

The 18th R&D Meeting

March 5, 2021
Sysmex Corporation

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Chairman and CEO

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Member of the Managing Board and
Senior Executive Officer
Senior Managing Director
COO LS Business Unit and CTO

3 Technology Innovation in the IVD Business

Hiroshi Kanda
Member of the Managing Board and
Senior Executive Officer
Managing Director

- (1) XQ-Series
- (2) New Hematology Products
- (3) Application of Astrego's Nanofluidic Technology

4 Initiatives in the LS Business

Mamoru Kubota
Senior Executive Officer

- (1) COVID-19 PCR Testing (PCR Reagents and Instruments, CoviLab)
- (2) COVID-19 HISCL™ Tests (Antigen, Influenza, Antibody, Cytokine)
- (3) Cancer Genome Tests (OncoGuide™ NCC Oncopanel System)
- (4) Cancer Liquid Biopsy Tests (OncoBEAM™, PSS)

5 Initiatives for the Realization of Personalized Medicine

Tomokazu Yoshida
Senior Executive Officer

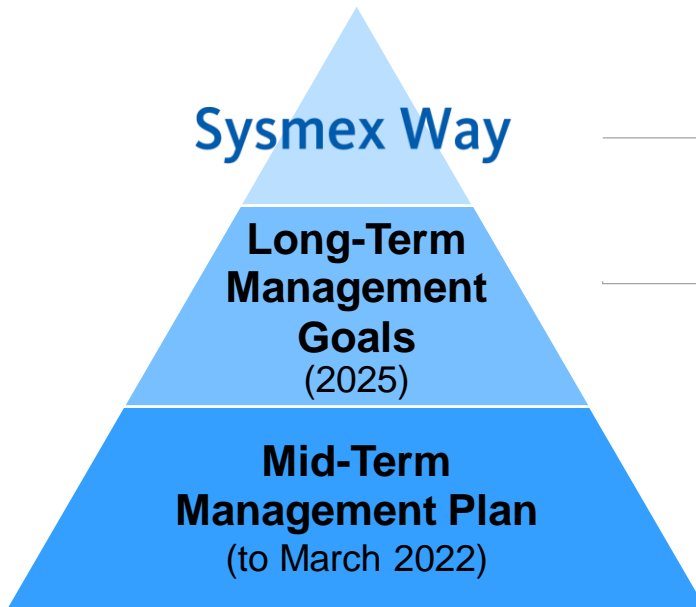
- (1) Testing for Alzheimer's Disease
- (2) HDL Testing

Appendix Glossary, etc.

1

Opening Presentation

Hisashi Ietsugu,
Chairman and CEO



Mission

Shaping the advancement of healthcare.

Value

We continue to create unique and innovative values, while building trust and confidence.

Mind

With passion and flexibility, we demonstrate our individual competence and unsurpassed teamwork.

Long-Term Vision

Unique & Advanced Healthcare Testing Company

Positioning

- Creating innovative diagnostic value as a global top-five company in IVD
- A leading company in personalized diagnostics for optimizing medical treatment
- A solution provider contributing to the advancement of primary care diagnostics
- An attractive company providing value and instilling confidence
- One Sysmex carrying out high-speed management

New medical issues are arising, due to the COVID-19 pandemic and increasingly severe environmental issues stemming from global warming.

Main medical issues pre-COVID-19

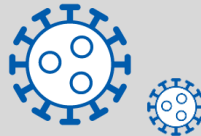
- Curtailing the rise in medical expenses
- Rise in diseases related to an aging society
- Responding to unmet medical needs
- Enhancing access to healthcare
- Realizing technological innovation

New issues post-COVID-19

- Reviewing policies for curtailing medical expenses
- Decentralizing healthcare, reducing personnel, digitalization (online medical care, use of robotics, etc.)
- Reducing the environmental burden on healthcare institutions
- Rise in diseases related to an aging society
- Responding to unmet medical needs
- Enhancing access to healthcare
- Realizing technological innovation

COVID-19's global spread

- Infection response measures (lockdowns, etc.)
- Responding to pressure on healthcare structures
- Expanding testing structures
- Developing vaccines, promoting inoculation



Increasingly severe environmental issues

- Lowering carbon emissions
- Reducing electricity use
- Decreasing water consumption
- Reducing waste
- Other



We are developing and moving toward practical realization of COVID-19 tests.



COVID-19 countermeasures becoming an urgent global issue

Status of global infection (cumulative)*1

Infections Approx. **110** million people

Deaths Approx. **2.5** million people

Economic loss due to decelerating growth (Next six years) Approx. **3,000** trillion yen*2



In addition to the stable provision of products and services, developing and working toward the realization of new tests and services

New tests and services

Checking for infection and monitoring treatment

- PCR tests
- Antigen tests
- COVID-19 testing labs
- Robotic PCR systems

Prediction of increasing severity, monitoring treatment

- IFN-λ3 reagent
- Cytokine tests

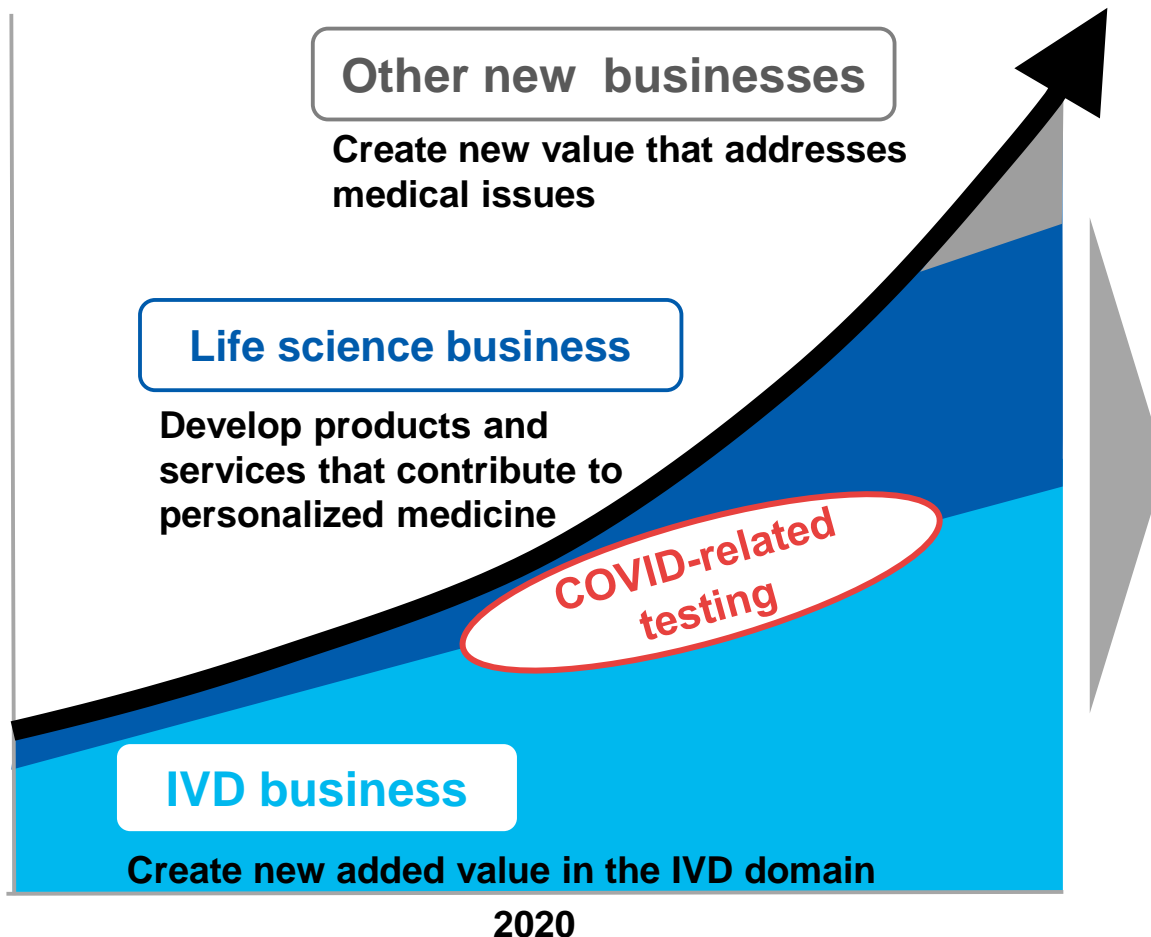
Measuring vaccine effectiveness, etc.

- Antibody tests
- ELISPOT tests

*1 Source: Google, statistical data on COVID 19 (as of March 1st, 2021)

*2 Source: International Monetary Fund (IMF) World Economic Outlook (WEO), revised October 13, 2020

By promoting new technological developments, we aim to help resolve medical issues and realize sustainable growth.



Today's agenda

- **Initiatives for Personalized Medicine**
 - Alzheimer's tests
 - HDL tests
 - Cancer Genomic Medicine
- **COVID-19-related testing**
 - Antigen/antibody tests
 - Cytokine tests
 - Compact immunochemistry system
 - Robotic PCR systems
 - COVID testing labs
- **Rapid drug susceptibility test**
- **New hematology products**

2

R&D Initiatives Amid COVID-19

Kaoru Asano

Member of the Managing Board and
Senior Executive Officer
Senior Managing Director
COO LS Business Unit and CTO

IVD business

- **Hematology**

- Development of a high-end multiparameter automated hematology analyzer model
 - Development of the XQ Series multiparameter automated hematology analyzer for emerging markets, conclusion of domestic notification

- **Hemostasis**

- Launch of CN-6500/CN-3500 automated blood coagulation analyzers

- **Immunochemistry**

- Launch in China of three reagent parameters (NT-ProBNP, C-Peptide, Insulin)

- **Urinalysis**

- Development with Astrego of rapid drug sensitivity test for urinary tract infections

- **FCM testing**

- Launch in North America of our first FCM product, the XF-1600 flow cytometer

LS business

- **Cancer genome tests**

Approval for a partial change to the OncoGuide NCC Oncopanel System
(Genes: 114 →124, the addition of an MSI evaluation function)

Launch of OncoGuide NET

- **High-sensitivity digital PCR**

Insurance reimbursement (7500 points) for OncoBEAMRAS CRC kit for CDx as
molecularly targeted therapy for colon cancer

(First ctDNA test in Japan using high-sensitivity digital PCR technology)

- **High-sensitivity NGS (Plasma SafeSEQ)**

Launch in Europe of RUO Kit for measuring gene mutations in colon cancer, lung
cancer, thyroid cancer and myeloma

- **Lymph node metastasis diagnose technology (the OSNA™ method)**

Launch in China of RD-100i Gene Amplification Detector and LYNOAMP™ BC

New initiatives in personalized medicine

- **Alzheimer's disease**

Discussions with authorities and obtainment of data with a view toward regulatory application (expect to apply in first half of FY2021 in Japan)

- **HDL function**

Start of clinical research with KOL (United States)

- **CTC**

Obtain data indicating potential for CTC detection of early-stage colon cancer in joint research

Open innovation

- **RIKEN**

Signing of collaborative agreement with RIKEN Innovation Co., Ltd. to return RIKEN's research results to society and commercialize them

- **Kobe City Eye Hospital**

Signing of comprehensive collaboration agreement related to the clinical implementation of genomic medicine for inherited retinal disease

Contributing to diagnosis with existing tests

Provision of parameters useful in cases of increasing severity



Hematology (XN Series)



Hemostasis (CN Series)



Immunochemistry (HISCL Series)

Providing highly reliable testing and diagnostic methods

Development of new parameters, automation of testing



PCR (IVD)



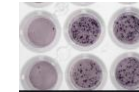
Antigen tests (IVD)



Antibody/cytokine lab assay service (for research)



Robots



Cellular immunity kit (for research)

Social activities, contribution to normalization

Tie-ups with PCR centers and governments, certification of negative results, stable supply, epidemiological surveys and evaluations of effectiveness



CoviLab, a PCR testing lab in Kobe

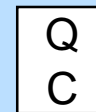
Efforts to control and curb COVID-19

Vaccines, effectiveness evaluation, monitoring

Ensuring the safety and peace of mind of medical professionals



Markers of increasing severity (IVD)



Quality control surveys

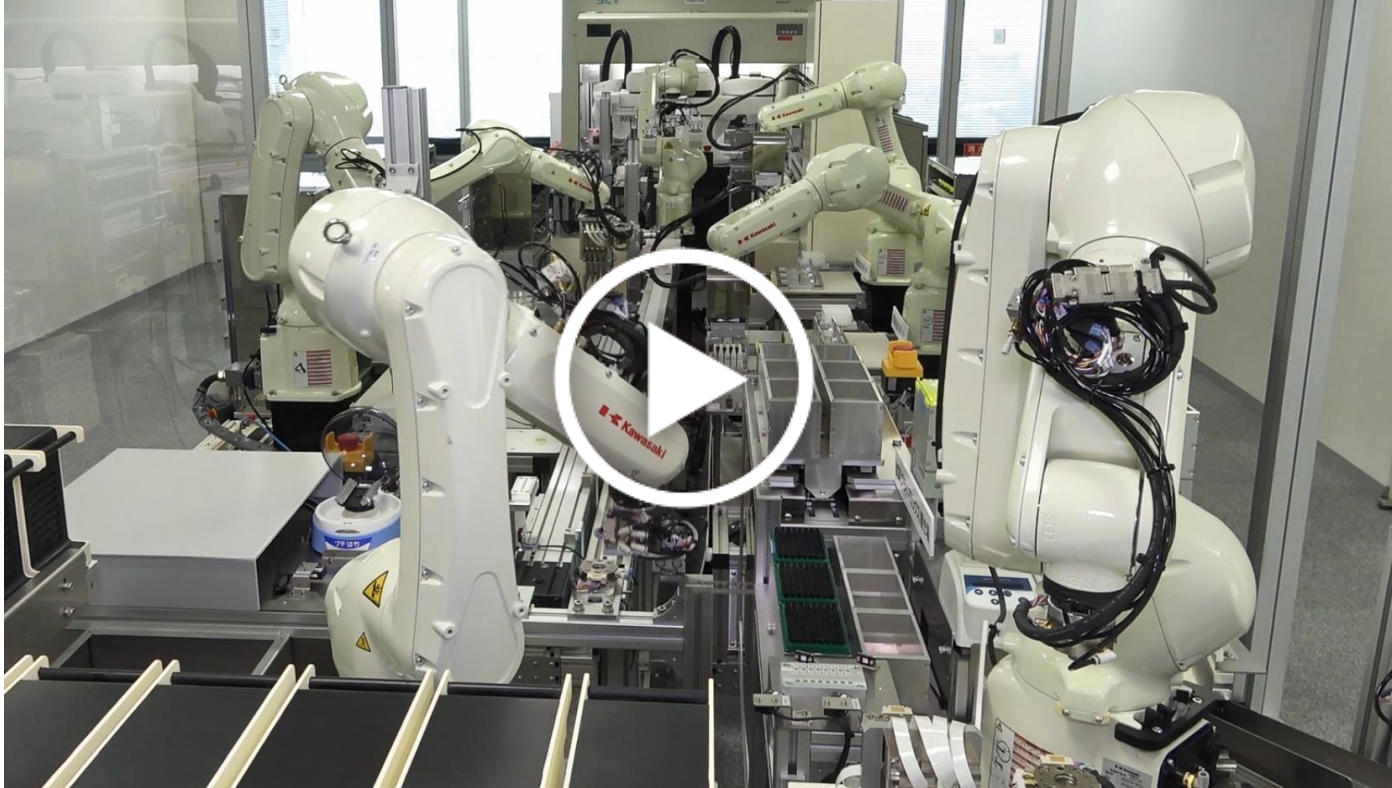


Robotic PCR testing system

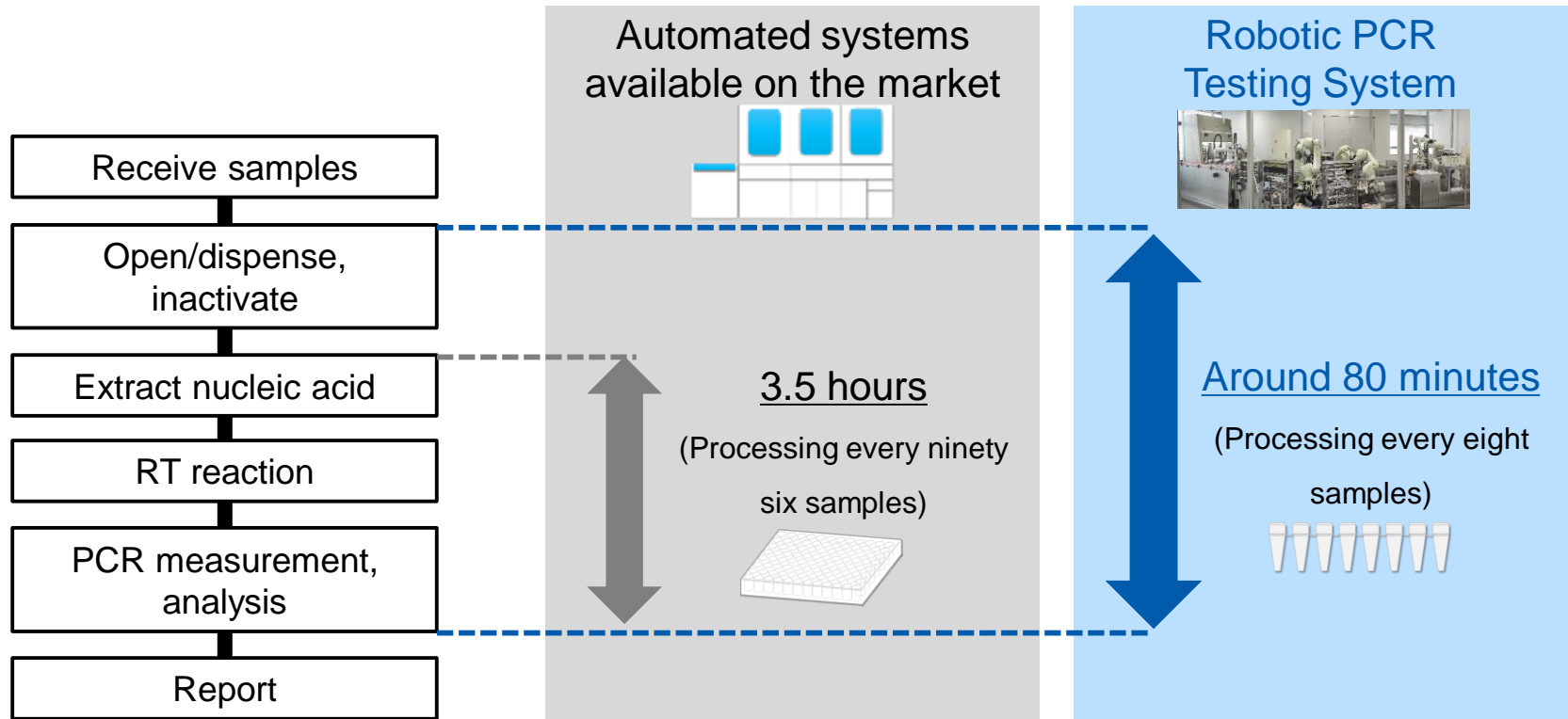


Influenza

Overview of the Robotic PCR Testing System



Provided by Kawasaki Heavy Industries, Ltd.



- Fully automated, from unsealing to measurement
- TAT* of approximately 80 minutes
- Handles up to 2,500 samples/day (if operational for 16 hours)
- Instruments can be transported in containers

*TAT: Turn Around Time

Key devices, reagents (Sysmex in charge)

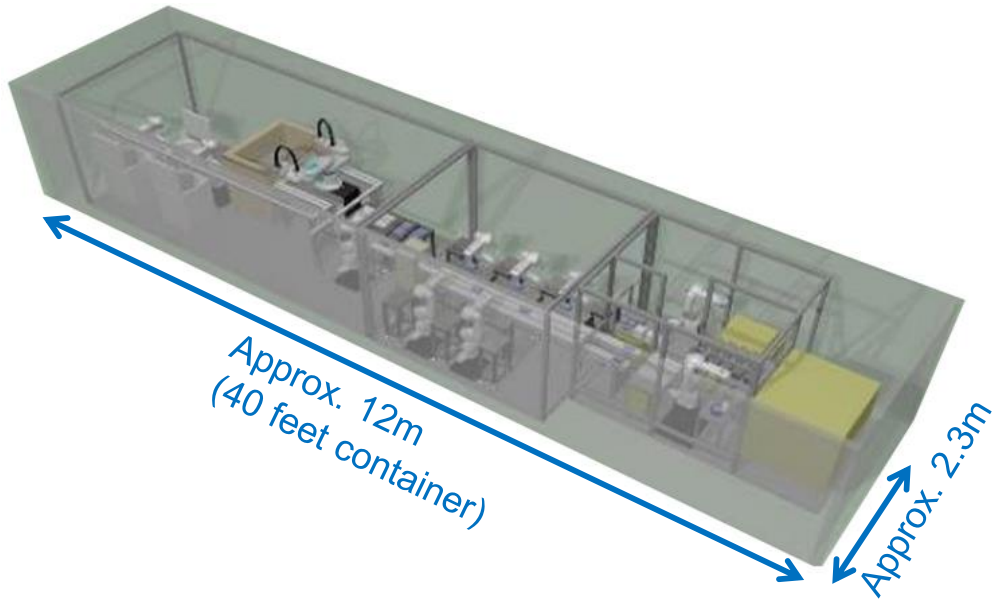


Sequential PCR



Proprietary reagents under development

Easy to install by transporting with a trailer



Sales scheme

Robotic PCR Testing System

Kawasaki Heavy Industries



Sysmex



Kawasaki Heavy Industries

Testing service

Medicaroid

Sysmex

Sales to Medical institution

3

Technology Innovation in the IVD Business

Hiroshi Kanda

Member of the Managing Board and
Senior Executive Officer
Managing Director

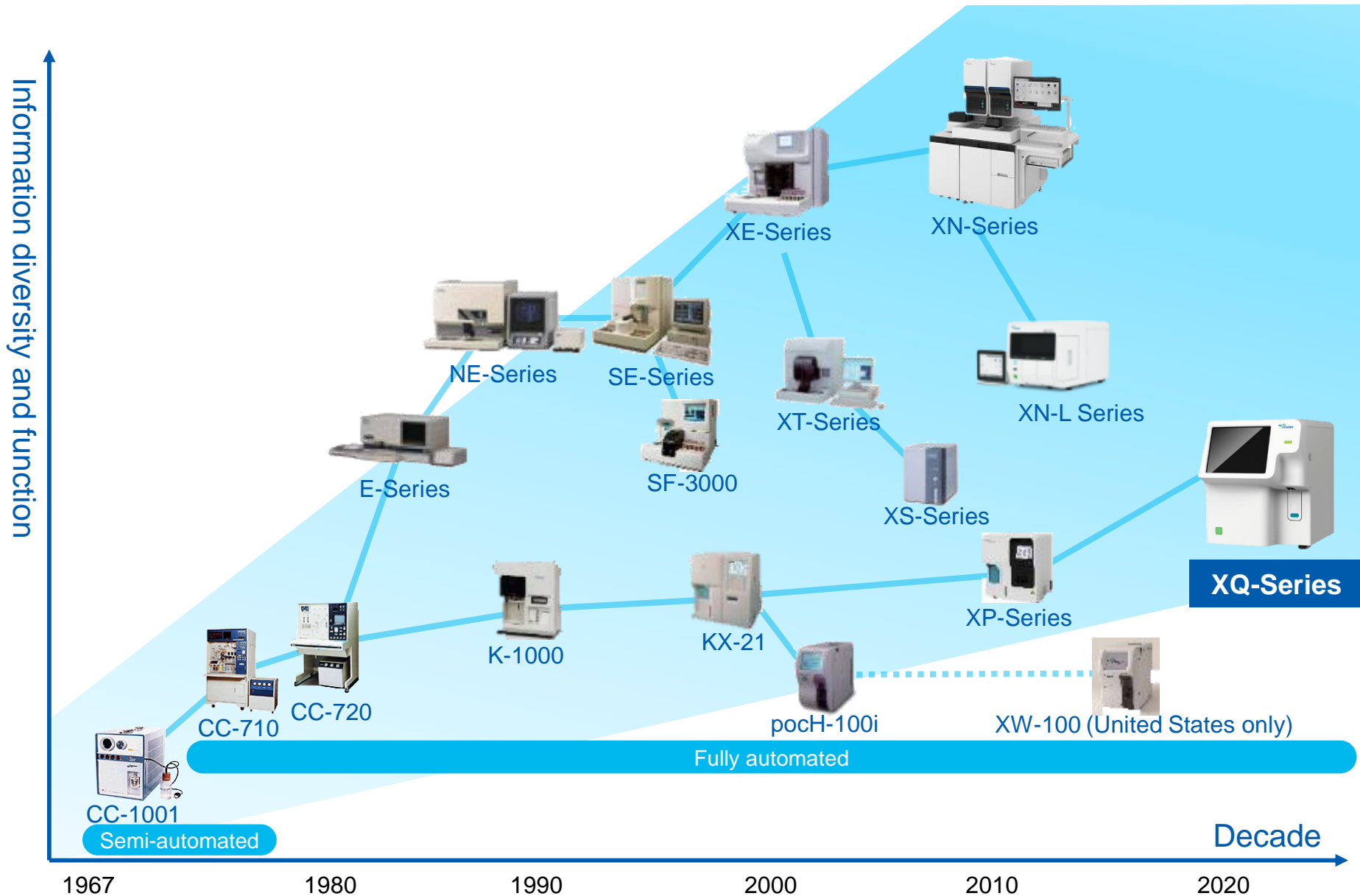
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Technology Innovation in the IVD Business

