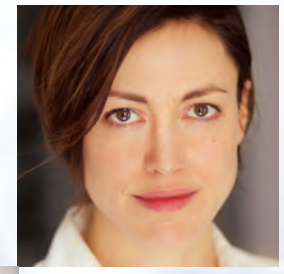
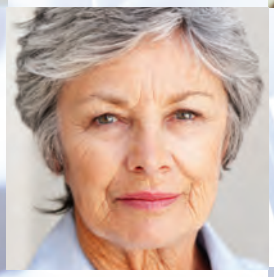
eurofins | Diatherix



Genital Health

The Right Test –
For the Right Time

Genital Health

Developed by a unique laboratory providing accurate and actionable results in one day for infectious diseases and antibiotic resistance genes utilizing innovative molecular technologies, including proprietary TEM-PCR™.

DxRx *Linking Diagnostics to Therapeutics™*

Eurofins Diatherix Distinctions:

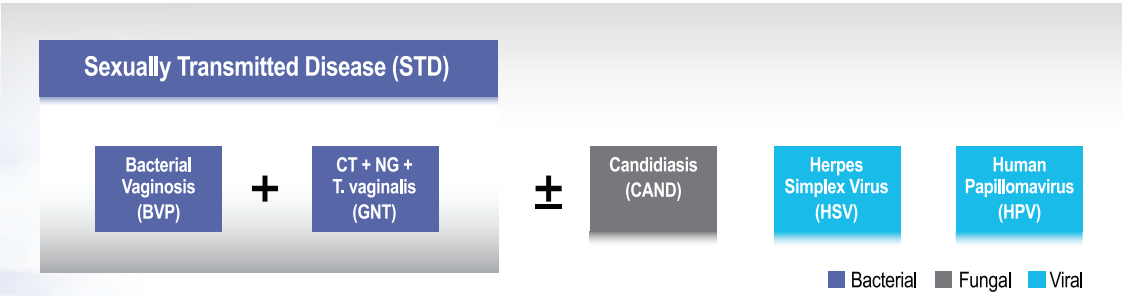
- *Delivers one-day results*
- *Identifies bacteria regardless of recent antibiotic use*
- *Offers simplicity of single-sample collection*
- *Identifies difficult-to-culture pathogens*
- *Yields a high level of sensitivity and specificity*

Eurofins Diatherix Benefits:

TEM-PCR technology is a proprietary, multiplex amplification platform designed to overcome the challenges that exist with conventional laboratory methods.

Improved speed and accuracy of laboratory results lead to:

- *Reduced antibiotic utilization*
- *Improved patient outcomes*
- *Cost reduction and avoidance*
- *Increased patient satisfaction*
- *Greater clinical value*



Sexually Transmitted Disease:

Designed to provide diagnostic information on patients who present with symptoms of sexually transmitted diseases. This test identifies 8 bacterial pathogens.

Comprehensive screening for sexually transmitted disease (STD) pathogens improves patient outcomes and reduces the risks of transmission to sexual contacts according to the recommendations set-out by the Centers for Disease Control (CDC).[1]

Bacterial Vaginosis:

Designed to identify 5 bacterial pathogens providing diagnostic information on patients with suspected Bacterial Vaginosis. BV has been linked to preterm delivery in pregnant females, and the risk of acquiring STDs and HIV.[2]

The CDC warns that culture of many of the organisms associated with BV (including Atopobium vaginae and Gardnerella vaginalis) is not recommended as a diagnostic tool because it is not practical and specific. In addition, cervical Pap tests have no clinical utility for the diagnosis of BV because of their low sensitivity.[3]

CT + NG + *T. vaginalis*:

Designed to identify the 3 principal organisms associated with STDs in the U.S. *Prevalence rates of many sexually transmitted diseases are highest among adolescents. Most Chlamydia infections are asymptomatic and may persist if left untreated. The AAP recommends annual screening for Chlamydia trachomatis and Neisseria gonorrhoeae for all sexually active female adolescents and young adults aged younger than 25 years.*[4]

Candidiasis:

This test provides diagnostic information for symptomatic females and identifies 5 different types of Candida.

