

Presolicitation Notice

SUBJECT* 36C249-23-AP-0270-HOLOGIC Aptima SARS-COV-2 ASSAYS KITS

GENERAL INFORMATION

CONTRACTING OFFICE'S ZIP CODE*	37129
SOLICITATION NUMBER*	36C24923Q0038
RESPONSE DATE/TIME/ZONE	02-16-2022 4:00 PM CENTRAL TIME, CHICAGO, USA
ARCHIVE	15 DAYS AFTER THE RESPONSE DATE
SET-ASIDE	
PRODUCT SERVICE CODE*	6515
NAICS CODE*	334516
PLACE OF PERFORMANCE	Department of Veterans Affairs VA Medical Center Veterans Way and Lamont Dogwood Avenue Bldg. 205 Mountain Home TN
POSTAL CODE	37684
COUNTRY	United States

CONTACT INFORMATION

CONTRACTING OFFICE ADDRESS	Department of Veterans Affairs Network Contracting Office 9 (90C) NCO 9 1639 Medical Center Parkway, Suite 400 Murfreesboro TN 37129
POINT OF CONTACT*	Contracting Officer Corey Maliki correy.malik@va.gov 615-225-5967

*=Required Field

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ADDITIONAL INFORMATION

AGENCY'S URL	https://www.va.gov/tennessee-valley-health-care/locations/na
URL DESCRIPTION	Nashville VA Medical Center
AGENCY CONTACT'S EMAIL ADDRESS	
EMAIL DESCRIPTION	

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DESCRIPTION

Subject: SPECIAL NOTICE 36C24922Q0038

Description: NOTICE OF INTENT TO AWARD A SOLE SOURCE

The Department of Veterans Affairs (VA), Network Contracting Office (NCO) 9, intends to issue a Firm Fixed Priced contract under the authority of Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements as implemented by FAR 6.302-2. Award is anticipated to occur on or about November 21st, 2022 to Hologic Sales and Services, LLC. The period of performance will be for fifteen calendar days after issuance of the notice to proceed.

According to Hologic, it is the sole source of the instrument system, assay kits, and associated kits and reagents listed below. All of Hologic procurements of this nature must come directly from Hologic. Currently, the Hologic Panther firmware system is presently in use at the facility and the Aptima assays have been validated for use with the Panther system. The firmware in the Panther system is necessary for running the Aptima assays and is unique to Hologic. Hologic is the sole source of this firmware. Additionally, Hologic is the manufacturer and meets the requirement as it applies to the Non manufacturer rule (NMR).

ITEM NO. OR STOCK NO.	DESCRIPTION	QUANTITY	UNIT	ESTIMATED
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PRD-06419	1 Aptima SARS-CoV-2 Assay EUA, 250-Test.	60	EA	
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PRD-06420	2 Aptima SARS-CoV-2 Assay Controls EUA	35	EA	
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PRD-06997	3 Hologic Direct Load, Tube, 100/bag	135	EA	
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PRD-03705	4 Aptima HCV Quant Dx Assay Kit, 100-test	10	EA	3500.0000
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PRD-03706	5 Aptima HCV Quant Dx Control Kit			
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	QUANTITY UNDETERMINED - AS NEEDED	1	KT	N/C
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PRD-03707	6 Aptima HCV Quant Dx Calibrator Kit			
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	QUANTITY UNDETERMINED - AS NEEDED	1	KT	N/C
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303096	7 Panther System Run Kit (includes product no. 303014,303013,104772-02,902731 and 504405)			
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	QUANTITY UNDETERMINED - AS NEEDED	1	KT	N/C
104772-02	8 MTUs (multi-tube units) (100 Tubes/Case)			
	QUANTITY UNDETERMINED - AS NEEDED	1	EA	N/C
303013	9 Aptima Auto Detect (1000 Tests)			
	QUANTITY UNDETERMINED - AS NEEDED	1	EA	N/C
303014	10 Aptima Assay Fluids (1000 Tests)			
	QUANTITY UNDETERMINED - AS NEEDED	1	EA	N/C
504405	11 Waste Bin Covers (10/ea)			
	QUANTITY UNDETERMINED - AS NEEDED	1	EA	N/C
902731	12 Waste Bin Bags (10/ea)			
	QUANTITY UNDETERMINED - AS NEEDED	1	EA	N/C
CL0040	13 Spare Caps, TCR + Select 250 kit			
	QUANTITY UNDETERMINED - AS NEEDED	1	KT	N/C
CL0041	14 Spare Caps, AMP & Probe 100 & 250 kit Enzyme 100 kit			
	QUANTITY UNDETERMINED - AS NEEDED	1	EA	N/C
303085	15 Panther Advanced Cleaning Solution			
	QUANTITY UNDETERMINED - AS NEEDED	1	EA	N/C
501616	16 Spare Caps, Enzyme 250 kit			
	QUANTITY UNDETERMINED - AS NEEDED	1	EA	N/C
501604	17 Spare Caps, TCR, Aptima 2x50 kit			
	QUANTITY UNDETERMINED - AS NEEDED	1	EA	N/C
503762	18 Specimen Aliquot Tubes (SAT), 100/pack			
	QUANTITY UNDETERMINED - AS NEEDED	1	EA	
504415	19 Transport Tube Cab, 100/pack			

