

Leading Company in Biochip

Biometrix Technology, Inc. 2010 Company Presentation

Please visit www.bmtchip.com
for further information



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Materials

- All values in this file is predicted values based on BMT internal database.
- The net sales and revenue would be changed according to the business environment.

CHAPTER 01. Company Profile

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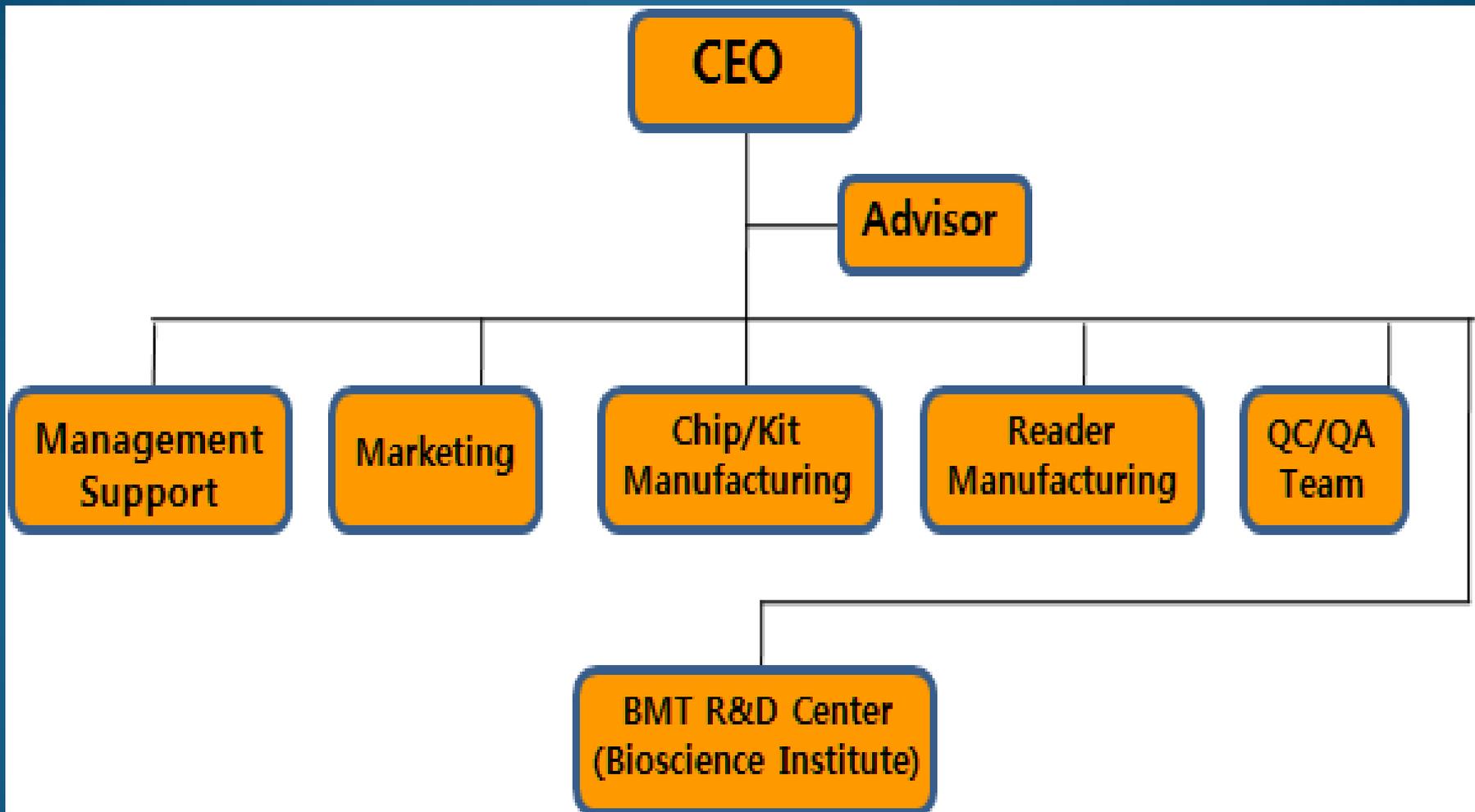
CHAPTER 04. Feasibility Study

Materials

○ Company Outline

Company Type	Biochip Manufacturer
CEO	Taisun Kim
Main Products	HPV 9G DNA KIT (KFDA Approved/CE Declared) HPV 9G Membrane KIT (CE Declared) 9G DNA Chips and Membranes for DDI Application
Employee #	11
Established Year	Year 2000
Sales and Net Income	US \$ 317,000
Research Center	Bioventure Plaza 2-2, 2-3 Chuncheon, Korea
Homepage	www.bmtchip.com

○ Organization Chart



○ History of CEO

Year	Work and Educational History
2000-present	CEO of BMT
1995-present	Chemistry Professor of Hallym University
1993-1995	Post Doc. at Texas A&M University
1987-1993	Ph.D Student at U of Texas at Austin
1985-1987	Research Scientist at KIST
1978-1985	Undergraduate and Graduate Study at Seoul National University

He was a synthetic chemist during Ph.D program. Right after he joined post Doc. Program he began to work on Self-Assembled Monolayer on Au surface and published a few paper in JACS. When he came back to Korea he applied the SAM technology to fabricate Protein Chips which has been published on Proteomics as a coverpaper. After several years of developing protein chips, he started to develop DNACHips based on Molecular Recognition of 9 consecutive guanine bases (called 9G Method). 9G method is the unique DNACHip technology to bind target DNAs at room temperature with over 80% yield in 5 min and high specificity. 9G DNACHips are now applied to immobilize DNA-tagged Proteins, Aptamers, and Small Molecules after all reacted in solution phase. The DDI technology is long awaited platform technology for protein chip and biochip development and manufacturing.

○ Business Area

● 9G DNA Chips, KITs, and Application to DDI Method

9G DNA
Chips

Diagnostic
KITs and
Detection
System

Protein and
Aptamer
Chips

Platform Technology Development

9G
Immobilization
Method

Diagnostic
Kits

DDIMethod

Reader and
Software

**DNA Directed Immobilization Method for
Proteins, Aptamer, and Small Molecules like Drugs.**

○ **Business Strategy**

1. Development Strategy

- Products designed by BMT based on BMT platform technology: Co-research with the companies and the universities with Bio contents**
- OEM, ODM products designed by the world-wide distributors**

2. Sales Strategy

- Approvals of products : HPV DNA KIT (KFDA approved, CE declared)**
- Competitive Rapid Strips based on DDI method :
Detection Limits 5ng/mL~50pg/mL**
- Platform Technology makes the production of the least expensive products among its competitors possible**

○ **BMT History**

Approvals

- . 2010.08 HPV DNA KIT KFDA Approved**
- . 2010.03 HPV Membrane KIT CE Declared**
- . 2010.03 BMT 1-D Scanner CE Declared**
- . 2009.10 ISO13485 Certified**
- . 2009.11 HPV DNA KIT CE Declared**

Booths

- . AACCC Booth 2007-2010**
- . MEDICA Booth 2009-2010**
- . Compamed 2007-2008**

○ **Research History**

Governmental Projects

- The number of performed : 19 cases**
- The duration : Year 2003 ~ 2010**
- Projects Gross : 4,755,327 US\$**

Development of Platform Technology & Products of Biochip

○ Patented and Applied

1. Domestic

Patented : 11cases (KR 10-0698763, KR 10-0786577, KR 10-0748082, KR 10-0785655, KR 10-0787471, KR 10-0725303, KR 10-0869916, KR 10-0883763, KR- 10-0924243, KR 10-0904772, KR 10-0923345)

Applied : 2cases (KR 10-2008-0016007, KR 10-2009-0085651)

2. Foreign (USA, EU, China, Japan)

**Applied : 7cases (11/816,022 , 12/266,480 , 11/910,164 ,
12/267,421 , 06757689.2 , 08723418.3 ,
200680038071.4)**

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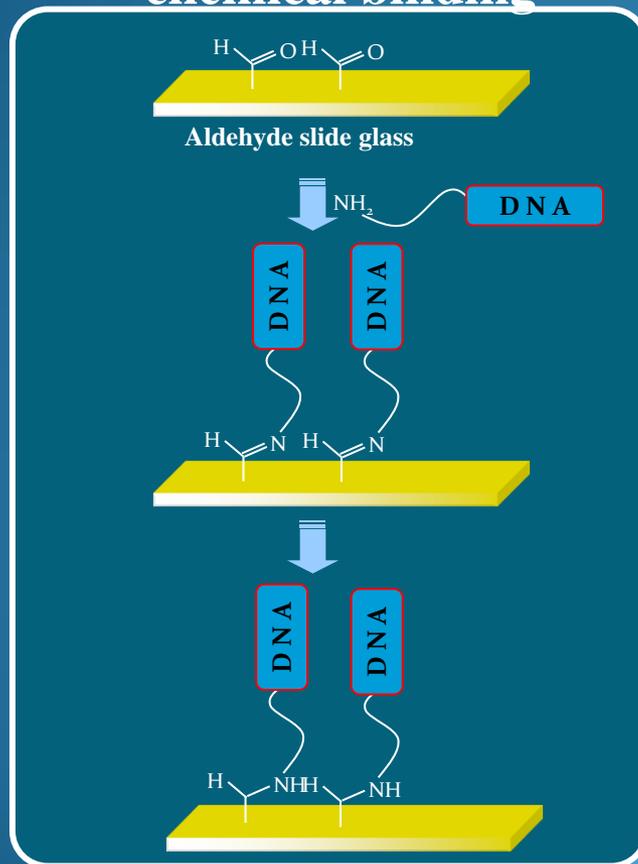
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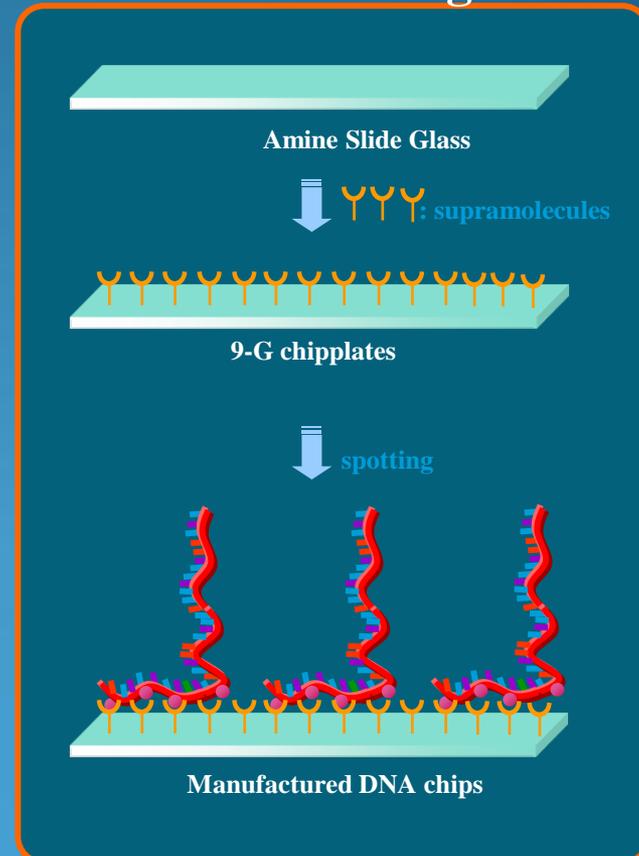
○ 9G Technology for DNA chip

- The lateral spacing between probes is not only important to make DNA chips but also to make arrays of the proteins DDI method.
- The immobilization of the oligonucleotides with lateral spacing not only ensures the accessibility of a target probe but also increase the yield of the hybridization.
- 9G is the only commercialized technology to manufacture DNA chips.