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History of Hematology Instruments



About the XQ-Series

- A product focused on low-end hematology markets in emerging countries
(The 3PD market size is approximately 40,000 units/year)
- Carries forward the XP Series functionality

XQ-Series concept

Excellence in **Q**uality and Usability



KX-21



XP-Series



- Compact and lightweight
- Reduced burden on patients
- Enhanced differentiation

- Higher throughput
- Environmentally friendly design
- Increased operability



Designed to meet SDGs



	KX/XP-Series	XQ-Series
Size, in mm (D x W x H)	355 x 420 x 480	450 x 365 x 440
Weight (kg)	30	22
Throughput (tests/hour)	60	70
Aspirated volume (whole blood, μL)	50	16
Display size (inches)	5.7	10.4
Power consumption (VA)	<200	<160
Reagent consumption / test (mL)	35	27

Compact and lightweight

Footprint* **9% smaller**

Weight **30% lighter**

* Protruding portion(s) are not included.

Higher throughput

60 samples/h \Rightarrow **70 samples/h**

Reduced burden on patients

50 μL \Rightarrow **16 μL**

Environmentally friendly design

Power consumption

down by 25%

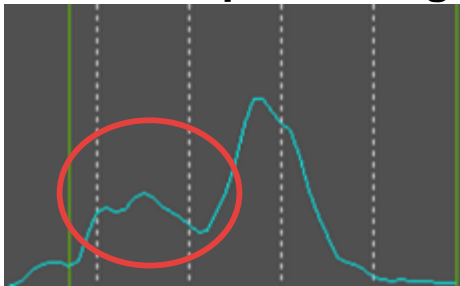
Reagent consumption

down by up to 30%

Enhanced differentiation

Employs the leading-edge digital waveform processing circuits used on the XN-Series to improve differentiation

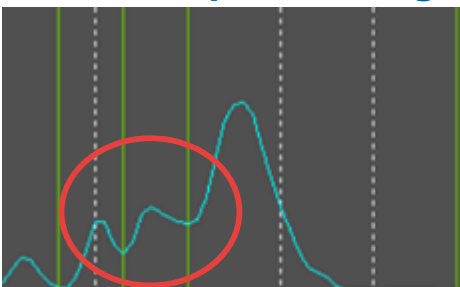
Analog waveform processing



Differentiation was difficult



Digital waveform processing



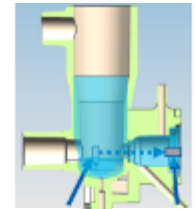
White blood cells are well separated

Increased operability

Enhanced safety

Developed and included an emissions monitoring function in the detection chamber that utilizes changes in voltage

- Prevents output of mistaken data
- Prevents water leakage due to overflow



Anode (-) Cathode (+)

Automatic wakeup function

Measure immediately without wait time



Supports regulations and ISO compliance

Includes QC lockout function
⇒ Possible to prevent measurement unless quality control performed

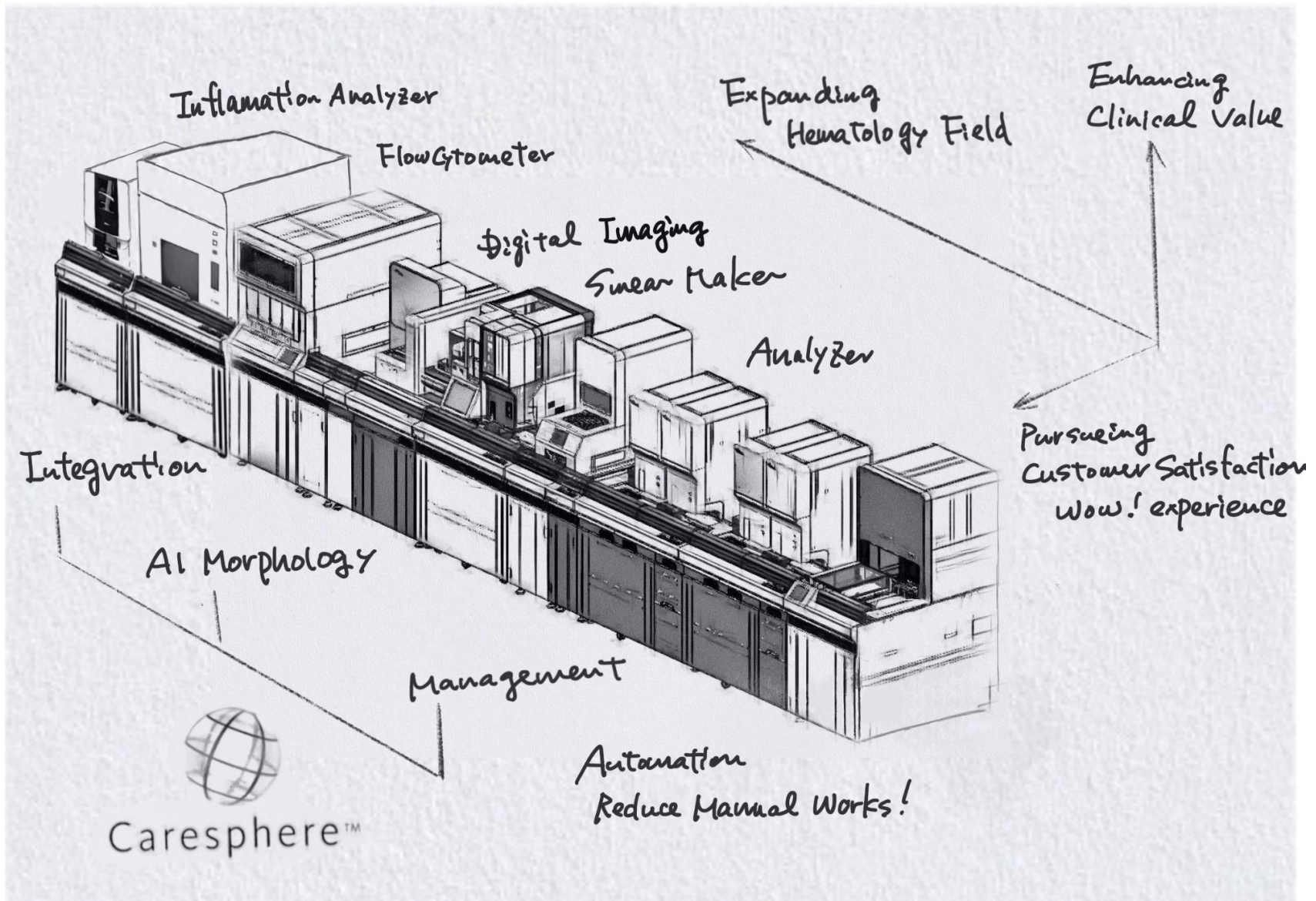


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Technology Innovation in the IVD Business

- (1) XQ-Series
- (2) New Hematology Products
- (3) Application of Astrego's Nanofluidic Technology

The Concept of New Hematology Products



“Providing more valuable test results and realize laboratory environment where customer can focus on specialized work utilizing those results”

OPERATIONAL VALUE

Bringing surprise and pleasure to customer by reducing workloads (Wow! Experience)

Reduce manual operations thoroughly by shifting to automation, reduction and integration, and realize environment where customer can focus on specialized work.

CLINICAL VALUE

Lighting the shortest route to diagnosis by utilizing test results

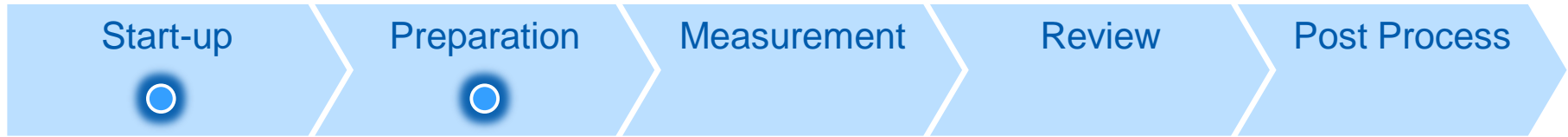
Provide test results which are valuable for patients and clinicians by both defense and offense approach.

MANAGERIAL VALUE

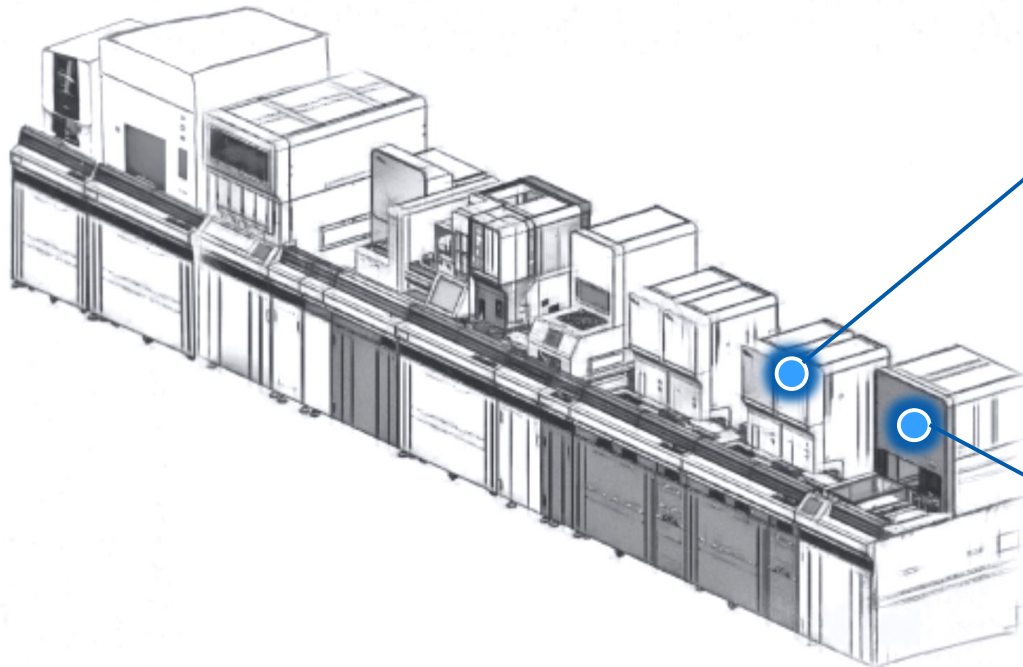
Delivering best quality assurance to improve role and reliability of laboratory

Support smooth acquisition and operation of ISO by improving efficiency in document maintenance before and after acquiring ISO, as well as contribute to hospital management by improving laboratory operation efficiency

New Value from New Hematology Products: Operational Value



- ✓ Automatically start up instruments at the preset time, so testing can start quickly
- ✓ Automatically perform the quality control management required for quality assurance on clinical tests



New hematology analyzer
Automatically start up according to a preset schedule

New transport module
Prepare and transport quality control materials to the designated analyzers so quality control measurement can be performed at the scheduled time

New Value from New Hematology Products: Operational Value

Start-up

Preparation

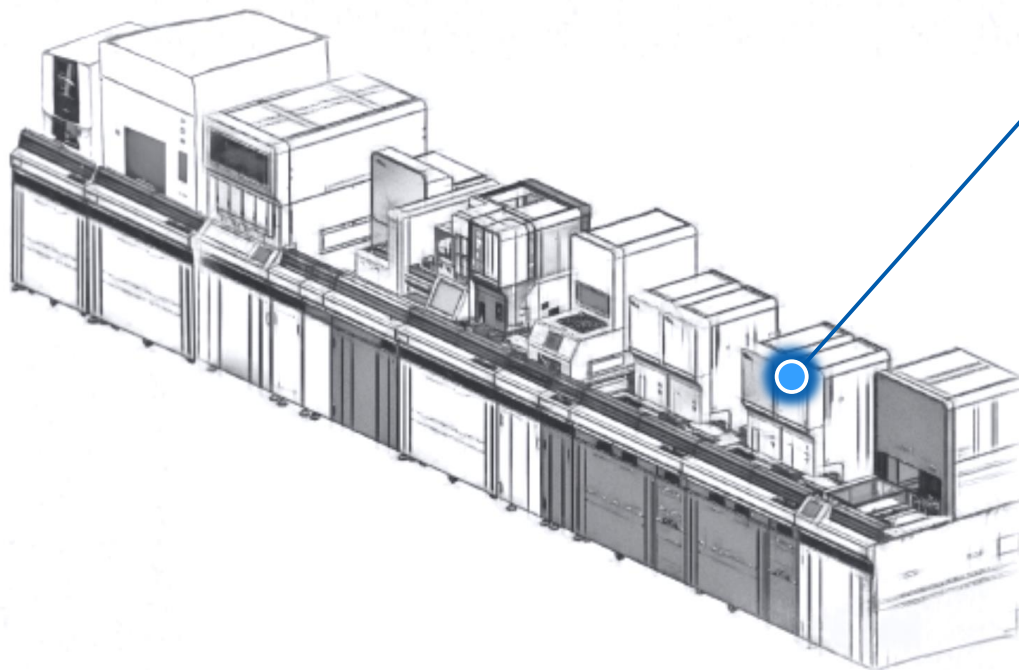
Measurement

Review

Post Process



- ✓ Automatically start up instruments at the preset time, so testing can start quickly
- ✓ Automatically perform the quality control management required for quality assurance on clinical tests

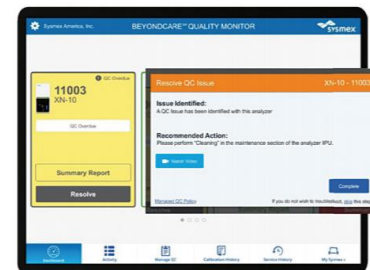


New hematology analyzer

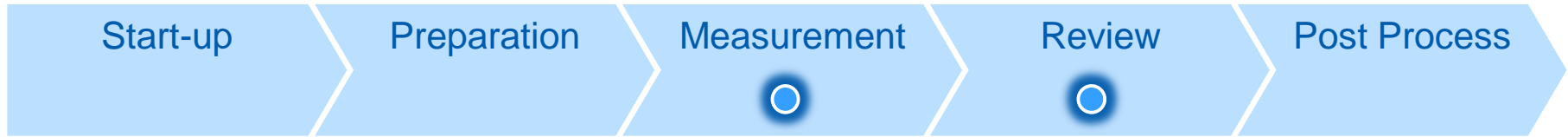
Automatically measure the quality control materials, and display quality control results

Caresphere™

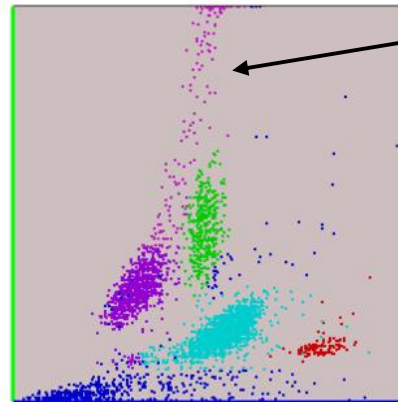
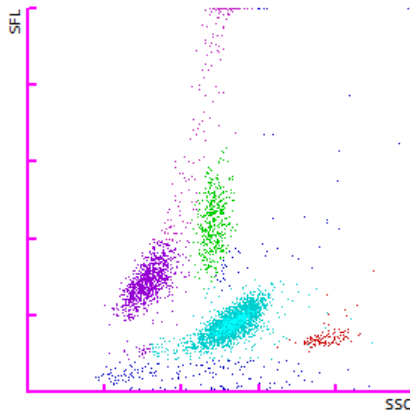
Use network service to judge quality control results



New Value from New Hematology Products: Clinical Value

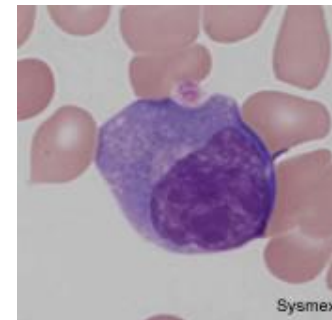
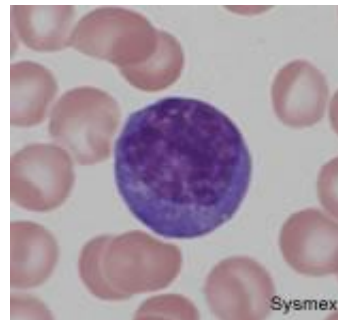


Example: Virus infection



When lymphocytes are stimulated by virus infection, cells containing particularly high amounts of nucleic acid appear in this area

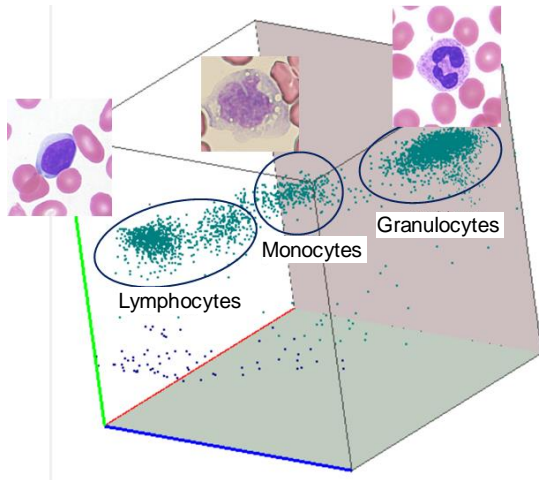
⇒ Possibility to suggest virus infection



Activated plasmacytoid atypical lymphocytes that synthesize antibodies were confirmed.

