

Seegene's Solution for “Back to Normal” and the Future of MDx

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Founder / CEO

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Seegene Overview

Seegene Global Top 5 in Molecular Diagnostics (MDx)

Company Overview


- Established : Sep 15, 2000 (Listed on KOSDAQ : Sep 10, 2010)
- Mission : Global Adoption of MDx to Daily Life
- '20 Financial Result

Revenue	1.0 B USD	(YoY 9-fold ↑)
Operating Income	0.6 B USD	(YoY 33-fold ↑)
- No. of Employees : 1,230
(HQ : 1,024, Overseas subsidiaries : 206) '21.11
 - ※ Half of employees are in R&D division


Business Overview

- Business Area: Development and Sales of Molecular Diagnostics Assays and Instruments


124 Assays



Infectious Diseases




Genetics




Oncology


Instruments



Large Scale



Medium Scale



Small Scale

- Global Network : 8 subsidiaries, ~100 distributors

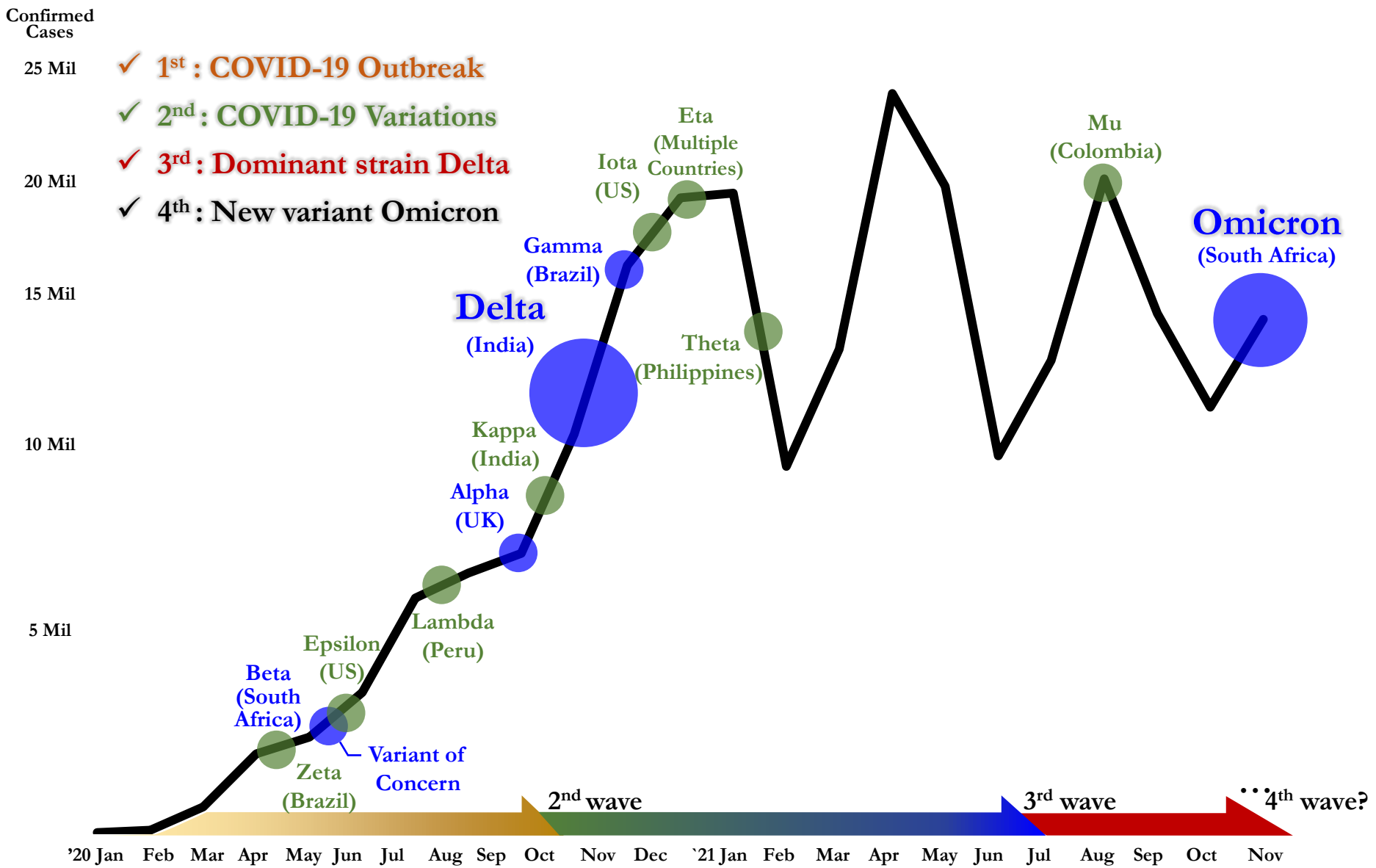
Seegene Medical Foundation (Related Party)

- Business area : Clinical testing service (C-Lab)
- Established : Oct 26, 1990
- No. of employees : 1,050 (Medical Doctors: 53) '21.11
- COVID-19 test capacity : 290,000 samples / day
 - ※ Non COVID-19 Capacity : 180,000 tests (20,000 patients)/day



Seegene's Solution “Living with COVID-19”

Response to COVID-19 “Prompt and Advanced”



- ✓ 1st : COVID-19 Outbreak
- ✓ 2nd : COVID-19 Variations
- ✓ 3rd : Dominant strain Delta
- ✓ 4th : New variant Omicron

Response to COVID-19 “Prompt and Advanced”

(Feb 2020)
 COVID Screening
Allplex™ 2019-nCoV



- N Gene
- E Gene
- RdRP Gene
- Exo IC

(Apr 2020)
 Upgrade COVID Screening
Allplex™ SARS-CoV-2



- N Gene
- E Gene
- RdRP Gene
- S Gene
- Exo IC

(Mar 2021)
 Detect variants from US, SA, & Brazil
Allplex™ SARS-CoV-2 Variants I



- RdRP Gene
- HV69/70del
- E484K
- N501Y
- Endo IC

(Jun 2021)
 Detect variants from US Cal, SA, & Brazil
Allplex™ SARS-CoV-2 Variants II



- L452R
- W152C
- K417T
- K417N
- Endo IC

(Sep 2020)
 Triple-demic : COVID-19, Flu, RSV
Allplex™ SARS-CoV-2 /FluA/FluB/RSV



- N Gene
- S Gene
- RdRP Gene
- Influenza A
- Influenza B
- RS virus
- Endo IC
- Exo IC

(Apr 2021)
 Full Screening of COVID-19 and Variants
Allplex™ SARS-CoV-2 Master



- E Gene
- N Gene
- RdRP Gene
- S Gene
- Endo IC
- HV69/70del
- Y144del
- E484K
- N501

(Nov 2021)
 Full Screening of Respiratory Viruses
Allplex™ RV Master



- S/N Gene
- RdRP Gene
- Adenovirus
- Rhinovirus
- Metapneumovirus
- Influenza A
- Influenza B
- RS virus
- Parainfluenza
- Exo IC

(Jul 2021)
 Detect variant from India
Novaplex™ SARS-CoV-2 Variants III



- E484Q
- Y145/H146del
- P681R
- Endo IC

(Jul 2021)
 Detect Delta & Delta+ from India
Novaplex™ SARS-CoV-2 Variants IV



- L452R
- P681R
- K417N
- Endo IC

(Sep 2021)
 Detect variants from India and SA
Novaplex™ SARS-CoV-2 Variants V



- L452Q
- F490S
- P681R
- L452R
- Endo IC

(Oct 2021)
 Detect Lambda and Mu Variants
Novaplex™ SARS-CoV-2 Variants VI



- L452Q
- F490S
- R346K
- D950N
- Endo IC

(Dec 2021)
 Detect Omicron & Omicron Stealth
Allplex™ SARS-CoV-2 Variants



- Dual Target RdRP Gene
- E484A
- P681R
- HV69/70del
- Endo IC

(Dec 2021)
 Fast COVID Screening within 1 Hour
Allplex™ SARS-CoV-2 Fast PCR



- E Gene
- N Gene
- RdRP Gene
- Endo IC

(Dec 2021)
 Fast MDx via Isothermal Lamp
Allplex™ SARS-CoV-2 Fast MDx



- N Gene
- RdRP Gene
- Endo IC

New Assay for COVID-19
Allplex™ SARS-CoV-2 Series



...

