April 24, 2018

To Whom It May Concern:

This letter is to verify that Hologic, Inc. is the sole source of the fully automated, nucleic acid-based system and associated kits and reagents listed below for use in determining the presence of *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae, human papillomavirus (HPV), and Trichomonas vaginalis* in a test sample.

Instrument System

Cat. #303095 Panther® System is covered by U.S. Patent Nos. 6,605,213, 7,135,145, 7,033,820, and 7,638,337.

Assay Kit for Use on the Instrument System

Cat. #303094 Aptima Combo 2® Assay for detection of *Chlamydia trachomatis and Neisseria gonorrhoeae* (250 test kit), and Cat. #302923 Aptima Combo 2 Assay for detection of *Chlamydia trachomatis and Neisseria gonorrhoeae* (100 test kit) are covered by U.S. Patent Nos. 6,090,591 and 7,172,863.

Cat. #303585 Aptima® HPV Assay for detection of *human papillomavirus (HPV)* (250 test kit) and Cat. #303570 Aptima HPV Assay for detection of *human papillomavirus (HPV)* (100 test kit) are covered by U.S. Patent Nos. 6,090,591 and 6,245,519.

Cat. # 303537 Aptima *Trichomonas vaginalis* Assay for detection of *T. vaginalis* (250 test kit) and Cat. #303536 Aptima *Trichomonas vaginalis* Assay for the detection of *T. vaginalis* (100 test kit) are covered by U.S. Patent Nos. 6,090,591, 6,245,519, 6,294,338 and 7,632,934.

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. #301162 Aptima Vaginal 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

Hologic does not sell through dealers or distributors in the U.S. Sales are made directly to the end user only. Additional patent information can be found by visiting www.hologic.com/ip.

If you have any questions or need any additional information, please feel free to call Hologic Customer Service at 1.800.442.9892.

Sincerely,

Thomas West
Division President, Diagnostics

**LEGAL NOTICE AND DISCLAIMER: The United States Food and Drug Administration (FDA) has not cleared or approved the use of urine collection devices for female urine specimens for use with the Aptima Combo 2 Assay on the Panther System. Accordingly, any such use of urine collection devices shall be at the sole risk of customer and Hologic shall have no liability therefor.*

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