Trend in diagnostic biochip development

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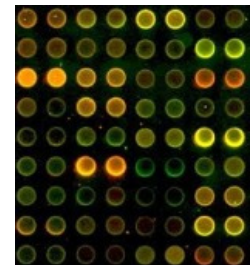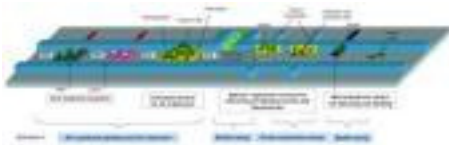International University of Health and
Welfare Hospital

Handling of the early stage is important for the treatment of diseases, and the importance of early discovery and diagnosis has been pointed out since the era of Hippocrates in Greece.

What is " biochip"?

'Biochips' are defined as boards on which biomolecules, such as DNA, proteins, sugar chains, and cells containing these are fixed in a large number, termed DNA, protein, glyco-, and cell chips, respectively.

A large number of target molecules and compounds which specifically interact with biomolecules on chips can be simultaneously analyzed in a large number of samples in parallel, and DNA chips are typical ones.
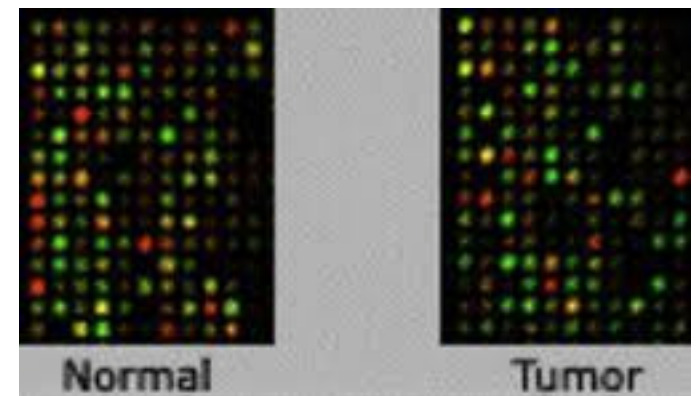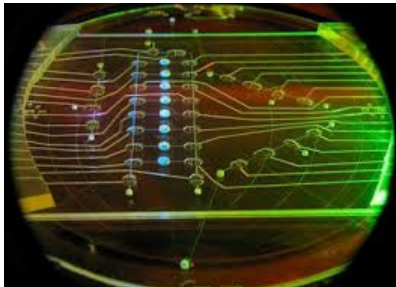
Requirements for expansion of diagnostic biochip market

Technological problem

Social/institutional problem

Market/economic problem

Normal

Tumor

Requirements for expansion of diagnostic biochip market

Technological problem
Social/institutional problem
Market/economic problem

Detection technology

In some cases, <u>greater accuracy and reliability</u> are required compared to biochips for research. (depends on each field)

Convenience

Identical results should be obtained by anybody. <u>Simple operation</u> with an <u>easy procedure</u> is required.

Cost reduction

Utilization of <u>resin-made</u> chips, <u>mass production</u> technology, and <u>reduction</u> of the use of reagents, etc.

Content development

Improvement of the <u>quality and breadth of diagnosis</u>, <u>expansion of contents</u> mounted on diagnostic biochips, such as specific genes , proteins characterizing diseases, antibody discontinuation , regulatory pathways, lot to lot variation, etc.

Requirements for expansion of diagnostic biochip market

Technological problem

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Systematization

**Utilization of network and electronic medical records
for effective utilization of diagnostic data.**

Social aspect

**Adverse effects of drugs, protection of personal information,
and solving of ethical problems.**

Institutional aspect

Pharmaceutical approval.

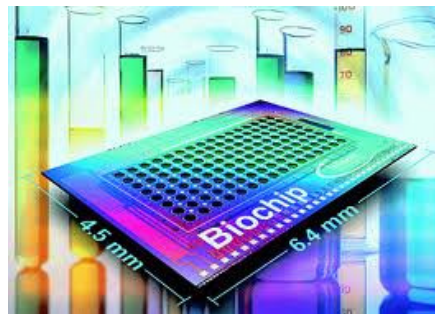Requirements for expansion of diagnostic biochip market

Technological problem
Social/institutional problem
Market/economic problem

Actualization of molecular target drugs, increased importance of diagnosis with advancement in personalized medicine.

Growing awareness of preventive medicine and health problems.