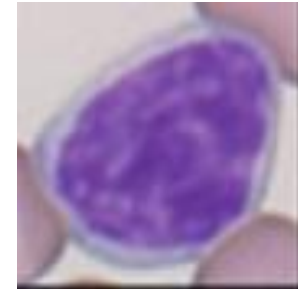
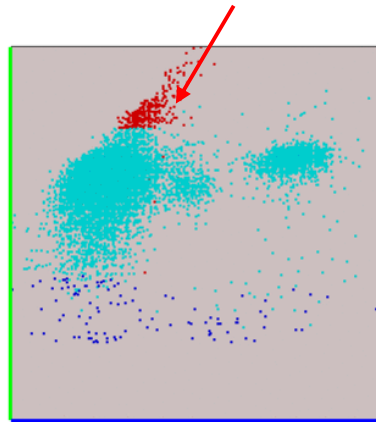
New Value from New Hematology Products: Clinical Value

Normal case



Malignant lymphoma (chronic lymphocytic leukemia)

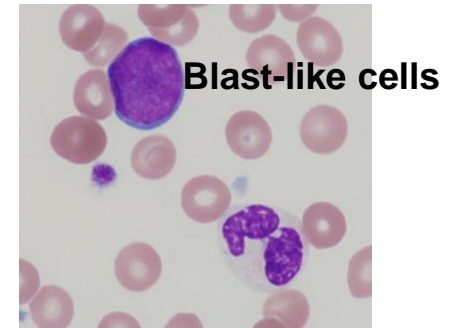
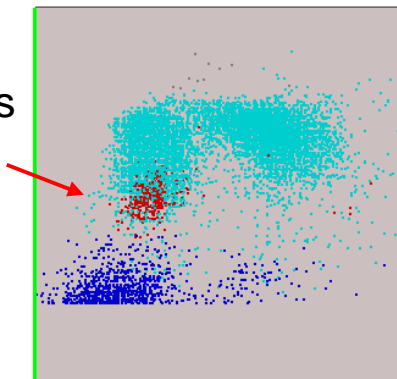
Extends directly upward from lymphocyte cluster
Suggests possibility of malignant lymphoma



**Malignant lymphoma cell
(difficult to differentiate by microscopy)**

Myelodysplastic syndrome with blast increase (pre-leukemia)

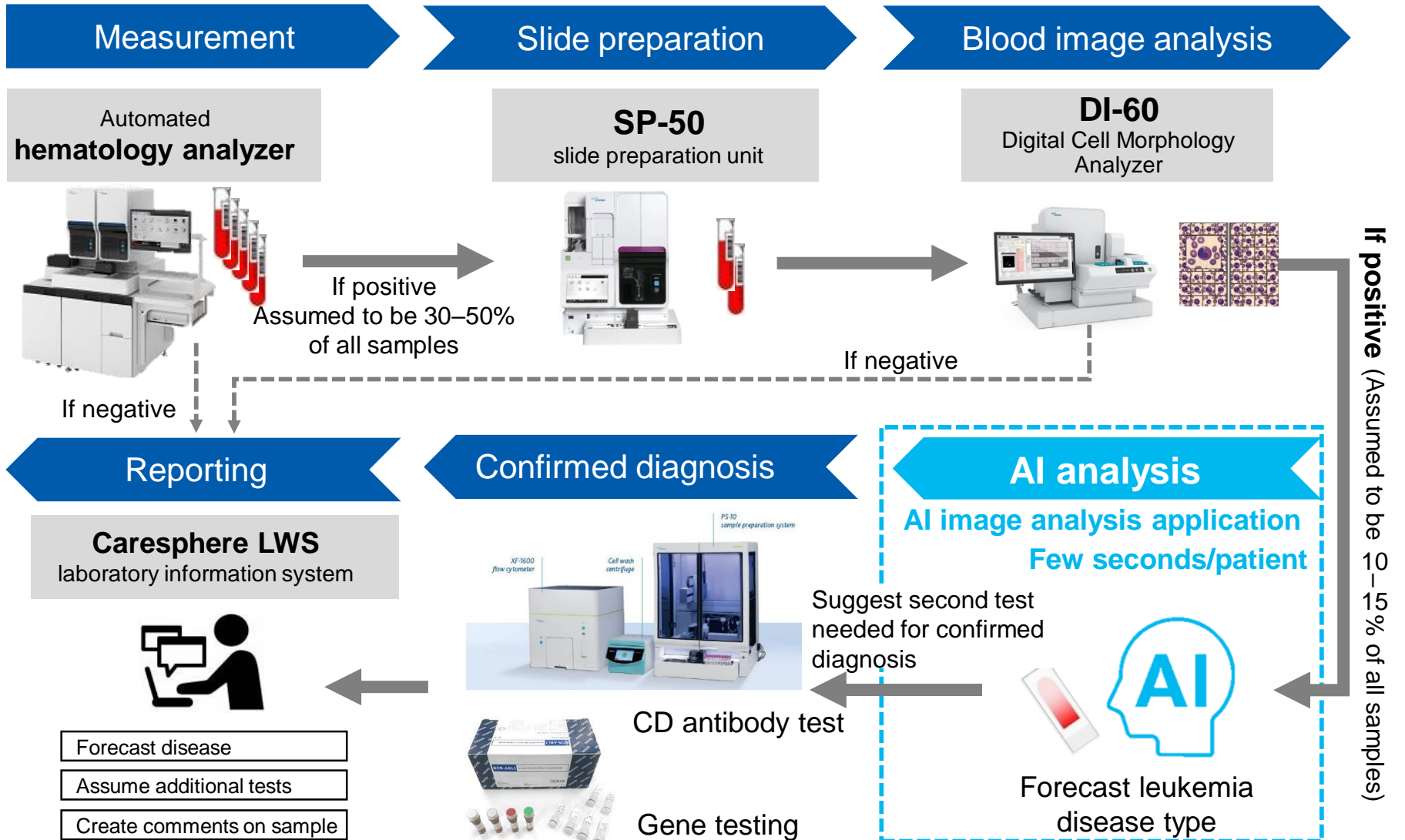
A cluster appears below monocytes
In case of acute leukemia, the
cluster often appears



The Future of Hematology Testing Sysmex Envisions



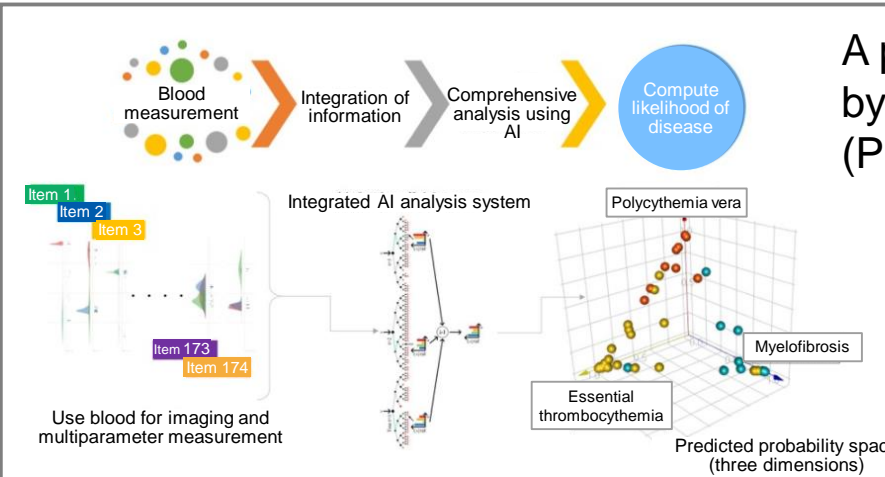
Create an automated system that performs at least on a par with an expert technologist



Working Toward Early-Stage AI Screening and Diagnostic Support Technology

Enable highly precise automated distinction of Philadelphia chromosome-negative myeloproliferative neoplasms

Success in using an AI automated system for the highly precise distinction of hematologic cancer
(From a Juntendo University news release dated February 10, 2021)



A paper published in *Scientific Reports*^(*4), a series by *Nature*, a UK-based journal
(Published February 9, 2021)

- Configure integrated AI analysis system capable of differentiating hematologic diseases
- Enable highly precise automated distinction of Philadelphia chromosome-negative myeloproliferative neoplasms, a type of hematologic cancer
- Advance toward the realization of simple and rapid screening and diagnosis support using peripheral blood via AI automated analysis

In cases of hematopoietic stem cell abnormalities, ability to distinguish^(*1) between MDS^(*2) and AA^(*3) → reaching 90%

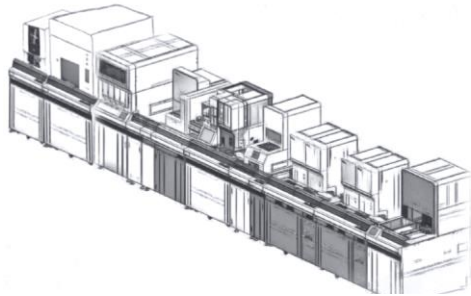


A paper published in *Scientific Reports*^(*4), a series by *Nature*, a UK-based journal (Published September 16, 2019)

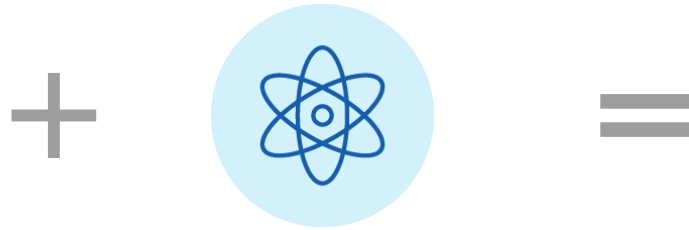
<https://www.nature.com/articles/s41598-019-49942-z>

(*1) Sensitivity, specificity
(*2) Myelodysplastic syndrome
(*3) Aplastic anemia
(*4) *Scientific Reports*: Impact factor 4.011

New Value from New Hematology Products: Managerial Value



New hematology products



Caresphere

Enhanced medical outputs

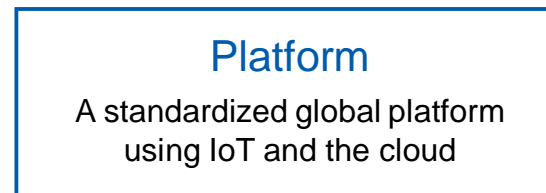
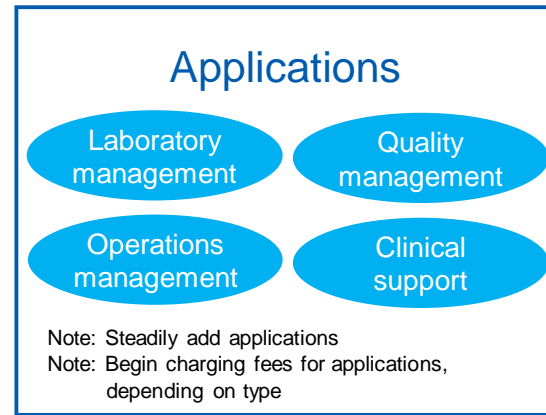
Measurement results

Quality control data

Instrument logs

Test operation records

-
-
-



More productive laboratory operations

Reduced patient burden
(Shorter wait times, etc.)

Increased diagnostic precision
(Suggestions to clinician)

Realization of medical collaboration
(Standardization of testing data)

Toward Future Advances in Hematology

More productive laboratory operations

Reduced patient burden
(Shorter wait times, etc.)

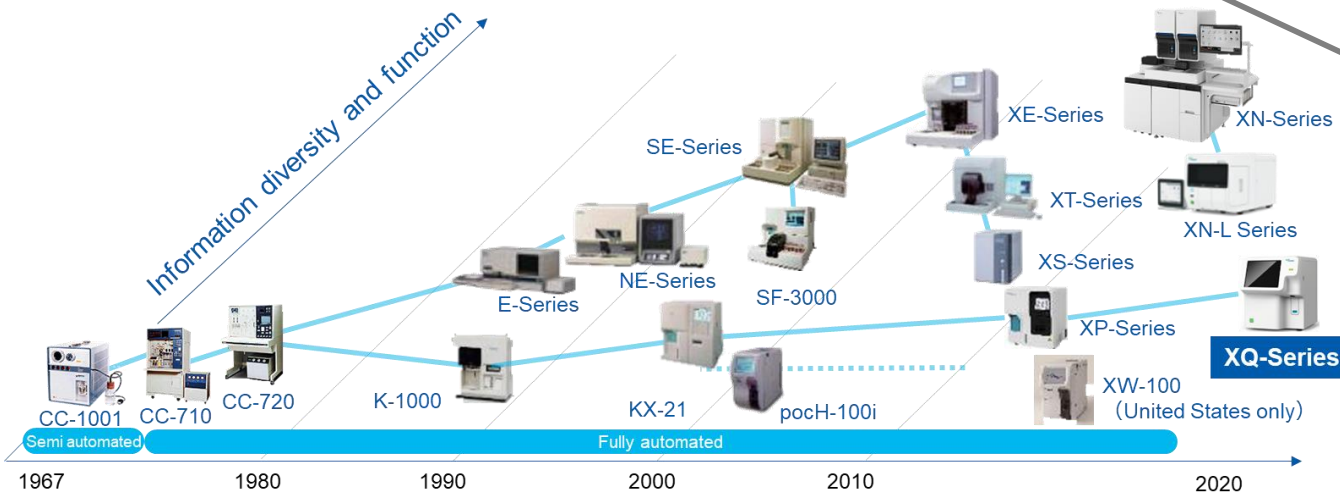
Increased diagnostic precision
(Suggestions to clinician)

Realization of medical collaboration
(Standardization of testing data)

Clinical Value

Managerial Value

Operational Value



3

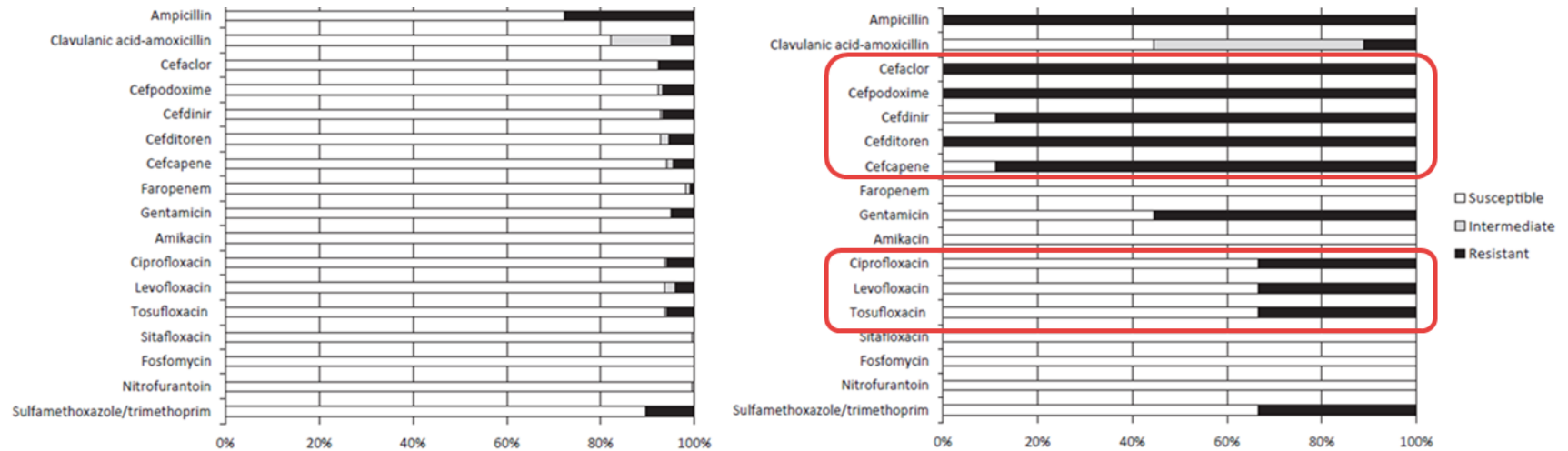
Technology Innovation in the IVD Business

- (1) XQ Series
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The Issue of Antimicrobial Resistance (AMR)

- By 2050, it is estimated that more people will die as the result of AMR than cancer. Owing to a decrease in the development and launch of antimicrobial, it is possible that supplies of these drugs will become depleted. Against this backdrop, measures to counter AMR are an important issue from the public health perspective.
- In Japan, instances categorized as AMR are rising in cases of respiratory infections and urinary tract infections, which have a high number of patients, indicating a high resistance to certain broad-spectrum antimicrobial recommended by the guidelines. (See figure below.)

The figure on the left indicates general antimicrobial drugs used to treat urinary tract infections, tolerance rates for n=220 E. coli bacteria. Of these, the figure on the right indicates tolerance rates for ESBL-produced E. coli bacteria



Source: 2019 Journal of Infection and Chemotherapy (joint surveillance results by three Japanese societies)

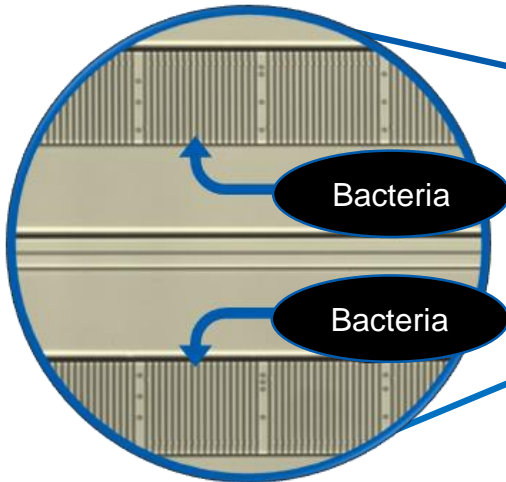
Each year, resistance to antimicrobial that cause relatively common urinary tract infections is rising, pointing to the need for measures to address the emergence of routine AMR.

Use of Nanofluidic Technology to Realize Rapid Antimicrobial Susceptibility Tests

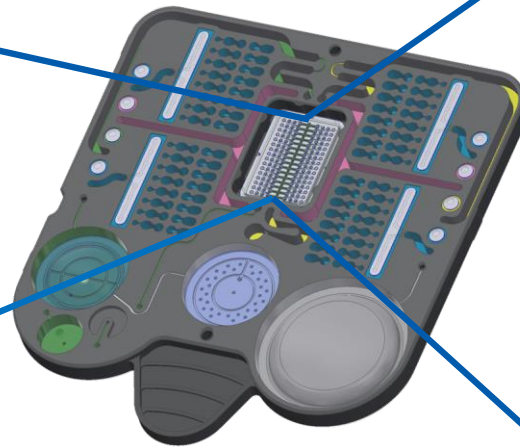
- In the conventional method of bacteria culturing, bacteria are placed on a culture medium in agar plates, where they grow in all directions. Typically, more than 10 hours is required for bacteria to form colonies. Astrego's technology uses nanochannels that allow bacteria to grow only in one direction. This arrangement, plus the ability to see minute changes, enables rapid, 30-minute tests. This is expected to facilitate appropriate diagnosis and treatment even in first visit for a patient.
- In the measurement part of the reagent cartridge, nanochannels are divided into 32 compartments. Each of these compartments is tested for, calculation of reference value for the bacteria growth rate, presumptive identification of bacteria as pathogens, and susceptibility tests with different antimicrobial drugs and concentrations are conducted.

Application of nanofluidic compartment

Magnified view of nanochannel compartment

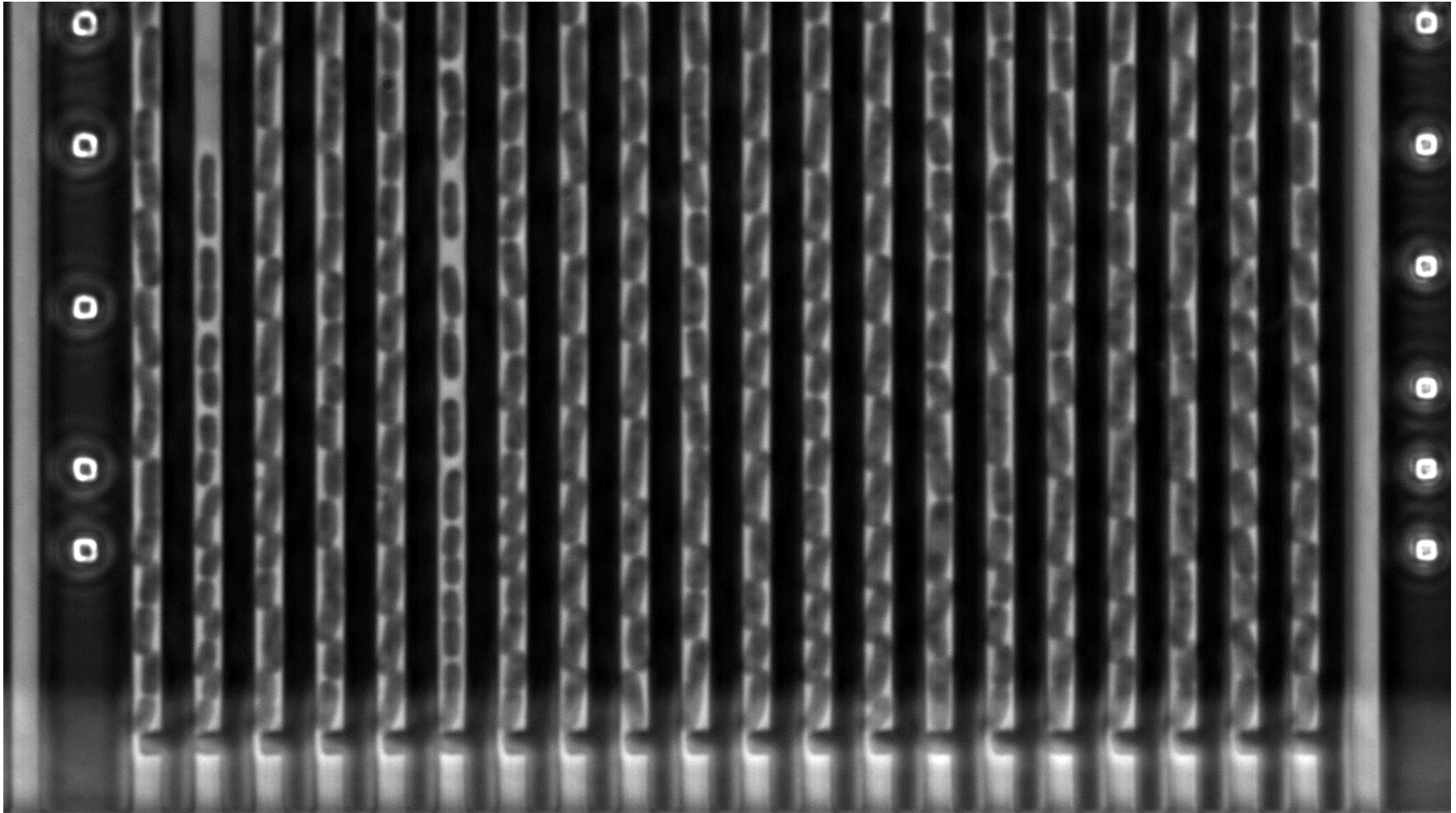


Final prototype cartridge



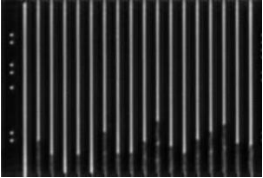
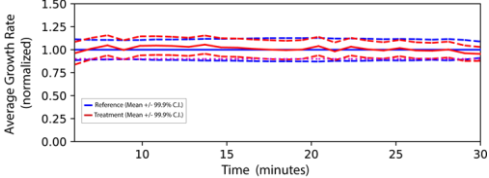
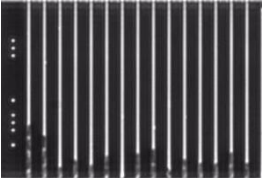
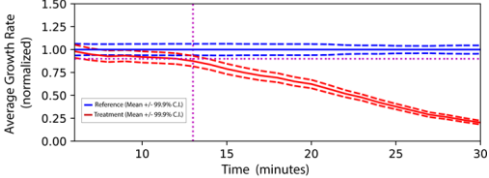
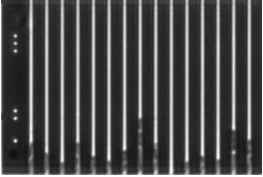
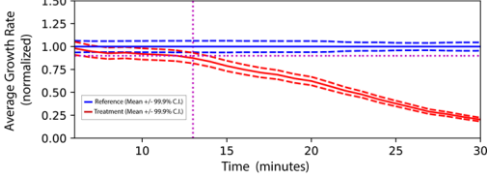
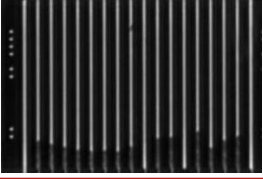
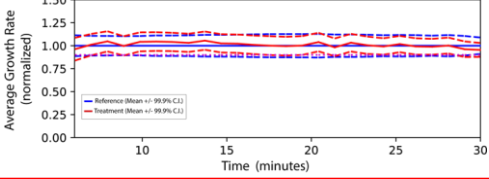
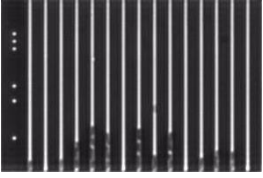
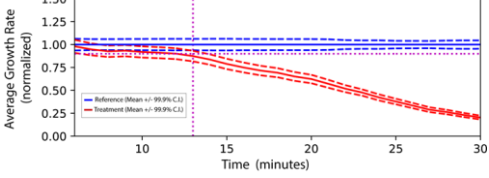
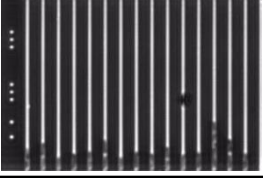
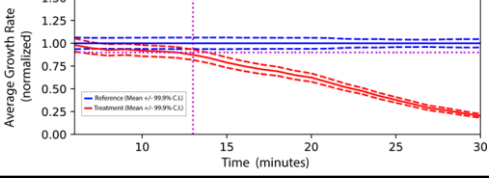
Reference 1	Drug B, concentration 5
Reference 2	Drug C, concentration 1
Reference 3	Drug C, concentration 2
Reference 4	Drug C, concentration 3
Presumptive identification 1	Drug C, concentration 4
Presumptive identification 2	Drug C, concentration 5
Presumptive identification 3	Drug D, concentration 1
Drug A, concentration 1	Drug D, concentration 2
Drug A, concentration 2	Drug D, concentration 3
Drug A, concentration 3	Drug D, concentration 4
Drug A, concentration 4	Drug D, concentration 5
Drug A, concentration 5	Drug E, concentration 1
Drug B, concentration 1	Drug E, concentration 2
Drug B, concentration 2	Drug E, concentration 3
Drug B, concentration 3	Drug E, concentration 4
Drug B, concentration 4	Drug E, concentration 5

