The 12th Technology Presentation

March 13, 2015

Sysmex Corporation

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1. Opening Remarks

Hisashi Ietsugu, Chairman and CEO

<Today's Themes>

- Technology Strategy Progress
  - Overall Technology Strategy
  - Strengthening and Expanding Technology Platforms (Genes, Cells, Proteins)
  - Development of Applications through Advances in Open Innovation
- Progress on Research and Development Themes

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2. Technology Strategy Progress

Kaoru Asano, Member of the Managing Board and
Senior Executive Officer, Head of R&D

(1) Overall Technology Strategy

(2) Strengthening and Expanding Technology Platforms

(3) Development of Applications through Advances in Open Innovation

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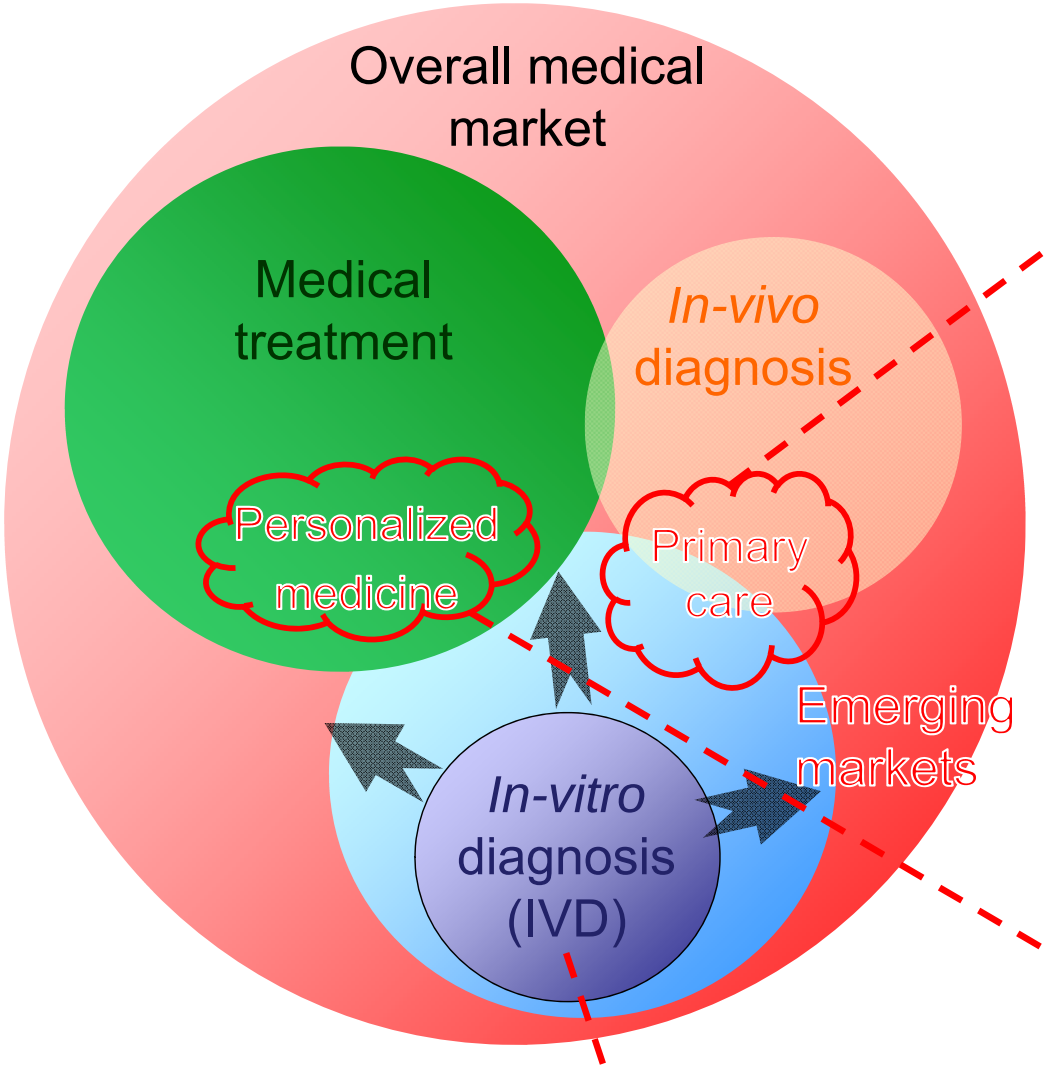
Overall Technology Strategy



Disease prevention based on testing data

Enhance the performance/function of analytical platform

Develop applications through advances in open innovation

ICT utilization

Establishing personalized medicine through CDx

Organic growth in existing IVD fields

CDx: Companion diagnostics

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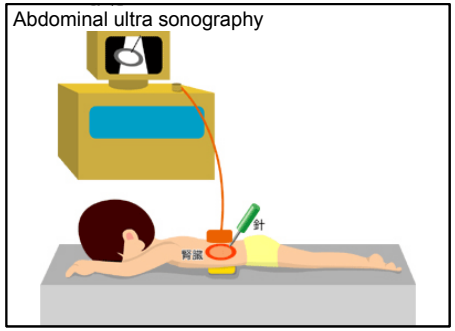
Platforms Targeting Personalized Medicine

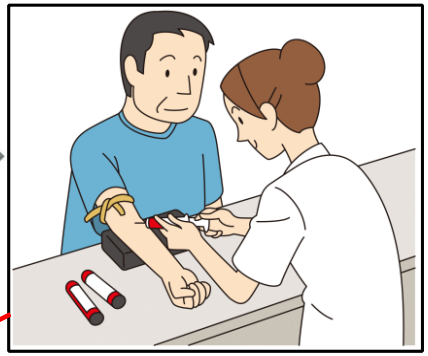
Conventionally



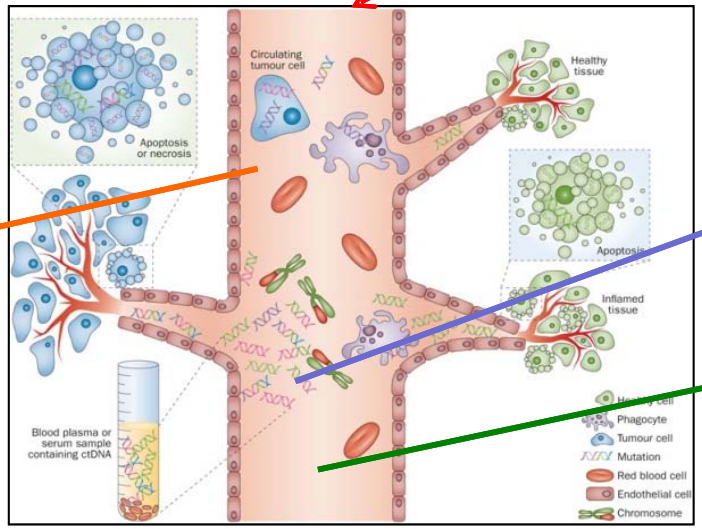
Direct analysis of affected specimen

From biopsy to liquid biopsy

In Future



Analyze disease-derived components that have leaked into the blood (bodily fluid)



Cells
CTC (circulating tumor cells)
CAG (circulating abnormal cells)
Stem cells
Etc.

Genes
CTG (circulating tumor genes)
cfDNA (cell-free genes)
miRNA (micro RNA)
Etc.

Proteins
Circulating trace molecules
Peptides
Microparticles
Etc.

Liquid biopsy:
Detection of cancer or other diseases by testing blood or other bodily fluids. This type of testing is less invasive than conventional physical biopsies.

Nature Reviews Clinical Oncology 10, 472-484 (August 2013)

Detection sensitivity will need to be 100 to 1,000 times higher than conventional methods

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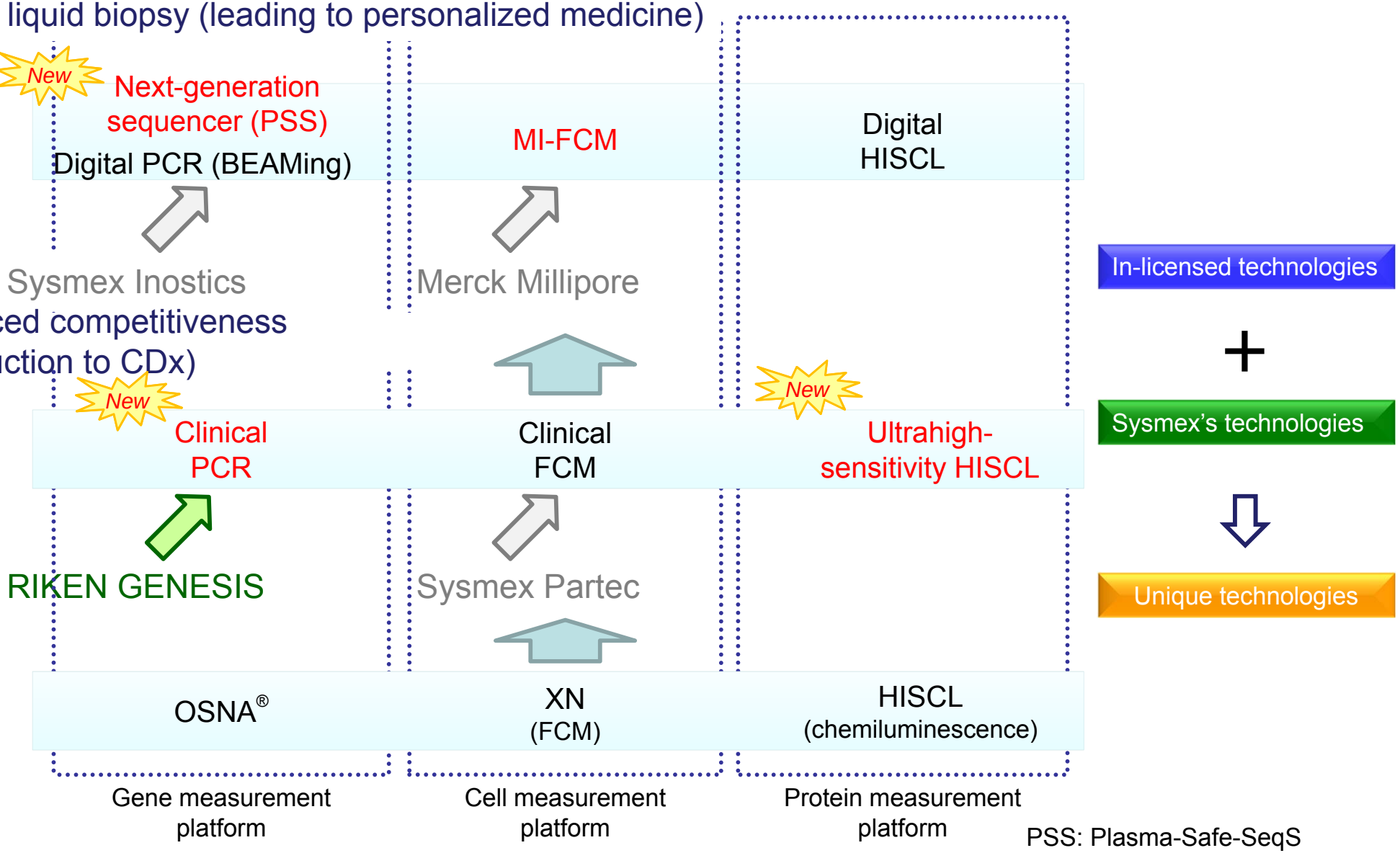
Technology Platform Enhancement

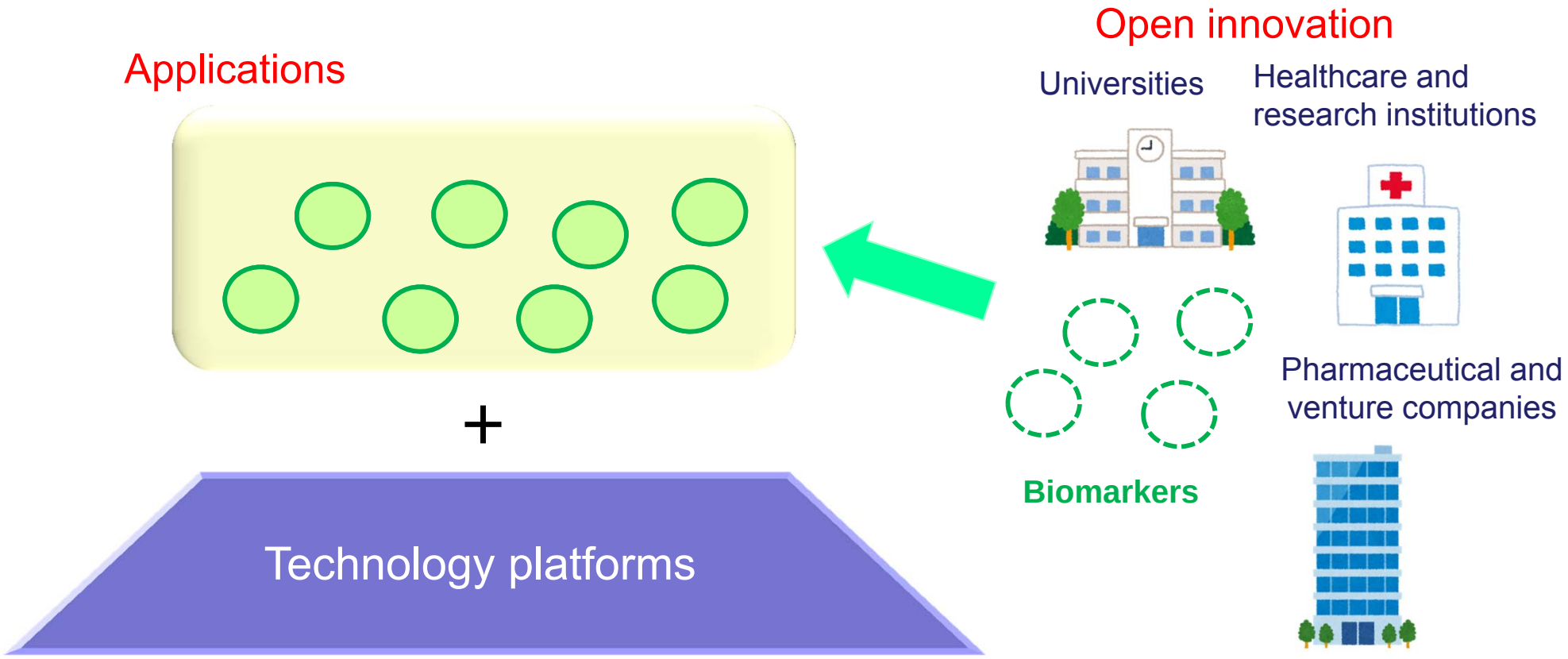
- Toward liquid biopsy (leading to personalized medicine)
- Enhanced competitiveness (introduction to CDx)



PSS: Plasma-Safe-SeqS
MI-FCM: Molecular imaging FCM

Development of Applications through Advances in Open Innovation

Achieve advances in open innovation and develop applications with high clinical value



2. Technology Strategy Progress

(1) Overall Technology Strategy

(2) Strengthening and Expanding Technology Platforms

(3) Development of Applications through Advances in Open Innovation

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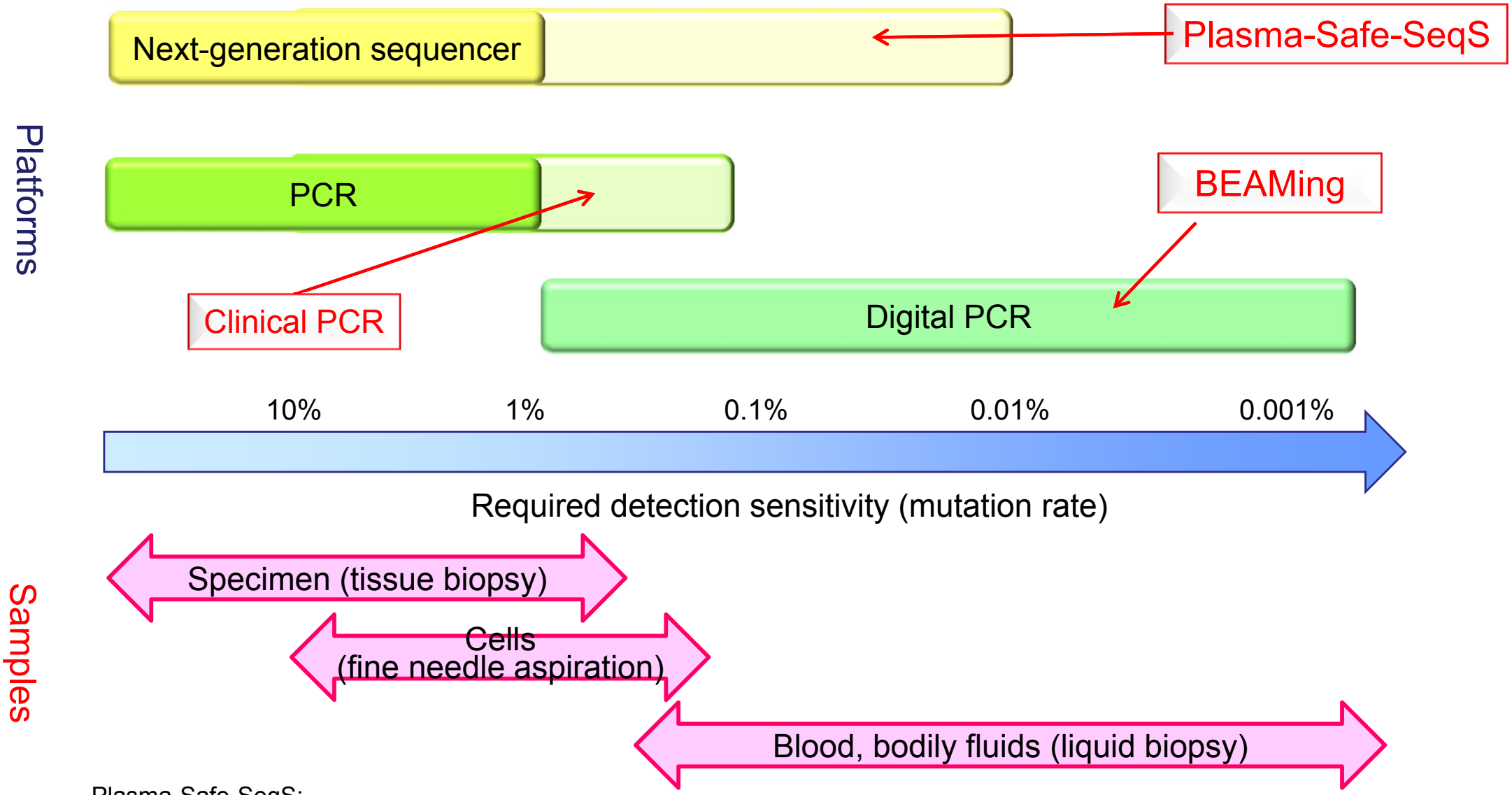
1) Gene Measurement Platform
Overview of Gene Testing Technology



Plasma-Safe-SeqS:
Technology for achieving high sensitivity in next-generation sequencer by tagging genes

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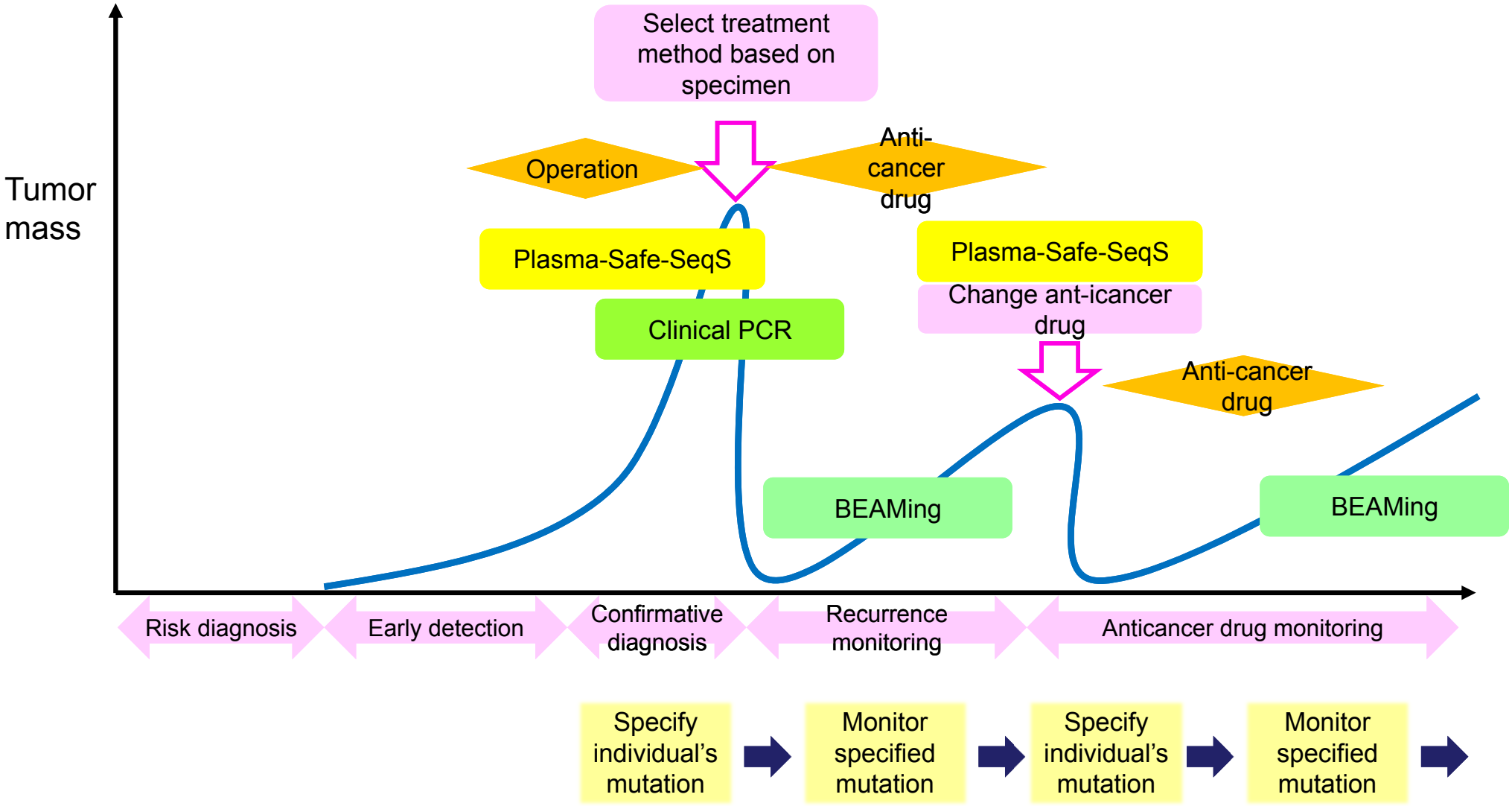
Realization of Personalized Medicine through Gene Measurement

Cancer example



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RIKEN GENESIS

RIKEN GENESIS CO., LTD.
Established October 15, 2007

It was established to take up RIKEN's genetics analysis resources

[RIKEN GENESIS strengths and technologies (1)]

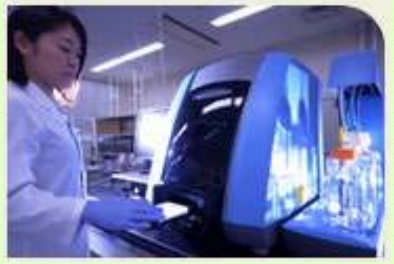
- SNPs fully automated gene analysis (PCR) system, including pretreatment
  Process completed from blood in approximately 60 minutes


Quimple/Aglail

→ Joint development of clinical PCR for lab use

[RIKEN GENESIS strengths and technologies (2)]

- Gene analysis service
  Provide Japanese and overseas research institutes and companies with leading-edge gene analysis technology (genotyping and next-generation sequencing)



→ Development of new applications using next-generation sequencer

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Development of Clinical PCR

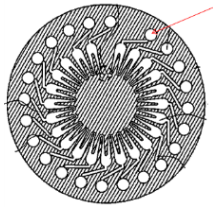
[Issue with PCR]
Work is cumbersome (extensive manual labor), so difficult to do in hospital labs

[Clinical PCR Concept]

