Only one drop…

DRI-CHEM BOOK

…Full time Real time.

FUJIFILM

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FUJIFILM

Value from Innovation

For medical professionals

Only one drop…

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Full time, Real-time.

Any time immediately.

Today when the quality of medical care is questioned, giving a patient medical attention as quickly as possible is the oldest and the newest theme. The test data that supplies objective information for making a decision is required as soon as possible to provide appropriate medical care. We never know when sickness or injuries may happen. Therefore, it would be ideal to provide medical care any time, immediately 24 hours a day. The goal aspired to and obtained by DRI-CHEM is the very immediacy of test results. Only one drop of blood applied on a small slide can provide test data in an easy and rapid manner. The exemplary features of DRI-CHEM give it the competitive edge in the testing market. Keep this mind as you proceed through the following pages.

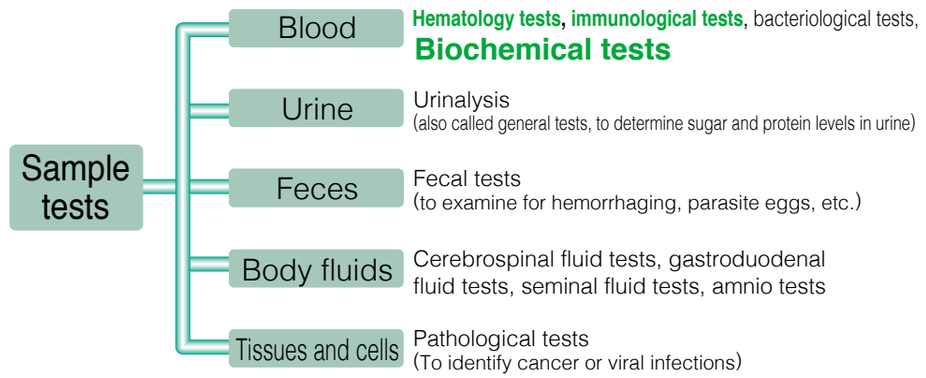
Clinical Chemistry Analyzer

Clinical tests and biochemical tests

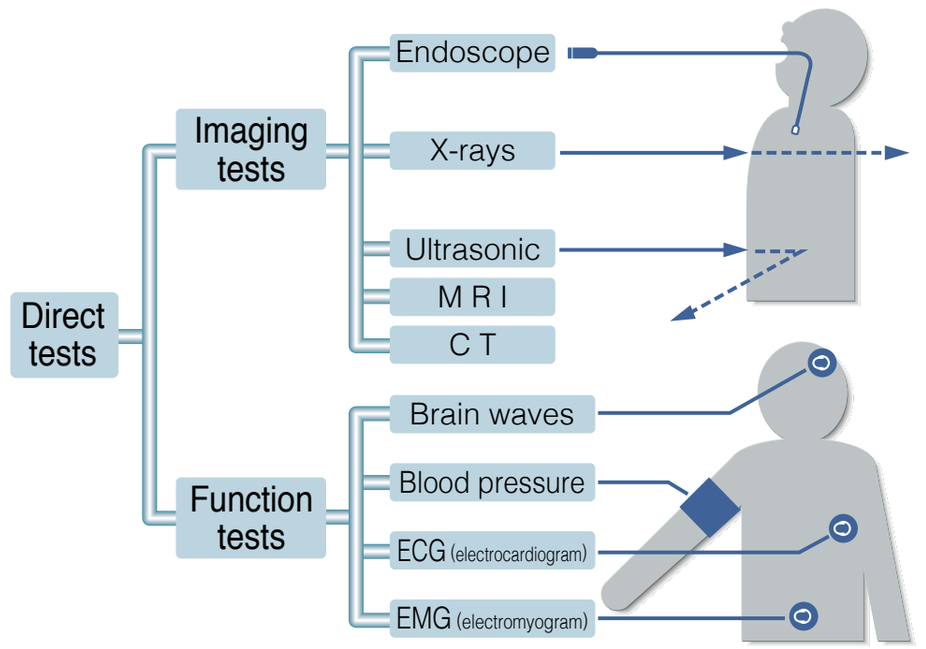
When someone feels a change for the worse or experiences strange symptoms, a large number of specific components that exist in the blood increase or decrease. By examining which component has increased or decreased and to what extent, it is possible to presume a disease or condition and its severity. This is what biochemical tests do. Biochemical tests are used to analyze the components of blood, which are like a mirror reflecting the physiological state of the patient, and biochemical tests form the basis of clinical tests that play a key role in addition to the physical examination. For example, most people are familiar with tests related to adult-onset diseases such as glucose (blood sugar), which is indispensable in the diagnosis of diabetes, total cholesterol (TCHO), which is related to hyperlipemia, high density cholesterol (HDL-C), which is the so-called good cholesterol, and triglycerides (TG) and γ-GTP, that increase in alcoholic hepatopathy.

