

# CITY OF COLUMBUS – SOLE SOURCE INFORMATION FORM

To accompany legislation which waives any provisions of  
Columbus City Code Chapter 329  
(LIMIT YOUR RESPONSE TO THIS SHEET)

**Name: Gen-Probe Technologies**

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**1. Verification of sole source: (Why no other individual or business entity is capable of supplying the needed item/service.**

- Sole source manufacturer/distributor.
- Sole source distributor authorized for this territory.
- Patented product purchased for owner/developer.
- Sole company offering this unique service.
- Other:

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**2. Describe any effort to bid for alternate item (service or product) that is not provided by a sole source that would meet this need:**

The Gen-Probe Tigris/Aptima Gonorrhea& Chlamydia tests offer the best combination of accuracy, ease of use, automation, amplification and cost effectiveness for our public health needs. We have been using Gen-Probe for over 15 years. These tests are proprietary items.

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**3. Describe efforts to determine/verify that the company is the sole source:**

No other company has an isothermal amplification system capable of simultaneous detection of Gonorrhea & Chlamydia in swab or urine specimens.

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**4. Indicate how the price or fee structure was determined:**

Pricing sheet noted on following sheet, fixed until 2014

Gen- Probe Pricing 2010  
Pricing guaranteed until November 2014

Item	QTY	Price	Part #
Multi pack Test kit	1000	\$12,750.00	1130B
Aptima urine	50	\$62.50	1040
Aptima swab	50	\$62.50	1041
Aptima auto detection*	1000	-----	1048-01
STD Panel (proficiency panel)			2325
TECAN TIPS	9600	\$850.00	901121
Aptima Controls	5 sets	\$150.00	1110
AR spare Caps, Amp & Probe	100 bag	\$75.00	CL0041
AR spare Caps, Enzyme	100 bag	\$87.50	501616
AR spare Caps, TCR/Select	100 bag	\$32.50	CL0040
*Lower bay fluids & system pres.	1000	-----	2382 2380
Run Kit	13000	-----	1191
Lower Bay oil reagent		-----	LR0354
Pierceable caps		\$50.00	5668



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Tuesday, June 01, 2010

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

Dear Melissa:

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<sup>®</sup> DTS<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> CT Assay for detection of *Chlamydia trachomatis* (250 test kit)

Cat. #302224 APTIMA<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> Assays have been validated for use with the TIGRIS<sup>®</sup> DTS<sup>®</sup> 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<sup>®</sup> Unisex Swab Specimen Collection Kit for Endocervical and Urethral Swab Specimens

Cat. #301040 APTIMA<sup>®</sup> Urine Specimen Collection Kit for Male and Female Urine Specimens

Cat. #301162 APTIMA<sup>®</sup> Vaginal Swab Specimen Collection Kit

Cat. #301154C APTIMA<sup>®</sup> Specimen Transfer Kit

Cat. #301048 APTIMA<sup>®</sup> Auto Detection Reagent Kit

Cat. #105575 APTIMA<sup>®</sup> Urine Collection Tubes, Bulk

Cat. #301110 APTIMA<sup>®</sup> Controls Kit

Cat. #302380 APTIMA<sup>®</sup> AC2 SYS FL PRES, TIG, IVD-CE

Cat. #302382 APTIMA<sup>®</sup> 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*  
SR VP & GENERAL COUNSEL

for

Brian B. Hansen  
Vice President, North American Sales