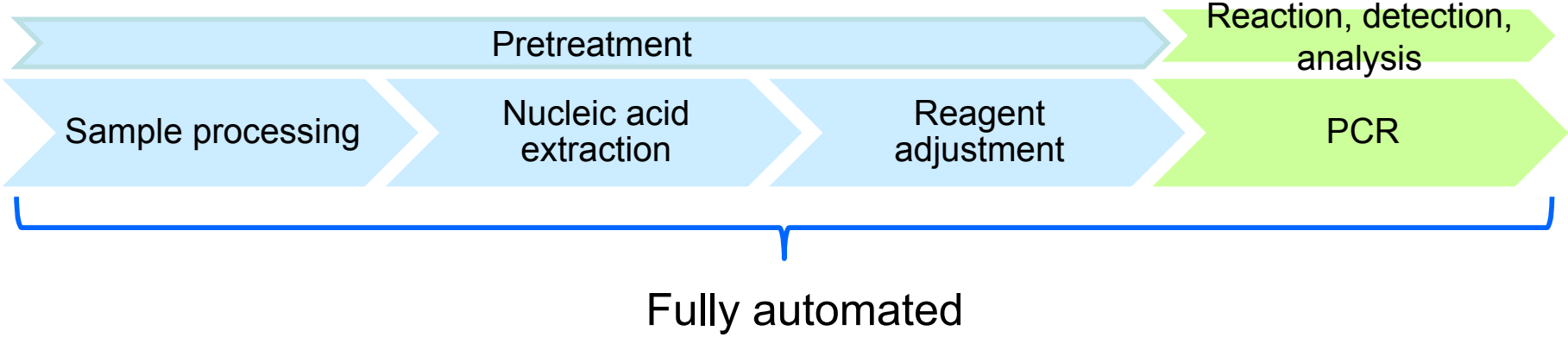
Cancer diagnosis system for use in hospital labs

- Fully automated from pretreatment to detection
- Highly sensitive detection of somatic mutation (target: 0.1%)
- Quality control
- Clinically useful marker set
- Compact

Instrument



Reagent kit



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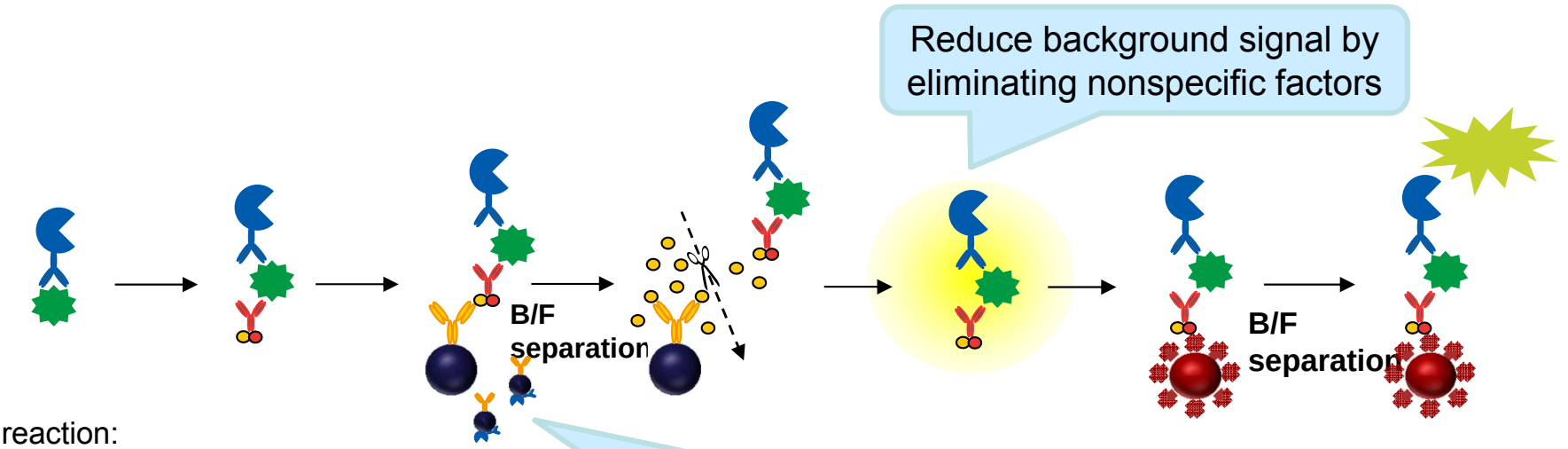
2) Protein Measurement Platform
Principles of Ultrasensitive HISCL

Use immune complex transfer method to achieve ultrahigh-sensitivity HISCL

(High sensitivity of approximately 60 times* when measuring HBsAg)

* Comparison of HISCL

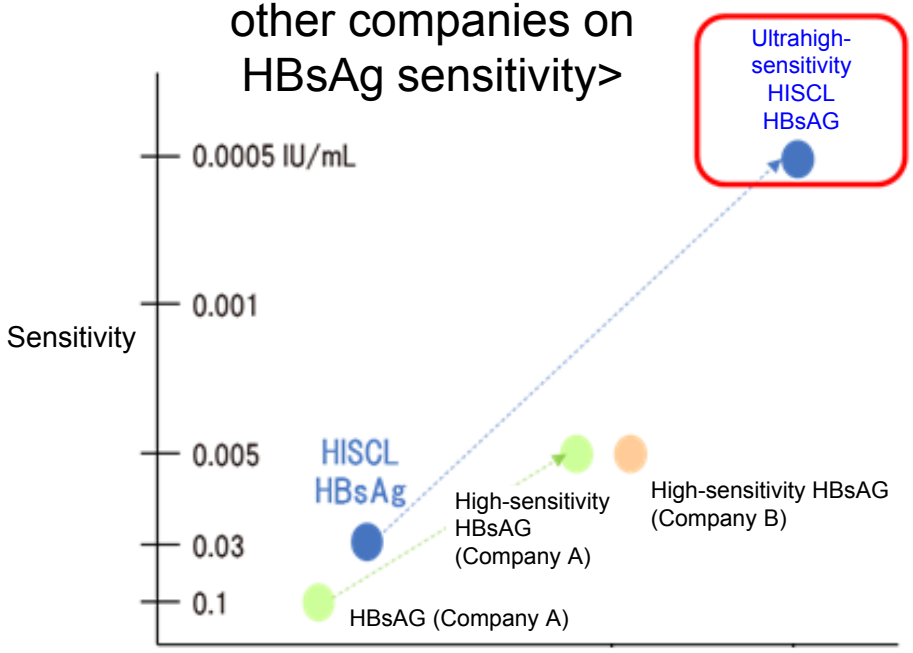


Nonspecific reaction:
A reaction not arising from an antigen-antibody reaction

B/F separation:
The separation of antigens combined with antibodies and antigens not combined with antibodies

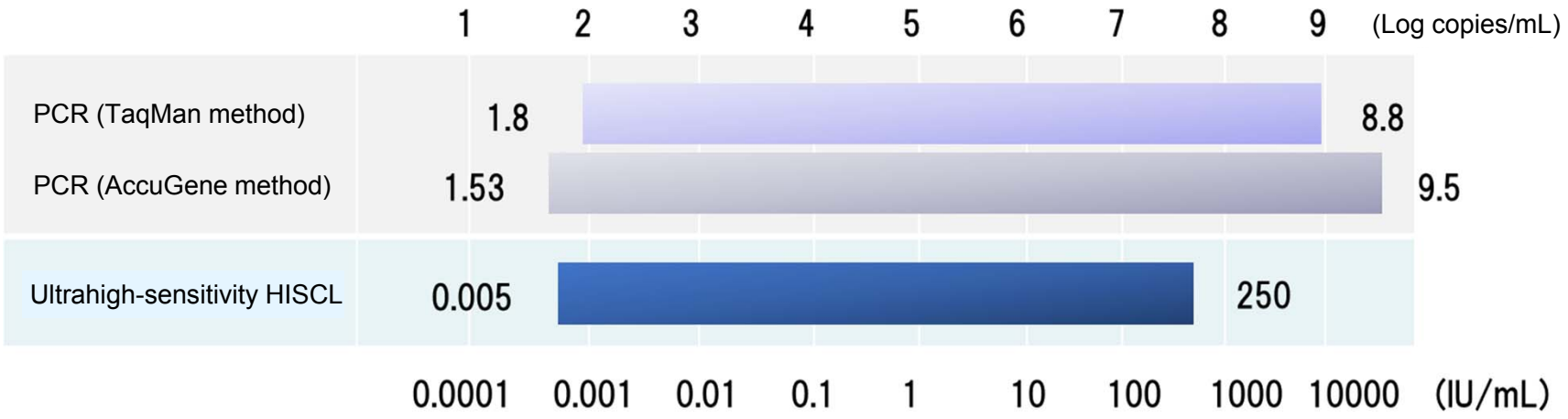
Sensitivity of Ultrasensitive HISCL

<Comparison with other companies on HBsAg sensitivity>



Using HISCL for HBsAg measurement achieves ultrahigh sensitivity (essentially the same level as PCR)

<Comparison of HBsAg sensitivity with PCR>



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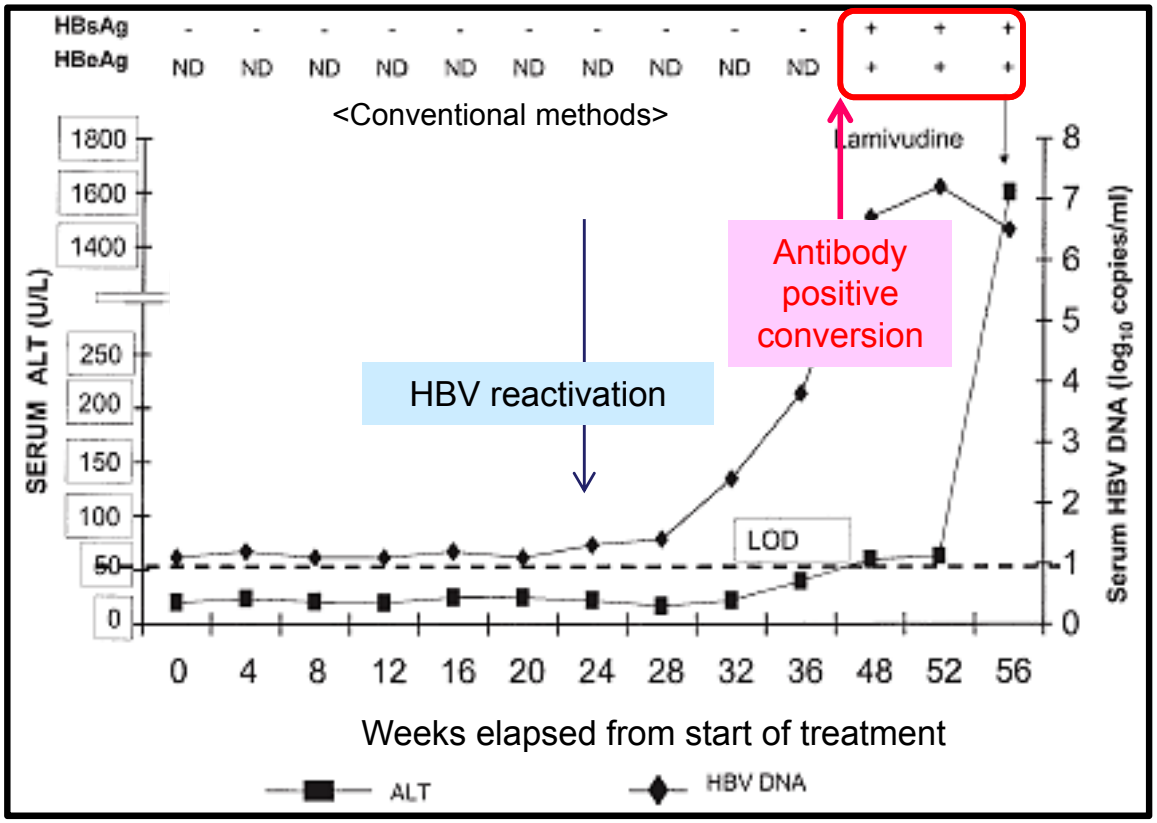
Ultrasensitive HISCL Applications

◆Monitoring for reactivation of the hepatitis B virus

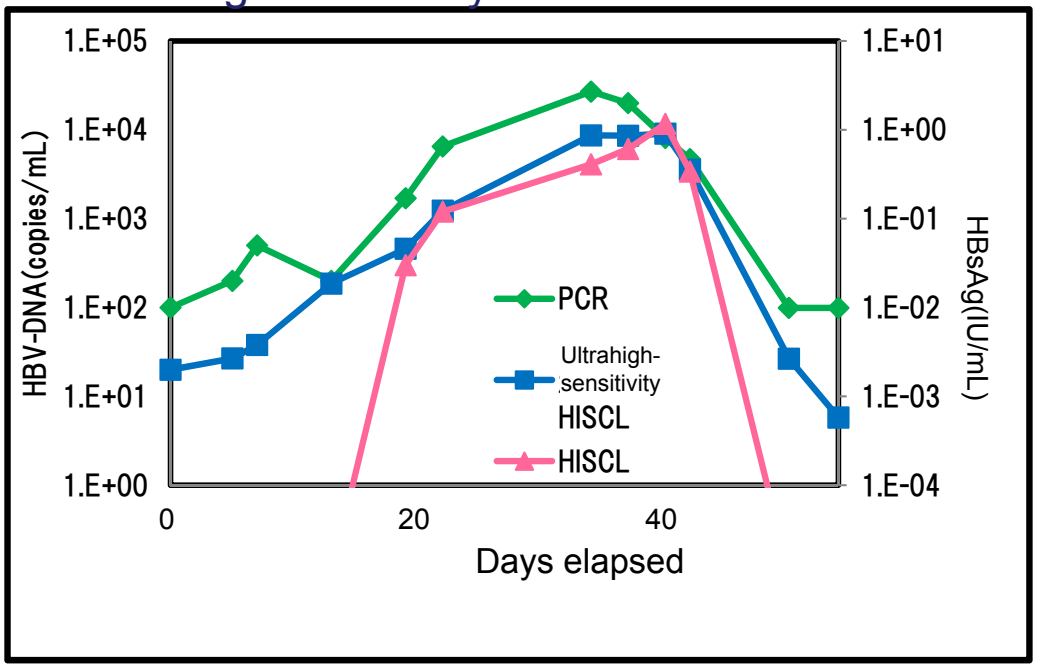
Type B hepatitis can recur when immunity is reduced, presenting the danger of severe hepatitis occurring, leading to the need for early diagnosis of virus reactivation and the start of treatment

<HBV reactivation>



Adopted from C-K Hui, et al. Gastroenterology 2006;131:59–68

<Clinical research results: comparison of ultrahigh-sensitivity HISCL with PCR>



Enables simple testing with approximately the same sensitivity as PCR

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Future Developments in Ultrasensitive HISCL

Develop unique applications that leverage the characteristics of ultrahigh sensitivity

- **Virus reactivation monitoring**

  Reduced immunity and the administration of anticancer drugs or immunosuppressants can cause viruses to reactivate and disease severity to increase. By providing a simple monitoring test method as an alternative to DNA testing, prevent condition from growing more severe.

- **Measurement of PharmacoDynamics (PD) markers**

  In particular, the concentration of the drug antibodies by antibody drugs and their target molecules in the blood

- **Central nerve disease and other conditions requiring ultrahigh-sensitivity measurement**

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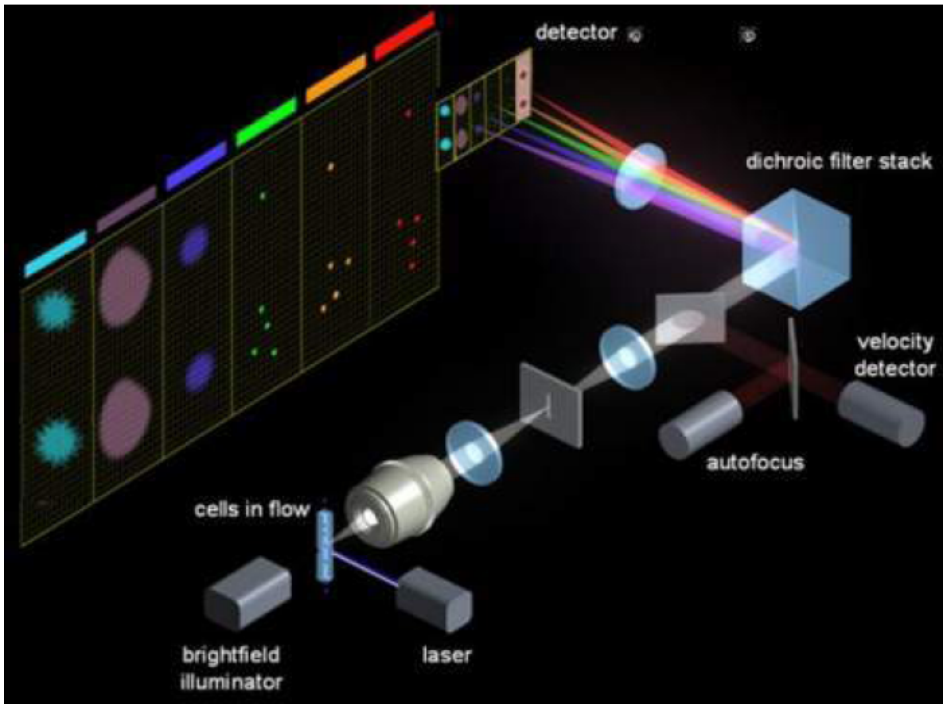
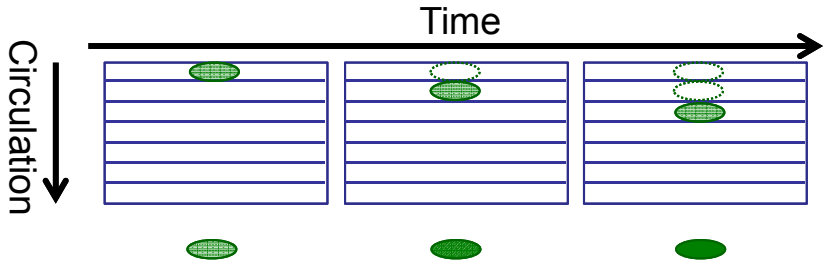
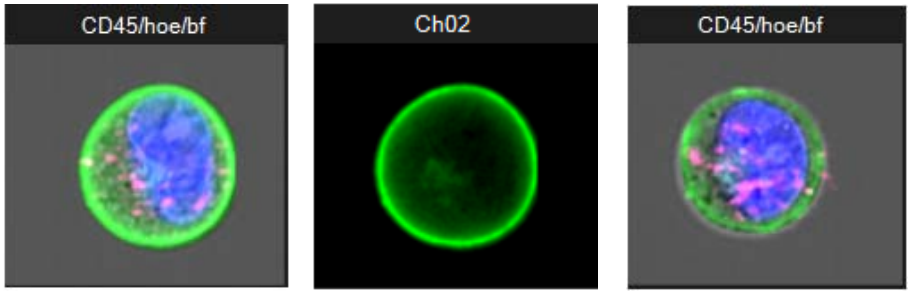
3) Cell Measurement Platform
MI (Molecular Imaging)-FCM



https://www.amnis.com/multispectral.html



The accumulation of images enables the highly sensitive capturing of cells circulating at high speeds



Combining this technology with Sysmex's own technologies will lead to the development of MI (molecular imaging)-FCM, which should enable the highly sensitive measurement in clinical settings of abnormal cells in-flow

CAC (circulating abnormal cells)
CTC (circulating tumor cells)

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Morphological/Fluorescent Analysis Capability

<Morphological Analysis Capability>

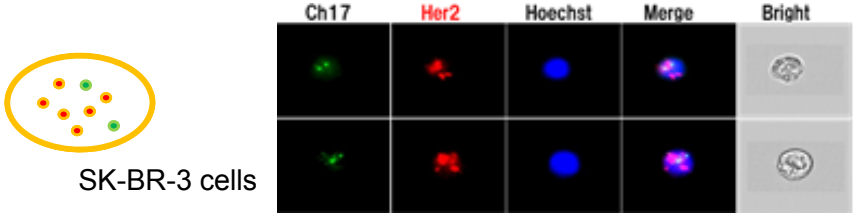
Note: Evaluation of clinical samples

	Sensitivity
Neutrophils	98.4%
Lymphocytes	98.0%
Monocytes	97.0%
Eosinophils	100.0%
Abnormal lymphocytes	79.1%

Molecular probe ⇒ Circulating abnormal cells / Circulating tumor cells ⇐

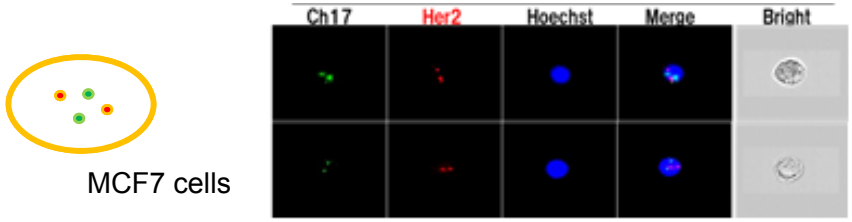
<Fluorescent Analysis Capability>

Her2 amplification cells



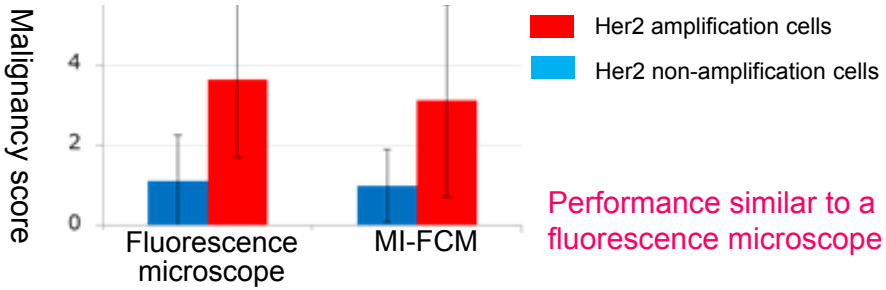
SK-BR-3 cells

Her2 non-amplification cells



MCF7 cells

Comparison with Her2/Ch17 using the FISH method (malignancy score)



Performance similar to a fluorescence microscope

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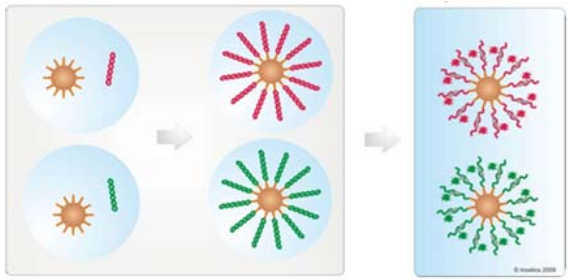
4) Progress on Other Technology Platforms

Theme	Objective	Progress in Fiscal 2014	Items Planned in and after Fiscal 2015
Clinical FCM 	Development of FCM that can be easily used in clinical setting	Pretreatment-integrated FCM under development	Prototype completion and evaluation
Digital PCR (BEAMing) 	Development of automated system	Reconfiguration of optimal protocol toward fully automated system	Start development of fully automated system

2. Technology Strategy Progress

(1) Overall Technology Strategy

(2) Strengthening and Expanding Technology Platforms

(3) Development of Applications through Advances in Open Innovation

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Status of Open Innovation

◆ Universities and Research Institutions

● National Cancer Center

Development of diagnostic technology to predict response to preoperative chemotherapy for bone cancer
Development of diagnostic technology related to hepatic cancer recurrence risk classification
Feasibility research toward development of diagnostic technology for early detection of pancreatic cancer
Establishment of highly precise epigenetic stomach cancer risk diagnosis

● Kobe University (Endowed course on assessment of clinical testing)

Development of cardiovascular disease risk diagnosis system: Development of method for evaluating HDL function

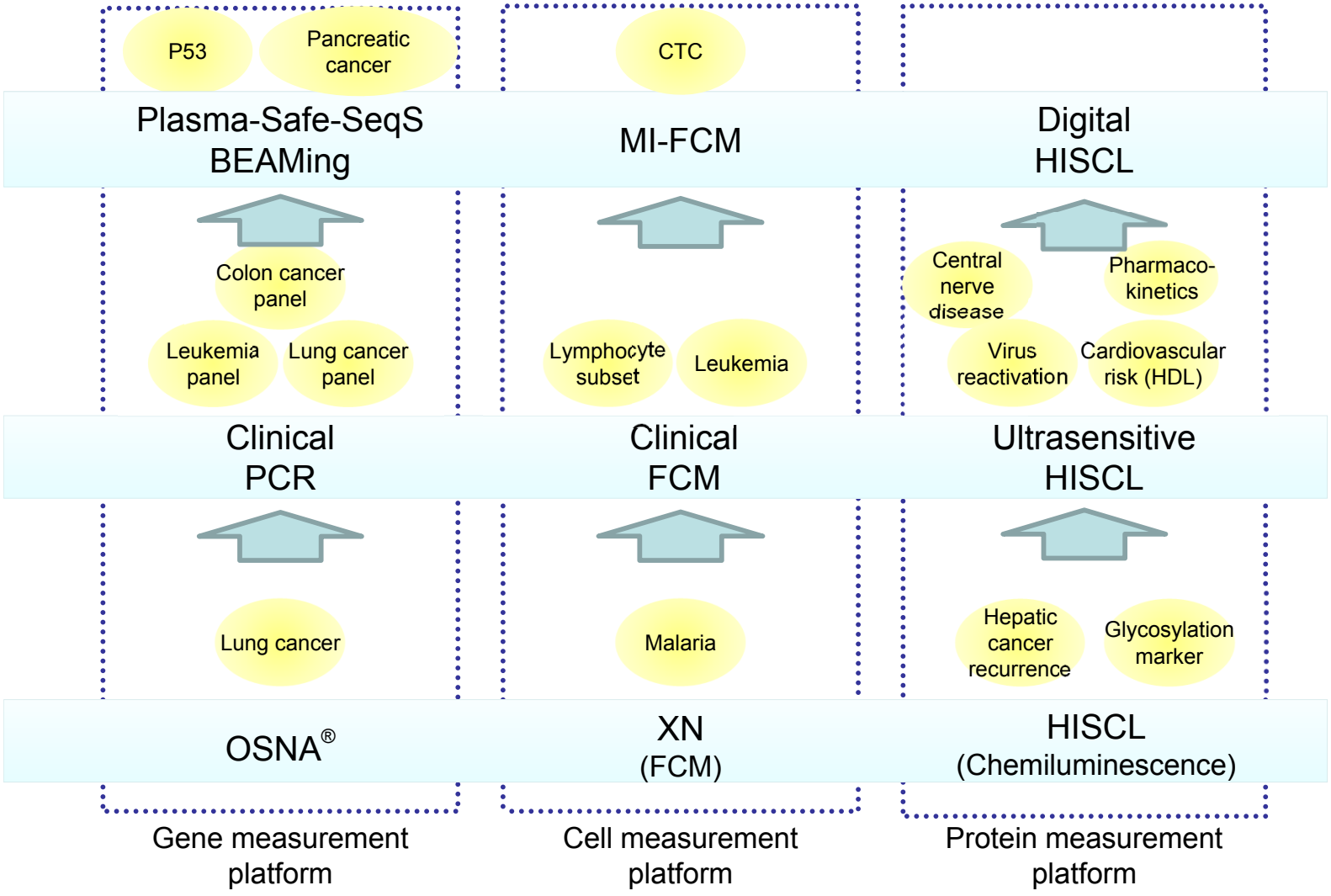
. . . . . .

