are brought back to NEXT for analysis. In addition, NEXT hosts walk-in patients who need testing at its facility in Chester.
2. NEXT currently offers CoV-2 PCR and rapid antigen tests, as well as a molecular genetic panel assay for other respiratory viruses RPP (Influenza A, Influenza A H1, Influenza A H3, Influenza A 2009 H1N1, Influenza B, Respiratory Syncytial Virus (RSV) A, Respiratory Syncytial Virus (RSV) B, Parainfluenza Virus (PIV) 1, Parainfluenza Virus (PIV) 2, Parainfluenza Virus (PIV) 3, Human Metapneumovirus (hMPV), Human Rhinovirus, (HRV), Adenovirus B/E, Adenovirus C, Coronaviruses NL62, OC453, HKU-1, and 229E).
3. In addition to these viruses, the NEXT RPP panel also incorporates detection and confirmation of the following respiratory bacterial pathogens: *Chlamydia pneumoniae*, *Mycoplasma pneumoniae*, *Bordetella holmesii* and *B pertussis*, *Legionella pneumophila*, *Moraxella catarrhalis*, *Streptococcus pneumoniae* and *S pyrogenes*.
4. NEXT does not currently offer TB testing but does offer immune analysis for the presence of antibodies to the CoV-2 nucleocapsid and spike proteins (Wuhan/Delta and Omicron specific assays). If - required by Henrico, NEXT could readily implement TB testing.
5. While not specifically addressed in the RFP, NEXT also can provide molecular and/or immuno assays for detection and confirmation of: *Bacillus anthracis*, *Yersinia pestis*, West Nile Virus, Venezuelan Equine Encephalitis virus (VEE), Eastern Equine Encephalitis virus (EEE) as well as for the food pathogens, *Lysteria monocytogenes*, *Salmonella typhi* (and other *Salmonella* family members), and *E. coli* O157. HOWEVER, it is important to understand that collection of clinical samples (or food stuffs) suspected of containing these pathogens is NOT likely to come from an on-site testing event. Rather, any samples would likely come through a clinical setting or would be obtained at a food enterprise. They are mentioned here because Henrico expressed interest in our provider conference about all of NEXT's capabilities with respect to analysis of test samples for infectious agents.
6. All testing services will be "turn-key" as specified by Henrico. All testing methods at NEXT are either FDA approved methods or have received EUA from the FDA.
7. NEXT has extensive experience in registering patients into our proprietary LIMS system and in reporting our results to the appropriate data managers either by fax or electronic upload.

8. NEXT has its own medical billing team and is in network with several insurance providers.
9. NEXT operates under a Laboratory Quality Management system and under the aegis of more than 350 company SOPs. NEXT has an internal Quality Assurance panel which routinely monitors all testing programs. We have been consistently audited by outside agencies (for example, by CLIA, California, the New York State Department of Health, the CDC, various private companies) and are proud of our spotless record with regard to these inspections. Our current CLIA audit returned no findings, and our license will be renewed in August for the next two-year period.
10. NEXT can provide support services for vaccinations but cannot assume responsibility of physician oversight at the vaccination clinic. NEXT can also provide vaccine storage at its site in Chester, which includes ultra-low storage at $<-65^{\circ}\text{C}$. Vaccination costs are dependent on the particular vaccine to be administered, the type of injection required (i.e., IM, sub Q, intradermal, IV, etc.) , and the number of vaccinations that are administered. For the purpose of this BAFO, NEXT has exemplified administration of the covid 19 vaccines. For covid 19, typical vaccination fees are \$45/per patient with a minimum of 5,000 vaccinations ordered per contract period. However, NEXT reserves the right to adjust this price based on the particulars of the actual vaccination program to be done. Pricing for other vaccination programs will be provided when the details are made known to NEXT. Please also note that NEXT cannot order vaccines as this aspect of the program would be under the auspices of Henrico County. Vaccine storage fees are dependent on the number of boxes of vaccine to be stored (i.e., the number of shelves taken up by storage) as well as the conditions ($5\pm 2^{\circ}\text{C}$, $-20\pm 3^{\circ}\text{C}$, $<-65^{\circ}\text{C}$) and duration of storage. If interested, NEXT will quote these costs at the appropriate time.

Finally, please note that the senior scientific and administrative staff are available to provide consulting services with regard to laboratory sample analysis and testing or communal event planning and staging. In short, we are confident that NEXT will meet the standards and requirements set by Henrico County and we look forward to establishing a productive relationship. No component of our RFP response need be protected from FOIA inquiry.

Thank you for your consideration. We look forward to your reply

Respectfully,

A handwritten signature in black ink, appearing to read 'Robert B Harris', with a stylized flourish at the end.

Robert B Harris, Ph.D.
CFO/CSO/co-founder

NEXT Price Proposal Sheet ("BAFO")

RFP 22-2356-5JOK - Onsite Infectious Disease Testing Services

Item	Description	Unit	Unit Price
<i>Virus Test Fees</i>			
1	PCR (includes all labor, supervision, equipment, material, etc. to administer and complete PCR testing regardless of where administered) Targets included are listed below * Collection fees for specimens collected on NEXT's premises - \$25.00 Collection fees for specimens collected off NEXT's premises (ie. Henrico field sites)- \$40.00	TEST NEXT Henrico	\$100 \$25 \$40
2	Fees for Flu A and B testing (laboratory processing only) - \$150.00	Test	\$ 150.00
3	COVID19 Rapid Antigen (includes all labor, supervision, equipment, material, etc. to administer and complete Rapid Antigen testing regardless of where administered)	Test	\$ 75.00
4	Antibody (includes all labor, supervision, equipment, material, etc. to administer and complete Antibody testing regardless of where administered) *Targets currently include COVID19 antibody tests but this can be done for any commercially available FDA approved antibody test.	Test	\$ 110.00
<i>Bacteria Test Fees</i>			
5	Complete Blood Count (includes all labor, supervision, equipment, material, etc. to administer and complete Complete Blood Count testing regardless of where administered)	Test	\$ 39.00
6	Antibody Sensitivity (includes all labor, supervision, equipment, material, etc. to administer and complete Antibody Sensitivity testing regardless of where administered)	Test	\$ 40.00
7	Gram Stain (includes all labor, supervision, equipment, material, etc. to administer and complete Gram Stain testing regardless of where administered)	Test	\$ 32.00
8	Coagulase (includes all labor, supervision, equipment, material, etc. to administer and complete Coagulase testing regardless of where administered)	Test	\$ 59.00
9	Catalase (includes all labor, supervision, equipment, material, etc. to administer and complete Catalase testing regardless of where administered)	Test	\$ 39.00
<i>Administrative Fees</i>			
10	Onsite Admin Setup Fee (includes mobilization, setup, takedown, etc. of the onsite testing center). This is for sites that may remain up for an extended period and pricing in #12 does not apply.	Per Site	\$ 350.00

