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# Seegene

## 2016 Investor Relations

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2016.11

# Seegene Overview

## Overview of Seegene

- CEO/CTO: Dr. Jong-Yoon Chun
- Established: Sept. 15, 2000
- Listed on KOSDAQ: Sept. 10, 2010
- Paid-in capital: KRW 13,117mn (as of Dec. 31, 2015)
- Number of employees: 243 (as of Dec. 31, 2015)
- Business area: Molecular Diagnostics(MDx)
- Key proprietary MDx technologies  
: DPO™(2005), TOCE™(2011), MuDT™(2014)

## Major Products

### MDx Reagents



- Respiratory Infection
- Gastrointestinal Infection
- Women's Health
- Other Infections disease

### Instruments (OEM or re-sale)



Nimbus (Hamilton)



STARlet (Hamilton)

**OEM**

[Extraction]



CFX96 (Bio-Rad)

**Re-sale**

[Real-time PCR]

## Global Network

- Headquarter: Seoul, South Korea
- Foreign subsidiaries: Italy, Dubai, US, Canada
- Branch office : Germany
- Joint Venture: Mexico
- Supplying reagents/instruments through 82 agencies
  - 21 distribution agencies in Korea
  - 61 distribution agencies in 55 overseas markets

### Foreign subsidiaries & Branch office



# Industry Overview

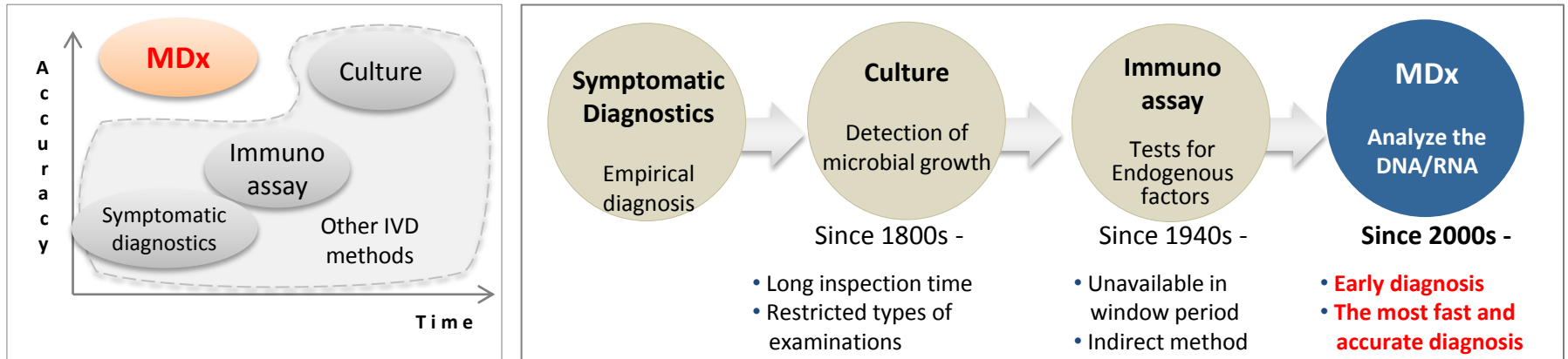
A 3D rendering of a DNA double helix structure, colored in shades of blue and white, set against a light blue background with abstract, flowing shapes. The DNA structure is positioned on the right side of the image, extending from the top to the bottom. The background features a light blue gradient with abstract, flowing shapes that resemble waves or smoke, creating a sense of movement and depth. The overall aesthetic is clean, modern, and scientific.

# IVD Market

## Classification of Diagnostics Methods

- **In vivo Diagnostics** : Analyze the health status inside of the human body. ex) X-ray, CT, MRI
- **In vitro Diagnostics** : Analyze the specimens derived from the body such as **blood, urine etc.**

## Evolving IVD Method



## Process of MDx



# MDx Market Trend

## Market Size of IVD & MDx Industry

Classification		Market Size					CAGR (%)	
		`12	`13	`14(E)	`15(E)	`16(E)		`17(E)
Global IVD Market (Unit : USD bn)		45.7	48.7	52.2	55.9	<b>60.1</b>	64.7	7.2
MDx Market	Global (Unit : USD bn)	5.0	5.6	6.3	7.2	<b>8.1</b>	9.1	<b>12.6</b>
	Korea (Unit : KRW bn)	57.7	64.9	73.0	82.6	<b>93.5</b>	106.4	13.0

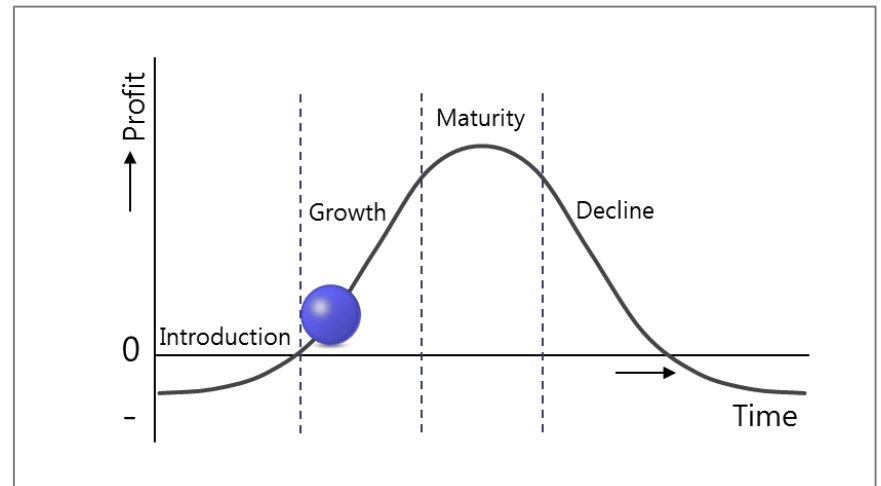
[Source] Analysis of the Global In Vitro Diagnostics Market, Frost & Sullivan(2013), Analysis of the Asia-Pacific Molecular Diagnostics Market, Frost & Sullivan(2013)