[Clinical Tests]

Clinical tests are a scientific approach to diagnosing a disease based on objective information (ie, test data), which is in contrast to the information obtained by interviewing the patient or a medical examination involving taking the patient's body temperature or palpation. In addition to providing confirmation to support a diagnosis obtained by test data, clinical tests are also used to determine the therapeutic effect as well as the prognosis of a patient.



In Biochemical tests, urine and spinal fluid are sometimes used aside from blood. Test using blood as a sample is called blood chemistry test.



Clinical Chemistry Analyzer

FUJI DRI-CHEM can use plasma or serum

Whole blood drawn from a patient coagulates when it leaves the body and the component change their form, so it is unstable and therefore not appropriate as a specimen for most tests. Stable samples for biochemical tests can be plasma obtained by centrifuging whole blood, or serum obtained after centrifuging coagulated whole blood. Also, because glucose in blood is consumed after blood sampling, a glycolysis inhibitor is used in conjunction with anticoagulants in blood used for glucose tests.

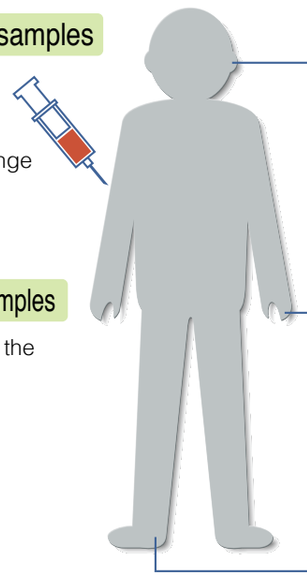
[Types of Blood Sampling]

Venous blood samples

The conventional blood sampling method. Blood is withdrawn by syringe or vacuum into a tube or syringe.

Arterial blood samples

Used primarily for the measurement of blood gases.

