

**CITY OF EL PASO, TEXAS  
AGENDA ITEM  
DEPARTMENT HEAD'S SUMMARY FORM**

**AGENDA DATE:** June 20, 2023  
**PUBLIC HEARING DATE:** Not Applicable

**CONTACT PERSON(S) NAME AND PHONE NUMBER:**  
Hector I. Ocaranza, MD, - Interim Director/Health Authority (915)212-0200  
K. Nicole Cote, Managing Director (915) 212-1092

**DISTRICT(S) AFFECTED:** All

**STRATEGIC GOAL:** No. 8 - Nurture and Promote a Healthy, Sustainable Community

**SUBGOAL:** 8.1 Deliver prevention, intervention and mobilization services to promote a healthy, productive and safe community

**SUBJECT:**  
Request that the Managing Director of the Purchasing & Strategic Sourcing Department be authorized to issue a Purchase Order(s) to Hologic Sales and Services, LLC, the sole distributor for the Hologic Testing Supplies for Public Health Department for a term of three (3) years for an estimated amount of \$225,000.00, with the stipulation that the vendor provides an updated sole source letter and affidavit each year. This contract will allow the Public Health Department to purchase associated kits, assays and reagents for their Panther instrument system.

**BACKGROUND / DISCUSSION:**  
The items in this request are necessary to carry out diagnostic testing for all divisions and programs within Public Health. This testing is conducted in compliance with the guidelines and regulations established by the Centers for Disease Control (CDC) and the Texas Department of State Health Sciences (DSHS). The Department of Public Health requires specific items for diagnostic testing purposes. These items could include medical equipment, laboratory supplies, or other resources necessary to conduct tests accurately and efficiently. These diagnostic tests aim to assess individuals' health conditions within different divisions of Public Health and across the city and county of El Paso.

**SELECTION SUMMARY:**  
Hologic, Inc is the sole source for the Panther instrument system supplies. The assays have been validated for use with the Panther system. The firmware in the Panther system is necessary and unique to Hologic the sole source of this firmware. Hologic does not sell through dealers or distributors in the U.S. All sales are made directly to end users.

**CONTRACT VARIANCE:**  
There is no variance, estimated amount remains the same.

**PROTEST**  
N/A

**PRIOR COUNCIL ACTION:**  
N/A

**AMOUNT AND SOURCE OF FUNDING:**  
Amount: \$225,000.00  
Funding Source: General Fund  
Account: 531120-341-1000-41130

**HAVE ALL AFFECTED DEPARTMENTS BEEN NOTIFIED?  YES \_\_\_ NO**

**PRIMARY DEPARTMENT:** Public Health Department

**SECONDARY DEPARTMENT:** Purchasing & Strategic Sourcing

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\*\*\*\*\***REQUIRED AUTHORIZATION**\*\*\*\*\*

**DEPARTMENT HEAD:**



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Hector I. Ocaranza, MD, - Interim Director/Health Authority

**COUNCIL PROJECT FORM  
(Sole Source)**

\*\*\*\*\***POSTING LANGUAGE BELOW**\*\*\*\*\*

Please place the following item on the **CONSENT AGENDA** for the Council Meeting of **June 20, 2023.**

**STRATEGIC GOAL: No. 8: Nurture and Promote a Healthy, Sustainable Community**

The linkage to the Strategic Plan is subsection 8.1 Deliver prevention, intervention and mobilization services to promote a healthy, productive and safe community.

Request that the Managing Director of the Purchasing & Strategic Sourcing Department be authorized to issue a Purchase Order(s) to Hologic Sales and Services, LLC, the sole distributor for the Hologic Testing Supplies for Public Health Department for a term of three (3) years for an estimated amount of \$225,000.00, with the stipulation that the vendor provides an updated sole source letter and affidavit each year. This contract will allow the Public Health Department to purchase associated kits, assays and reagents for their Panther instrument system.

Contract Variance:

There is no variance, estimated amount remains the same.

Department:	Public Health
Vendor:	Hologic Sales and Services, LLC Marlborough, MA
Initial Term:	3 years
Annual Estimated Award:	\$75,000.00 (1 year)
Total Estimated Award:	\$225,000.00 (3 years)
Account No.:	531120-341-1000-41130
Funding Source:	General Fund
District(s):	All
Reference No.	2023-0520

This is a Sole Source, unit price contract.

The Purchasing & Strategic Sourcing and the Public Health Departments recommend award as indicated to Hologic Sales and Services, LLC the sole distributor for Hologic Testing Supplies.