◆ Pharmaceutical companies

◆ Venture companies

Technology Platforms and Applications

Creating new clinical value by leveraging the strengths of Sysmex's technologies



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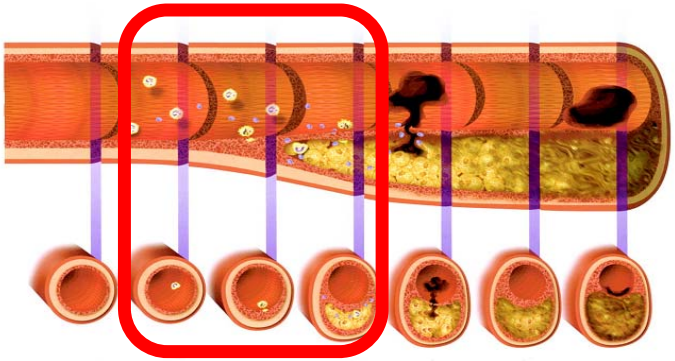
Development of Method for Diagnosing Risk of Cardiovascular Disease
Development of Method for Evaluating HDL Function
(Joint Development with a Course at Kobe University, “Assessment of Clinical Testing”)

sysmex

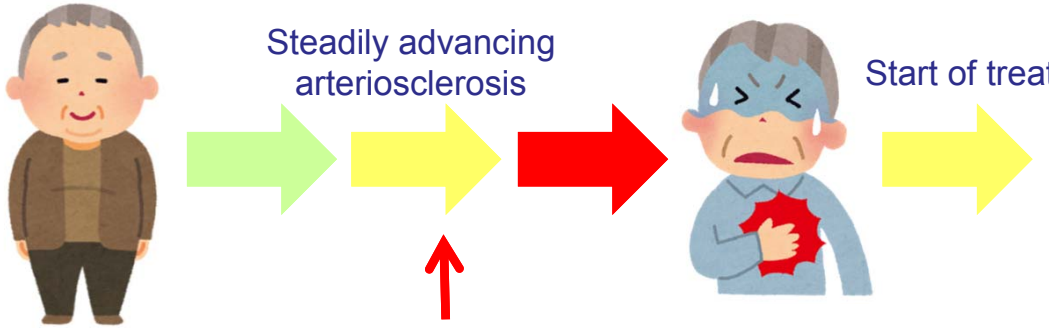
Development of method for evaluating HDL function and realizing method for diagnosing cardiovascular risk



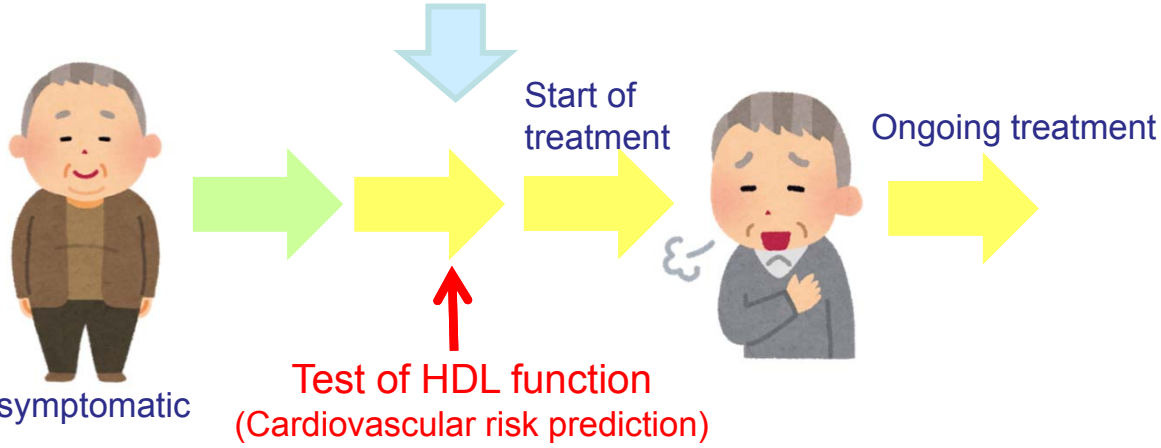
Arteriosclerosis progression

HDL-C concentration
(Existing clinical chemistry tests)

HDL function



Disrupting the HDL-C myth?
(Increase in HDL-C does not reduce cardiovascular risk)



(Khera et al. Jan 13, 2011, New England Journal of Medicine)

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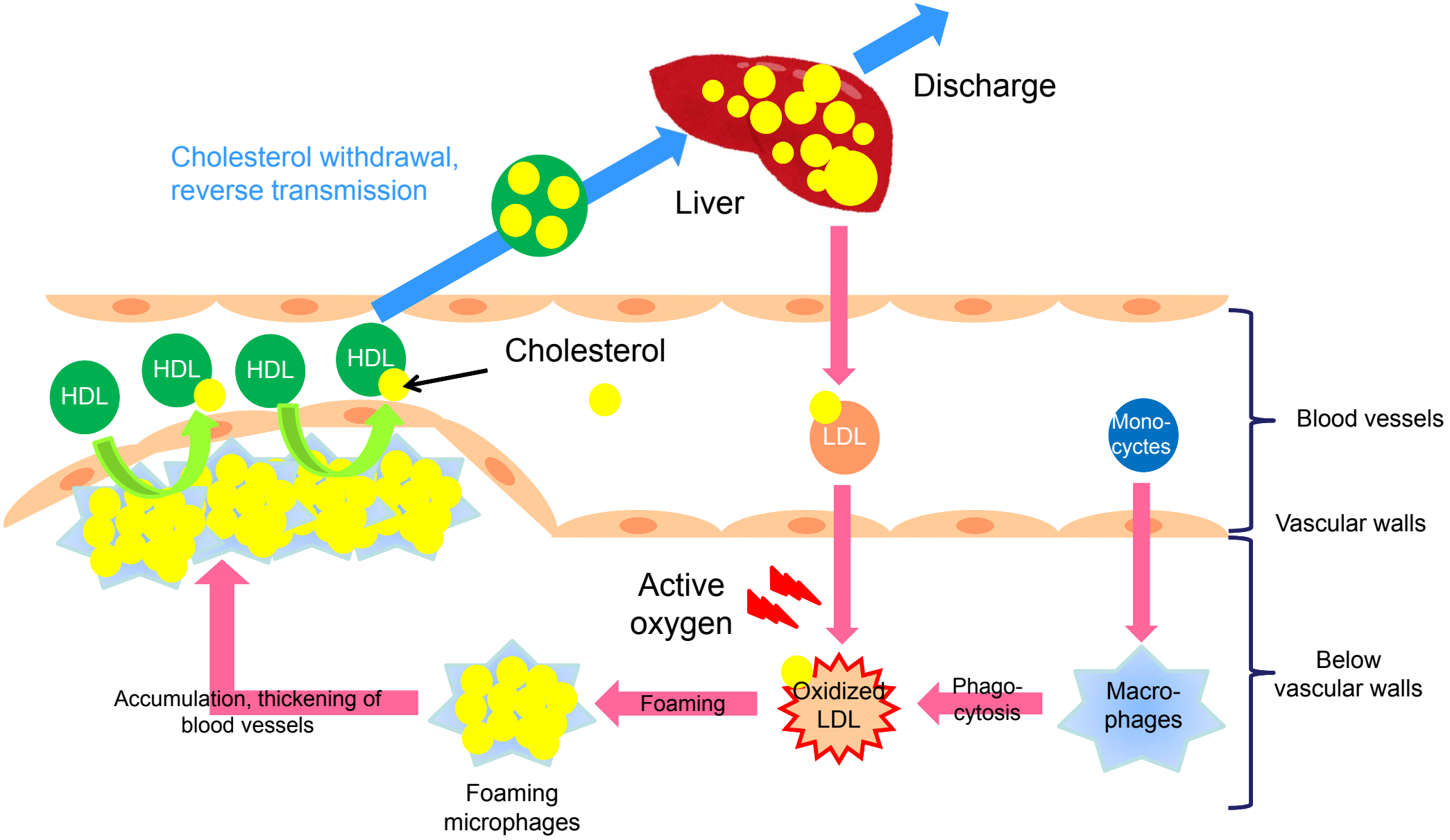
Arteriosclerosis Incidence and Control Mechanism



Microphages: In one type of leukocyte, prey on and extinguish necrotic cells and foreign matter within a body

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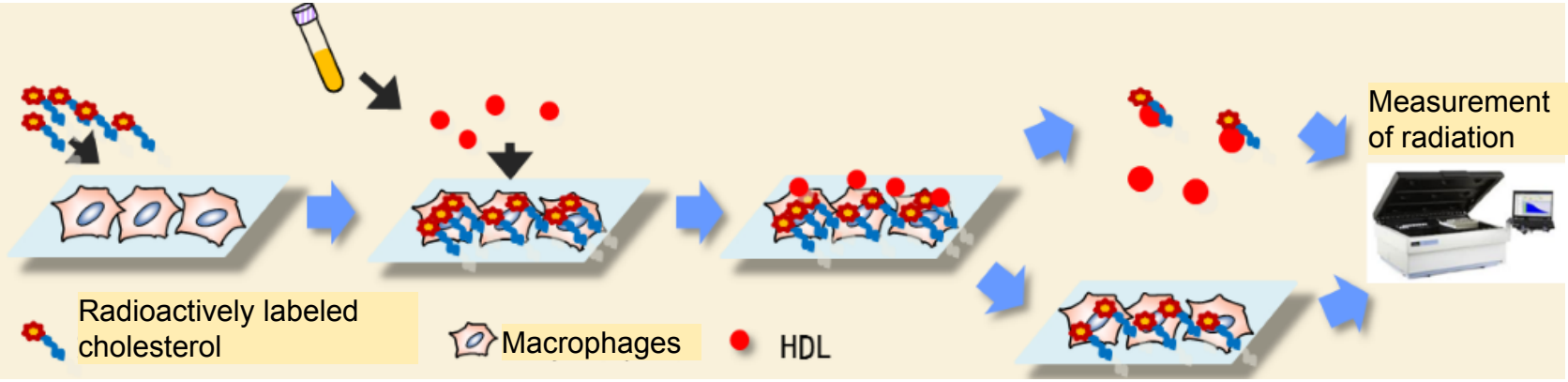
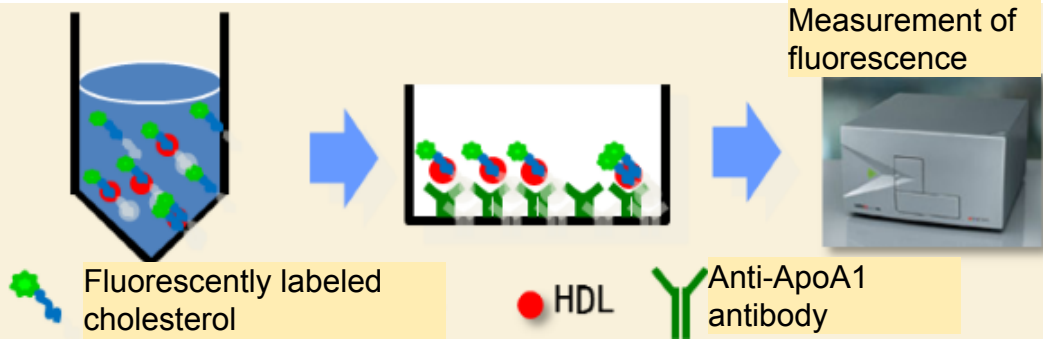
Testing of HDL Function

HDL function: Ability to eliminate excess cholesterol

[Conventional method] Testing method employing radioactive labeling and cells



[New technology] Testing method employing fluorescent labeling, but no cells



Ultimately

Use in ultrahigh-sensitivity HISCL

Summary of Progress on Ongoing R&D Themes

Theme	Items Planned at the 11th Technology Presentation (March 14, 2014)	Progress in Fiscal 2014	Items Planned in and after Fiscal 2015
Glucose AUC (Minimally invasive interstitial fluid extraction technology)	Japan Complete clinical trials, apply for approval of application	・Completed clinical trials ・Preparing to apply for approval of application	・Apply for approval of application and prepare for commercialization
Diabetes bio-simulation (Disease state simulation technology)	Japan Aim for application as diabetes diagnosis support system	・Guidelines for approval of application formulated, conducted deliberations toward clinical trials	・Discuss with authorities ・Consider application to big data analysis
Development of raw materials for diagnostic reagents using silkworms	Develop diagnostic reagents using silkworms	・Used in raw materials for Sysmex reagents ・Continued research on functional proteins	・Use in raw materials for Sysmex reagents ・Continue research on functional proteins

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3. Progress on Research and Development Themes

(1) HU Business Unit

Kensaku Aota, Executive Vice President of the
UB Product Engineering Div.

1) Malaria Detection Technology Using Blue LD FCM

2) Progress on Cervical Cancer Screening System

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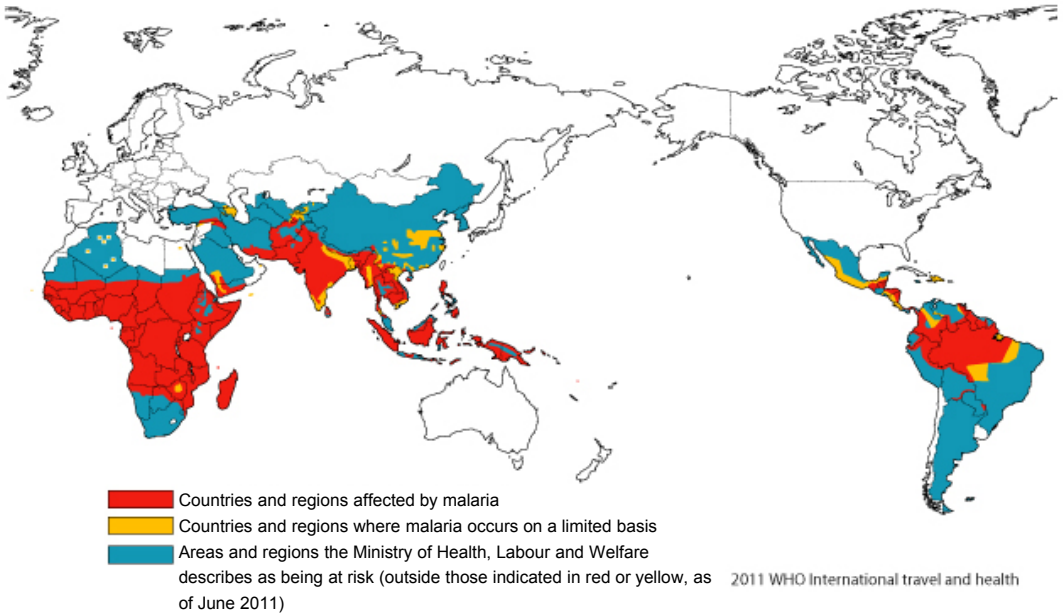
1) Malaria Detection Technology Using Blue LD FCM

Blue LD: Blue laser diode

Malaria

Endemic area

Centered on tropical and subtropical regions



Individuals affected: 198 million/year

Deaths: 580,000/year

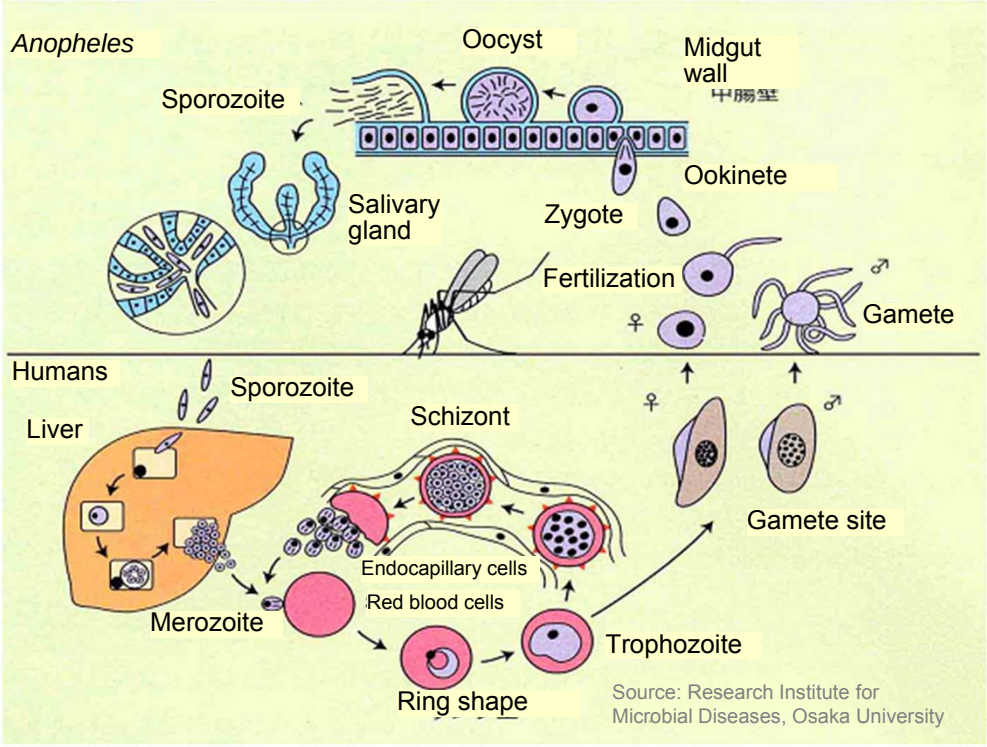
WHO estimate

Types (*Plasmodium*)

P.falciparum, *P.vivax*, *P.malariae* and *P.ovale*

Note: If not treated within 24 hours of infection, *P. falciparum* becomes more severe and can ultimately result in death.

Infection and propagation mechanisms



(1) Disease enters the body via malarial plasmodium from a bite by an *Anopheles* mosquito

(2) The plasmodia propagate in the liver, infected red blood cells

(3) Propagation occurs through repetition of the ring → trophozoite → schizont → merozoite cycle

(4) Some of the propagated malaria changes form on the gametocytes infecting the mosquitos

Note: It is known that only the rings and gametocytes exist *in vitro* blood sample of *P. falciparum* .

