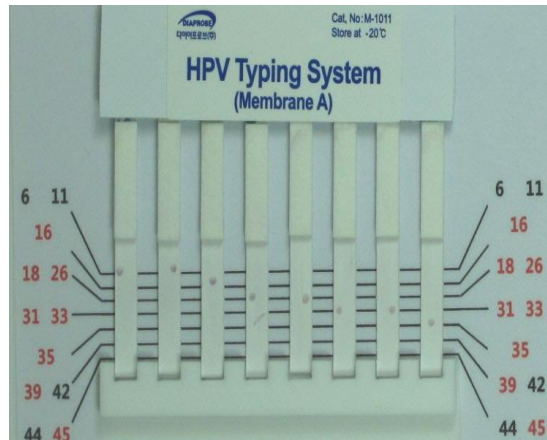
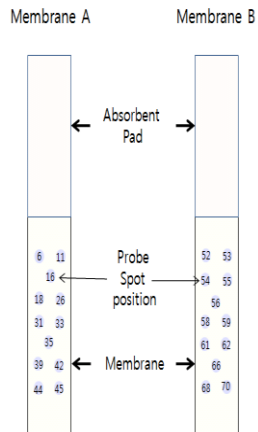
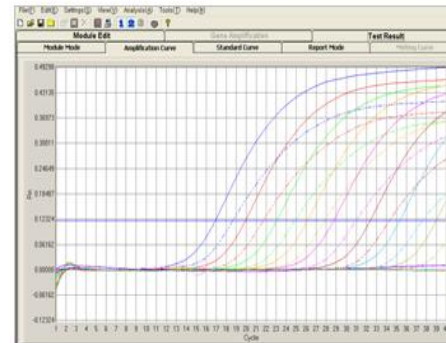


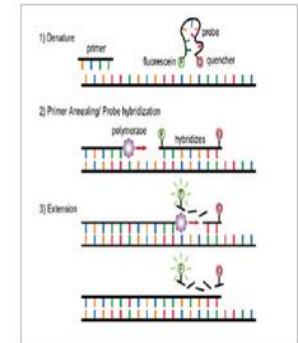
HPV and STD Multiplex PCR



HPV genotyping DNA array



(Typical real-time PCR curves)

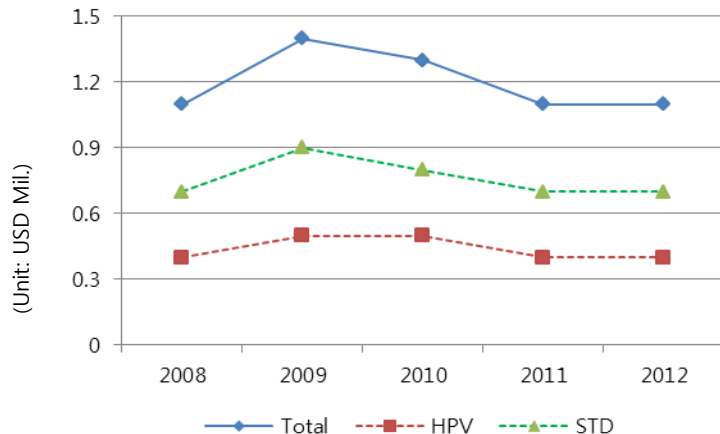


(Principle of Real-time PCR)

HPV and STD Real-time PCR



*** Total Revenue ***



Unit: USD 1 = KRW 1,000

▪ **Molecular diagnostic service**

- Multiplex/Real time PCR service
- Consignment HPV/STD mol., Dx test from hospitals and centralized lab in Korea
- Use swab sample
- **In processing KFDA Approval(STD)**

