Seegene

Cutting-edge Real-time PCR "Seegene's Next Step"

J.P. Morgan 34th Annual Healthcare Conference

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Contents

Part 1 MDx Trend & Seegene's key performance in 2015

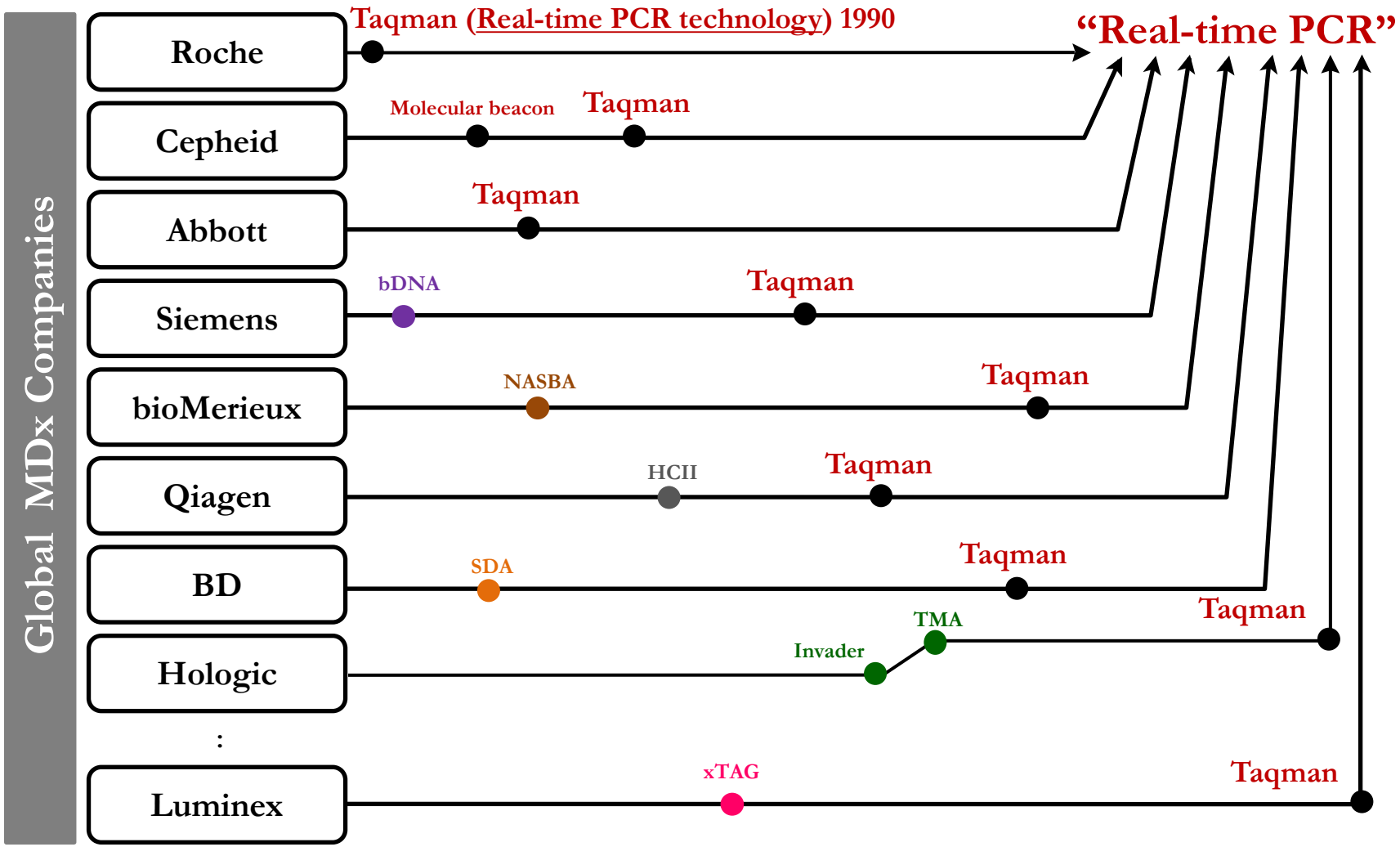
1. MDx Trend
   1) Focus on Technology ---------- 5
   2) Focus on Instrumentation ---------- 6
   3) Focus on "The necessity of multiplex testing" ---------- 7
2. Seegene's Key performance in 2015
   1) Cutting-edge Real-time PCR ---------- 8
   2) Multiplex Menu Expansion ---------- 12
   3) ODM Agreement with Global Companies ---------- 13

Part 2 Seegene's Next Step

1. Hurdles & Solutions of MDx Market Expansion ---------- 15
2. Hurdles & Solutions of Menu Expansion ---------- 17
3. Seegene's Future Product Portfolio ---------- 20
4. Seegene's Strategic Alliance for Next Step ---------- 22
5. Seegene's Business Plan ---------- 24

Seegene's Evolution of MDx (Molecular diagnostics)