Seegene's Omicron Solution

(Dec 2021)
 Detect **Omicron & Omicron Stealth**
 Allplex™ SARS-CoV-2 Variants



- Dual Target RdRP Gene
- E484A
- P681R
- HV69/70del
- Endo IC

This assay identifies positive **COVID-19** cases and distinguishes between **Alpha, Beta/Gamma, Delta, Omicron**, and its **Stealth** version

Associated Variants		Allplex™ SARS-CoV-2 Variants Assay				Results
		HV69/70del	E484A	P681R	RdRP	
Omicron	BA.1/BA.3	+	+	-	+	Omicron
	BA.2 (Stealth)	-	+	-	+	Omicron Stealth
Alpha		+	-	-	+	Alpha
Others including Beta/Gamma		-	-	-	+	Others including Beta/Gamma
Delta		-	-	+	+	Delta

This assay was developed **within a week.**

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- K417T
- K417N
- Endo IC

Triple-demic : COVID-19, Flu, RSV
Allplex™ SARS-CoV-2 /FluA/FluB/R
 (For Living with COVID)

Twin-demic : COVID-19, Flu
SARS-CoV-2 & Influenza A/B Assay
 (Other Company's Product)

Full Screening of Respiratory Viruses
Allplex™ RV Master
 (For Living with COVID)



- N Gene
- S Gene
- RdRP Gene
- Influenza A
- Influenza B
- RS virus
- Endo IC
- Exo IC



- RdRP Gene
- Influenza A
- Influenza B
- Exo IC



- S/N Gene
- RdRP Gene
- Adenovirus
- Rhinovirus
- Metapneumovirus
- Influenza A
- Influenza B
- RS virus
- Parainfluenza
- Exo IC

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- N Gene
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- Endo IC

(Dec 2021)
Fast MDx via Isothermal Lamp
Allplex™ SARS-CoV-2 Fast MDx



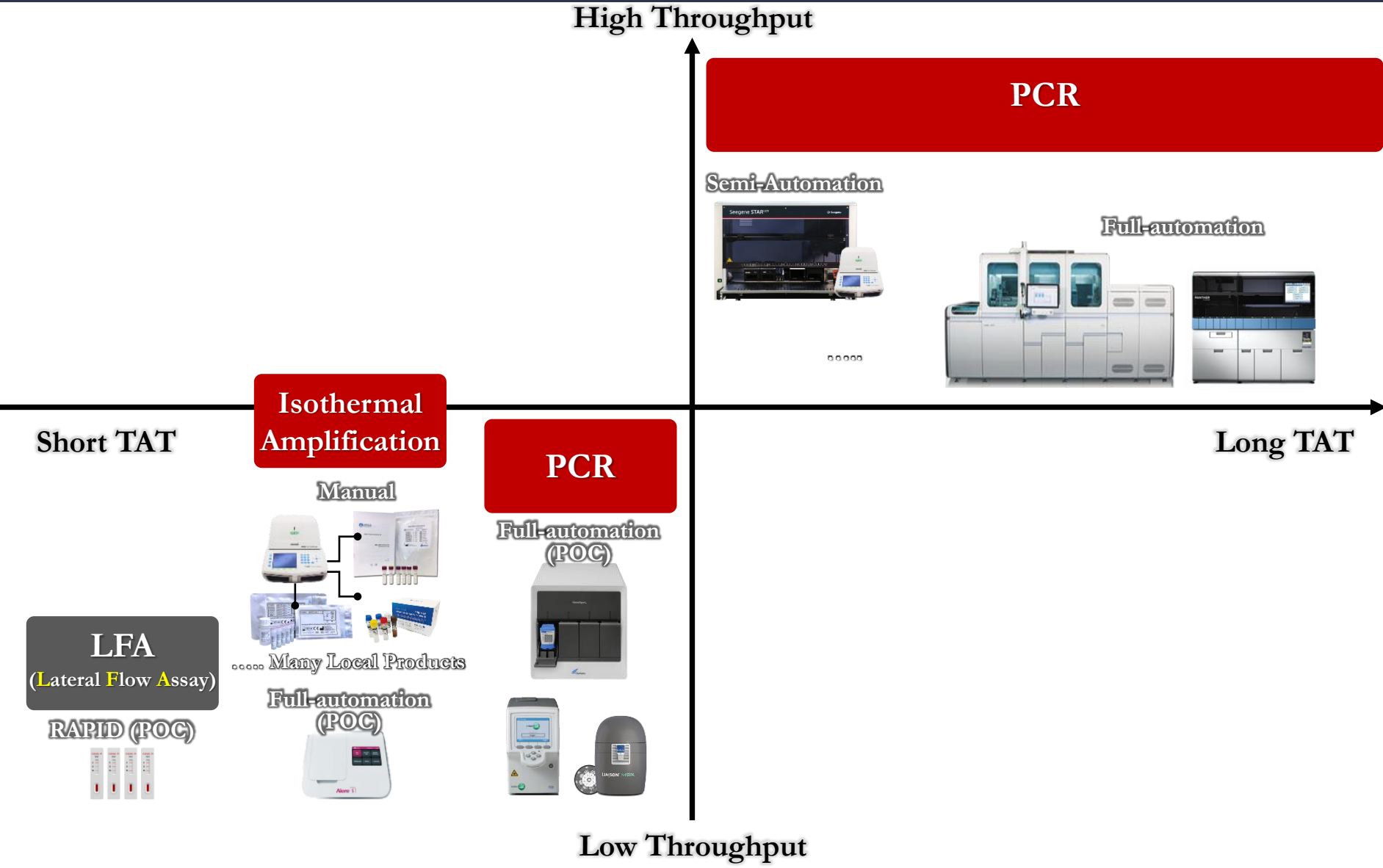
- N Gene
- RdRP Gene
- Endo IC

New Assay for COVID-19
Allplex™ SARS-CoV-2 Series

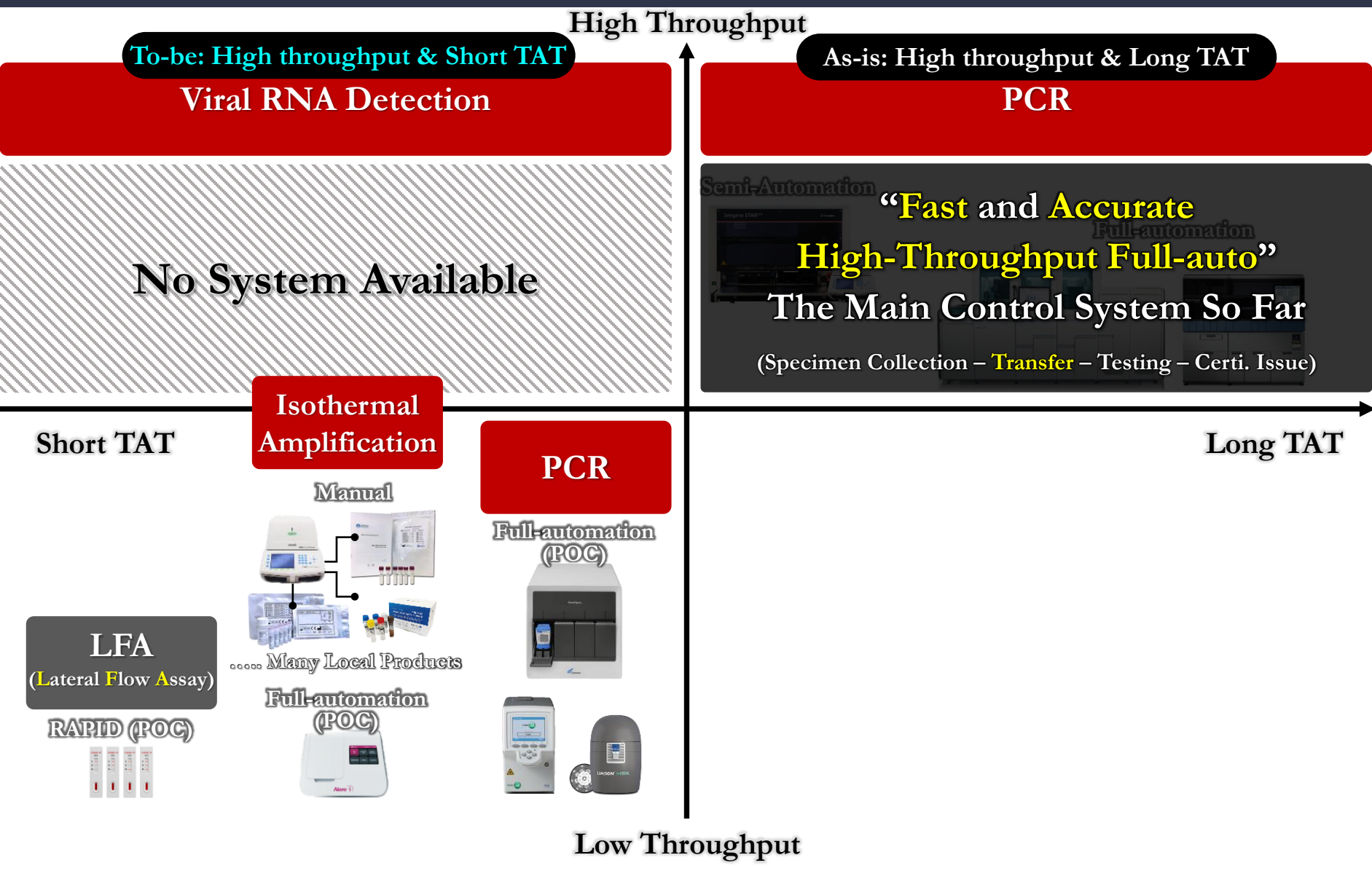


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Different COVID-19 Tests



Different COVID-19 Tests



Seegene's Solutions For "Living with COVID"

High Throughput

To-be: High throughput & Short TAT

To-be: Automated Syndromic Testing

Viral RNA Detection

"Asymptomatic: COVID-19 Screening Test"

PCR

"Symptomatic: Respiratory Infection Test"

SG Solution 1
"Onsite Testing"

SG Solution 2
"Centralized Testing"

SG Solution 3
"RV Master Testing"

MDx System with the same cost and TAT as antigen tests

MDx System using current PCR with shorter TAT and larger capacity

MDx System that simultaneously detect 22 subtypes of respiratory viruses including COVID, Flu, and RSV

Isothermal Amplification

PCR

Short TAT

Long TAT

Manual

Full-automation (POC)



LFA
(Lateral Flow Assay)

Many Local Products

Full-automation (POC)



RAPID (POC)



Low Throughput

Seegene's Solutions For "Living with COVID"

To-be: High throughput & Short TAT

Viral RNA Detection

"Asymptomatic: COVID-19 Screening Test"

SG Solution 1 "Onsite Testing"

MDx System with the same cost and TAT as antigen tests

SG Solution 2 "Centralized Testing"