Antimicrobial Susceptibility Tests Using Nanofluidic Technology

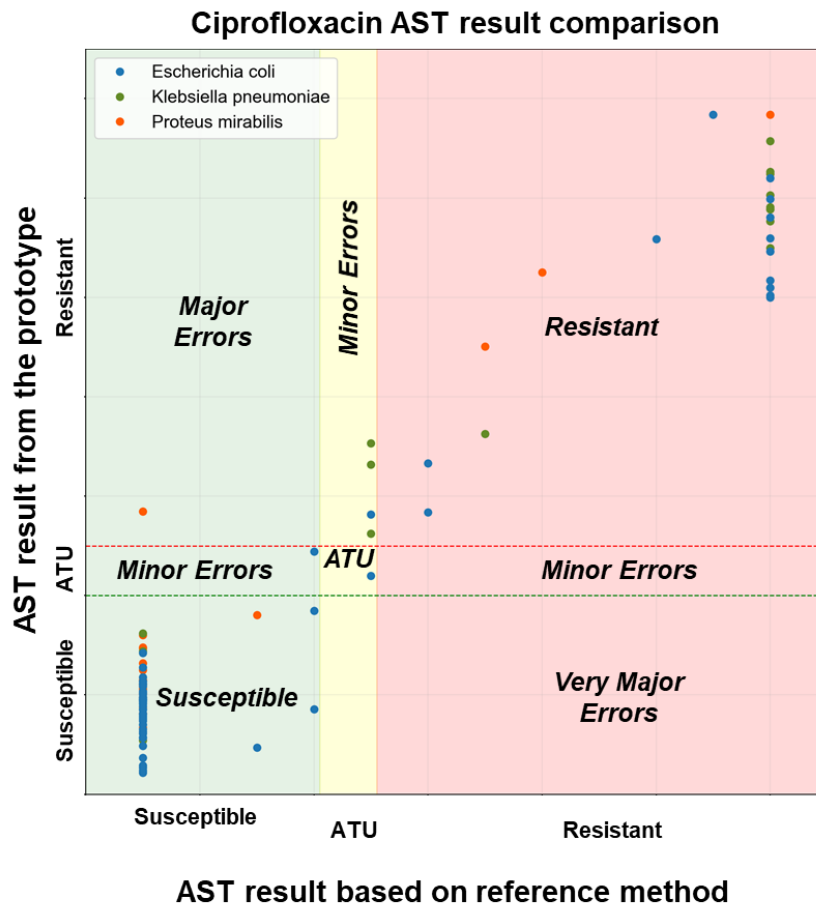


Each bacterium can grow in only one direction within the nanochannel. Minute changes can therefore be detected, facilitating rapid bacterial culturing and antimicrobial susceptibility testing.

Antimicrobial Susceptibility Tests Using Nanofluidic Technology

Nanochannel compartment	Application	Changes in growth rate	Measurement results
	Reference (growth media)		--
	Susceptibility test (antimicrobial 1)		S: susceptibility (Antimicrobial causes growth rate to level off.)
	Susceptibility test (antimicrobial 2)		S: susceptibility (Antimicrobial causes growth rate to level off.)
	Susceptibility test (antimicrobial 3)		R: resistant (Antimicrobial has no impact on growth)
	Susceptibility test (antimicrobial 4)		S: susceptibility (Antimicrobial causes growth rate to level off.)
	Susceptibility test (antimicrobial 5)		S: susceptibility (Antimicrobial causes growth rate to level off.)

- Performance data from reagent calibration process on the cartridge
 - Adjusting concentration of antimicrobial on the cartridge by comparing correlation with reference method in order to finalize the productization.
 - Internal verification using spike samples (307 samples). Clinical validation is planned.



Categorical agreement	Result	ISO standard
Categorical agreement with reference method	91.2%	$\geq 90\%$
Minor Errors (Fales ATU* or Resistant)	7.2%	$\leq 10\%$
Major Errors (Fales Resistant)	1.5%	$\leq 3\%$
Very Major Errors (Fales Susceptible)	0.1%	$\leq 1.5\%$

(*) Area of Technical Uncertainty which is an area between susceptible and resistant with interpretative difficulties defined by EUCAST.

4

Initiatives in the LS Business

Mamoru Kubota
Senior Executive Officer

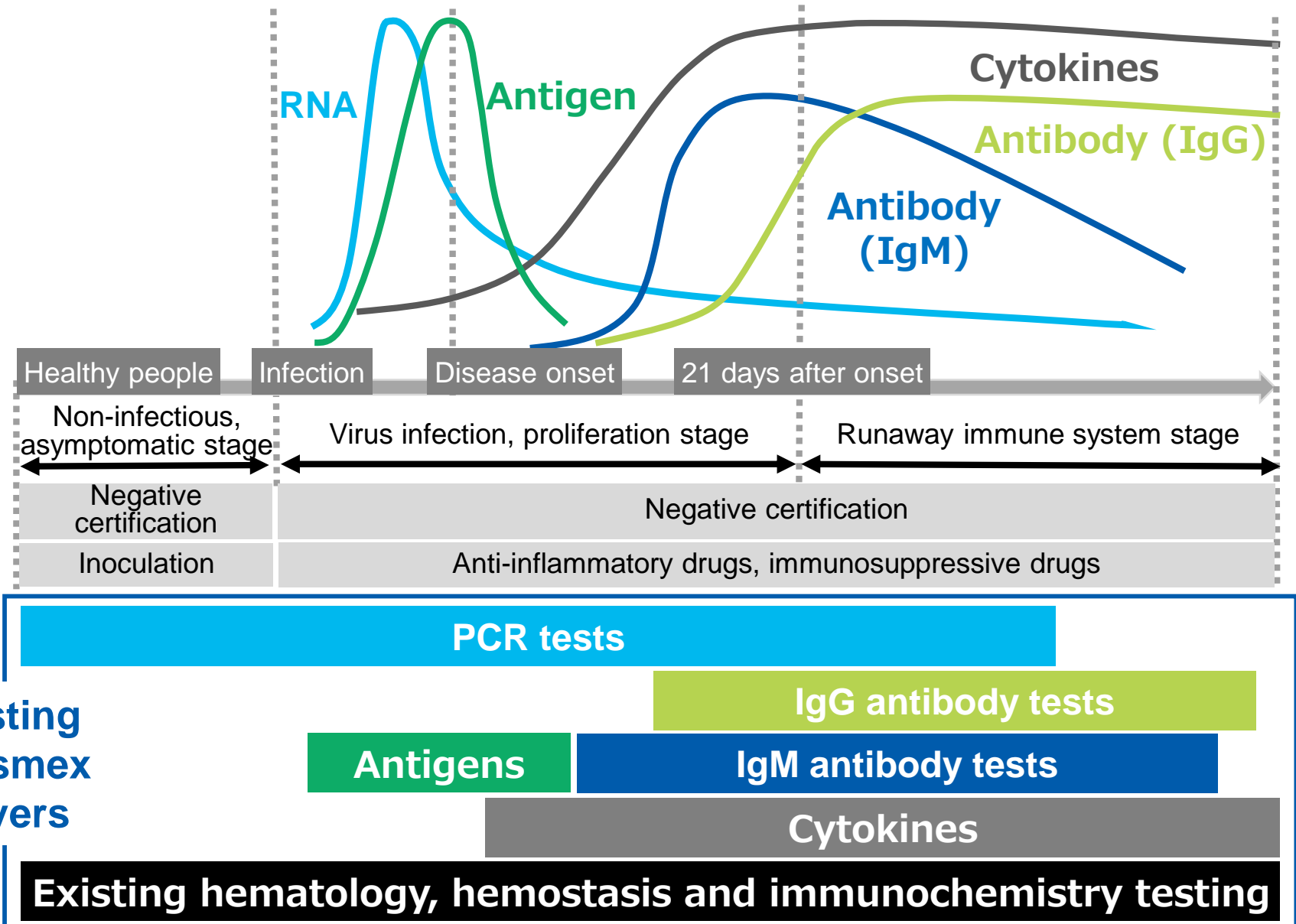
- (1) COVID-19 PCR Testing (PCR Reagents and Instruments, CoviLab)
- (2) COVID-19 HISCL Tests (Antigen, Influenza, Antibody, Cytokine)
- (3) Cancer Genome Tests (OncoGuide NCC Oncopanel System)
- (4) Cancer Liquid Biopsy Tests (OncoBEAM, PSS)

4

Initiatives in the LS Business

- (1) COVID-19 PCR Testing (PCR Reagents and Instruments, CoviLab)
- (2) COVID-19 HISCL Tests (Antigen, Influenza, Antibody, Cytokine)
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Overview of COVID-19-Related Tests Provided by Sysmex



PCR test reagent : First in Japan to obtain regulatory approval
(March 27, 2020)



Product name: 2019-nCoV Fluorescence Detection Real-Time RT-PCR Kit
(in vitro diagnostic medical device registration number: 30200EZ00017000)

Lab assay: 1,800 points
Non-lab assay: 1,350 points

Concept behind the new PCR test reagent



- Use raw materials from Japanese manufacturers to ensure high quality, stable supply
- Provide same sensitivity as conventional methods, conduct quality control using in-house standard parameters
- Respond to increase in infections and rising number of tests with shorter turnaround time.

■ Shorter detection time

Reaction time for existing PCR reagent

Steps	Cycles
50°C, 20 min.	1 cycle
95°C, 10 min.	1 cycle
95°C, 15 sec.	40 cycles
64°C, 30 sec.	
Total: Approx. 70 min.	

Reaction time for new PCR reagent

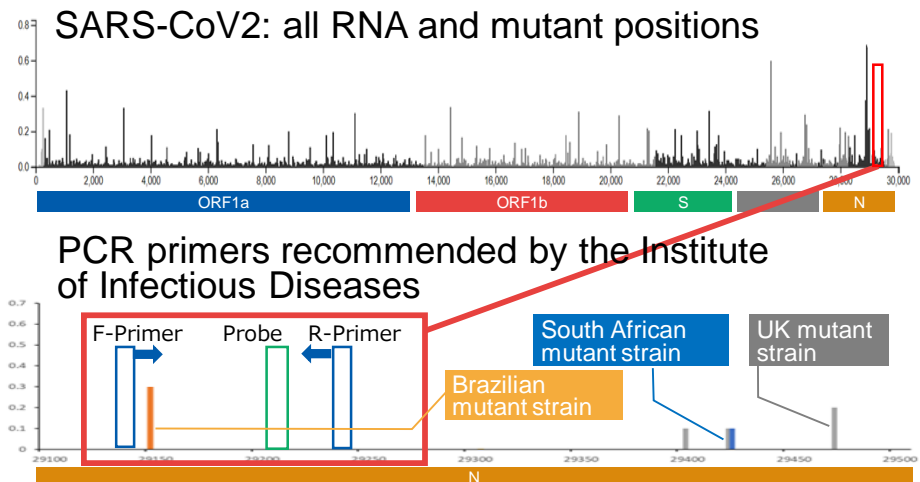
Steps	Cycles
60°C, 10 min.	1 cycle
95°C, 1 sec.	45 cycles
64°C, 16 sec.	
Total: Approx. 40 min.	



By using highly reactive enzymes, shorten detection time by approximately 30 minutes

■ Ability to detect mutant strains of the virus

Design of primers that enable detection of mutant strains



Inactivated Novel Coronavirus Liquid, Cotton Swabs for Taking Saliva Samples

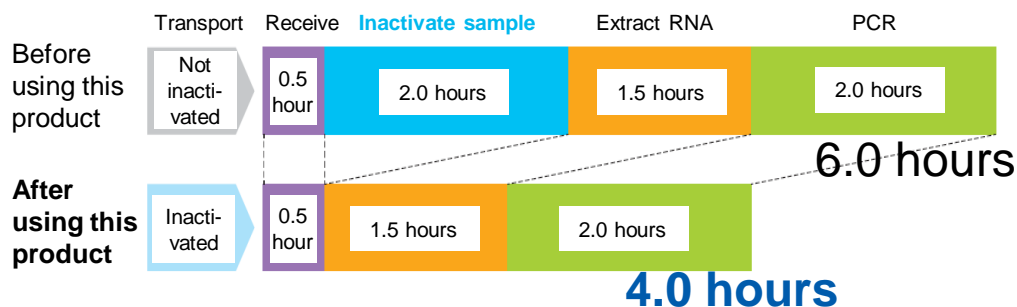
■ Inactivated virus liquid

Contribute to reduce time to handle samples and test



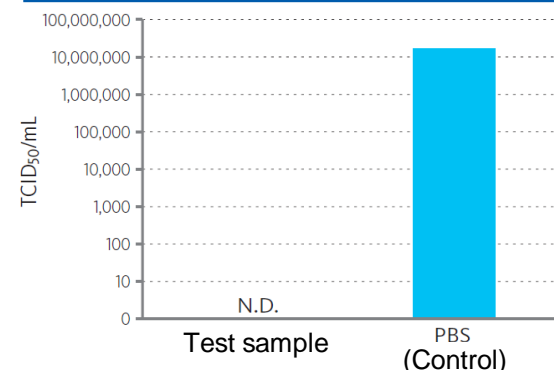
Product name (code)	SARS-CoV2 inactivation reagent (CJ897767)
Purpose of use	Inactivate SARS-CoV2 present in nasopharyngeal liquids, nasal liquid or saliva and save the viral nucleic acid
Principle, characteristics	Stably store the sample, including components that inhibit Dnase/Rnase, without disassociation of the viral nucleic acid

Inactivation in a short period of time



Note: Trial calculation assuming the processing of 50 samples

SARS-CoV-2 inactivation capacity



Evaluation test sample: Used strain provided by the Kanagawa Prefectural Institute of Public Health
TCID₅₀: tissue culture infectious dose

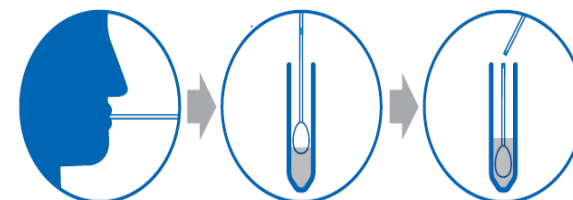
■ Cotton swabs for taking saliva samples

Help increase test operability



Product name (code)	Sterilized cotton swab, 1mL absorption capacity (BT305237)
Purpose of use	Use of cotton swab specifically for saliva sampling

General medical device marketing notification number : 21B2X10012000044



Leave cotton swab in mouth for approximately 1 minute to ensure saturation with saliva

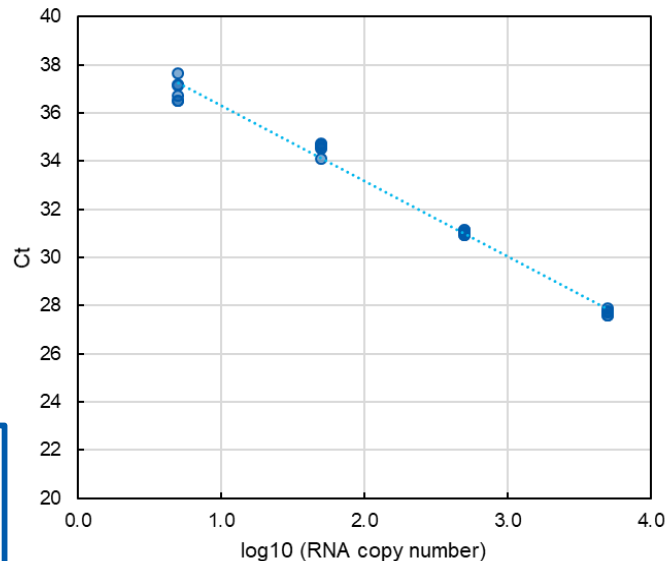
Insert cotton swab in the tube, breaking off the swab at the colored location

A compact PCR instrument linked with a robotic system that sequentially measures every eight samples



Ability to measure up to five RNA copies confirmed

nCoV-19



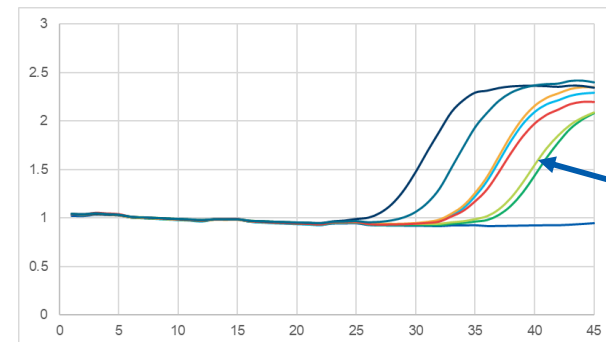
When using 2019-nCoV detection fluorescent real-time RT-PCR kit

- **Reproducibility:** SD < 1 cycle
- **Lower limit of determination:** > 5 copies

- Sequentially processes each small batch (8 samples), uses robotics for full automation, providing test results quickly
- Compact system, 15cm wide

<Reduction in TAT time (PCR time)>

- ✓ 80–90 minutes (2019-nCoV detection fluorescent real-time RT-PCR kit)
- ✓ **Approx. 40 minutes** (when using reagent produced in-house)



5 copy

Establishment of CoviLab (Lab offering COVID-19 PCR Clinical Testing Service)



Commenced lab assay in June 2020

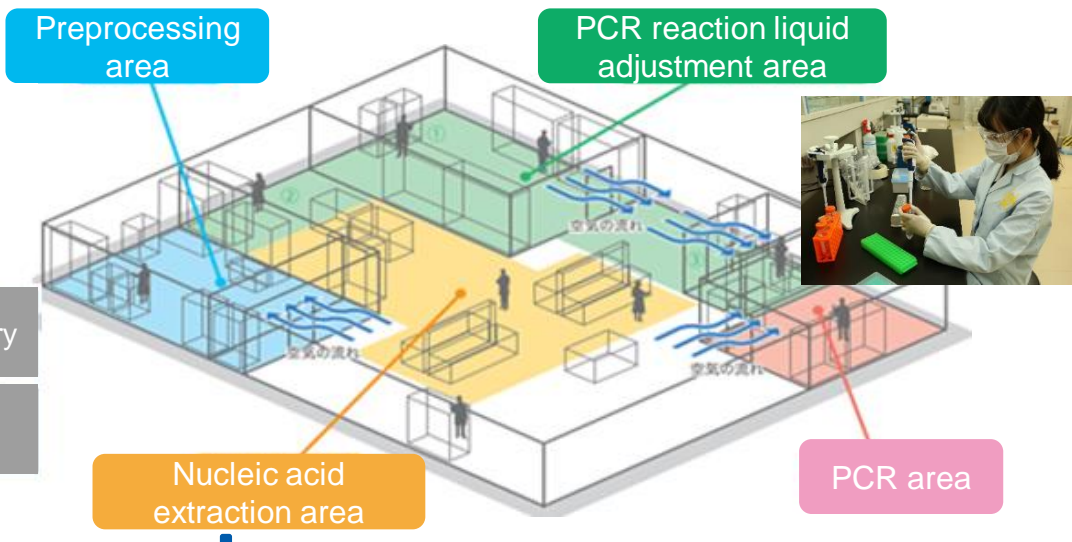
Establishment of a high-quality PCR lab assay system (CoviLab)



Registered sanitary laboratory

BSL-2+ standard

Kobe Port Island



The City of Kobe, Sysmex and SRL Agree to Configure a PCR Testing System within the Kobe Biomedical Innovation Cluster
 New PCR Testing Facility the First in Japan Established through Public-Private Participation
 (Extraordinary press conference by the Mayor of Kobe, May 18, 2020)



Lab assay results: Total of more than 15,000 samples (As of February 16, 2021)



Proactive testing at care facilities and facilities for the disabled

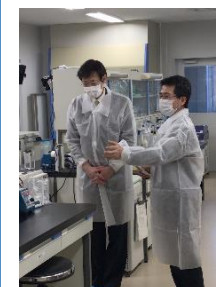


Lab assay from medical facilities



Lab assays from companies (for research)

Visited: More than 10 times (As of January 31, 2021)



Mayor of Kobe

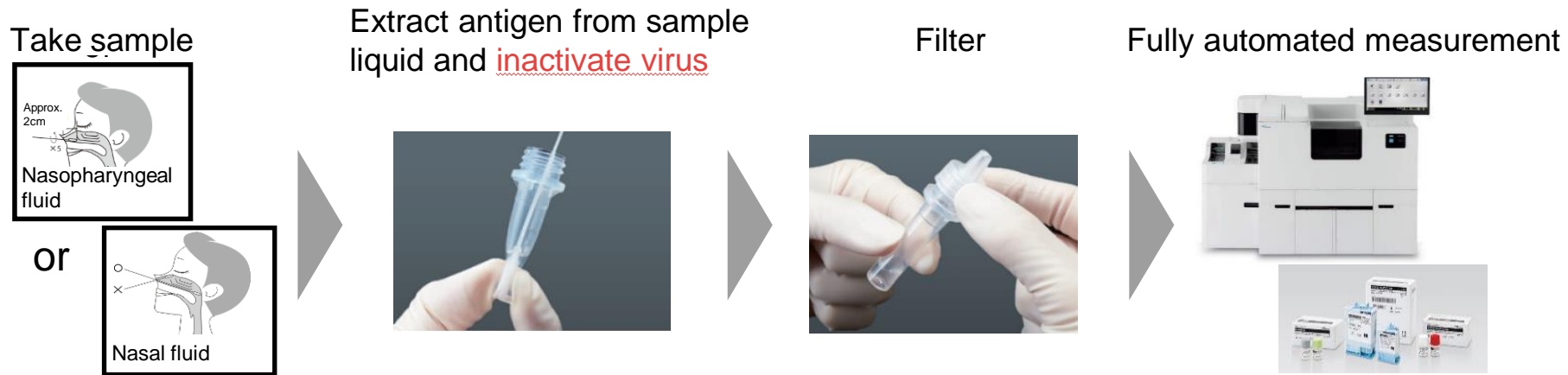
Deputy Mayor of Kobe

People in charge of health centers

Companies in Hyogo Prefecture

HISCL PF SARS-CoV-2 Ag (Antigen) Tests

Obtained domestic manufacturing and marketing approval and health insurance coverage (600 points)(November 10, 2020)



Product name: HISCL™ SARS-CoV-2 Ag Reagent
(In vitro diagnostic medical device registration number: 30200EZ00078000)

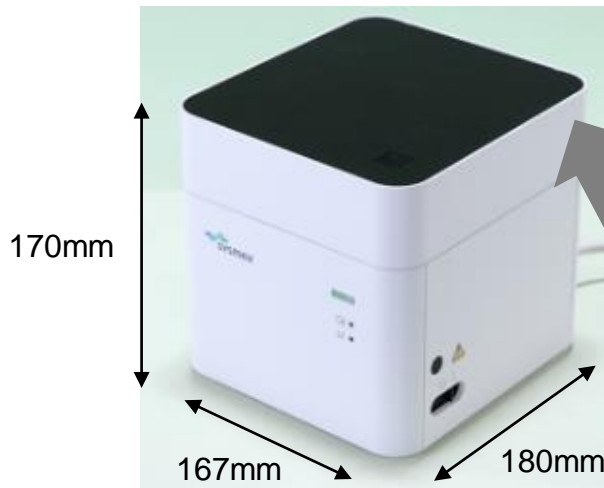
Results of clinical evaluation test
(Concordance rates with Institute of Infectious Diseases, RT-PCR method)

Sample group		Nasopharyngeal swab	Nasal swab
Positive concordance rate	Test groups of 1,600 copies/test or more	100% (15/15)	-
	Test groups of 400 copies/test or more	100% (19/19)	-
	Test groups of 100 copies/test or more	95.5% (21/22)	100% (19/19)
	Test groups of 50 copies/test or more	87.5% (21/24)	100% (20/20)
Negative concordance rate	Negative sample	100% (69/69)	100% (35/35)

Expanding application is expected to expand the target of testing to asymptomatic cases.