MDx Migration to Real-time PCR



"Taqman technology is 1~3 analytes/test"

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Necessity of a Broad Menu of MDx Assays

- *Single : 1~3 analytes/test (Taqman)*
- *Multiplex : Over 5 analytes/test*

Multiplex assays ✚ Roche (2014)

Multiplex assays ✚ Qiagen (2010)

Multiplex assays ✚ Abbott (2005)

Major Real-time PCR Instrumentation

Current available menu: "Single assays"

Hologic (2010) ✚ Multiplex assays

Beckman Coulter (2014) ✚ Multiplex assays

Cepheid (2006) ✚ Multiplex assays

BD (2011) ✚ Multiplex assays

Menu expansion: Multiplex Assays

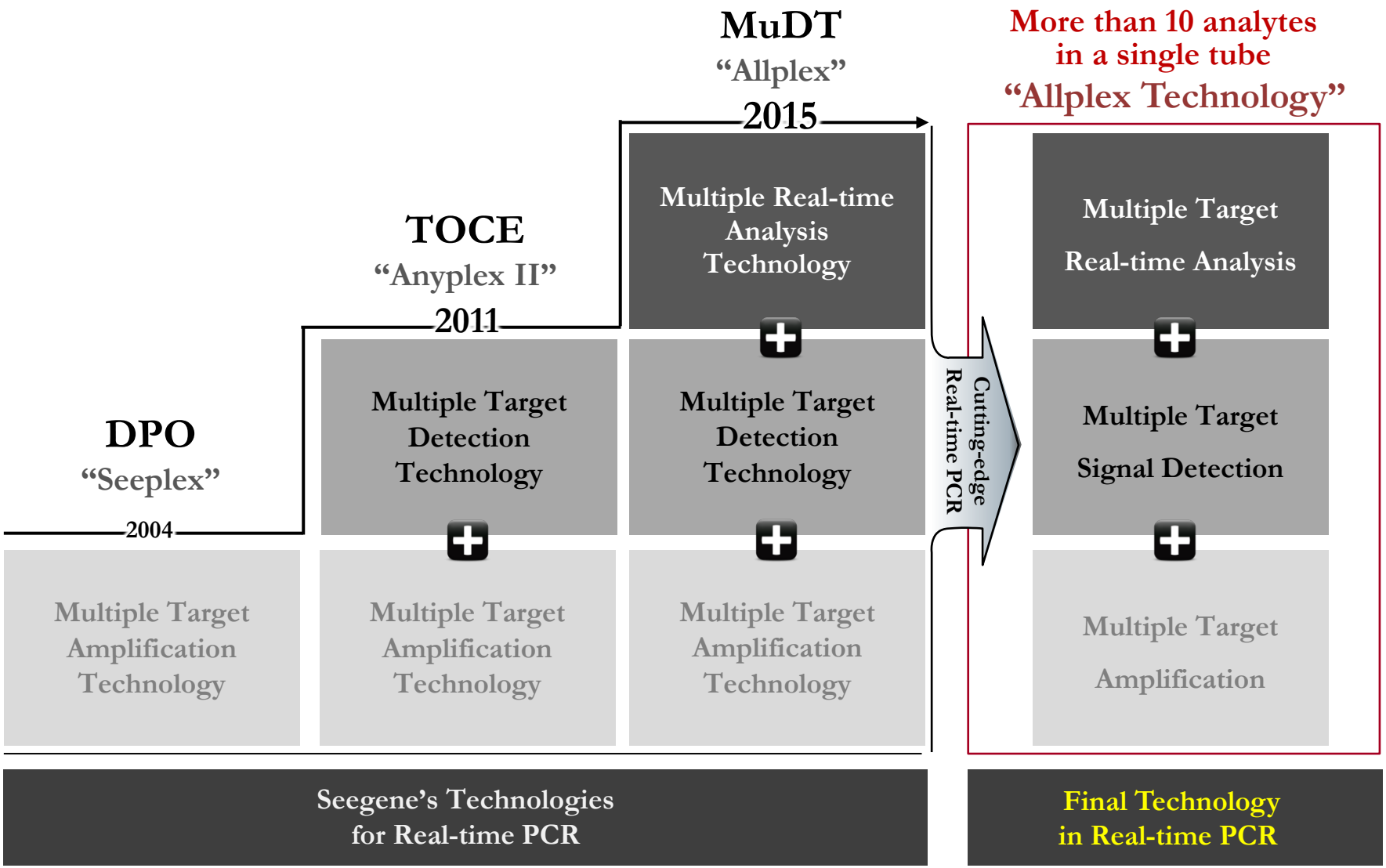
One Disease, Multiple Pathogens

Disease	Causing pathogen
Respiratory disease	**Over 26 pathogens** (7 bacteria, 19 virus) Adenovirus, Influenza A virus, Influenza B virus, Parainfluenza virus1, Parainfluenza virus2, Parainfluenza virus3, Parainfluenza virus4, Rhinovirus A/B/C, Respiratory syncytial virus A, Respiratory syncytial virus B (RSV B), Bocavirus 1/2/3/4, Metapneumovirus, Coronavirus 229E, Coronavirus NL63, Coronavirus OC43, Enterovirus, *M.pneumoniae, C.pneumoniae, L.pneumophila, B.pertussis, Bparapertussis*
STI **(Sexually transmitted infection)**	**Over 28 pathogens** (7 bacteria, 19 virus) *C. trachomatis, N. gonorrhoeae, M. genitalium, M. hominis, T. vaginalis, U. urealyticum, U. parvum,* HSV 1, HSV 2, *T. pallidum, H. ducreyi,* LGV, CMV, VZV, *C. albicans, C. glabrata, C. tropicalis, C. parapsilosis, C. krusei, C. lusitaniae, C. dubliniensis, G. vaginalis, A. vaginae, Megasphaera type 1, BV-associated bacteria 2, Mobiluncus spp., B. fragilis, Lactobacillus spp.*
Gastrointestinal disease	**Over 27 pathogens** (14 bacteria, 7 virus, 6 parasite) *S. bongori, S. enterica, S. flexneri, S. boydii, S. sonnei, S. dysenteriae, V. cholerae, V.parahaemolyticus, V. vulnificus, C. jejuni, C. coli, C.difficile* Toxin B, *C.perfringens, A. media, A. veronii, A. salmonicida, A. sobria, A. bivalvium, A. hydrophila* , Verocytotoxin-producing *E. coli, Yersinia enterocolitica, E. coli* O157:H7, Group A rotavirus, Enteric adenovirus, Norovirus GI/GII (NoV-GI/GII), Astrovirus(AstV)
Tuberculosis	**Over 38 mutations** *M.tuberculosis,* Isoniazid-resistance (7 mutations), Rifampicin-resistance(18 mutations), Fluoroquinolone-resistance (7 mutations), Injectable drug-resistance(6 mutations)