MDx System using current PCR with shorter TAT and larger capacity

To-be: Automated Syndromic Testing

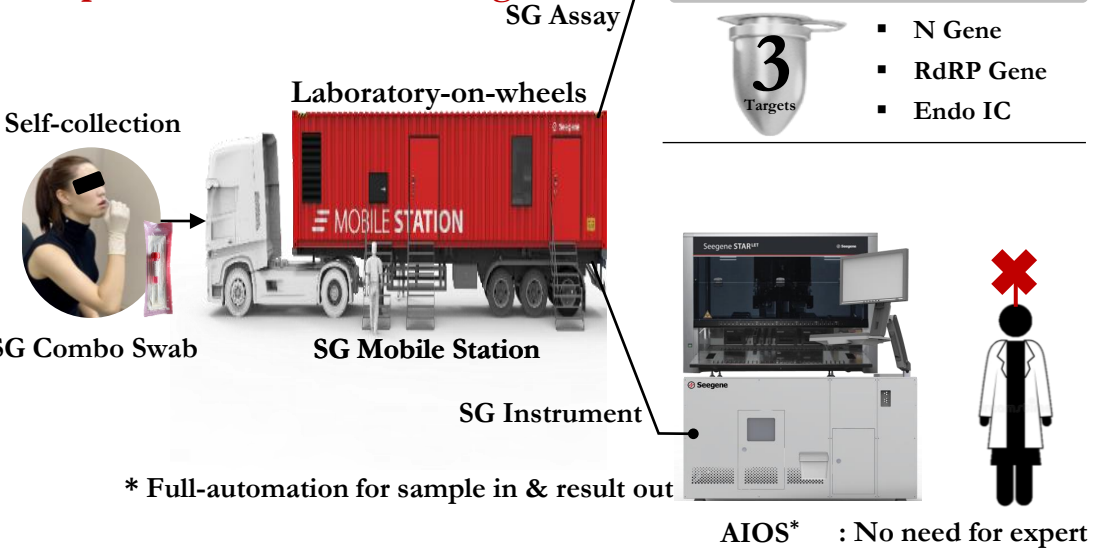
PCR

"Symptomatic: Respiratory Infection Test"

SG Solution 3 "RV Master Testing"

MDx System that simultaneously detect 22 subtypes of respiratory viruses including COVID, Flu, and RSV

SG Solution 1 "Rapid-Mass Full-auto Testing"



Seegene's Solutions For "Living with COVID"

To-be: High throughput & Short TAT

Viral RNA Detection

"Asymptomatic: COVID-19 Screening Test"

SG Solution 1 "Onsite Testing"

MDx System with the same cost and TAT as antigen tests

SG Solution 2 "Centralized Testing"

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To-be: Automated Syndromic Testing

PCR

"Symptomatic: Respiratory Infection Test"

SG Solution 3 "RV Master Testing"

MDx System that simultaneously detect 22 subtypes of respiratory viruses including COVID, Flu, and RSV

SG Solution 2

"Doubled capacity with existing instruments"

Self-collection



Centralized Lab

Current System

Capacity
(C-lab in Korea)

160,000
Tests / day

2x

320,000
Tests / day

SG MDx System

Extraction



40min

PCR Set-up



20min

Amplification



120min

Fast COVID Screening within 1 hr
Allplex™ SARS-CoV-2 Fast PCR



- E Gene
- N Gene
- RdRP Gene
- Endo IC

- Cost ↓
- TAT ↓

Ex-free

20min



20min



50min

- TAT ↓

Seegene's Solutions For "Living with COVID"

To-be: High throughput & Short TAT

Viral RNA Detection

"Asymptomatic: COVID-19 Screening Test"

SG Solution 1 "Onsite Testing"

MDx System with the same cost and TAT as antigen tests

SG Solution 2 "Centralized Testing"

MDx System using current PCR with shorter TAT and larger capacity

To-be: Automated Syndromic Testing

PCR

"Symptomatic: Respiratory Infection Test"

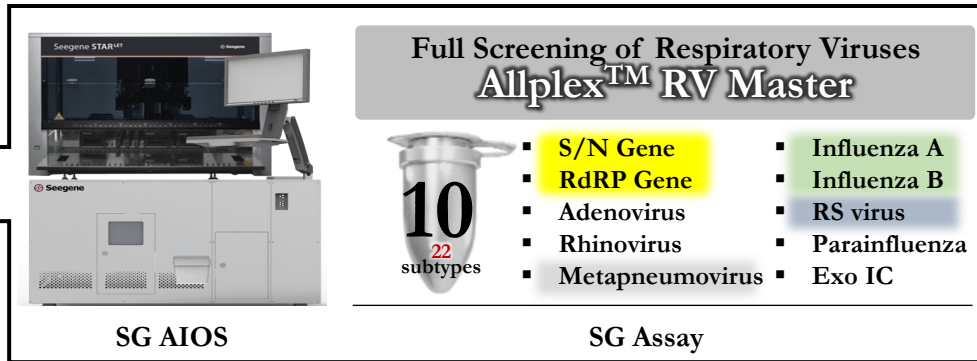
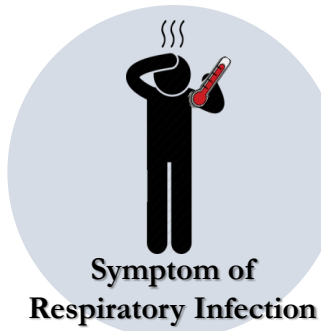
SG Solution 3 "RV Master Testing"

MDx System that simultaneously detect 22 subtypes of respiratory viruses including COVID, Flu, and RSV

SG Solution 3

"Accurate diagnosis for respiratory symptoms"

For outpatients at local hospitals



- ✓ Test 22 subtypes of viruses
- ✓ Treatment for COVID-19
- ✓ Treatment for Flu
- ✓ Treatment for RSV
- ✓ Symptomatic Treatment
- ✓ Prioritization in case of Multiple Infections

For inpatients at large hospitals

Blueprint for Seegene's MDx Platform



**Introduction of
Seegene's MDx Platform
“The Great Inception”**

Syndromic Assay: Simultaneous testing for all potential causative pathogens of the symptom

The Advantage of MDx “Syndromic Assay”

Symptom of Respiratory Infection

Quantification Ct=21
Influenza A(H1N1) virus

Quantification Ct=38
SARS-CoV-2 (COVID-19)

Quantification Ct=19
Influenza A H5 virus

Human parainfluenza virus 4

Influenza C virus

Klebsiella pneumoniae

Legionella pneumophila

MERS-CoV

Influenza A H5 virus

Quantification Ct=19
Mycoplasma pneumoniae

Pneumocystis jirovecii

Pseudomonas aeruginosa

HRV

Staphylococcus aureus

Staphylococcus pneumoniae

Human rhinovirus

Human parainfluenza virus 3

Human parainfluenza virus 2

Human parainfluenza virus 1

Human paraechovirus

Human RS viruses A/B

Influenza B virus

Influenza A(H3) virus

Influenza A virus

Bordetella spp.

Bordetella parapertussis

Bordetella pertussis

Chlamydomphila pneumoniae

Haemophilus influenzae

Human adenovirus

Human bocavirus

Human coronavirus 229E

Human coronavirus HKU1

Human coronavirus NK63

Human metapneumoviruses A/B

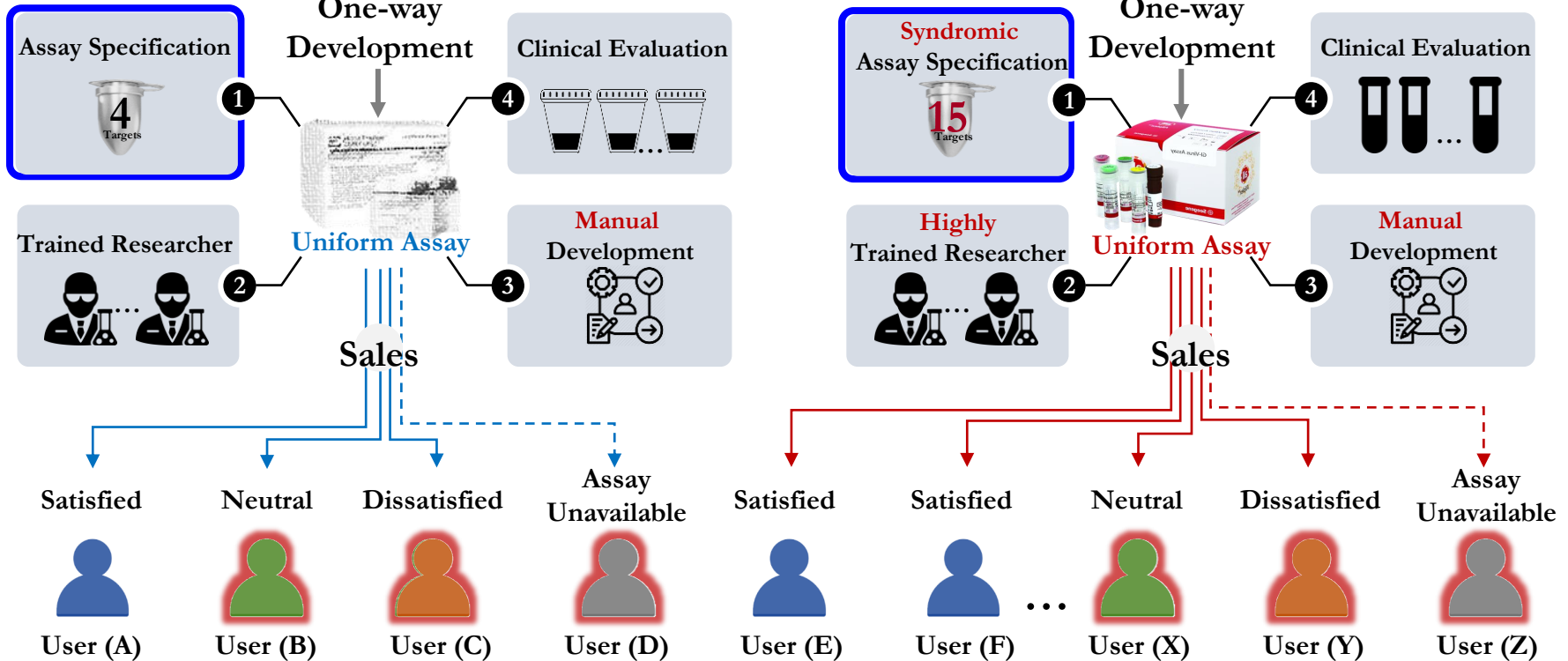
Human coronavirus OC43

Current MDx Business “Manual”