Compact Immunoassay System

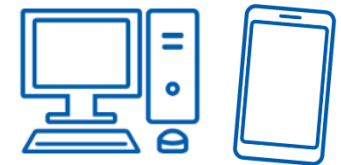
Highly sensitive and rapid measurement (within 30 minutes) using reagent for HISCL fully automated immunoassay system



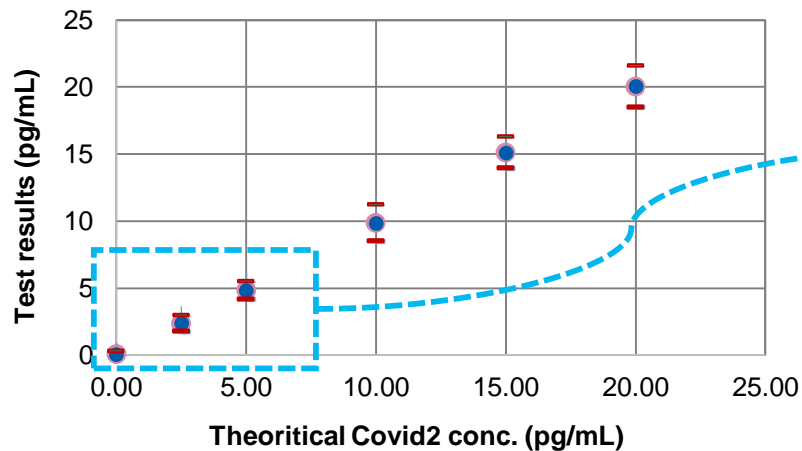
- Compact instrument, so can also be used in clinics
- Simple operation, using smartphone or other IT device
- Includes wireless network functionality
- All reaction reagents enclosed in CD disk-shaped cartridge
- Disk only disposed of after measurement



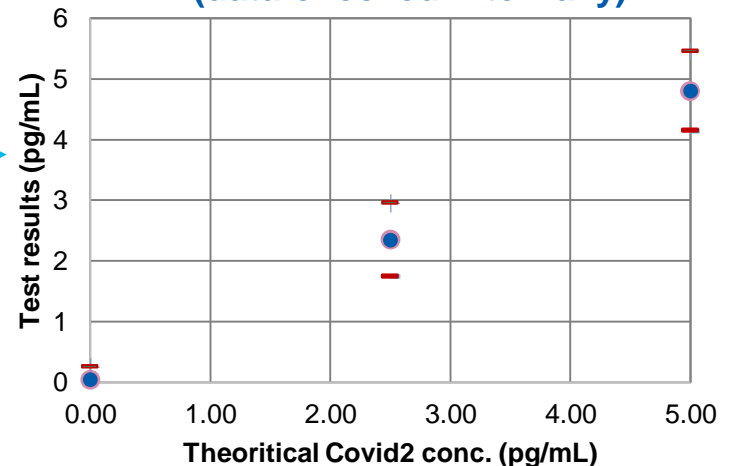
Product developed jointly with JVCKENWOOD Corporation



Covid-2 antigen test reagent



Performance in areas of low concentration (data checked internally)

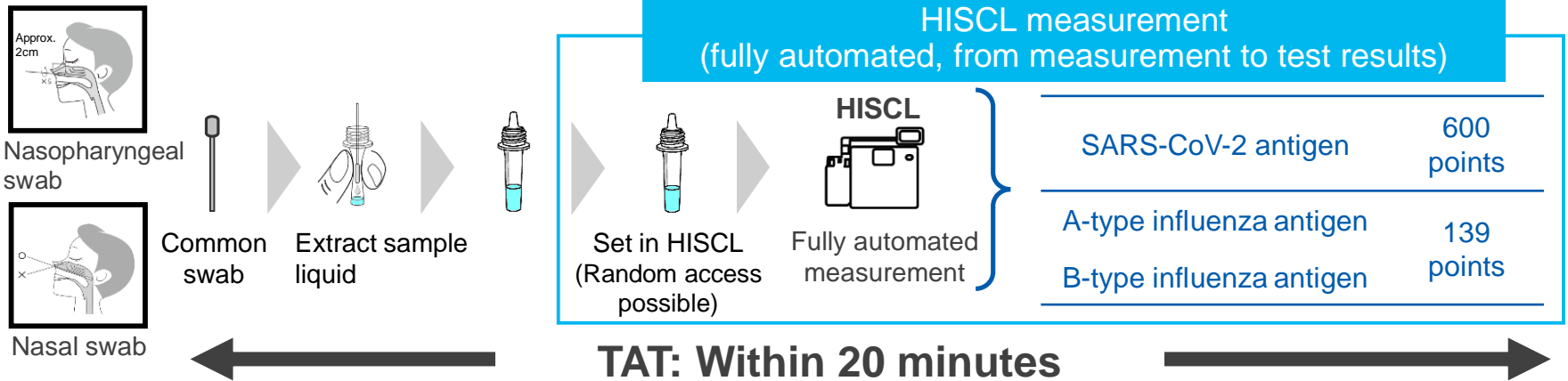


HISCL: Reagent for Detection Alongside Influenza

Reagent makes it possible to simultaneously test for the SARS-CoV-2 antigen and the A- and B-type influenza antigens using the same sample

Obtained manufacturing and marketing approval and insurance coverage (February 18, 2021)

Product name: HISCL™ Influenza Assay Kit
(in vitro diagnostic medical device registration number: 30300EZ00018000)



1) Detection sensitivity

HISCL FLU-A: 32 times

Dilution factor	HISCL FLU A-type	Immuno-chromatography method (visual judgment)
3.2x10 ⁴	+	+
6.4x10 ⁴	+	+
1.3x10 ⁵	+	-
2.6x10 ⁵	+	-
5.1x10 ⁵	+	-
1.0x10 ⁶	+	-
2.0x10 ⁵	+	NT
4.1x10 ⁵	-	NT
NC	-	-

HISCL FLU-A: 64 times

Dilution factor	HISCL FLU B-type	Immuno-chromatography method (visual judgment)
1.0x10 ³	+	+
2.0x10 ³	+	-
4.0x10 ³	+	-
8.0x10 ³	+	-
1.6x10 ⁴	+	-
3.2x10 ⁴	+	-
6.4x10 ⁴	+	-
1.3x10 ⁵	-	NT
NC	-	-

2) Concordance rate

Note: Results when virus added to samples

FLU-A	Nasopharyngeal	Nasal
Positive concordance rate	92.5%	92.1%
Negative concordance rate	100%	98.9%
FLU-B	Nasopharyngeal	Nasal
Positive concordance rate	100%	98.5%
Negative concordance rate	97.7%	100%

HISCL SARS-CoV-2 Ab (Antibody) Tests

Lab assay services for research use

- S-/N-IgM: In combination with PCR, effective for double negative certification
- S-IgG: Relevance to neutralized antibody
- N-IgG: Antibody level and treatment monitoring, epidemiological studies, etc.



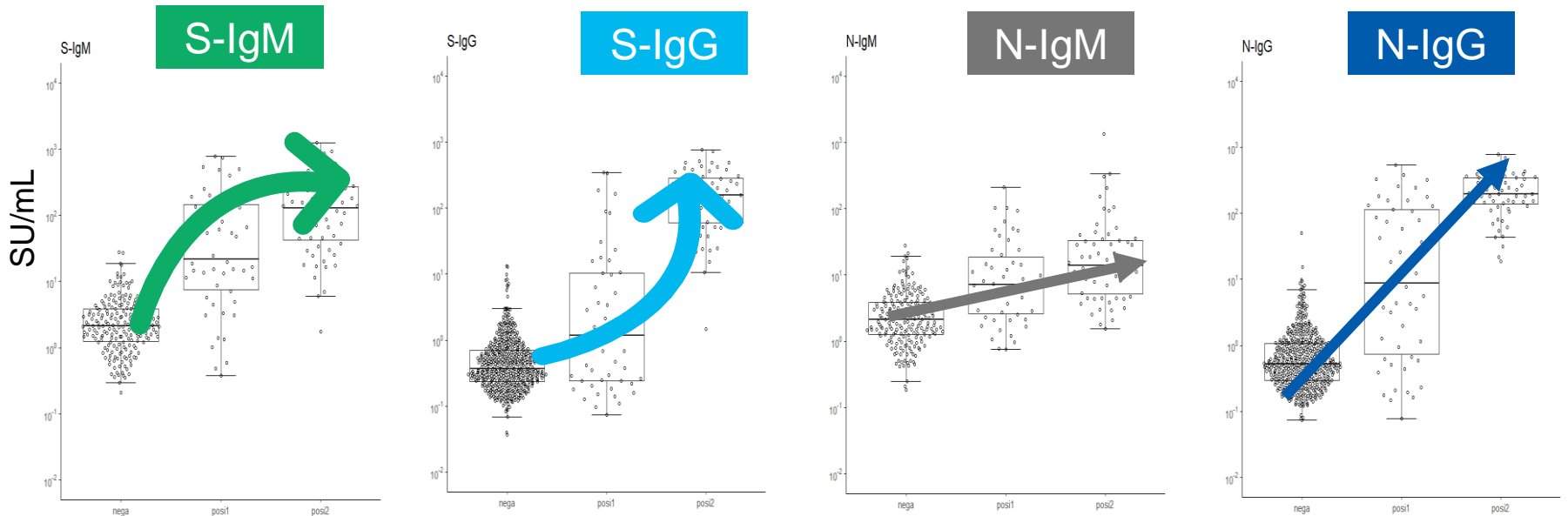
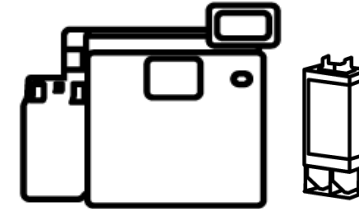
Measure effects of vaccine



Epidemiological studies



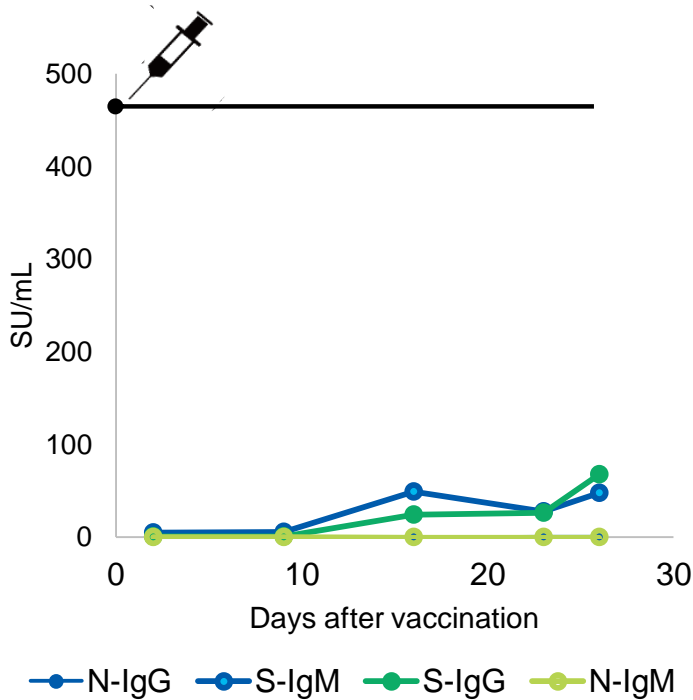
Confirm activity indicators



Uninfected person Admission patients (PCR positive) Convalescent patients
 n = 500 n = 50 n = 60

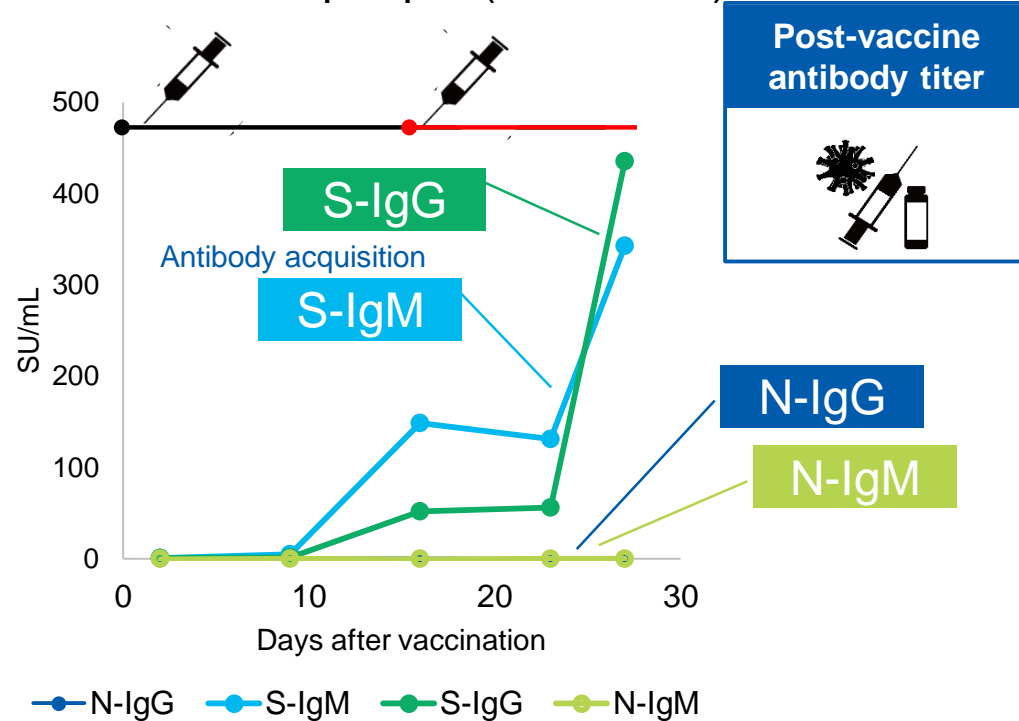
Ability to quantitatively track antibody titers after vaccination

Vaccinated patients (single dose)



	Days			
	2	10	16	23
N-IgG	0.0	0.0	0.0	0.0
S-IgG	0.1	5.3	54.1	52.7
N-IgM	0.0	0.0	0.0	0.0
S-IgM	0.4	12.7	39.2	15.2

Vaccinated people (two doses)



	Days				
	2	9	16	23	27
N-IgG	0.0	0.0	0.0	0.0	0.0
S-IgG	0.0	0.8	28.9	48.4	427.5
N-IgM	0.0	0.0	0.0	0.0	0.0
S-IgM	0.2	6.3	82.5	58.3	243.3

#This data does not indicate the efficacy or neutralizing activity of the vaccine.

HISCL PF Cytokine IFN-λ3 Tests

Purpose of use: Auxiliary diagnosis of risk of severity increasing

Predicting the risk of severity increasing could help in determining treatment methods and in early treatment, preventing severity from increasing.

HISCL™ IFN-λ3 reagent: Regulatory approval on December 22, 2020, insurance coverage on February 3, 2021 (340 points)

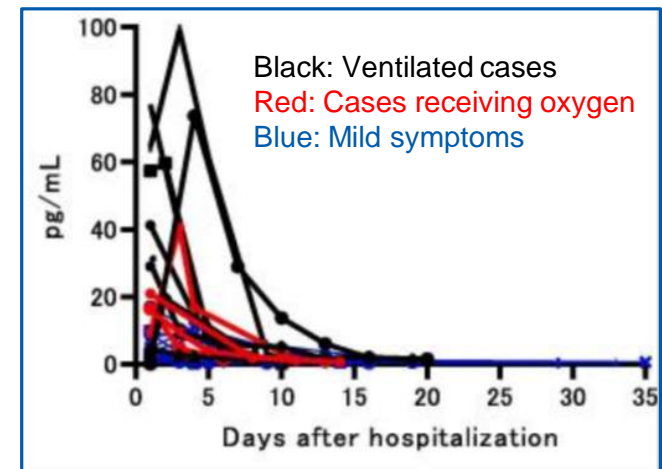
IFN-λ3: One type of cytokine related to protection from viral infection (marker for predicting increased severity)

Report on effective markers in predicting the increasing severity of COVID-19 cases by Sugiyama M, et al.*, of the National Center for Global Health and Medicine (joint research with Sysmex)

*Sugiyama M, et al., Gene. 2021 Jan 15;766:145145.

<Characteristics>

- Measured values increased one–three days before exhibiting moderate symptoms II
- Testing for which increased severity could be predicted on cases exhibiting moderate symptoms II, requiring oxygenation



Changes in IFN-λ3 during treatment progression

		Treatment progression	
		Severity increasing (oxygenation)	Severity not increasing (no oxygenation)
Cases not oxygenated at time of initial measurement (22 cases)			
IFN-λ3 Cutoff: 13.6 pg/mL	Positive	8	2
	Negative	1	11

Clinical performance

Sensitivity: 89.8%
 Specificity: 84.6%
 Positive predictive value: 80.0%
 Negative predictive value: 91.7%



Responding to global needs after vaccination



<https://www.nikkei.com/article/>

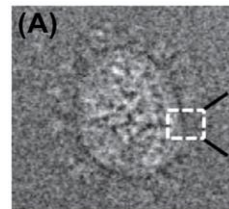


<https://www.jiji.com/jc/article>

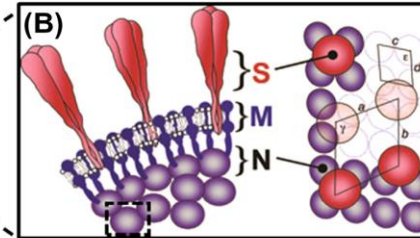
S antigen section (proteins, mRNA) on the virus surface used in vaccines



Measure quantity of S-IgG antibody including neutralized antibody after vaccination



Virus structure



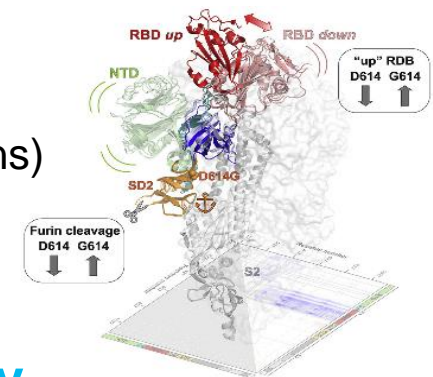
Antiviral Res. 2014 Mar;103:39-50

Response to viral mutation

Mutation causes structural changes in the virus.
(European, South African, Brazilian, Canadian and other mutations)



Once mutation is confirmed, work to improve PCR test reagents as necessary



4

Initiatives in the LS Business

- (1) COVID-19 PCR Testing (PCR Reagents and Instruments, CoviLab)
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- (4) Cancer Liquid Biopsy Tests (OncoBEAM, PSS)

Cancer Genome Tests (OncoGuide NCC Oncopanel System)

December 25, 2018: Japan's first cancer genome profiling to receive regulatory approval
June 1, 2019: Insurance coverage (56,000 points)

- Testing of approximately 3000 cases in Japan, C-CAT registration, drug arrival rate of approximately 13%
- Promotion of advanced medical care as pre-administration testing for anti-cancer drugs (NCC, from June 15, 2020) Progress rate of approximately 35% of 200 target cases



Obtained approval of partial change (February 1, 2021)

- Addition of *NTRK3* as a gene to be analyzed (114⇒124 genes)
- Addition of the *MSI-H* score detection function
- Enhanced functionality for detecting gene abnormalities and extension of panel kit's period of validity (from 6 months to 12 months)

Gene	Mutation type	Significance
Tumor-suppressor gene		
<i>MSH6</i>	Mutation/amplification	Diagnosis of colon cancer, endometrial cancer, ovarian cancer and Lynch syndrome; related to Pembrolizumab sensitivity and MSI
<i>PMS2</i>	Mutation/amplification	
<i>MEN1</i>	Mutation/amplification	Diagnosis of multiple endocrine neoplasia type 1, etc.
Related to drug sensitivity		
<i>B2M</i>	Mutation/amplification	Results of treatment with immune checkpoint inhibitors
<i>MTAP</i>	Mutation/amplification	Related to PRMT inhibitor sensitivity
<i>TSC2</i>	Mutation/amplification	Related to MTOR inhibitor sensitivity
<i>NF2</i>	Mutation/amplification	Related to MTOR inhibitor side effects
<i>CCNE1</i>	Mutation/amplification	Related to PARP inhibitor sensitivity, prognosis
<i>CDK6</i>	Mutation/amplification	Related to CDK4/6 inhibitor sensitivity
<i>CDK12</i>	Mutation/amplification	Immune checkpoint sensitive gene
Related to drug sensitivity (fusion)		
<i>NTRK3</i>	Mutation/amplification/fusion	Related to TRK inhibitor treatment results Note: Also for fusion detection
<i>ETV6</i>	Fusion	Added for <i>NTRK3</i> fusion partner side gene

NTRK3 gene:

This gene produces proteins related to the differentiation and maintenance of nerve cells. It is thought that when the *NTRK* gene fuses with numerous other genes and *NTRK* fusion genes create abnormal proteins, unnecessary cells can proliferate, increasing the likelihood that cancer will develop.

