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February 1, 2010

CLIENT LETTER — TEST UPDATES

Dear Colleague:

Pathology, Inc. is pleased to announce the availability of five new assays for identifying gynecologic-related infections:

- **AFFIRM™ Microbial Identification Test for Vaginitis [527]**
- **Herpes Simplex Virus Types 1 & 2 [522]**
- **Herpes Simplex Virus Type 1 [520]**
- **Herpes Simplex Virus Type 2 [521]**
- **ThinPrep® 5-in-1 Liquid-Based Pap Test (HPV Reflex, NG, CT, HSV-1 / HSV-2) [528]**

The **AFFIRM™ Microbial Identification Test for Vaginitis [527]**, which includes the detection of *Candida* species, *Trichomonas vaginalis*, and *Gardnerella vaginalis*, is performed using the FDA approved DNA probe technology by Becton-Dickinson. The assay can identify the most common causes of infectious vaginitis, even in mixed infections, with a turnaround time of the following business day. The assay requires use of the BD AFFIRM™ VPlll collection and transport kit. Please call client services at 877-922-7284 to request your collection kits.

The **Herpes Simplex Virus Types 1 & 2 (HSV-1 / HSV-2) [522]** test identifies the presence of HSV-1 or HSV-2 and is performed by polymerase chain reaction (PCR). Turnaround time is 48 to 72 hours. Proper HSV identification is important in selecting the most appropriate treatment option, particularly in pregnant women. At this time, the Herpes Simplex viral tests will be offered only on ThinPrep® prepared specimens. The test is not offered with SurePath™ prepared specimens due to low levels of specificity and sensitivity with the current methodology.

Testing for Herpes Simplex Virus types 1 & 2 can be ordered individually or for your convenience, we offer the HSV 1 & 2 test as part of our new **ThinPrep® 5-in-1 Liquid-Based Pap Test (HPV reflex, NG, CT, HSV-1 / HSV-2) [528]** profile. Results are available in 48 to 72 hours. Please note that this test is not a covered benefit for Medi-Cal Family Pact or PE patients.

We thank you for choosing Pathology, Inc. and look forward to your continued support. For additional information, please visit our website at www.pathologyinc.com or contact client services at 877-922-7284.

Respectfully yours,

A handwritten signature in black ink, appearing to read "Alfred Lui".

Alfred Lui, M.D.
Chief Medical Officer



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New Tests

Available February 1, 2010

527 AFFIRM™ Microbial Identification Test for Vaginitis

<u>Component</u>	<u>Method</u>	<u>Reference Range/Units</u>
<i>Candida</i> species	DNA probe	Positive/Negative
<i>Trichomonas vaginalis</i>		
<i>Gardnerella vaginalis</i>		

Specimen/Stability	BD Vaginal swab: Ambient temperature for 72 hours
Collection Instructions	BD AFFIRM™ VPIII collection and transport kit required
Schedule	Mon - Fri
Report	Next business day
Sensitivity*	Relative to Microscopy: <i>G. vaginalis</i> – 95%, <i>T. vaginalis</i> – 93% Relative to Culture: <i>Candida</i> species – 82%, <i>G. vaginalis</i> - 98%, <i>T. vaginalis</i> - 90%
Specificity*	Relative to Microscopy: <i>G. vaginalis</i> – 100%, <i>T. vaginalis</i> – 99.9% Relative to Culture: <i>Candida</i> species – 98.4%, <i>G. vaginalis</i> – 100% <i>T. vaginalis</i> – 99.9%
Clinical Utility	CDC indicates that both <i>Trichomonas</i> and bacterial vaginosis may put a woman at increased risk for some complications of pregnancy, such as preterm delivery, and can increase the risk of post gynecological surgery infections. If left untreated, both conditions could lead to Pelvic Inflammatory Disease (PID). Detection of microbial components of vaginitis can assist with proper patient management and treatment planning.

*Test performance characteristics data is based on Becton Dickinson kit insert

522 Herpes Simplex Virus Types 1 & 2 (HSV-1 and HSV-2)

520 Herpes Simplex Virus Type 1 (HSV-1)

521 Herpes Simplex Virus 2 (HSV-2)

528 ThinPrep® 5-in-1 Liquid-based Pap (HPV reflex, NG, CT, HSV-1 / HSV-2)

<u>Component</u>	<u>Method</u>	<u>Reference Range/Units</u>
Herpes Simplex 1 & 2	PCR	Positive/Negative/ Indeterminate

Specimen/Stability	ThinPrep® liquid Pap: Ambient temperature for 14 days
Collection Instructions	Cervical brush, spatula, broom (No Swabs)
Report	48 to 72 hours
Clinical Utility	Genital Herpes is an infectious, sexually transmitted disease, which can lead to potentially fatal infections in babies born to women with an active herpes infection. Detection and identification of HSV-1 and HSV-2 is especially important in treatment planning for pregnant women and people with immune suppressed systems.