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Current Testing Methods and Issues

Indicator	Microscopy (Blood smear Giemsa stain)	PCR method (*Plasmodium* DNA detection)	Fluorescent staining method	Antigen detection method (Immunochromatography)
Detection sensitivity (/μℓ)	500–5,000 (1/1,000–1/10,000)	5 (1/1,000,000)	50 (1/100,000)	500 (1/1,000)
Malaria type (*Plasmodium* type) identification	Possible	Not possible simultaneously	Not possible	*P.falciparum* or other (General estimate)
TAT (Turn Around Time)	60 minutes	12–24 hours	30–60 minutes	10–15 minutes
Skill required	High	Moderate	Moderate	Slight
Instrument required	Light microscope	PCR instrument	Fluorescence microscope	Kit only
Cost	Low	High	Moderate	Low–moderate

Desired test method

- Able to identify type of malaria (*Plasmodium* type)
- System for quick and simple testing alongside standard blood testing (measurement with routine equipment)

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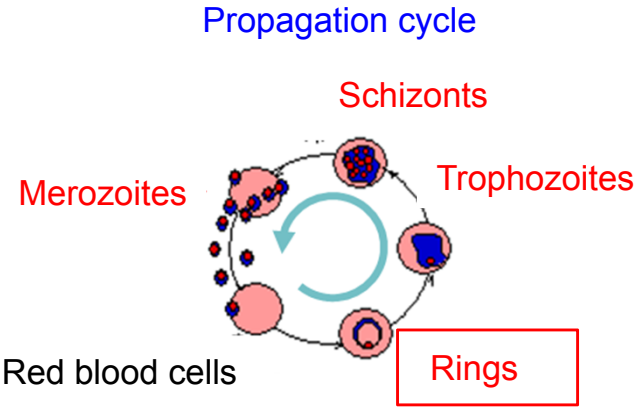
Sysmex's Current Products/Technologies

Allow malaria to be detected with standard blood tests (available as a function on hematology analyzers)
Abnormal blood cell morphology resulting from malarial infection detected as a flag

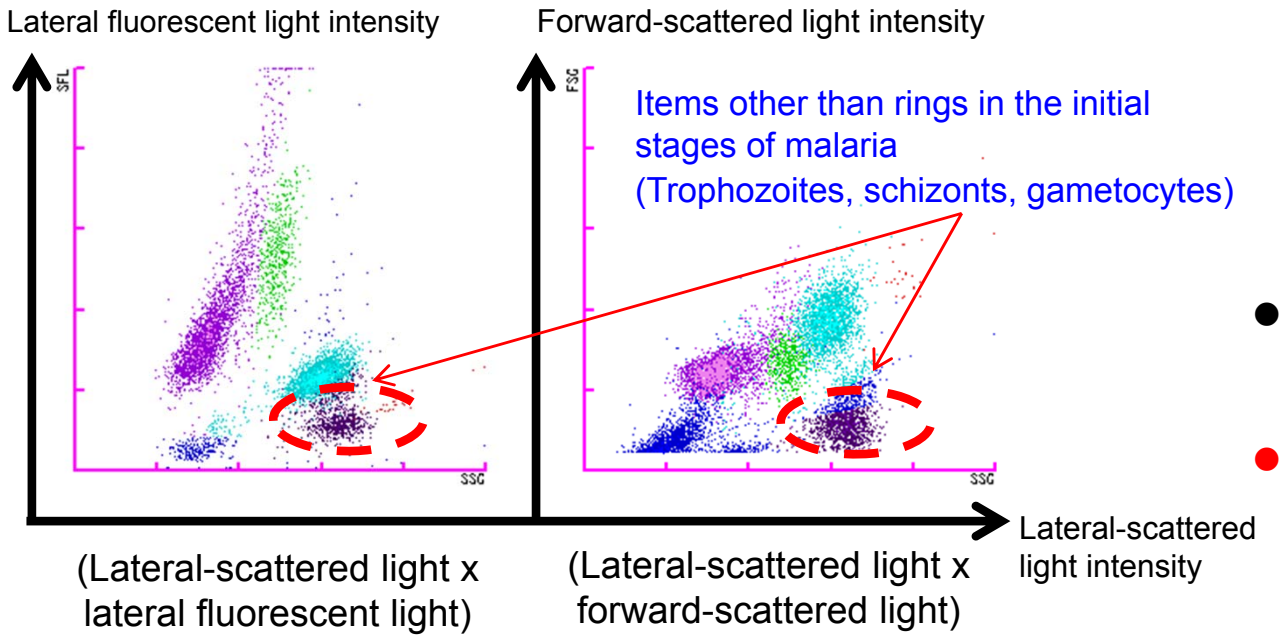
XS-Series

XN-Series

XN-L-Series (new product)



White blood cell analysis channel Scattergram



- Analyze the signal information from the white blood cell analysis channel three-dimensionally and identify cells other than rings (trophozoites, schizonts, gametocytes) at an early stage of the malaria propagation to qualitatively flag malaria in the blood

- As signals of ring forms are minute in the early stages, it is difficult to detect the signals.
- Detection sensitivity is low for *P.falciparum*, which appears only in rings

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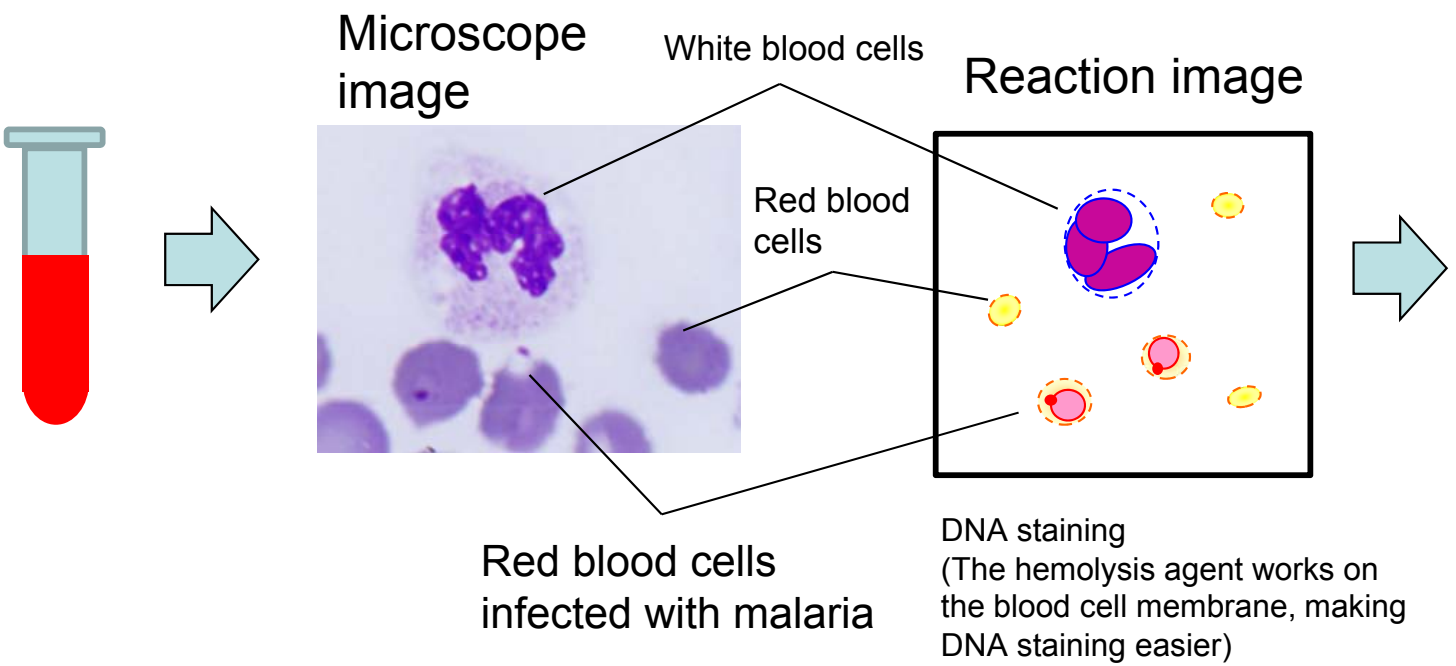
Malaria Detection Technology Using Blue LD FCM to Achieve Further Value Increases

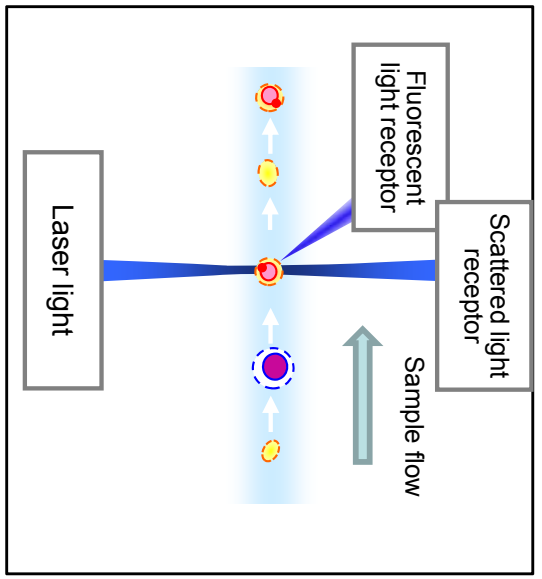
Development of FCM capable of identifying malaria types

Aspirate blood and determine quantity → DNA (malaria, white blood cell) staining → FCM measurement

Stain malaria-infected cells with dye that has excellent affinity for rings

Count the number of malaria-infected cells





Laser light wavelength: 405nm (blue laser diode)

Detection of the malaria cells included in approximately 1μL of blood in around 2 minutes
Detection sensitivity of 50/μL (1/100,000)

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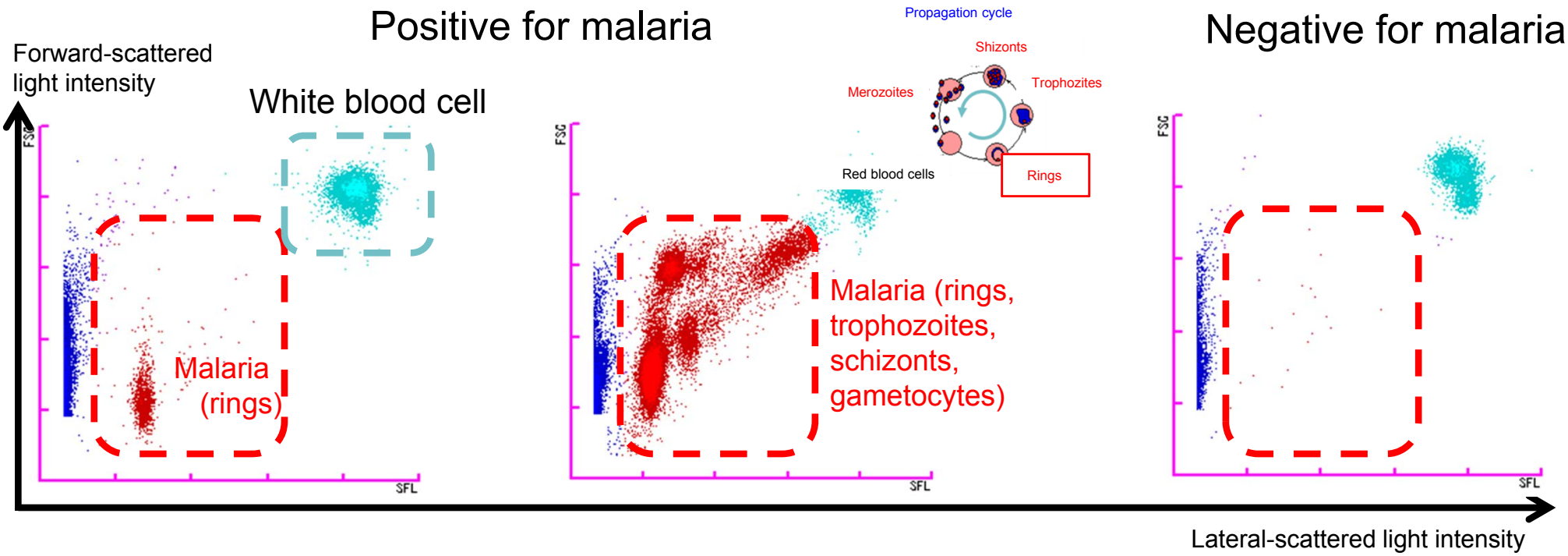
Malaria Detection Technology Using Blue LD FCM: Verification of Principle



Malaria type	*P.falciparum*
Microscopy	Positive Infection rate 0.1% or less
FCM malaria detection method	Positive Infection rate 0.029%

Malaria type	*P.Vivax*
Microscopy	Positive Infection rate 0.5%
FCM malaria detection method	Positive Infection rate 0.498%

Malaria type	-
Microscopy	Negative Infection rate -
FCM malaria detection method	Negative Infection rate -

Allows detection and determination of amount of each cell in the propagation cycle (possible to identify malaria type)
→ Malaria infection rate can be calculated, and the level of severity (clinical state) accurately measured)

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Malaria Detection Technology Using Blue LD FCM: Function Evaluation Results

Evaluation of 420 samples containing *P.falciparum*

Evaluation location: South Africa

Evaluation period: January–July 2014

		Comparison method (microscope)		
		Positive group	Negative group	Total
Blue LD FCM malaria detection system	Positive determination	139	23	162
	Negative determination	3	255	258
	Total	142	278	420

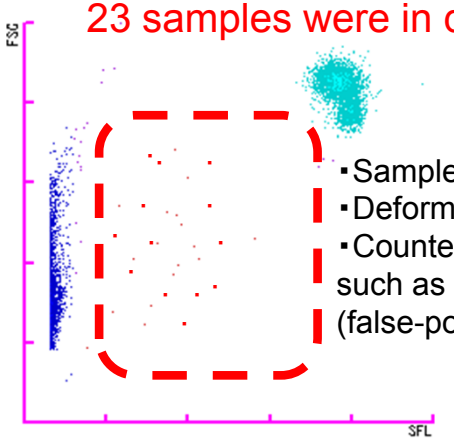
Sensitivity = 97.9% (139/142)

Specificity = 91.7% (255/278)

Note: Sensitivity is the percentage of positive cases correctly identified as positive
Specificity is the percentage of negative cases correctly identified as negative.

○Conference presentation
ASLM (AFRICAN SOCIETY FOR LABORATORY MEDICINE)

23 samples were in disagreement



- Samples with high RET
- Deformed white blood cells
- Counted because of factors such as Howell-Jolly bodies (false-positives)

Further increase specificity

For malaria infection,
Develop an analysis algorithm that uses the existence of 100 or more cells and cluster formations as a condition

Sensitivity and specificity are both high (high evaluations), but work to increase specificity further (improve on number of samples in disagreement)

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Malaria Detection Technology Using Blue LD FCM: Function Evaluation Results

Using the algorithm we developed,

Evaluation of 487 samples containing *P.falciparum* and *P.vivax*

Evaluation location: South Africa

Evaluation period: November 2014 – January 2015

		Comparison method (microscope)		
		Positive group	Negative group	Total
Blue LD FCM malaria detection system	Positive determination	119	19	138
	Negative determination	1	348	349
	Total	120	367	487

19 samples were in disagreement

The reason being that around 80% were overlooked with microscopy

Negative group
4 (-15)
363 (+15)
367

Increased specificity

Sensitivity = 99.2% (119/120)

Specificity = 94.87% (348/367) ⇒ 98.9% (363/367)

Note: Sensitivity is the percentage of positive cases correctly identified as positive
Specificity is the percentage of negative cases correctly identified as negative.

Sensitivity and specificity are both high, allowing malaria infection to be detected with a high degree of precision

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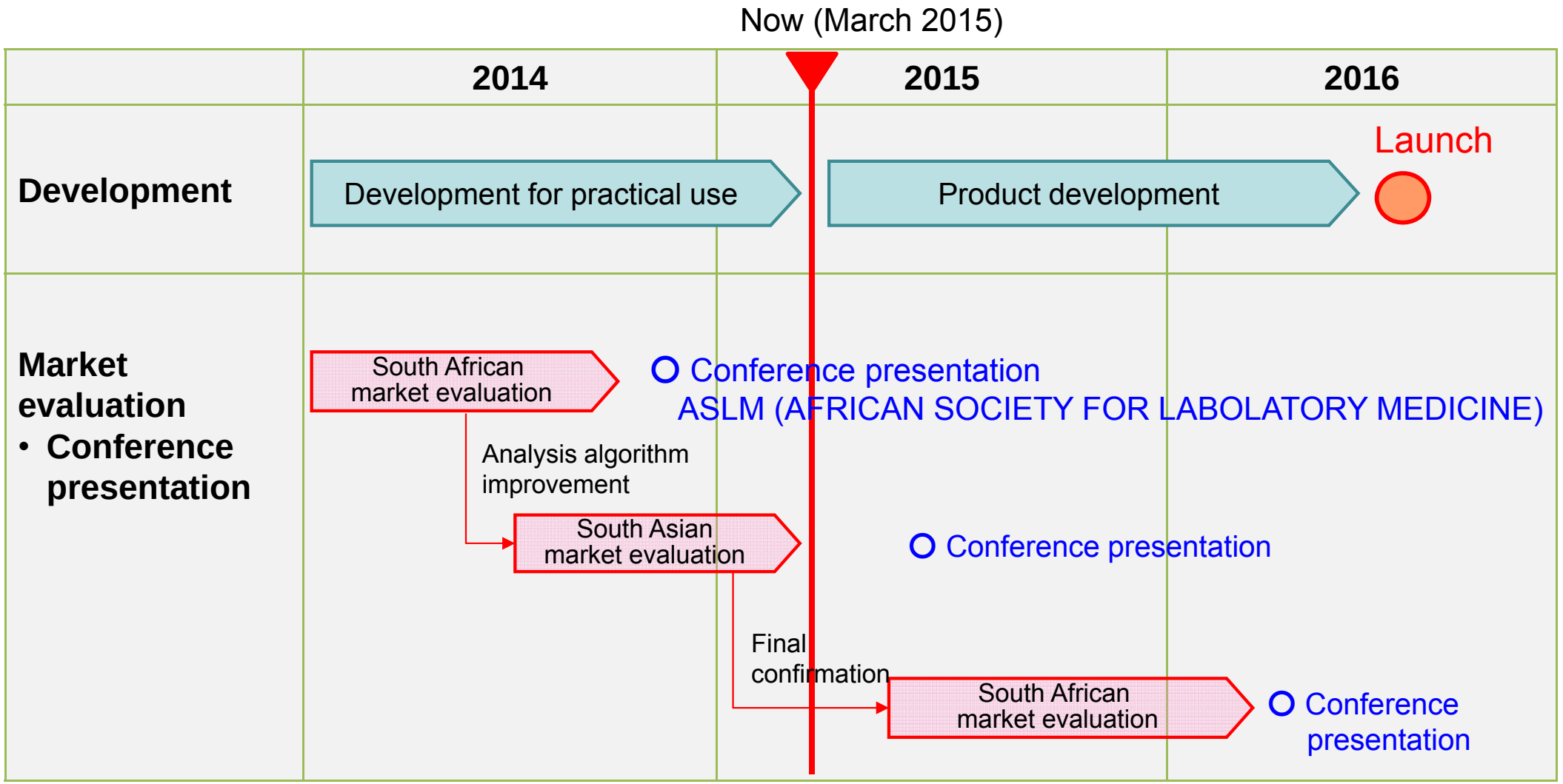
Current Progress and Future Expectations



Conduct market evaluations and conference presentations in parallel with product development, with the aim of launching a product in 2016

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2) Progress on Cervical Cancer Screening System

Cytology Support: LC-1000 Release

LC-1000 exfoliative cell analyzer

Released in November (in Japan) as general-purpose FCM (medical device class 1: notification)

Aim for use in cervical cancer examinations

- Measurement period: Approx. 30 minutes
- Processing capacity: 20 tests/hour
- Running cost (target)

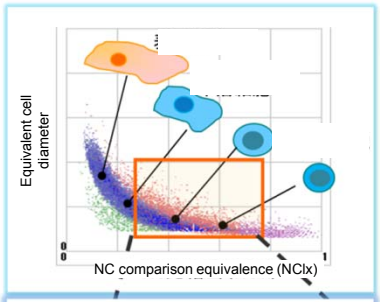
  Equivalent to cytology or less, 1/3 for HPV test or less

[Features]

- Uses system to measure cytology samples (LBC)
- Using "original index for cell proliferation," shows the existence of precancerous lesions and other aberrant cells

(Produces objective data)

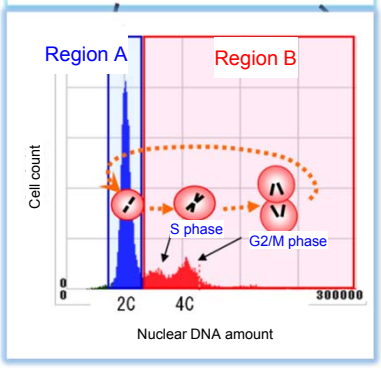
LBC: Liquid-based cytology



(1) Select group of cells to be analyzed based on NC comparison equivalence indicator

Indicator related to cell morphology

$$NCIx = \frac{\text{N (equivalent nuclear diameter)}}{\text{C (equivalent cell diameter)}}$$



(2) DNA histogram analysis

Indicator related to cell proliferation activity

$$CPIx = \frac{\text{Cell count in region B}}{\text{Cell count in region A}}$$

[CPIx: Abbreviation for Cell Proliferation Index

Resolve problems in cytology (low sensitivity, uneven results, shortage of cytologists) supporting by lower-cost and faster measurement than manual cytology

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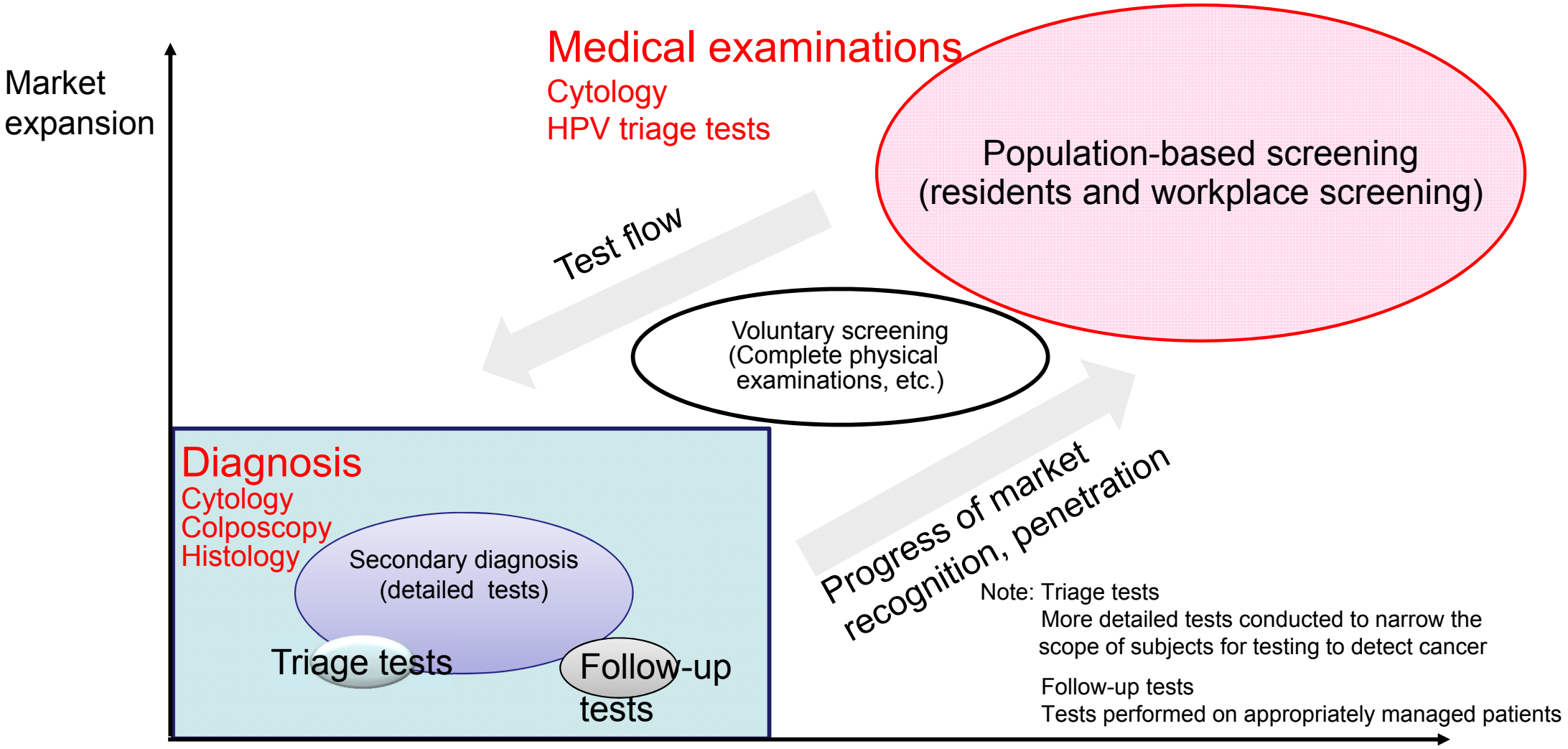
Cervical Cancer Screening and Activities for Promoting Market Recognition and Penetration



Market Recognition and Penetration Activities in Japan

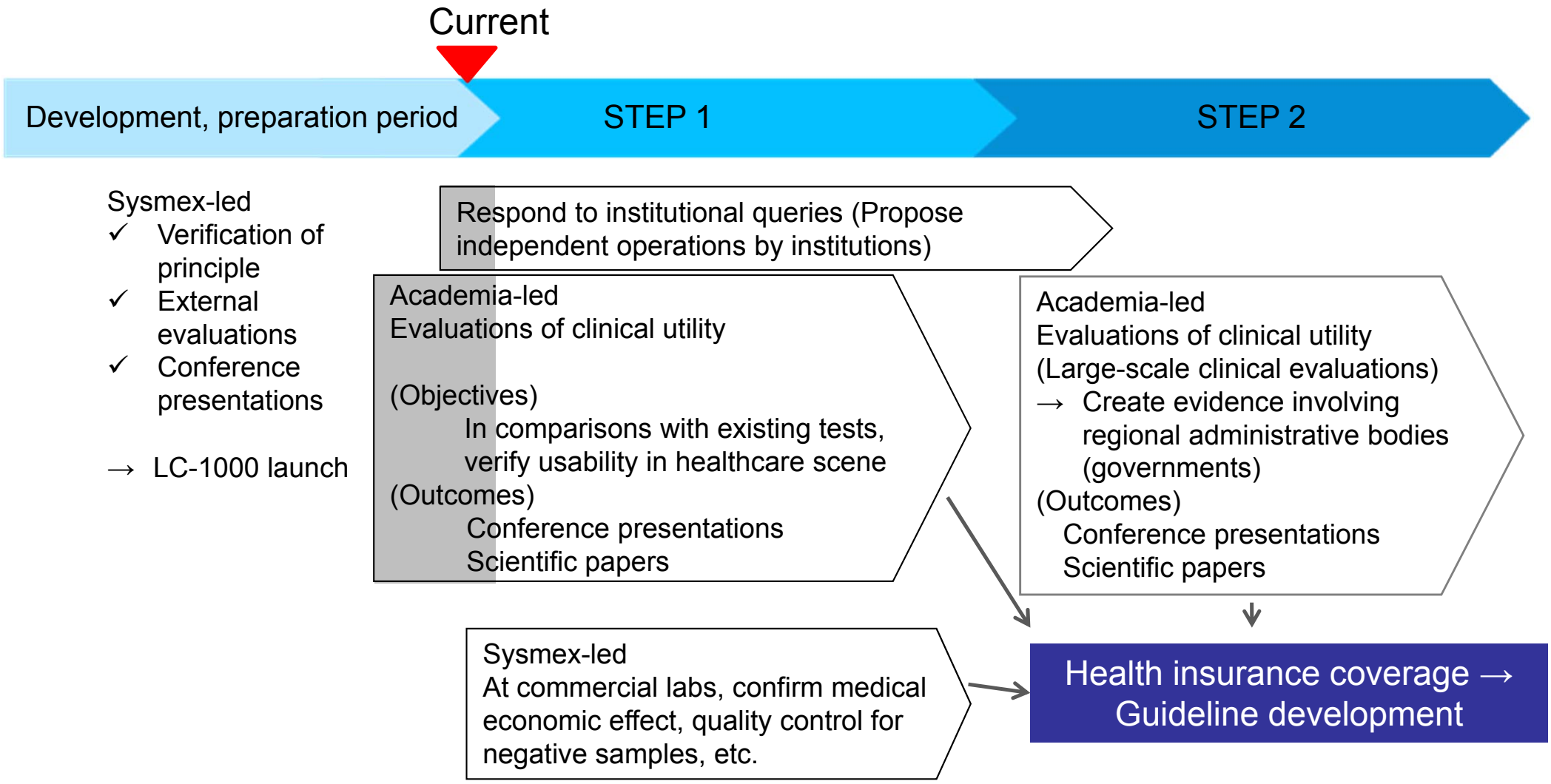


Exhibit the LC-1000 at major academic conferences, announce technologies and clinical utility

Japan Society of Clinical Cytology	Japan Society of Gynecologic Oncology	Japanese Society of Gynecological Cancer Screening	Japan Cytometry Society

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Market Recognition and Penetration Activities Overseas

Current

Development, preparation period	CFDA application activities (STEP 1)	Insurance coverage activities (STEP 2)

Joint research with well-known Chinese hospital specializing in cancer treatment

Joint research → Prepare for scientific paper → Publish original papers

Supporting evidence

Insurance coverage

Activities toward CFDA approval

Preparation period for studying new legislation → Field trials → Clinical studies → CFDA application

Activities toward insurance coverage

Connection with KOL → Obtain data toward insurance coverage by ministries

Asia

Europe

Select evaluating institutions → Sysmex-led
Evaluations of clinical utility and economic performance → Institution-led
Trial operation→actual operation

3. Progress on Research and Development Themes

(2) ICH Business Unit

Hiroshi Kanda, Executive Officer, Executive Vice President
of the Hemostasis Product Engineering Div.