chemical binding

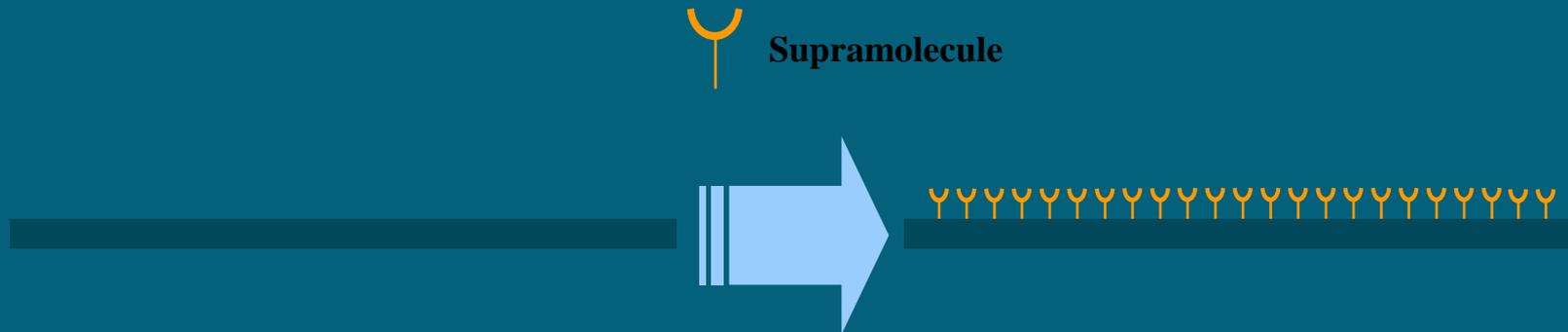


9G molecular recognition



○ 9G Slides Preparation

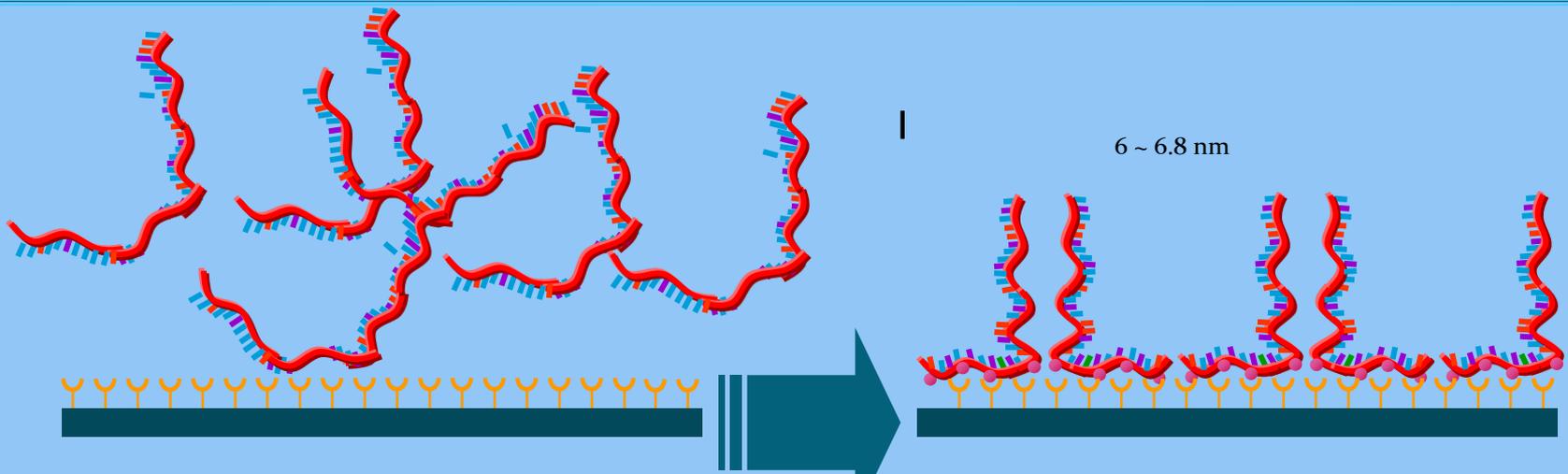
The supramolecular self-assembled monolayer is called 9G Slides



● **9G Slides patented : domestic 5 patents/ 2 PCT, US patent, Eu patent, China patent, Japan patent Applied**

○ 9G DNAChip Preparation

Probes immobilized on the 9G slides via Molecular Recognition of 9 consecutive guanine bases to fabricate BMT's Unique 9G DNAChips.

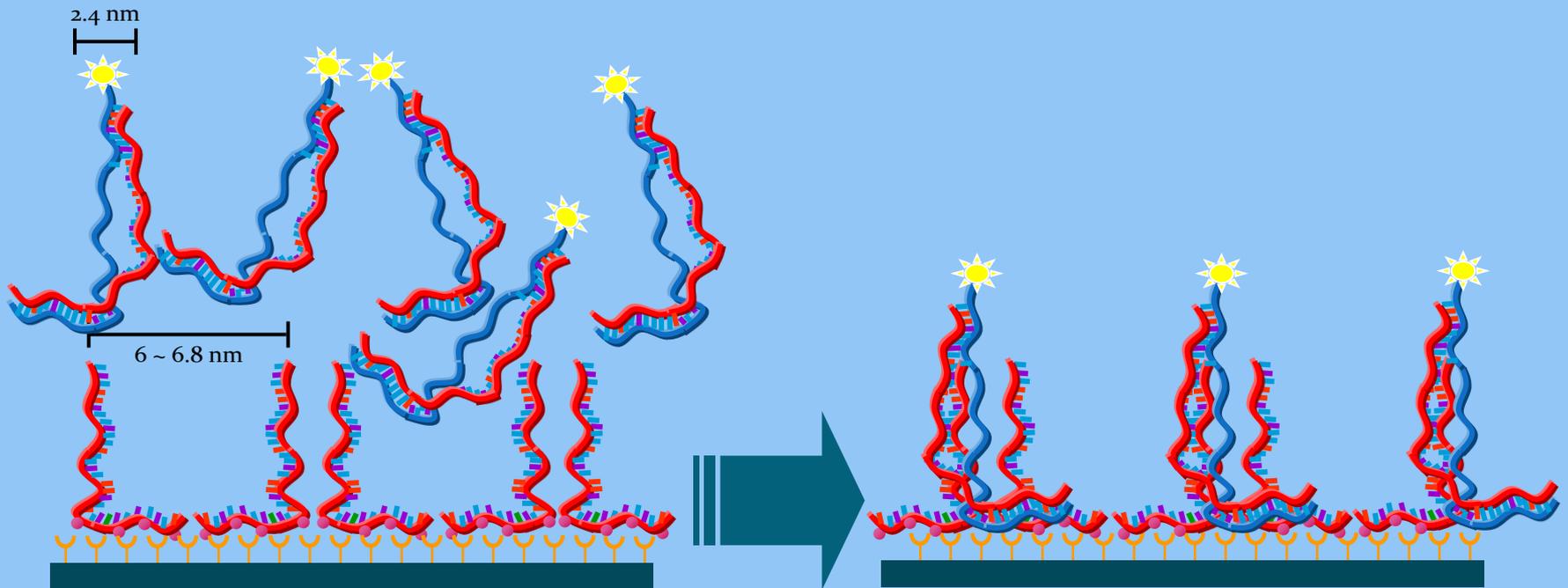


Recognized 9G provides over 6nm lateral spacing between capture probes.

Probe DNA design has been patented: 1 domestic patent/ 1 PCT, 1 US patent, 1 Eu patent Applied

○ 25°C Hybridization with PCR products

Probes with lateral spacing hybridize at 25°C with PCR products with exceptional intensity. (32time higher than company A and B DNA chips with same PCR products)



Recognized 9G provides lateral spacing enough for binding PCR products

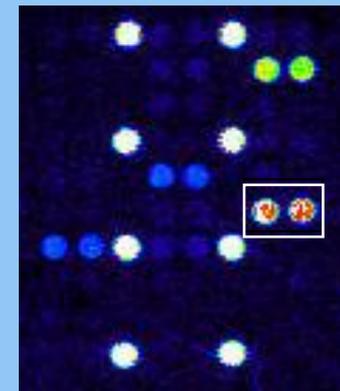
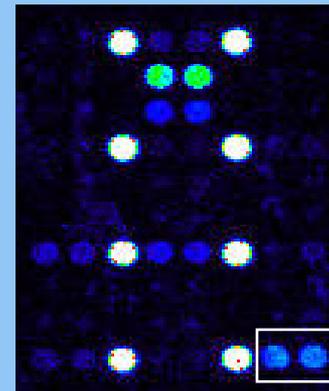
○ Split system to enhance hybridization yield

Conventional DNA chips hybridize with PCR products at high temperature to lose intensity and specificity

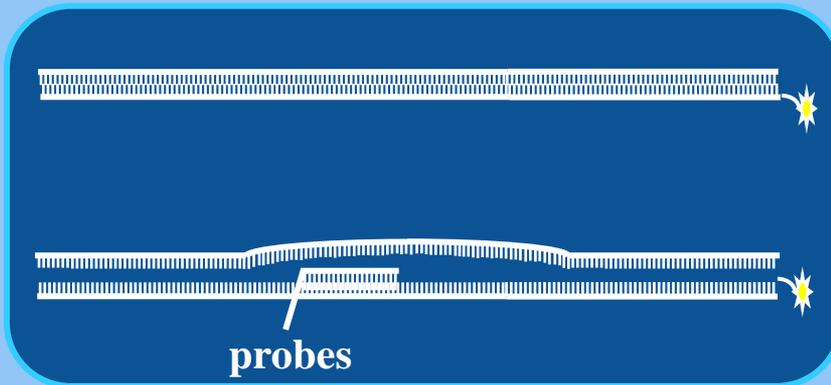
Hybridization at high temperature

Type 66

Type 40



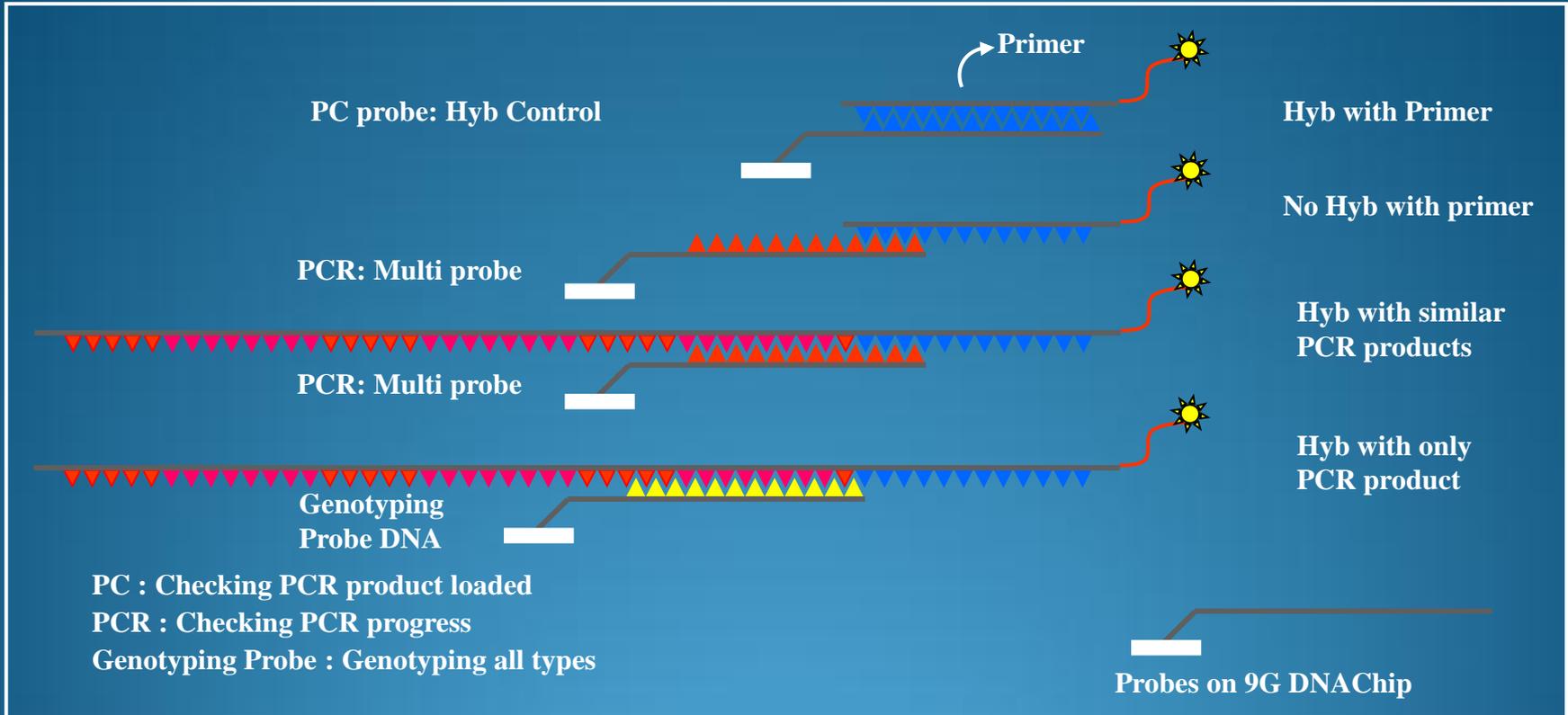
Specific spots



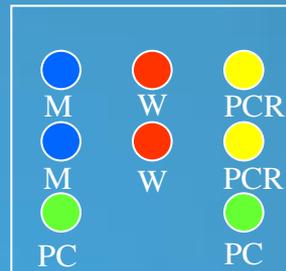
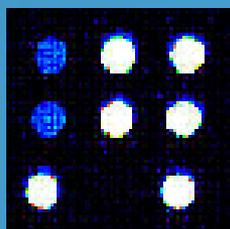
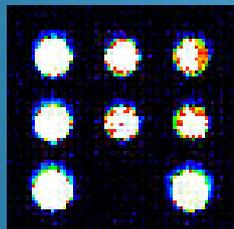
Split system helps the binding of dd-DNA on DNAChip probes at room temperature.