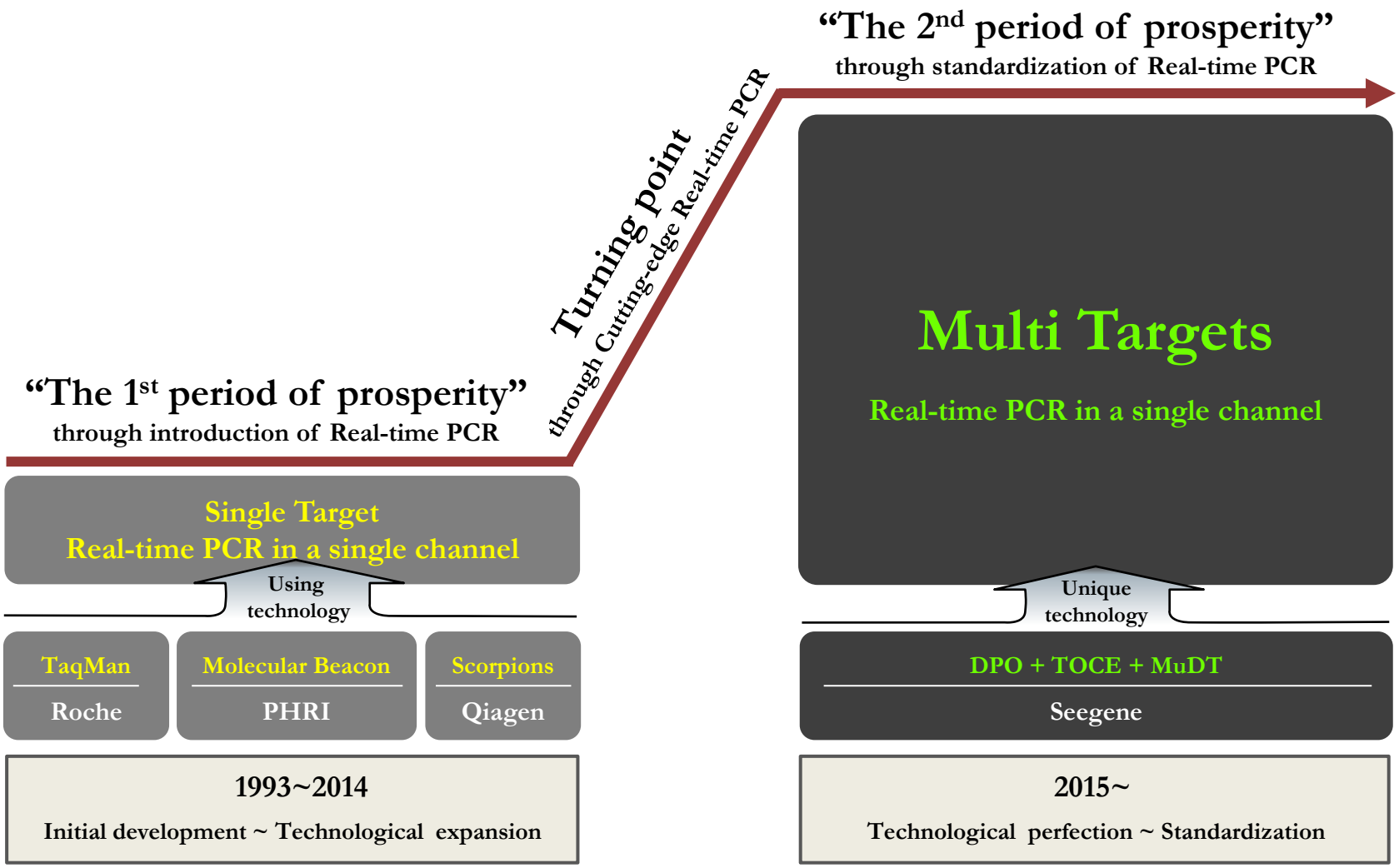
⋮

Pathogen-based Test ⇒ **Symptom-based Test**

Technological Perfection of Real-time PCR



Industrial Prospects for Real-time PCR



Example Application of Seegene's Technology: "Specification" Product Competitive Advantage (1)

Trends in HPV Testing for cervical cancer screening

Real-time PCR

2004	2008	2012 Jul	2012 Nov	2014 Feb	2014 Jan
QIAGEN	HOLOGIC The Women's Health Company	HOLOGIC The Women's Health Company	Roche	BD	Seegene

With our innovative technology!

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Anyplex II HPV HR (14 types)

"One tube"

HPV16
HPV18
HPV31
HPV33
HPV35
HPV39
HPV45
HPV51
HPV52
HPV56
HPV58
HPV59
HPV66
HPV68
Internal control

Approved for public health and clinical use in cervical cancer screening

International guidelines

- ☑ Sensitivity
- ☑ Specificity
- ☑ Intra-lab reproducibility
- ☑ Inter-lab agreement

Example Application of Seegene's Technology: "Performance" Product Competitive Advantage (2)

Proved by Global HPV Lab Network (41 products, 119 labs)

GLOBAL HPV LABNET

Continued global improvement in HPV DNA genotyping: The 2014 HPV LabNet International Proficiency Study

Human Papillomavirus Reference Center International

Carina Eklund*, Keng-Ling Wallin^, Ola Forslund#, Joakim Dillner* and the Global HPV Laboratory Network
* Departments of Laboratory Medicine, Medical Epidemiology & Biostatistics, Karolinska Institutet, Stockholm, Sweden, ^Equalis, Uppsala, Sweden, #Skåne University Hospital, Malmö, Sweden

Type of HPV assay	Number of datasets	100% proficient	99-90 % proficient	89-80 % proficient	<80 % proficient	Not proficient
All assays	146	86	16	9	5	30
Anyplex II HPV28 (Seegene)	10	10	0	0	0	0
Onclarity (E	5	4	1	0	0	0
Linear A	14	7	1	1	0	5
Cobas 4800 (Roche)	4	4	0	0	0	0
Realtime PCR (Abbott)	3	1	0	2	0	0
Other Commercial assays	14	9	1	0	1	3
:	:	:	:	:	:	:

- 100% proficiency at all 10 lab participants.
- Detection of all 5 HPV subtypes and its multiple co-infection.
- The best performance in sensitivity, specificity and reproducibility.

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Launching MuDT-Based Allplex Products

Respiratory Full Panel Assay

Panel 1	Panel 2	Panel 3	Panel 4
- Flu A	- AdV	- HBoV	- MP
- Flu B	- HEV	- HRV	- CP
- RSV A	- PIV 1	- CoV NL63	- LP
- RSV B	- PIV 2	- CoV 229E	- HI
- H1	- PIV 3	- CoV OC43	- SP
- H1pdm09	- PIV 4		- BP
- Flu A-H3	- MPV		- BPP

* Current technology requires 10 tubes for 26 pathogens

Gastrointestinal Full Panel Assay

Panel 1	Panel 2	Panel 3	Panel 4
- NoV GI	- *Campylobacter*	- *CD hypervirulent*	- *G. lamblia*
- NoV GII	- *CD toxin B*	- *E. coli O157*	- *E. histolytica*
- RTV	- *Salmonella*	- *EHEC*	- *Cryptosporidium*
- ADV	- *EIEC/Shigella*	- *EPEC*	- *B. hominis*
- ATV	- *Vibrio*	- *ETEC*	- *D. fragilis*
- SPV	- *Y. enterocolitica*	- *EAEC*	- *C. cayetanensis*
	- *Aeromonas*		

* Current technology requires 10 tubes for 25 pathogens

Tuberculosis Test

MTB

Multi-Drug Resistance
- Isoniazid-resistance (7 mutations)
- Rifampicin-resistance (18 mutations)