Microsatellite instability (MSI):

In this condition, a "satellite" in a genome's DNA (a short reiterated sequence of one to several bases in a base sequence) can reduce the ability to repair mistaken base sequences when duplicating DNA, causing differences in the number of iterations between tumor tissue and non-tumor (normal) tissue.

Cancer Liquid Biopsy Tests (OncoBEAM, PSS)

OncoBEAM CRC RAS Kit (regulatory approval on July 19, 2019)

World's first insurance coverage (on August 1, 2020) of ctDNA/CDx using high-sensitivity digital PCR technology

Decision category	Main purpose of use	Measured parameter	Measurement method	Samples used	Detection sensitivity	Insurance points	Points of note (excerpted)
E3 (new parameter)	To detect RAS (KRAS and NRAS) gene mutations in genome DNA extracted from plasma (assist in determining suitability of Cetuximab and Panitumumab for use in patients with colon and rectal cancer)	RAS gene mutation (plasma)	High-sensitivity digital PCR and flow cytometry methods (Approved as new methods)	Plasma	0.03% (Highest level of sensitivity with genetic testing method)	7,500 points (Maximum number for a single genetic test)	Calculated as being limited to once per person for diagnosis or determining treatment methods. However, calculation can take into account selection of repeated treatment methods. =>Multiple calculations per patient are possible.



➔ Joint marketing by Merck BioPharma and Takeda Pharmaceutical (approx. 250 facilities) + lab assay by SRL (approx. 1000 samples)

Paper presented: Combined Analysis of Concordance between Liquid and Tumor Tissue Biopsies for RAS Mutations in Colorectal Cancer with a Single Metastasis Site: The METABEAM Study | *Clinical Cancer Research* (aacrjournals.org)

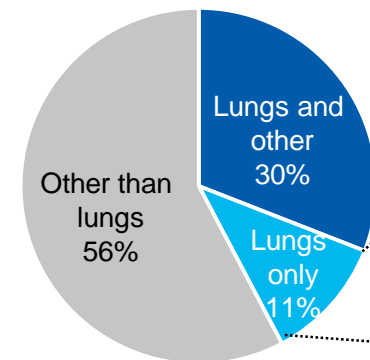
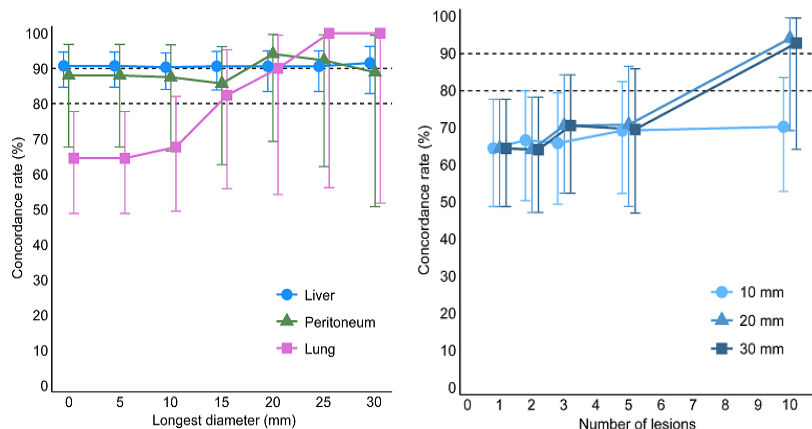
Y. Kagawa et al. Feb. 18, 2021

Results of meta analysis with a total of 221 cases (110 from Japan + 111 from Spain)

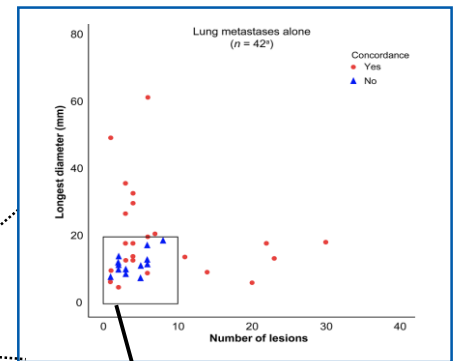
Important precaution: For patients with metastasis to the lungs only, conduct tests on tumor tissue when possible

Quoted from the package insert of OncoBEAM RAS CRC Kit

➔ Suggest narrowing to fewer than 10 lung metastases and metastatic tumor major diameter of less than 20mm

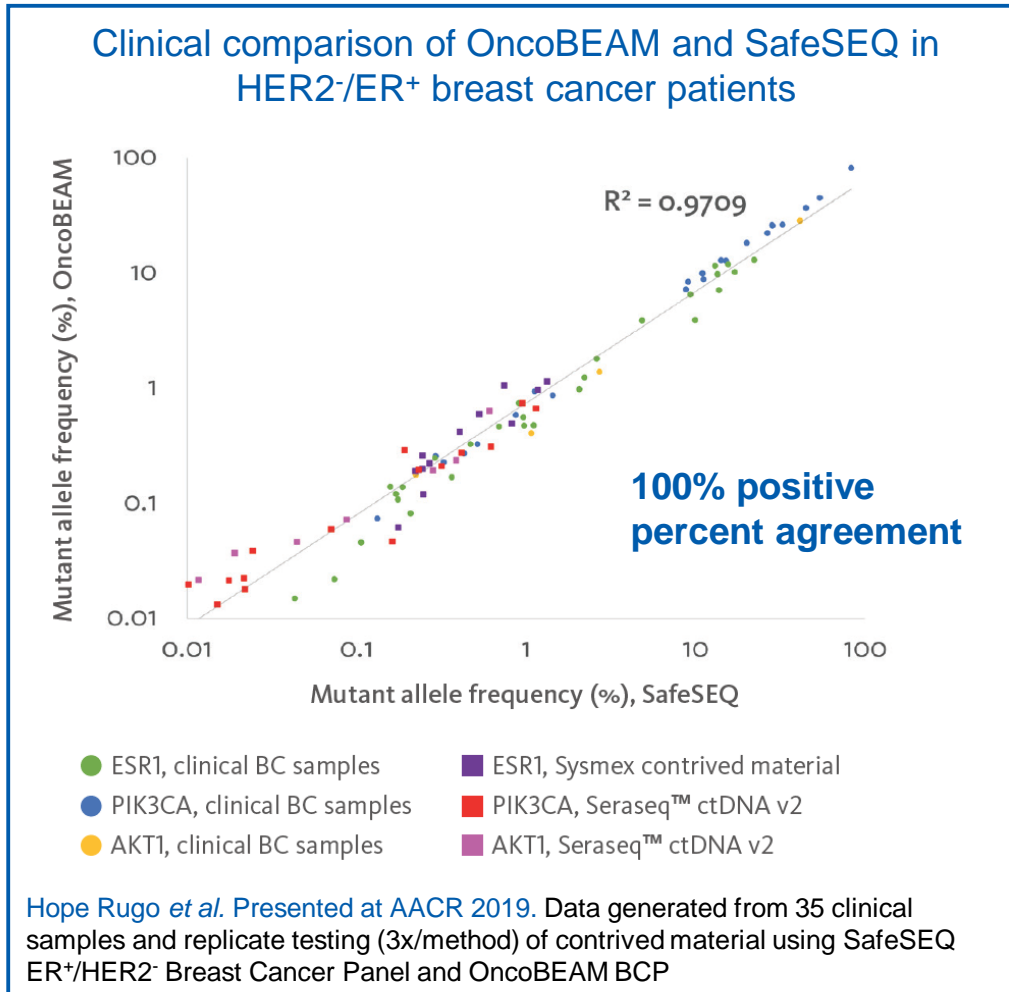


Colon cancer metastasis, ratio by organ



Below cutoff:
Approximately 60% of pulmonary mono-metastasis

Evaluation of Plasma SafeSEQ's clinical utility



Development of PSS business at Sysmex Inostics

CRO assay service
(Tie-ups with around 20 pharmaceutical manufacturers)

Breast and colon cancer, leukemia, head and neck carcinoma, etc.

ISO9001 **CLIA**

Launched PSS gene panel RUO kit
(January 2021)
Colon cancer, lung cancer, melanoma, thyroid cancer

Configuration	Format	Clinically relevant gene regions
Colorectal cancer	KIT (RUO)	BRAF, KRAS, NRAS, PIK3CA
Non-small cell lung cancer	KIT (RUO)	BRAF, EGFR, KRAS, PIK3CA
Melanoma	KIT (RUO)	BRAF, NRAS
Thyroid cancer	KIT (RUO)	BRAF, NRAS

In future, pursue IVD/CDx development

5

Initiatives for the Realization of Personalized Medicine

Tomokazu Yoshida
Senior Executive Officer

- (1) Testing for Alzheimer's Disease
- (2) HDL Testing

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Initiatives for the Realization of Personalized Medicine

- (1) Testing for Alzheimer's Disease
- (2) HDL Testing

Liquid Biopsy (Alzheimer's Disease)

Development of therapeutic drugs targeting amyloid β (monomer, aggregate) is moving forward in the aim of curtailing symptoms at an early stage.

- **Aducanumab**
Applications for approval
US Food and Drug Administration (FDA)
PDUFA action data: 6/7/2021
European Medicines Agency (EMA)
Pharmaceuticals and Medical Devices Agency (PMDA)
- **Lecanemab (BAN2401) (FDA Ph3)**
- **Gantenerumab (FDA Ph3)**
- **Solanezumab (FDA Ph3)**
- **Donanemab (FDA Ph2)**
Positive results (1/14/2021)

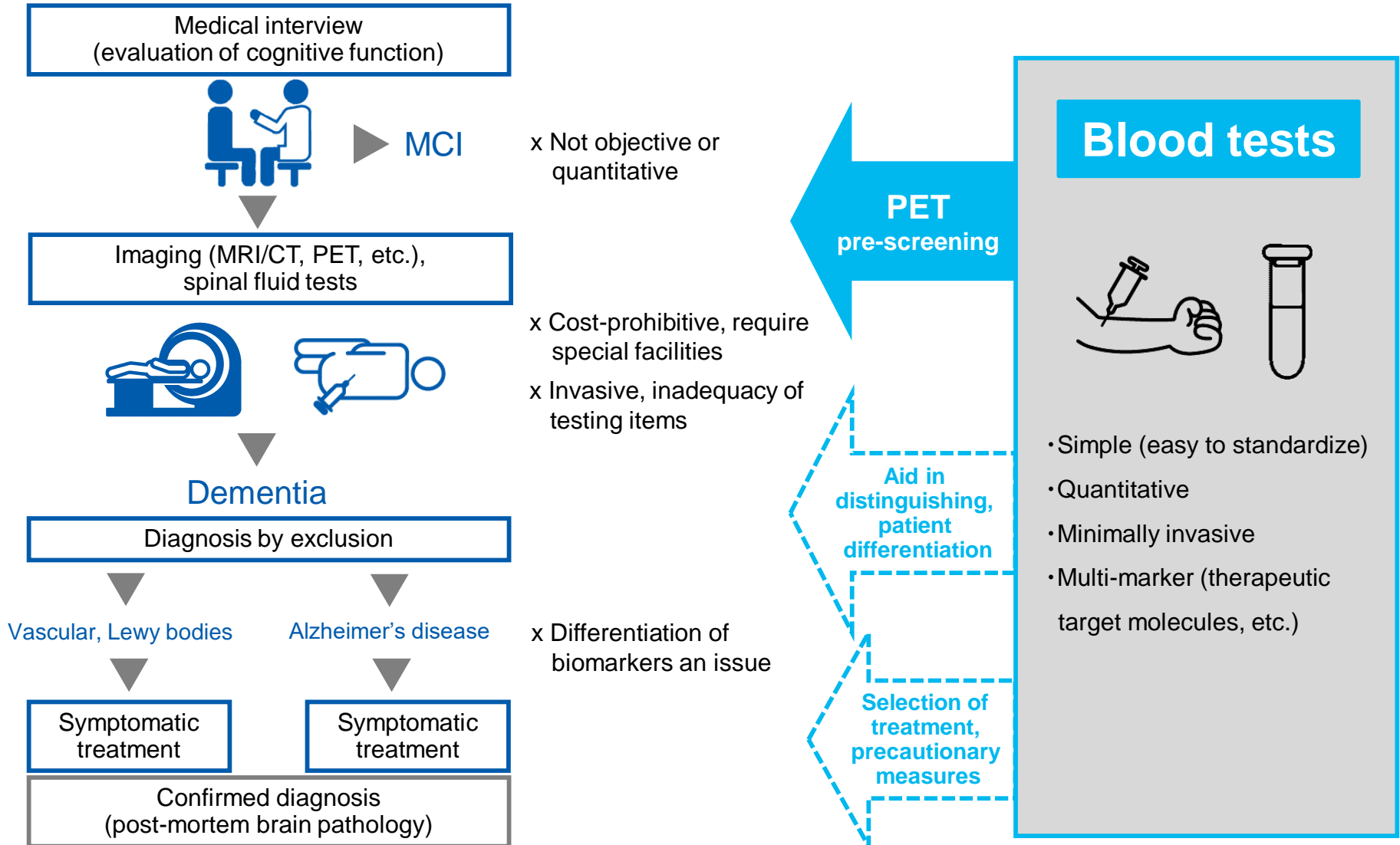
	Monomers	Oligomers	Protofibrils	Fibrils
				
Aducanumab				
Lecanemab				
Gantenerumab				
Solanezumab				
Donanemab				

<https://alzheon.com/pipeline/>

Prepared with reference to Tolar et al. Alzheimer's Research & Therapy 12, 95 (2020)

New Blood Tests

The realization of blood tests for Alzheimer's disease will help provide new therapeutic opportunities.

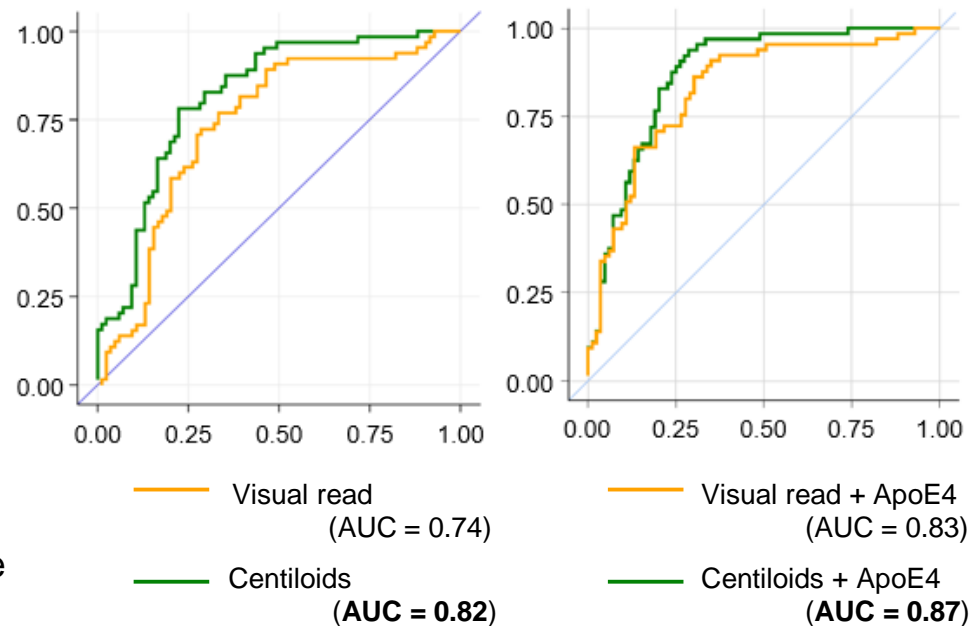


Performance Verification with a View to PET Prescreening

A high degree of concordance has been determined with amyloid PET (status of amyloid β accumulation in the brain) (same level as mass spectrometry)

Results of positive PET predictions in clinical subjects (n= approx. 150 cases) in amyloid PET diagnosis (Additional verification based on of PET judgment using the Centiloid method and verification of effects of ApoE4 gene information)

Background of subjects (n=149)	
Average age (SD)	73.3 years (6.08)
Race: Caucasian / other	93.3% / 6.7%
Gender: Male / female	50.3% / 49.7%
APOE4: - / +	59.7% / 39.6%
MCI due to Alzheimer's disease	82.6%
Early stage of mild Alzheimer's disease	11.4%



Amyloid positivity in patients with clinical cognitive dysfunction in clinical trials

Negative: Cognitive dysfunction without amyloid β accumulation in the brain

Positive: MCI, mild AD with amyloid β accumulation in the brain

◆ Prediction performance of amyloid β accumulation in the brain by IP-MS (Comparison with PET using flutemetamol)

Sensitivity: 78.7%/specificity: 82.4%

(From *Nature*. 2018 Feb 8; 554(7691): 249-254.)

Sensitivity/specificity

73%/71% A β (Visual read)

78%/78% A β (Centiloids)

94%/71% A β (Centiloids) + ApoE4

Note: Used cutoffs based on Youden Index

From a poster at the 39th Annual Meeting of Japan's Society for Dementia Research

Impact of Blood-Based Tests for Dementia: Estimated Market Size

Testing objective

PET pre-screening (support confirmative diagnosis)

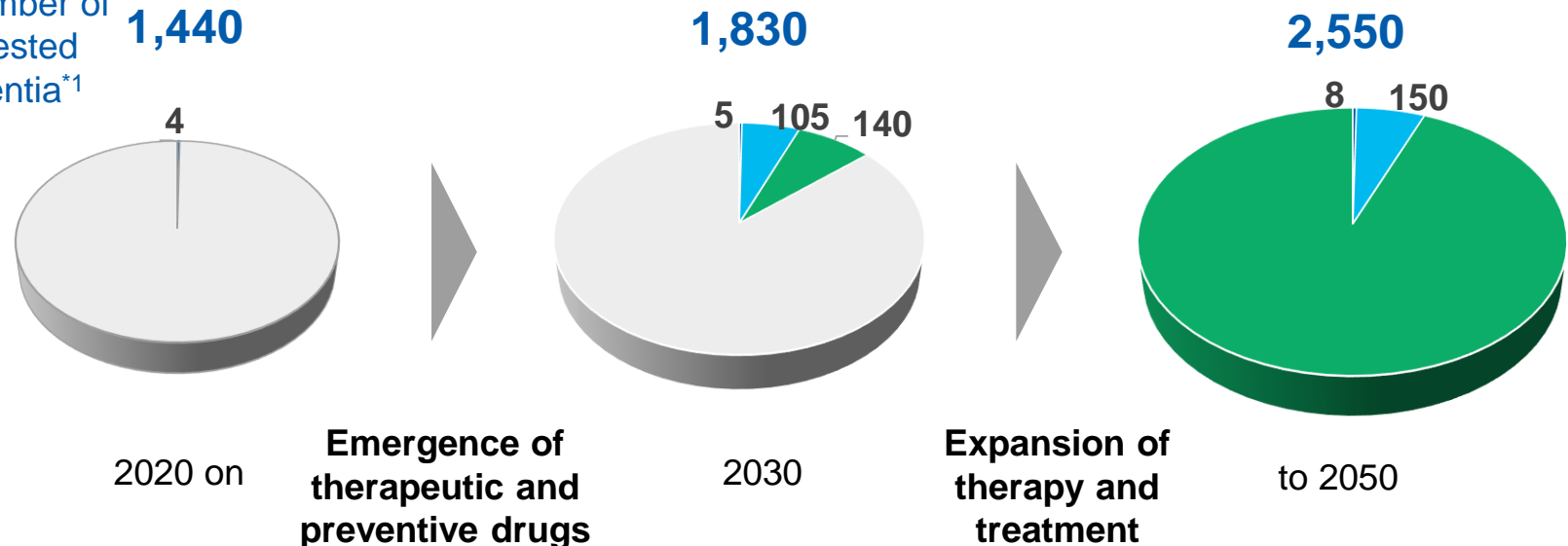
Classify the disease state based on the status of progression (selection of therapeutic drugs/patient differentiation)

Early-stage detection (early-stage screening/monitoring treatment results)

Number of people tested (estimated)

(Millions of people)

Total number of people tested for dementia*1



*1 Number of people tested (world) = Estimated populations in individual age groupings multiplied by the following coefficients (10% for 40s, 60% for 50s, 80% for 60s, 100% for 70s or older)

System's estimates based on information from UN (Population Statistics): World Population Prospects - Population Division - United Nations, number of people with dementia: Dementia (who.int), the Japan Institute of Life Insurance website

Creation of an HISCL measurement system for parameters other than amyloid β (total tau, phosphorylated tau, NfL)

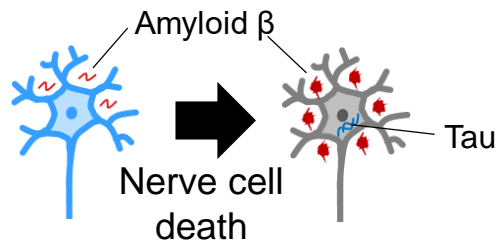
Around the world, work is being conducted to classify the stages of cognitive impairment by using ATN.