1) Developing Future Clinical Value, Hyphen BioMed's Strength, and Realization via the CS-Series Platform

- Market Environment Surrounding Hemostasis Testing
- Recent Development in Thrombosis Treatment
- Sysmex's Measurement Platform
- Hyphen BioMed and Its Strengths
- Application to CS-Series Platform

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Market Environment Surrounding Hemostasis Testing

☐ Statistics on causes of death for each 100,000 Japanese people (fiscal 2012)*

No. 1 Malignant tumors: 286.4 people (28.7%)

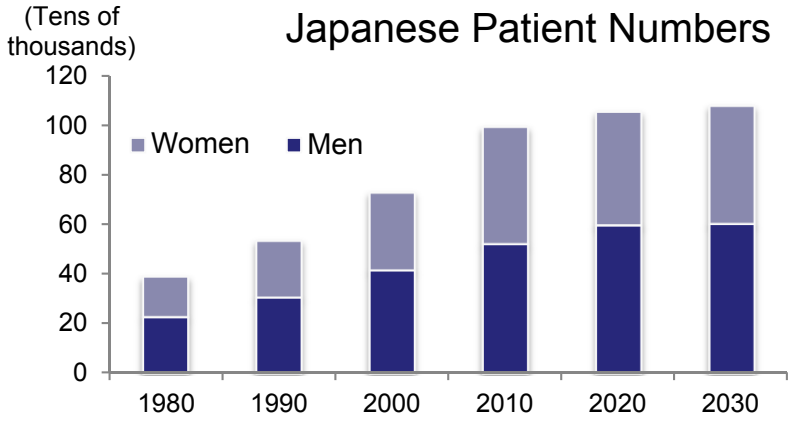
No. 2 Cardiovascular disorders: 157.7 people (15.8%)

No. 3 Pneumonia: 98.3 people (9.9%)

No. 4 Cerebrovascular disease: 96.5 people (9.7%)

*Based on statistical survey results on the Ministry of Health, Labour and Welfare's website

☐ Non-Valvular Atrial Fibrillation (NVAF)



Approximately 990,000 patients (2010) are affected by non-valvular atrial fibrillation (NVAF) caused by such factors as coronary arteriosclerosis, hypertension and cardiac insufficiency, increasing with advancing age.

Cerebral infarctions caused by thrombus prompted by NVAF are said to be the cause of death for approximately 20%.

Accordingly, atrial fibrillation is the most critical complication for thrombotic embolisms.

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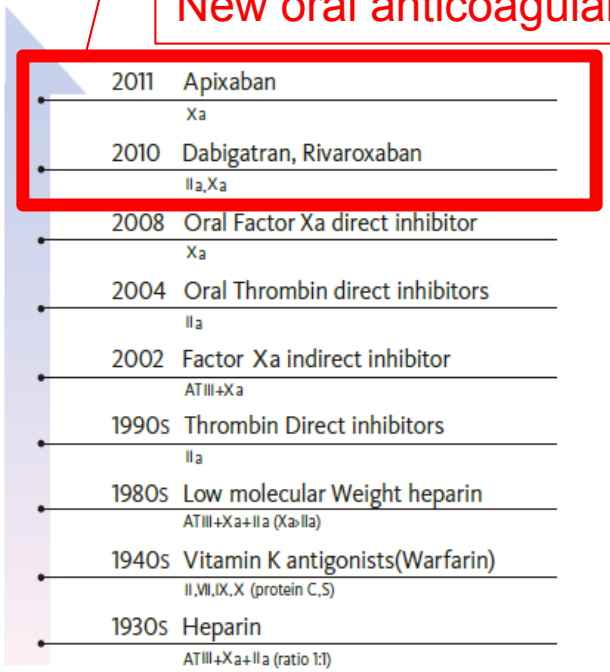
Recent Developments in Thrombosis Treatment

Rapid advances in therapeutic drugs (anticoagulants)

New oral anticoagulants (NOACs)



An era of selecting the drug best suited to the patient (personalized medicine)

Dabigatran
(Product name: Pradaxa®)
Nippon Boehringer Ingelheim Co., Ltd.

Rivaroxaban
(Product name: Xarelto®)
Bayer Yakuhin, Ltd.

Apixaban
(Product name: Eliquis®)
Bristol-Myers Squibb Company
Pfizer Japan Inc.

Edoxaban
(Product name: Lixiana®)
Daiichi Sangyo Co., Ltd.

Therapeutic drug	Warfarin	Dabigatran	Rivaroxaban
Launch	1962	2011	2012
Therapeutic range	Narrow	**Broad**	**Broad**
Monitoring	Necessary (frequent blood sampling)	**Unnecessary**	**Unnecessary**

Although monitoring is considered to be unnecessary, there is a growing need for checks following administration and before operation, owing to reported side effects of severe hemorrhaging.

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Sysmex's Measurement Platform

CS-5100 Launched July 2011

CS-2500 Launched October 2014

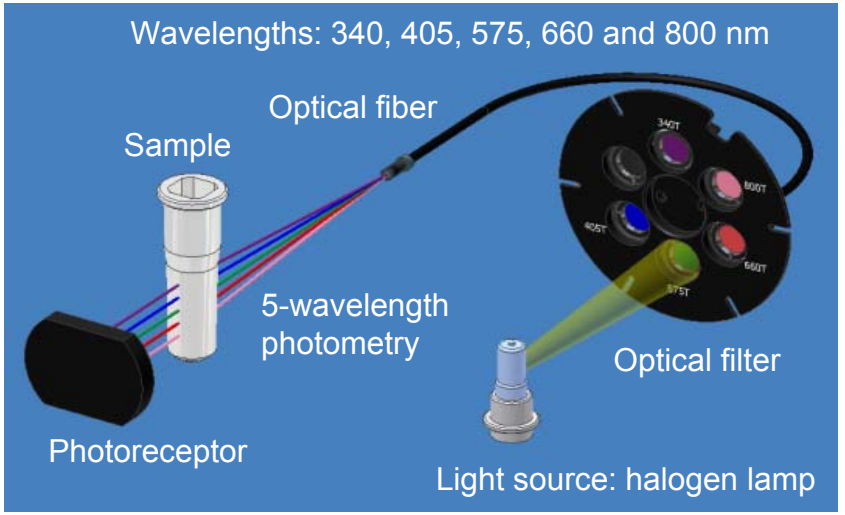
CS-1600 Launched January 2015

Note: The CS-1600 does not employ the agglutination method.

Measurement principles

Coagulation time method	Light source: halogen lamp Wavelengths: 405, 660 and 800 nm
Chromogenic substrate method Turbidimetric immunoassay method Agglutination method	Light source: halogen lamp Wavelengths: 340, 405, 575 and 800 nm

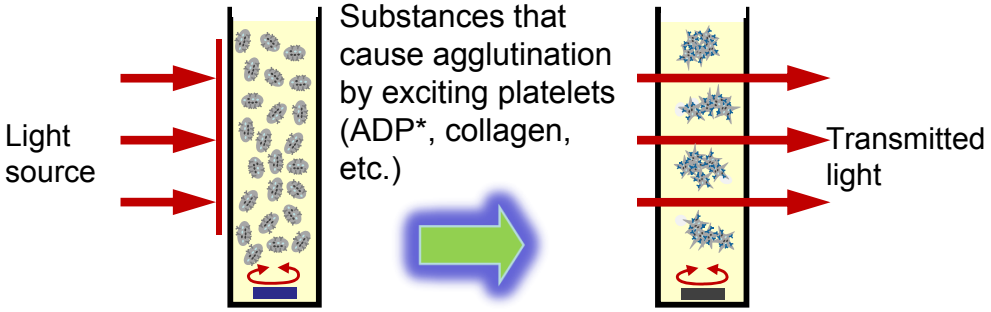
Multi-wavelength detection technology



Note: By rotating the optical filter continuously at a rate of 10 revolutions per second, changes in the specimen can be determined as the measured wavelength switches.

Sysmex's Measurement Platform

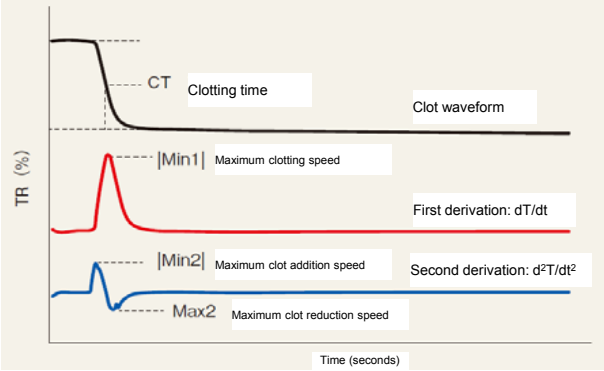
■ By using agglutination method principles to measure platelet aggregation assay, application is expected for arterial thrombosis treatment (determination of antiplatelet drug efficacy)



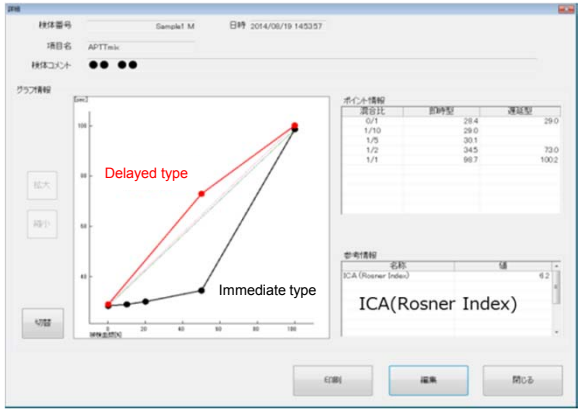
* ADP: Adenosine diphosphate

■ Analysis methods for which broad clinical application is expected

<Clot waveform analysis (for research)



<Cross-mixing test>



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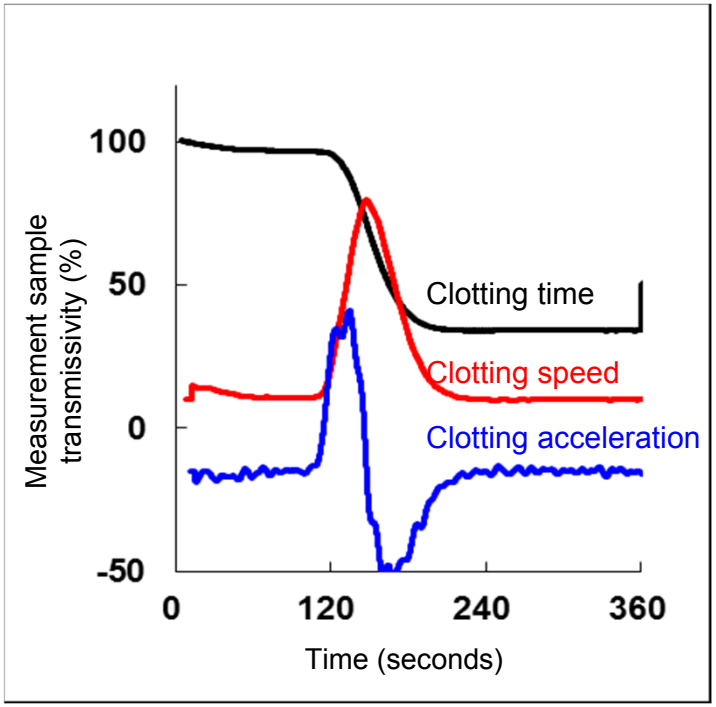
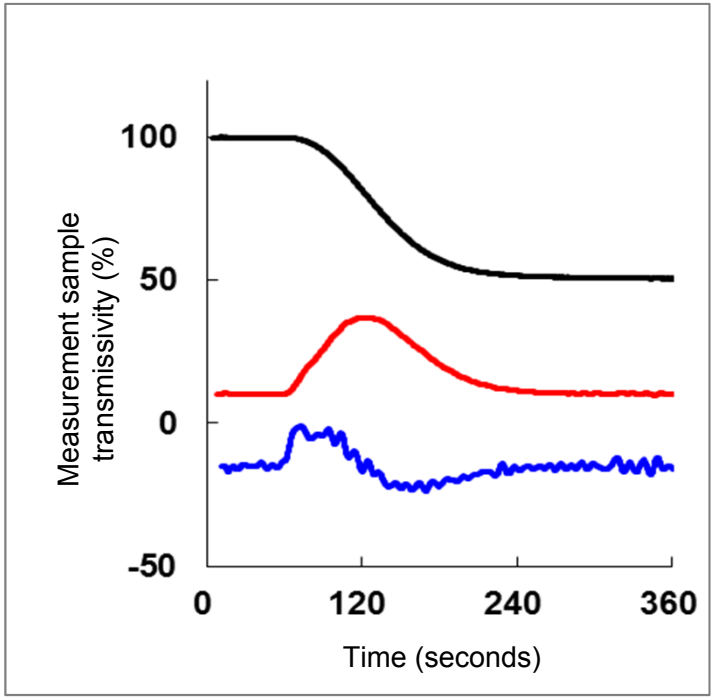
The Future of Clot Waveform Analysis Function

Example) For one blood clotting test, measurement of the activated partial thromboplastin time, a comparison of three examples of clot waveform analysis having approximately the same degree of clotting time extension

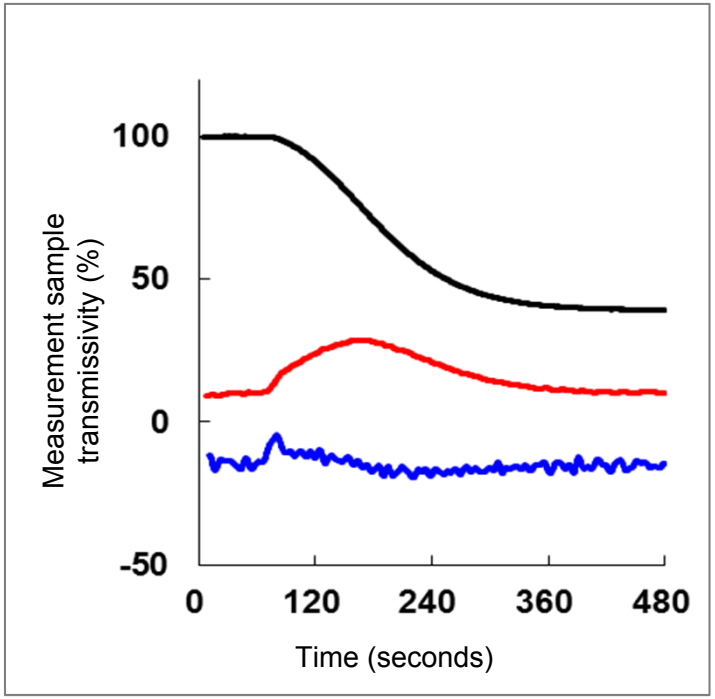
Lupus Anticoagulant
<Thrombotic disease>



Hemophilia A (No Inhibitor*)
<Hemorrhagic disease>



Hemophilia A (With Inhibitor*)
<Hemorrhagic disease>



Expected application for separating pathological conditions (diagnostic aid) for conditions that are difficult to assess using clotting time alone

- The inhibitors referred to here are circulating antibodies that attack coagulation factor proteins, a cause of hemophilia, and inhibit their function.

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Hyphen BioMed (HBM) and Its Strengths

Hyphen BioMed
(Joined the Sysmex Group in October 2010)

Corporate Profile

Headquarters	Outskirts of Paris, France
Established	January 1999
Employees	80 (fiscal 2014)
Principal businesses	Development, manufacture and sale of diagnostic reagents for thrombotic, hemostasis and autoimmune disorders
Major customers	Hospitals, pharmaceutical companies, scientific and research institutions

HBM's Business Model

Pharmaceutical companies:
Boehringer-Ingelheim, Bayer,
Bristol-Myers Squibb, others

Evaluate therapeutic drug efficacy and request development of testing kits for quality control

Improve existing assays, provide quickly

Hyphen BioMed

Determine breaking trends (pre-emptive launch) and provide assays that serve as the gold standard

Hyphen BioMed Diagnostic Drugs for NOACs

Antithrombotic Therapy	Diagnostic Drug	Control Calibrator
Dabigatran	Hemoclot® Thrombin Inhibitor	Dabigatran Calibrator and Controls
Rivaroxaban	Biophen® DiXaI Biophen® Heparin LRT	Biophen® Rivaroxaban
Apixaban	Biophen® DiXaI Biophen® Heparin LRT	Biophen® Apixaban

Coagulation tests and their interpretation[2]

PRADAXA® treatment does not need routine clinical monitoring, neither for short-term nor for long-term treatment. However, in cases of suspected overdose or in patients treated with PRADAXA® presenting in emergency departments, it may be advisable to assess the anticoagulation status of a patient treated with PRADAXA®. There is a close correlation between plasma dabigatran concentration and degree of anticoagulant effect. The following tests may serve to assess the risk of bleeding (see Figure 1):

- **Activated partial thromboplastin time (aPTT)** test may be useful in determining an excess of anticoagulant activity, despite aPTT being less sensitive to the activity of dabigatran above therapeutic levels.[1,2] **Please note:** in the first 2–3 days after surgery, false prolonged measures may be detected.[2,3]
  - **An aPTT >80 seconds at trough (when the next dose is due)** is associated with a higher risk of bleeding.[2,4]
- The actual **Thrombin Time (TT)** test measure will depend on the coagulometer and of the thrombin lot used for the measurement. It is therefore advisable to use the **calibrated Hemoclot® Thrombin Inhibitor assay** (a diluted TT assay) with dabigatran standards to calculate the dabigatran concentration rather than to determine TT.[2]

- The actual **Thrombin Time (TT)** test measure will depend on the coagulometer and of the thrombin lot used for the measurement. It is therefore advisable to use the **calibrated Hemoclot® Thrombin Inhibitor assay** (a diluted TT assay) with dabigatran standards to calculate the dabigatran concentration rather than to determine TT.[2]

Hyphen BioMed is a pioneer in the development of diagnostic drugs for new oral anticoagulants (NOACs)

In Europe, it is already recommended practice to use Hyphen BioMed's kit for Dabigatran

■ Excerpted from the Prescriber Guide (published by Boehringer-Ingelheim) for Dabigatran in Europe (product name: Pradaxa in Japan, Pradaxa in Europe)

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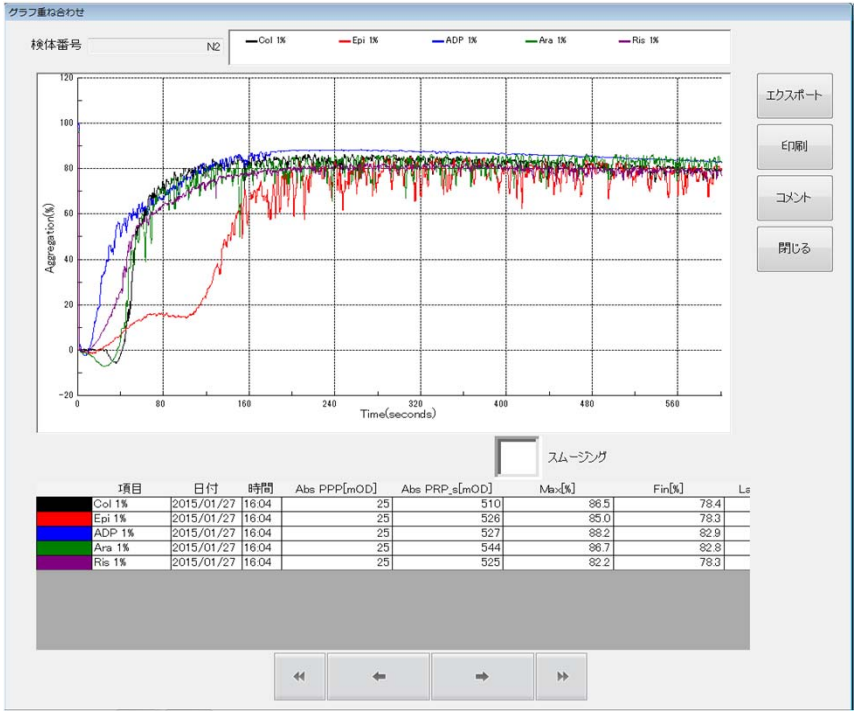
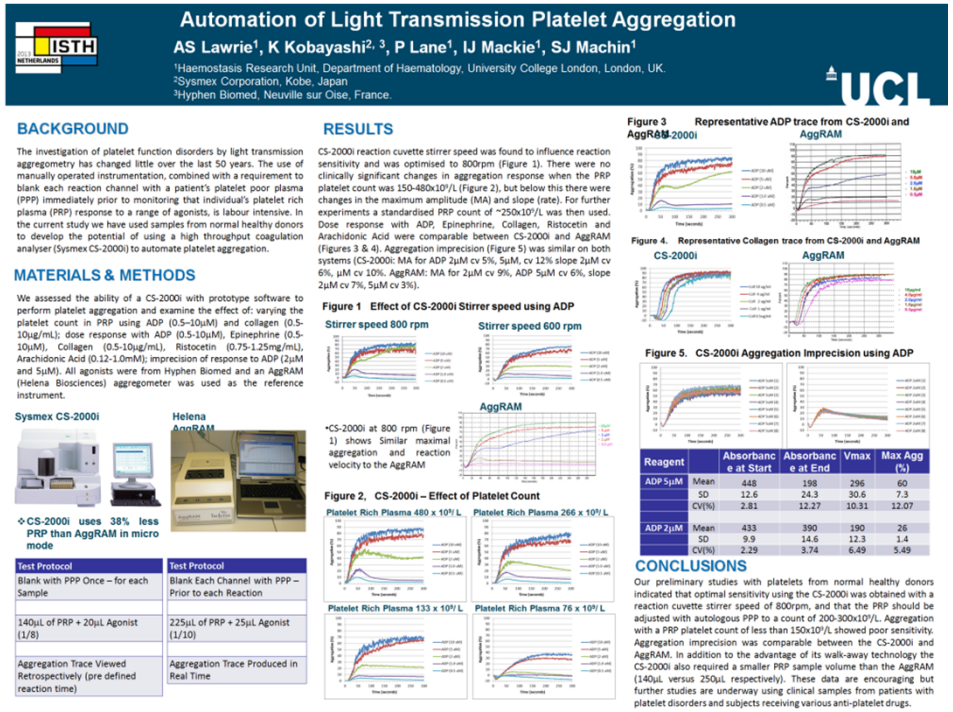
Application to Measurement of Platelet Aggregation

Example of platelet aggregation measurement using the CS-Series and Hyphen BioMed's reagents (showing the superposition of aggregation waveforms due to various causative agents)



Report of results obtained in collaboration with the University of London clearly indicating equivalent measurement results obtained by the CS-Series and a conventional method using a platelet aggregometer. Reported at the 24th Congress of ISTH (International Society on Thrombosis & Haemostasis), which took place in the Netherlands in 2013.