Seegene HPV HR (14)

- HPV16	- HPV39	- HPV58
- HPV18	- HPV45	- HPV59
- HPV31	- HPV51	- HPV66
- HPV33	- HPV52	- HPV68
- HPV35	- HPV56	

Seegene HPV 28

Panel 1		Panel 2	
- HPV16	- HPV51	- HPV69	- HPV43
- HPV18	- HPV52	- HPV73	- HPV44
- HPV31	- HPV56	- HPV82	- HPV54
- HPV33	- HPV58	- HPV 6	- HPV 61
- HPV35	- HPV59	- HPV11	- HPV70
- HPV39	- HPV66	- HPV40	- HPV26
- HPV45	- HPV68	- HPV42	- HPV53

STI/BV Full Panel Assay

Panel 1	Panel 2	Panel 3	Panel 4
- *C. trachomatis*	- HSV 1	- *C. albicans*	- *G. vaginalis*
- *N. gonorrhoeae*	- HSV 2	- *C. glabrata*	- *A. vaginae*
- *M. genitalium*	- T. pallidum	- *C. tropicalis*	- *Megasphaera type 1*
- *M. hominis*	- H. ducreyi	- *C. parapsilosis*	- *BV-associated bacteria 2*
- *T. vaginalis*	- LGV	- *C. krusei*	- *Mobiluncus spp.*
- *U. urealyticum*	- CMV	- *C. lusitaniae*	- *B. fragilis*
- *U. parvum*	- VZV	- *C. dubliniensis*	- *Lactobacillus spp.*

* Current technology requires 10 tubes for 28 pathogens

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Adding Multiplex Menus to Global Company's Instruments

Real-time PCR Instruments

- *Single : 1~3 analytes/test*
- *Multiplex : Over 5 analytes/test*

"ODM 1"

[Beckman Coulter]

Current menu

- HIV-1
- HCV
- HBV
- CMV

Single assays

+

Seegene's Multiplex Assays

"ODM 2"

[Qiagen]

Current menu

- HIV-1
- HCV
- HBV
- CMV
- CT/NG
- C.difficile
- MRSA
- VRE

Single assays

+

Seegene's Multiplex Assays

"ODM 3"

[Becton Dickinson]

Current menu

- FluA/B
- GC
- GBS
- C.difficile
- MRSA
- Staph SR

Single assays

+

Seegene's Multiplex Assays

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5. Seegene's Business Plan ---------- 24

Hurdles of MDx Market Expansion

1 **Pathogen-based Test** ⇒ **"Limited information"**

Ex. Gastrointestinal disease

Over 27 pathogens

Norovirus GI/GII , S. bongori, S. enterica, S. flexneri, S. boydii, S. sonnei, S. dysenteriae, V. cholerae, V.parahaemolyticus, V. vulnificus, C. jejuni, C. coli, C.difficile Toxin B, C.perfringens, A. veronii, A. salmonicida, A. sobria, A. bivalvium, A. hydrophila , Verocytotoxin -producing E. coli, Yersinia enterocolitica, E. coli O157:H7, Group A rotavirus, Enteric adenovirus, Astrovirus

2 **Costly Test** ⇒ **"Limited use"**

Ex. Gastrointestinal patients

$5.6B*

Current Situations

* *Reference: Analysis of the Global In Vitro Diagnostics Market, Frost & Sullivan (2013)*

Solution of MDx Market Expansion

1 Symptom-based Test → "Full information"

Ex. Gastrointestinal disease

Over 27 pathogens

Norovirus GI/GII , S. bongori, S. enterica, S. flexneri, S. boydii, S. sonnei, S. dysenteriae, V. cholerae, V.parahaemolyticus, V. vulnificus, C. jejuni, C. coli, C.difficile Toxin B, C.perfringens, A. media, A. veronii, A. salmonicida, A. sobria, A. bivalvium, A. hydrophila , Verocytotoxin -producing E. coli, Yersinia enterocolitica, E. coli O157:H7, Group A rotavirus, Enteric adenovirus, Astrovirus

2 Cheap Test → "Common use"

Ex. Gastrointestinal patients

$5.6B*

Future Potential Market

* *Reference: Analysis of the Global In Vitro Diagnostics Market, Frost & Sullivan (2013)*

Hurdles of Menu Expansion

For menu expansion.....

1. Requiring more than a year for one product development
2. Requiring a variety of technologies for covering a variety of menu

Barriers faced by Lab Operations

Solution of Menu Expansion

For menu expansion.....