○ Split system to enhance hybridization yield

Probes with lateral spacing hybridize at 25 °C with PCR products with exceptional specificity. (Single mutation can be discriminated 10 times on fluorescence intensity)

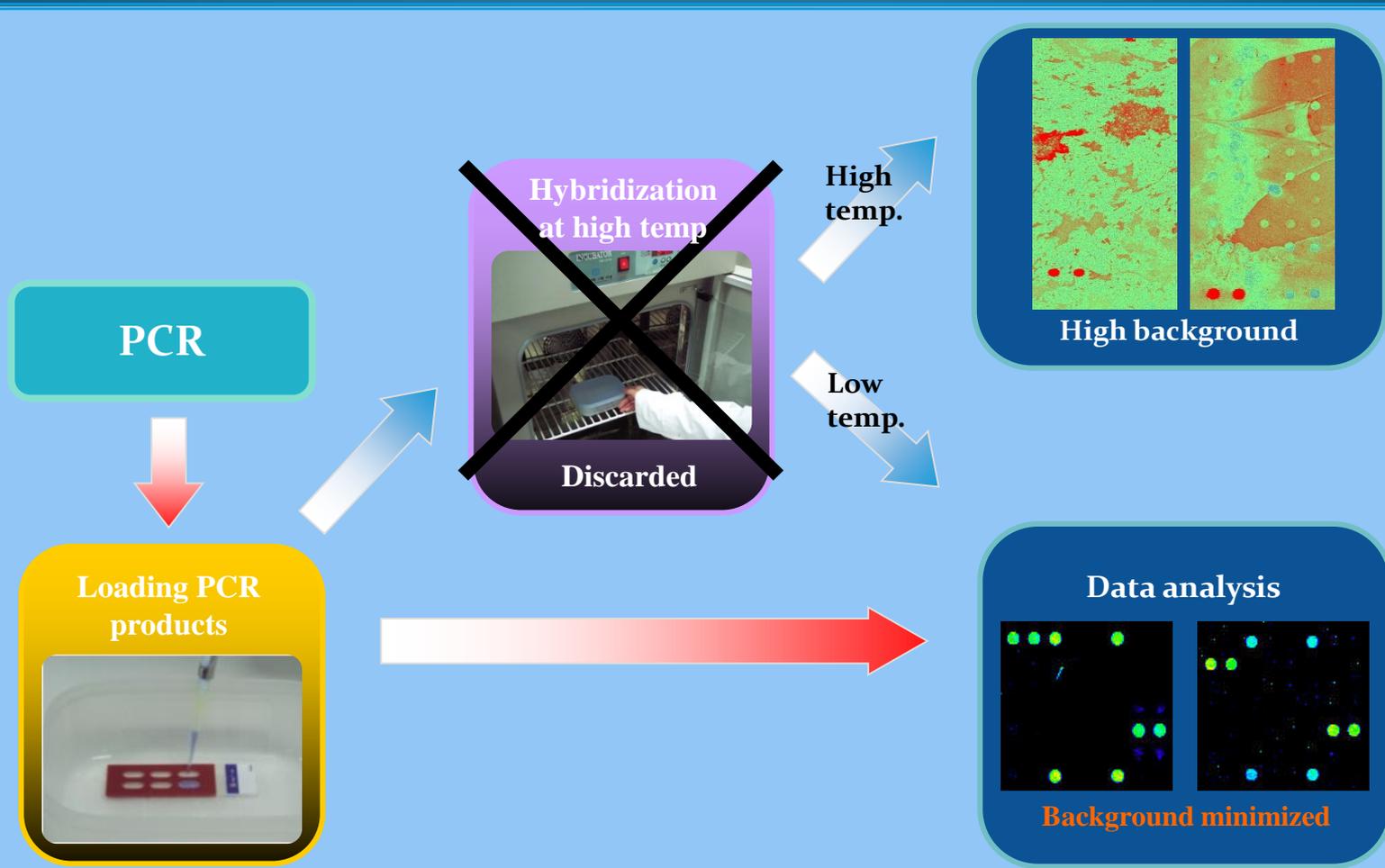


Wild CCA Mutation CAA

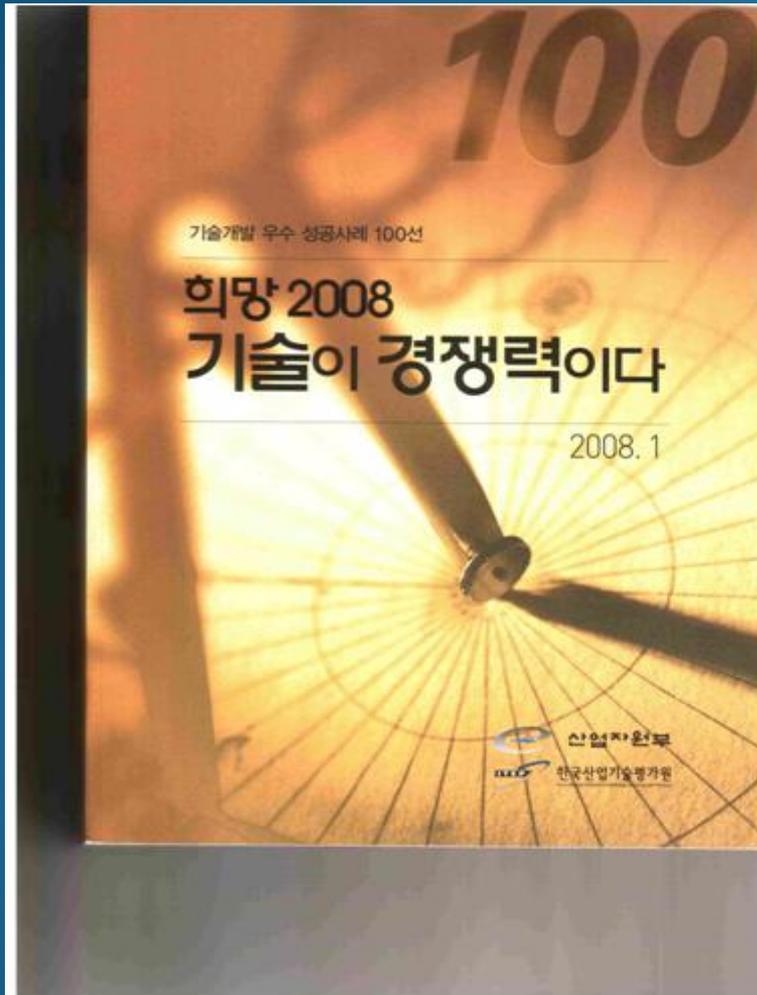


○ 25°C Hybridization with PCR products guarantees nice background

Hybridization solution reserved more safely at 25°C than at 45°C. The dry effect would be minimized on 9G DNAChip



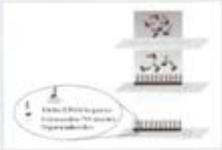
○ 9G Technology has been selected as one of 100 outmost industrial technology in 2008



(주)바이오메트릭스 테크놀로지 82

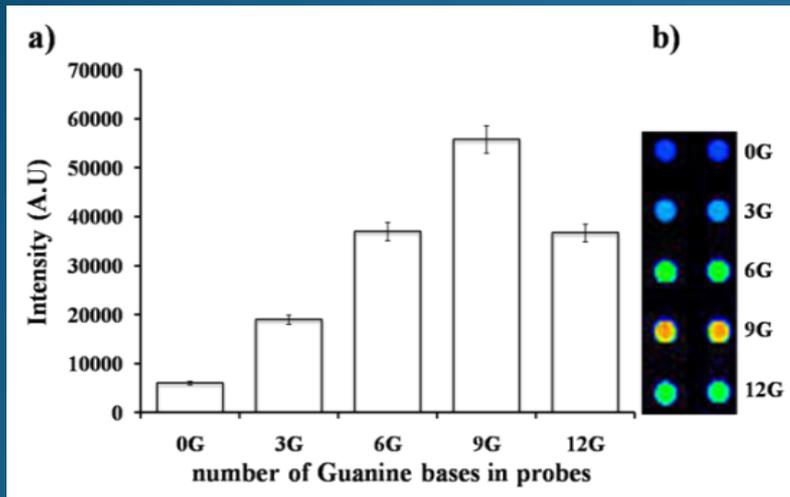
분자인식을 이용한 Biochip 제조기술개발 및 제품화기술개발

- 대 목 자 : 김 태 선
- 출개발기간 : 2003. 11. 1 ~ 2005. 10. 31
- 총 개발비 : 300백만원
- 핵심 기술 : 분자인식을 이용한 바이오칩 제조기술개발

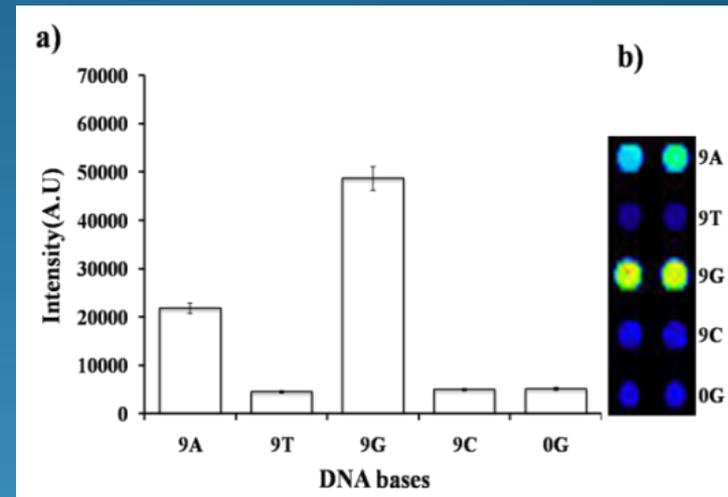


(Optimal length of consecutive guanine)

○ 9G DNAChip made by molecular recognition of 9 consecutive Guanine bases

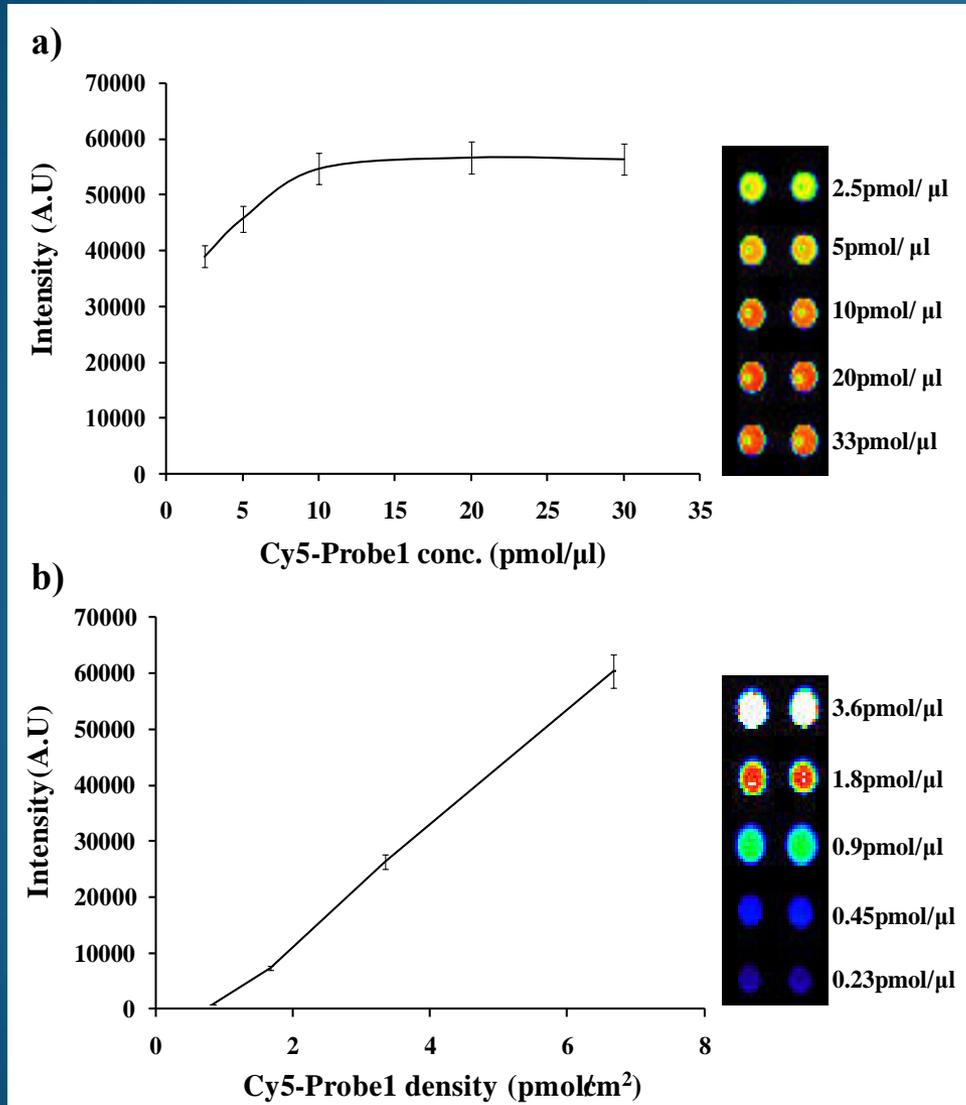


The probes appended with consecutive 9G subunits provide higher signal after immobilization on the 9G slide a) A graph representing the effect of the number of the guanine bases in oligonucleotide probes on the immobilization of probes on the 9G slides. b) Fluorescence map obtained by the immobilization of the Probe6 (0G), Probe7 (3G), Probe8 (6G), Probe1 (9G), and Probe9 (12G) after the hybridization with Cy5-T1



The probes appended with guanine subunits provide higher signal after immobilization on the 9G slide than other DNA bases a) A graph representing the effect of nine consecutive DNA bases in oligonucleotide probe on the immobilization of the probes on the 9G slides. b) Fluorescence map obtained by the immobilization of the Probe3 (9A), Probe5 (9T), Probe1 (9G), Probe4 (9C), and Probe6 (0G) after the hybridization with Cy5-T1.