■ Use of the CS-Series in combination with Hyphen BioMed's reagents is expected to contribute to the standardization of simple measurement results in tests for platelet aggregation, without requiring specialized platelet aggregometers

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Application to CS-Series Platform

Hyphen BioMed

Development of diagnostic drugs suited to new medications

- NOACs
- Platelet inhibitors
- Extended-use hemophilia therapies

sysmex

Development of platforms suited to various assays

CS-5100

CS-2400/2500

CS-1600

- Clot waveform analysis (CWA)
- Cross-mixing test
- Four measurement principles
  - Coagulation
  - Chromogenic substrate
  - Turbidimetric immunoassay
  - Agglutination

+

Development of applications to maximize the performance of diagnostic drugs

Achieve through HBM's strength in developing future clinical value and the CS-Series

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3. Progress on Research and Development Themes

(2) ICH Business Unit

Youichi Takahama, Executive Vice President of the
Immunology & Chemistry Product Engineering Div.

2) HISCL Reagent Portfolio and Technology Perspectives

- M2BPGi Reagent；N-Linked Gi（Glycosylation isomer）measurement
- Newly developed O-Linked Gi Measurement Technology
- Development of New Bile Duct Cancer Marker

3) HISCL Instrument Superiority

4) Manufacturing Immunochemistry Reagents Employing Leading-Edge Technologies

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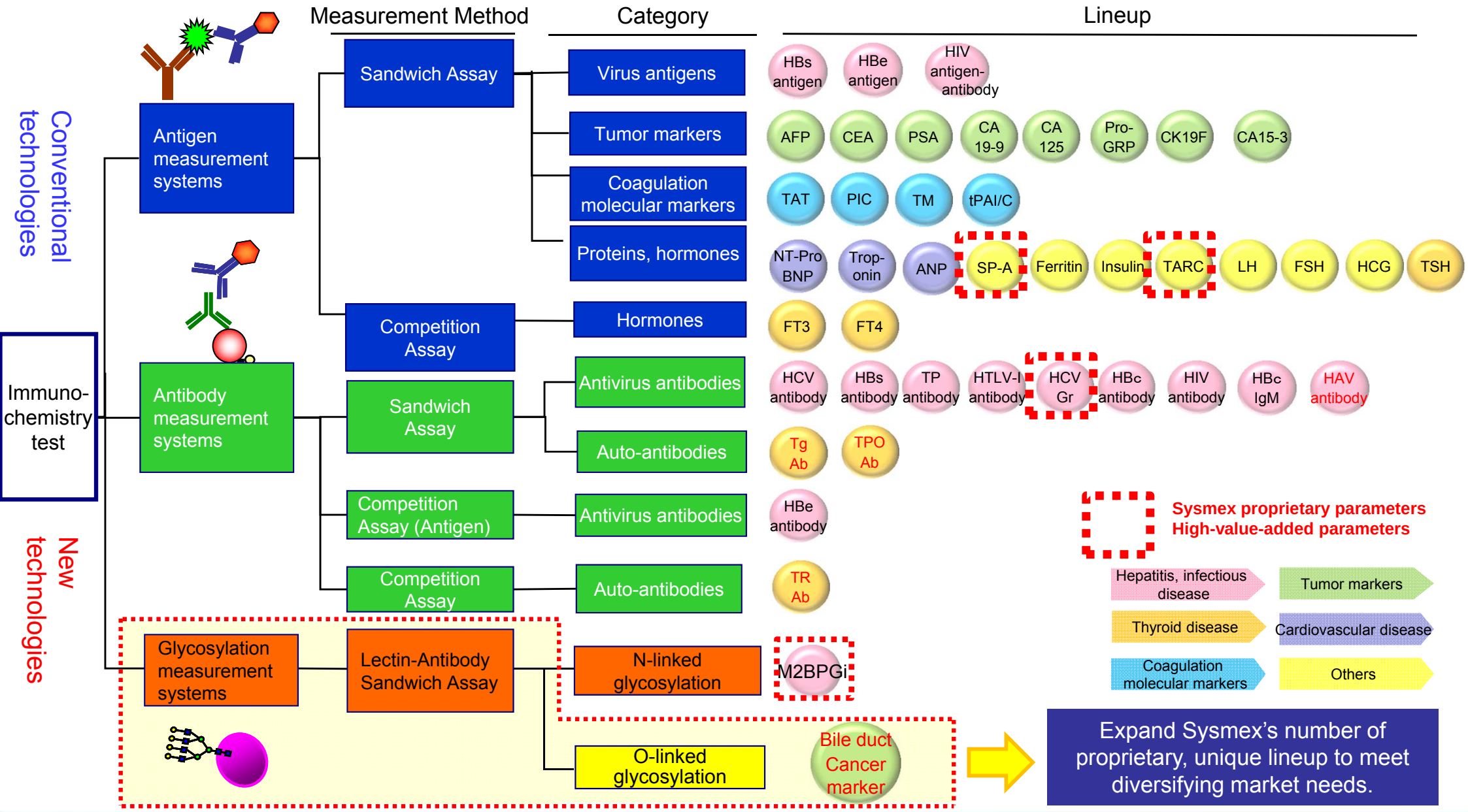
2) HISCL Reagent Portfolio and Technology Perspectives



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M2BPGi Assay Kit

Date of insurance coverage: January 1, 2015

Content of insurance coverage

- Measurement item: Mac-2 Binding Protein (M2BP) glycosylation isomer
- Medical fee points: D215-2 liver stiffness measurement 200 points
  D026-3 clinical chemistry test (I) diagnosis fee 144 points

Overview of the M2BP glycosylation isomer

- Measuring method: Chemiluminescent enzyme-linked immunoassay using a two-step sandwich method
- Content of measurement: Measurement of M2BP glycosylation isomer in the serum (Support in diagnosing the progression of hepatic fibrosis)
- Efficacy: For use with respect to diagnosis and treatment of chronic hepatitis and liver cirrhosis (including suspected cases) in support of assessment of the stage of hepatic fibrosis, indication of therapeutic regimen, and therapeutic monitoring.

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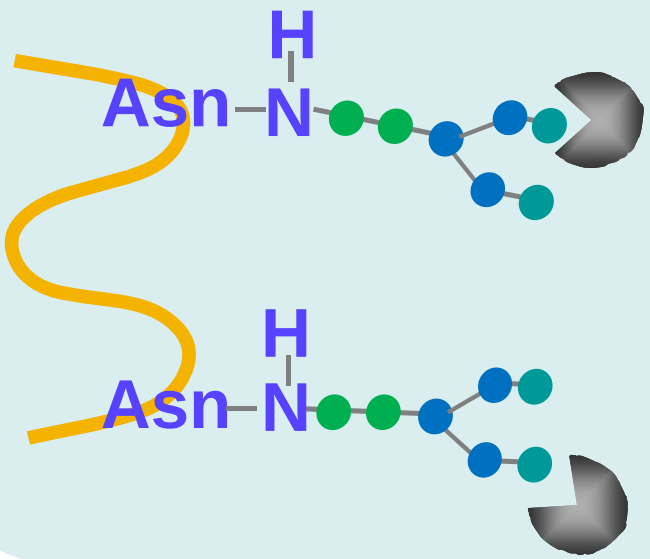
Newly developed O-Linked Gi Measurement Technology

N-linked glycoproteins

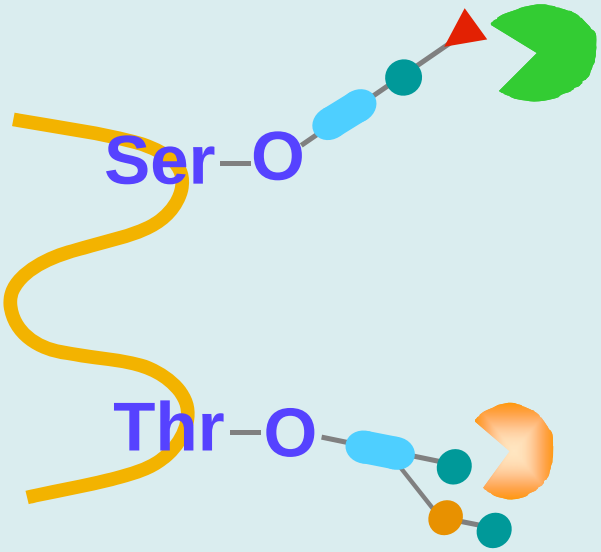
M2BPGi: Hepatic fibrosis marker



New technology

O-linked glycoproteins

Consider application as marker for bile duct cancer



Following N-linked glycoproteins, the established technology allows to detect Glyco-alterations in the O-linked glycoproteins.

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Development of Novel cholangiocarcinoma Marker

- Bile duct cancer has an extremely high degree of malignancy, and the prognosis is unfavorable.
- This cancer is difficult to distinguish from hepatocelluer carcinoma, which has an altogether different treatment regimen.

→ If early detection were possible, cures could be anticipated for an increased number of patients.

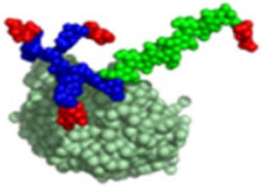
[Issues with existing image inspection]

- The bile duct is located within the liver, so histological differentiation using such methods as echographic testing is problematic.
- Tends to miss initial-stage cancer.
- Unsuited to screening tests

Glycosylation markers (detecting qualitative changes) are effective at obtaining a differential diagnosis between bile duct cancer and hepatocelluer carcinoma.

HISCL-5000

Glycosylation marker



Assay configuration to enable measurement in 17 minutes

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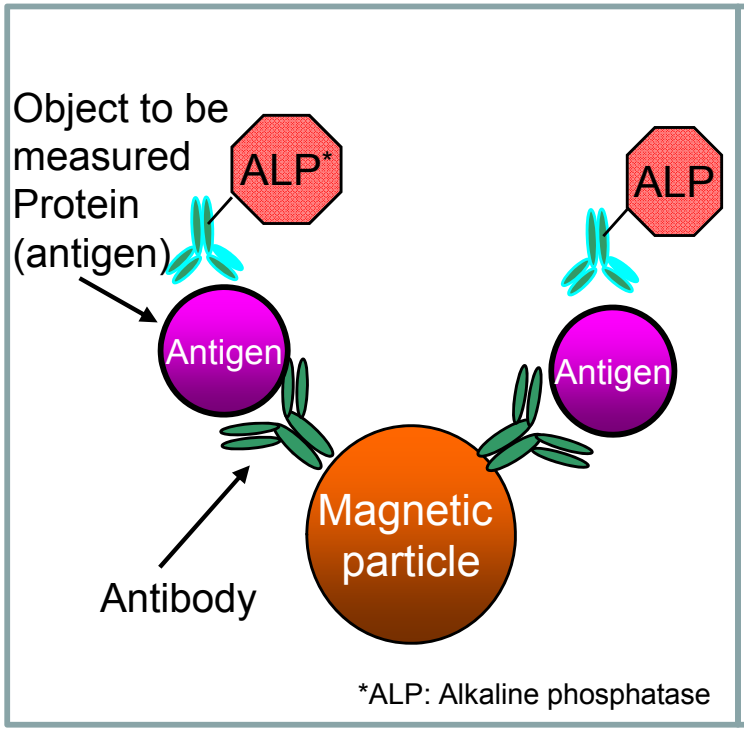
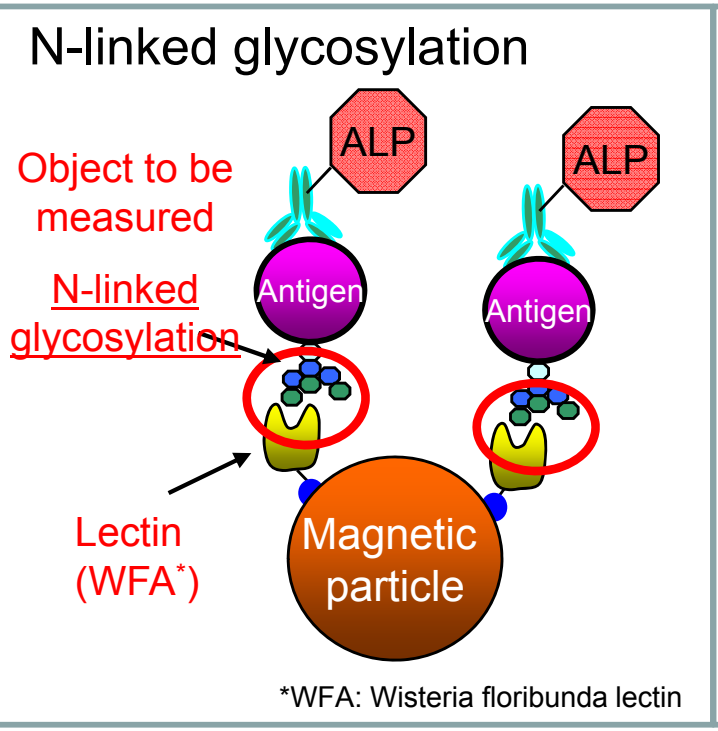
Development of Novel cholangiocarcinoma Marker

[Conventional technology]



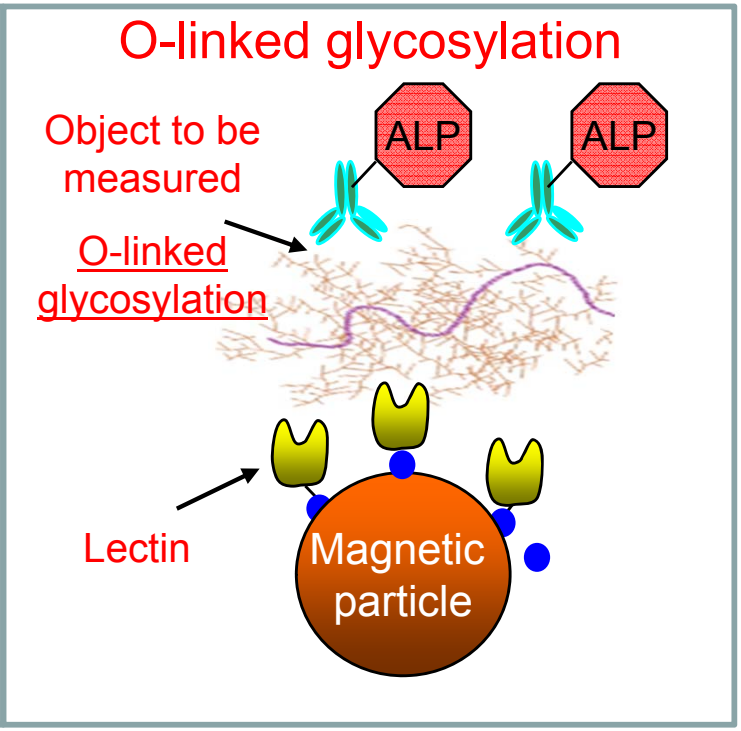
- Infectious disease, tumor marker, etc.

N-linked glycosylation



- M2BPGi (hepatic fibrosis marker)

[New technology] O-linked glycosylation



- Glycosylation marker for bile duct cancer

We have accumulated proprietary technologies and extended our product lineup, Gi-Series of glyco-biomarkers to meet diversifying market needs.

Copyright by Sysmex Corporation

3) HISCL Instrument Superiority

Copyright by Sysmex Corporation

Development Concept Behind New HISCL-800

HISCL-800 development concept

New

A space-saving model that carries forward the HISCL-Series product concept

Highly sensitive

Rapid

Minute specimens

High usability

+

- ✓ Compact
- ✓ Environmentally responsive
- ✓ Data compatibility

=

HISCL-800

Sample HISCL-800 Applications

Routine testing
For rapid measurement to meet nighttime or urgent testing requirements
As a specialized instrument for specific parameters
As a backup instrument
For introduction in emerging markets, etc.

Allows for a wide range of proposals in response to operational needs

Copyright by Sysmex Corporation

Space-Saving, Electricity-Saving Design, Fast Measurement (17 Minutes)

Approximately 60% the size of the HISCL-5000

- ✓ Internal component layout rearranged
- ✓ Housing configuration changed
- ✓ Reduced number of attached reagents, decreased volumes

Maximum power usage reduced to less than 1,200VA

- ✓ Reduced reaction tower heater capacity
- ✓ Reconfigured instrument operating controls

⇨ Able to operate on 100V AC

An easy-to-position instrument with a smaller footprint and compatible with 100V AC electricity

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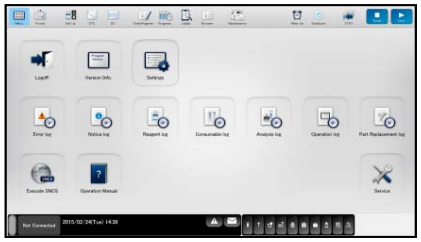
Simple Operation, Convenient Functions

Large 21-inch color touch-screen display (same for the HISCL-5000 and 800)

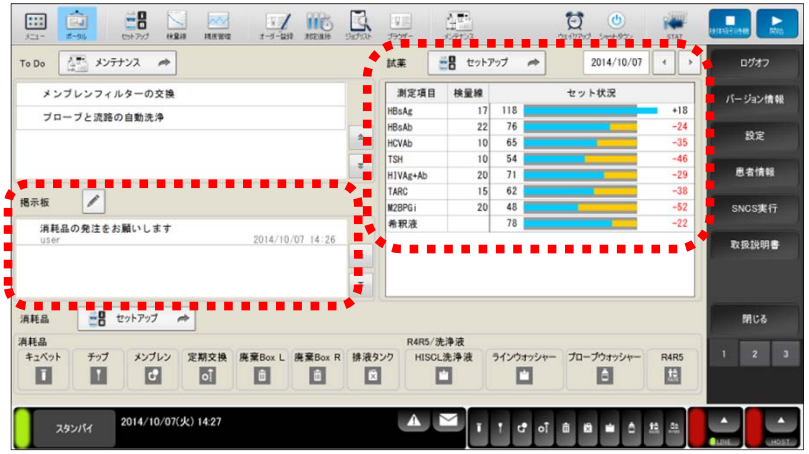
<<Choice of three languages>>

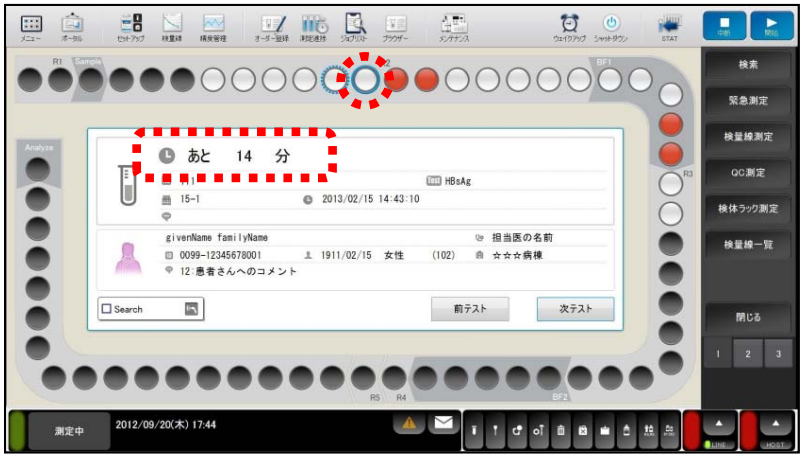
Japanese

English



Chinese





<<Portal screen>>

* Based on past results, simulates number of tests and indicates excesses and deficiencies
  ⇒Increase operating efficiency through advance preparation

* Column for entering comments
  ⇒Effective when passing on operations to someone else

<<Measurement progress screen>>

* Indicates time until measurement of each test is complete
* Allows searches by patient information and by IDs
  ⇒Enables swift response to lab inquiries

User-friendly interface to support routine testing operations

Copyright by Sysmex Corporation

Reagent Management Technologies

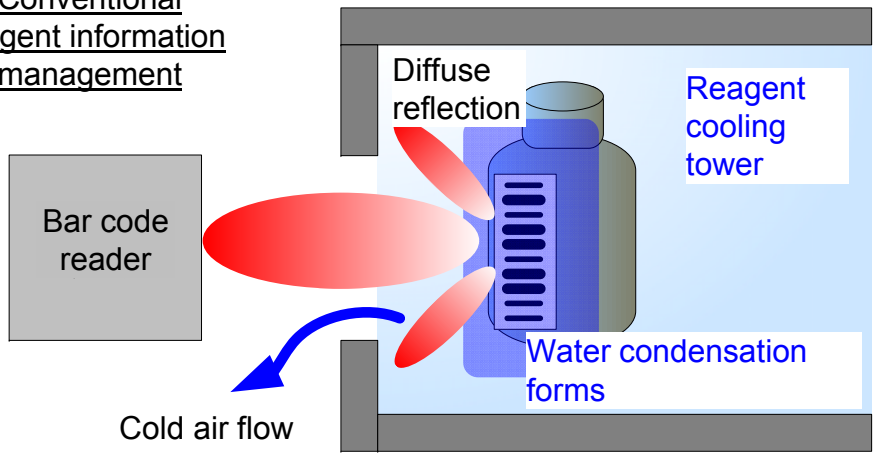
Reagent management technology using RFID* (same for the HISCL-5000 and 800)

*Radio Frequency IDentifier

●Reagent containers store information
Read from/write to the container's ID tag to determine measurement items, lot and serial numbers, storage life, date opened, remaining quantity and other information

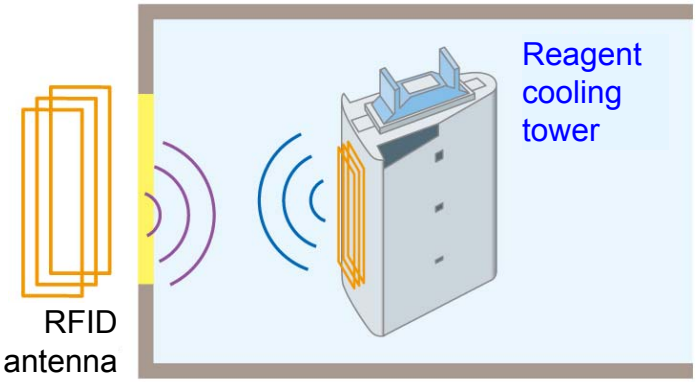
[Applying for several patents related to this technology]
- Reagent management technology
- RFID-usage technology, and several others

Conventional reagent information management



In some cases, bar codes cannot be read if dirty or water condensation forms

Reagent information management using RFID



- Can be read accurately regardless of condition
- Can be shared on HISCL-5000 and 800

Only Sysmex provides immunoassay analyzers with RFID reagent management

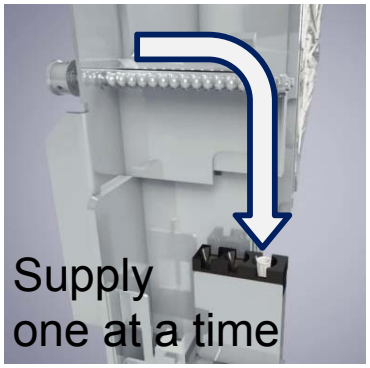
Copyright by Sysmex Corporation

Automated Consumables Supply Technology

Automated disposable tip supply technology for sample dispensing (same for the HISCL-5000 and 800)

- Simply load directly from the bag; instrument automatically sorts and supplies
  Note: The same for reaction cuvettes