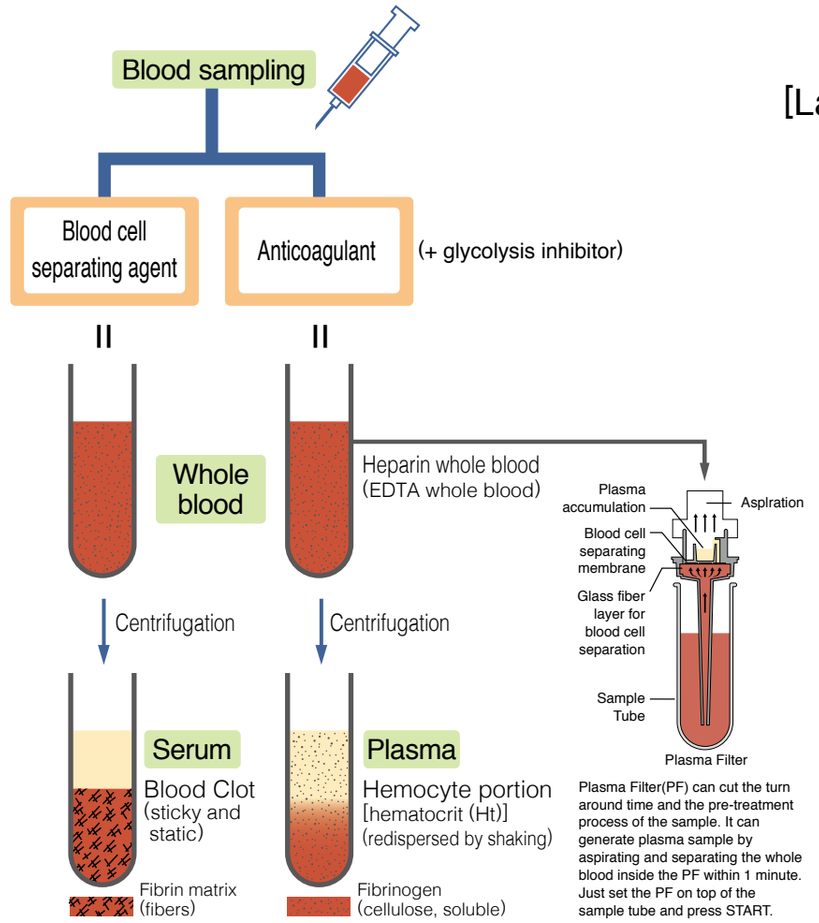


Capillary blood samples

Ear lobe blood sampling (capillary)
Fingertip prick blood sampling
Heel cut blood sampling (newborns)

Vacuum blood sampling tubes
Vacuum blood sampling tubes, which are used most often, may already contain, depending on the usage, an anticoagulant, coagulation accelerator, or blood separating agent.

[Blood processing and types of samples]



Plasma Filter(PF) can cut the turn around time and the pre-treatment process of the sample. It can generate plasma sample by aspirating and separating the whole blood inside the PF within 1 minute. Just set the PF on top of the sample tube and press START.

[Laboratory Tests]

Blood tests
[Hematological tests]
Number, shape, color, and type of RBC, WBC, and platelets, hemorrhaging, coagulation

Bacteriological tests
[microbiologic tests]
Bacteria tests

Immunological tests
[Serum tests, serum immunological tests]
Testing for infectious diseases, etc. using antigen-antibody reaction

Biochemical tests
[Blood chemistry tests]
Measurement of amounts and activities of chemical components contained within this liquid portion of blood

Hematology-related technical terms

Anticoagulant
Components such as heparin, EDTA, and citric acid that prevent blood clotting.

Blood cell separating agents
Blood cell separating agents, which are gels that have a specific gravity partway between blood clots and plasma, produce better separation between the solid blood components (blood clots and blood cells) and plasma and serum during centrifugation and stabilizes plasma and serum.

Coagulation accelerators
Substances such as silica powder, glass powder, snake venom, etc. that accelerate the fibrination of fibrinogen, accelerate coagulation, and shorten the length of time to arrive at the serum fraction.

Glycolysis inhibitors
Since erythrocytes are still alive after blood has been withdrawn they continue to consume glucose, resulting in decrease of the measured value of glucose. Glycolysis inhibitors stabilizes the blood glucose value.

Hematocrit (Ht, Hct)
When whole blood is centrifuged the solid components such as erythrocytes, leucocytes, and platelets go to the bottom. The hematocrit is defined as the percentage of the total volume accounted for by these solid components. (Normal range: 38% to 47%)

