



GEN-PROBE

January 3, 2013

Melissa Ervin MT (ASCP)
Laboratory Manager
Columbus Public Health
240 Parsons Ave
Columbus, Oh 43215

Dear Ms. Ervin:

This letter is to verify that Gen-Probe Incorporated 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; D520,352; 6,335,166; 6,605,213; 6,658,946; 6,764,649; 6,890,742; 7,033,820; Australian Patent No. 765623; 2001245365; European Patent No. 1075328.

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. 4,851,330; 4,950,613; 5,030,557; 5,185,439; 5,283,174; 5,288,611; 5,399,491; 5,437,990; 5,480,784; 5,512,445; 5,514,551; 5,541,308; 5,556,771; 5,567,587; 5,585,481; 5,601,984; 5,612,200; 5,614,387; 5,639,604; 5,641,631; 5,656,207; 5,656,744; 5,658,737; 5,688,645; 5,693,468; 5,696,251; 5,714,324; 5,723,597; 5,756,011; 5,756,709; 5,827,656; 5,834,254; 5,840,488; 5,840,873; 5,888,779; 5,948,899; 6,004,745; 6,031,091; 6,090,591; 6,110,678; 6,150,517; 6,245,519; 6,280,952; 6,410,276; 6,414,152; RE37,891; 6,512,105; 6,534,273; Australian Patent No. 605743; 613989; 616646; 618965; 619223; 626319; 630076; 633474; 650622; 651371; 699590; 710884; 726821; 734526; 737017; 738708; Canadian Patent No. 1,215,904; 1,278,987; 1,314,009; 1,319,336; 1,333,396; 1,339,303; 1,339,871; 1,339,872; 1,340,843; 2,201,595; and other international counterparts.

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. 4,851,330; 4,950,613; 5,030,557; 5,185,439; 5,283,174; 5,288,611; 5,399,491; 5,437,990; 5,480,784; 5,512,445; 5,514,551; 5,541,308; 5,556,771; 5,567,587; 5,585,481; 5,601,984; 5,612,200; 5,614,387; 5,639,604; 5,641,631; 5,656,207; 5,656,744; 5,658,737; 5,688,645; 5,693,468; 5,696,251; 5,714,324; 5,723,597; 5,756,011; 5,756,709; 5,827,656; 5,834,254; 5,840,488; 5,840,873; 5,888,779; 5,948,899; 6,004,745; 6,031,091; 6,090,591; 6,110,678; 6,150,517; 6,245,519; 6,280,952; 6,410,276; 6,414,152; RE37,891; 6,512,105; 6,534,273; Australian Patent No. 605743; 613989; 616646; 618965; 619223; 626319; 630076; 633474; 650622; 651371; 699590; 710884; 726821; 734526;



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737017; 738708; Canadian Patent No. 1,215,904; 1,278,987; 1,314,009; 1,319,336; 1,333,396; 1,339,303; 1,339,871; 1,339,872; 1,340,843; 2,201,595; and other international counterparts.

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. 4,946,958; 4,950,613; 5,030,557; 5,185,439; 5,283,174; 5,399,491; 5,437,990; 5,480,784; 5,512,445; 5,514,551; 5,556,771; 5,585,481; 5,612,200; 5,614,387; 5,639,604; 5,656,744; 5,693,468; 5,696,251; 5,714,324; 5,723,597; 5,834,254; 5,840,488; 5,888,779; 5,948,899; 6,004,745; 6,031,091; 6,090,591; 6,110,678; 6,150,517; 6,280,952; 6,410,276; 6,414,152; RE37,891; 6,512,105; 7,087,742; 7,090,972; Australian Patent No. 613989; 616646; 618965; 619223; 626319; 630076; 633474; 650622; 651371; 699590; 708583; 738708; Canadian Patent No. 1,278,987; 1,314,009; 1,319,336; 1,333,396; 1,339,303; 1,339,871; 1,339,872; 1,340,843; and other international counterparts.

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. 4,946,958; 4,950,613; 5,030,557; 5,185,439; 5,283,174; 5,399,491; 5,437,990; 5,480,784; 5,541,308; 5,556,771; 5,585,481; 5,612,200; 5,614,387; 5,639,604; 5,656,744; 5,696,251; 5,714,324; 5,723,597; 5,834,254; 5,840,488; 5,888,779; 5,948,899; 6,004,745; 6,031,091; 6,090,591; 6,110,678; 6,150,517; 6,280,952; 6,410,276; 6,414,152; RE37,891; 6,512,105; 7,087,742; 7,090,972; Australian Patent No. 613989; 616646; 618965; 619223; 626319; 630076; 633474; 650622; 651371; 699590; 737017; 738708; Canadian Patent No. 1,278,987; 1,314,009; 1,319,336; 1,333,396; 1,339,303; 1,339,871; 1,339,872; 1,340,843; and other international counterparts.

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 Gen-Probe. Gen-Probe 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. Gen-Probe 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



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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)

Gen-Probe 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 personally if you should need further assistance.

Sincerely,

Brian B. Hansen
Senior Vice President, North American
Diagnostic Sales and Customer Support