[Several patents pending on this technology]
- Automated alignment technology
- Tip shape to prevent double-insertion, and several others

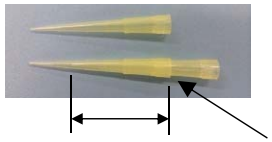


Note: Possible even during measurement

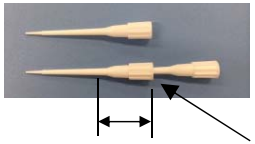
- HISCL tip shape

Difficult to split into two, and easy to misalign

Standard tip



HISCL tip



Automated consumables supply function essential at high-volume labs in China and other locations

Copyright by Sysmex Corporation

Sample Amount Used

(μL)

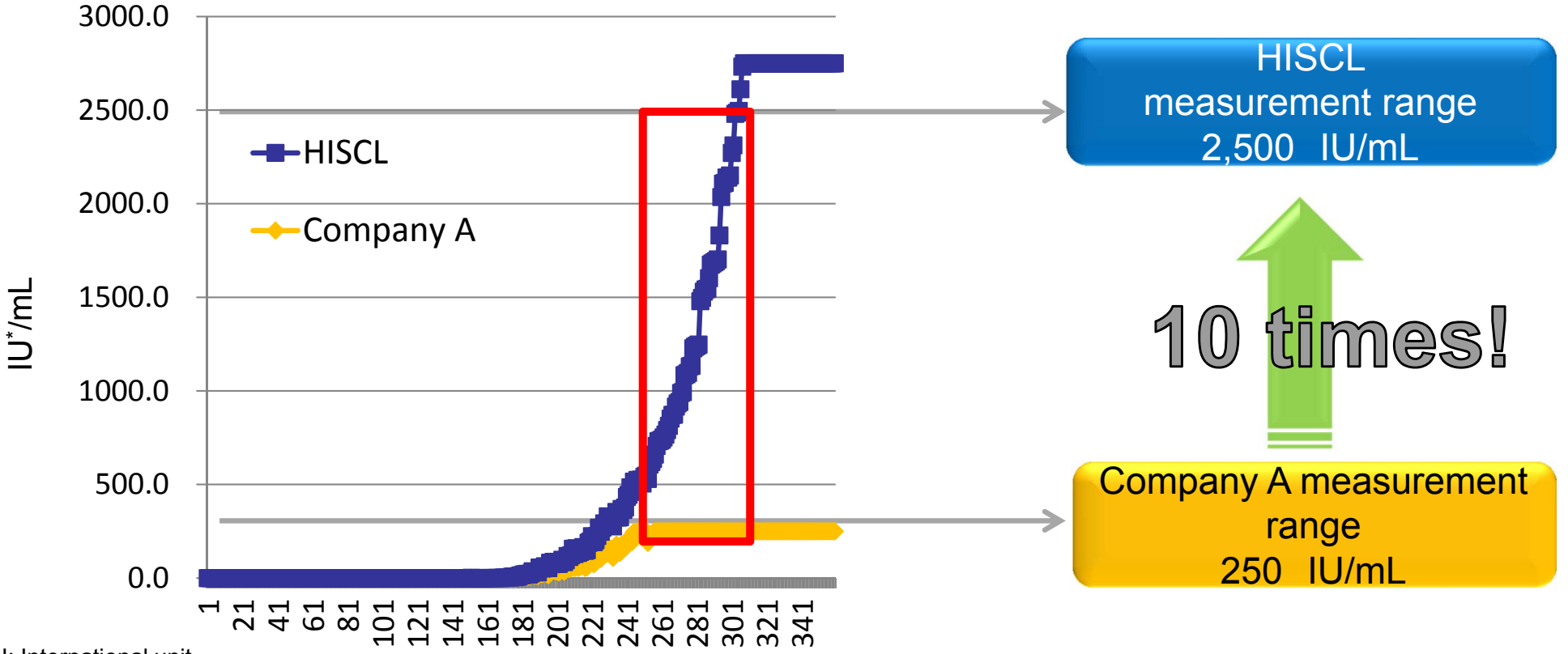
		HISCL CLEIA Method	Company A CLIA Method	Company B CLEIA Method
Preoperative testing Transfusion-transmitted diseases 4 parameters	HBsAg	20	75	100
	HCV	10	20	10
	HIV	30	100	100
	TP	20	30	20
	Total (Compared with HISCL)	**80**	225 (2.8 times)	230 (2.9 times)
Prediagnostic testing Thyroid gland 3 parameters	FT3	10	25	50
	FT4	10	45	10
	TSH	30	150	50
	Total (Compared with HISCL)	**50**	220 (4.4 times)	110 (2.2 times)

Compatible with minute sample quantities, allowing samples to be used for retesting

Copyright by Sysmex Corporation

Strengths of HISCL HBsAg (Wide Range)

■ HBsAg measurement diffusion data (positive) from results of clinical studies in China



*IU: International unit

	0.05–250	250–2500	More than 2500	Total
HISCL	80	67	53	200
Company A	92	108 (55)	-	200

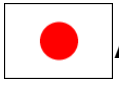
Wide-ranging measurements reduce the retesting rate and shorten reporting times

Copyright by Sysmex Corporation

HISCL Instrument Superiority

	HISCL CLEIA Method	Company A CLIA Method	Company B CLEIA Method
High sensitivity (* luminescent substrate)	Employs CDP-Star*	CDP-Star offers several times higher sensitivity than the luminescent substrates used by other companies.	
Reaction time	17 minutes	29 minutes	20 minutes/ 25 minutes
Minute samples Wide range	All parameters 10–30μL	For certain parameters, required sample volumes are several times that for the HISCL, and measurement ranges are narrower than on the HISCL	
Usability	Multifunctional, Simple operation	The HISCL has an as-needed reagent top-up function. Only Sysmex provides RFID reagent management.	
Common reagents (data compatibility)	Common across the series	Common across the series	Reagents differ within the series

[Number of patent applications on the HISCL-Series]


Approx. 60


Approx. 40



Approx. 80

Future Immunochemistry Business Employing HISCL Systems

Provide new value and expand globally

Create value by obtaining biomarkers through open innovation

Collaborative research, development and practical realization

- Industry
- Government
- Academia

Further HISCL-Series advances

Ultrahighly sensitive system

- **M2BPGi: Contribute to new diagnoses in the progression of hepatic fibrosis**
- **TARC: Rapid diagnosis of atopic dermatitis**
- **HIV Ag+Ab: Enhance attributes through human monoclonal antibodies**
- **HCV Gr: By differentiating HCV groups, predict results of interferon therapy for hepatitis C**
- **HBsAg: Improve quality of HBV testing flow with speed, high sensitivity, wide range and enhanced characteristics**

Technology platform

HISCL-Series

Provide clinical value by expanding globally

- Starting with Japan, full-fledged development into China, AP and other regions
- Contribute to healthcare by providing high clinical value

Copyright by Sysmex Corporation

4) Manufacturing Immunochemistry Reagents Employing Leading-Edge Technologies

Copyright by Sysmex Corporation

Manufacturing Immunochemistry Reagents Employing Leading-Edge Technologies

SPring-8 & SACLA

- All-Japan, national critical technologies project
- This facility located in northwestern Hyogo Prefecture, adjacent to Sysmex company

Lectin Arrays

- National Institute of Advanced Industrial Science and Technology
- World's first glycan profiling technology

Mass Spectrometry

- Technology developed by Dr. Koichi Tanaka
- Nobel Prize-winning technology

Creation of integrated fundamental technologies contribute to the elucidation of biological diagnostic reagents.

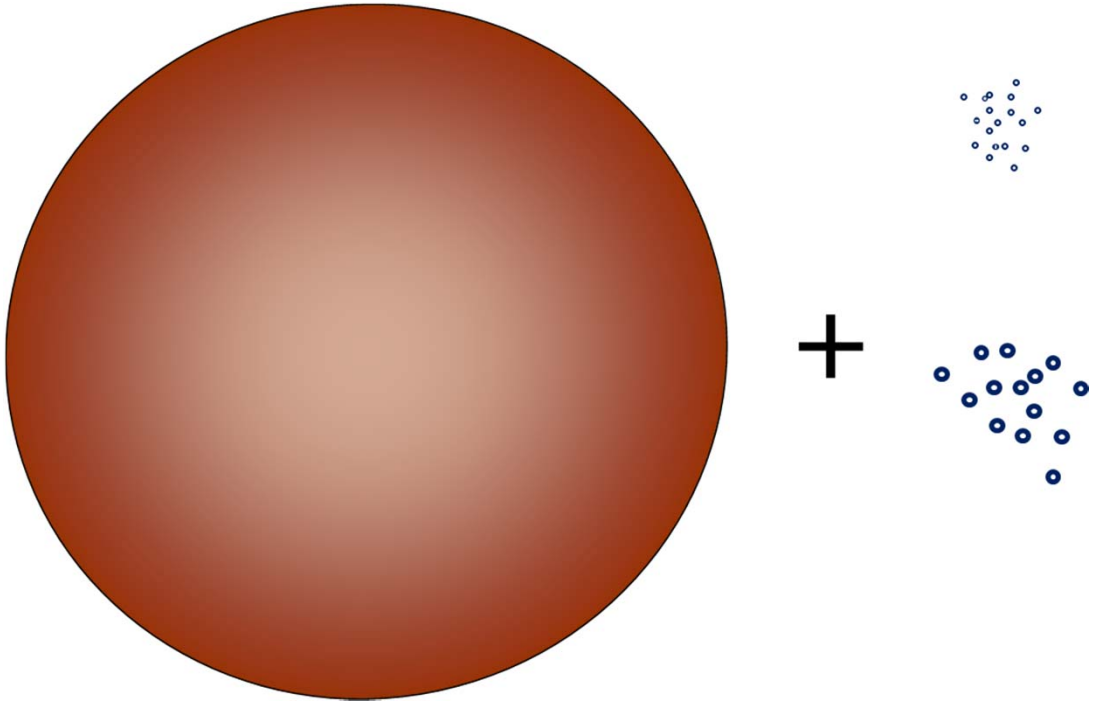
Copyright by Sysmex Corporation

Manufacturing Immunochemistry Reagents Employing Leading-Edge Technologies

Milli → 1/1000 → Micro → 1/1000 → Nano

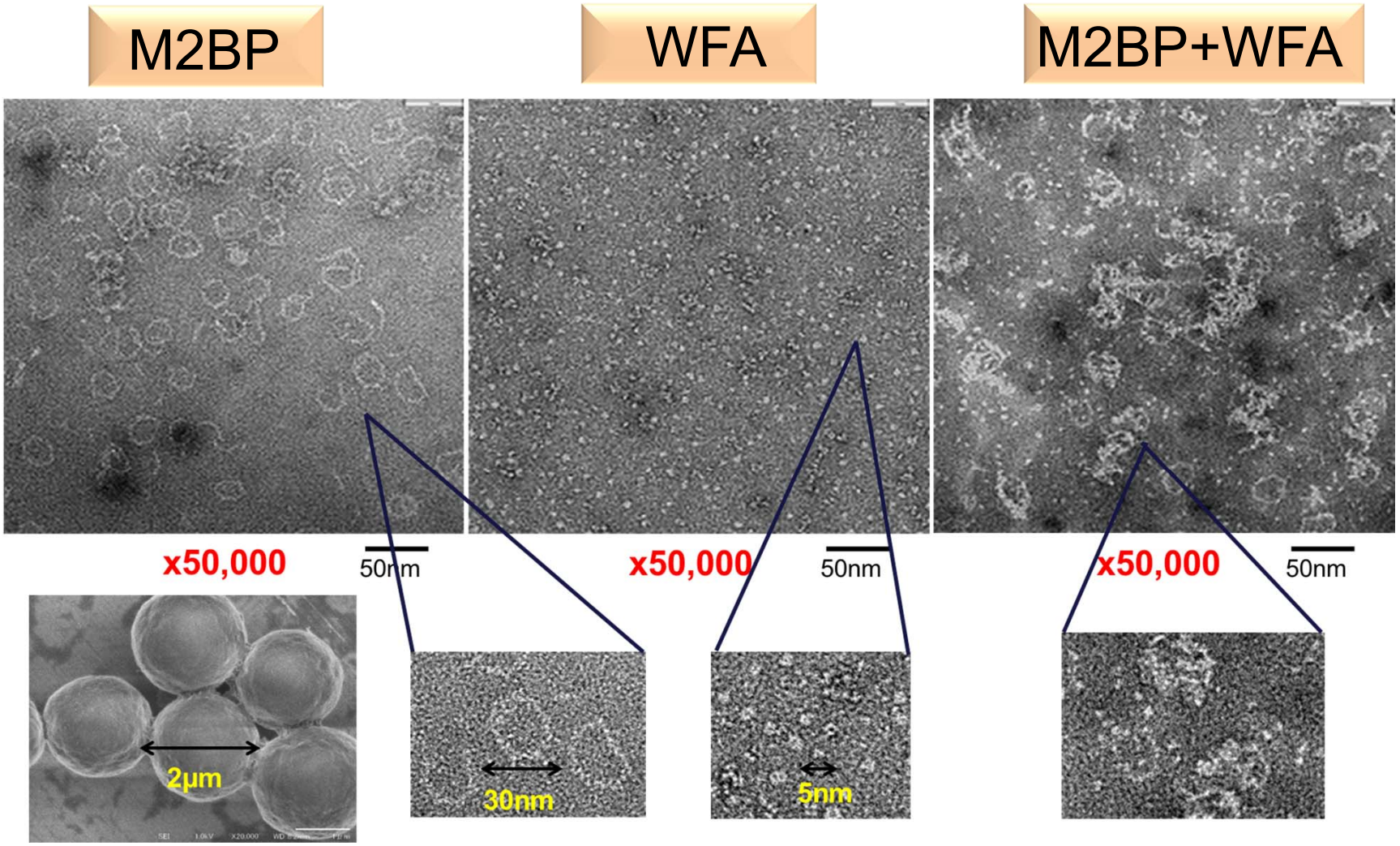
Magnetic particles

Antibodies, lectin



Product developments in the nanotech (1/1,000,000,000) world, where we could not visible.

Manufacturing Immunochemistry Reagents Employing Leading-Edge Technologies



The overview of visible particle inspection, which will lead us to resolve many unknown issues until now.

3. Progress on Research and Development Themes

(3) LS Business Unit

Mamoru Kubota, Executive Vice President of the
Life Science Product Engineering Div.

[Progress on the Sysmex Inostics Business]

1) Business Progress Since Acquisition

2) OncoBEAM™ Assay Service Products

3) Plasma-Safe-SeqS (PSS) Technology

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1) Business Progress Since Acquisition

Acceleration of Global Business Development

Develop therapeutic drugs

Pharmaceutical companies

Drug discovery → Preclinical → Clinical → Approval → Market launch → Standard-ization

Academia

Research support (CRO* business)
Search for and validate molecular markers

sysmex

Molecularly targeted therapeutic drugs

Patients

Companion drugs

Increase the efficacy and safety of therapeutic drugs (CDx business)
Selection and monitoring of applicable diseases

Patient therapy selection (Patient Testing business)
Coverage by insurance, inclusion in medical care guidelines

Sysmex Inostics lab
Hamburg, Germany

Fiscal 2014

Partner lab in Beijing, China

Fiscal 2014

Sysmex IMP lab
Kobe, Japan

IMP: ITOCHU Medical Plaza

Sysmex Inostics
<CLIA* lab>
Baltimore, USA

Fiscal 2014

Certified lab in Europe
Established in January 2015
Vall d'Hebron Hospital in Spain

Prominent commercial labs

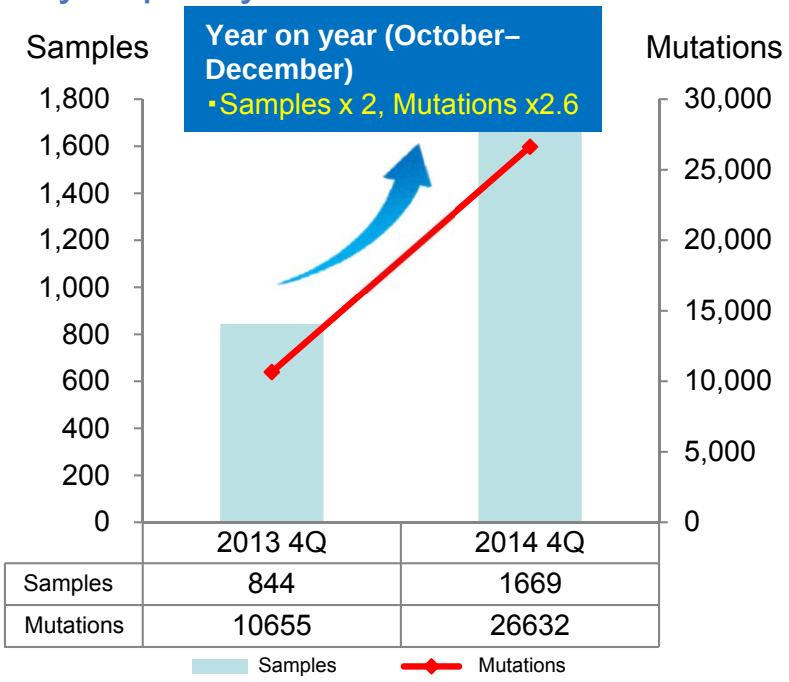
***CRO**: Clinical Research Organization

***CLIA**: Clinical I Laboratory Improvement Amendments

Business Progress Topics (1)

CRO Business

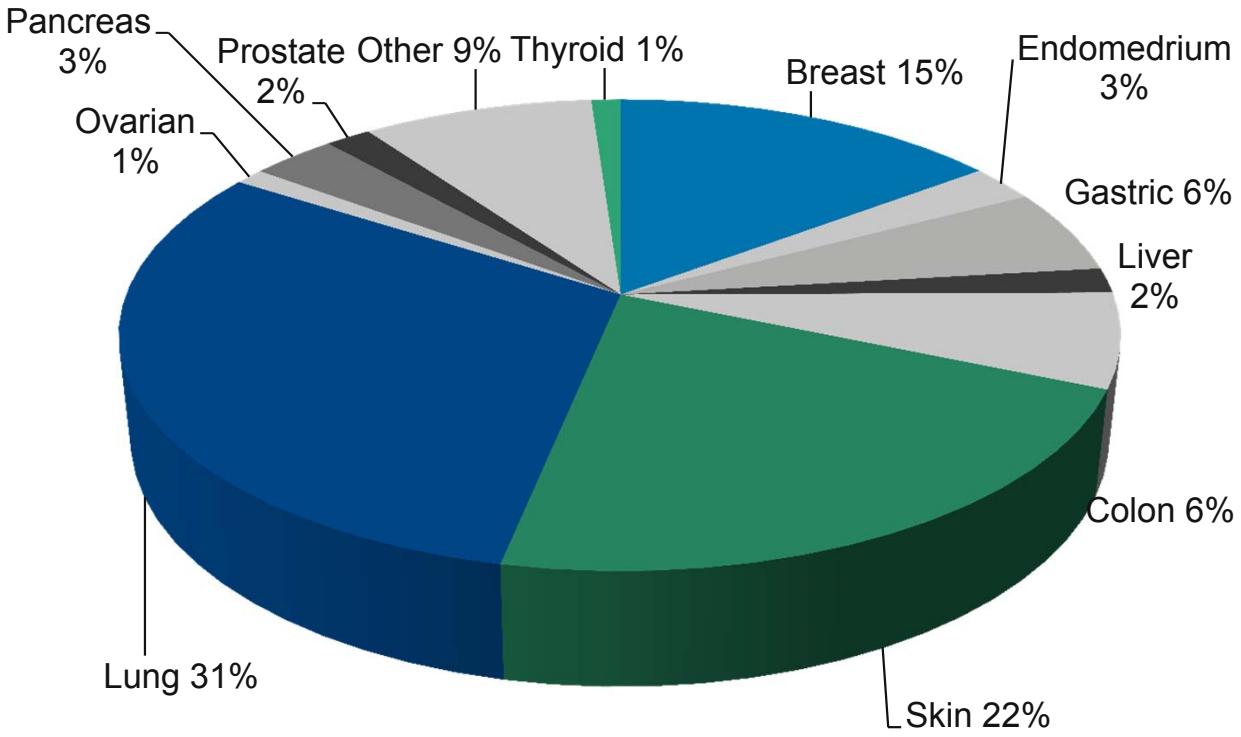
Expand business along with increase in assay capacity



Hamburg lab

Baltimore lab

- Consignments from leading pharmaceutical manufacturers (covering 70% of the top 20)
- Have measured more than 8,000 samples since acquisition
- Assays of blood tests with many types of cancer

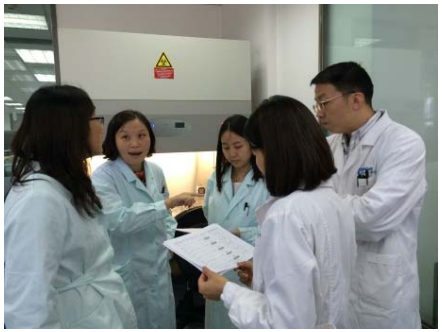


Types of Cancer Measured

Business Progress Topics (2)

CDx Business

- Completed first project with partner lab in China



- Highly regarded among customers

  Received Bayer Best Partner Award (May 2014)

From Bayer's website

Patient Testing Business

- In June 2014, Sysmex Inostics and **Merck Serono** entered into a collaboration agreement for the development and commercialization of a RAS kit for patients with mCRC

  RAS gene: Gene that controls proliferation of cancer cells

- In Barcelona, Spain, established certified laboratory in vall d'Hebron Hospital
- Also plan to establish laboratories in four other EU countries (Germany, Italy, the United Kingdom and France) and Australia

2) OncoBEAM™ Assay Service Products

OncoBEAM:

Name of the assay service product developed by Sysmex Inostics using digital PCR (high-sensitivity) technology (BEAMing method)

Copyright by Sysmex Corporation

Flow of the BEAMing Method

Gene amplification processing

Amplify the target DNA region extracted from the blood plasma

DNA extraction

Tumor DNA
Wild-type DNA

Emulsion PCR

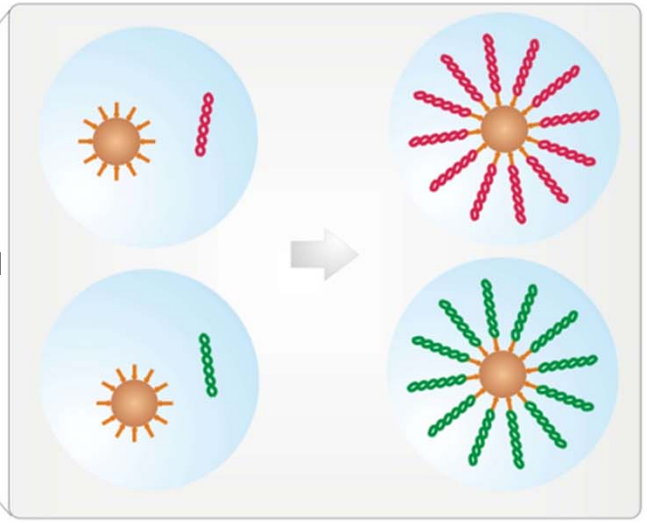
With a PCR reaction, amplify the target cancer molecules in the water-in-oil emulsion into which a magnetic bead and DNA molecule have been encapsulated

Magnetic beads coated with primer

Amplified DNA

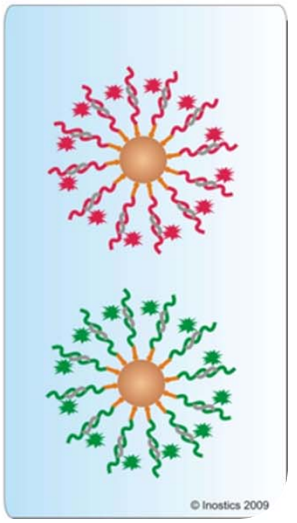
dNTP
(deoxy Nucleotide Tri-Phosphate)
Polymerase primer

