

March 1, 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* in a test sample.

### **Instrument System**

Cat. #105118 Tigris DTS System

This product and its use are covered by one or more of the following patents: U.S. Patent No. D410,080; 6,335,166; 6,605,213; 6,658,946; 6,764,649; 6,890,742; 7,033,820; 7,118,892; 7,135,145; 7,267,795; 7,384,600; 7,396,509; 7,482,143; 7,524,652; 7,560,255; 7,560,256; 7,638,337; 7,666,602; 7,666,681; 8,137,620; 8,192,992; 8,221,682; 8,309,358; 8,318,500; 8,337,753; 8,546,110; 8,569,019; and 8,569,020.

### **Assay Kit for Use on the Instrument System**

Cat. #301130 Aptima Combo 2 Assay for detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* (250 test kit)

The contents of this product and its use are covered by one or more of the following patents: U.S. Patent No. 5,656,207; 5,656,744; 5,658,737; 5,693,468; 5,696,251; 5,714,324; 5,723,597; 5,756,709; 5,827,656; 5,834,254; 5,840,488; 5,840,873; 5,948,899; 6,090,591; 6,110,678; 6,150,517; 6,245,519; 6,280,952; RE37,891; 6,534,273; 7,070,925; and 7,172,863.

Cat. #301130B Aptima Combo 2 Assay for detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* (1000 test multi-pack)

The contents of this product and its use are covered by one or more of the following patents: U.S. Patent No. 5,656,207; 5,656,744; 5,658,737; 5,693,468; 5,696,251; 5,714,324; 5,723,597; 5,756,709; 5,827,656; 5,834,254; 5,840,488; 5,840,873; 5,948,899; 6,090,591; 6,110,678; 6,150,517; 6,245,519; 6,280,952; RE37,891; 6,512,105; 6,534,273; 7,070,925; and 7,172,863.

Cat. #301199 Aptima CT Assay for detection of *Chlamydia trachomatis* (250 test kit)

Cat. #302224 Aptima CT Assay for detection of *Chlamydia trachomatis* (2 x 50 test kit)

The contents of these products and their use are covered by one or more of the following patents: U.S. Patent No. 5,656,744; 5,693,468; 5,696,251; 5,714,324; 5,723,597; 5,834,254; 5,840,488; 5,948,899; 6,090,591; 6,110,678; 6,150,517; 6,280,952; RE37,891; and 7,070,925.

Cat. #302225 Aptima GC Assay for detection of *Neisseria gonorrhoeae* (2 x 50 test kit)

The contents of these products and their use are covered by one or more of the following patents: U.S. Patent No. 5,656,744; 5,696,251; 5,714,324; 5,723,597; 5,834,254; 5,840,488; 5,948,899; 6,090,591; 6,110,678; 6,150,517; 6,280,952; RE37,891; and 7,070,925.

The Aptima Assays have been validated for use with the Tigris DTS System. The firmware in the Tigris DTS 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. #301041 Aptima Unisex Swab Specimen Collection Kit for Endocervical and Urethral Swab Specimens

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

Cat. #301162 Aptima Vaginal Swab Specimen Collection Kit

Cat. #301154C Aptima Specimen Transfer Kit

Cat. #301048 Aptima Auto Detection Reagent Kit

Cat. #105575 Aptima Urine Collection Tubes, Bulk

Cat. #301110 Aptima Controls Kit

Cat. #302380 Aptima AC2 SYS FL PRES,TIG,IVD-CE

Cat. #302382 Aptima AC2 ASSAY FL, TIG, IVD-CE

Cat. #301191 Aptima Tigris Run Kit

Cat. #301189 Aptima Combo 2 Tigris DTS Start-Up kit (refrigerated)

Cat. #301190 Aptima Combo 2 Tigris DTS Start-Up kit (room-temp)

Hologic does not sell through dealers or distributors in the U.S. Sales are made directly to the end user only.

Please do not hesitate to contact me if you should need further assistance.

Sincerely,



Thomas West  
Division President, Diagnostics

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