Conventional Value-chain of “One-way” Development and Sales

Companies **Develop Single-spec** Products while Users’ Needs are **Diverse**

Global Top 5 MDx Company



Current MDx Business “Manual”

- Companies **unaware** of user’s **needs**
- **Unable** to develop **customized** product

Conventional Value-chain of “**One-way**” Development and Sales

Companies **Develop Single-spec** Products while Users’ Needs are **Diverse**

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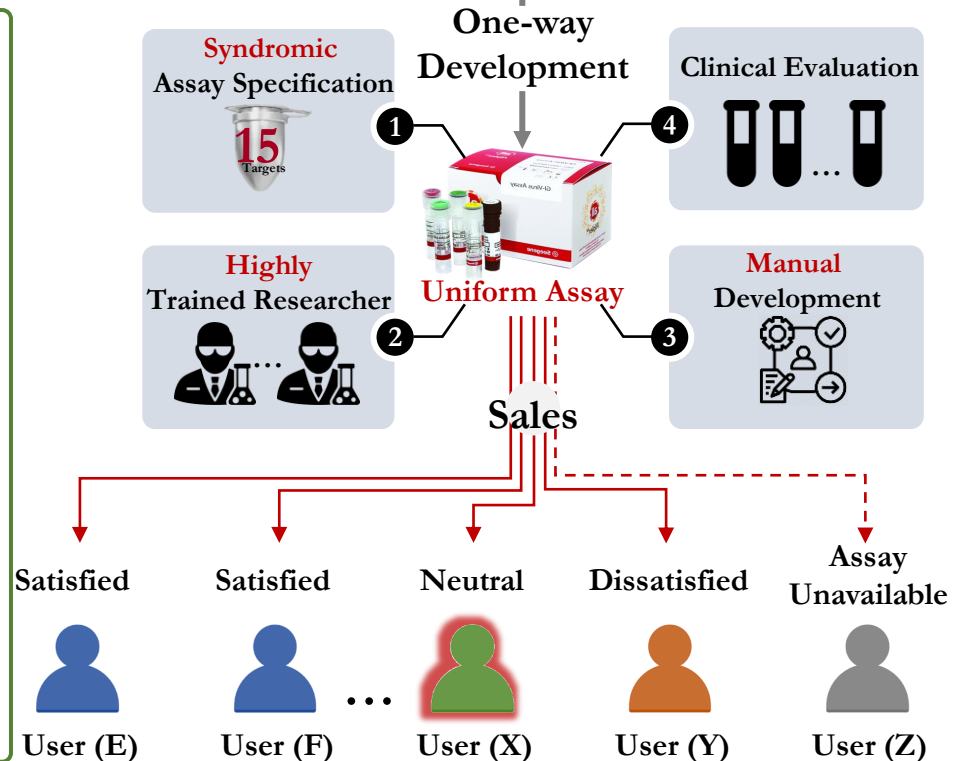


Assay Spec.



User Needs

- | | | |
|-------------------|----------|-------------------|
| ▪ S/N COVID gene | Separate | ▪ S COVID gene |
| ▪ RdRP COVID gene | | ▪ N COVID gene |
| ▪ Adenovirus | Delete | ▪ RdRP COVID gene |
| ▪ Rhinovirus | | ▪ Rhinovirus |
| ▪ Metapneumovirus | | ▪ Metapneumovirus |
| ▪ Influenza A | | ▪ Influenza A |
| ▪ Influenza B | | ▪ Influenza B |
| ▪ RS virus | | ▪ RS virus |
| ▪ Parainfluenza | | ▪ Parainfluenza |
| ▪ Exo IC | Change | ▪ Endo IC |



Current MDx Business “Manual”

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Conventional Value-chain of “**One-way**” Development and Sales

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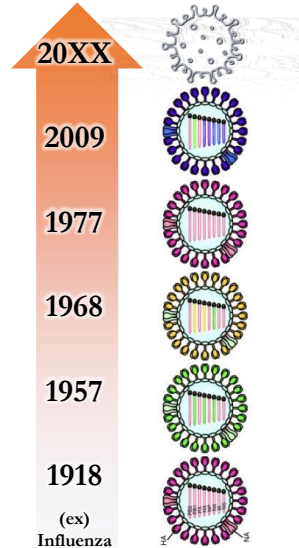
Assay Spec.



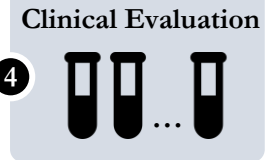
User Needs

- S/N COVID gene
- RdRP COVID gene
- Adenovirus
- Rhinovirus
- Metapneumovirus
- **Influenza A (ex) Upgrade**
- Influenza B
- RS virus
- Parainfluenza
- Exo IC

Improved coverage



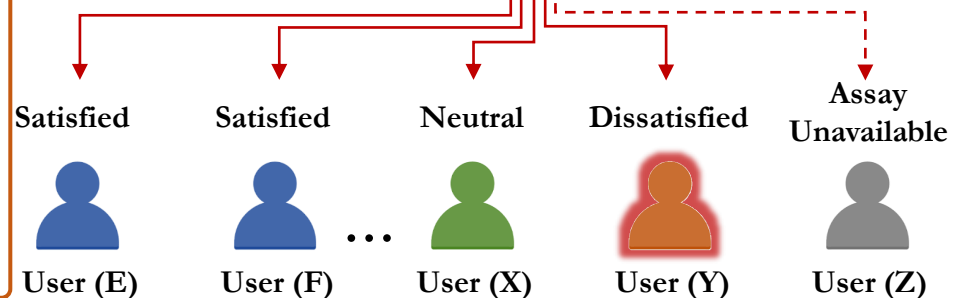
One-way Development



Uniform Assay



Sales



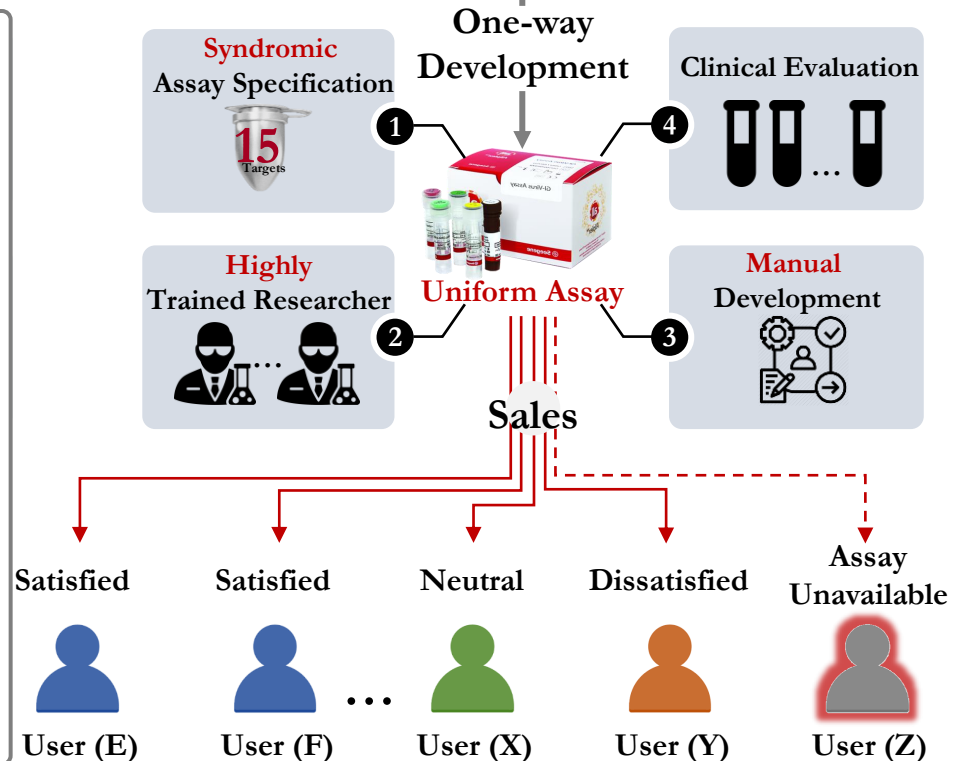
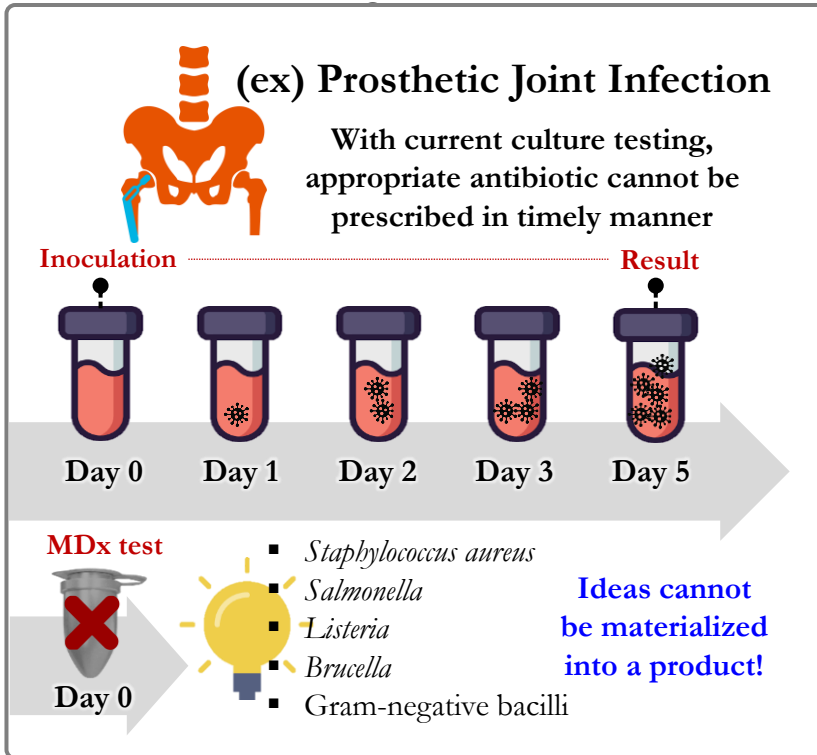
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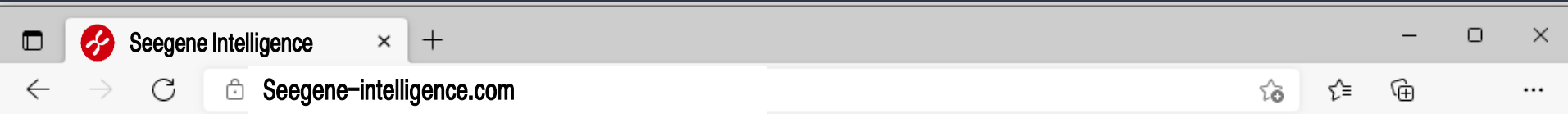
Conventional Value-chain of “**One-way**” Development and Sales