(Research framework from the National Institute on Aging and the Alzheimer's Association)

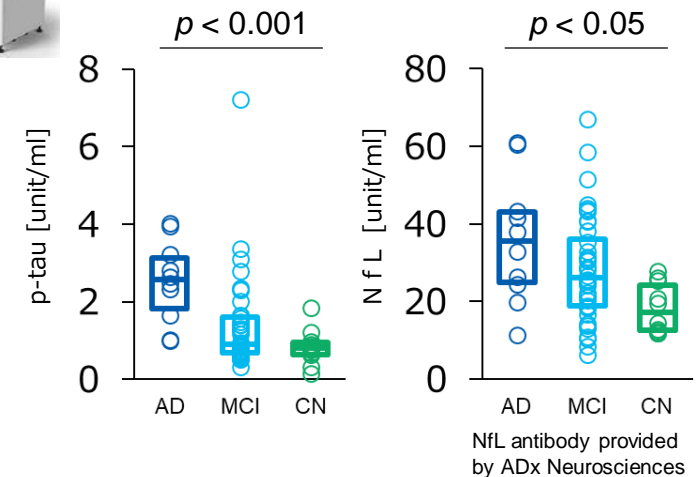
Stage of cognitive impairment						
Biomarker profile	A	T	N	Normal	Mild cognitive impairment	Dementia
	-	-	-	Normal		Non AD
	+	-	-			AD cognitive impairment
	+	-	+			AD and Non AD
	+	+	-	Pre-symptomatic AD	Prodromal AD	AD
	+	+	+			

A: Amyloid β , T: Tau protein, N: Neurodegeneration / nerve damage

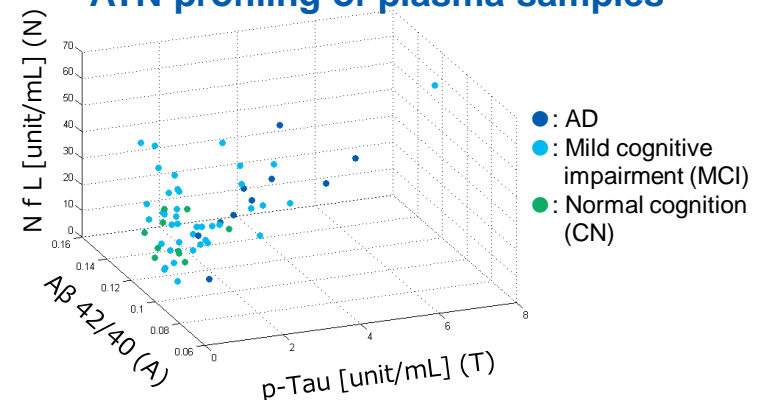
Adapted from Alzheimer's Dementia. 2018 Apr; 14(4): 535-562



Plasma biomarker measurement



ATN profiling of plasma samples



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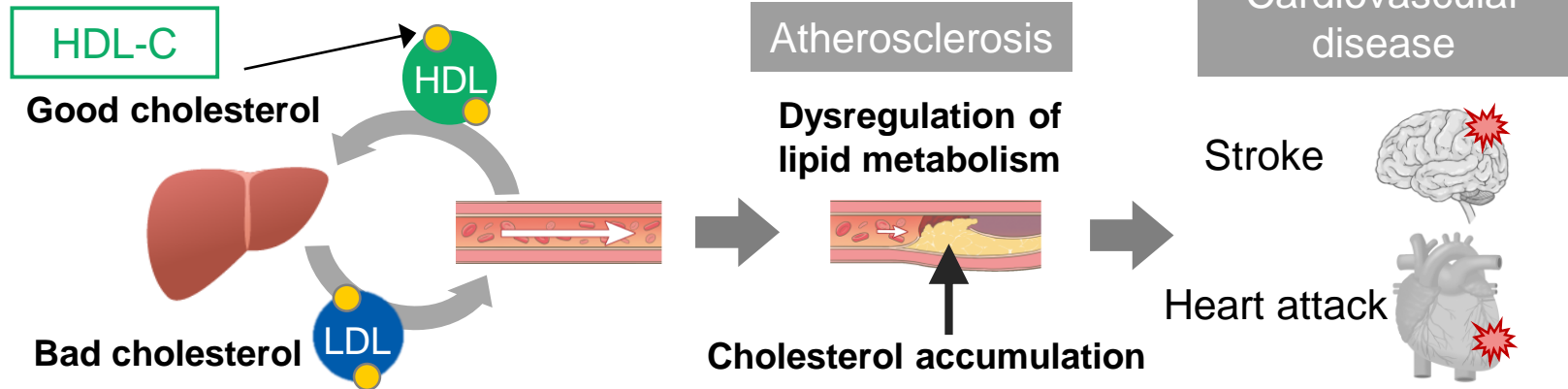
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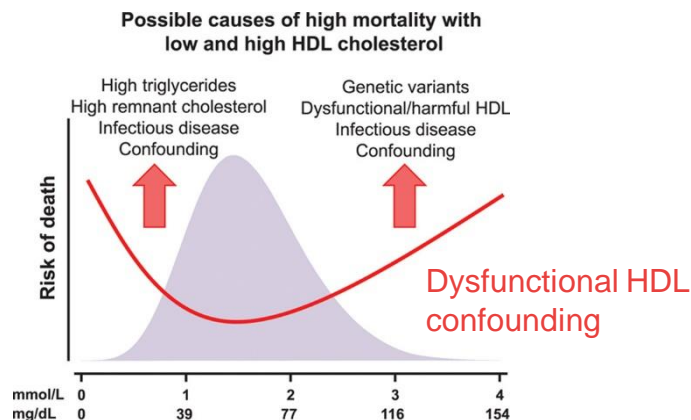
Role of HDL and Issues with HDL-C Testing

The conventional view that “HDL is good” is being revised.
New diagnostic indicators are needed.

Role of HDL in suppressing cardiovascular disease



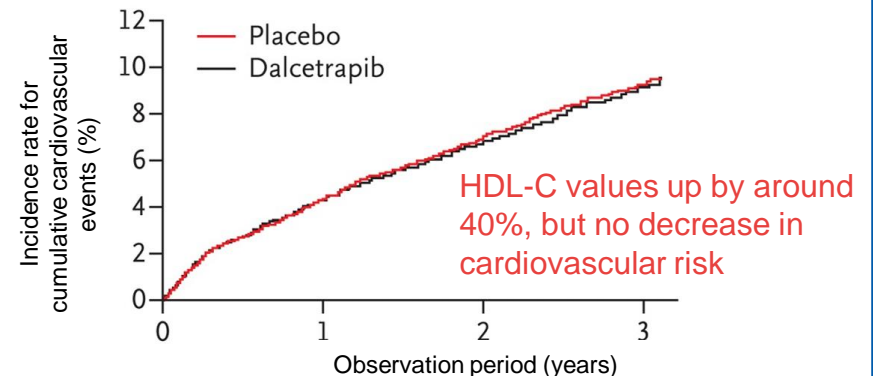
High HDL-C value \neq reduced CVD risk



Arterioscler Thromb Vasc Biol (2018)

HDL-C

Development of HDL-C-elevating drugs suspended



N Engl J Med. (2012)

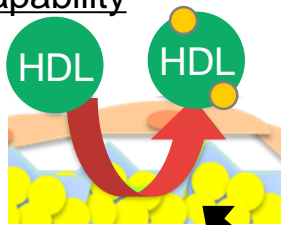
Development of HDL Function Assay

As HDL function correlates with the incidence risk for cardiovascular disease, developed proprietary measurement technologies

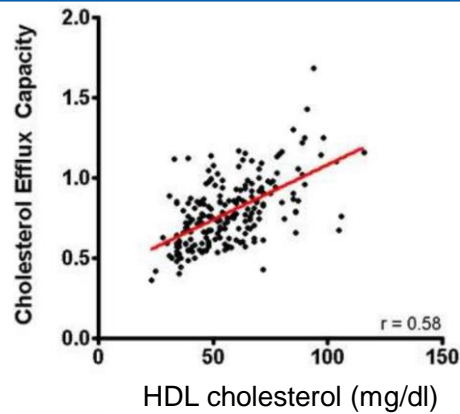
Even at same HDL-C values, function differs

HDL function

Cholesterol collection capability



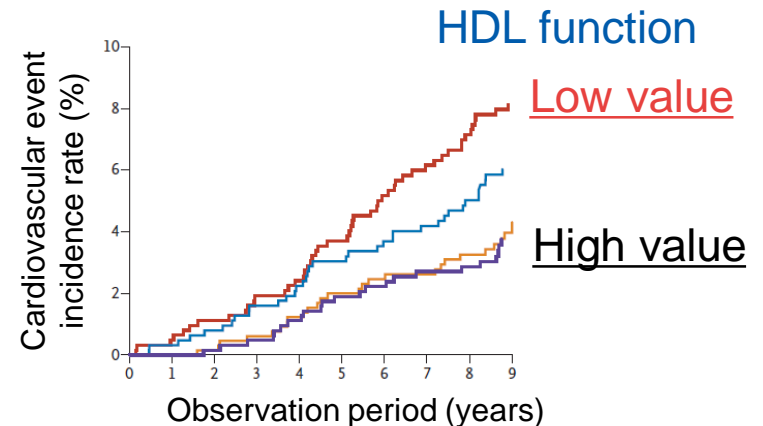
Cholesterol



HDL-C

N Engl J Med (2011)

Reduced HDL function a risk of cardiovascular disease incidence



N Engl J Med. (2014)

Conventional method

Clinical application, standardization are difficult

Assess cholesterol efflux capacity from cultured cells

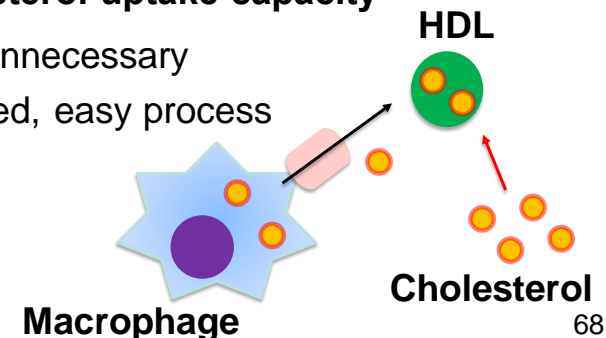
- ✓ Use cells, RI
- ✓ Cumbersome process, requiring three days

New concept

Measurement can be automated

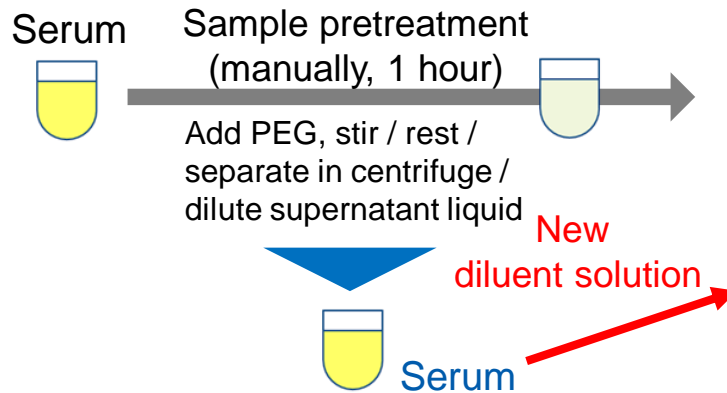
Assess HDL's cholesterol uptake capacity

- ✓ Cultured cells, RI unnecessary
- ✓ Simple, standardized, easy process



Full Automation of HDL Function Assay

By optimizing the diluent solution, established a fully automated system that can directly measure serum samples



HI-1000



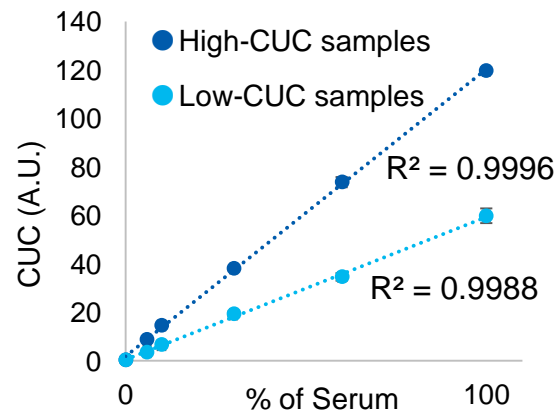
Addition of automated pretreatment function

Measurement capability

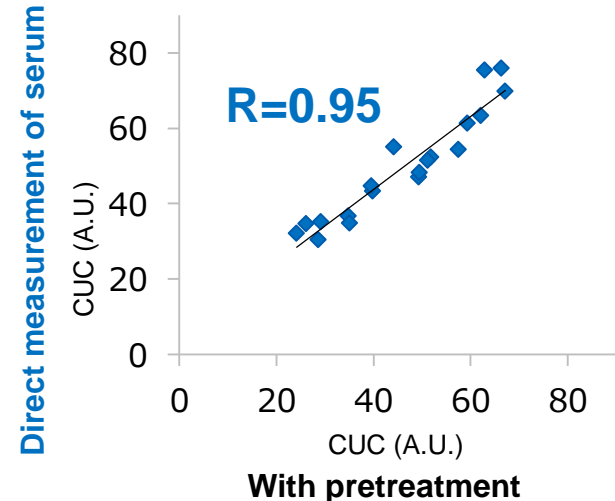
Reproducibility: CV < 10%
(within-run, between-run)
Throughput: 25 tests/hour
(Cell-based assay: 1 batch/3 days)

Reported at a meeting of the Japan Atherosclerosis Society (2020)

Dilution linearity



Correlation with conventional method (with pretreatment)

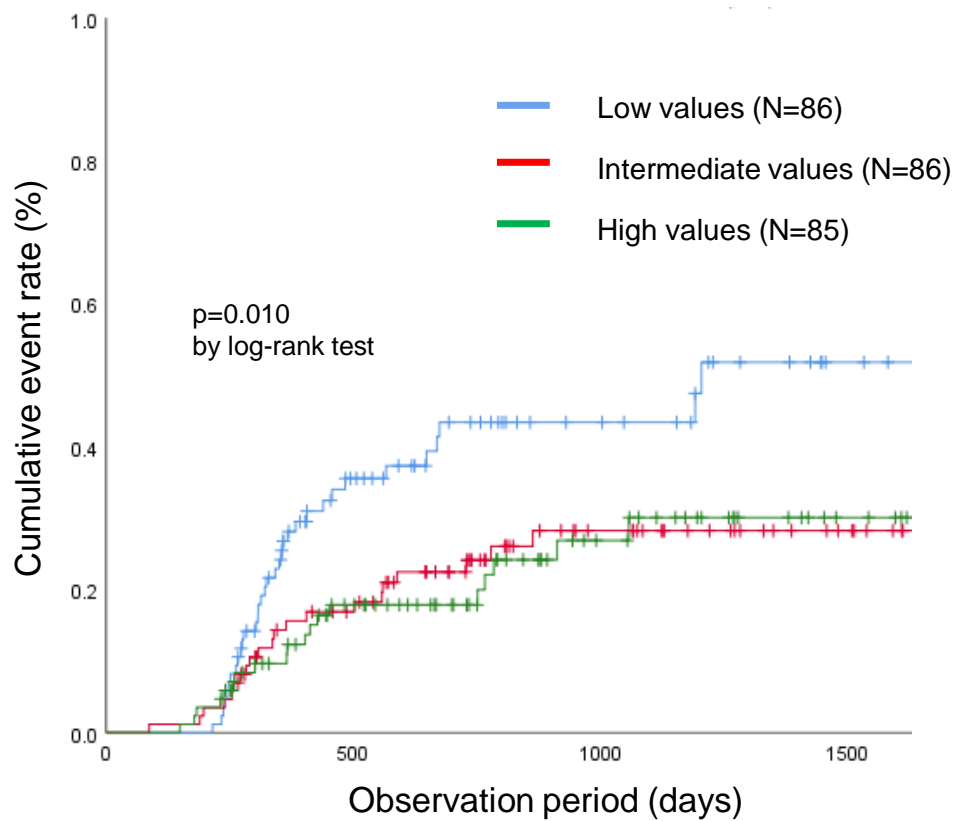
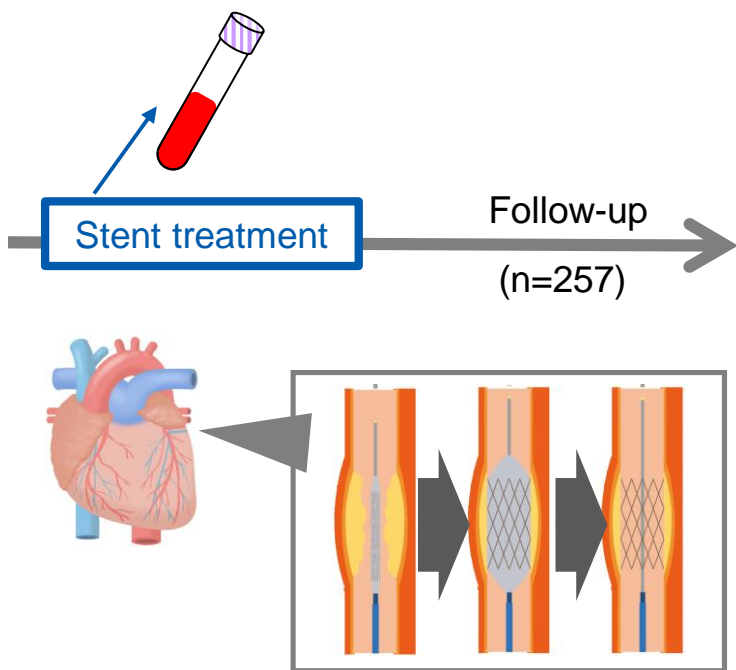


Stratification of Cardiovascular Disease Recurrence Risk by Measuring HDL Function

Confirmed that the recurrence rate was significantly higher among the group with low HDL function following stent treatment

Joint research with the Founded Course at Kobe University Graduate School, Department of Internal Medicine, Division of Cardiovascular Medicine, Kobe University

HDL function assay



Reported at the European Society of Cardiology (ESC2020)

Market Prospects for Testing of HDL Function

Testing objective

Evaluation of recurrence risk (recurrence risk screening/monitoring treatment response)

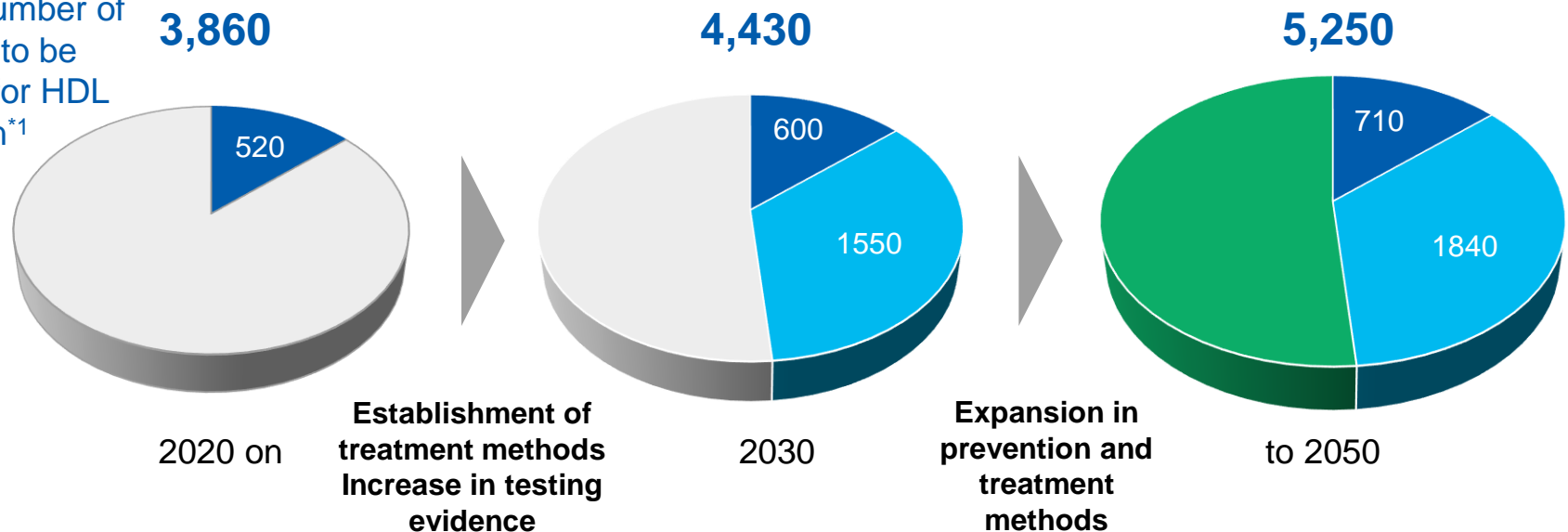
Early-stage detection for malignance, selection of therapeutic drugs
(malignancy risk screening/selection of therapeutic drugs)

Early-stage detection
(early-stage screening/patient stratification)

Number of people tested (estimated)

(Millions of people)

Total number of people to be tested for HDL function*1

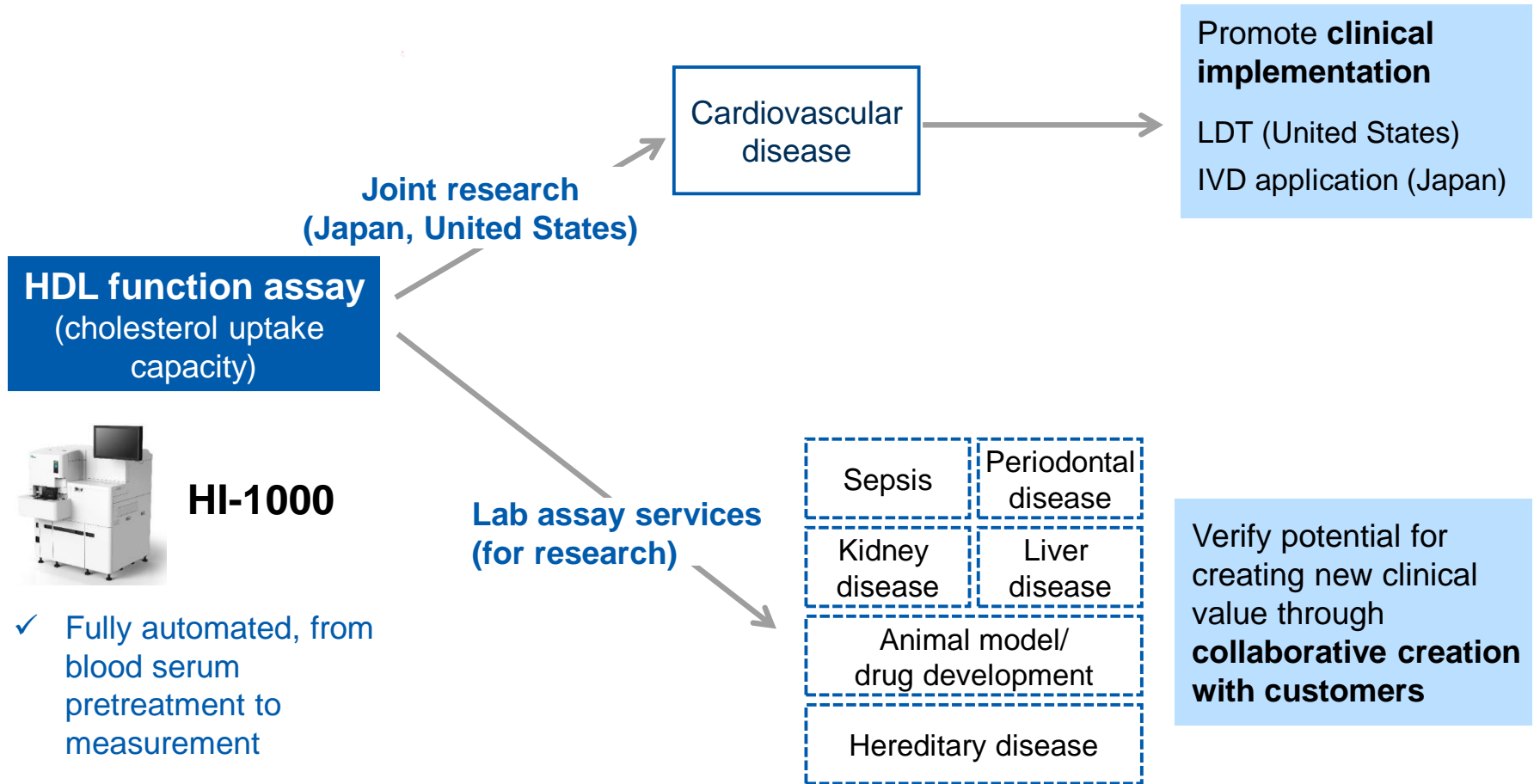


*1 Number of people to tested (world) = Estimated total population aged 30s to 70s