11	Daily Onsite Admin Fees (includes all additional labor, supervision, equipment, material, etc. to administer testing services onsite (administrative costs per day)) (<i>*Assume a minimum of 5,000 tests will be performed daily</i>) This is for sites that may remain up for an extended period and pricing in #12 does not apply.	Per Day	\$ 1,000.00																
Additional Services Set up Fees																			
12	Fee for Community testing events (CTE) is based on expected volume levels as follows: # of expected specimens/per day/per event (may include NEXT bringing tents, tables, chairs, traffic cones, signs, etc. and includes supervision, materials, labor, etc.) This is for sites that are set up and taken down each time and pricing in #10 & #11 do not apply. Setup fee <table> <tr> <td># of patients</td><td>costs</td><td></td><td></td></tr> <tr> <td>0-75</td><td>\$500</td><td>0-75</td><td>\$500</td></tr> <tr> <td>76-250</td><td>\$900</td><td>76-250</td><td>\$900</td></tr> <tr> <td>250+</td><td>\$1350</td><td>250+</td><td>\$1350</td></tr> </table>	# of patients	costs			0-75	\$500	0-75	\$500	76-250	\$900	76-250	\$900	250+	\$1350	250+	\$1350		
# of patients	costs																		
0-75	\$500	0-75	\$500																
76-250	\$900	76-250	\$900																
250+	\$1350	250+	\$1350																
13	Consulting for Pandemic Response (\$250/hour)		\$250/hour																
Additional Assays Available																			
14	Respiratory Testing Panel (multiple targets one swab) RPP Includes all of the viruses and bacterial targets listed below: Influenza A, Influenza A H1, Influenza A H3, Influenza A 2009 H1N1, Influenza B, Respiratory Syncytial Virus (RSV) A, Respiratory Syncytial Virus (RSV) B, Parainfluenza Virus (PIV) 1, Parainfluenza Virus (PIV) 2, Parainfluenza Virus (PIV) 3, Human Metapneumovirus (hMPV), Human Rhinovirus, (HRV), Adenovirus B/E, Adenovirus C, Coronaviruses NL62, OC453, HKU-1, and 229E bacterial pathogens include: Chlamydia pneumoniae, Mycoplasma pneumoniae, Bordatella holmesii and pertussis, Legionella pneumophila, Moraxella catarrhalis, Streptococcus pneumniae, and pyrognes. (Test is validated and LDT)	Test	\$ 350.00																

15	FDA approved BioFire Viral Respiratory Panel 2.1 . Includes the following respiratory viruses from one swab sample: - Adenovirus - Coronavirus 229E - Coronavirus HKU1 - Coronavirus NL63 - Coronavirus OC43 - Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) - Human Metapneumovirus - Human Rhinovirus/Enterovirus - Influenza A, including subtypes H1, H3 and H1-2009 - Influenza B - Parainfluenza Virus 1 - Parainfluenza Virus 2 - Parainfluenza Virus 3 - Parainfluenza Virus 4 - Respiratory Syncytial Virus - Bacterial targets include: - Bordetella parapertussis - Bordetella pertussis - Chlamydia pneumoniae - Mycoplasma pneumoniae	Test	\$ 500.00
----	---	------	-----------

16	Viral and bacterial targets which can be tested individually using the PCR platform price quote listed as item 1, each test done individually is quoted as \$100, does not include the collection fees: Adenovirus Coronavirus 229E Coronavirus HKU1 Coronavirus NL63 Coronavirus OC43 Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Human Metapneumovirus Human Rhinovirus/Enterovirus Influenza A, including subtypes H1, H3 and H1-2009 H1 N1 Influenza B Parainfluenza Virus 1 Parainfluenza Virus 2 Parainfluenza Virus 3 Parainfluenza Virus 4 Respiratory Syncytial Virus Bacterial targets include: Bordetella parapertussis Bordetella pertussis Chlamydia pneumoniae Klebsiella pneumoniae Legionella species Mycoplasma pneumoniae Non-infectious disease targets Zika Virus West Nile Virus	test	\$100
----	--	------	-------



Signature of Contractor's Authorized Official
Robert B Harris, Ph.D., CFO

Exhibit B

Table of Contents

I.	INTRODUCTION AND SIGNED FORMS.....	2
A.	Cover letter.....	2
B.	Proposal Signature Sheet – Attachment A.....	5
C.	Business Classification Form – Attachment B.....	6
D.	Virginia State Corporation Commission Registration Information – Attachment C.....	7
E.	Proprietary/Confidential Information – Attachment D.....	8
F.	Anti-Lobbying Certification – Attachment I.....	9
G.	Current Business License.....	11
II.	STATEMENT OF THE SCOPE.....	12
A.	Testing Methods.....	12
B.	Registration of Patients.....	13
C.	Reporting of results.....	14
D.	Coordination with Henrico County Employee Health Services (“EHS”) and Emergency Management and Workplace Safety (“EMWS”).....	14
E.	Invoicing Requirements.....	14
F.	Billing and Medical Records.....	14
G.	Extension of Services to County Residents.....	14
H.	Health Insurance Portability and Accountability Act (HIPAA).....	14
III.	OFFERER, QUALIFICATION, EXPERIENCE, and RESUMES.....	15
IV.	REFERENCES.....	17
V.	SERVICE APPROACH/IMPLEMENTATION OF SERVICES.....	18
VI.	PRICING/COST PROPOSAL.....	19
VII.	EXCEPTIONS.....	20
A.	Billing Exception Due to Lack of Coverage or Regulatory Requirement.....	20
B.	Billing Medical Insurance Companies, Medicare, or Medicaid.....	20
VIII.	ASSUMPTIONS.....	20
IX.	APPENDICES.....	20

I. INTRODUCTION AND SIGNED FORMS

A. Cover letter

NEXT Bio-Research Services, LLC dba



11601 Ironbridge Rd, STE 101

Chester, VA, 23831

Toll Free: 844-812-7415

Direct: 804-977-6603

Fax: 804-977-6630

Email: rharris@nextmolecular.com

www.nextmolecular.com

Robert B. Harris, Ph.D.

CSO, CFO/Co-Founder

6/16/22

County of Henrico
Department of Finance
8600 Staples Mill Rd
Henrico, VA 23273

RE: RFP 22-2356-5JOK
Onsite Infectious Disease Testing Services

Sir/Madam:

NEXT Bio Research Services LLC dba NEXT Molecular Analytics ("NEXT") is pleased to present its proposal for on-site infectious disease testing services in response to RFP 22-2356-5JOK. The enclosed proposal is response to all requested elements of the RFP.

