STD-6 Panel

Product Design

- The INFINITI™ STD-6 Assay is designed to detect six common sexually transmitted pathogens:
  - *Chlamydia trachomatis*
  - *Mycoplasma genitalium*
  - *Neisseria gonorrhoeae*
  - *Mycoplasma hominis*
  - *Ureaplasma urealyticum*
  - *Trichomonas vaginalis*
- The INFINITI STD-6 Assay utilizes the STD-6 Intellipac™, STD-6 Amp Mix and the STD-6 BioFilmChip™ Microarray.
- The INFINITI STD-6 Assay is automated by the 510(k) cleared INFINITI Analyzer.
- Clinical validation is currently in progress.

Benefits

VERSATILITY	Simultaneous multiplexed determination of six sexually transmitted microorganisms
EFFICIENCY	Rapid turnaround time enhances workflow efficiency
AGILITY	*Load N Go* automation with the INFINITI Analyzer
INTEGRITY	Replicate determinations on a single BioFilmChip Microarray ensure quality results

Microorganisms

Chlamydia trachomatis
Neisseria gonorrhoeae
Ureaplasma urealyticum
Mycoplasma genitalium
Mycoplasma hominis
Trichomonas vaginalis

Sample Type and Volume

Endocervical or urethral swab in 1 to 3 ml sample transport medium
Urine: to be evaluated

Product Information

Product No.	Product Name	Description	Pack Size
04 103	INFINITI STD BioFilmChip	12 BioFilmChips/magazine	4 Magazines / pack
04 203	INFINITI STD Intellipac	24 tests/IntelliPac	2 Intellipac / pack
04 303	INFINITI STD Amp Mix	250 ul/vial	4 vials / pack
12 010	STD-6 Control: CT	1 x 150 µL / pack	1 pack / case
12 011	STD-6 Control: NG	1 x 150 µL / pack	1 pack / case
12 012	STD-6 Control: TV	1 x 150 µL / pack	1 pack / case
12 013	STD-6 Control: UU	1 x 150 µL / pack	1 pack / case

Please contact AutoGenomics to obtain product information and for product status updates.

SM-40052 / 0508

1-866-STAT-MDx
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Product Information (cont.)

Product No.	Product Name	Description	Pack Size
12 014	STD-6 Control: MG	1 x 150 µL / pack	1 pack / case
12 015	STD-6 Control: MH	1 x 150 µL / pack	1 pack / case
12 016	STD-6 Controls Combo Pack (CT, NG, TV, UU, MG, MH)	6 x 150 µL / pack	1 pack / case
12 017	STD-6 Internal Control (Pos)	1 x 60 µL / pack	1 pack / case

Clinical Relevance

- Chlamydia trachomatis has been called the "silent epidemic" of reproductive age women and is the most common sexually transmitted bacterial infection in the United States. The majority of chlamydial infections in women are asymptomatic and, untreated may cause pelvic inflammatory disease (PID) and associated complications such as ectopic pregnancy, infertility, and chronic pelvic pain.[1]
- Neisseria gonorrhoeae is a major cause of pelvic inflammatory disease and may lead to tubal infertility, ectopic pregnancy and chronic pelvic pain. This microorganism can also cause urethritis in both men and women.[2]
- The ability of Mycoplasma genitalium, Mycoplasma hominis and Ureaplasma urealyticum to cause nongonococcal urethritis and cervicitis has been well established.[3]
- Mycoplasma hominis has also been linked to bacterial vaginosis, pelvic inflammatory disease, infertility, miscarriage, preterm labor, respiratory distress in newborns and neonatal meningitis.[3]
- Ureaplasma urealyticum is associated with preterm labor, intrauterine lung disease and neonatal pneumonia.[3]
- Trichomonas vaginalis, a parasitic protozoan, has been implicated as a cause in urethritis, adverse pregnancy outcomes and has been associated with an increased risk of human HIV transmission.[4, 5]

Clinical Utility

- Current guidelines from the Centers for Disease Control and Prevention (CDC) recommend STD screening for all high-risk women-usually defined as those younger than 25 and those with multiple or new partners.[6]
- STD prenatal screening is particularly important for positive pregnancy outcomes. Surveys suggest that universal prenatal screening is below recommended guidelines.[7]
- In the presence of urinary symptoms, testing for both urinary tract infections (UTIs) and sexually transmitted infections (STIs) may be helpful in directing initial therapy. Studies have demonstrated that 20% of adult women with culture-proven UTIs have concomitant vaginal or cervical infections with sexually transmitted organisms such as Trichomonas vaginalis, Chlamydia trachomatis, Neisseria gonorrhoeae.[8]
- Concurrent diagnoses in genital tract infections are frequent. Broad testing on the initial visit, instead of treating one entity at a time, could improve outcomes and save money.[9]
- Eliminate the need for specimen recollection and reculture in cases where a patient is presenting with concerns about STD exposure subsequent to examination.

References

1. Guerry SL, Bauer HM, Packel L, Samuel M, Chow J, Rhew M, Bolan G. Chlamydia screening and management practices of primary care physicians and nurse practitioners in California. J Gen Intern Med 2005 Dec;20(12):1102-1107.
2. Biro FM, Rosenthal SL, Kiniyalocts M. Gonococcal and chlamydial genitourinary infections in symptomatic and asymptomatic adolescent women. Clin Pediatr (Phila) 1995;34:419-423.
3. Schlicht MJ, Lovrich SD, Sartin JS, Karpinsky P, Callister SM, Agger WA. High prevalence of genital mycoplasmas among sexually active young adults with urethritis or cervicitis symptoms in La Crosse, Wisconsin. J Clin Microbiol 2004 Oct; 42(10):4636-4640.
4. Heine P and MacGregor JA. Trichomonas vaginalis: a re-emerging pathogen. Clin Obstet Gynecol 1993; 36:137-144.
5. Sorvillo F and Kerndt P. Trichomonas vaginalis and amplification of HIV-1 transmission. Lancet 1998;351:213-214.
6. Kershaw TS and Lewis J. Using clinical classification trees to identify individuals at risk of STDs during pregnancy. Perspect Sex Reprod Health 2007 Sept; 39(3): 141-148.
7. St. Lawrence JS, Montano DE, Kasprzyk D, Phillips RP, Armstrong K, Leichliter JS. STD screening, testing, case reporting, and clinical and partner notification practices: a national survey of US physicians. Am J Public Health 2002 Nov; 92(11):1784-1788.
8. Huppert JS, Biro F, Lan D, Mortensen JE, Reed J, Slap GB. Urinary symptoms in adolescent females: STI or UTI? J Adolesc Health 2007 May; 40(5): 418-424.
9. Carr PL, Rothberg MB, Friedman RH, Felsenstein D, Pliskin JS. "Shotgun" versus sequential testing. Cost-effectiveness of diagnostic strategies for vaginitis. J Gen Intern Med 2005 Sept; 20(9); 793-799.