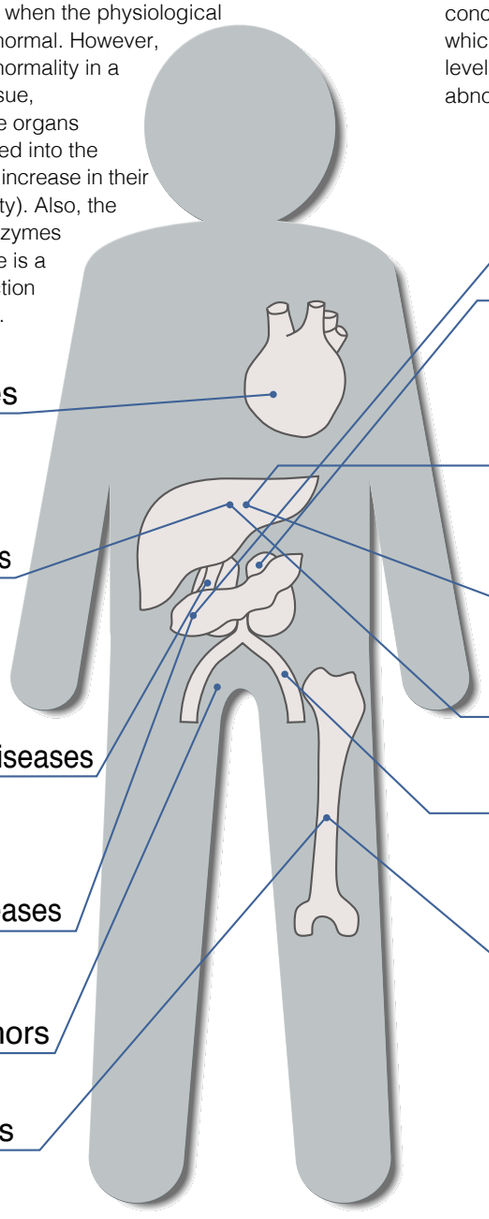
Hemolysis
The rupturing of the membrane of sac-shaped erythrocytes with the release of the internal contents of the cells, such as hemoglobin, is referred to as hemolysis. Plasma in which hemolysis has advanced is not a suitable specimen for biochemical tests because it contains the liquid contents from erythrocytes with markedly different amounts of chemical components.

Clinical Chemistry Analyzer

Test items

[Enzymes]

Various enzymes are present in the blood at fixed concentrations when the physiological state of a person is normal. However, when there is an abnormality in a specific organ or tissue, the enzymes in those organs or tissues are released into the blood resulting in an increase in their concentration (activity). Also, the concentrations of enzymes decrease when there is a decrease in the function of a particular organ.



Heart diseases

CPK／(CK)	↑
GOT／AST	↑
LDH／(LD)	↑
CKMB	↑

Hepatic diseases

GOT／AST	↑
GPT／ALT	↑
GGT(γ-GTP)	↑
CHE	↑↓

Hepatobiliary diseases

ALP	↑
LDH／(LD)	↑
LAP	↑

Pancreatic diseases

AMYL	↑
Lipase	↑

Malignant tumors

LDH／(LD)	↑

Bone diseases

ALP	↑

[General chemistry]

Like for enzymes, the blood concentrations of various metabolites, which are normally present at certain levels, increase or decrease when an abnormality occurs.

Diabetes mellitus

GLU	Glycemia (glucose)	↑

Renal disease

BUN	Urea nitrogen	↑
CRE	Creatinine	↑
IP	Inorganic phosphorus	↑
Mg	Magnesium	↑

Gout

UA	Uric acid	↑

Hepatic diseases (cirrhosis)