## PURCHASING & STRATEGIC SOURCING DEPARTMENT

### SOLE SOURCE AFFIDAVIT

THIS IS AN OFFICIAL PURCHASING DOCUMENT-RETAIN WITH PURCHASE ORDER FILE

Before me, the undersigned official, on this day, personally appeared \_\_\_\_\_ a person known to me to be the person whose signature appears below, whom after being duly sworn upon his/her oath deposed and said:

1. My name is Peter P. Dunne. I am over the age of 18, have never been of a convicted crime and am competent to make this affidavit.
2. I am an authorized representative of the following company or firm: Hologic Sales and Service, LLC
3. The above named company or firm is the sole source for the following item(s), product(s) or service(s):  
Supply Program for Molecular Testing Reagents and Supplies
4. Competition in providing the above named item(s) product(s), service(s) is precluded by the existence of a patent, copyright, secret process or monopoly as stated under Section 252.022, Subchapter A of the Local Governmental Code 7A or as provided for under 7B-F of the same section. Also, attached hereto is a sole source letter, which sets forth the reasons why this Vendor is a sole source provider (dated and signed).
5. There is/are no other like item(s) or product(s) available for purchase that would serve the same purpose or function.
6. **Note: This Vendor understands that by providing false information on this Sole Source Affidavit, it may be considered a non-responsible Vendor on this and future purchases and may result in discontinuation of any/all business with the City of El Paso.**

*See Attached.*

\_\_\_\_\_  
Signature

SUBSCRIBED AND SWORN to before me on this \_\_\_\_\_ day of \_\_\_\_\_

\_\_\_\_\_  
NOTARY PUBLIC

\_\_\_\_\_  
PRINTED NAME

\_\_\_\_\_  
MY COMMISSION EXPIRES

COMPANY NAME: Hologic Sales and Service, LLC

ADDRESS, CITY, STATE & ZIP CODE: 10210 Genetic Center Drive, San Diego, CA 92121

PHONE: 800-442-9892 FAX NUMBER: 800-409-7591

CONTACT NAME AND TITLE: Steve Veit, Account Executive

WEB ADDRESS: www.hologic.com EMAIL: steve.veit@hologic.com

FEDERAL TAX ID NUMBER: 54-2074352 TEXAS SALES TAX NUMBER: \_\_\_\_\_

**CALIFORNIA ALL-PURPOSE ACKNOWLEDGMENT**

**CIVIL CODE § 1189**

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California )  
County of San Diego )  
On May 17, 2023 before me, Tracy R. Koetter,  
Date Here Insert Name and Title of the Officer  
personally appeared Peter P. Dunne  
Name(s) of Signer(s)

who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.



Signature Tracy R. Koetter  
Signature of Notary Public

Place Notary Seal Above

**OPTIONAL**

Though this section is optional, completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

**Description of Attached Document**

Title or Type of Document: Sole Source Affidavit Document Date: 5-17-2023  
Number of Pages: 1 Signer(s) Other Than Named Above: \_\_\_\_\_

**Capacity(ies) Claimed by Signer(s)**

Signer's Name: Peter P. Dunne  
 Corporate Officer — Title(s): \_\_\_\_\_  
 Partner —  Limited  General  
 Individual  Attorney in Fact  
 Trustee  Guardian or Conservator  
 Other: \_\_\_\_\_  
Signer Is Representing: Hologic

Signer's Name: \_\_\_\_\_  
 Corporate Officer — Title(s): \_\_\_\_\_  
 Partner —  Limited  General TRK  
 Individual  Attorney in Fact  
 Trustee  Guardian or Conservator  
 Other: \_\_\_\_\_  
Signer Is Representing: \_\_\_\_\_



May 4, 2023

To Whom It May Concern:

This letter is to verify that Hologic Sales and Service, LLC (“Hologic”) is the sole source of the instrument system, assay kits, and associated kits and reagents listed below.

**Instrument System**

Cat. #303095 Panther® System

**Assay Kits for Use on the Instrument System**

Cat. #303094/PRD-05571 Aptima Combo 2® Assay Kit – Panther System (250 test kit) and Cat. #302923/PRD-05576 Aptima Combo 2 Assay Kit – Panther System (100 test kit) for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*

Cat. #303585 Aptima HPV Assay Kit – Panther System (250 test kit) and Cat. #303570 Aptima HPV Assay Kit – Panther System (100 test kit) for the detection of human papillomavirus (HPV)

Cat. #303537 Aptima *Trichomonas vaginalis* Assay Kit – Panther System (250 test kit) and Cat. #303536 Aptima *Trichomonas vaginalis* Assay Kit – Panther System (100 test kit) for the detection of *T. vaginalis*

Cat. #PRD-04037-D Aptima Zika Virus Assay, Kit – Panther System (1000 test kit)\*