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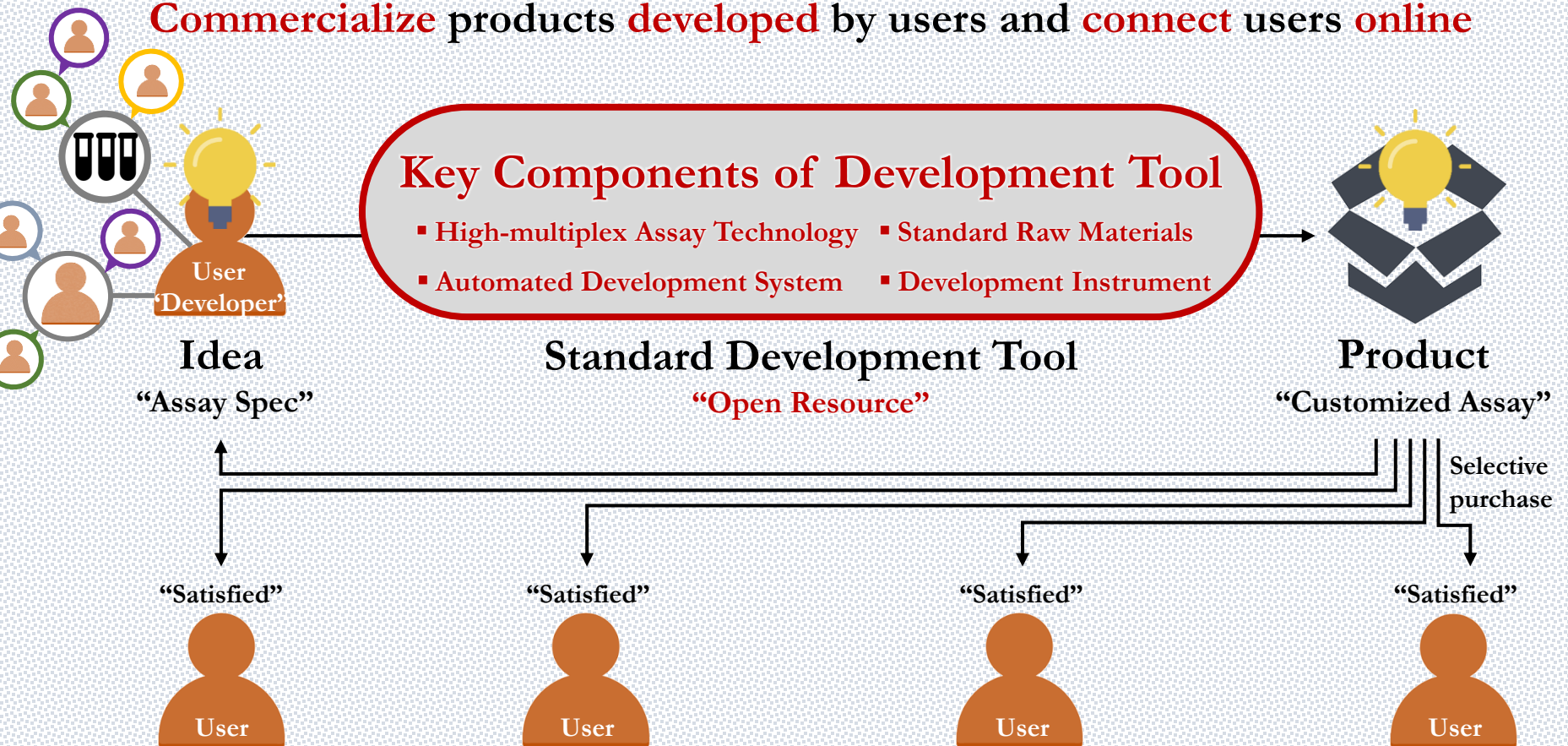


Future MDx Business



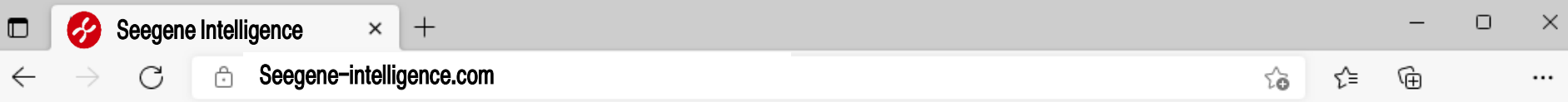
Platform based Value-chain of “Multi-directional” Development and Sales

Commercialize products developed by users and connect users online

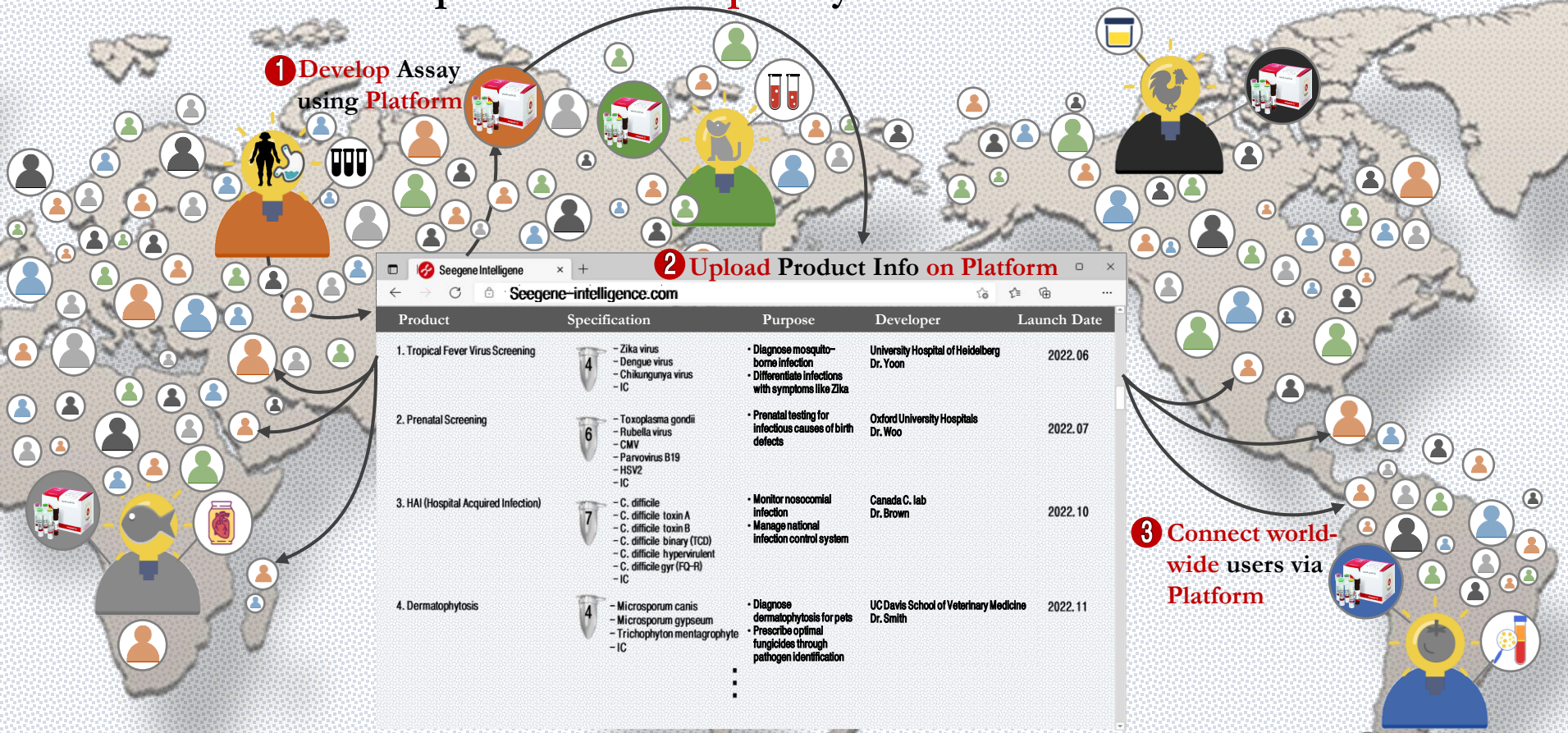


Future MDx Business “Platform”