Sysmex's estimates based on UN (Population Statistics): World Population Prospects - Population Division - United Nations and J Am Coll Cardiol (2020)

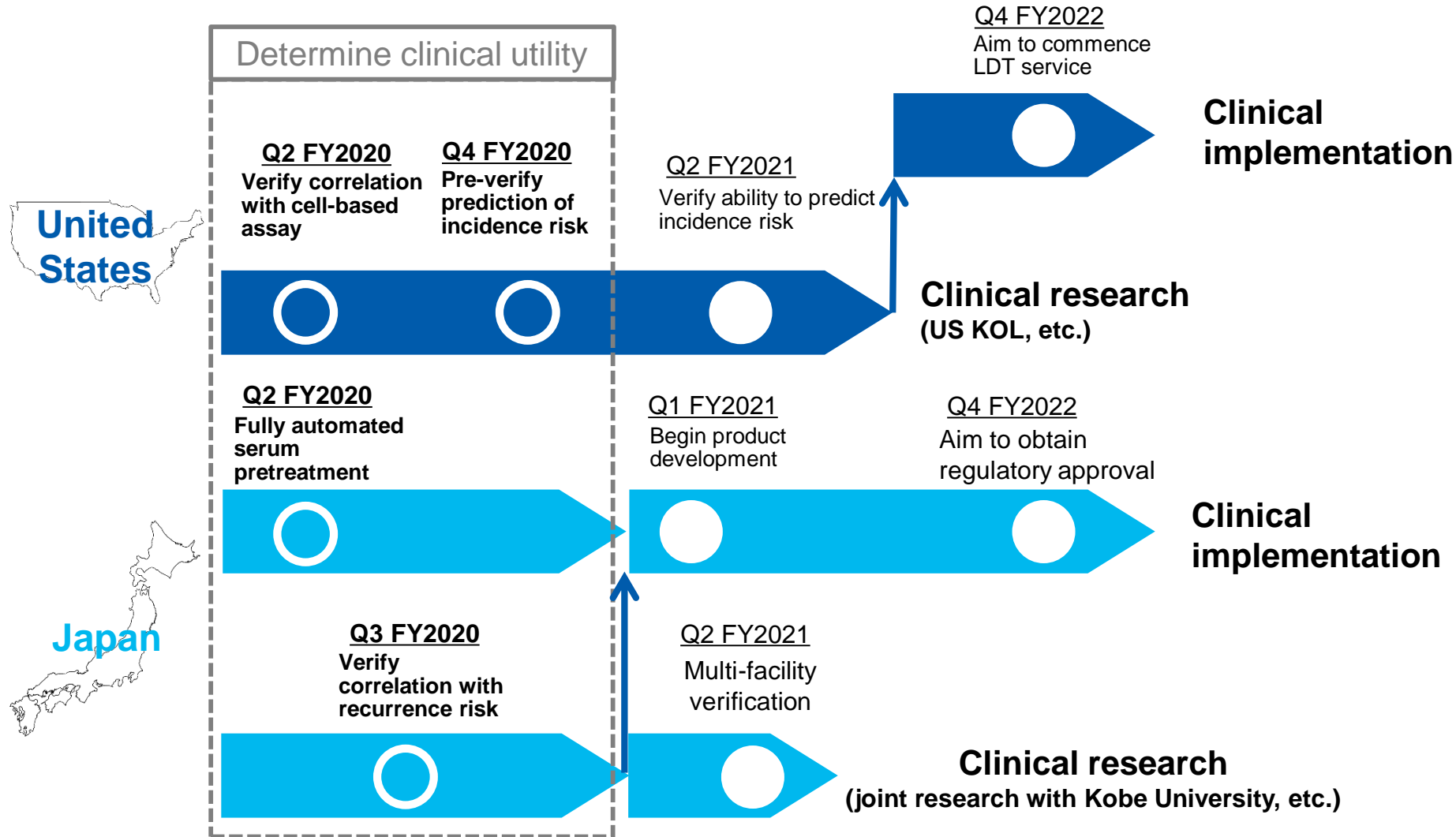
Increasing Application to Other Patients

Create new clinical value through collaborative creation with customers and by applying elemental technologies



Acceleration of R&D

Promote parallel activities in Japan and overseas with a view to early-stage clinical implementation

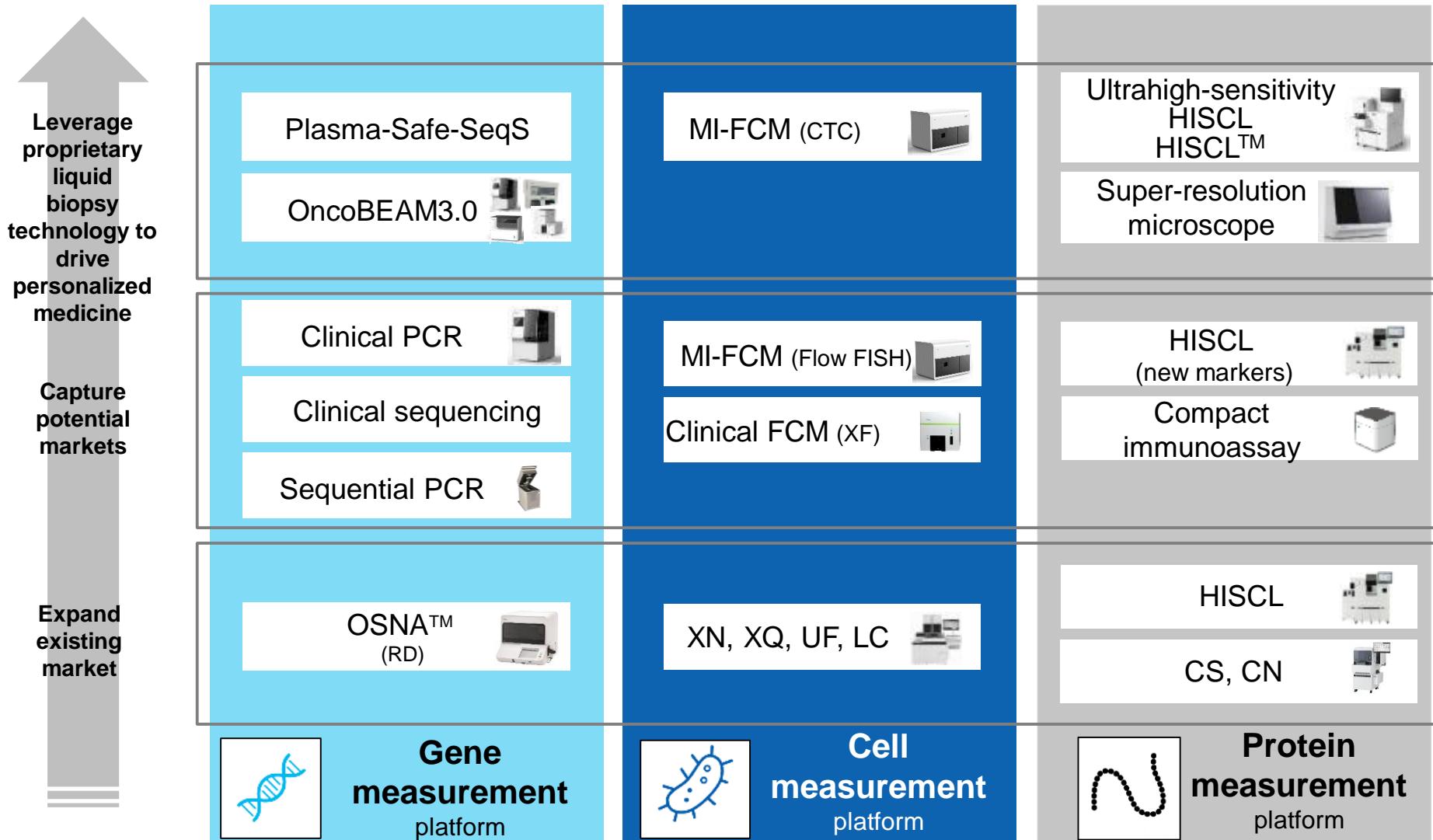


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Appendix

Established Technology Platforms

We have completed the establishment of technology platforms and are promoting the development of applications with a view toward commercialization.

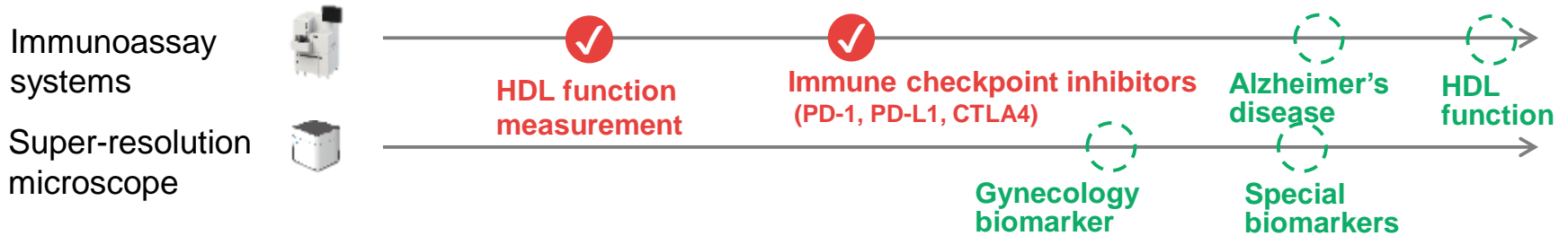


Application Launch Plans

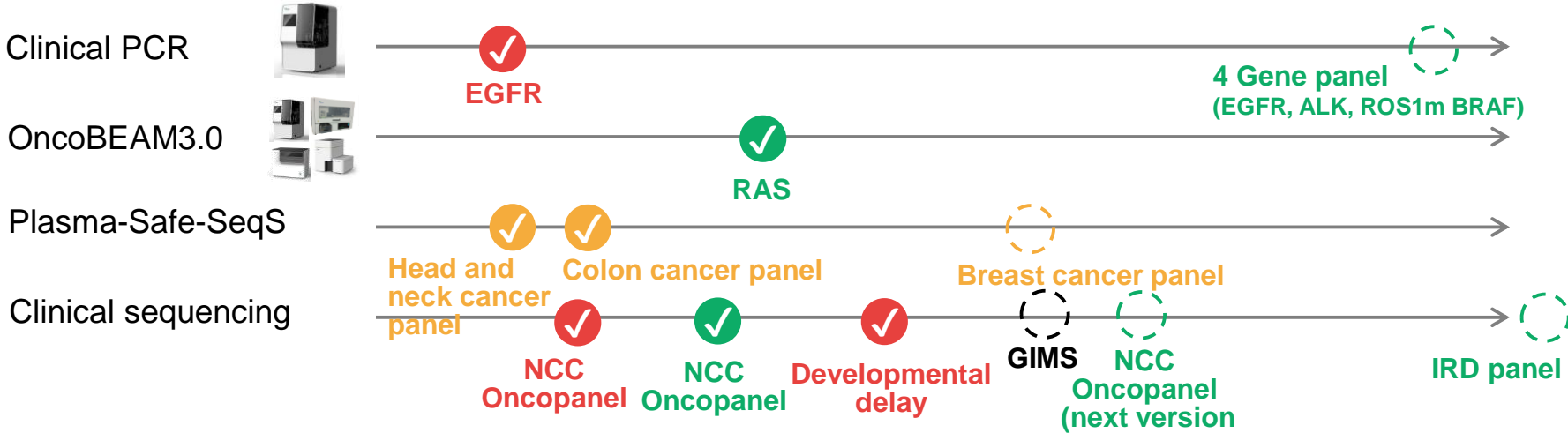
As indicated at the 17th R&D Meeting (Mar. 2020)



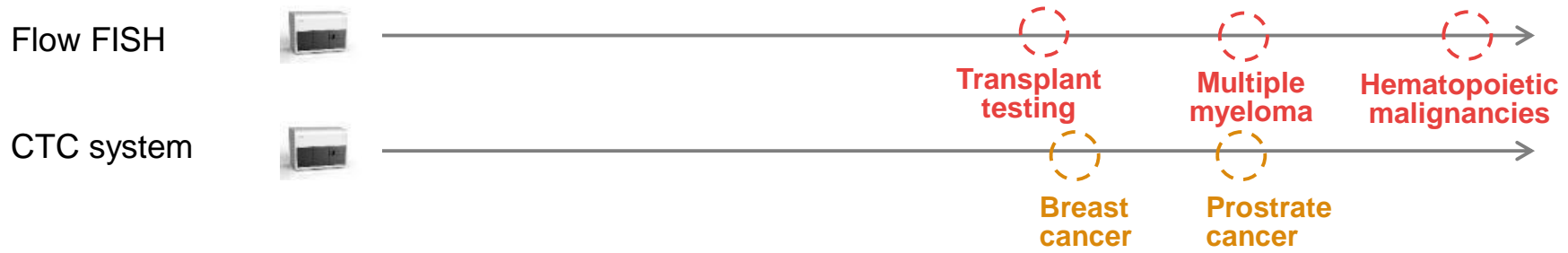
Proteins



Genes



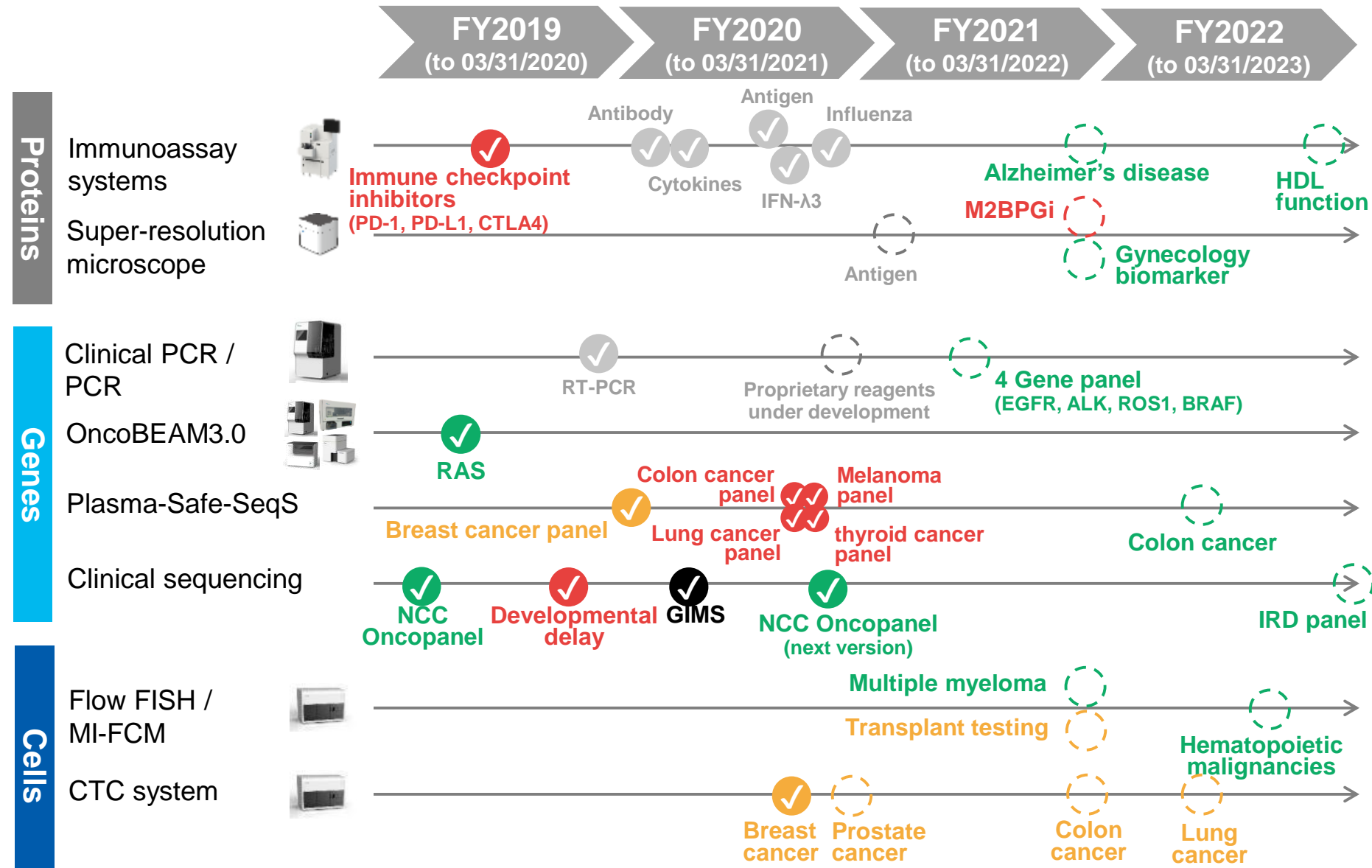
Cells



● RUO ● LDT ● IVD ● Other

Note: Dotted lines indicate expectations.

Application Launch Plans (March 2021 Update)



Amyloid-β	A key constituent of senile plaque, a pathological characteristic of the brain tissue of patients with Alzheimer’s disease, composed of around 40 amino acids.
Antimicrobial resistance	This phenomenon occurs when living organisms develop a resistance to a drug, whose efficacy is decreased or neutralized as a result. Bacteria that have developed microbial resistance are known as antimicrobial resistant bacteria.
APOE4	An isoform of apolipoprotein E (ApoE), a protein that contributes to lipid metabolism, APOE4 is the gene product of ApoE ε4. ApoE ε4 is thought to be a risk factor for Alzheimer’s disease.
Blasts	The most morphologically immature blood cells.
BSL	Laboratories and other facilities assign “biosafety levels” to bacteria, viruses, and other microorganisms and pathogens.
CAD	An acronym for “coronary artery disease,” CAD refers to coarctation and occlusion of the coronary arteries due to such factors as arteriosclerosis, preventing an adequate supply of blood to the myocardium that leads to oxygen deficiency.
Caresphere	Caresphere utilizes IoT and the cloud to establish a platform for the real time linking and analysis of a variety of information managed using testing instruments and clinical laboratory information systems. It is a new network solution that provides support for increasing the operational efficiency of professionals involved in testing and healthcare, enhancing quality and raising patient satisfaction.
C-CAT	A new cancer genomic medicine base established by the National Cancer Center. It was created to collect and store nationwide information regarding genomic medicine and to create mechanisms that enable the discovery of new medical treatments via the appropriate utilization and application of this information.
CLIA	Laboratories with U.S. CLIA (Clinical Laboratory Improvement Amendment) certification are required to undergo periodic inspections to ensure quality maintenance, and having such registration indicates that a lab meets world-class technology standards for quality assurance and sufficient reliability in genetic analysis.
CTC	Acronym for “circulating tumor cell.” CTCs refer to cancer cells that have broken away from primary or metastatic cancer sites and are circulating in the blood.
ctDNA	Cancer derived DNA circulating in the blood. A focus of growing attention as a non invasive cancer biomarker for testing using liquid biopsy.
DNase/RNase	Enzymes that degrade DNA and RNA. It is important to suppress DNase/RNase activity, as their presence in a specimen can affect the quality of DNA and RNA.

Drug susceptibility test	A test to determine the efficacy of various antimicrobial drugs against pathogenic bacteria detected in a sample.
ELISPOT	Short for "Enzyme-Linked ImmunoSpot," high sensitive immunoassay method that enables detection of T cell immune response at the single cell level.
Flow cytometry (FCM)	Method involving the flow dispersion of minute particles and the use of laser light to optically analyze minute flows.
GIMS	Acronym for "Genome Information Management System."
HDL	An acronym for "high-density lipoprotein," HDL has the role of collecting excess cholesterol in the vessel wall and returning it to the liver.
IFN-λ3 (interferon lambda 3)	This is a biomarker shown to rise suddenly in blood concentration several days before increasingly severe COVID-19 symptoms are detected.
IgG antibody	One of the most prevalent circulating antibodies, which has a strong neutralizing effect.
IgM antibody	One of the first antibodies produced when a foreign substance enters the body, causing its level to increase for a certain period of time.
IRD	Inherited Retinal Disease. Hereditary diseases characterized by abnormalities in the photoreceptor cells or epithelial cells that adhere to the retina.
IVD	Acronym for "in vitro diagnostics." Refers to in vitro diagnostic pharmaceuticals and products that have received regulatory approval.
LDT	Acronym for "laboratory developed test." LDTs, often testing methods that have not received regulatory approval, include highly sophisticated and complex gene testing that can only be performed in specific clinical testing labs.
Liquid biopsy	This is a general name for technology using blood or body fluid samples for diagnosis and the prediction of treatment impacts rather than through the conventional practice of tissue biopsy, in which diagnosis is performed on diseased tissue that has been collected. Liquid biopsy is less invasive than tissue biopsy, but more highly sensitive detection technologies are required.
Macrophage	A type of white blood cell. Macrophages excel in the ability to eat bacteria and other foreign substances that have entered the body, and to consume and sterilize these cells, preventing bacterial infections.
MCI	Acronym for "mild cognitive impairment."

Melanoma	A type of skin cancer, also known as “malignant melanoma.”
MIC value	An abbreviation for “minimum inhibition concentration,” MIC refers to the minimum concentration of antimicrobial drugs that suppresses the growth of bacteria.
NCC	National Cancer Center.
PCI treatment	Treatment using percutaneous coronary angioplasty (PCI) technology. This technology involves inserting a long, thin tube called a catheter into coronary arteries (which supply blood to the heart) that have constricted and expanding them and restore blood flow.
Personalized diagnostics	This type of medicine goes beyond the conventional practice of providing selected predetermined or uniform treatment for a given disease. Instead, the selection of treatment is optimized for individual patient characteristics, based on gene and other testing data.
Precision management	A management method used to guarantee the values measured by customers’ testing equipment and to confirm that a customer’s equipment is functioning correctly.
Primary care	The initial care provided at clinics or other locations when a patient first falls ill.
PSS (Plasma SafeSEQ)	Acronym for “Plasma Safe Sequencing.” This pretreatment technology is used to discern between gene mutations and read errors by attaching tags to genes to be amplified.
RAS	One of the gene that is known to cause cancer when it mutates.
RT reaction	Reaction that converts RNA to cDNA using reverse transcriptase (RT).
RUO	“Research use only.”
SD	An acronym for “standard deviation,” an indicator of variability in a sample.
TAT	Short for “turnaround time,” TAT is the period starting when a system is asked to begin processing and ending when results are output.
Tau	A microtubule associated protein that exists in central neuronal cells. Along with senile plaque, inordinately phosphorylated deposits of tau protein (neurofibrillary tangle) can be observed in the brains of patients with Alzheimer’s disease.
Urinary tract infections	The urinary tract runs between the kidneys and the urethral outlet. Inflammations due to the incursion of bacteria into the urinary tract are known as urinary tract infections. Such infections can lead to cystitis and pyelonephritis (inflammation of the kidneys).

Lighting the way **with diagnostics**