Fields expected to involve biochips

Diagnosis of disease risk

Preventive diagnosis

Early diagnosis

Definite diagnosis (support for decision-making on therapeutic policy)

Diagnosis prior to drug administration

Prognostication

Diagnosis in drug development

Target DNA

DNA Capture Probe

Fields expected to involve biochips

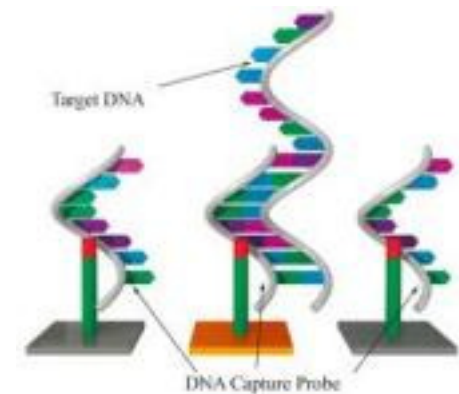## **Diagnosis of disease risk**
Preventive diagnosis
Early diagnosis
Definite diagnosis (support for decision-making on therapeutic policy)
Diagnosis prior to drug administration
Prognostication
Diagnosis in drug development

Type of diagnosis	Test and measurement items		Effect	Diagnostic technology
Diagnosis of disease risk	oral mucosa, blood	Polymorphism Protein	Identification of individual constitutions associated with polymorphism of genomic base sequence information and protein biomarkers. Elucidation of correlation of diet, lifestyle, and genomic polymorphism information with disease information is necessary.	Genomic sequence, Invader assay, DNA chip Immunoassay

Fields expected to involve biochips

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Type of diagnosis	Test and measurement items		Effect	Diagnostic technology
Preventive diagnosis	sweat, urine, saliva, expired gas, blood	Protein, Secondary metabolite	Support for health management corresponding to the individual disease risk.	Immunoassay, Protein chip

Fields expected to involve biochips

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Type of diagnosis	Test and measurement items		Effect	Diagnostic technology
Early diagnosis	blood, urine, saliva, expired gas	mRNA Protein, Saccharides	Addition of diagnostic items corresponding to the age to periodic examination, such as health checkups: support of fast screening for early discovery of diseases.	DNA chip, Immunoassay RT-RCR

Fields expected to involve biochips

Diagnosis of disease risk
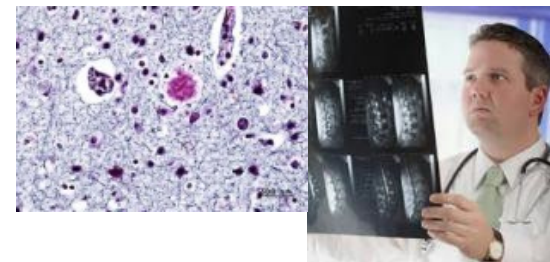Preventive diagnosis
Early diagnosis
Definite diagnosis (support for decision-making on therapeutic policy)
Diagnosis prior to drug administration
Prognostication
Diagnosis in drug development

Type of diagnosis	Test and measurement items		Effect	Diagnostic technology
Definite diagnosis	blood, urine, saliva, diseased tissue	mRNA	Identification of disease type by discovery of disease-related genes and analysis of profiles. Support for deciding on an optimum therapeutic policy in combination with clinical information. For infectious diseases, diagnosis of the presence or absence of infection by detecting virus-specific mRNA.	Internal diagnostic device, such as PET and MRI Tissue staining, RT-PCR, mass spectrometry technology, DNA chip, Protein chip
		Protein,	Identification of disease type by detection of biomolecules, such as disease-specific protein. Support for deciding on an optimum therapeutic policy in combination with clinical information.	

Fields expected to involve biochips

Diagnosis of disease risk

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Diagnosis in drug development

Type of diagnosis		Test and measurement items		Effect	Diagnostic technology
Diagnosis prior to drug administration	Dose of drug	oral mucosa, blood	Polymorphism	Avoidance of adverse effects by dose setting corresponding to inter-individual differences in drug metabolizing ability based on polymorphism analysis of liver drug-metabolizing enzymes.	Genomic sequence, Immunoassay DNA chip
		diseased tissue blood, urine, saliva	Protein	Avoidance of adverse effects by dose setting corresponding to inter-individual differences in drug incorporation ability of the target cells.	
	Response to drug	target molecule, blood, urine, saliva	Protein,	Selection and administration of drugs for individual cases based on whether the drug is effective or not.	Immunoassay Tissue staining, Protein chip

Fields expected to involve biochips
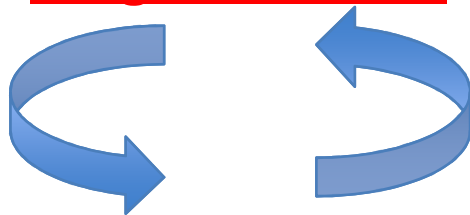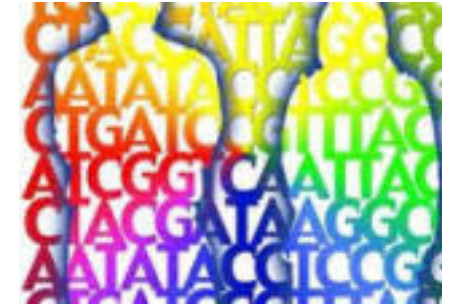
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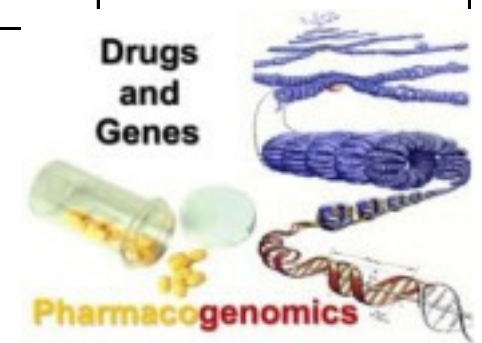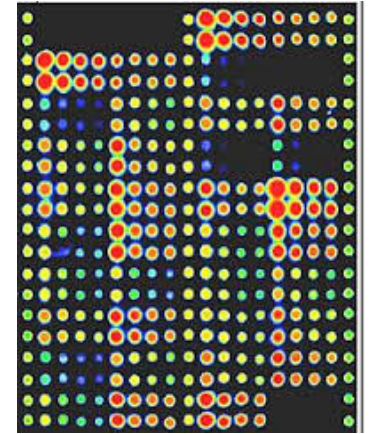
Diagnosis prior to drug administration