## Application Fields of Molecular Diagnostics

Classification		Share
Infectious disease		63%
Non-infectious disease	Cancer	20%
	Genetic disorder	9%
	Pharmacogenomics	8%

[Source] Molecular Diagnostics: Market Segmentation and Opportunities October 2010, DeciBio, Frost & Sullivan (2013)

## MDx Industry Life Cycle



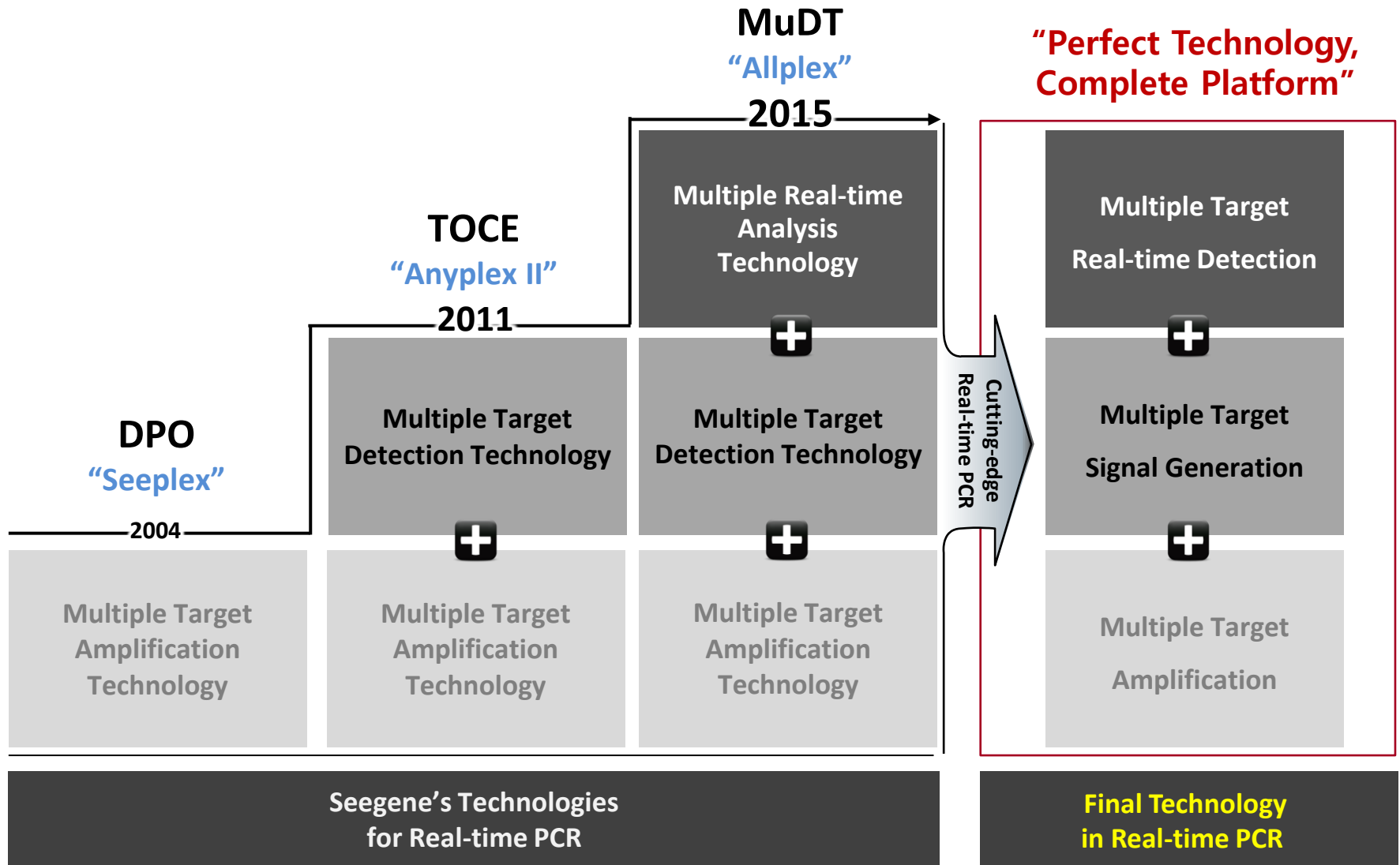
# Competitive Positioning of Real-time PCR Technology

Patent	DNA amplification technologies	Companies	Homogeneous (Closed System)	Multiplex (> 10-plex)	SNP (> 10 point mutations)	Quantification (> 10 analytes)
<b>1983</b>	<b>PCR</b>	<b>Roche</b>				
1989	bDNA	Siemens	→			
1989	Line Probe	Fujirebio	→			
<b>1990</b>	<b>TaqMan</b>	<b>Roche</b>	→			
1991	NASBA	bioMerieux	→			
1992	SDA	BD	→			
1993	Hybrid Capture	Qiagen	→			
1995	TMA	Hologic	→			
1995	Invader	Hologic	→			
1996	Molecular Beacon	PHRI	→			
1997	Hyb Probe	Roche	→			
1999	Scorpions	Qiagen	→			
1999	Bead Technology	Luminex	→			
<b>2011</b>	<b>TOCE</b>	<b>Seegene</b>	→			
<b>2014</b>	<b>MuDT</b>	<b>Seegene</b>	→			

# Technology Overview & Products

A 3D rendering of a DNA double helix structure, colored in shades of blue and white, set against a light blue background with abstract, flowing shapes.

