

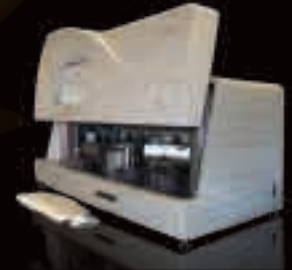
HPV Genotyping

Complete HPV Type Identification

SPOT ON

INFINITI™

The Automated Multiplexing MDx Solution



Product Design

- ▶ The INFINITI™ System HPV Genotype Panel is designed to detect 26 human papillomaviruses present in liquid cervical pathology specimens.
- ▶ The INFINITI System HPV Genotype Panel utilizes the HPV Genotype Panel Intellipac™, HPV Genotype Panel Amp Mix and HPV Genotype Panel BioFilmChip™ Microarray.
- ▶ The INFINITI HPV Genotype Panel can be automated by the 510(k) cleared INFINITI Analyzer.
- ▶ Clinical validation is currently in progress.

Benefits

	VERSATILITY	◆	Simultaneous multiplexed determinations of 26 human papillomavirus viruses with a single sample.
	EFFICIENCY	◆	Rapid turnaround time enhances workflow efficiency
	AGILITY	◆	<i>Load N Go</i> automation with the INFINITI Analyzer
	INTEGRITY	◆	Replicate determinations on a single microarray ensure quality results

Genetic Variants

HPV types:

High Risk	16, 18, 31, 33, 34, 35, 39, 45, 53, 58, 59, 66, 68
High Intermediate Risk	26, 51, 52, 56, 67, 69, 73, 82
Low Risk	6, 11, 30, 70, 85

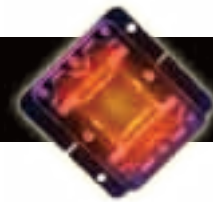
Sample Type and Volume

ThinPrep®	1.0ml
SurePath®	0.5ml

Product Information

Product No.	Product Name	Description	Pack Size
02 105	INFINITI HPV Genotype BioFilmChip	12 BioFilmChips/magazine	4 Magazines / pack
02 205	INFINITI HPV Genotype Intellipac	24 tests/IntelliPac	2 Intellipac / pack
02 305	INFINITI HPV Genotype Amp Mix	250 ul/vial	4 vials / pack

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

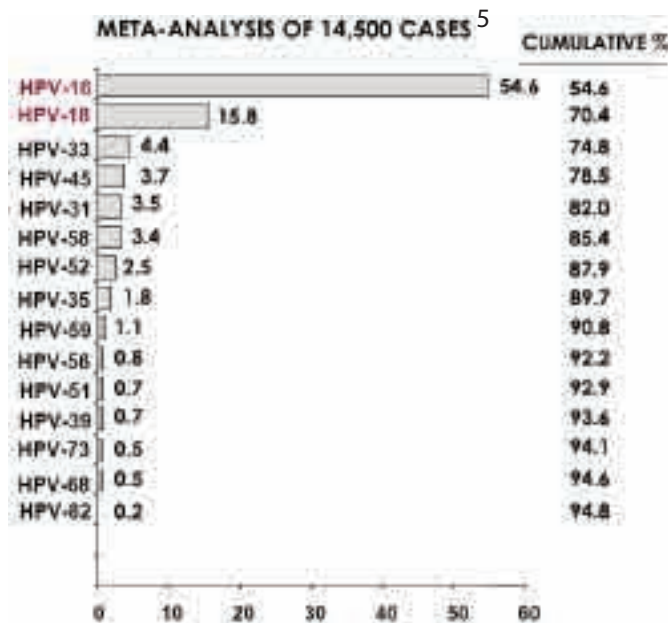


Clinical Relevance

- ▶ High Risk HPV types are detected in 99% of cervical cancers.¹
- ▶ HPV prevalence is 26.8% for women in the US aged 14–59 yrs¹
- ▶ Approximately 8% of HPV positive patients have multi-HPV type infections²
- ▶ Simultaneous HPV type infections increase the risk of squamous-cell cervical cancer²
- ▶ Cervical adenocarcinomas are increasing in developed countries³

Clinical Utility

- ▶ "...typing of HPV16 and HPV18, might be a more powerful predictor of future CIN3 and cancer than ASC or even LSIL cytology."⁴
- ▶ Risk of cervical cancer with Type16 plus another high risk type is 617.4 (odds ratio) vs. Type 6 at 4.3²
- ▶ Highest risk for cervical adenocarcinoma are from HPV types 18, 16, 59 and 33³



References

1. E.F.Dunne, et al., "Prevalence of HPV Infection Among Females in the United States", JAMA, Feb.28, 2007, Vol.297, No. 8, pp. 813-819.
2. N. Munoz, et al., "Epidemiologic Classification of Human Papillomavirus Types Associated With Cervical Cancer", NEJM Vol.348, No.6, Feb.6, 2003, P.518-527.
3. X.Castellsague, et al., "Worldwide Human Papillomavirus Etiology of Cervical Adenocarcinoma and Its Cofactors: Implications for Screening and Prevention", JNCI, Vol.98, No.5, p.303-315, March 1, 2006
4. M.J.Khan, et al. "The elevated 10-year risk of cervical precancer and cancer in women with human papillomavirus (HPV) type 16 or 18 and the possible utility of type-specific HPV testing in clinical practice", JNCI, Vol.97, No.14, p.1072-1079, July 20, 2005.
5. [http://www.ibec.ie/Sectors/ibia/ibiaDoclib3.nsf/wvPreviousEvents/F751D6597628AB488025723400582D3B/\\$File/21+John+Schiller.pdf](http://www.ibec.ie/Sectors/ibia/ibiaDoclib3.nsf/wvPreviousEvents/F751D6597628AB488025723400582D3B/$File/21+John+Schiller.pdf)