Established in 2015, NEXT is a comprehensive contract research organization located in Chester Virginia which provides integrated research and development sciences and clinical testing services to physicians and life science investigators in biotechnology and pharmaceutical companies, academic institutions, and in several different government agencies. We have extensive experience in providing such on-site services in response to the COVID-19 pandemic as well as extensive experience in implementing and validating critical laboratory services in response to public health demands. For instance, we have been contracted by the Virginia Department of Emergency Services and the Virginia Department of Health since 2020 and the Virginia Department of General Services (since 2021) to provide on-site collection and analysis of nasopharyngeal swabs for the presence of SARS CoV-2 by either PCR or rapid antigen tests. We have worked in tandem with DCLS to provide rapid turn-around (within 24 hours) of all PCR test results with electronic upload or sample results to the VDH data base within 24 hours. Our contract with VDH extends to the ViSSTA program wherein NEXT collects test samples from K-12 schools throughout the Commonwealth. Since the onset of the pandemic, NEXT has performed more than 500,000 PCR assays on behalf the Commonwealth as well as for numerous

private sector companies, nursing home facilities, long term care facilities, prisons, universities, colleges, and the like.

It is noteworthy that the collective research experience and expertise resident at NEXT enabled our lab to be among the first in Virginia (and in the country) to be approved by the CDC for performance of the CoV-2 PCR test. In fact, our expertise in molecular genetics, next gen sequence analysis and immunoassays allows us to respond rapidly and efficiently to pressing health-care issues as they emerge. For instance, we are progressing through development and validation studies for monkeypox in the event the CDC, the FDA, and CMS expand testing beyond the Laboratory Response Network to commercial laboratories (see Reuters June 10, 2022, "US Seeks to Expand Monkeypox Testing as Cases Rise") and the same flexibility and expertise allowed us to implement and validate a comprehensive panel of antibody assays (under Emergency Use Authorization from the FDA) which provides a detailed picture of a patient's antibody status (and response to vaccine treatment) against SARS CoV-2.

With respect to the particulars of the RFP:

1. NEXT will provide all labor, supervision, materials, equipment, and PPE necessary to provide turnkey on site infectious disease screening and diagnostic testing, as specified by Henrico County. Testing may be done at multiple locations, seven days per week, 12 hours per day Monday through Sunday. NEXT has its own contracted staff of certified and accredited NPs, RNs, ALS, LPNs, BLS, and EMTs who travel to collection sites throughout the Commonwealth. In addition, NEXT contracts with different professional agencies to provide qualified and licensed personnel to collect test samples. All samples are brought back to NEXT for analysis. In addition, NEXT hosts walk-in patients who need testing at its facility in Chester.
2. NEXT currently offers CoV-2 PCR and rapid antigen tests, as well as a molecular genetic panel assay for other respiratory viruses (Influenza A (Influenza A H1, Influenza A H3, Influenza A 2009 H1N1), Influenza B, Respiratory Syncytial Virus (RSV) A, Respiratory Syncytial Virus (RSV) B, Parainfluenza Virus (PIV) 1, Parainfluenza Virus (PIV) 2, Parainfluenza Virus (PIV) 3, Human Metapneumovirus (hMPV), Human Rhinovirus, (HRV), Adenovirus B/E, Adenovirus C). NEXT does not currently offer TB testing but does offer immune analysis for the presence of antibodies to the CoV-2 nucleocapsid and spike proteins (Wuhan/Delta and Omicron specific assays). If so, required by Henrico, NEXT could readily implement TB testing.
3. All testing services will be "turn-key" as specified by Henrico. All testing methods at NEXT for this contract will either FDA approved methods or have received EUA from the FDA, unless otherwise agreed to with Henrico.
4. NEXT has extensive experience in registering patients into our proprietary LIMS system and in reporting our results to the appropriate data managers either by fax or electronic upload.
5. NEXT has its own medical billing team and is in network with several insurance providers.
6. NEXT operates under a Laboratory Quality Management system including the development of more than 350 company SOPs. NEXT has an internal Quality Assurance panel which routinely monitors all testing programs. We have been consistently audited

by outside agencies (for example, by CLIA, California, the New York State Department of Health, the CDC, various private companies) and are proud of our spotless record with regard to these inspections. Our current CLIA audit returned no findings, and our license will be renewed in August for the next two year period.

In short, we are confident that NEXT will meet the standards and requirements set by Henrico County and we look forward to establishing a productive relationship. No component of our RFP response need be protected from FOIA inquiry.

Thank you for your consideration. We look forward to your reply

Respectfully,

A handwritten signature in black ink, appearing to read 'R. Harris', with a long, sweeping horizontal stroke extending to the left.

Robert B Harris, Ph.D.
CFO/CSO/co-founder

B. Proposal Signature Sheet – Attachment A

ATTACHMENT A

PROPOSAL SIGNATURE SHEET

My signature certifies that the proposal as submitted complies with all requirements specified in this Request for Proposal (“RFP”) No. 22-2356-5JOK – Onsite Infection Disease Testing Services.

My signature also certifies that by submitting a proposal in response to this RFP, the Offeror represents that in the preparation and submission of this proposal, the Offeror did not, either directly or indirectly, enter into any combination or arrangement with any person or business entity, or enter into any agreement, participate in any collusion, or otherwise take any action in the restraining of free, competitive bidding in violation of the Sherman Act (15 U.S.C. Section 1) or Sections 59.1-9.1 through 59.1-9.17 or Sections 59.1-68.6 through 59.1-68.8 of the Code of Virginia.

I hereby certify that I am authorized to sign as a legal representative for the business entity submitting this proposal.

LEGAL NAME OF OFFEROR (DO NOT USE TRADE NAME): Next Bio-Research Services, LLC.

ADDRESS: 11601 Iron Bridge Road, Ste 101, Chester VA 23831

FEDERAL ID NO: 47-4821293

SIGNATURE:

NAME OF PERSON SIGNING (PRINT): Robert B. Harris, Ph.D.

TITLE: CFO, CSO

TELEPHONE: 804-977-6603

FAX: 804-977-6630

EMAIL ADDRESS: rharris@nextmolecular.com

DATE: June 16, 2022

ATTACHMENT B

BUSINESS CATEGORY CLASSIFICATION FORM

Company Legal Name: Next Bio-Research Services, LLC.

This form completed by: Signature: _____ Title: _____

Date: June 16, 2022

PLEASE SPECIFY YOUR BUSINESS CATEGORY BY CHECKING THE APPROPRIATE BOX(ES) BELOW.

(Check all that apply.)

- ☒ SMALL BUSINESS
- ☐ WOMEN-OWNED BUSINESS
- ☐ MINORITY-OWNED BUSINESS
- ☐ SERVICE-DISABLED VETERAN
- ☐ EMPLOYMENT SERVICES ORGANIZATION
- ☐ NON-SWaM (Not Small, Women-owned, or Minority-owned)

SUPPLIER REGISTRATION – The County of

Henrico encourages all suppliers interested in doing business with the County to register with eVA, the Commonwealth of Virginia's electronic procurement portal, <http://eva.virginia.gov>.

eVA Registered? ☒ Yes ☐ No

If certified by the Virginia Minority Business Enterprises (DMBE), provide DMBE certification number and expiration date.
_____ NUMBER _____ DATE

DEFINITIONS

For the purpose of determining the appropriate business category, the following definitions apply:

"Small business" means a business, independently owned and controlled by one or more individuals who are U.S. citizens or legal resident aliens, and together with affiliates, has 250 or fewer employees, or annual gross receipts of \$10 million or less averaged over the previous three years. One or more of the individual owners shall control both the management and daily business operations of the small business.