# Technological Perfection of Real-time PCR





# Commercialized Multiplex Product Line & Global Certification

## Global Certification

Korea(MFDS)	EU(CE, CE0086)	Canada(Health Canada)	Australia(TGA)	U.S.(FDA)
<b>61 items</b> <ul style="list-style-type: none"> <li>• Class IV: 1</li> <li>• Class III: 52</li> <li>• Class II: 2</li> <li>• Class I :6</li> </ul>	<b>51 items</b> <ul style="list-style-type: none"> <li>• List B: 12</li> <li>• Others: 39</li> </ul>	<b>10 items</b> <ul style="list-style-type: none"> <li>• Class III: 1</li> <li>• Class II: 9</li> </ul>	<b>24 items</b> <ul style="list-style-type: none"> <li>• Class III: 20</li> <li>• Class II: 4</li> </ul>	<b>1 items</b> <ul style="list-style-type: none"> <li>• 510(k)</li> </ul>

※ Certified in other 16 countries

## Approval status of Allplex™ assays

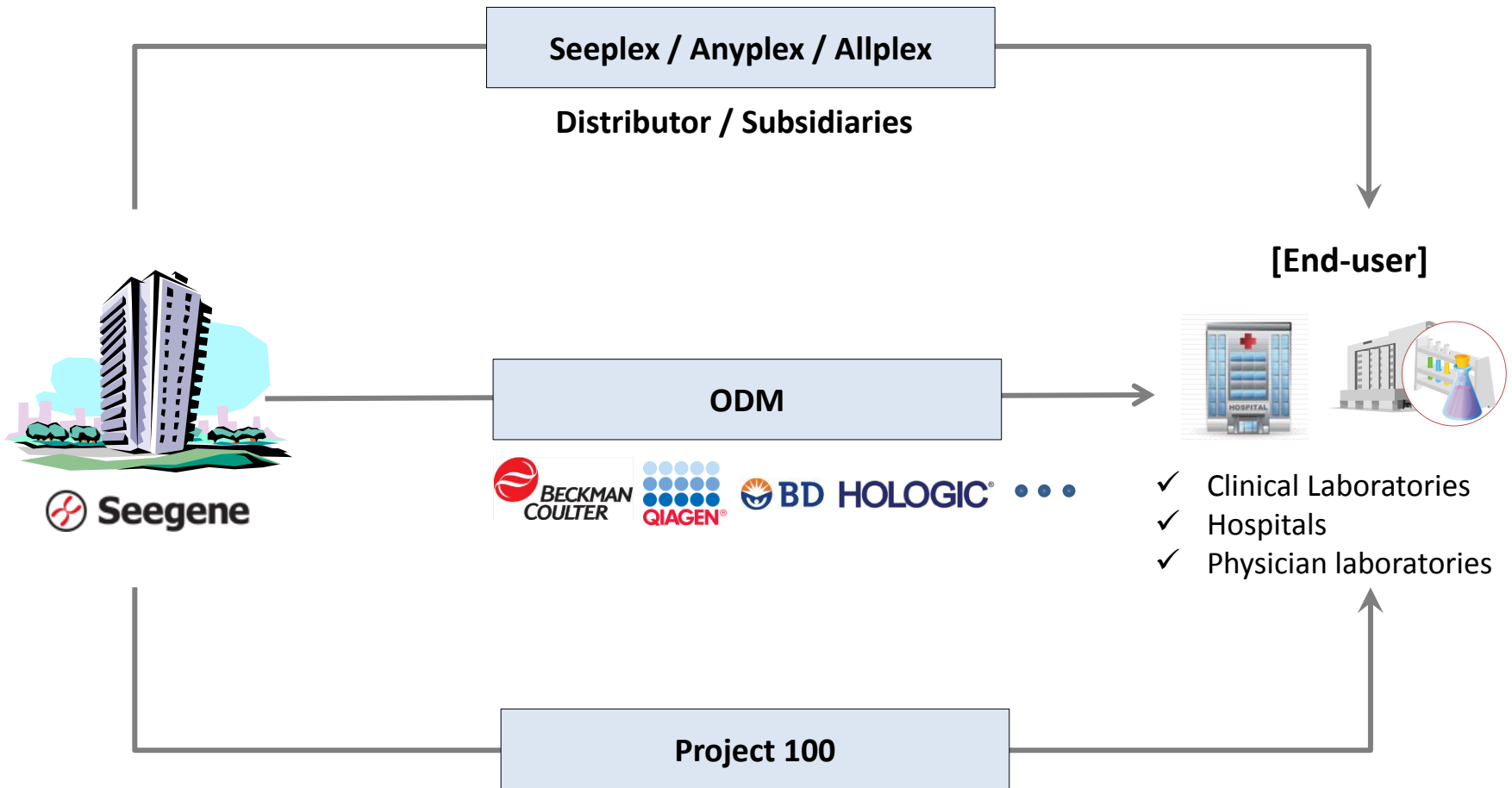
Line-up	Products	EU(CE-IVD)	Canada(Health Canada)	Australia(TGA)	Korea(MFDS)
Respiratory Infection	Allplex™ RP1	●	●	●	●
	Allplex™ RP2	●	●	●	◐
	Allplex™ RP3	●	●	●	◐
	Allplex™ RP4	●	○	●	◐
Gastrointestinal Infection: GI	Allplex™ GI1	●	●	●	◐
	Allplex™ GI2	●	◐	●	◐
	Allplex™ GI3	●	◐	●	◐
	Allplex™ GI4	●	●	●	◐
Sexually Transmitted Infection: STI	Allplex™ STI/BV 1	●	○	●	○
	Allplex™ STI/BV 2	●	○	●	○
	Allplex™ STI/BV 3	●	○	◐	○
	Allplex™ STI/BV 4	◐	○	○	○