NH_3	Ammonia nitrogen	↑
DBIL		↑

Jaundice

TBIL	Total bilirubin	↑

Atherosclerosis, obesity

TCHO	Total cholesterol	↑
HDL-C	HDL cholesterol	↑
TG	Triglyceride	↑

Bone and hormonal abnormalities

Ca	Calcium	↑↓
IP	Inorganic phosphorus	↑↓

Physical status

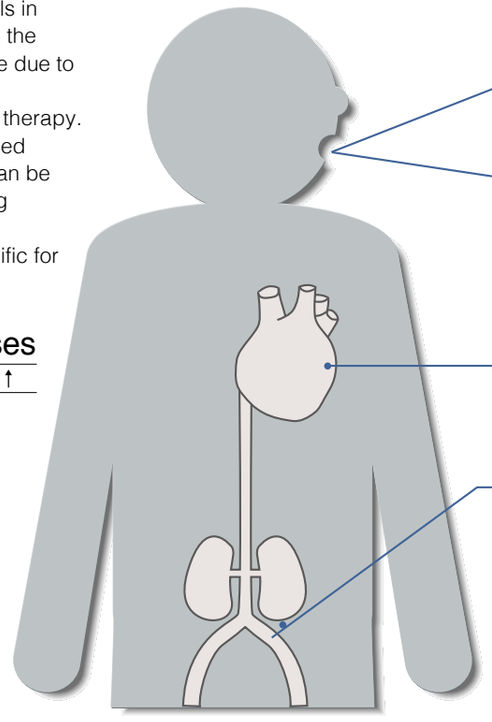
TP	Whole protein	↑↓
ALB	Albumin	↑↓

[Immunological test]

Specific proteins, endocrine hormones, drugs, etc, are present in the blood of healthy individuals in very small amounts, however, the blood concentrations increase due to acute inflammation, tissue destruction, medication, and therapy. These trace components, called immunological parameters, can be analyzed and measured using antigen-antibody reactions (immunological reaction specific for each component).

Inflammatory diseases

CRP	C-reactive protein(CRP)	↑



[Electrolytes]

The concentration of salt in plasma is approximately 0.9%. The molecular formula of salt (crystalline state) is NaCl, however, in aqueous solutions the NaCl exists as Na+ ions and Cl^- ions. These ions are called electrolytes.

Na	Sodium	↑↓
K	Potassium	↑↓
Cl	Chloride	↑↓

[Blood Gas]

The changes of CO_2 in blood may suggest the patient is retaining or losing fluid. This can cause imbalance in the body's electrolytes. This test is usually conducted with the electrolytes.

TCO_2	Total Carbon	↑↓

Na, K, and Cl
Na, K, and Cl are very useful biochemical test parameters for diagnosing the abnormal state of a patient.

Clinical Chemistry Analyzer

Special characteristics of FUJI DRI-CHEM

FUJI DRI-CHEM is a very simple biochemical test system that can measure substances by merely placing a drop of specimen on a small slide containing dry reagents. Standard biochemical test methods that use liquids are suitable if large sample volumes are processed all at once. However, the measuring equipment tends to be bulky and there are various time-consuming and laborious steps involved, such as rinsing with water, management of liquid reagents, preparations before and clean-up after the measurements. Practice and skill is required for precision control and other aspects of the liquid method. On the other hand, the FUJI DRI-CHEM method, which maximizes the advantages of dry chemistry, does not require any rinsing with water, the measuring equipment is compact, and the procedure is simple and straight forward. This means it is ideal for obtaining immediate measurements in emergency situations.

No water needed

- There is no need to prepare purified water that is used to rinse the cells, or other parts inside the equipment, etc. in liquid-based measurement methods.

Ancillary equipment not needed

- Equipment for supplying and draining water and water purifiers not needed
- Regular power source can be used so renovations to or upgrading of electrical power supply not required.

No need for preparations or clean-up

- Pre-measurement preparations and post-measurement cleaning and rinsing needed by standard methods that use liquids are not required.
- There are no substances or chemicals to dispose of.

Minute amounts of samples

- As only a minute amount of sample is required for a single measurement [colorimetry: 10μL, electrolytes: 50μL (Na, K, Cl)], the impact of blood sampling on newborns, the elderly, or a severely injured person can be greatly decreased.

Automatic Dilution Function

- The troublesome dilution procedure can be done automatically. Just by setting a dilution fluid with the sample, dilution will be performed with the assigned dilution factor.

Simple procedure

- The basic procedure involves only 3 simple steps: “Setting of the slide and pipette tip”, “Setting the sample”, and “Pressing the start button”.

Slide reagents

- Ready made slide reagents are individually packaged for each single use. They are very stable when stored and there is no wastage.