○ 9G DNAChip shows Slides and Membranes are the first commercialized DDI products

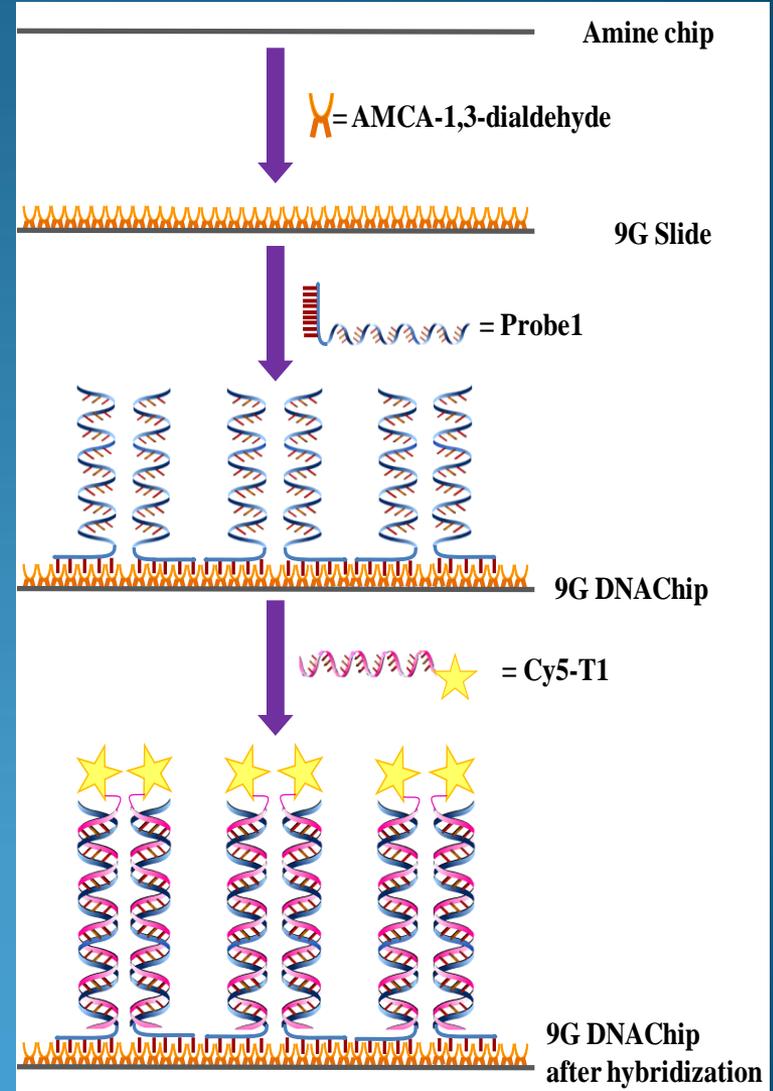
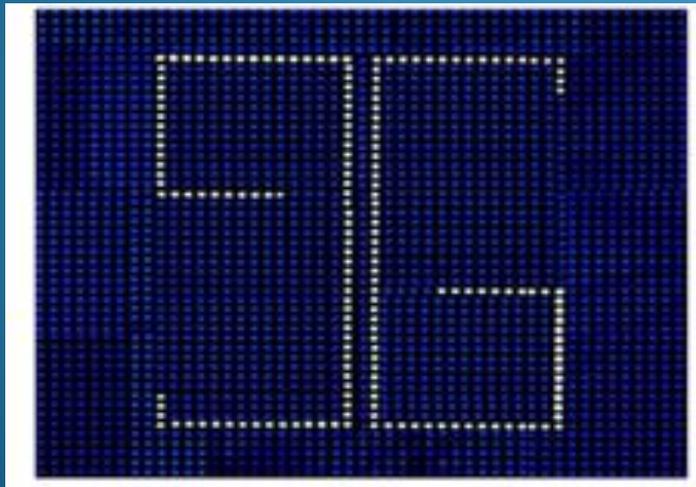
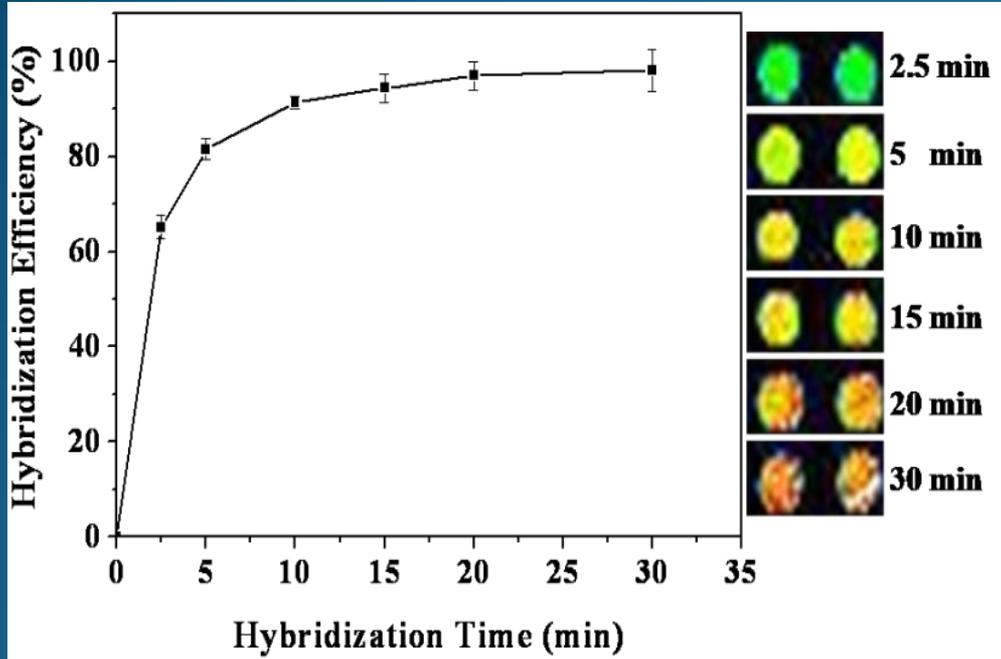


Immobilization density

- a) Immobilization of Cy5-Probe1 with 2.5, 5, 10, 20, and 33 pmol/μl concentrations for 4 h followed by capping and washing to obtain Cy5-9G DNAChip, respective fluorescence image (left)
- b) Standard slide prepared by the spotting of Cy5-Probe1 with 0.23, 0.45, 0.9, 1.8, 3.6 pmol/μl concentrations followed by drying, respective fluorescence image (left)

Over 80% Hybridization Efficiency in 5 min.

Time dependent hybridization efficiency

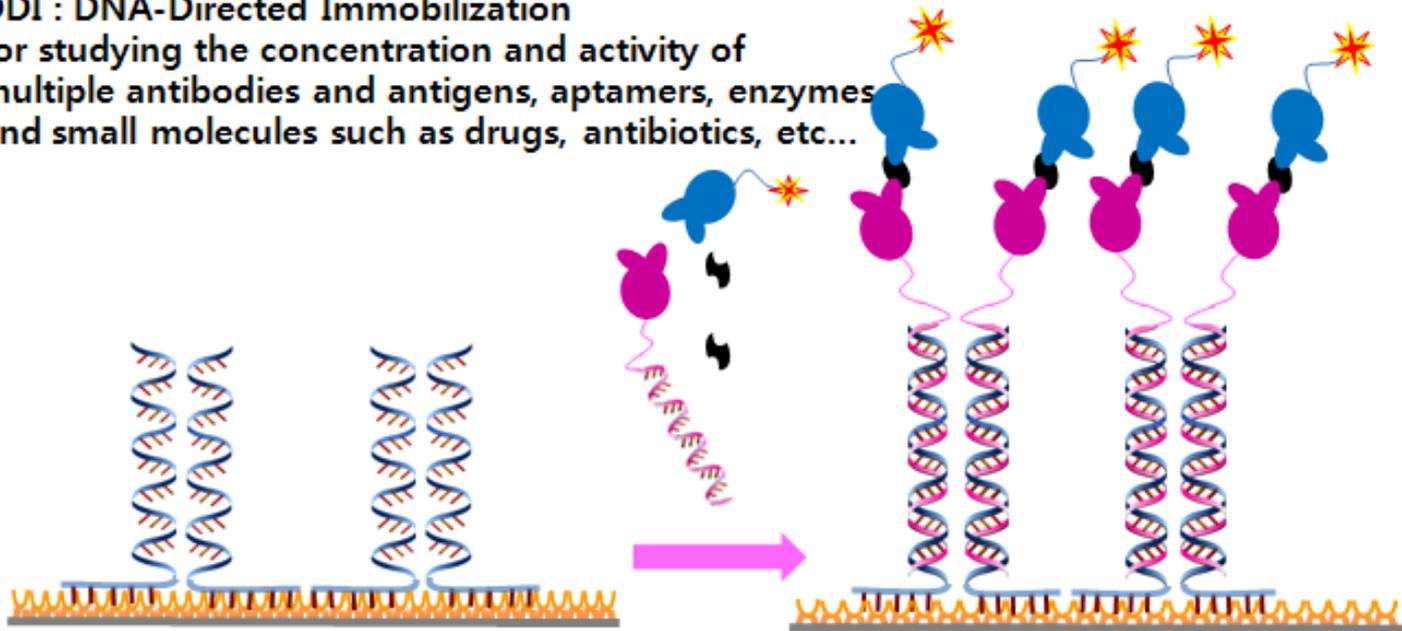


○ 9G Slides and Membranes are the first commercialized DDI products

9G DNAChip is the only DNAChip which hybridizes at 25°C with single stranded DNA and DNA-linked proteins, aptamers, and small molecules. It binds with DNA-linked biomolecules with exceptional strength. (32time higher than other DNA chip) Detection limit has been approved 5ng/ml-50pg/ml of proteins.

OEM / ODM DNA Chips for DDI Method

DDI : DNA-Directed Immobilization
for studying the concentration and activity of
multiple antibodies and antigens, aptamers, enzymes
and small molecules such as drugs, antibiotics, etc...



Make your Own Biochips on 9G DNA Chips !

Leading Company in Biochip

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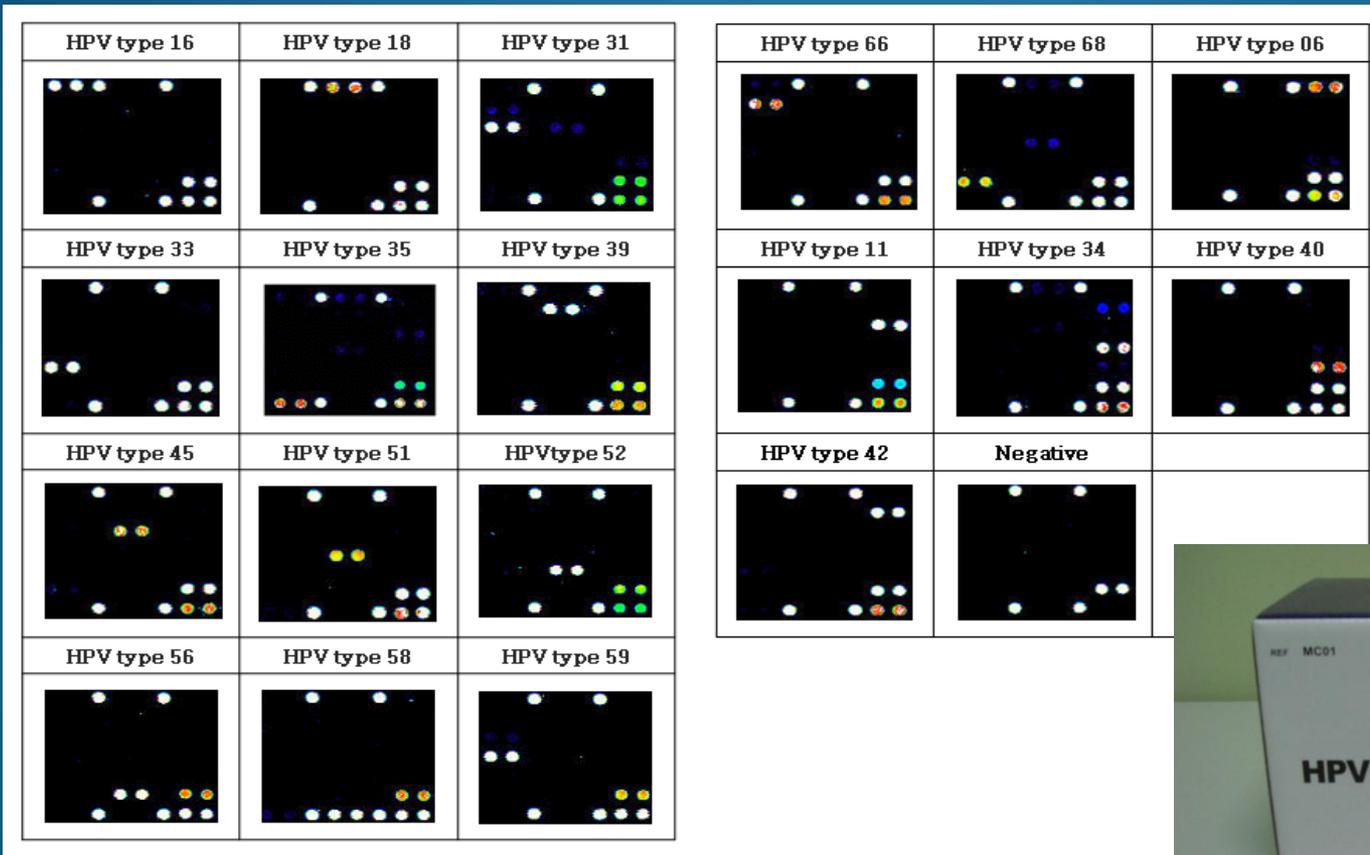
CHAPTER 04. Feasibility Study

