COMMISSIONERS COURT
COMMUNICATION

COURT ORDER NUMBER 145363
PAGE 1 OF 7
DATE: 6/3/2025

SUBJECT: **HOLOGIC, INC. - PANTHER SYSTEM AND ASSOCIATED ASSAY KITS AND REAGENTS - PUBLIC HEALTH**

***** CONSENT AGENDA *****

COMMISSIONERS COURT ACTION REQUESTED

It is requested that the Commissioners Court approve renewal of Hologic, Inc. as sole source for the purchase of Panther System and Associated Assay Kits and Reagents, for Public Health.

BACKGROUND

On June 7, 2022, the Commissioners Court, through Court Order #138296, approved Hologic, Inc. as sole source for Panther System and Associated Assay Kits and Reagents.

On June 4, 2024, the Commissioners Court, through Court Order #143268, approved renewal of this sole source.

Hologic, Inc. provided the Purchasing Agent documentation to substantiate the fact that their sole source status has not changed and they continue to be the sole source provider for the Panther System and Associated Assay Kits and Reagents. Hologic, Inc. does not sell through dealers or distributors in the U.S. All sales are made directly to end users.

Tarrant County Public Health North Texas Regional Laboratory uses Hologic test kits, reagents, and Panther instruments for the diagnostic testing of Chlamydia, Gonorrhea, SARS-Co V-2 (Covid), and HIV. The test results provided to healthcare providers by the laboratory support the diagnosis, treatment, and prevention of the above listed infections.

Under the County Purchasing Act, exemptions to the competitive bidding requirements are allowed for certain types of purchases. The statutes require that the Purchasing Agent advise the Commissioners Court of the existence of only one (1) source, with such notice to be entered into the minutes of the Court.

Accordingly, the above item has been determined to be sole source under the County Purchasing Act 262.024(a)(7) as follows:

"(7) an item can be obtained from only one (1) source, including:
(A) items for which competition is precluded because of the existence of patents, copyrights, secret processes, or monopolies".
(D) captive replacement parts or components for equipment."

SUBMITTED BY	Purchasing	PREPARED BY:	Wanyu Chen
		APPROVED BY:	Christopher Lax, CPSM, CPSD, CPCP

FISCAL IMPACT

Orders are placed on an as-needed basis.

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January 30, 2025

To Whom It May Concern:

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

Instrument Systems

Cat. #303095 Panther® system, #PRD-06067 Panther® Plus system, #PRD-04172 Panther Fusion® system, and #PRD-04173 Panther Fusion® Module

Assay Kits for Use on the Panther® system – Cat. #303095, Panther® Plus system – Cat. No. PRD-06067, and Panther Fusion® system - Cat. #PRD-04172

Cat. #PRD-05571 Aptima Combo 2® Assay Kit – Panther System (250 test kit) and Cat. #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)±

Cat. #PRD-05074 Aptima CMV Assay – Panther System (100 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 for Use on the Panther® system – Cat. #303095 and Panther Fusion® system - Cat. #PRD-04172

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-06997 Direct Load Tube

Cat. #PRD-06816 Aptima SARS-CoV-2/Flu Assay Controls

Cat. #PRD-06817 Aptima SARS-CoV-2/Flu Panel B

Assay Kits for Use on the Panther Fusion® system - Cat. #PRD-04172 and Panther Fusion Module Upgrade – Cat. #PRD-04173

Cat. #PRD-04328 Panther Fusion Flu A/B/RSV Assay (96 tests)

Cat. #PRD-04329 Panther Fusion Paraflu Assay (96 tests)

Cat. #PRD-04330 Panther Fusion AdV/hMPV/RV Assay (96 tests)

Cat. #PRD-04303 Open Access Cartridges (96 Tests)

Cat. #PRD-06391 Panther Fusion SARS-CoV-2 Primer Probe Reagent Mix (160 tests)°

Cat. #PRD-07400 - SARS/FLU A/B/RSV REAGENT, CARTRIDGES, FUSION, IVD

Cat. #PRD-04484 - GBS REAGENT CARTRIDGES, 96-TEST, FUSION, IVD

The Panther fusion assays have been validated for use with the Panther Fusion system and Panther Fusion Module Upgrade. The firmware in the Panther Fusion system and Panther Fusion Module Upgrade is necessary for running the Panther Fusion assays and is unique to Hologic. Hologic is the sole source of this firmware.