● Cleared ● Cleared in 3Q16 ● In progress ○ TBD





# **Business Strategy**



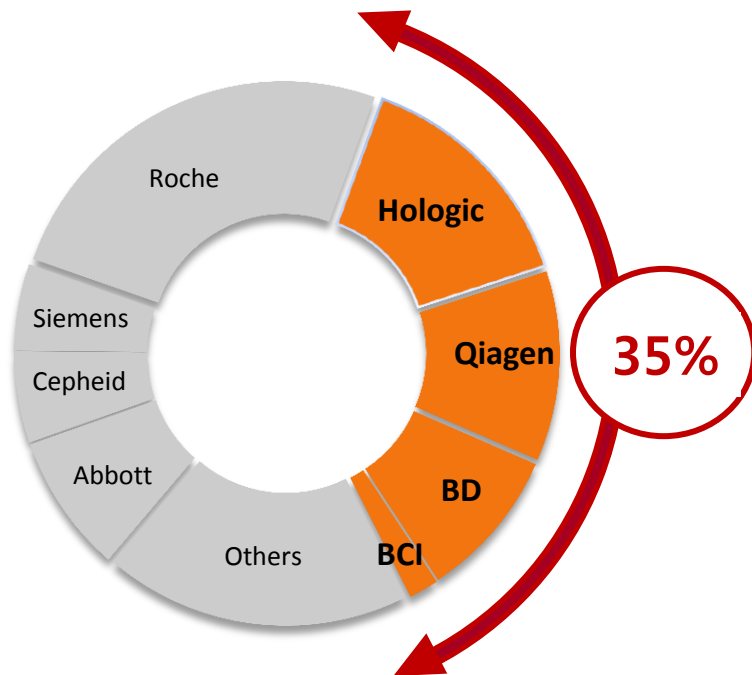
# Business Model



# ODM Partners

Danaher(Beckman Coulter)	Qiagen	Becton Dickinson	Hologic
Contracted in 2014.11.13	Contracted in 2015.07.09	Contracted in 2015.09.15	Contracted in 2016.11.04
<ul style="list-style-type: none"> <li>• No.3 in IVD market (M/S 10.3%)</li> <li>• No.1 in hematology market (M/S 33.3%)</li> </ul>	<ul style="list-style-type: none"> <li>• No.3 in MDx market (M/S 11.6%)</li> <li>• No.1 in HPV test market (M/S over 60%)</li> </ul>	<ul style="list-style-type: none"> <li>• No.4 in MDx market (M/S 9.2%)</li> <li>• No.6 in IVD market (M/S 5.4%)</li> </ul>	<ul style="list-style-type: none"> <li>• No.2 in MDx market (M/S 14.4%)</li> <li>• U.S No1 in CT, NG, HPV, Trichomoniasis test market</li> </ul>
 <p>VERIS (2014) (CE-IVD Cleared)</p>	 <p>QIASymphony (2010) (CE-IVD/FDA Cleared)</p>	 <p>BD MAX (2011) (CE-IVD/FDA Cleared)</p>	 <p>Panther Fusion (will be on 2017) (Expansion model of CE-IVD/FDA Cleared Panther system)</p>
<p><b>+</b></p> <p>Seegene's Multiplex Assays</p>	<p><b>+</b></p> <p>Seegene's Multiplex Assays</p>	<p><b>+</b></p> <p>Seegene's Multiplex Assays</p>	<p><b>+</b></p> <p>Seegene's Multiplex Assays</p>
<p><b>+</b></p> <p>Seegene's Multiplex Assays</p>	<p>• • •</p>	<p>• • •</p>	<p>• • •</p>

# Rank of Global Companies



**HOLOGIC**<sup>®</sup>  
The Science of Sure



**Seegene**

DPO + TOCE + MuDT = High Multiplex

**“Next Generation Gold standard of MDx PCR”**

# Financials



# Stock Information

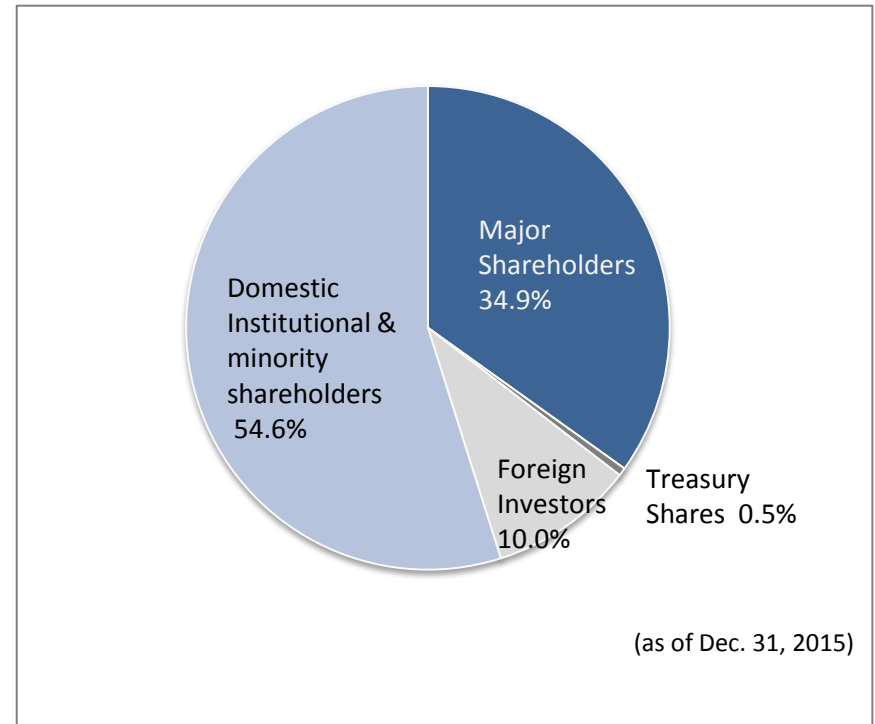
## Overview of Stock Information

- Ticker : 096530 KQ
- Shares Outstanding: 26,234,020 (as of Dec. 31, 2015)
- Par value : KRW 500
- Market Cap: KRW 937bn (as of Sep. 30, 2016)
- Stock volume turnover: 214,000 per day
- 52 week High / Low : KRW 44,400 / 29,500

## Subsidiaries

Subsidiary	Established
Arrow Diagnostics (Italy)	Jan, 2014
Seegene Middle East (Dubai)	Oct, 2014
Seegene Technologies (USA)	Apr, 2015
Seegene Canada (Canada)	July, 2015
Neo Probe (Korea)	July, 2016