Materials

○ 9G HPV Genotyping DNA KIT (KFDA Approved)

The kit is the only DNAChip which hybridizes at 25°C with exceptional s/n ratio and exceptional signal/background ratio. (10time higher than other DNA chip)

· Genotyping results



○ 9G HPV Genotyping DNA KIT (KFDA Approved)

The kit provides screening results of 38 HPV types (19 Genotyping and 19 Screening)

• Screening results

HPV type 03	HPV type 10	HPV type 26	HPV type 62	HPV type 67	HPV type 69
HPV type 27	HPV type 32	HPV type 43	HPV type 70	HPV type 71	HPV type 73
HPV type 44	HPV type 53	HPV type 54	HPV type 74		
HPV type 55	HPV type 57	HPV type 61			



9G HPV Genotyping DNA KIT (KFDA Approved)

The kit provides fully automated data analysis

· Final Results by “Digieye“

Data Analysis Window
✕

Control Window

Intensity of HC
= 65535.0

Intensity of PC
= 50082.4

Intensity of PCR
= 65535.0

Settings

BG threshold
7000

HC threshold
60000

PC threshold
10000

PCR threshold
10000

Spot threshold
20000

save

Select Print

Low Intensity High



Spot Data

16  65535	16  65535	HC  65535	18  1504	18  1131	HC  65535	06  1428	06  1030
66  1393	66  1849	BG  873	39  2601	39  1978	BG  1576	42  2058	42  2011
31  4762	31  4824	BG  1347	45  3548	45  3093	BG  1797	11  3238	11  2659
59  2388	59  2157	BG  1159	51  6176	51  5327	BG  1488	34  2870	34  2608
33  2394	33  2733	BG  900	52  2152	52  1178	BG  1591	40  4747	40  4910
68  5152	68  4870	BG  994	56  2197	56  1760	BG  808	PC  53487	PC  46678
35  2697	35  2446	HC  65535	58  2673	58  2113	HC  65535	PCR  65535	PCR  65535

Report

Health Window

Detection Window

HPV Detected!

Type 16 (High Risk)

Status Window

>>
 <<

○ 9G HPV Genotyping DNA KIT (KFDA Approved) Detection Limits and Spec.

HPV	Detection limit
16	10 ¹ copies
18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68	10 ² copies
53, 54, 69, 73	10 ³ copies
06, 11, 34, 40, 42	10 ² copies
03, 10, 26, 27, 32, 43, 44, 55, 57, 61, 62, 67, 70, 71, 74	10 ³ copies

- **Hybridization Temperature and Time**

- 20~30 °C/30min

- **Washing Temperature and Time**

- Step I : 20~30 °C/5min

- Step II : 20~30 °C/5min

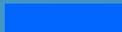
- **Scanners needed**

- Prekin-Elmer scanner, Exon scanner, Capitalbio scanner And other scanners can be standardized using BMT standard slides.

- **Expiration date**

- 6 Month

 : HPV Hi-Risk Type

 : HPV Low-Risk Type

○ 9G HPV Genotyping Membranes



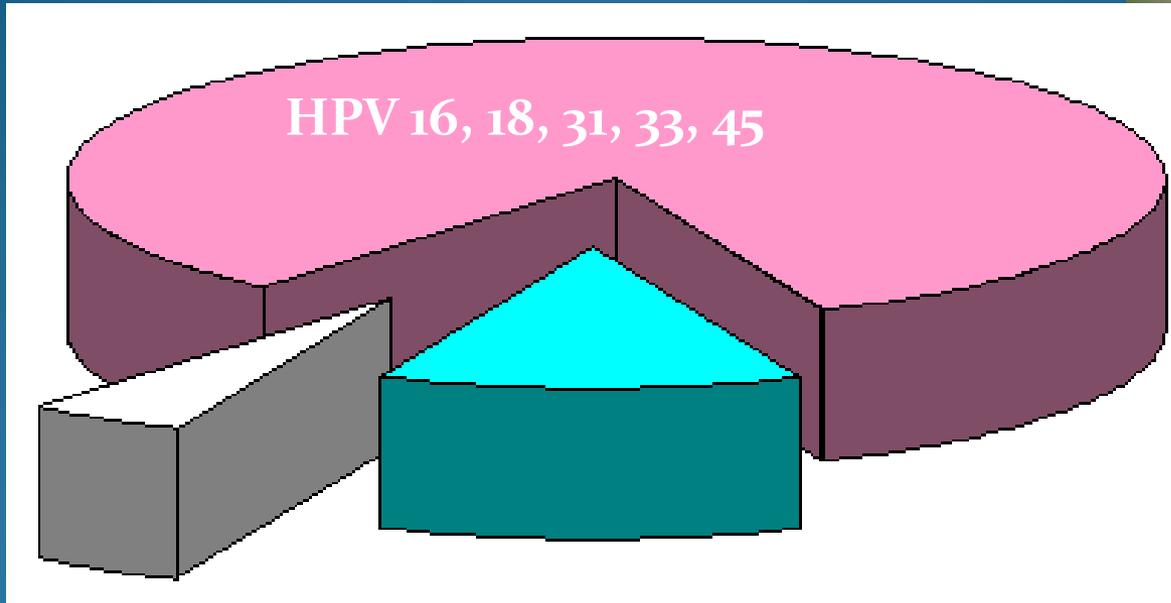
1. HPV DNAs are extracted and amplified via PCR
2. PCR products mixed with hybridization solution are loaded on 9G DNA Membrane
3. Membrane washing
4. Scan the Membrane and automatic data analysis



○ 9G HPV Genotyping Membrane KIT

Genotyping (5 types)

82.9%



Other type
4.7%

Screening (31 types)

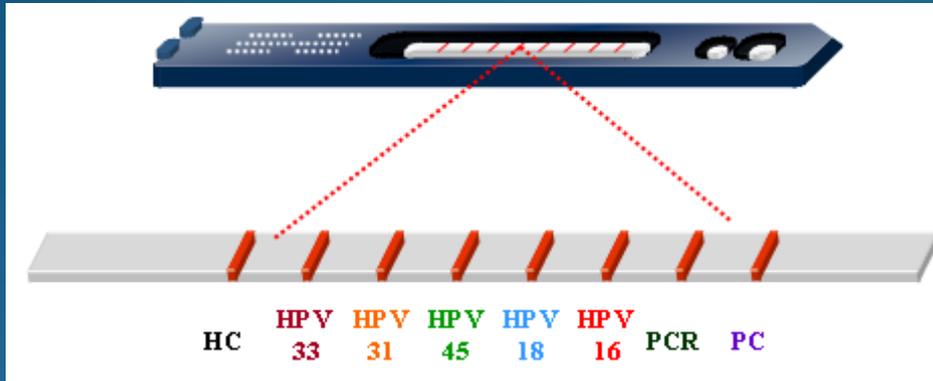
12.4%

Source By GSK report

Screening types : 52, 58, 35, 59, 56, 51, 39, 68, 66, 69, 73, 53, 54,
06, 11, 34, 40, 42, 26, 43, 67, 70, 71, 44, 10, 32, 55, 03, 27, 57, 74

* HPV Hi-risk types are underline.

9G HPV Genotyping Membrane KIT Spec. and Detection Limits

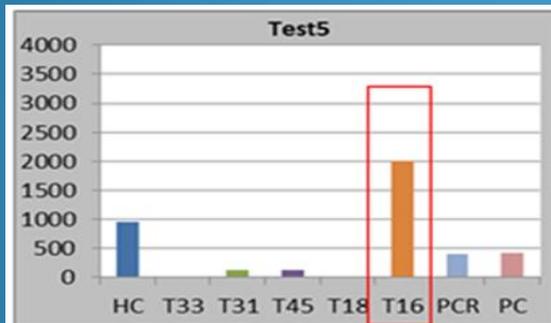
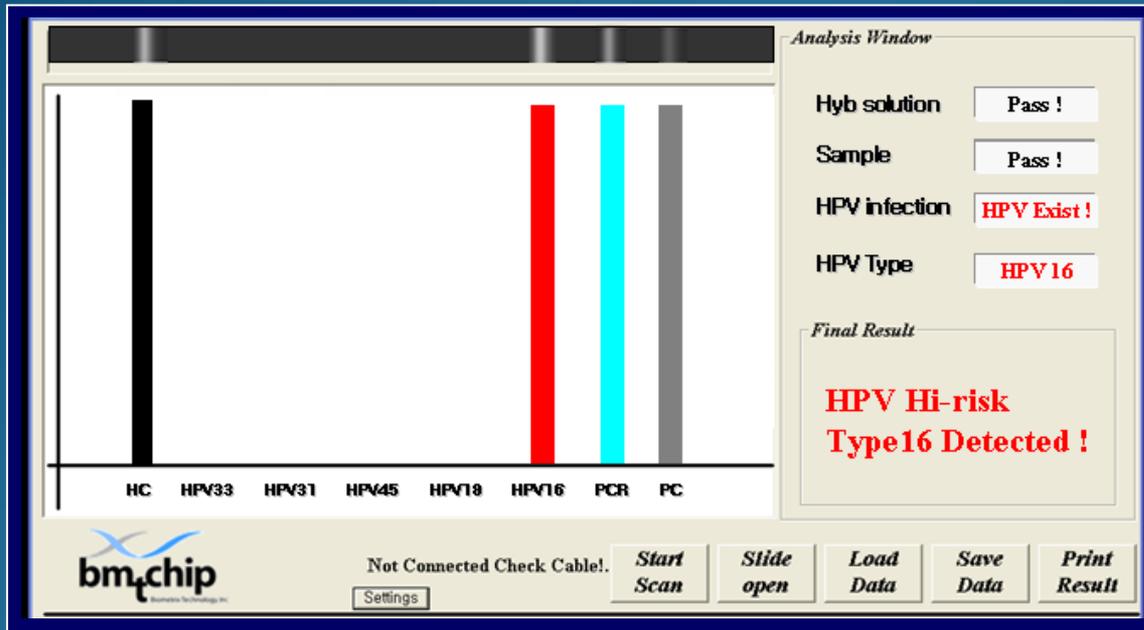


- HC** : Hybridization Control
- HPV Type** : HPV Genotypes Line (16, 18, 45, 33, 31)
- PCR** : HPV Screening Line (HPV Other 31 type)
- PC** : PCR Internal Control

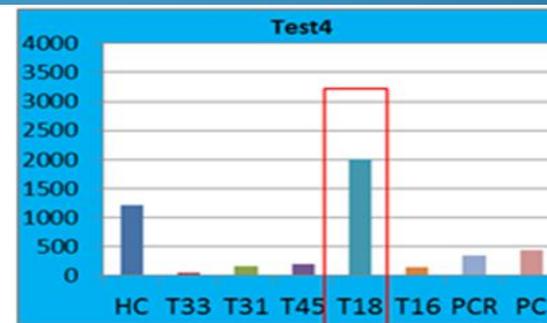
HPV	Detection limit
16, 18	10^2 copies
31, 33, 45, 35, 39, 51, 52, 53, 54, 56, 58, 59, 66, 68, 69, 73	10^3 copies
03, 06, 10, 11, 26, 27, 32, 34, 40, 42, 43, 44, 55, 57, 67, 70, 71, 74	10^5 copies

9G HPV Genotyping Membrane KIT

- Final Results by “Digieye II”