Kits and Reagents Associated with the Assays Kits for Use on the Panther Fusion® system - Cat. #PRD-04172 and Panther Fusion Module Upgrade – Cat. #PRD-04173

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

Cat. #PRD-04000 Panther Fusion Tube Trays

Cat. #PRD-04337 Panther Fusion Paraflu controls

Cat. #PRD-04336 Panther Fusion Flu A/B/RSV controls

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Cat. #PRD-04338 Panther Fusion AdV/hMPV/RV controls

Cat. #PRD-04332 Panther Fusion Internal Control-S

Cat. #PRD-04333 Panther Fusion Reconstitution Buffer I

Cat. #PRD-04334 Panther Fusion Elution Buffer

Cat. #PRD-04335 Panther Fusion Oil Reagent

Cat. #PRD-04331 Panther Fusion Extraction Reagent-S

Cat. #PRD-04305 Open Access Pack - Fusion

Cat. #PRD-04477 Panther Fusion Extraction Reagent-X

Cat. #PRD-04476 Panther Fusion Internal Control-X

Cat. #PRD-04304 Aptima Oil Reagent

Cat. #PRD-04311 Primer/Probe Tubes, Open Access, Fusion

Cat. #PRD-04312 Primer/Probe Caps, Open Access, Fusion

Cat. #PRD-06404 Panther Fusion SARS-CoV-2 Controls

Cat. #PRD-07401 SARS/FLU A/B/RSV CONTROLS, FUSION, IVD

Cat. #PRD-07152 SARS/FLU A/B/RSV PANEL B, FUSION

Cat. #PRD-04485 GBS CONTROLS, FUSION, IVD

Cat. #PRD-07769 GBS PANEL 2, FUSION

Hologic does not sell through dealers or distributors in the U.S. All sales are made directly to end users. For additional patent information concerning the above products, please visit www.hologic.com/ip.

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

Sincerely,

Douglas Donovan
VP, US Sales, 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.

°The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to authorize the use of the Panther Fusion® SARS CoV-2 Assay on the Panther Fusion 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 Panther Fusion 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 Panther Fusion SARS CoV-2 assay has not been FDA cleared or approved. The Customer acknowledges and agrees that the Panther Fusion SARS CoV-2 Assay is only available for sale and use while the EUA is in effect. Hologic reserves the right to discontinue the Panther Fusion SARS CoV-2 Assay product at any time.

TAKINGS IMPACT ASSESSMENT CHECKLIST

Complete this form for any county action that involves the adoption of a regulation, policy, guideline, court resolution, or order.

Project/Regulation Name: Hologic, Inc. - Panther System and Associated Assay Kits and Reagents - Public Health

County Department: PURCHASING

Contact Person: Melissa Lee, C.P.M., A.P.P.

Phone Number for Contact Person: (817) 884-3245

Type of TIA Performed: (SHORT TIA) or FULL TIA. Circle one after answering the questions in Sections II and III below.

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I. Stated Purpose

Attach to this checklist an explanation of the purpose of the regulation, policy, guideline, court resolution, or order.

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Note: The remainder of this Takings Impact Assessment Checklist should be completed in consultation with the Criminal District Attorney's Office.

II. Potential Effect on Private Real Property

1. Does the county action require a physical invasion, occupation, or dedication of real property?

   Yes_____ No √

2. Does the county action limit or restrict a real property right, even partially, or temporarily?

   Yes_____ No √

If you answered yes to either question, go to Section III. If you answered no to both, STOP HERE and circle SHORT TIA at the top of the form.

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