▪ **Sales**

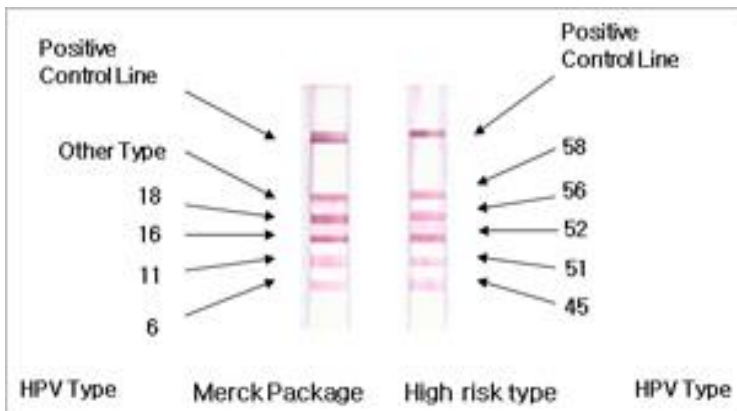
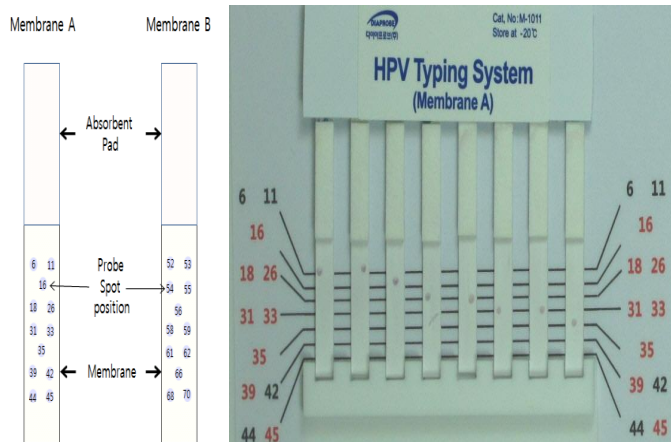
Market share No. 2 in HPV/STD mol., Dx service and related area from 2008 to present

▪ **Target Market**

Clinical centralized laboratories, Local/Mid/Big Hospital

▪ **Success Points**

- Professional scientific knowledge/wet experiment know-how
- High sensitivity & specificity result
- Technical supports for customers
- **Publishing scientific result onto the journals and Patents**



▪ **Molecular diagnostic tools & Kits**

- PCR based and to reduced cost and to increase PCR efficiency
- **Considerations of supplying as the LDT(laboratory developed test) items.**

▪ **Strong Points**

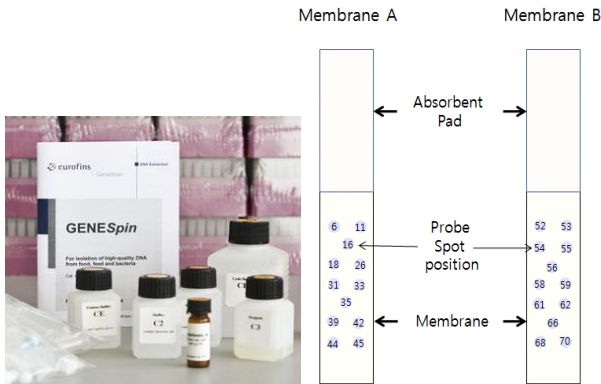
- **Creative ideas**
- **Know-how** through long-term experiences in mol., Dx area

▪ **Certifications**

- ISO 9001, CE/IVD (planning in 2013)

▪ **Patents**

- A method for detecting a specific nucleic acid, a kit therefor and an apparatus for driving it: **KR 10-0401389-0000.**
- A measure for hormone relate to down's syndrome and a kit therefor: **KR 10-0401390-0000.**
- Using membrane as a support, a method for the preparation thereof and a method for detection of proteins using the chip: **KR 10-0492393-0000.**
- Method for the detection and analysis of nucleotide sequence using membrane lateral flow, and kit for the same: **KR 10-0679088-0000.**



▪ HPV genotyping DNA array

- HPV PCR and membrane array based genotyping kit
- Reduced assay time against existed DNA chip methods **(from 6 to 2.5h)**
- Enable high throughput test
- 24 Types HPV
- Published patent (No. KR 10-0679088-0000)

▪ Target market and

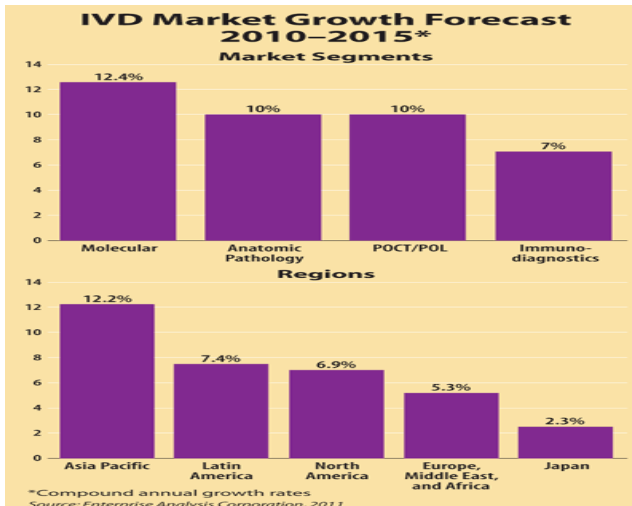
- Centralized lab and Diagnostic laboratories in Hospitals
- WHO, CDC tender
- Synergy effects with HPV vaccine promotions