HPV 16 detected



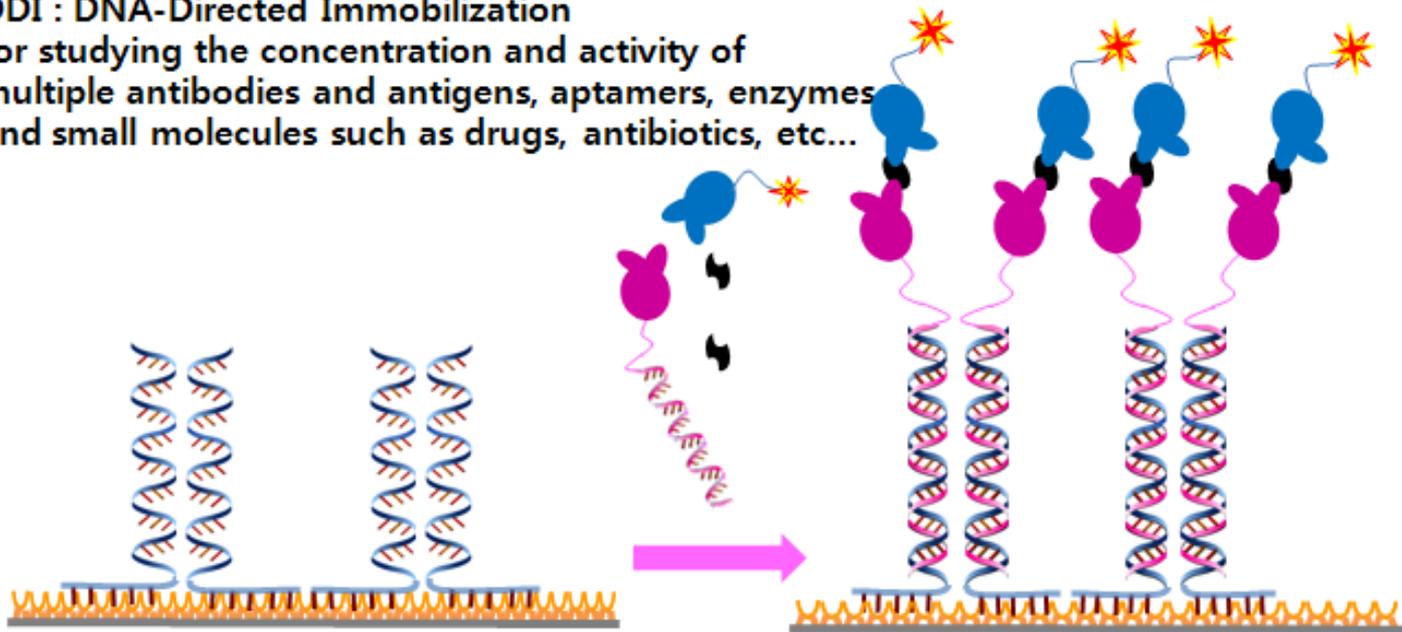
HPV 18 detected

○ 9G Slides and Membranes are the first commercialized DDI products

9G DNAChip is the only DNAChip which hybridizes at 25°C with single stranded DNA and DNA-linked proteins, aptamers, and small molecules. It binds with DNA-linked biomolecules with exceptional strength. (32time higher than other DNA chip) Detection limit has been approved 5ng/ml-50pg/ml of proteins.

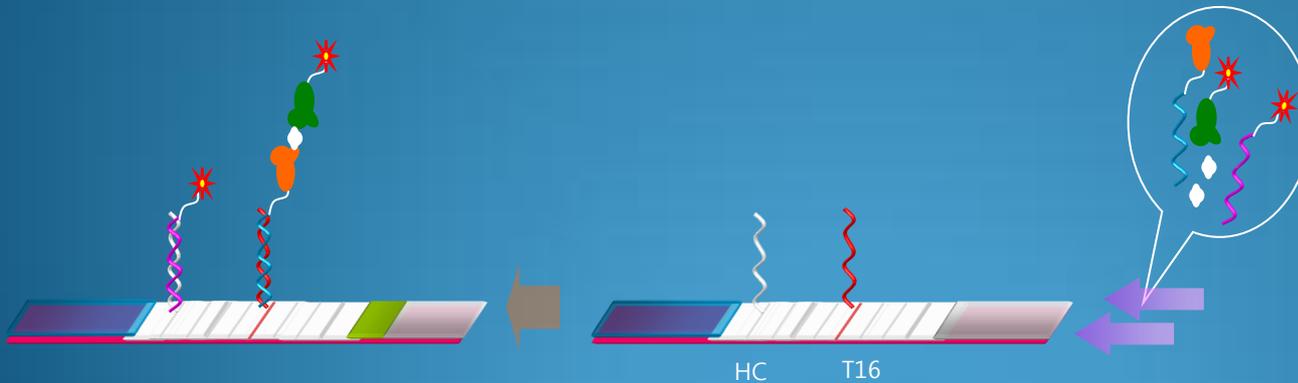
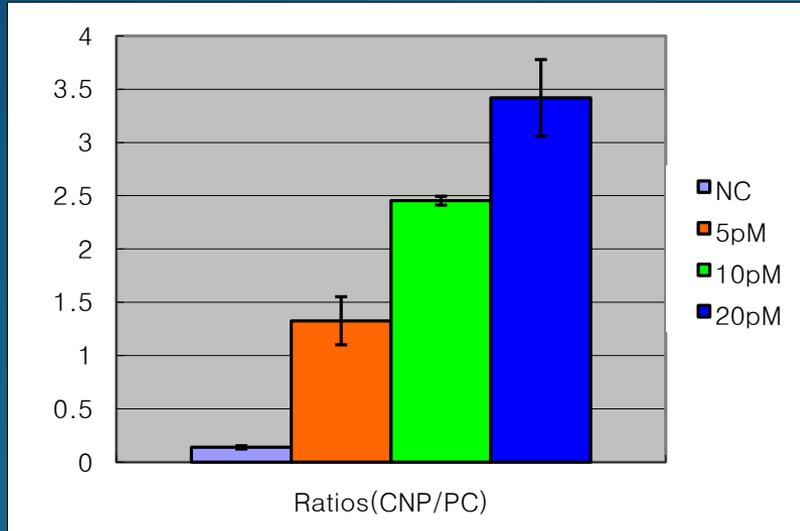
OEM / ODM DNA Chips for DDI Method

DDI : DNA-Directed Immobilization
for studying the concentration and activity of
multiple antibodies and antigens, aptamers, enzymes
and small molecules such as drugs, antibiotics, etc...



Make your Own Biochips on 9G DNA Chips !

Protein Detection via DDI Method



Loading mixture of antibodies and antigen in hybridization solution on strip
Hybridization process binds the reacted biomolecules on specific sites.

○ 9G is the ultimate platform technology for all biochips

- All companies use chemical and biological method to immobilize DNAs on chip surface. The technology has shown problems to generate spacing among DNA's on DNA chips. Target DNA should need spacing between capture DNAs to get in and bind efficiently and specifically. Unfortunately, classical methods failed to prove spacing among the immobilized DNAs.
- 9G Technology proved spacing among the DNAs on 9G DNAChip. Target DNAs connected to proteins, aptamers, and even small molecules like drugs can bind on specific capture DNA after whatever solution-phase reaction with targets.
- 9G Technology is the only technology for 25°C hybridization with over 80% yield in 5 min.
- For DNA chips, the designing capture probe is very hard and time-consuming. BMT has patents for designing capture probes on selected areas on the PCR regions including the primer regions. The split method which split the PCR products to make them easy to hybridize on BMT 9G DNAChip shows 32times better intensity compared to other DNA chips when the same PCR condition and product are applied to analyze the samples.

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○ Competing Companies

Section	company	Developed technology
DNA Chip	Genomictree	DNA chip, Biomarker development
	Mygene	HPV DNA chip
	Biomed lab	HPV DNA chip
	Bioland	DNA chip
	Bioneer	DNA Synthesis and reagents
	Macrogen	DNA chip, genome analysis
	Diachip	DNAChip for cancer detection
	Greiner Bioone	HPV DNA chip
Protein chip	Boditech Med	Diagnostic Kit
	Genetica	Protein Chip
	Proteogen	Protein chip and reader

○ SWOT

Strength

- **Securing patents of Platform Technology**
- **Development of a variety of biochip products**
- **Secure a manufacturing technology of new protein chip**
- **Secure a manufacturing technology of new DNA chip and competitive price**
- **Secure early diagnostic chip and low-cost scanners**

Weakness

- **Lack of R&D and commercialization funds**
- **Staffing issues by geographical constraints**
- **Low international recognition**

○ SWOT

Opportunity

- HPV Vaccine and drug development due to activation of the HPV DNA chip diagnostics market
- New technology of patient convenience to paradigm shift (Simultaneous diagnosis of various kinds of diseases of disease, etc.)
- Atrophy of the project area due to large corporations, creating a niche market
- The necessity of quick and cheap test methods
- Expansion of interest in DNA chip & protein chip

Threat

Threat

- Patent disputes
- The emergence of competing technologies
- Lack of manufacturing facilities
- Lack of licensing and marketing system
- Competition from companies with global sales

Avoidance plan

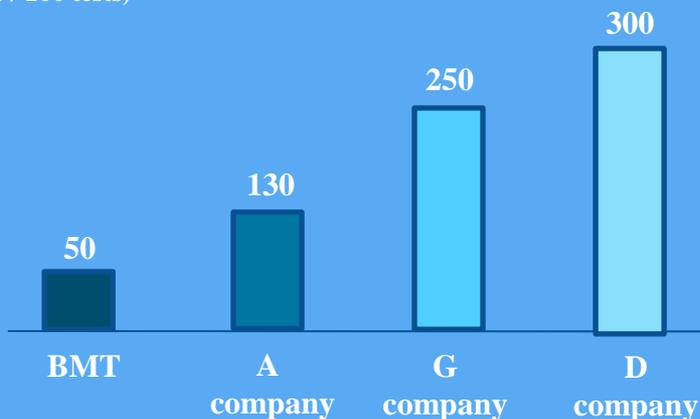
- Securing patents of platform Technology
- Ensure competitive prices
- Secure manufacturing facility
- Approval obtained and expansion of sales
- Secure a manufacturing technology and price advantages of products

○ Comparing Prices

- More than 3 million per year to produce a test kit to secure a manufacturing facility
- Self-produced raw materials, manufacturing process optimization due to securing of the global price competitiveness
- Securing of low-cost manufacturing techniques of DNA chip and detector
- The latest quality management systems operating (ISO 13485)

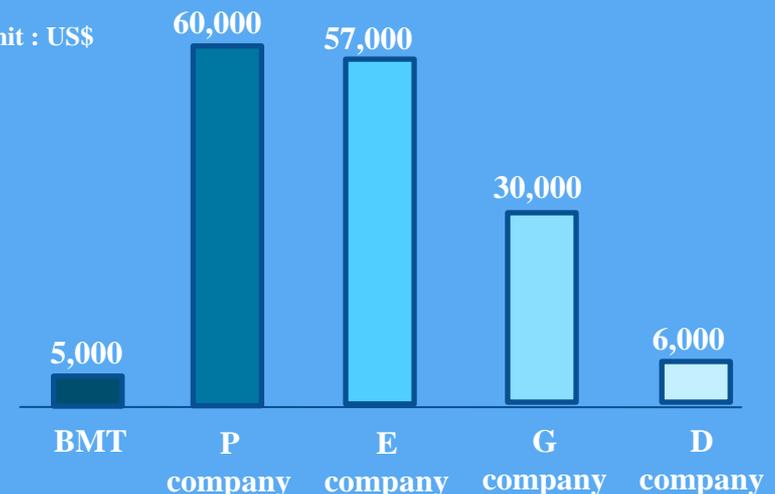
Comparison of DNA chip prices(HPV)

Unit : 10,000 won
(Price / 100 tests)