"Women-owned business" means a business that is at least 51 percent owned by one or more women who are U.S. citizens or legal resident aliens, or in the case of a corporation, partnership, or limited liability company or other entity, at least 51 percent of the equity ownership interest is owned by one or more women who are U.S. citizens or legal resident aliens, and both the management and daily business operations are controlled by one or more women.

"Minority-owned business" means a business that is at least 51 percent owned by one or more minority individuals who are U.S. citizens or legal resident aliens, or in the case of a corporation, partnership, or limited liability company or other entity, at least 51 percent of the equity ownership interest in the corporation, partnership, or limited liability company or other entity is owned by one or more minority individuals who are U.S. citizens or legal resident aliens, and both the management and daily business operations are controlled by one or more minority individuals.

"Minority individual" means an individual who is a citizen of the United States or a legal resident alien and who satisfies one or more of the following definitions:

1. "African American" means a person having origins in any of the original peoples of Africa and who is regarded as such by the community of which this person claims to be a part.
2. "Asian American" means a person having origins in any of the original peoples of the Far East, Southeast Asia, the Indian subcontinent, or the Pacific Islands, including but not limited to Japan, China, Vietnam, Samoa, Laos, Cambodia, Taiwan, Northern Mariana Islands, the Philippines, a U.S. territory of the Pacific, India, Pakistan, Bangladesh, or Sri Lanka and who is regarded as such by the community of which this person claims to be a part.
3. "Hispanic American" means a person having origins in any of the Spanish-speaking peoples of Mexico, South or Central America, or the Caribbean Islands or other Spanish or Portuguese cultures and who is regarded as such by the community of which this person claims to be a part.
4. "Native American" means a person having origins in any of the original peoples of North America and who is regarded as such by the community of which this person claims to be a part or who is recognized by a tribal organization.

"Service disabled veteran business" means a business that is at least 51 percent owned by one or more service disabled veterans or, in the case of a corporation, partnership, or limited liability company or other entity, at least 51 percent of the equity ownership interest in the corporation, partnership, or limited liability company or other entity is owned by one or more individuals who are service disabled veterans and both the management and daily business operations are controlled by one or more individuals who are service disabled veterans.

"Service disabled veteran" means a veteran who (i) served on active duty in the United States military ground, naval, or air service, (ii) was discharged or released under conditions other than dishonorable, and (iii) has a service-connected disability rating fixed by the United States Department of Veterans Affairs.

"Employment services organization" means an organization that provides community-based employment services to individuals with disabilities that is an approved Commission on Accreditation of Rehabilitation Facilities (CARF) accredited vendor of the Department of Aging and Rehabilitative Services.

D. Virginia State Corporation Commission Registration Information

ATTACHMENT C

Virginia State Corporation Commission (SCC)

Registration Information

The Offeror:

☒ is a corporation or other business entity with the following SCC identification number:
55747961 **-OR-**

☐ is not a corporation, limited liability company, limited partnership, registered limited liability partnership, or business trust **-OR-**

☐ is an out-of-state business entity that does not regularly and continuously maintain as part of its ordinary and customary business any employees, agents, offices, facilities, or inventories in Virginia (not counting any employees or agents in Virginia who merely solicit orders that require acceptance outside Virginia before they become contracts, and not counting any incidental presence of the Bidder in Virginia that is needed in order to assemble, maintain, and repair goods in accordance with the contracts by which such goods were sold and shipped into Virginia from Bidder's out-of-state location) **-OR-**

☐ is an out-of-state business entity that is including with this bid/proposal an opinion of legal counsel which accurately and completely discloses the undersigned Bidder's current contracts with Virginia and describes why those contracts do not constitute the transaction of business in Virginia within the meaning of §13.1-757 or other similar provisions in Titles 13.1 or 50 of the Code of Virginia.

Please check the following box if you have not checked any of the foregoing options but currently have pending before the SCC an application for authority to transact business in the Commonwealth of Virginia and wish to be considered for a waiver to allow you to submit the SCC identification number after the due date for bids: ☐

E. Proprietary/Confidential Information – Attachment D

ATTACHMENT D

PROPRIETARY/CONFIDENTIAL INFORMATION IDENTIFICATION

NAME OF OFFEROR: Next Bio-Research Services, LLC.

Trade secrets or proprietary information submitted by an Offeror shall not be subject to public disclosure under the Virginia Freedom of Information Act; however, the Offeror must invoke the protections of Va. Code § 2.2-4342(F) in writing, either before or at the time the data or other materials are submitted. The Offeror must specifically identify the data or materials to be protected including the section(s) of the proposal in which it is contained and the pages numbers, and state the reasons why protection is necessary. A summary of trade secrets and proprietary information submitted shall be submitted on this form. The proprietary or trade secret material submitted must be identified by some distinct method such as highlighting or underlining and must indicate only the specific words, figures, or paragraphs that constitute trade secret or proprietary information. Va. Code § 2.2-4342(F) prohibits an Offeror from classifying an entire proposal, any portion of a proposal that does not contain trade secrets or proprietary information, line item prices, or total proposal prices as proprietary or trade secrets. If, after being given reasonable time, the Offeror refuses to withdraw such classification(s), the proposal will be rejected.

SECTION/TITLE	PAGE NUMBER (S)	REASON(S) FOR WITHHOLDING FROM DISCLOSURE
N/A	N/A	N/A

F. Anti-Lobbying Certification – Attachment I

ATTACHMENT I

ANTI-LOBBYING CERTIFICATION

Byrd Anti-Lobbying Clause (2 C.F.R. PART 200 APPENDIX II(I))

Contractors who apply or bid for an award of \$100,000 or more shall file the required certification. Each tier certifies to the tier above that it will not and has not used Federal appropriated funds to pay any person or organization for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, officer or employee of Congress, or an employee of a Member of Congress in connection with obtaining any Federal contract, grant, or any other award covered by 31 U.S.C. § 1352. Each tier shall also disclose any lobbying with non-Federal funds that takes place in connection with obtaining any Federal award. Such disclosures are forwarded from tier to tier up to the recipient who in turn will forward the certification(s) to the awarding agency.

Required Certification. If applicable, contractors must sign and submit to the agency the following certification.

The undersigned certifies, to the best of his or her knowledge and belief, that:

No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit Standard Form-LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions.

The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.

The Contractor, certifies or affirms the truthfulness and accuracy of each statement of its certification and disclosure, if any. In addition, the Contractor understands and agrees that the provisions of 31 U.S.C. Chap.

38, Administrative Remedies for False Claims and Statements, apply to this certification and disclosure, if any.