Vulvovaginal candidiasis (VVC) is the second most common cause of vaginitis. Although vaginal candidiasis is most commonly caused by Candida albicans, it can be caused by other species of Candida that may not respond to conventional anti-fungal medications.

Herpes Simplex Virus:

This test provides diagnostic information on symptomatic patients with typical ulcerations. A significant number of infected patients can be intermittently asymptomatic, continue to shed virus, and may infect sexual contacts[5]. This test identifies Herpes Simplex Virus type 1 and type 2.

Both HSV-1 and HSV-2 can cause similar genital and orofacial primary infections after contact with infectious secretions containing either HSV-1 (usually oral secretions) or HSV-2 (usually genital secretions).

HPV High Risk Typing:

Designed to provide diagnostic information on patients who may be infected with Human Papillomavirus (HPV), and identifies 15 High Risk HPV types.

HPV is a common virus that is spread through sexual contact. Most often, HPV has no symptoms and those who are infected are unaware. Some HPV types can cause changes in a woman's cervix which can lead to cancer over time.[6]

Genital Health Tests:

The tests below can be ordered as single or multiple test combinations.

Sexually Transmitted Disease:
Atopobium vaginae
Chlamydia trachomatis
Gardnerella vaginalis
Mycoplasma genitalium
Mycoplasma hominis
Neisseria gonorrhoeae
Trichomonas vaginalis
Ureaplasma urealyticum

Bacterial Vaginosis:
Atopobium vaginae
Gardnerella vaginalis
Mycoplasma genitalium
Mycoplasma hominis
Ureaplasma urealyticum

CT+NG+T. Vaginalis:
Chlamydia trachomatis
Neisseria gonorrhoeae
Trichomonas vaginalis

Candidiasis:
Candida albicans
Candida glabrata
Candida krusei
Candida parapsilosis
Candida tropicalis

Herpes Simplex Virus:
Herpes Simplex Virus type 1
Herpes Simplex Virus type 2

HPV High Risk Typing:
HPV High Risk types: 16, 18, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 67, 68

Accurate diagnostic results lead to better treatment for patients.

(STD) TEST PATHOGEN DETECTION	# Tests	%Tests**
1 detection	158,479	28.18%
2 detections	134,897	23.98%
3+ detections	63,052	11.21%
Zero detection	206,012	36.63%
Total tests	562,440	100.00%

*** Data on file: August, 2010 – December, 2019*

Advantages of TEM-PCR detection of *Chlamydia trachomatis*:

- **Enhances sensitivity due to the inclusion of two gene targets –** *one plasmid and one genomic*
  - Many Nucleic Acid Amplification Tests for Chlamydia only incorporate the plasmid target.
- **Tests for sufficient cellularity –** Chlamydia is an intracellular organism requiring a sufficient number of epithelial cells in the specimen to prevent a "false negative" result.
  - TEM-PCR includes a host cell control to ensure the specimen is adequate.
  - Current commercial assays that only test for the Chlamydia plasmid target do not have a control to ensure the specimen is adequate.

References:

1. Sexually Transmitted Diseases Treatment Guidelines. CDC MMWR, December 17, 2010, Vol. 59 Number RR-12.
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4. Screening for Nonviral Sexually Transmitted Infections in Adolescents and Young Adults: Pediatrics, Official Journal of the American Academy of Pediatrics Number 1, July 2014: 302-311.
5. G.J. Mertz. Asymptomatic Shedding of Herpes Simplex Virus 1 and 2: Implications for Prevention of Transmission. J. Infect. Dis. (2008) 198(8): 1098-1100.
6. Han et al. Simultaneous amplification and identification of 25 Human Papillomavirus Types with Templex Technology. Journal of Clinical Microbiology. Nov. 2006: 4157-4162.

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