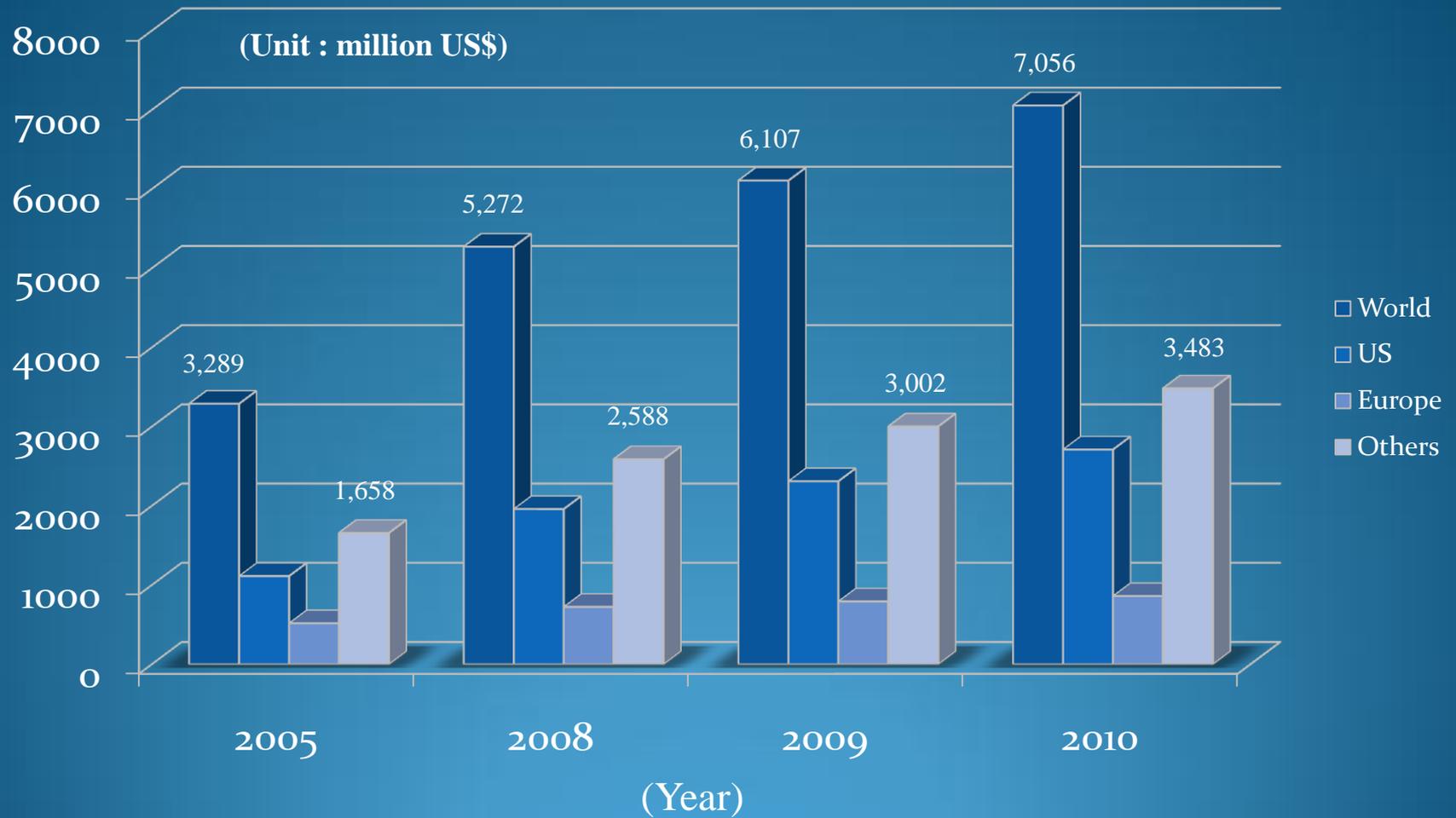


Comparison of detector prices

Unit : US\$

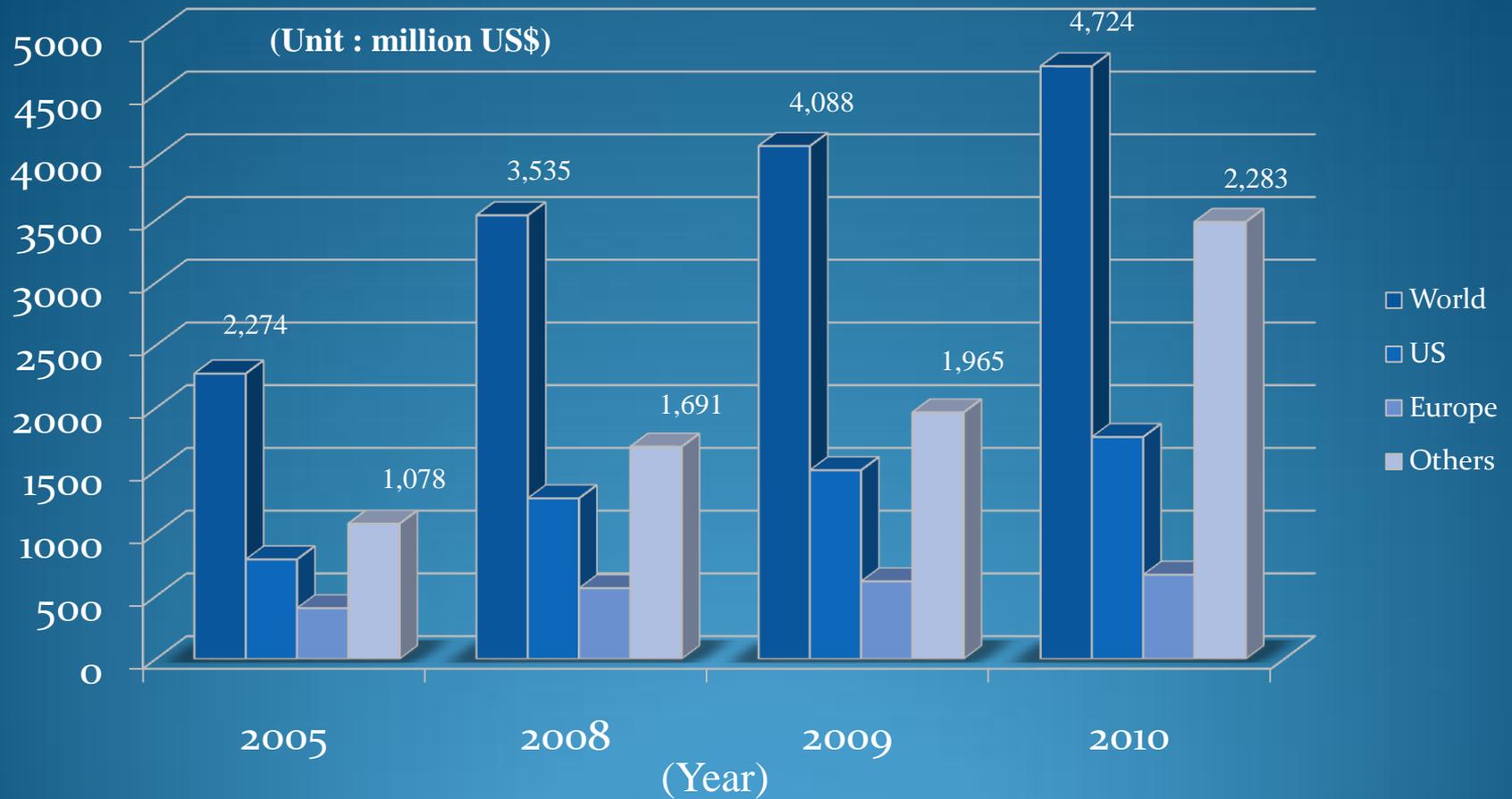


○ Molecular Diagnostics Market Analysis



(SOURCE: Frost & Sullivan)

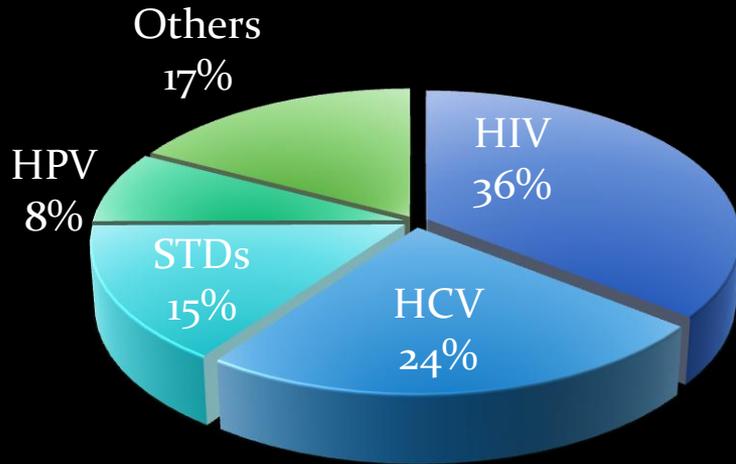
○ Infectious Disease Market Analysis



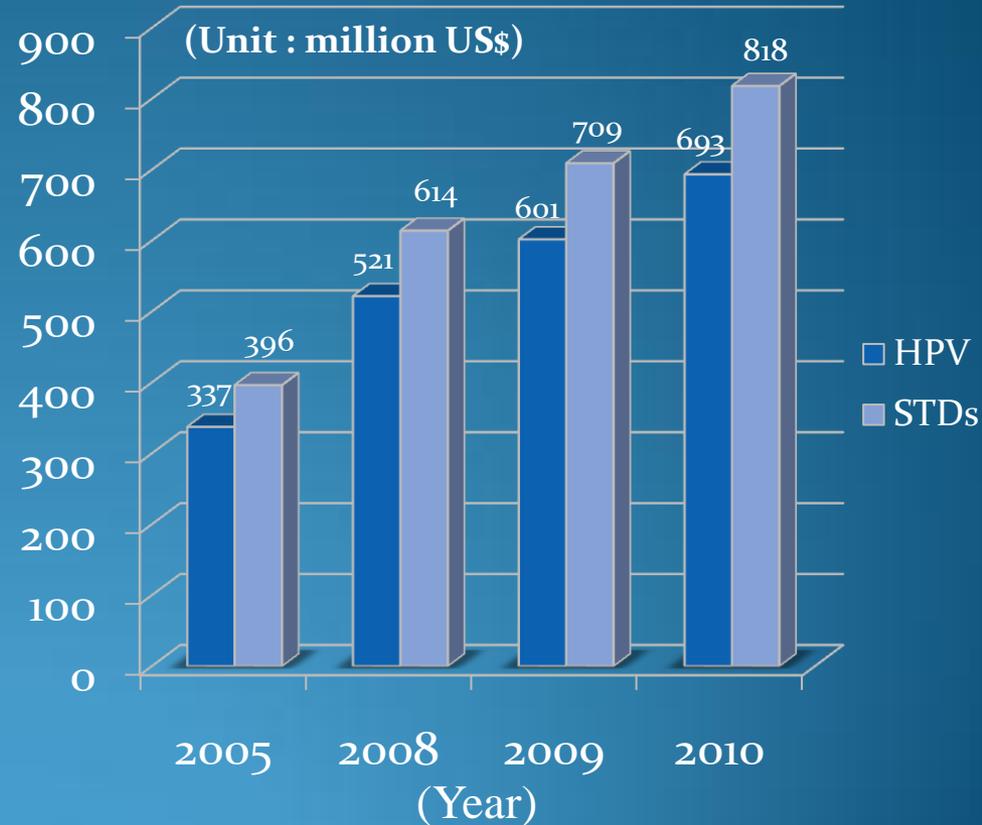
(SOURCE : Frost & Sullivan)

○ Market Analysis of Infectious Disease

Market Share by Revenues for the Infectious Disease Testing Segment(World),2005



(SOURCE: Frost & Sullivan)

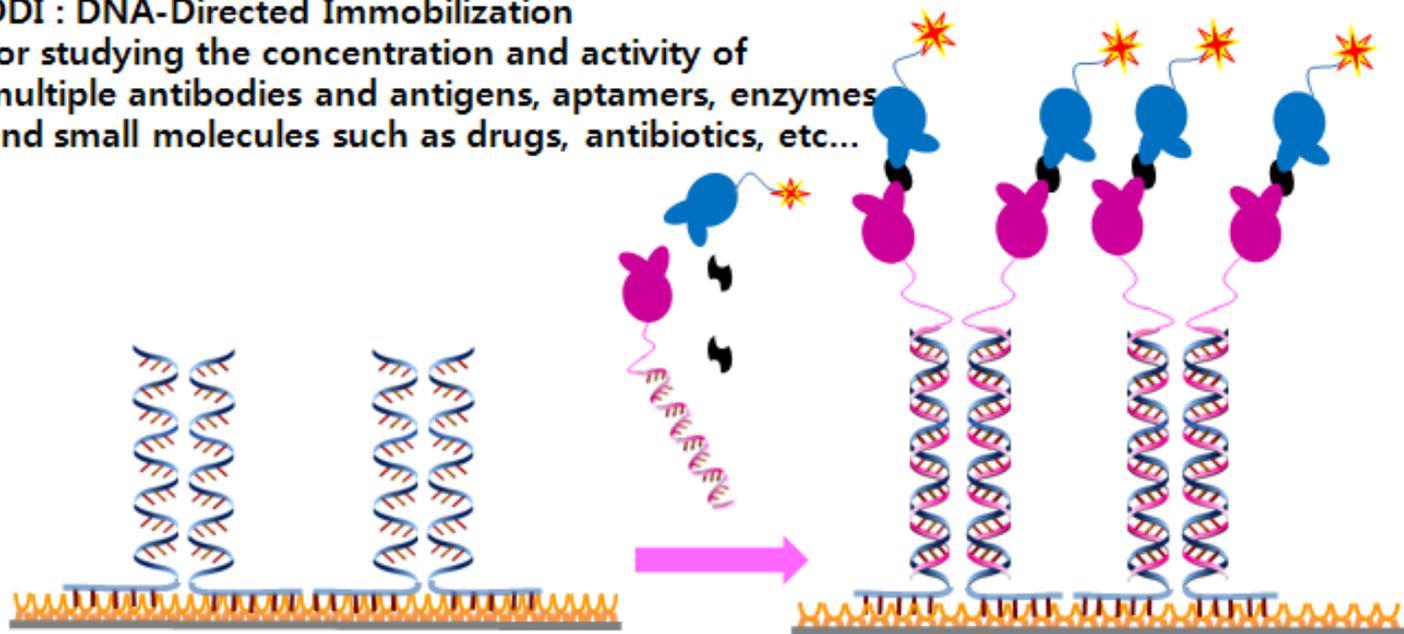


○ Expectations for Future of 9G Technology

- 9G DNAChip Products are ready to sell in Korea and EU. US market after 510K approval should be fruitful. Expected Revenue would be doubled 2010 and tripled in 2011.
- DDI products are expected to give revenues in year 2012. Whole revenue would be very close to 2 million US dollars at the end of year 2012.

OEM / ODM DNA Chips for DDI Method

DDI : DNA-Directed Immobilization
for studying the concentration and activity of
multiple antibodies and antigens, aptamers, enzymes
and small molecules such as drugs, antibiotics, etc...



Make your Own Biochips on 9G DNA Chips !