Signature of Contractor's Authorized Official

Robert B Harris, Ph.D., CFO

Name and Title of Contractor's Authorized Official

Printed Name of Offeror
(if different than Representative)

G. Current Business License

Jenefer S. Hughes, MBA, ACA
Commissioner of the Revenue
CHESTERFIELD COUNTY BUSINESS LICENSE

BUSINESS LOCATION:	11601 IRON BRIDGE RD STE 101 CHESTER VA 23831-1468	LICENSE NUMBER:	113177
BUSINESS OWNER:	NEXT BIO-RESEARCH SERVICES, LLC	LICENSE PERIOD:	01/01/2022 TO 12/31/2022 Must be renewed by 03/01/2023
		START DATE:	08/25/2015
TRADE NAME:	NEXT BIO-RESEARCH SERVICES, LLC	CLASSIFICATION:	600190 BUSINESS SERVICE - GENERALLY
ADDRESS:	STE 101 11601 IRON BRIDGE RD CHESTER VA 23831-1468		



II. STATEMENT OF THE SCOPE

General Requirements: NEXT will provide all labor, supervision, materials, equipment, and PPE necessary to provide turnkey on site infectious disease screening and diagnostic testing, as specified by Henrico County. Testing may be done at multiple locations, seven days per week, up to 12 hours per day Monday through Sunday. NEXT has its own contracted staff of certified and accredited NPs, RNs, ALS, LPNs, BLS, and EMTs who travel to collection sites throughout the Commonwealth. In addition, NEXT contracts with different professional agencies to provide qualified and licensed personnel to collect test samples. NEXT also has W-2 and contracted staff to assist with administrative functions such as registration at events and uses contracted staff through agencies for this function as well. All samples are brought back to NEXT, at NEXT's expense, for laboratory analysis. In addition, NEXT hosts walk-in patients who need testing at its facility in Chester. Testing for Infectious Disease will be on an as needed basis for Henrico County general government employees, students and faculty of HCPS, Henrico County's general public, as well as populations outside of the county, as directed by Henrico County. NEXT will set up and conduct Infectious Disease specimen collection at designated locations, provide the appropriate collection kits, collect the samples, conduct laboratory testing, and provide result reporting services. NEXT will process all laboratory tests and provide results within 48 hours of collection; however, results are typically returned within 24 hours or less. The assays being utilized are EUA approved by the FDA. NEXT also reports daily to the VDH through electronic feeds that automatically run each night to transfer data directly to the state for all results obtained during the course of that day.

A. Testing Methods

NEXT will only use approved methods that have an EUA approval from the FDA or other FDA approval, unless otherwise agreed to with Henrico. NEXT follows all government regulations (federal, state, and local), is CLIA certified for high complexity testing, follows OSHA, and other government regulations. NEXT will provide all methods to the County for approval prior to initiation of testing if requested. NEXT routinely participates in proficiency and sample confirmation studies as required by the FDA. The first 10 positive and negative samples were shared with the Virginia Division of Consolidated Laboratories for the CDC SARS CoV-2 rtPCR assay, as well as the antibody testing assay with 100% confirmation (100% concordance) of our results. NEXT continues to participate in correlation studies for all clinical testing that is performed at our laboratory. Twice yearly, positive and negative samples are exchanged with another validated, CLIA certified, High Complexity lab. Results obtained by both laboratories are compared and a report prepared. All reports are signed by both participating parties and filed for reference at NEXT. All reported results come with certification of the lab in the report. All results are reported to the VDH as required by law.

NEXT is continuously researching newly available options that allow for testing of the needed organisms, accuracy and appropriate sensitivity in testing, high throughput options for volume testing, and FDA/EUA approvals when available. While NEXT will discuss available options with Henrico County, NEXT will only use assays approved by Henrico County for testing those patients sent by Henrico County as testing needs are presented.

1. NEXT's COVID test assay is the EUA approved BioGx Xfree assay for the detection of COVID-19. The Xfree assay is a real-time RT PCR (rRT-PCR) assay for the in vitro qualitative detection of 2019-Novel Coronavirus (2019-nCoV) in respiratory specimens intended for the presumptive detection of nucleic acid from the SARS-CoV-2 in nasal or nasopharyngeal swabs taken from individuals suspected of COVID-19. NEXT Bio-Research Service laboratories are Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263 a certified high-complexity laboratory.
2. NEXT has implemented and validated the "Platelia" SARS CoV-2 Total Antibody test

and currently provides this assay to doctors, hospitals, clinics and individual patients. The assay detects and confirm the presence of antibodies (IgM/IgG/IgA) to SARS-CoV-2 nucleocapsid protein in human serum and EDTA plasma samples. The presence of antibodies to the nucleocapsid protein indicates that a person has or had COVID 19 infection within the past 12 months. The Platelia assay was commercialized by Bio Rad Inc, Hercules, CA, and has received Emergency Use Authorization (EUA) from the United States Food and Drug Administration (FDA). The assay is run on the Evolis™ Microprocessor system (Bio Rad Inc). NEXT has also implemented and validated under CLIA regulations and Good Laboratory practices three additional ELISA tests; our spike protein ELISA reveals the presence of antibodies to the receptor binding domain (“RBD”) of the CoV-2 spike protein (Wuhan/delta strains). If a patient sample tests positive for these antibodies, the level of antibody (titer) is then determined. All positive samples are then subjected to two different “cPass” assays. The first cPass assay reveals whether the patient’s antibodies are capable of neutralizing (blocking) binding between the Wuhan/delta strain spike protein and its endogenous receptor, human angiotensin converting enzyme 2 (hACE2). The second cPass assay is reveals whether a patient’s antibodies are capable of neutralizing binding between the Omicron strain and hACE2. This cPass assays have been commercialized by GenScript USA, Inc, Piscataway, NJ, and have received EUA from the FDA. Although the spike protein RBD ELISA is not approved by the FDA and has not received EUA, the platform of antibody assays in place at NEXT provides a comprehensive picture of a patient’s immune competence with regard to the CoV-2 virus and moreover, indicates the success of vaccination with any of the current FDA-approved covid 19 vaccines. The antibody assays require single blood draw (lavender cap vacutainer EDTA tube).

3. For rapid antigen testing NEXT uses will provide the QuickVue (Quidel) test kits. Collectors will take a nasal swab from the patient and complete the QuickVue test following the Quidel protocol. Results will be provided immediately upon completion of the test both verbally and via a paper handout directly to the patient, and can be followed up with a text or email as directed by the county. The results will also be reported to the county designated person by excel spreadsheet no later than 10 AM the next day. A call to the county on positives can also be place immediately if needed.
4. NEXT also performs respiratory testing including Flu testing. Testing is performed using both the BioFire Respiratory 2.1 Panel, an FDA approved assay, as well as using ThermoFisher’s respiratory assays for a higher throughput option. While the ThermoFisher assays are not FDA approved, they have shown 100% concordance with the BioFire panel in comparative studies and allow for a larger volume of samples to be run.