1. Simultaneous product co-development for complete menu
2. One platform technology to cover a variety of menu

Providing solutions to barriers faced by Lab Operations

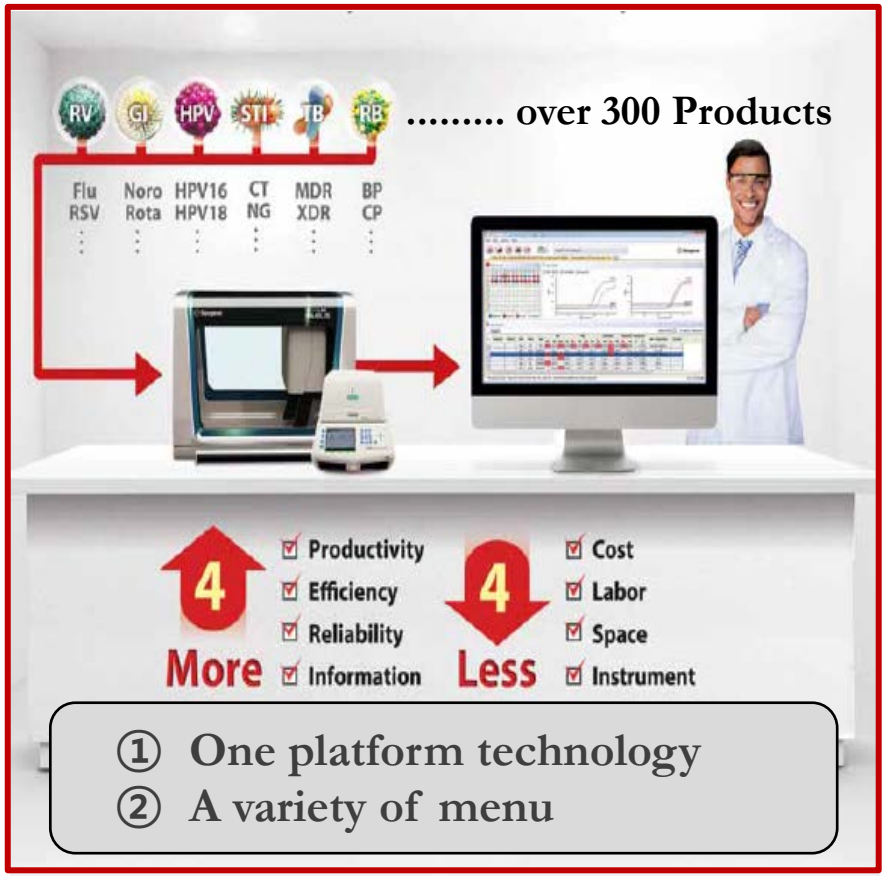
Simulation of Test Lab Operation

Which is more efficient?

Multiple platforms

"Current lab situation"

One platform



"Ideal lab operation"

Seegene's Future Product Portfolio (1)

Infectious Disease

Blood

- HBV/HCV/HIV
- Culture ID
- Chikungunya/Dengue
- Chikungunya
- Dengue
- HAV
- HBV
- HCV
- HIV
- WNV
- HEV
- CMV
- Ebola
- Filovirus
- Malaria
- Parvo B19

Respiratory

- RV full panel
- RB full panel
- RV 3~7
- NTM panel
- Atypical CAP
- Influenza A/B
- Influenza typing
- RSVA/B
- Adenovirus
- HRV
- MPV
- PIV
- Coronavirus
- Measles
- MERS
- Mumps

STI (Sexually Transmitted Infection)

- HPV HR/LR typing
- HPV HR screening
- STI full panel
- STI 10
- STI 9
- STI 8
- STI 7
- Candida 6
- CT/NG/MG/HSV/TP
- HSV 1/ HSV 2/TP
- CT/NG/TV
- CT/NG/MG
- UU/MG/NH
- CT/NG
- CT
- NG

GI (Gastrointestinal Infection)

- GI full panel
- GI bacterial 6
- GI virus 6
- Stool parasites 6
- GI bacteria 4
- Salmonella typing
- Stool parasites 3
- *C.diff* A, B
- *C.difficile, Epi*
- Noro I/II
- Noro-C.diff
- *C.difficile*
- Adenovirus
- Astrovirus
- Rotavirus
- EHEC

...

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Seegene's Future Product Portfolio (2)

Personalized medicine

Oncology

- Wilms tumor
- Melanoma cancer panel
- Prostate cancer panel
- Lung cancer panel
- Colorectal cancer panel
- Endometrial cancer panel
- BCR-ABL
- BCR-ABL 1 mbcr
- BCR-ABL 1 Mbcr
- BRAF V600E
- BRCA1 and BRCA2
- BRCA1 /2 Ashkenazi
- BRCA1 / 2 Ashkenazi
- Breast cancer HR panel
- Breast/Ovarian panel
- Comprehensive cancer panel

SNP/DR
(Single Nucleotide Polymorphism/Drug Resistance)

- ApoE
- MDR
- XDR
- HBV DR (lamivudine, adefovir, & entecavir ...)
- Sepsis DR (carbapenemase & ESBL...)
- Warfarin
- CYP2C19
- CYP450 2C19+
- CYP450 2C19+ Duplex
- CYP450 3A4
- CFTR-31
- Factor II
- Factor II & V Leiden
- Factor V Leiden