Water-in-oil emulsion



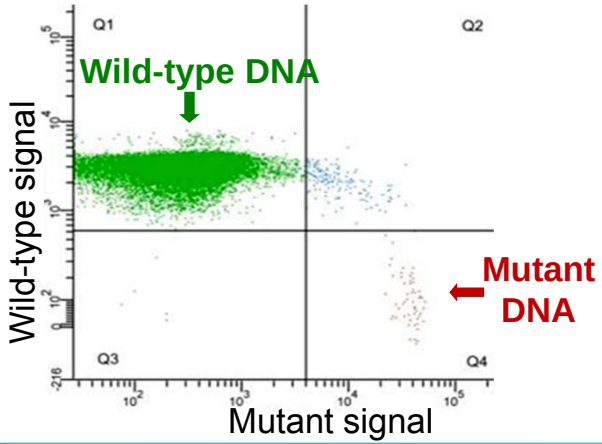
Hybridization

On the magnetic bead, form a complementary complex of the cancer cell (mutation) and fluorescent probe



Flow Cytometry Separation

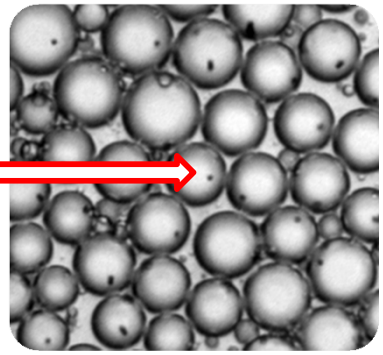
Flow cytometry analysis using the flow cytometry method



*Emulsion Characteristics

- Droplet size:
  Diameter: 3–10 μm
- Droplet density:
  ~1.5×10^6 beads/μl

Light microscope (200x)



PCR: Polymerase chain reaction

Initiatives for Automating the OncoBEAM Assay Flow

Automate assay processes (introduce liquid handling instrument)

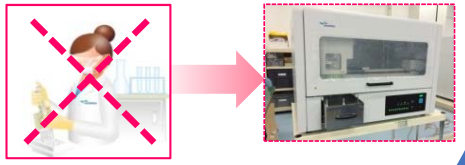
✓Labor savings (approx. 80% reduction) ✓Shorten delivery times (from three days to two)

(1) DNA extraction

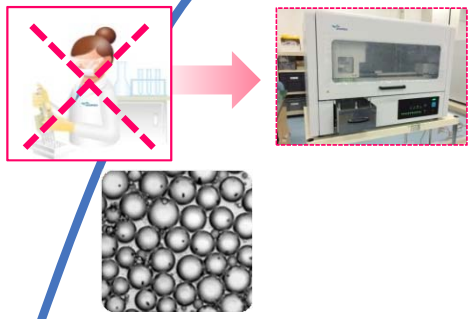
(2) PCR reagent preparation

(3) PCR

(4) Emulsion PCR reagent preparation



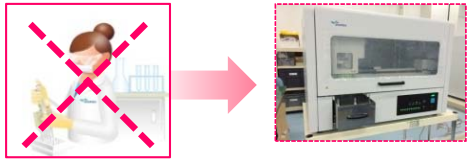
(5) Emulsification



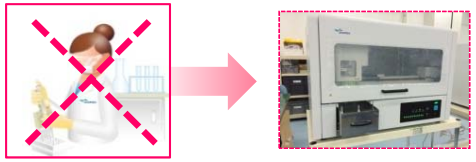
OncoBEAM liquid handling instrument

(6) Emulsion PCR

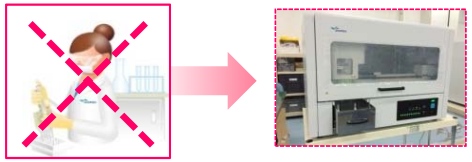
(7) Emulsion breaking



(8) Fluorescent probe hybridization



(9) Washing



(10) Flow cytometry analysis

Clinical Significance of Liquid Biopsy Analysis Using the BEAMing Method (1)

- Liquid biopsy testing delivers essentially the same level of performance on genetic mutations as tissue testing

Source	Cancer Type	Marker	Patients	Analysis Method		Concordance Rate
				Specimen	Plasma	
AACR 2013, Bayer oral presentation (AACR: American Association for Cancer Research)	Non-small-cell lung cancer	EGFR KRAS	78	PCR method PCR method	BEAMing method BEAMing method	99% 92%
ASCO 2014, AstraZeneca poster presentation (ASCO: American Society for Clinical Oncology)	Non-small-cell lung cancer	EGFR(L858R) Exon 19 deletion	38	PCR method	BEAMing method	93% 93%
CCR 2012, Higgins et al paper presentation (CCR: Clinical Cancer Research)	Breast cancer	PIK3CA	34	BEAMing method	BEAMing method	100%
JCO 2010, Angenedt et al paper presentation (JCO: Journal of Clinical Oncology)	Breast cancer	PIK3CA	50	BEAMing method	BEAMing method	100%
Nature Medicine 2013, Vogelstein et al paper presentation	Colon cancer	KRAS	10	Sanger sequencing method	BEAMing method	100%
ASCO 2013, GSK poster presentation (ASCO: American Society for Clinical Oncology)	Melanoma	BRAF (V600E/ V600K)	305	PCR method	BEAMing method	95.7%

Possible to development of companion diagnostics which are minimally invasive and convenient for cancer types or patients difficult to tissue test

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Clinical Significance of Liquid Biopsy Analysis Using the BEAMing Method (2)

For extremely small genetic mutations related to acquired resistance, possible to conduct testing with higher sensitivity than using the existing PCR method

- ✓ On plasma samples from non-small-cell lung cancer patients (n=38), the BEAMing method detected EGFR mutations with a high degree of sensitivity

EGFR Gene	Company X, PCR Method	BEAMing Method
Exon 19 deletion test	82%	90%
L858R mutation test	78%	100%
T790M mutation test	29%	69%

ASCO 2014, Company A poster presentation (partly revised)
(ASCO: American society for Clinical Oncology)

BEAMing method also useful for treatment monitoring

ESMO 2014, Company C poster presentation
(ESMO: European Society for Medical Oncology)

- ✓ For non-small-cell lung cancer patients with EGFR T790M mutation, 45% (14/31) was observed in patients who were plasma T790M positive (BEAMing method) but tissue T790M negative.

	Specimen	Plasma	
Patient	Company Y, PCR Method	BEAMing Method	Company Z, PCR Method
1	not detected	mutant (2.243%)	
2	not detected	mutant (2.036%)	mutant
3	not detected	mutant (1.113%)	mutant
4	not detected	mutant (0.491%)	mutant
5	not detected	mutant (0.344%)	
6	not detected	mutant (0.34%)	mutant
7	not detected	mutant (0.124%)	
8	not detected	mutant (0.092%)	
9	not detected	mutant (0.08%)	not detected
10	not detected	mutant (0.059%)	
11	not detected	mutant (0.058%)	
12	not detected	mutant (0.054%)	not detected
13	not detected	mutant (0.026%)	not detected
14	not detected	mutant (0.024%)	

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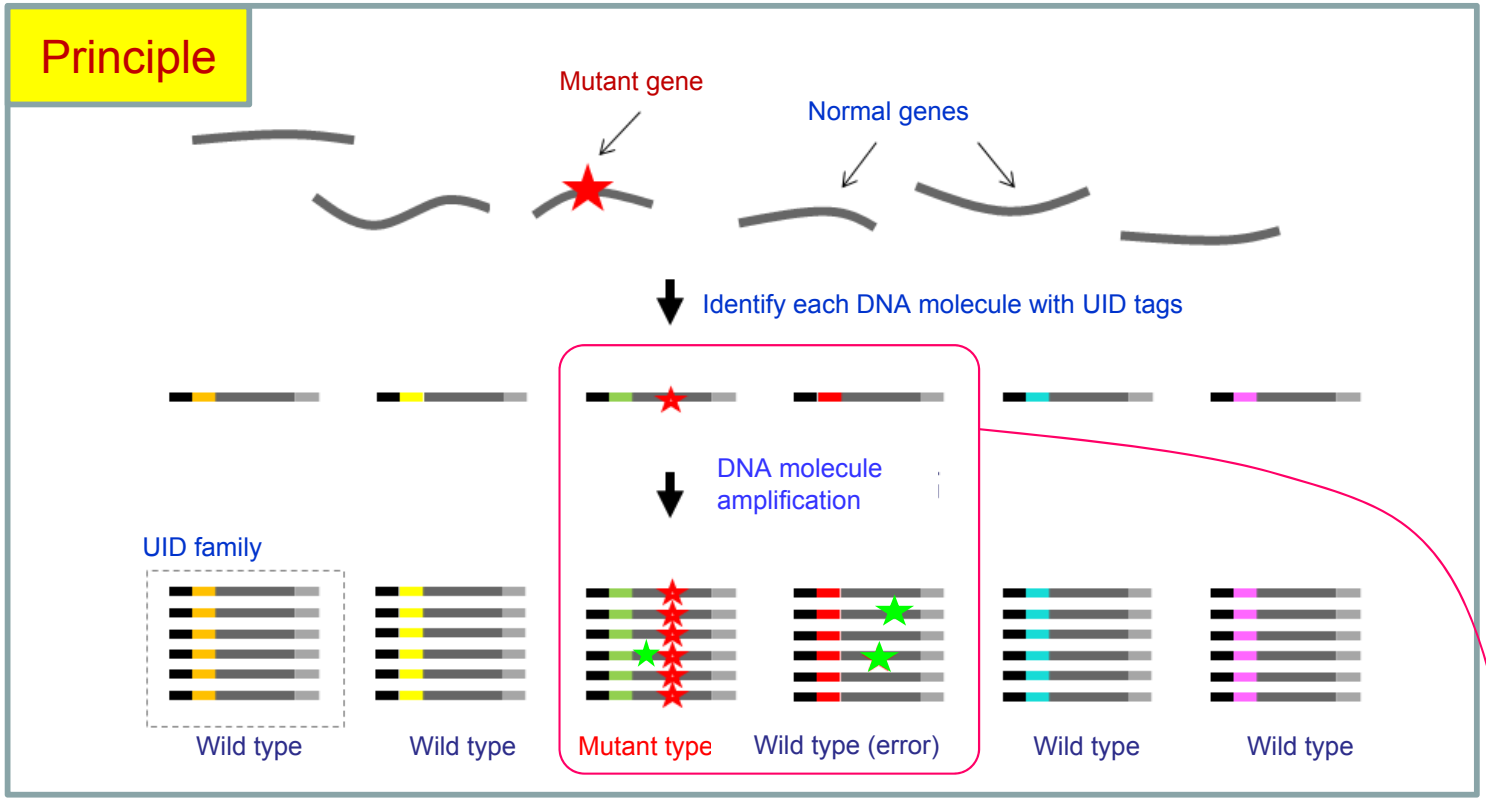
3) Plasma-Safe-SeqS (PSS) Technology

Plasma-Safe-SeqS: Highly sensitive next-generation sequence technology developed by Sysmex Inostics

Principles of Plasma-Safe-SeqS (PSS) Technology

Principle



UID: unique identifier

Measurement Flow

(1) Plasma separation and isolation of circulating DNA

↓

(2) Reaction with UID tags

↓

(3) DNA molecule amplification reaction

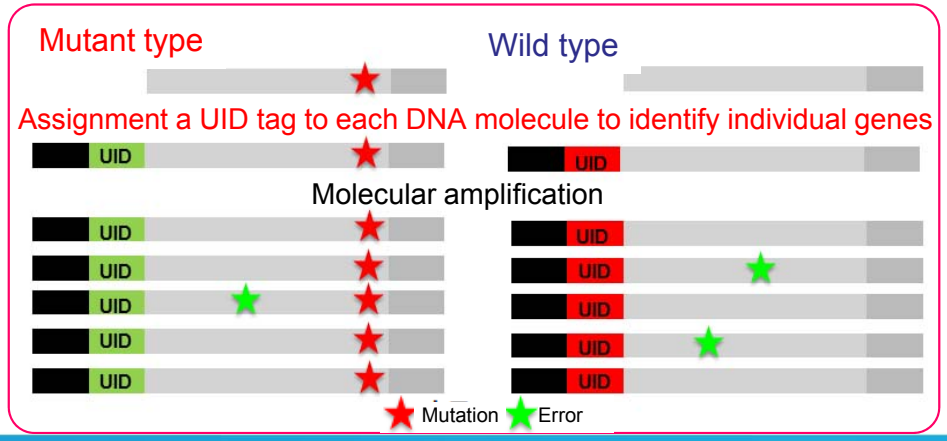
↓

(4) Sequencing analysis of target genes with next-generation sequencer

[Characteristics]

- Expected to detect specific mutant sequences on target DNA molecules with reduced error rate
- Ultrahigh sensitivity (gene mutation detection limit is generally around 1% for next-generation sequencing (NGS), but PSS achieves around 0.01%)

Effective on highly sensitive multi-gene mutation testing of liquid biopsy samples



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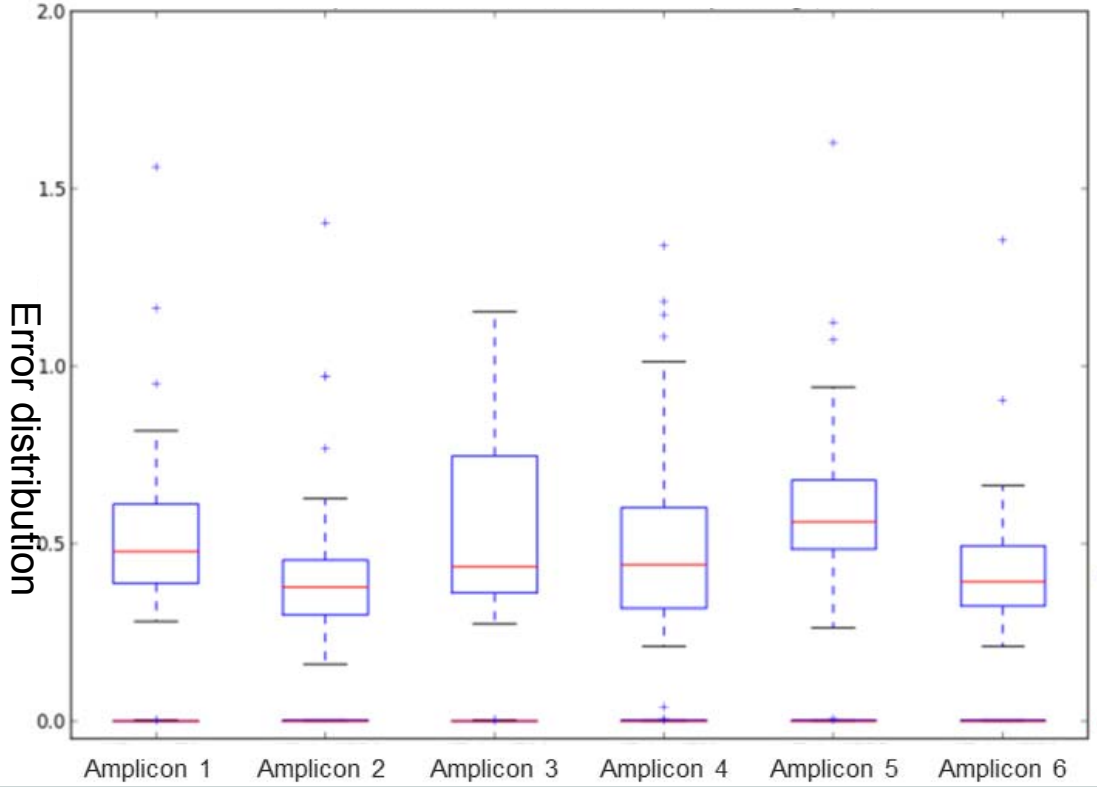
Plasma-Safe-SeqS (PSS) Technology Features



Next-Generation Sequencing
~0.5%

Plasma-Safe-SeqS
~0.0006%

[Future technology issues]
- ✓Objective and efficient target gene marker selection
- ✓Verification of marker effectiveness and correlation to diseases and drugs
- ✓Establishment of measurement platform

[Issues for diagnosis application]
- ✓Simplification of sample pretreatment and data analysis workflow and presentation of data in a manner that is easy for medical professionals to understand

Literature related to Plasma-Safe-SeqS technology

- Evaluation of DNA from the Papanicolaou test to detect ovarian and endometrial cancers. Kinde I, Bettegowda C, Wang Y, Wu J, Agrawal N, Shih IeM, Kurman R, Dao F, Levine DA, Giuntoli R, Roden R, Eshleman JR, Carvalho JP, Marie SK, Papadopoulos N, Kinzler KW, Vogelstein B, Diaz LA Jr (2013) Sci Transl. Med. 9;5(167):167ra4.
- Detection and quantification of rare mutations with massively parallel sequencing. Kinde I, Wu J, Papadopoulos N, Kinzler KW, Vogelstein B (2011) Proc Natl Acad Sci U S A. 108(23):9530-5.

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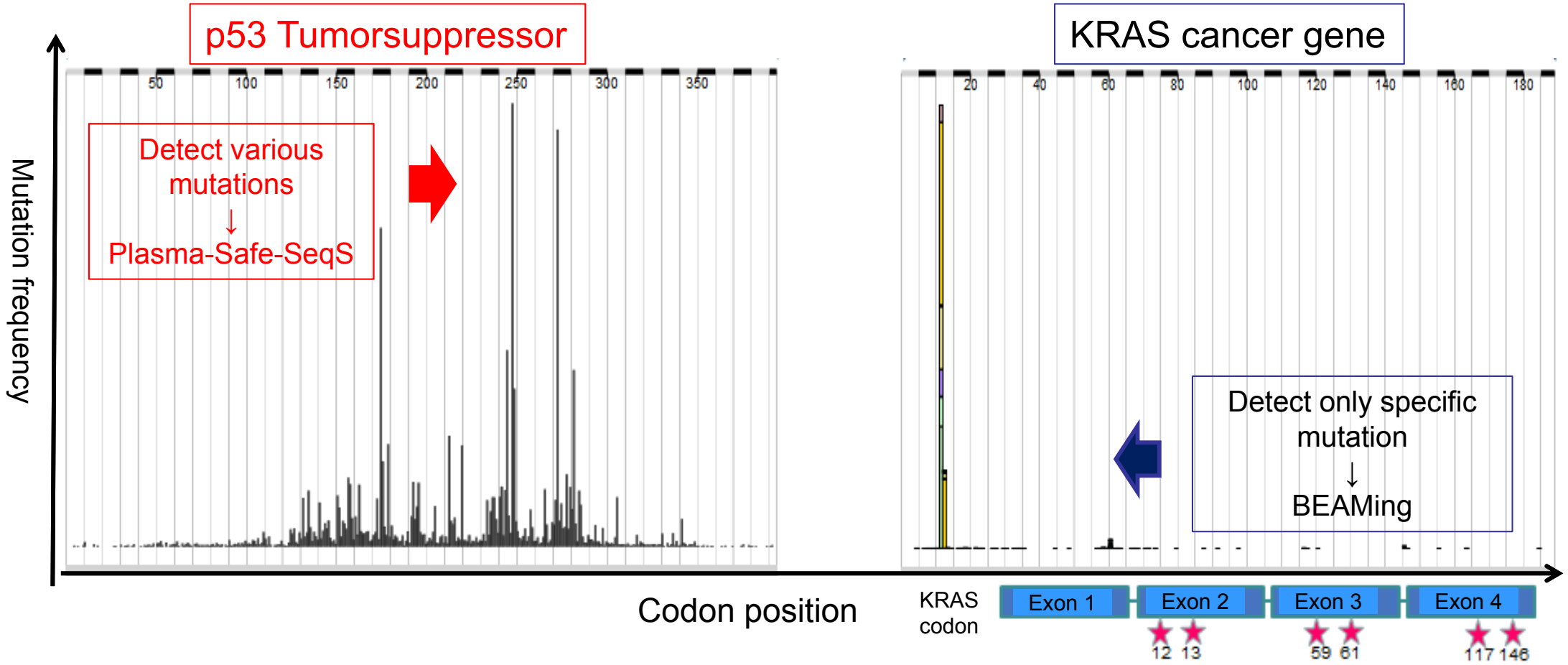
Example of Detecting Genetic Mutations Using Plasma-Safe-SeqS (PSS) Technology



Plasma-Safe-SeqS technology is effective in cases where mutations are generated on multiple codons as with the P53 gene, specifically conducting an exhaustive gene search for expression patterns of multiple gene mutations

Where mutations having a high expression frequency are limited to a specific codon, as with the KRAS gene, BEAMing technology is effective at the highly sensitive detection of specific gene mutations

Codon: When translating proteins into their constituent amino acid sequences, the triplet base sequence for each amino acid

Exon: In the base sequence of DNA or RNA, the portion that remains as mature RNA (the portion that does not remain is called intron)

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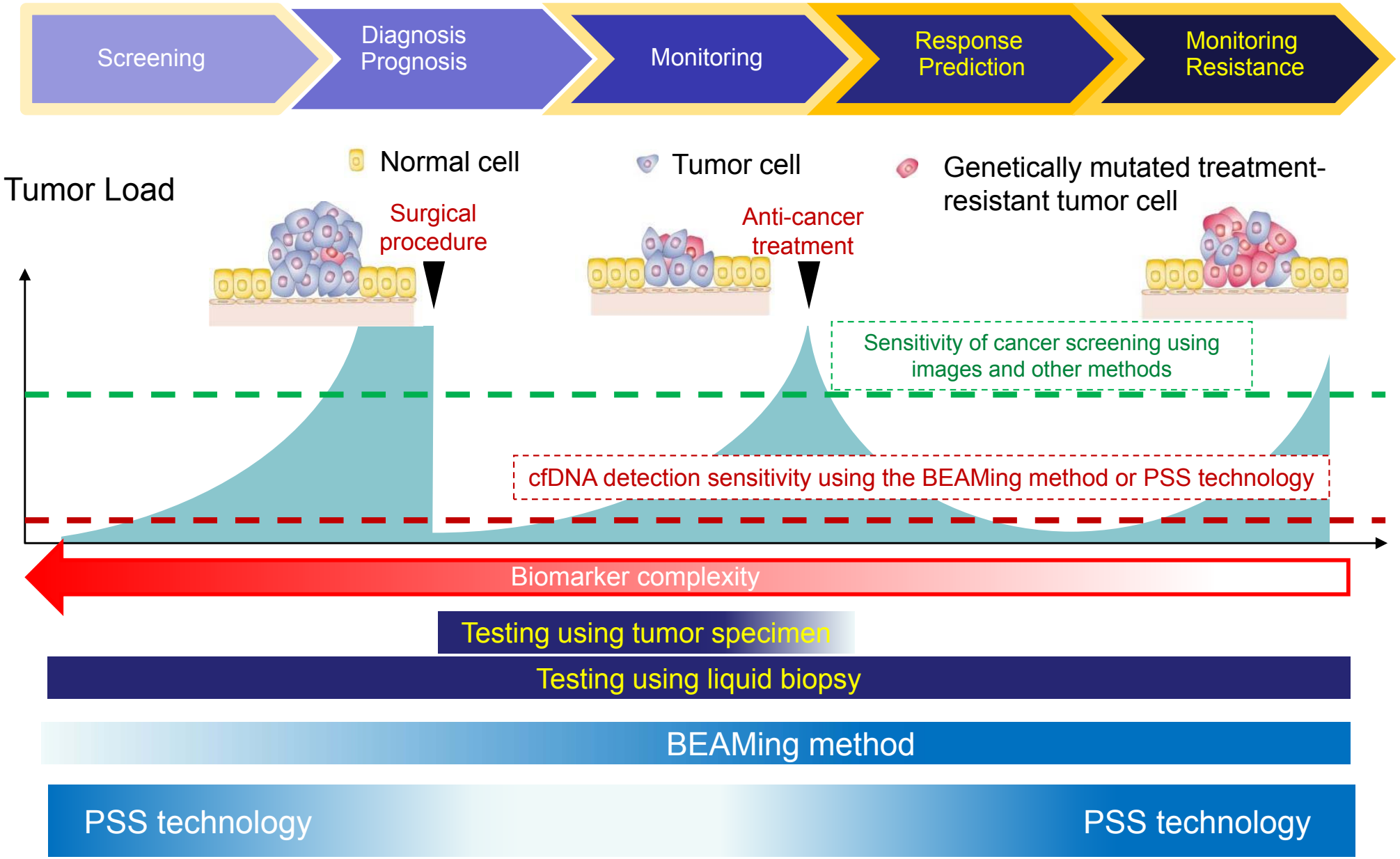
Positioning of Cell Free DNA (cfDNA) Gene Testing in Cancer Diagnosis using BEAMing Technology and Plasma-Safe-SeqS (PSS) Technology



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We Believe the Possibilities.

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