B. Registration of Patients

NEXT will provide procedures for testing county employees that may differ based on the type of testing site and type of testing to be conducted. Testing conducted for HCPS typically require advance registration while drive thru testing may have on-site registration. NEXT has worked with HR departments and school divisions, among many others, to obtain electronic rosters so that the person only has to verbally provide their name and date of birth when being tested; NEXT will already be in possession of their other information and will only perform testing that has prior approval by the county. NEXT has considerable knowledge of VDH requirements for registration having been under contract with VDH since May 2020. NEXT obtains all demographic information such as name, date of birth, address, phone, gender, race, and ethnicity. While VDH will accept other information, this is currently the demographics requested for reporting purposes along with the type of testing completed, the type of swab used, and the platform/equipment used for testing. As requested by Henrico County,

NEXT can readily provide additional information. NEXT does provide all of this information along with the project information (name, address, ordering clinician, etc.) directly to the VDH daily through the electronic feed. NEXT also has extensive experience with holding large scale drive-through or walk-up testing sites. These types of sites may or may not include pre-registration. All pre-registration sites are managed as detailed above. At sites without pre-registration, NEXT will obtain the needed information while the patient is on-site. They will be given a requisition for normal demographic information which may also include patient consent, HIPAA consent, insurance info, and pertinent travel information and health information where applicable or required. All reporting remains the same as above.

C. Reporting of results

NEXT will provide COVID-19 rapid antigen results per section III.A.3. NEXT will provide each patient with immediate results, both verbal and written, with a follow up to the county by the next morning and referrals if needed for treatment and medical consultation. NEXT will provide the county with daily reports of all testing results and will provide daily results to the VDH. COVID-19 PCR, antibody, and respiratory results will all be provided within 48 hours or less with a feed to the VDH overnight each night as described in section III as required by the state. NEXT will work in conjunction with Henrico County to provide additional analytics and trends as needed. In certain situations, results can be emailed directly to the patient also if desired by the county.

D. Coordination with Henrico County Employee Health Services (“EHS”) and Emergency Management and Workplace Safety (“EMWS”)

NEXT will coordinate with Henrico County EHS and EMWS for sharing of data and continuity of patient care for county employees regardless of whether the test results indicate the need for follow up.

E. Invoicing Requirements

NEXT will invoice the county monthly and will include all pertinent information as defined in the RFP.

F. Billing and Medical Records

NEXT will bill the county directly for services provided monthly. All billing, testing and other documents are the property of NEXT and will be treated confidentially.

G. Extension of Services to County Residents

If providing services to non-County General Government and HCPS employees under the direction of Henrico County and in situations where the county does not intend to pay for these services, NEXT is capable of billing medical insurance companies, Medicare, or Medicaid. In this case, patients would be held responsible for patient cost-sharing such as deductibles, co-pays, and/or co-insurance as allocated by their payer. NEXT does NOT balance bill any patient. In addition, NEXT would still provide all results to VDH daily through the nightly feed.

H. Health Insurance Portability and Accountability Act (HIPAA)

NEXT abides by all federal, state, and local laws and regulations including HIPAA. NEXT will certify compliance with these laws and regulations.

III. OFFERER, QUALIFICATION, EXPERIENCE, and RESUMES

Next Bio-Research LLC, d/b/a NEXT Molecular Analytics (NEXT) is a comprehensive contract research organization which provides integrated research and development sciences and clinical testing services to physicians and life science investigators in biotechnology and pharmaceutical companies, academic institutions, and in several different government agencies. Located in a suburb of Richmond Virginia, NEXT was founded by three seasoned executives who have worked together for >30 years and have accumulated over 100 collective years of contract lab and clinical services experience. Using the latest in next generation sequencing technology, bioinformatics, immunoassay and bioanalytics, NEXT occupies a highly desired niche in clinical diagnostics and life science research. The founders have impeccable reputations and represent a strong customer base which allows NEXT to rapidly grow its revenue stream. Our ability to leverage our considerable strengths in the Life Sciences developed through 30 years of contract research experience makes us uniquely able to rapidly apply, convert, implement, and distribute the best technologies to the market for future advancements. This ability has allowed NEXT to rapidly implement its own custom clinical and basic science assays to exploit openings in the market. NEXT has the ability and experience to provide testing to the 14,000 employees of Henrico County as well as the general public and has performed on-site collections for the Commonwealth of Virginia under multiple contracts totaling over 165,000 tests for similar turnkey services for COVID-19 testing since May of 2020. NEXT provides the specific services requested in the RFP and currently possess all laboratory space required, staffing, instrumentation, validated assays, logistical and administrative support to meet the requirements listed.

Thomas R Reynolds is the President of NEXT. He brings >30 years executive level Biotech experience to NEXT. In his previous professional positions, Reynolds was a co-founder of Commonwealth Biotechnologies, Inc, the predecessor company to NEXT Molecular Analytics, founded in 1992, and continuously served as its Executive Vice President, Director, and Secretary. Reynolds helped take CBI public in 1997, with an IPO and listing on NASDAQ. In 2009 Reynolds and Dr. Harris spun out US based operations of CBI into a private company, American International Biotechnology, LLC. Expertise in clinical molecular diagnostics and genetics, woman's health testing, next generation sequencing and personal medicine related technologies, as well as operation of BSL-3 labs. Subject matter expert in biodefense/bio-crime and human DNA forensics areas. From 1987 until 1997, Reynolds was in the Department of Microbiology Biology and Immunology at Virginia Commonwealth University where he served as Manager of the Nucleic Acids Core Laboratory as part of the Massey Cancer Center. Reynolds is a co-inventor of US patents, and co-author of more than 45 peer reviewed journal articles and book chapters, in the research area of molecular genetics.

Gregory Meyers is the Chief Operating Officer (COO) of NEXT. He brings >25 years of laboratory operation experience to NEXT. Previously, he was Vice President of DNA Services at American International Biotechnology, LLC., in Richmond, VA. He was responsible for oversight and direction of, among other labs, the clinical molecular diagnostic lab where he designed and led the development and validation of several next generation sequencing diagnostic assays used for clinical practice. Prior to that, he served as a Senior Systems Analyst for Analytic Services, Inc. (ANSER), providing advisory and assistance service support to the Department of Defense Transformational Medical Technologies program, serving as a subject matter expert focused mainly on the areas of pathogen identification and characterization and bioinformatics. Prior to joining ANSER, Mr. Meyers was a Group Leader, DNA Services, Commonwealth Biotechnologies, Inc., where he oversaw laboratory operations and scientific

program direction of molecular biology, DNA sequencing, and microbial forensic and diagnostic service areas, and Project Manager, Icoria, Inc. where he was responsible for all project management aspects of \$55million agricultural genomics collaboration between Monsanto Inc. and Icoria. Mr. Meyers received his BS degree from Virginia Tech in Biology, with an emphasis on microbiology, and his MS degree from VCU/MCV in Microbiology and Immunology. Mr. Meyers is the author of numerous peer reviewed publications and is a co-inventor on several US patents.