Genetics

- Familial Hypercholesterolemia
- Cystic Fibrosis
- Familial Mediterranean Fever
- Ashkenazi Jewish Panel
- Fragile X Syndrome
- Tay-Sachs disease
- Cardio IQ 9p21 Genotype
- ANCA Screen
- CNBP Repeat Analysis
- B-negative SCID Panel
- B-positive SCID Panel
- Cardiomyopathy Panel
- Childhood-Onset Epilepsy Panel
- CNBP Repeat Analysis
- Combined Cardiac Panel
- DPD-Mutation

Seegene's Strategic Alliance for Next Step

Direction of Market Expansion

"Complete Menu on One Platform"

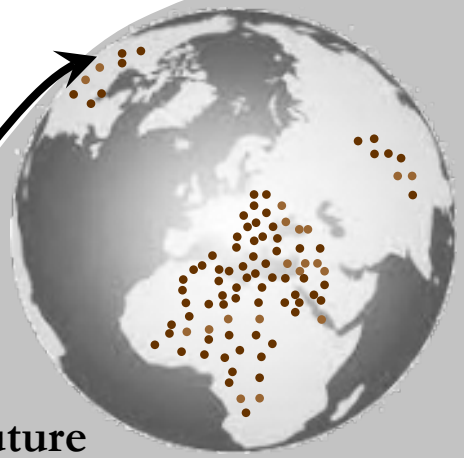
Quick product development using Seegene's advanced technology

"Seegene's Next Steps"