## Shareholder Structure



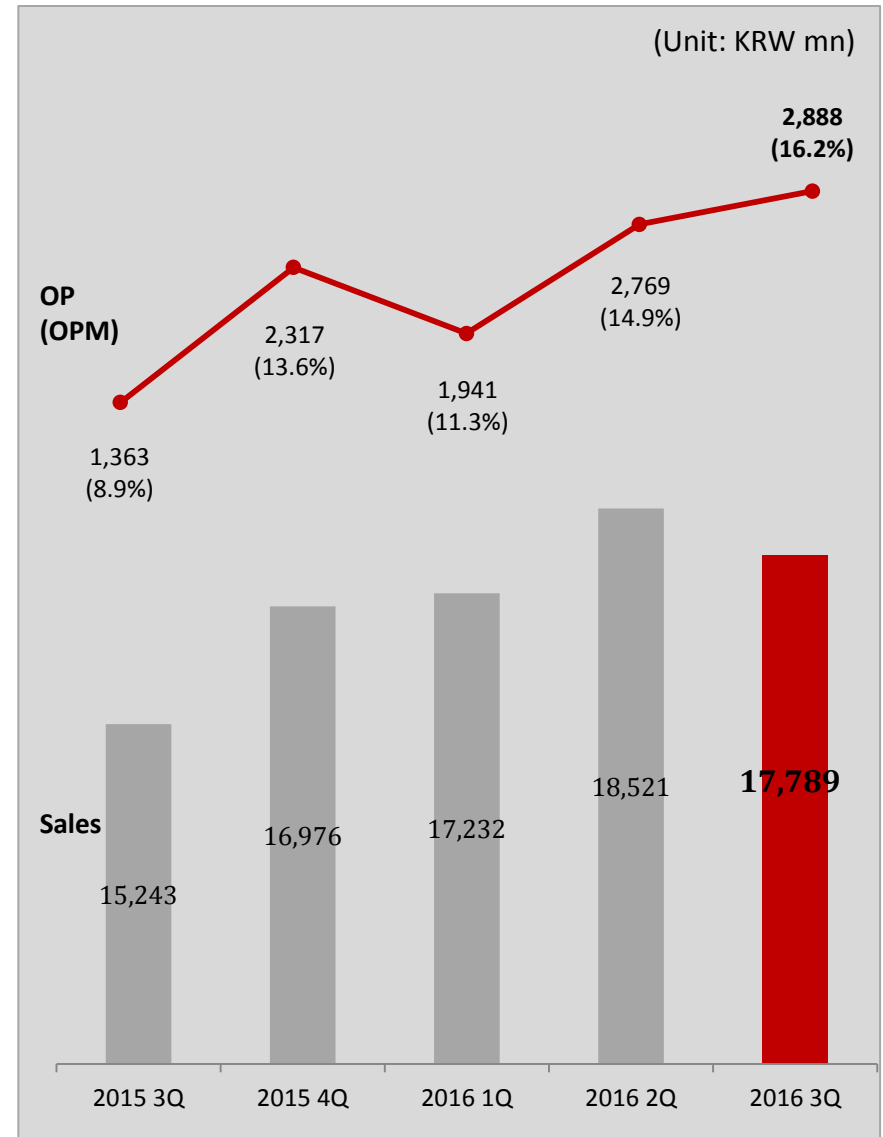
Major Shareholder	Ownership
CEO	18.1%
Related parties	16.8%

# Key Figures

## 2016 Q3 Business Results (Consolidated)

- Upward trend in OPM growth
- (Consolidated) OP KRW 2,888mn / OPM 16.3%
- (Separated) OP KRW 2,816mn / OPM 19.7%

(Unit: KRW mn)	3Q16	2Q16	QoQ	3Q15	YoY
Sales	17,789	18,521	-4.0%	15,243	16.7%
Gross Profit	13,072	13,324	-1.9%	11,484	13.8%
SG&A	10,184	10,556	-3.5%	10,121	0.6%
Operating Profit	2,888	2,769	4.3%	1,363	111.9%
(%)	16.2	14.9%		8.9%	
Pre-tax Profit	-351	2,557	-113.7%	4,152	-108.5%
(%)	-2.0%	13.8%		27.2%	
Net Profit	-504	2,044	-124.9%	3,031	-116.6%
(%)	-2.8%	11.0%		19.9%	



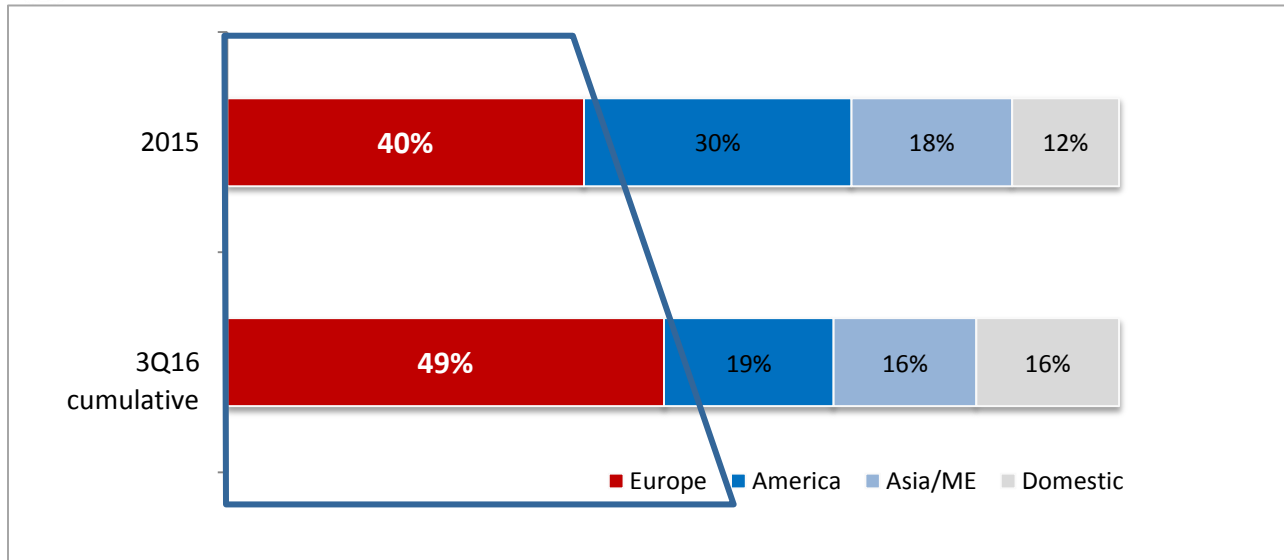


# Sales Breakdown

## Revenue by Region

(Unit: KRW mn)	3Q'16	2Q'16	1Q'16	4Q'15	3Q'15	QoQ	YoY
Europe	7,327	10,043	8,693	7,291	5,573	-26.0%	32.1%
America	3,519	4,040	2,784	5,387	4,407	-12.5%	-20.5%
Asia / Middle East	3,825	2,455	2,479	2,638	3,023	52.0%	26.7%
Domestic	3,118	1,983	3,276	1,659	2,240	55.0%	40.9%
<b>Total Sales</b>	<b>17,789</b>	<b>18,521</b>	<b>17,232</b>	<b>16,975</b>	<b>15,243</b>	<b>-3.8%</b>	<b>17.1%</b>