Prognostication

Diagnosis in drug development

Type of diagnosis	Test and measurement items		Effect	Diagnostic technology
Prognostication	blood, urine, saliva	Protein	Support for appropriate treatment based on judgment of the therapeutic effect and tendency of recovery.	Immunoassay, Mass spectrometry technology, Protein chip

Fields expected to involve biochips

Diagnosis of disease risk

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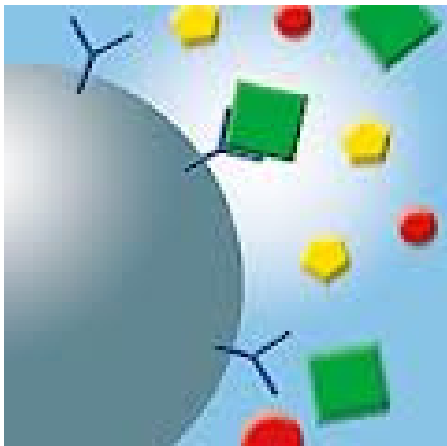**Diagnosis prior to drug administration**

Prognostication

Selection of a biomarker matching the objective of diagnosis utilizing knowledge obtained in drug development

Type of diagnosis	Test and measurement items		Effect	Diagnostic technology
Diagnosis in drug development (**pharmacogenomics**)	blood, urine, saliva, diseased tissue	mRNA Protein	Reduction of dropout risk by performing a clinical study based on profiles analyzed in patients who respond to the drug through the pharmacological mechanism being developed.	Mass spectrometer RT-PCR

What changes are expected in medical care with the spread of diagnostic biochips?

Medical expenses for the elderly have been markedly Increasing continuously in Japan.

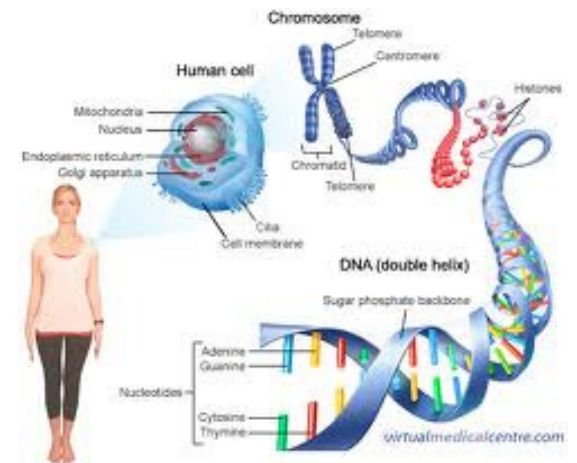**For the elderly to spend an active daily life, prevention is important.**

And high expectations are placed on biochip development enabling simple and reliable simultaneous diagnoses of many items in a small blood sample collected at home.

For personalized medicine, it is important to diagnose the hereditary background and disease condition by prior tests.

And the expansion of needs for these diagnoses with the spread of personalized medicine is predicted.

However, although the basic technologies of biochips for research and development and diagnosis have some commonality, specifications to be realized are markedly **different**.
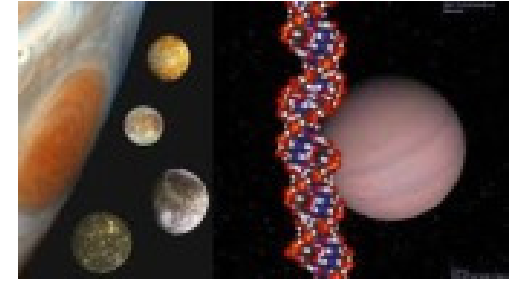
And a technological **breakthrough** is necessary.

5 years view of diagnostic biochip development

As biochip technology further progresses,
mobile and wearable disease diagnosis systems
will be developed.

And connection to a ubiquitous network may facilitate
diagnoses at home.

It is expected that the application of these technologies
will facilitate not only 'super' early diagnosis of diseases
and disease prevention based on the diagnosis,
but also 'super' early treatment.

Reference

Ichiishi E. Trend in diagnostic biochip development. *Expert Review of Molecular Diagnostics.* 13(4) 331-337, 2013

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- [One should go to specialists for the best results](#).