Robert B. Harris, Ph.D., is the current Chief Financial Officer and Chief Scientific Officer of NEXT. Harris has nearly 50 years of executive level life science experience. In his previous professional positions, Harris was a co-founder of Commonwealth Biotechnologies, Inc, the predecessor company to NEXT Molecular Analytics, founded in 1992, and continuously served as its President, Director, and CEO. Then, Harris served as President and CSO of American International Biotechnology LLC. Until 1997, Dr. Harris was employed in the Department of Biochemistry and Molecular Biophysics at Virginia Commonwealth University, rising through the academic ranks to full Professor. Dr. Harris received a joint Bachelor's degree in Chemistry and Biology from the University of Rochester, Rochester, NY, and the Master's and Doctoral degrees from New York University, in Biochemistry and Biophysical Chemistry. Dr. Harris is the co-author of more than 75 peer reviewed journal articles and book chapters, mostly in areas of his research expertise: the role of macromolecular structure in biological function. Dr. Harris is a former Established Investigator of the American Heart Association, and is co-inventor of US and foreign patents and is the holder of the Certificate of Quality (COQ) form the New York State Department of Health for conduct of L-asparaginase testing done under accreditation from the NYS DOH. Dr. Harris is the co-lab Director (with Dr. Li) for the State of California Department of Health and is the Lab Director for the NYS DOH.

Dai "Dave" Li MD, MSc. PhD, is the Chief Medical Officer and Laboratory Director of NEXT. Dr. Li brings to NEXT Molecular Analytics over 25 years of experience in health and clinical sciences. He obtained his MB/MD at the Sun Yat-Sen University School of Medicine and Cancer Center in Guangzhou, China, and his MSc/PhD from the University of Texas M.D. Anderson Cancer Center. He received additional training in tumor immunology from the Department of Surgery and Organ Transplantation at the University of Texas Health Science Center in Houston, as well as in Clinical Informatics from the Department of Health Informatics at The Johns Hopkins University School of Medicine in Baltimore, Maryland.

He completed a combined residency in medical oncology and laboratory medicine at the Sun Yat-sen University Cancer Center. Subsequently, he did clinical fellowships in Clinical Pathology at the University of Texas Southwestern Medical Center, Parkland Memorial Hospital, and at The Johns Hopkins Medical Institutions. Dr. Li then accepted a faculty position of pathology at the Johns Hopkins Medical Institutions with the Division of Clinical Pathology. In 1999 he became the Manager of Clinical Development, and Medical Director of Wako Clinical Laboratory of Wako Chemicals, USA, Inc., a subsidiary of Wako Pure Chemical Industries, Ltd and Takeda Pharmaceutical Company Ltd of Osaka, Japan. In 2004, he was recruited as a Medical Officer for the US/HHS Food and Drug Administration (FDA), Office of Device Safety and In Vitro Diagnostics in Rockville, Maryland. In 2010, he became the Chief Medical Officer at Wako Life Sciences, Inc. in charge of medical and regulatory affairs. In 2013, he assumed a position of Director of Clinical Informatics with Health Diagnostic Laboratory, Inc.

Dr. Li is a physician certified by the American Medical Association (AMA) and the United States National Board of Medical Examiners/ECFMG. He is also certified by College of American Pathologists (CAP) and Center for Medicare and Medicaid Services (CMS/CLIA) as a clinical laboratory director.

Eric L. Bachrach, M.D., serves as a paid consultant to NEXT. He oversees the collection process of COVID-19 PCR, rapid antigen, and CoV-2 Antibody specimens. Dr. Bachrach conducts random site audits, reviews/writes training documents, and conducts trainings as appropriate for the collection teams be they W-2 employees or direct contractors to NEXT, or through a professional staffing agency.

Dr Bachrach is Board Certified in Emergency and Family Medicine and held a fellowship from the Academy of Wilderness Medicine. His professional career spans 20 years and includes faculty and teaching positions at public and private entities including, most recently, the Hunter McGuire VA Medical Center (Attending Physician), Virginia Commonwealth University Medical Center (Faculty Assistant Professor), Virginia Emergency Consultants Inc (Attending Physician), and Eric L Bachrach, PLC (Attending Physician). He is the current Operational Medical Director for the Prince George Fire Department. Dr. Bachrach is licensed in Virginia, Ohio, and Arkansas.

NEXT uses certified and accredited staff and/or specially trained staff for specimen collections. All staff engaged in school or government testing are background checked per federal, state, and/or local guidelines. All staff are required to read and understand NEXT's training materials and must undergo training in chemical and biohazards, chem and biohazard safety measures, and privacy and HIPAA rules and regulations. All employees must confirm their understanding of these measures (and pass a test in each area) and must understand and adhere to the necessity of wearing proper PPE. Further they must understand how swabs are to be collected for each project (nasal vs nasopharyngeal, etc.). NEXT uses a point of contact (POC) person for each job and this POC is typically a W-2 employee of NEXT or is directly contracted with NEXT. The POCs go through additional training and have a very good understanding of NEXT's expectations and standards for patient care, customer service, how to set up each type of testing site, and NEXT's normal protocols. All new collectors to NEXT, will work with a veteran NEXT collector prior to being released to work on their own or with another new collector. Specific resumes, certifications, and licenses can be provided if NEXT is awarded the contract.

NEXT was founded in August, 2015 and has operated continuously in its present location since that time. We are a private company and our financial reports are reviewed by an independent accounting firm, but are not audited. We operate on a cash basis; copies of our tax returns will be made available on request.

IV. REFERENCES

A. Michelle Oakes, VP. Testing Logistics, 774-274-1426, michelle@testinglogistics.com, Testing Logistics, November 2020

B. Beth Cheuk, Coordinator of Community Relations and Development, 434-531-2484, cheukbl@charlottesvilleschools.org, Charlottesville City Schools, August 2021

C. Beth Baptist, Interim Director of HR and Student Services and Achievement, 540-556-3261, beth.baptist@charlottesvilleschools.org, Charlottesville City Schools, August 2021

D. Kris Vass, Coordinator of Operations, 540-434-9916, kvass@harrisonburg.k12.va.us, Harrisonburg City Schools, February 2022

E. Chris Patterson, Assistant State Planning and SNS Coordinator, 804-905-8623,

F. Dr. Edwin Roman, Medical Doctor and Owner of his medical practice, 917-400-7000, eroman@jcefootankle.com, JCE Foot and Ankle, March 2016

V. SERVICE APPROACH/IMPLEMENTATION OF SERVICES

As previously stated, NEXT uses W-2 employees, direct contractors, and contractors through staffing agencies. All staff go through a thorough background check and are confirmed to meet all federal, state, and local standards for being on the property of schools or governmental buildings. In addition, all staff are required to read our training materials and sign off confirming their understanding of HIPAA, the necessity of wearing proper PPE and how to properly use it, and how we swab for each project (nasal vs nasopharyngeal, etc.). NEXT uses a point of contact (POC) person for each job who is typically a NEXT employee or is a direct contractor to NEXT. The POCs go through additional training and have a very good understanding of NEXT's expectations and standards for patient care, customer service, how to set up each type of testing site, and NEXT's normal protocols. In addition to Dr. Bachrach randomly auditing testing sites, NEXT regularly sends the President, the Director of Clinical Business Operations, or our Project Coordinator to the sites to audit professionalism, swabbing techniques, and overall processes. NEXT's extremely high standards, quick turnaround times, flexibility in meeting client needs, and accuracy in laboratory testing, account for the continued contract renewals with the Commonwealth of Virginia, the Virginia Department of General Services, as well as other private and public sector clients, including colleges, universities, long term care facilities, prisons, nursing homes, and film and T.V. production companies.