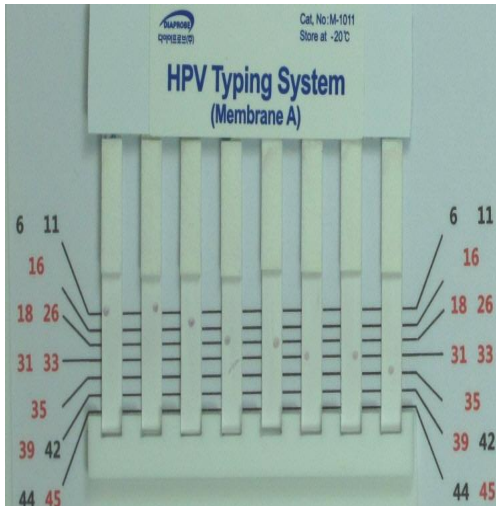
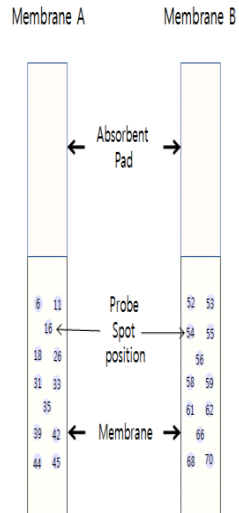
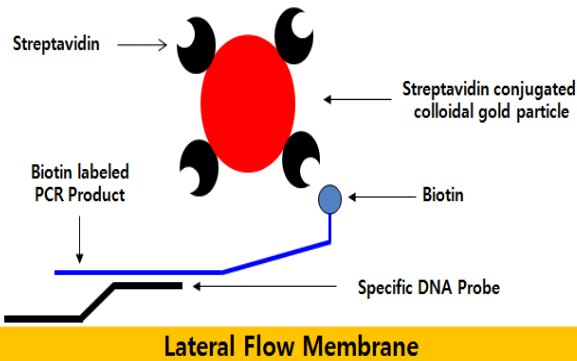
▪ Applications

- 100% compatible with existing HPV PCR kit

▪ Molecular diagnostics

- **Emerging and 10% more grown market**





Composition

- HPV PCR master mix
- HPV membrane array A and B
- Nano gold solution
- Positive control

Formation

- High risk: 16, 18, 26, 31, 33, 35, 39, 45, 52, 56, 58, 59, 66, 68, 70
- Low risk: 6, 11, 42, 44, 53, 54, 55, 61, 62

Workflow

- Extract DNA from the swab sample (Not included extraction kit)
- HPV PCR
- Hybridize PCR product with captured probes on the strips
- React nano-gold solution onto the strips
- Read

Further works

- **Capable of developing new membrane array (Short term - STD, Biochemical weapon detection)**



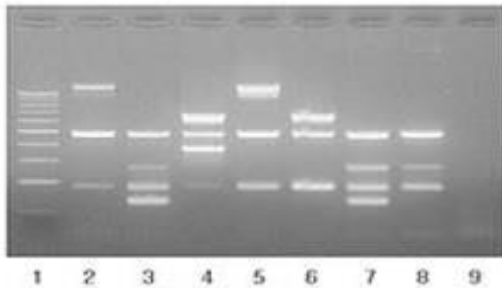
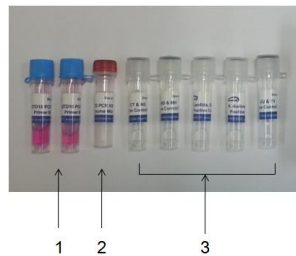
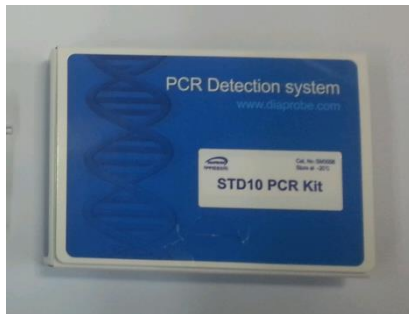
DATA SHEET

▪ Limit of Detection(LOD)