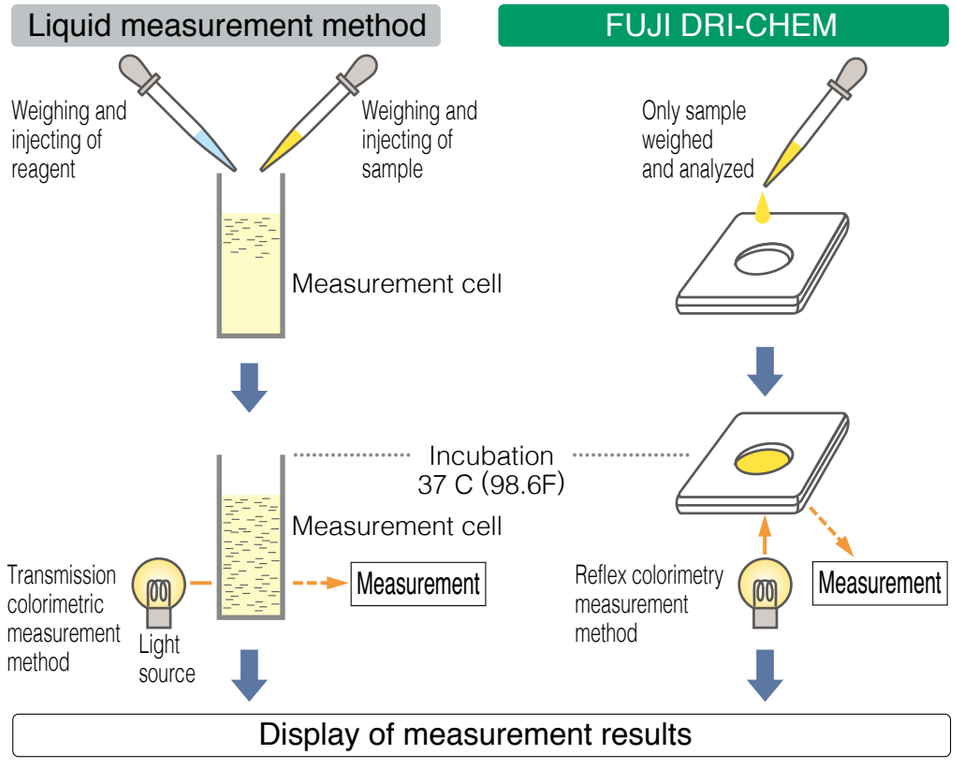
Calibration not necessary

- If the lot number of the slides change, one merely has to insert the QC card supplied with the slides to correct for any differences from the new lot (CRP is an exception). Correction using a QC card is not needed for electrolytes.

Calibration

The liquid measurement method has built-in reagent tanks inside the apparatus for each test item. The calibration must be checked everyday, calibrator (liquid) must be measured regularly, and the reagent and equipment are corrected.

[Comparison of measurement procedure]



[Comparison of handling procedure]

Liquid method	FUJI DRI-CHEM
<Preparations until start of measurement>	
Approximately 1 hour (i) Turn power button to ON (ii) Check amount of reagent remaining (fill if necessary) (iii) Calibration (iv) Data check and confirmation of normal state	5 to 10 minutes (i) Turn power button to ON (ii) Preparation and replacement of Fuji Auto Tips and reference solution RE (for electrolytes) (iii) Preparation of slide of items to be measured
Measurement	
Approximately 30 minutes (i) Rinsing/cleaning, check cell (ii) Turn power button to OFF	1 minute (i) Emptying of waste box (ii) Turn power button to OFF

Clinical Chemistry Analyzer

Measurement principles of FUJI DRI-CHEM slides

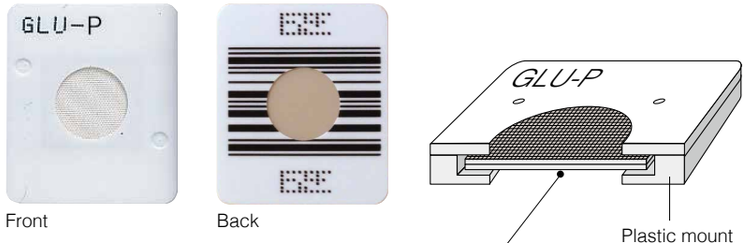
There are 2 types of FUJI DRI-CHEM slides with a different measurement principle, neither type requires the preparation of any reagents.

