

January 5, 2024

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)±

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**

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,



Douglas Donovan  
Vice President, US Sales, Diagnostic Solutions  
Hologic Sales and Service, LLC

*\*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.*