

January 2, 2019

To Whom It May Concern:

This letter is to verify that Hologic, Inc. ("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 Aptima Combo 2® Assay for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*, Kit – Panther System (250 test kit)

Cat. #302923 Aptima Combo 2 Assay for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*, Kit – Panther System (100 test kit)

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

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

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

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

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

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

Cat. # PRD-03705 Aptima HCV Quant 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)

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 Multitest Swab Specimen Collection Kit
- 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)

Hologic does not sell through dealers or distributors in the U.S. All sales are made directly to end users. Representative patents covering the above products in the U.S. include the following: 6,245,519, 6,910,720, 7,381,811, 9,523,133 9,598,723, and 9,624,557. For additional patent information concerning the above products, please visit <https://www.hologic.com/patent-information>.

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

Sincerely,



Thomas West  
Division President, Diagnostics

*\*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.*

**Gen-Probe Sales & Service, Inc. is a subsidiary of Hologic, Inc.**