Simultaneous Co-development through worldwide collaboration

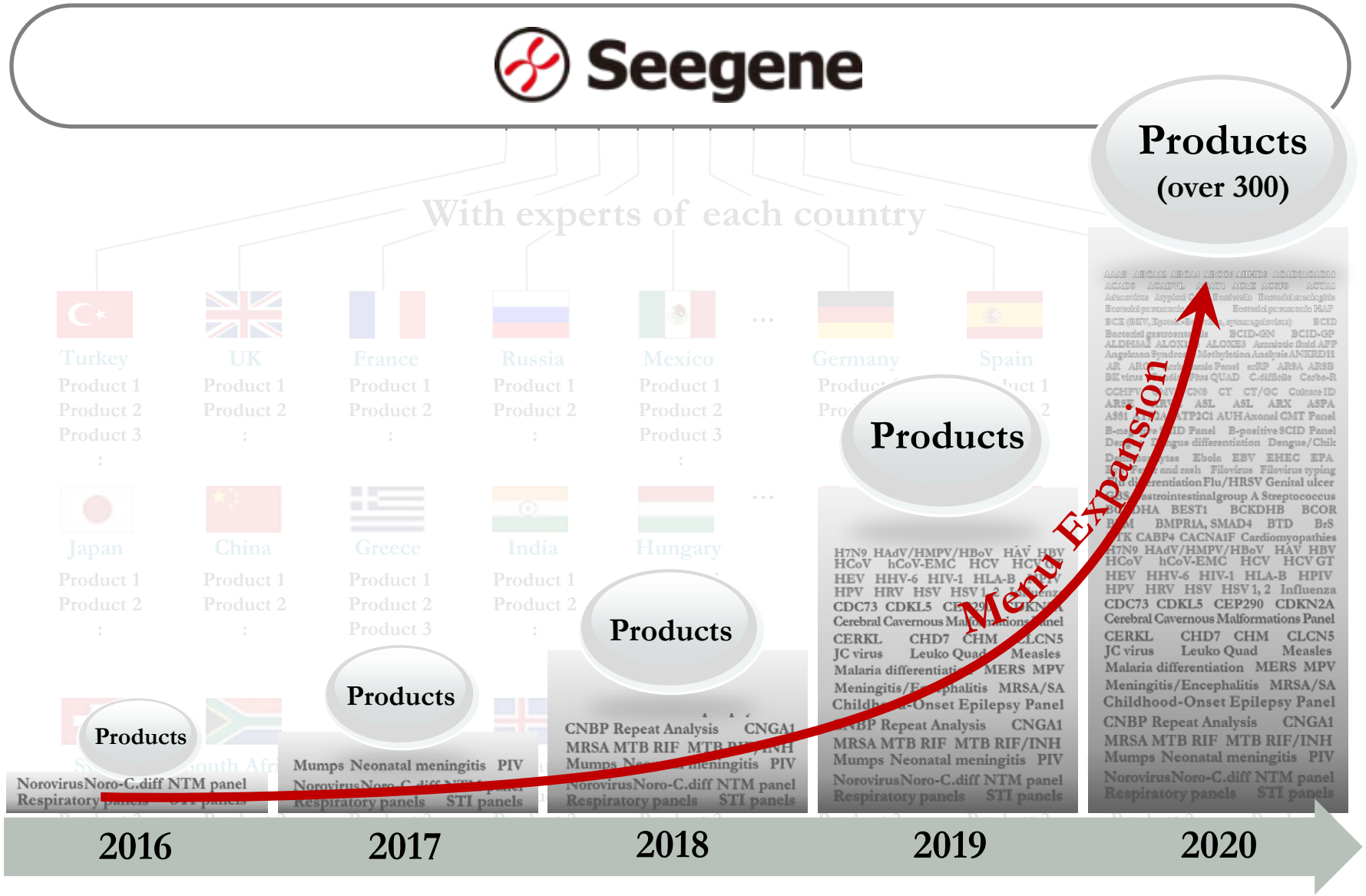
Current

To ramp up the market



Future

Co-development through Worldwide Collaboration



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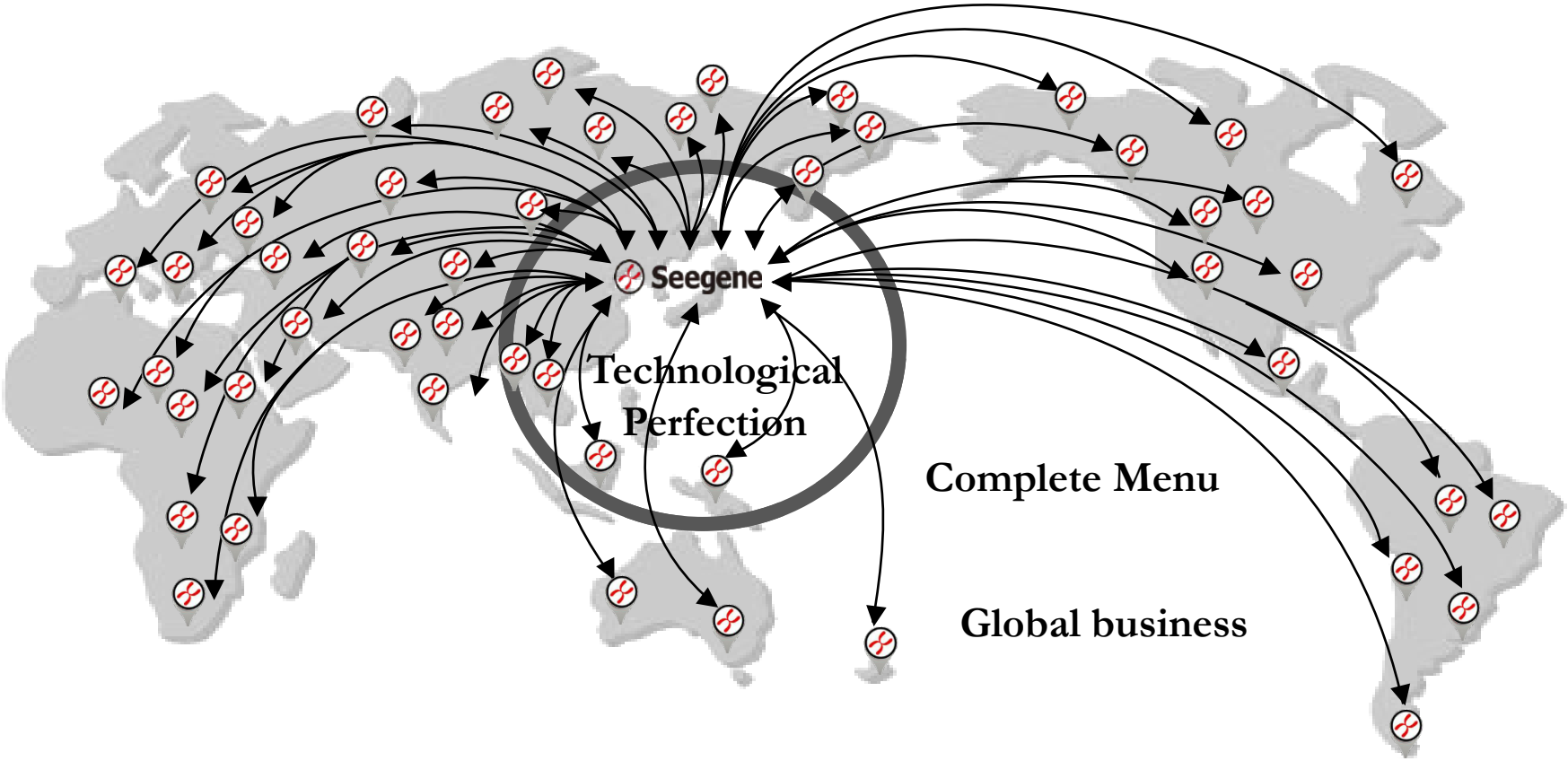
Seegene's Business Plan



Step 1	2015	Technological perfection of real-time PCR
Step 2	2016~	Worldwide collaborations for co-development
Step 3	Future	Expand the market with broad menu developed around the world

Thank You!

Seegene