## Regional Sales Trend

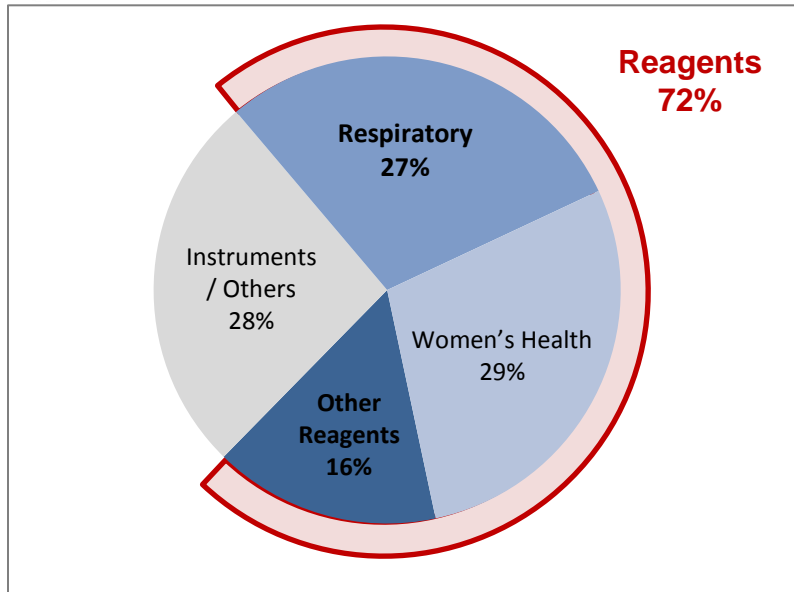


# Sales Breakdown

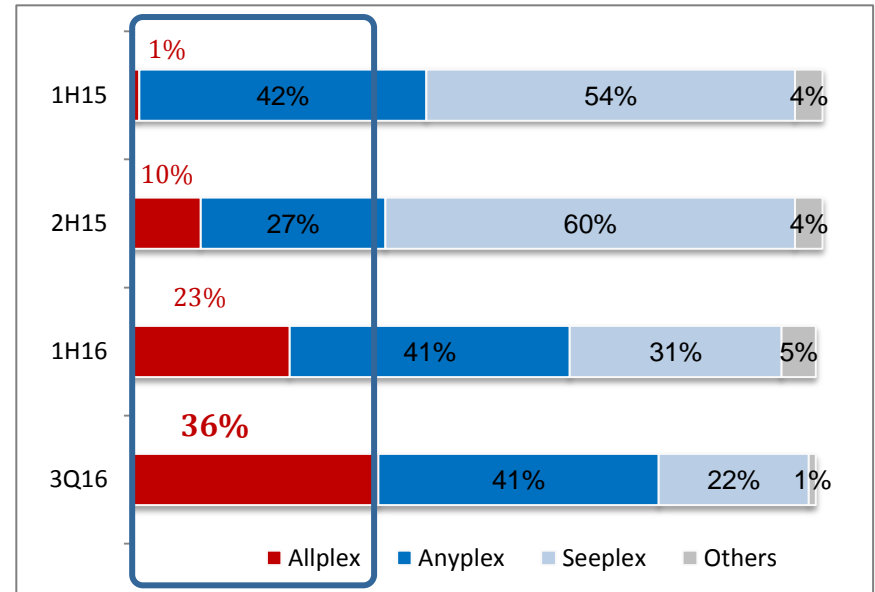
## Reagent & Instrument Sales

(Unit: KRWmn)	3Q'16	2Q'16	1Q'16	4Q'15	3Q'15	QoQ	YoY
Reagent Sales	12,694	13,280	11,782	12,517	11,711	-4.5%	8.5%
Instrument/Others	5,095	5,242	5,450	4,459	3,532	-1.9%	45.7%
<b>Total Sales</b>	<b>17,789</b>	<b>18,521</b>	<b>17,232</b>	<b>16,976</b>	<b>15,243</b>	<b>-3.8%</b>	<b>17.1%</b>

## Revenue by Product (3Q16)



## Reagent Sales Trend



# Allplex™ Promotion Status

## 2016 (Total 157 sites)

Pathogen	RP	GI	STI
Site	100 (▲91)	36 (▲25)	21 (▲21)

(as of Sep. 30, 2016)

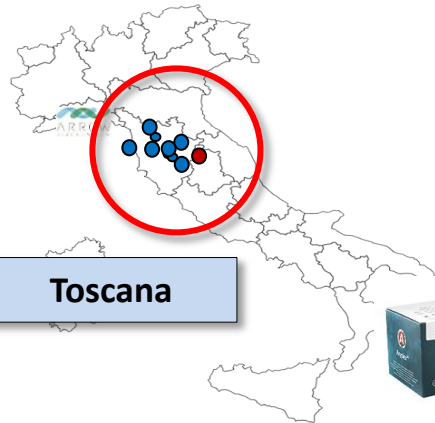
## 2015 (Total 20 sites)

Pathogen	RP	GI	STI
Site	9	11	0

(as of Dec. 31, 2015)