- Users **self-develop** customized product
- **Materialize** diverse **ideas** & **share** online

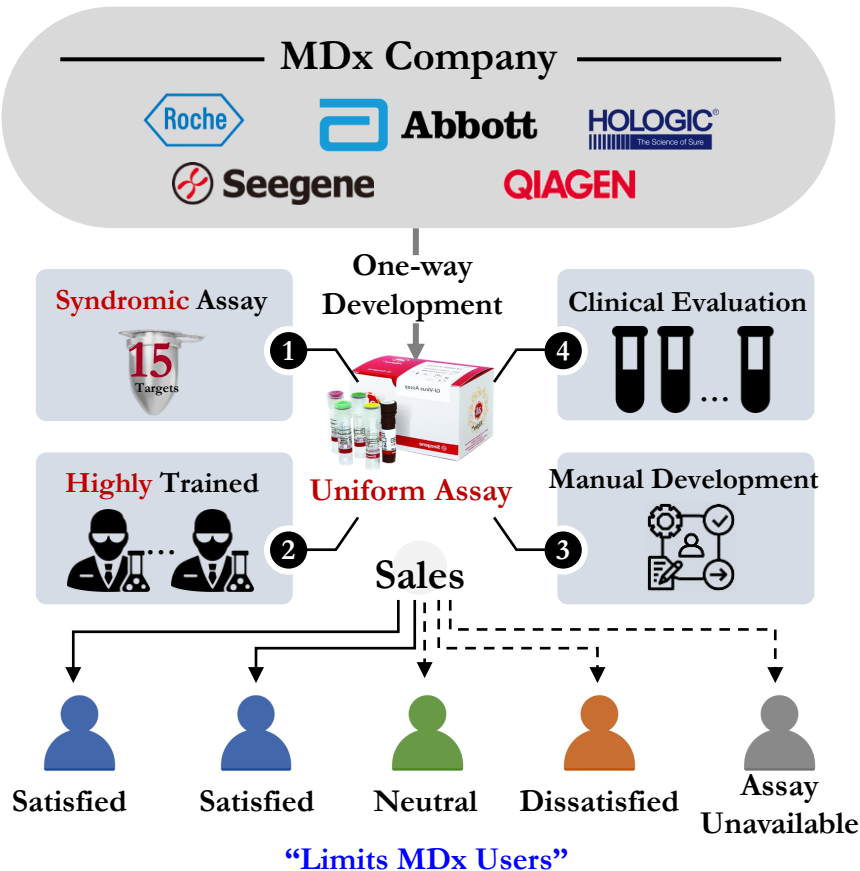


Platform based Value-chain of “Multi-directional” Development and Sales Commercialize products developed by users and connect users online



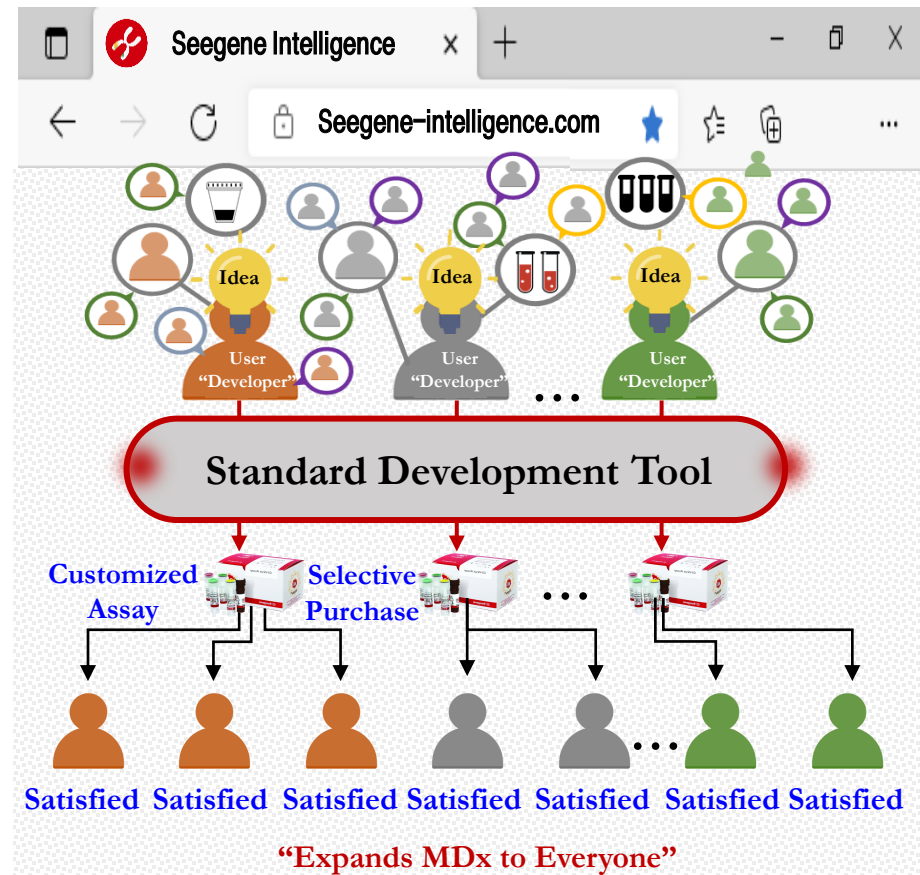
MDx Business Model Comparison

Current Manual Approach



- Companies develop **Uniform** assays
- Do **not** meet **diverse needs** and **limit** usage

Future (2022) Platform Approach



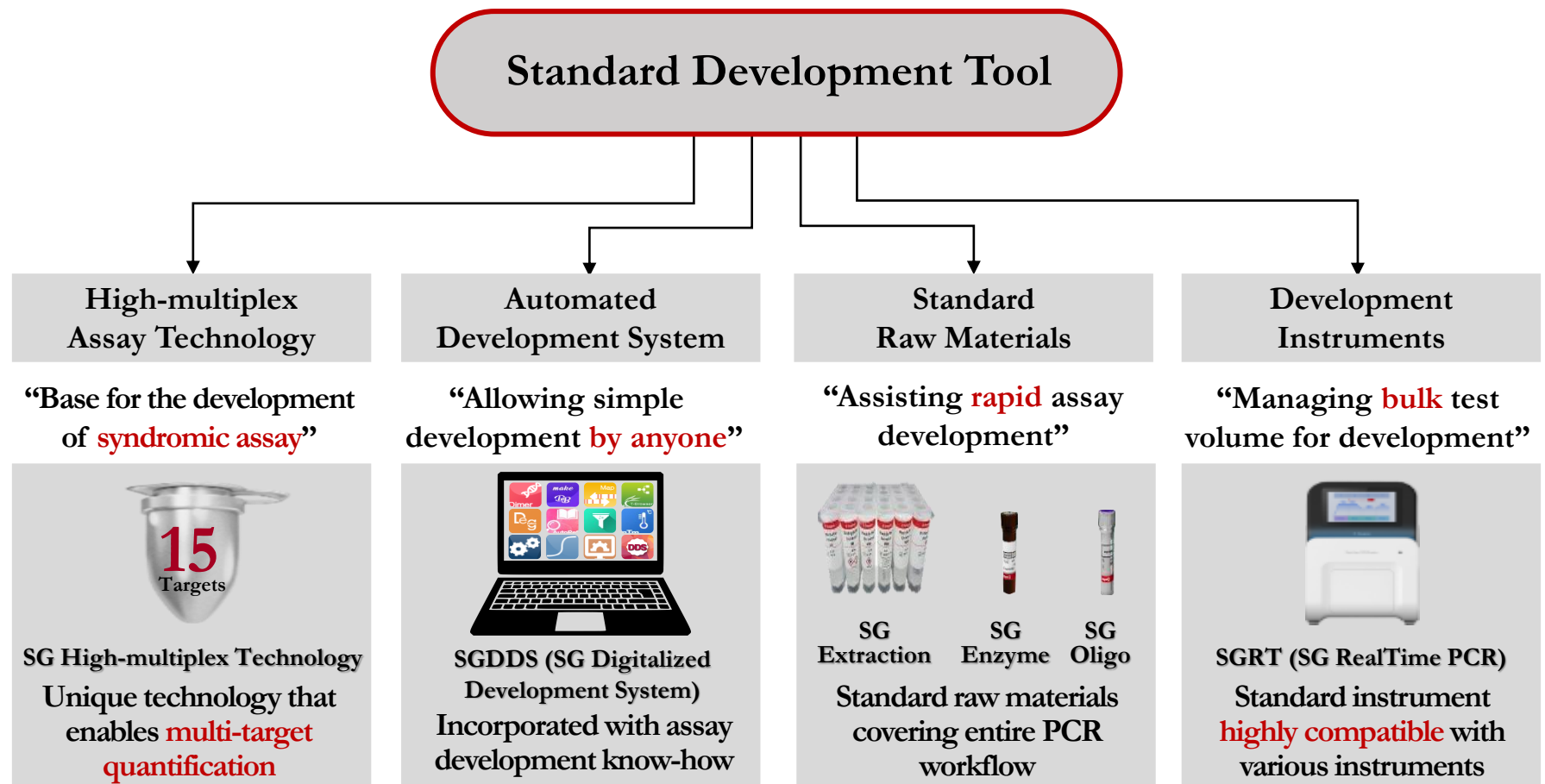
- Users **self-develop** assays and **selectively purchase**
- **Customized assays** across **all fields** become available