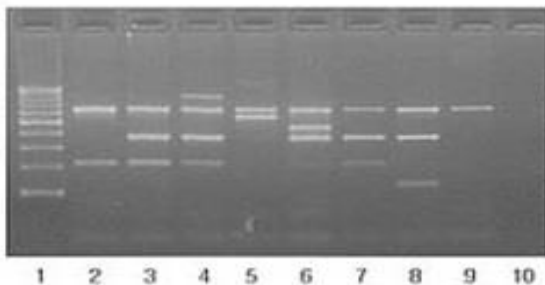
	6	11	16	18	26	31
LOD	10 ⁻³	10 ⁻⁴	10 ⁻⁵	10 ⁻⁵	10 ⁻²	10 ⁻³
	1pg/μℓ	100fg/μℓ	10fg/μℓ	10fg/μℓ	10pg/μℓ	1pg/μℓ
	33	35	39	42	44	45
LOD	10 ⁻⁵	10 ⁻⁵	10 ⁻²	10 ⁻¹	10 ⁻³	10 ⁻⁵
	10fg/μℓ	10fg/μℓ	10pg/μℓ	100pg/μℓ	1pg/μℓ	10fg/μℓ
	52	53	54	55	56	58
LOD	10 ⁻²	10 ⁻²	10 ⁻⁵	10 ⁻³	10 ⁻¹	10 ⁻³
	10pg/μℓ	10pg/μℓ	10fg/μℓ	1pg/μℓ	100pg/μℓ	1pg/μℓ
	59	61	62	66	68	70
LOD	10 ⁻³	10 ⁻³	10 ⁻²	10 ⁻²	10 ⁻³	10 ⁻³
	1pg/μℓ	1pg/μℓ	10pg/μℓ	10pg/μℓ	1pg/μℓ	1pg/μℓ

▪ Cut off Value

	6	11	16	18	26	31
Cut off Value	10 ⁻³	10 ⁻⁴	10 ⁻⁴	10 ⁻⁵	10 ⁻²	10 ⁻³
	1pg/μℓ	100fg/μℓ	100fg/μℓ	10fg/μℓ	10pg/μℓ	1pg/μℓ
	33	35	39	42	44	45
Cut off Value	10 ⁻⁵	10 ⁻⁵	10 ⁻²	10 ⁻¹	10 ⁻³	10 ⁻⁵
	10fg/μℓ	10fg/μℓ	10pg/μℓ	100pg/μℓ	1pg/μℓ	10fg/μℓ
	52	53	54	55	56	58
Cut off Value	10 ⁻²	10 ⁻²	10 ⁻⁴	10 ⁻³	10 ⁻¹	10 ⁻³
	10pg/μℓ	10pg/μℓ	100fg/μℓ	1pg/μℓ	100pg/μℓ	1pg/μℓ
	59	61	62	66	68	70
Cut off Value	10 ⁻³	10 ⁻²	10 ⁻²	10 ⁻¹	10 ⁻³	10 ⁻³
	1pg/μℓ	10pg/μℓ	10pg/μℓ	100pg/μℓ	1pg/μℓ	1pg/μℓ



M. genitalium
 C. trachomatis
 Internal Control
 N. gonorrhoeae
 M. hominis
 U. urealyticum
 T. vaginalis



HSV Type I
 Internal Control
 HSV Type II
 M. ductleyi
 G. vaginalis
 C. albicans
 T. pallidum

▪ **Composition**

- STD10 multiplex PCR master mix
- STD10 multiplex PCR enzyme mix
- Positive control

▪ **Formation**

- *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Trichomonas vaginalis*, *Mycoplasma hominis*, *Mycoplasma genitalium*, *Ureaplasma urealyticum*, *Haemophilus ducreyi*, *Herpes simplex virus(HSV)*, *Candida albicans*, *Gardnerella vaginalis*

▪ **Workflow**

- Extract DNA from the sample(Not included extraction kit)
- STD multiplex PCR
- Read on the result of gel electrophoresis

▪ **Features**

- **Enable detection of 10 types microbes(as above)**
- **One tube reaction(competitors-2 or 3 tubes)**



▪ **Limit of Detection(LOD)**

	CT	MH	NG	MG	UU
LOD	10 ⁻⁸	10 ⁻⁵	10 ⁻⁷	10 ⁻⁵	10 ⁻⁶
	0.1fg/μℓ	100fg/μℓ	1fg/μℓ	100fg/μℓ	10fg/μℓ
	TV	HD	HSV	CAN	GAD
LOD	10 ⁻⁶	10 ⁻⁵	10 ⁻⁶	10 ⁻⁶	10 ⁻⁵
	10fg/μℓ	100fg/μℓ	10fg/μℓ	10fg/μℓ	100fg/μℓ

▪ **Cut off Value**

	CT	MH	NG	MG	UU
Cut off Value	10 ⁻⁸	10 ⁻⁵	10 ⁻⁷	10 ⁻⁵	10 ⁻⁶
	0.1fg/μℓ	100fg/μℓ	1fg/μℓ	100fg/μℓ	10fg/μℓ
	TV	HD	HSV	CAN	GAD
Cut off Value	10 ⁻⁶	10 ⁻⁵	10 ⁻⁶	10 ⁻⁶	10 ⁻⁵
	10fg/μℓ	100fg/μℓ	10fg/μℓ	10fg/μℓ	100fg/μℓ