# Allplex™ Promotion Status



**Anyplex II  
STI-7**



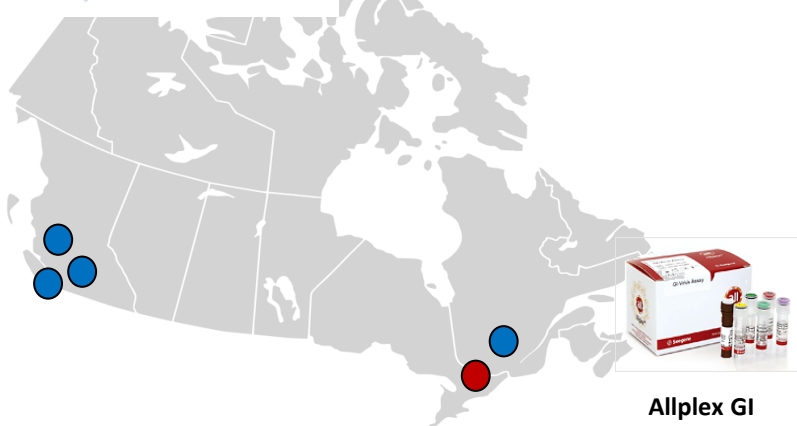
**Anyplex II  
HPV28**



## Successful Bid in Italian National Hospitals

- Customer: 17 Italian National hospitals
- Contract Period: 5 yrs
- Contract Amount: €7.5mn/5 yrs (USD 8.4mn)
- Product: Anyplex II STI-7, Anyplex II HPV28
- Initial Order: Nov, 2016

**LifeLabs** 5 C-Labs & 360 Distributors



**Allplex GI**



## Supply Contract with the biggest lab in Canada

- Customer: Canadian C-lab 'Lifelabs'
- Contract Period: 5 yrs
- Contract Amount: C\$7mn/5 yrs (USD 5.1mn)
- Product: Allplex™ GI-parasite panel
- Initial Order: Jan, 2017

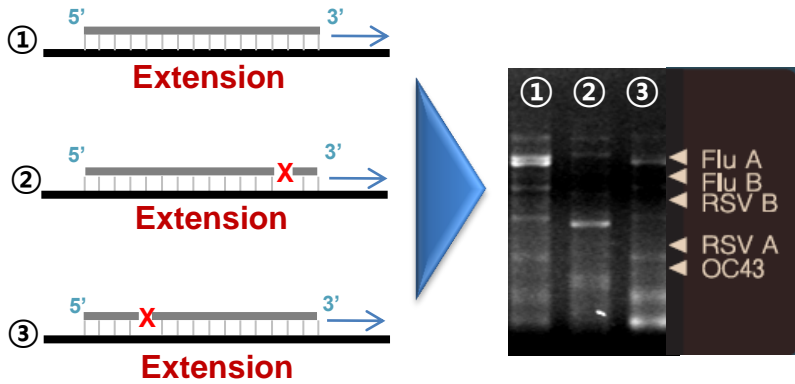
# Key Proprietary Technologies



# DPO™ (Dual Priming Oligonucleotide)

## Conventional PCR

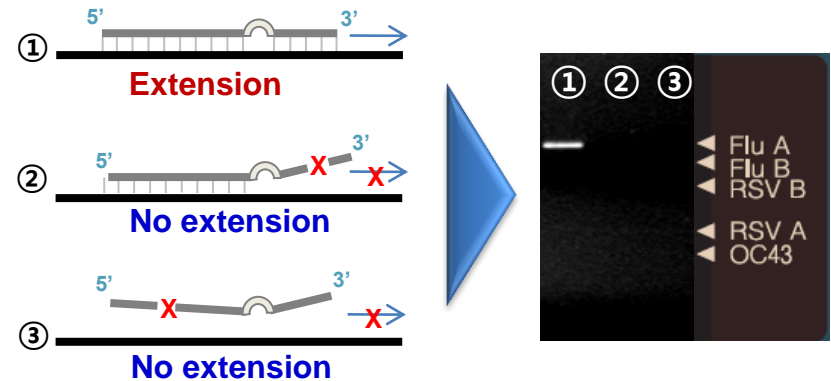
### <Conventional Primer>



- Non-target genes are amplified together
- Limited multiplexing

## DPO PCR

### <DPO Primer>

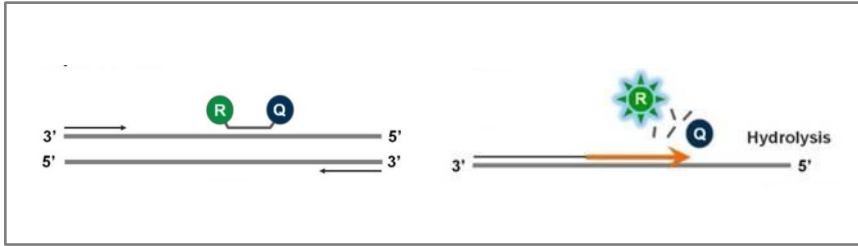


- Only the target gene is specifically amplified
- Highly reliable multiple target amplification