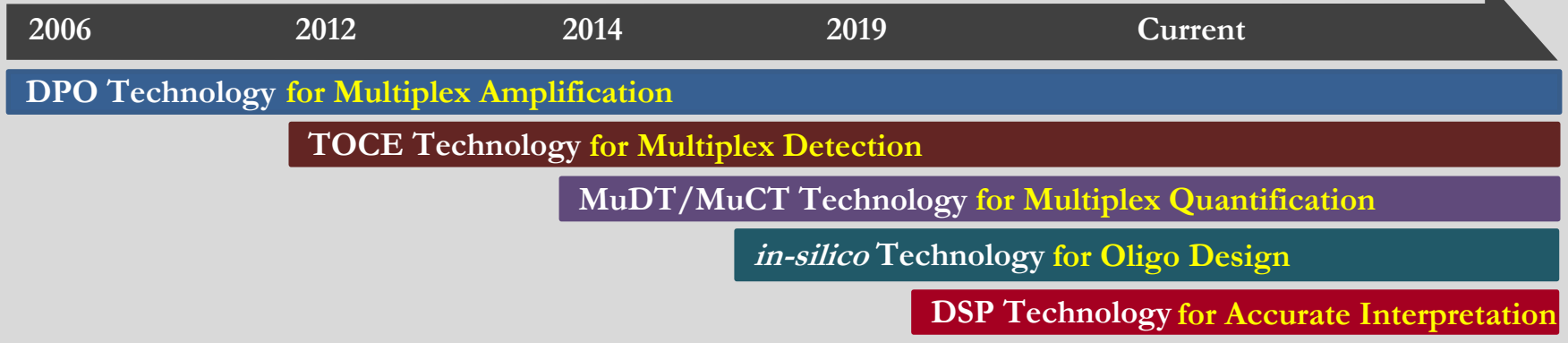
**Essential for
Seegene's MDx Platform
“Standard Development Tool”**

Essential for Platform **“Standard Tool”** “Only by SG”

The key to create a condition that **anyone** can develop a **syndromic product**
⇒ **Development Tool** with Seegene’s 20 years of Technology and Know-how



Five Proprietary Technology Groups for High Multiplex PCR Testing



Symptom based multiplex testing
“Unique Set of Technologies that enables Syndromic Assay”

Current Technology : Taqman (1990)



- 4 Ct * / tube
- Targeted Assay**

SG Technology



- 15 Ct (Up to 25 Ct) / tube
- Syndromic Assay ***

* Ct : Cycle threshold, Quantification of Pathogen

** Targeted : Selective testing for suspicious causative pathogen

*** Syndromic : Comprehensive and simultaneous testing for all potential causative pathogens

Revolution of Assay Development (AI based SGDDS)

* SGDDS : Seegene Digitalized Development System

01 Idea



Without knowledge, experience, know-how
& skilled technicians for product development

02 By following SG guideline



Product



No More

Complicated Processes

Essential for Platform “Standard Tool”

Automated
Development System

“SGDDS” automated 20 years of processes and know-hows

* Seegene Digitalized Development System

⇒ Allows **simple & simultaneous** development of **various** assays



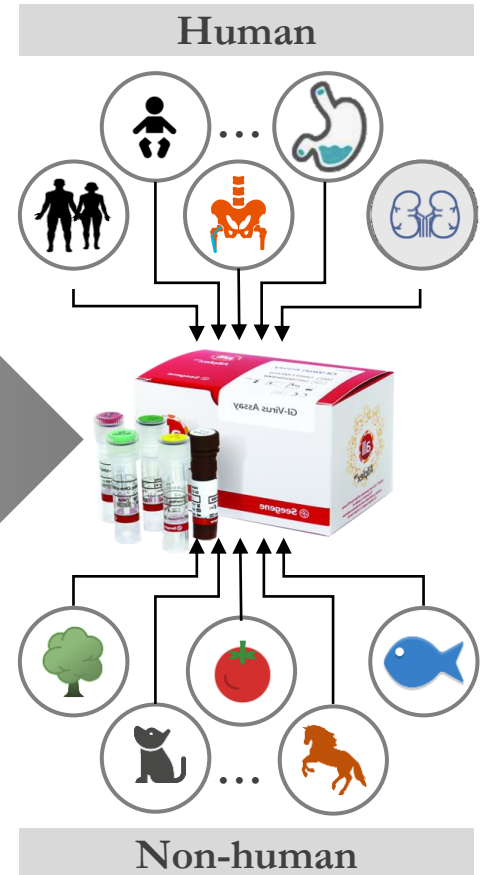
AI based Oligo Design SW

Multiplex oligo with various specification designed by AI

Without knowledge, experience, know-how & skilled technicians for product development

Development Automation SW

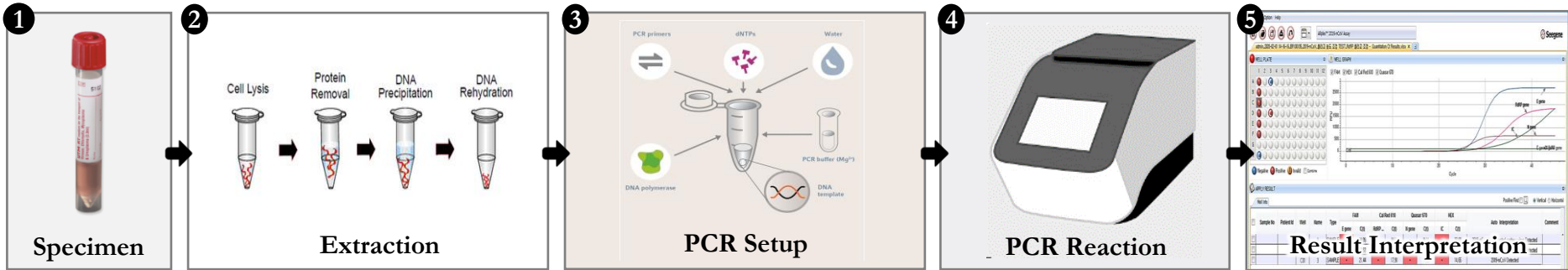
Standardization of massive experiment process, data analysis, and documentation



Essential for Platform “Standard Tool”

Standard
Raw Materials

MDx Testing Workflow



Providing **standard solution** for each step of real-time PCR to develop **syndromic** assay



SG Extraction

+



SG Enzyme

+



SG Oligo

Constrained extraction condition challenges assay development

“ **Standard** reagents for various specimen and **extraction design** ”

Using commercialized enzyme challenges assay development

“ **Standard rapid enzyme** and **optimal buffer** ”

Using outsourced oligo challenges assay development

“ **Standard** oligonucleotides for assay development ”

“SGRT” Standard Instrument for Assay Development

Optimal for **One System**

- **5 Channels**
- **Fast real-time PCR**
- Applicable to all systems via customization & optimization



Manage **R&D** Test Volume

- 96-well-scale **bulk** experiment
- **Simultaneous** development
- Rapid regulatory process for multiple products

Various assays developed with SGRT can be applied to all “**One System**”

1 Real-time PCR System



“CFX96”



“SGRT”

2 Full-automation System



“AIOS”

3 POC System



“Seegene POC”



**The Future of MDx
is
Age of Seegene's Platform**

Beginning of Platform Business “P100”, Road to P1000

(100 Products)