Leading Company in Biochip

CHAPTER 01. Company Profile

CHAPTER 02. Platform Technology

CHAPTER 03. BMT Products

CHAPTER 04. Feasibility Study

Materials

KFDA certificate

제 1 호 접수번호 : 20100078421

의약품 제조판매
 의약외품 수입

품목허가증

업종 : 의약품 허가번호(업신고번호, 수입자번호) : 300 / (구)

제품명	비엔티 에이치피브이 9지 디엔에이 키트(BMT HPV 9G DNA KIT)	분류번호	기타의 진단용약 (07290)
원료약품(원자재) 및 분량	별첨	의약품분류	진문의약품
성상(형상 및 구조)	제조방법 뒤에 첨부		
제조방법	별첨		
효능, 효과	별첨		
용법, 용량	별첨		
사용상의 주의사항	별첨		
포장단위	사용상 주의사항 뒤에 첨부		
저장방법 및 사용(유효)기간	용법용량 뒤에 첨부 제조일로부터 6개월		
기준 및 시험방법	별첨		
제조사	자사제조, (주)바이오메트릭스 테크놀로지, 한국, 강원 춘천시 후평동 198-60 바이오벤처프라자 2-2호		
허가조건			

「약사법」 제31조 및 제42조에 따라 위와 같이 허가합니다.

내수용, 2010 년 08 월 19 일

식품의약품안전청장 인



품목기준코드 201005069

Plant registration / Manufacturing license certificate



문서확인번호: 1279-1557-2883-4872 (신청인 : 바이오메트릭스테크놀로지)



[별지 제8호의2서식]

등록번호 2010-13		공장등록증명(신청서)	
신청인	회사명	(주)바이오메트릭스 테크놀로지	
	대표자성명	김태선	주민등록번호 (법인등록번호) 601124- (170111-0182014)
	대표자주소 (법인의 경우에는 소재지)	춘천시 후평동 198-60 바이오벤처프라자 2-2호	
등록내역	공장소재지	춘천시 후평동 198-60 바이오벤처프라자 2-3호	지목 대지
	공장등록일	2010.05.17	사업시작일 2000.10.04
	공장의업종(분류번호)	452.71	제조시설면적(㎡) 부대시설면적(㎡)
	21300	80.71	372.00
등록조건	동 사업장은 특수배출시설인 이황화수소시설에서 발생하는 폐수를 처리하기 위하여 물리화학 및 생물학적처리방법으로 1일 처리능력 100㎥ 규모로 1989.11.2 특수배출시설 설치신고를 득한사업장으로, 새로운 특수배출시설을 설치코자 할 경우에는 사전에 설치신고를 득하여야 함.		
등록변경·중실등 기재사항변경내용 (변경일자및내용)	1. 설계고-24416(2010.07.14) 업종변경: 21210에서 21300으로		
산업집적활성화 및 공장설립에 관한 법률 시행규칙 제12조의3의 규정에 의하여 위와 같이 공장등록증명서를 신청합니다.		수수료 1,000원	
(주)바이오 메트릭스 테크놀로지 (서명또는인)			
춘 천 시 장 귀하			
산업집적활성화 및 공장설립에 관한 법률 제16조(○제1항 ●제2항 ○제3항)의 규정에 의하여 위와 같이 등록된 공장임을 증명합니다.			
2010년 07월 15일		담당부서 경제 과 책임자 양승국 담당자 이주경 전화번호 250-3361	

당신의 참여가 대한민국의 힘입니다!



서울 지방 식품의약품안전청

인상주고 기쁨주는
국민안전의 첫단추
KIFDA
식품의약품안전청

수신자 수신자참조 (경유)

제목 의약품제조업(체외진단용의약품) 허가 (알림)[(주)바이오메트릭스 테크놀로지]

1. 귀하["(주)바이오메트릭스 테크놀로지"(대표:김태선)]가 2010.05.14일자 우리청에 제출하신 의약품제조업(체외진단용의약품) 허가신청 건을 검토한 결과, 「약사법」 제31조(제조업 허가 등) 등 관계법령에 적합하여 다음과 같이 허가 하였음을 알려드립니다.

○ 허가 내역

- 가. 업소명: (주)바이오메트릭스 테크놀로지
- 나. 업신고번호: 제서울-300호
- 다. 소재지: (200-160)강원 춘천시 후평동 198-60 바이오벤처프라자 2-2호
- 라. 대표자: 김태선 (601124-1*****)
- 마. 제조관리자: (540204-2*****, 약사면허번호:20121호)
- 사. 허가조건: 체외진단용의약품 제조에 한함
- 사. 허가일자: 시행일자 와 동일

2. 귀하께서는 약사법 등 관련법규를 준수하시기 바라며, 동 신고수리사항과 관련하여 지방세법 제168조의 규정에 의거 관할기관(시·군·구청)에 면허세를 납부하시기 바랍니다.[식품의약품안전청 의약품전자민원창구(<http://ezdrug.kfda.go.kr>)에서 납부 가능].

3. 아울러, 본 민원처리결과에 대하여 이의가 있을 때에는 「민원사무처리에 관한 법률」 제18조제1항 및 같은 법 시행령 제29조제1항에 따라 신고 수리일로부터 90일 이내에 우리 청에 불임의 '민원처리결과 이의신청서' 양식에 따라 이의신청할 수 있음을 알려드립니다.

4. 또한, 생산실적 보고와 관련하여 아래 사항을 안내해 드리니 업무에 참고하시기 바랍니다.

□ 의약품 등 생산실적 보고

○ 관련법규: 「약사법」 제38조, 같은 법 시행규칙 제44조 및 「의약품등 생산실적



◆본 증명서는 인터넷으로 발급되었으며, 전자민원G4C(www.egov.go.kr)의 발급문서확인메뉴를 통해 문서확인번호 또는 문서하단의 바코드로 내용의 위·변조 여부를 확인해 주십시오. 다만, 문서확인번호를 통한 확인은 발급일로부터 90일까지 가능합니다.

ISO 13485 certificate / CE Declaration of conformity

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT



Product Service

CERTIFICATE

No. Q1N 09 09 70854 001

Holder of Certificate: Biometrix Technology Inc.
#2-2 BioVenture Plaza
198-60, Hupyongdong, Chuncheon
Kangwon 200-160
REPUBLIC OF KOREA

Facility(ies): Biometrix Technology Inc.
#2-2 BioVenture Plaza, 198-60, Hupyongdong, Chuncheon,
Kangwon 200-160, REPUBLIC OF KOREA

Certification Mark:



Scope of Certificate: Design, Development, Production and Distribution of In Vitro Diagnostic DNA Test Kits
Production and Distribution of In Vitro Diagnostic Analysers

Applied Standard(s): EN ISO 13485:2003/AC:2007
Medical Devices - Quality Management Systems - Requirements for regulatory purposes

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality system which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 74920407

Valid until: 2012-09-16

Hans-Heiner Junker



Date, 2009-10-22

Page 1 of 1

TÜV SÜD Product Service GmbH
Zertifizierstelle
Ridlerstr. 65 - 80339 München
Germany



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZO-999.98.12-46



EU Declaration of conformity

Product Name : BMT HPV 9G DNA KIT
Cat. Number : MC01

Manufacturer

Name : BIOMETRIX TECHNOLOGY INC.
Address : #2-2 BioVenture Plaza 198-60 Hupyongdong, Chuncheon Kangwon 200-160, Korea

EU Authorized Representative

Name : MT Promedt Consulting GmbH
Address : Altenhofstr. 80 66386 St. Ingbert Germany

Standards Applied

EN 13485:2003
EN 14971:2007
EN 375:2001
EN 980:2003
EN 17511:2003
EN 13611:2002
EN 13640:2002
EN 13641:2002

Mean of Conformit

We, Biometrix Technology Inc. declared that the product listed above is in conformity with the essential requirements and provision of Council Directive 98/79/EEC.

A. Technical file No : BMT-TCF-001

B. Certification Number : BMT-CE09-001

C. Date : November 05, 2009

Name & signature of authorized person

BIOMETRIX TECHNOLOGY INC.

#2-2 BioVenture Plaza 198-60 Hupyongdong, Chuncheon Kangwon 200-160, Korea
Tel : 82-33-258-6097/6098 Fax : 82-33-258-6099

CE Declaration of conformity



EU Declaration of conformity

Product Name : BMT HPV 9G MEMBRANE DNA KIT
Cat. Number : MC07

Manufacturer

Name : BIOMETRIX TECHNOLOGY INC.
Address : #2-2 BioVenture Plaza 198-60 Hupyongdong, Chuncheon Kangwon 200-160, Korea

EU Authorized Representative

Name : MT Promedt Consulting Gmbh
Address : Altenhofstr. 80 66386 St. Ingbert Germany

Standards Applied

EN 13485:2003
EN 14971:2007
EN 375:2001
EN 980:2003
EN 17511:2003
EN 13611:2002
EN 13640:2002
EN 13641:2002

Mean of Conformit

We, Biometrix Technology Inc. declared that the product listed above is in conformity with the essential requirements and provision of Council Directive 98/79/EEC.

A. Technical file No : BMT-TCF-002

B. Certification Number : BMT-CE10-001

C. Date : April 05, 2010

Kim, Taisun
Name & signature of authorized person

BIOMETRIX TECHNOLOGY INC.

#2-2 BioVenture Plaza 198-60 Hupyongdong, Chuncheon Kangwon 200-160, Korea
Tel : 82-33-258-6097/6098 Fax : 82-33-258-6099



EU Declaration of conformity

Type of Equipment : In Vito Diagnostic Analysers
Product Name : BMT 1-D Scanner
Product Number : 1DF-929740-003

Manufacturer

Name : BIOMETRIX TECHNOLOGY INC.
Address : #2-2 BioVenture Plaza 198-60 Hupyongdong, Chuncheon Kangwon 200-160, Korea

EU Authorized Representative

Name : MT Promedt Consulting Gmbh
Address : Altenhofstr. 80 66386 St. Ingbert Germany

Standards Applied

Safety :
IEC / EN 61010-1 : 2001
IEC / EN 61010-2-101 : 2002
IEC / EN 61010-2-081

EMC : Conform to the following product Specification; EMC Directive 2004/108/EC
Standard :
EN 61326-2-6 : 2006

Reference :
EN 55011 : 2007
EN 61000-3-2 : 2006
EN 61000-3-3 : 1995 + A1 : 2001 + A2 : 2005
EN 61000-4-2 : 1995 + A1 : 1998 + A2 : 2001
EN 61000-4-3 : 2002
EN 61000-4-4 : 2004 + A2 : 2004
EN 61000-4-5 : 1995 + A1 : 2001
EN 61000-4-6 : 1996 + A1 : 2001
EN 61000-4-8
EN 61000-4-11 : 1996

Mean of Conformit

We, Biometrix Technology Inc. declared that the product listed above is in conformity with the essential requirements and provision of Council Directive 98/79/EEC.

A. Technical file No : BMT-TCF-003

B. Certification Number : BMT-CE10-002

C. Date : April 05, 2010

Taisun Kim
Name & signature of authorized person

BIOMETRIX TECHNOLOGY INC.

#2-2 BioVenture Plaza 198-60 Hupyongdong, Chuncheon Kangwon 200-160, Korea
Tel : 82-33-258-6097/6098 Fax : 82-33-258-6099

○ Venture Company Certificate / INNO-BIZ Certificate

제 20100200600 호

벤처기업확인서

업 체 명 : (주)바이오메트릭스테크놀로지
대 표 자 : 김태선
소 재 지 : 강원 춘천시 후평동 198-60 바이오벤처프라자 2-2호
확 인 유 형 : 기술평가보증기업(기술보증기금)
평 가 기 관 : 기술보증기금
유 효 기 간 : 2010년 02월 25일 ~ 2011년 02월 24일

위 업체는 벤처기업육성에관한특별조치법 제25조의 규정에 의하여 벤처기업임을 확인합니다.

2010년 02월 25일

KIBO 기술보증기금 이사장



제 R7085 - 2388 호

기술혁신형 중소기업(INNO-BIZ) 확인서

업 체 명 : (주)바이오메트릭스테크놀로지
대 표 자 : 김태선
주 소 : 강원 춘천시 후평동 198-60 바이오벤처프라자 2-2호
등 급 : A
유 효 기 간 : 2010. 6. 16 ~ 2013. 6. 15

위 업체는 기술혁신형 중소기업 발굴 육성사업에 의해 선정된 기술혁신형 중소기업(INNO-BIZ)임을 확인합니다.

※ 요청에 의한 재교부



2010년 6월 3일

중 소 기 업 청 장



○ Certificate of R & D Center

제 20021951 호

기업부설연구소인정서

1. 연구소명: (주)바이오메트릭스테크놀로지 R&D Center
[소속기업명: (주)바이오메트릭스테크놀로지]
2. 소재지: 강원 춘천시 후평동 198-60 바이오벤처프라자
2-2-A,B,C,D호
3. 신고연월일: 2002년 6월 10일
(최초인정일: 2002년 7월 22일)

* 변경내역: 소재지 변경: 2010년 7월 1일

기술개발촉진법 제16조 및 동법 시행령 제15조 제1항의
규정에 의하여 위와 같이 기업부설연구소로 인정합니다.

2010년 7월 1일



사단
법인 한국산업기술진흥협회장