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QUANTITY UNDETERMINED - AS NEEDED 1 EA

PRD-03455 20 Panther Run Kit for Real Time Assays

QUANTITY UNDETERMINED - AS NEEDED 1 EA N/C

PRD-03503 21 Aptima Specimen Diluent US 1 EA

PRD-03654 22 Aptima Specimen Diluent Kit US

QUANTITY UNDETERMINED - AS NEEDED 1 EA

The Aptima® SARS-CoV-2 assay is a nucleic acid amplification in vitro diagnostic test intended for the qualitative detection of RNA from SARS-CoV-2 isolated and purified from nasopharyngeal (NP) and oropharyngeal (OP) swab specimens, nasopharyngeal washes/aspirates or nasal aspirates (collected by a healthcare provider (collected by a healthcare provider) and nasal and mid-turbinate nasal swab specimens (collected under observation of or by a healthcare provider) from any individual, including from individuals without symptoms or other reasons to suspect COVID-19. The Aptima SARS-CoV-2 assay is for use only under Emergency Use Authorization (EUA) in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests. This test is also for the qualitative detection of nucleic acid from SARS-CoV-2 in pooled samples containing up to 5 individual NP or OP swabs (collected by a healthcare provider), nasal, or nasal swabs (collected under observation of or by a healthcare provider) where each specimen is collected using individual vials containing transport media. Negative results from pooled testing should not be treated as definitive. If a patient's clinical signs and symptoms are inconsistent with a negative result or if results are necessary for patient management, then the patient should be considered for individual testing. Specimens included in pools with a positive or invalid result must be tested individually prior to reporting a result. Specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing. For specific patients, whose specimen(s) were the subject of pooling, a notice that pooling was used during testing must be included when reporting the result to the clinician or healthcare provider.

NCO 9 intends to non-competitively award this requirement to Hologic since its all of Hologic procurements of this nature must come directly from Hologic. As a result, any contractor other than Hologic would unintentionally cause a delay in treatment and evaluation activities. Unnecessary delays cannot be endured.

The North American Industry Classification System (NAICS) code for this requirement is 334516 with the size standard of 1,000. The applicable Product Service Code is 6640.

This notice of intent is not a request for proposals or quotes. However, all responsible veteran owned small businesses and service-disabled veteran owned small businesses may submit an offer and technical capabilities/narrative that proves by clear

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and convincing evidence that similar Carto 3 Ablation System and its warranties are available and will provide comparable treatment and evaluation capabilities for the facility. **If said OFFER and technical capabilities/narrative is received within SEVEN calendar days of publication of this notice, the narrative will be considered by NCO 9.** All responses must be submitted to the Government point of contact at the email address shown below. **A determination by the Government not to open the requirement to competition based upon the responses to this notice is solely within the discretion of the Government. Information received will generally be considered solely for the purpose of determining whether to conduct a competitive procurement.**

Contracting Office Address:
Point of Contact:

Government
Corey Malik

Department of Veterans Affairs
Contracting Officer
Network Contracting Office 9
corey.malik@va.gov
1639 Medical Center Parkway, 400 Murfreesboro, TN 37129

Corey Malik

Telephone:

(615)-225-6957