Cat. #PRD-03565 Aptima HIV-1 Quant DX Assay, Kit – Panther System (100 test kit)

Cat. #PRD-03705 Aptima HCV Quant DX Assay, Kit – Panther System (100 test kit)

Cat. #PRD-03568 Aptima HSV 1 & 2 Assay, Kit – Panther System (100 test kit)

Cat. #PRD-03868 Aptima HBV Quant Assay, Kit – Panther System (100 test kit)

Cat. #PRD-03919 Aptima Mycoplasma genitalium Assay, Kit, Panther System (100 test kit)

Cat. #PRD-05186 Aptima BV Assay, Kit – Panther System (100 test kit)

Cat. #PRD-05189 Aptima CV/TV Assay Kit – Panther System (100 test kit)

Cat. #PRD-06419 Aptima SARS-CoV-2 Assay Kit—Panther System (250 test kit)\*\*

Cat. #PRD-06815 Aptima SARS-CoV-2/Flu Assay Kit – Panther System (250 test kit)±

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.

**Kits and Reagents Associated with the Assay Kits**

The following kits and reagents were developed and qualified to be used with the Aptima assays and may include proprietary technology. Hologic is the sole source of these kits and reagents.

Cat. #301040 Aptima Urine Specimen Collection Kit for Male and Female Urine Specimens

Cat. #301041 Aptima Unisex Swab Specimen Collection Kit for Endocervical and Urethral Swab Specimens

Cat. #PRD-03546 Aptima Multi-test Swab Specimen Collection Kit


Cat. #105575 Aptima Urine Specimen Transport Tubes for Male and Female Urine Specimens  
Cat. #301154C Aptima Specimen Transfer Kit  
Cat. #301048 Aptima Auto Detection Reagent Kit  
Cat. #301110 Aptima Controls Kit  
Cat. #303001 Aptima Assay Fluids Kit  
Cat. #303000 Aptima Auto Detect Kit  
Cat. #303096 Panther System Run Kit  
Cat. #303085 Advanced Cleaning Solution  
Cat. #303099 Panther System Start-Up kit  
Cat. #PRD-03455 Panther Run Kit for Real Time Assays (for real time assays only)  
Cat. #PRD-06420 Aptima SARS-CoV-2 Assay Controls  
Cat. #PRD-03836 Universal Panel A  
Cat. #PRD-06506 Aptima SARS-CoV-2 Assay Panel C  
Cat. #PRD-04339 Specimen Lysis Tube Bag  
Cat. #PRD-06554 Solid Cap Specimen Lysis Tube Bag  
Cat. #PRD-06997 Direct Load Tube  
Cat. #PRD-06952 Direct Load Capture with Floq Swab  
Cat. #PRD-06816 Aptima SARS-CoV-2/Flu Assay Controls  
Cat. #PRD-06817 Aptima SARS-CoV-2/Flu Panel B

Hologic does not sell through dealers or distributors in the U.S. All sales are made directly to end users.

U.S. patents covering the Panther system and associated assay kits, reagents, and consumables can be found at <https://www.hologic.com/IP>.

If you have any questions or require additional information, please call Hologic Customer Service at 1.800.442.9892.

Sincerely,



Jennifer Schneiders, PhD  
President, Diagnostic Solutions  
Diagnostic Solutions

*\*The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to authorize the use of the Aptima Zika Virus Assay on the Panther System for the in vitro qualitative detection of RNA from Zika virus in human serum and plasma specimens. This EUA will terminate when the Secretary of Health and Human Services' declaration terminates unless the FDA revokes the EUA sooner. The Customer acknowledges and agrees that the Aptima Zika Virus Assay is only available for sale and use while the EUA is in effect. Hologic reserves the right to discontinue the Aptima Zika Virus Assay product at any time.*

*\*\* The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to authorize the use of the Aptima SARS CoV-2 assay on the Panther System by authorized laboratories for the detection of nucleic acid from SARS-CoV-2 virus only and not for any other viruses or pathogens. The Aptima SARS CoV-2 assay is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner. The Aptima SARS CoV-2 assay has not been FDA cleared or approved. The Customer acknowledges and agrees that the Aptima SARS CoV-2 assay is only available for sale and use while the EUA is in effect. Hologic reserves the right to discontinue the Aptima SARS CoV-2 assay product at any time.*

*±The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to authorize the use of the Aptima SARS CoV-2/Flu assay on the Panther and/or Panther Fusion System. This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories. This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, Flu A, and/or Flu B, not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal, Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner. The Customer acknowledges and agrees that the Aptima SARS CoV-2/Flu assay product and pricing is only available for sale and use while the EUA is in effect. Hologic reserves the right to discontinue the Aptima SARS CoV-2/Flu assay product at any time.*