Human IVD Infectious Disease and Customized MDx Assay Menu

Gastrointestinal Infection

Respiratory Infection

Oncology

Genetics

Sexually Transmitted Infection

Blood Infection

Drug Resistance

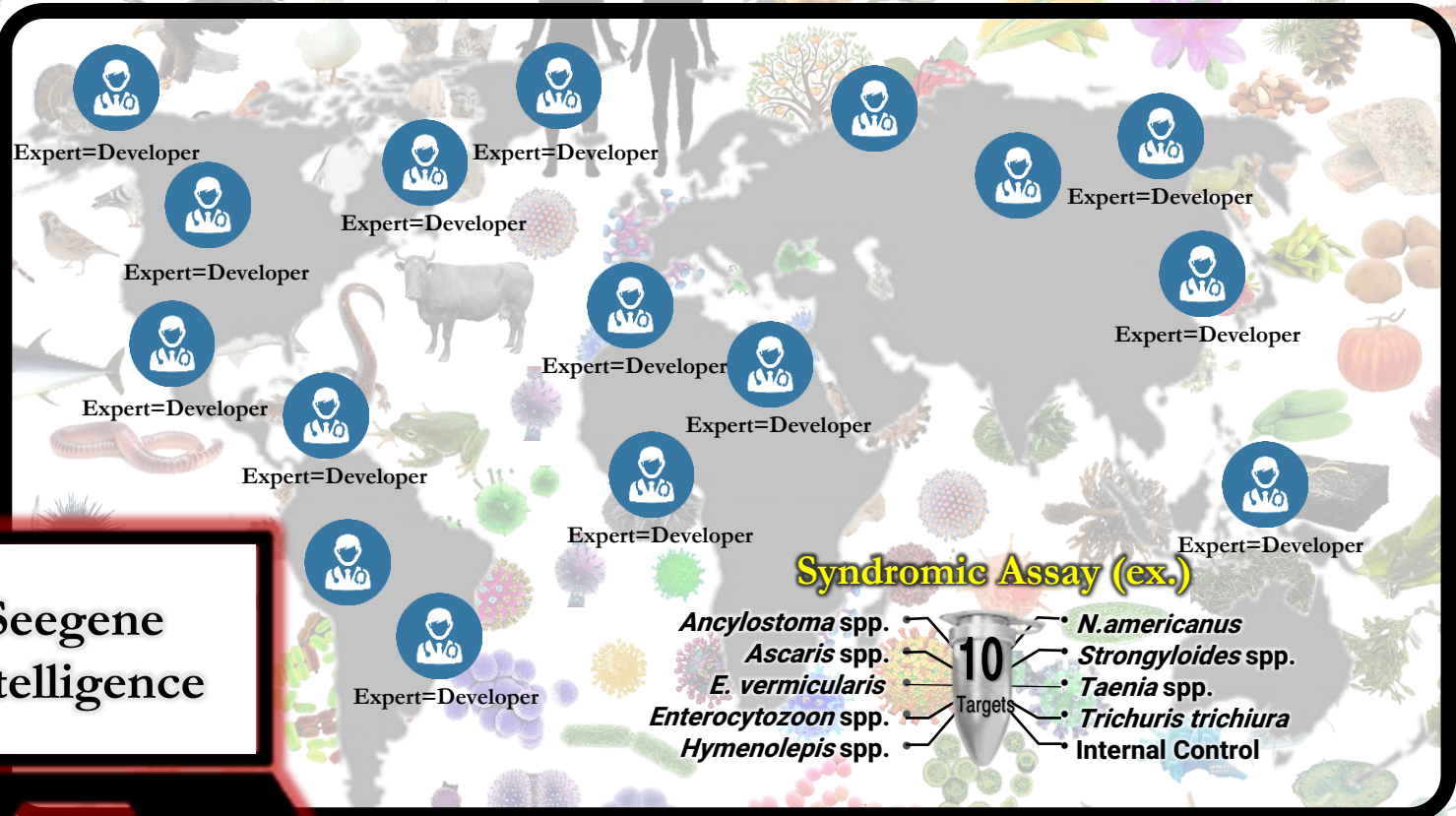
Post-transplant



“To Launch Syndromic P100 Menu in 2022”

Apply Assays of All Fields on Full-automation System

Through **SG Development Platform**(Seegene Intelligence),
Global Experts Across All Fields Develop Syndromic MDx Assay



Syndromic Assay (ex.)

- Ancylostoma* spp.
 - Ascaris* spp.
 - E. vermicularis*
 - Enterocytozoon* spp.
 - Hymenolepis* spp.
 - N.americanus*
 - Strongyloides* spp.
 - Taenia* spp.
 - Trichuris trichiura*
 - Internal Control
- 10 Targets

Apply Assays of All Fields on Full-automation System

Through **SG Development Platform**(Seegene Intelligence),
Global Experts Across All Fields Develop Syndromic MDx Assay

Syndromic P1000

Seegene STAR4T

Seegene

Seegene Intelligence

Expert=Developer

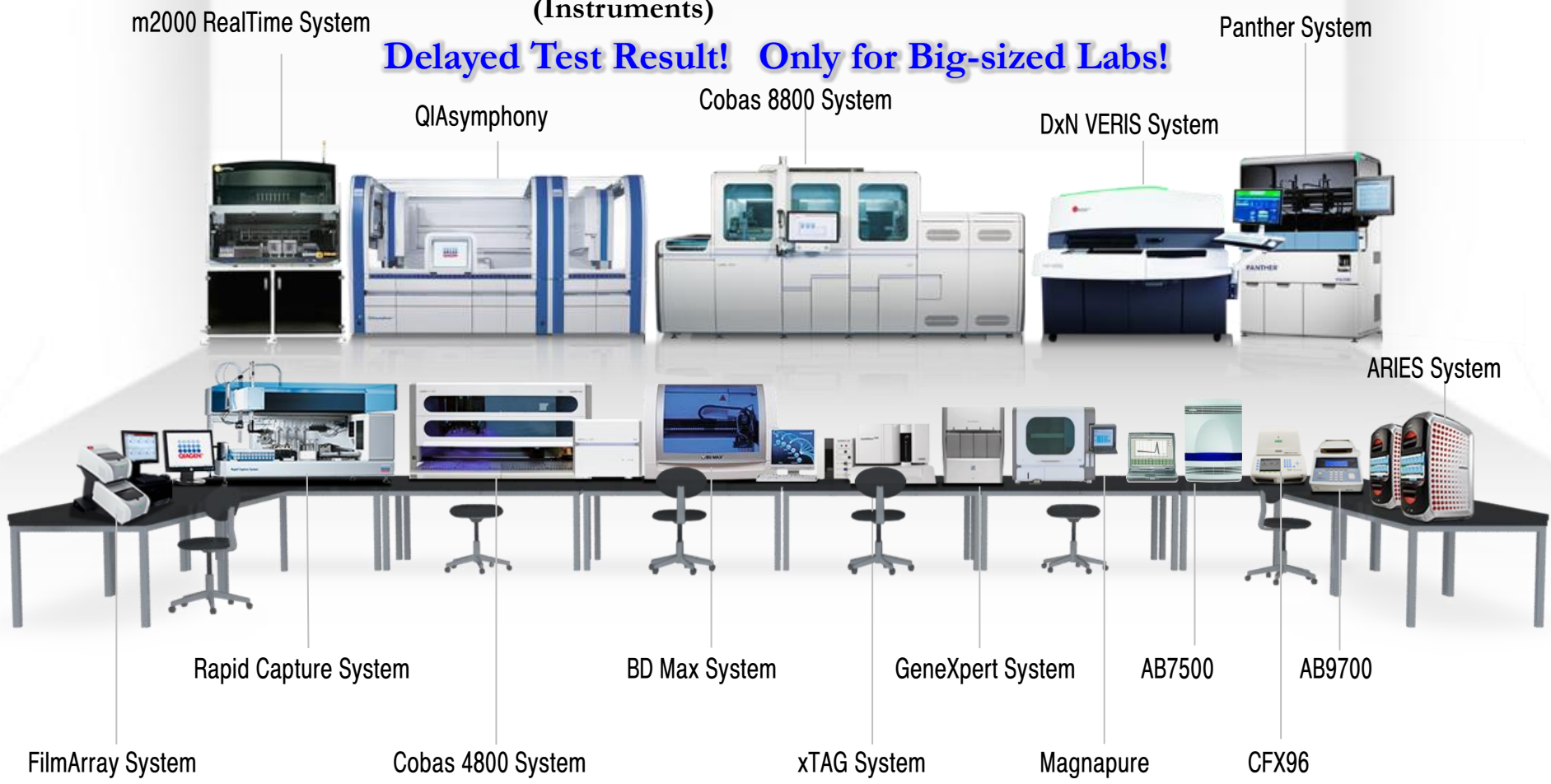
Full-Automation One-System

Multiple Systems in Current MDx Laboratory

16 Systems 077 Assays

(Instruments)

Delayed Test Result! Only for Big-sized Labs!

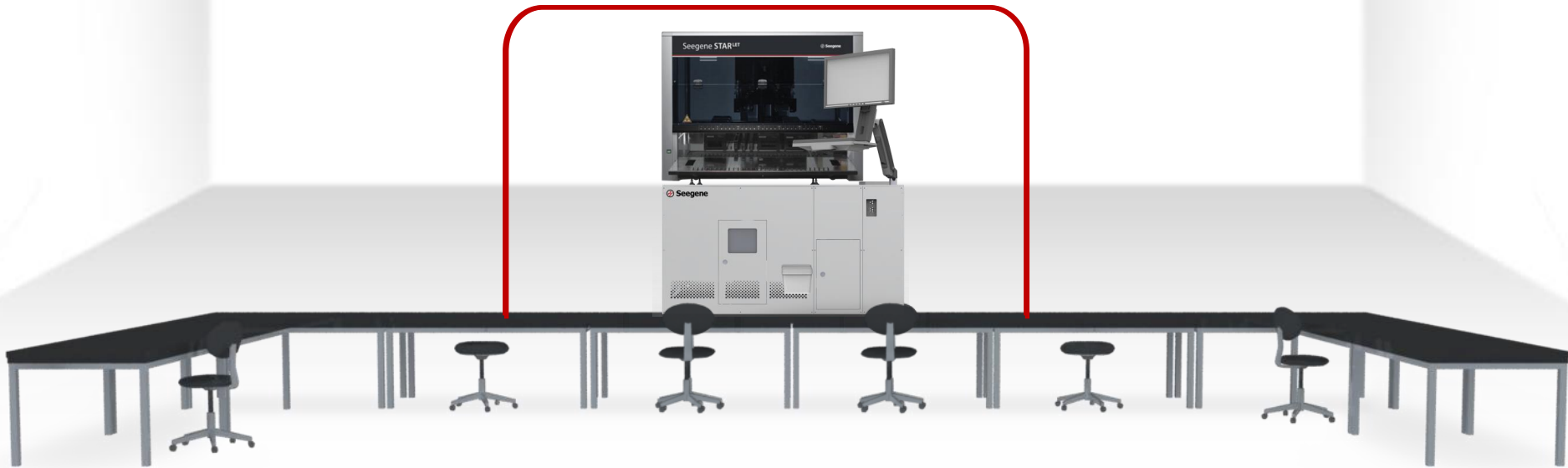


One System in **Future** MDx Laboratory

One System **All** Assays
(Instrument) **Syndromic**

Same-day Test Result! Suitable for All Labs and Home!

Seegene



One System: All-in-One System that can perform all MDx assays

Seegene's Vision for the Future of MDx