In many instances, NEXT invoices its clients directly for the work done, but NEXT also has its own in-house Medical Billing Department and can bill medical insurance companies, Medicare, and Medicaid.

A. Testing Situations

NEXT will provide turnkey setup for Infectious Disease testing for all required situations listed in this RFP. NEXT will always provide PPE (gloves, jackets, N/KN 95 masks, face shields, testing glasses, bleach/antibacterial wipes, hand sanitizer) and supplies (FDA approved kits, clip boards, pens, labels, sealable bags for completed samples, trash bags, red bio-hazard bags, requisitions in English and Spanish if necessary, and consent forms in English and Spanish if necessary). NEXT can provide yard signs and/or A-frame signs, traffic cones, shade tents, tables, and chairs when needed along with someone to manage traffic control when on private property. NEXT has also worked with local law enforcement when provided by the locality for traffic control. NEXT can grant Henrico County the testing capacity of 2500 per day over one or multiple locations. NEXT will also provide literature explaining how test results will be provided, a contact number and email if needed for questions, CDC guidance, and has a medical doctor and a Ph.D. available for questions related to test results. NEXT can also provide referrals to medical facilities for follow-up if requested.

1. NEXT will provide individual testing of all persons listed in Section III, as authorized by the county, at NEXT's facility for testing on an as needed basis throughout the contract period. NEXT will provide these services at its laboratory in Chester, Virginia and may be able to locate an office in Henrico County to use for collections as well if needed. Clients may schedule an appointment online and then may be tested in our office or in the parking lot adjacent to our office, as appropriate. NEXT has dedicated space to test both inside and outside. COVID-19 or Flu swabs may be obtained inside or outside but blood draws for CoV-2 Antibody testing will be conducted inside. NEXT will obtain proper paperwork at the time of testing that will either be completed at that time or printed off

from the appointment scheduler.

2. NEXT will provide drive-through or similar mass testing of people identified in Section III, as authorized by the county, if there is widespread contagion of large numbers of the public requiring testing. NEXT has performed mass testing turnkey services for the Commonwealth of Virginia since May 2020. This type of setup is usually used for PCR COVID-19 testing but potentially could be used for Flu testing. Most of these types of events do not have pre-registration so NEXT obtains the registration information from the patient at the time of service. NEXT has managed many large drive-through sites with the VDH and has been successful at keeping lines to a minimum even with heavy testing. NEXT may run multiple lines at a single event which allows more people to be serviced in a defined area. Registration begins in one area by handing out bleached clipboards, pens, and paperwork. The patient can complete that paperwork while others are being tested. They will drive through to where everything is collected and reviewed. The kit is labeled and placed on the windshield and the patient moves up to where the collectors are. Names and dates of birth are verified, and the patient(s) are swabbed. All completed samples are placed into a container/sealable bag and the collector removes gloves, uses hand sanitizer, and re-gloves. All clipboards and pens are cleaned with bleach wipes and provided back to the first station.
3. NEXT will provide testing in schools or governmental buildings with staff that meets all necessary state and county screenings and background checks for safety measures. NEXT has been providing weekly testing in school systems for the Commonwealth of Virginia since August 2021. NEXT also conducts testing in schools for special events, e.g., band or choral trips, athletic events, back to school events. In addition, NEXT has tested in governmental buildings through both the contract with the Commonwealth of Virginia, the City of Richmond, and other city entities. Typically, tables and chairs are provided by the facility (but can be provided by NEXT if necessary). NEXT will setup at the site prior to the onset of sample collections. This type of testing usually includes a form of pre-registration by signing consent forms ahead of time and may include long term testing usually on a weekly basis. NEXT will come in with pre-printed information for the samples and requisitions so the patient will not need to complete any form of paperwork on-site. The patient will verbally provide their name and date of birth and then will be tested. NEXT will have consent forms on site as well in case the adult patient cares to register then if they haven't before. The patient will then return to work or class as soon as the swab is obtained or after the results has been provided if this is a rapid antigen test. This type of setup is usually for COVID-19 PCR or rapid antigen testing.

VI. PRICING/COST PROPOSAL

Henrico County will be billed monthly for all work completed in the prior month for which they consented to be responsible. Charges will consist of:

Collection fees for specimens collected on NEXT's premises - \$25.00

Collection fees for specimens collected off NEXT's premises - \$42.00

Fees for COVID-19 PCR laboratory testing for non-HCPS employees- \$100.00

Fees for COVID-19 PCR laboratory testing for HCPS employees - \$50.00

Fees for COVID-19 PCR laboratory testing (pooled samples up to 5 samples) - \$50.00

Fees for COVID-19 rapid antigen testing (laboratory processing only) - \$50.00

Fees for CoV-2 Antibody testing comprehensive platform (laboratory processing only) - \$315.00

Fees for Flu testing (laboratory processing only) - \$150.00

Setup fees for Community Testing Events (excluding HCPS events) are on tiers:

Tier	# of expected specimens	Setup fee
1	0-75	\$500
2	76-250	\$900
3	250+	\$1350

For non-county General Government and HCPS employees, NEXT can bill medical insurance/Medicare/Medicaid if needed and not covered by Henrico County. When billing medical insurance/Medicare/Medicaid, NEXT will bill the full charge of the service instead of the contracted county rate as NEXT incurs other financial obligations in using their billing team for claim filing, appeals, posting, write-offs per the payer, patient billing per the payer, mailing costs, credit card costs, etc.

VII. EXCEPTIONS

A. Billing Exception Due to Lack of Coverage or Regulatory Requirement

There may be billing exceptions to medical insurance companies, Medicare, or Medicaid based on the patient not having an existing policy, not having coverage for the test in question, or NEXT not being allowed to order the specific test without a physician signing the order and/or physically seeing the patient. Lastly, NEXT cannot engage in using their ordering provider and billing medical insurance, Medicare, or Medicaid for tests outside of the Public Health Emergency where self-referrals would be considered a kick-back/violation of STARK Law.

B. Billing Medical Insurance Companies, Medicare, or Medicaid

When billing medical insurance, Medicare, or Medicaid, NEXT would bill their normal bill rate and not the Henrico County contracted rate due to the additional fees incurred for their billing team and potential mailings.

VIII. ASSUMPTIONS

No Assumptions

IX. APPENDICES

No Appendices