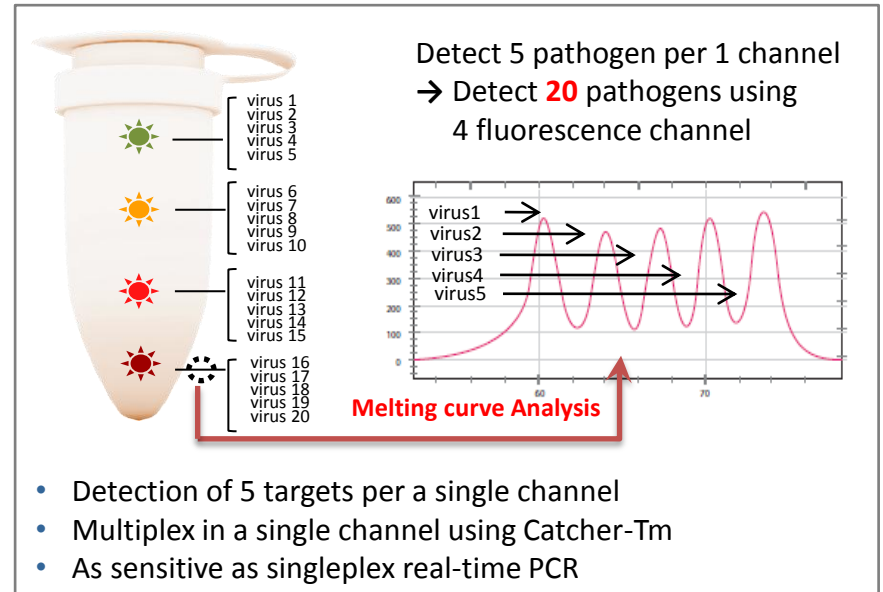
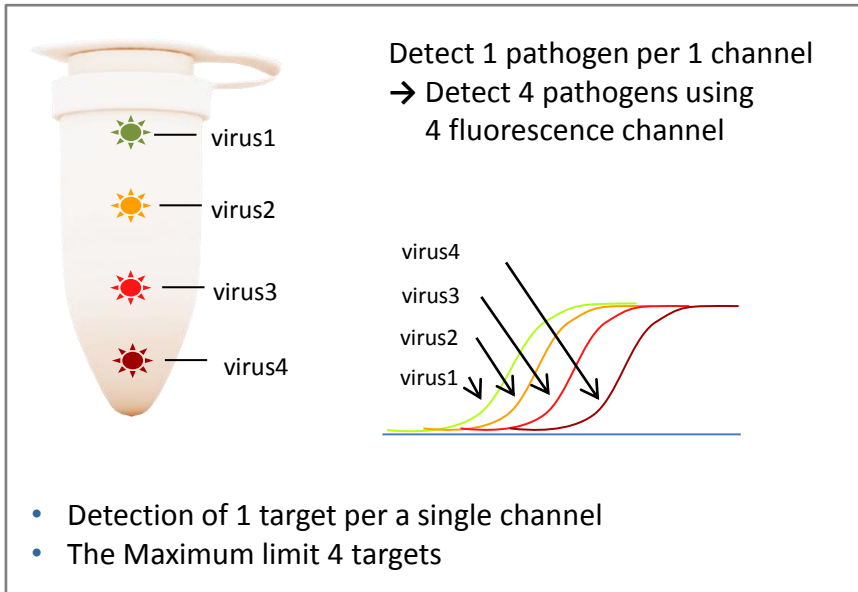
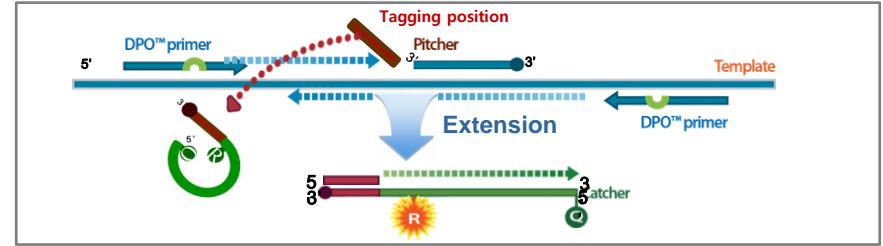
**Multiplex + High Accuracy = Realization of Multiplex MDx**

# TOCE™ (Tagging Oligonucleotide Cleavage & Extension)

## Conventional Real-time PCR



## TOCE Real-time PCR

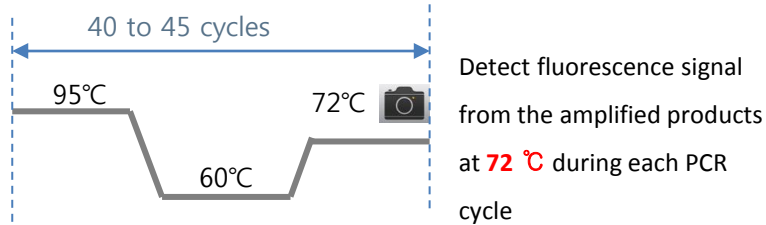


**High Multiplex Real-time PCR + Quantitative Analysis(Melting Curve Analysis)**

# MuDT™ (Multiple Detection Temperatures)

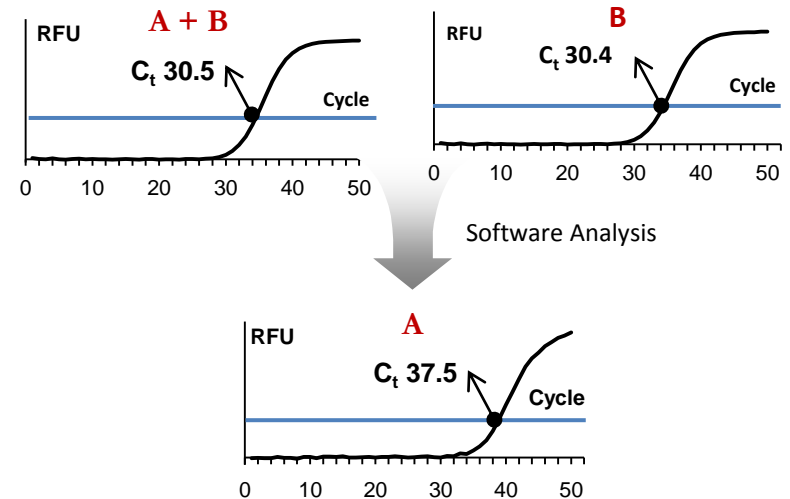
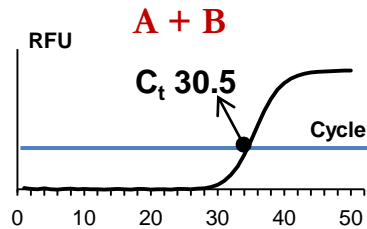
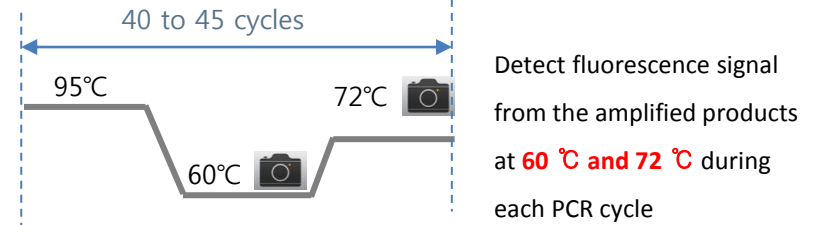
## Conventional Real-time PCR

[PCR cycle]



## MuDT Real-time PCR

[PCR cycle]



Multi qualitative/quantitative Analysis in Single channel = **Multi Ct value in Single channel**



# Disclaimer

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