[Colorimetric method slides]

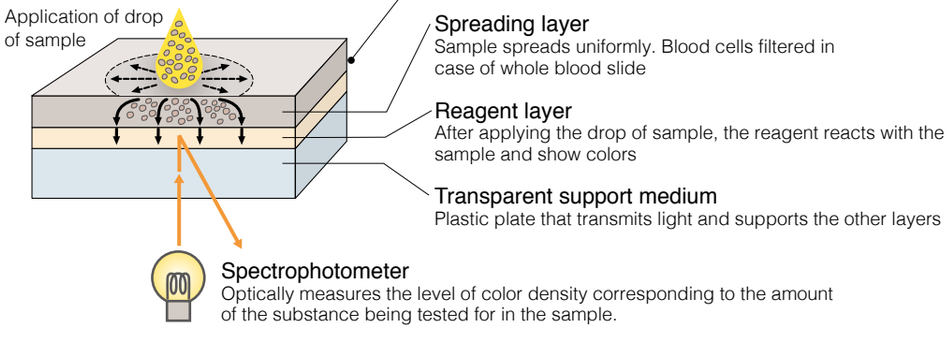
The enzymes, general chemical components, and immunological components in the samples are measured by colorimetry. Application of the sample to the slide results in a reaction between the component and the reagent, the formation of a pigment, and measurement of the concentration of chromophore that corresponds to the amount of component. The multilayered film slide begins with dry reagent needed for one measurement and has successive layers of functional materials. In the colorimetry slides, there is the end-point method (general chemistry) and rate method (enzymes, Mg, CRP).

Example: Glucose

External view of slide



Multilayer analysis film



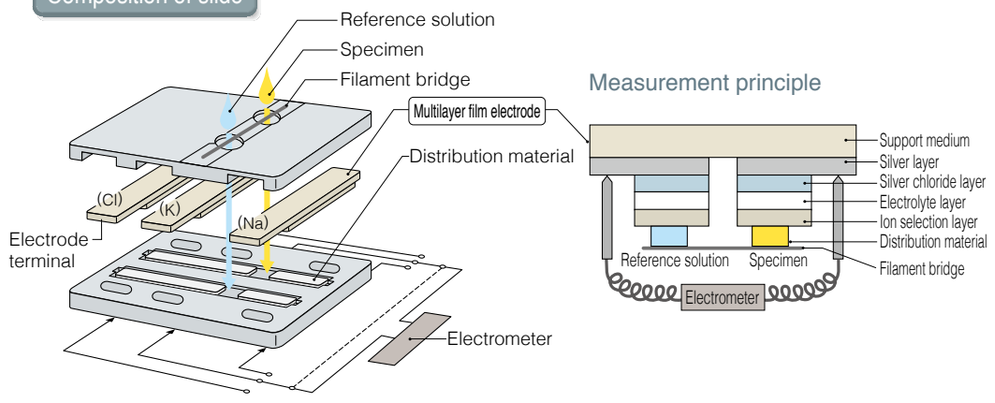
[Potentiometric method slide]

Assays the electrolytes in the specimen. The specimen and an electrolyte reference solution with a fixed concentration of electrolytes are applied to the slide. The concentrations of the electrolytes are measured by the change in potential between two electrodes. One slide contains 3 types of film electrodes (Na, K, and Cl) and all three can be measured at once simultaneously in only 1 minute.

Example: Measurement of Na, K, Cl

External view of slide

Composition of slide



Clinical Chemistry Analyzer

Stable manufacturing of FUJI DRI-CHEM slides

Points in stabilizing the manufacturing quality
4Ms

Man : The same person or a person with the same skill
Material : Using a constant standard, degree of purity and material
Method : Work and operate with the constant prescription and method
Machine : Always produces the constant and same quality products using the same machine and equipment maintained and adjusted in the constant condition.

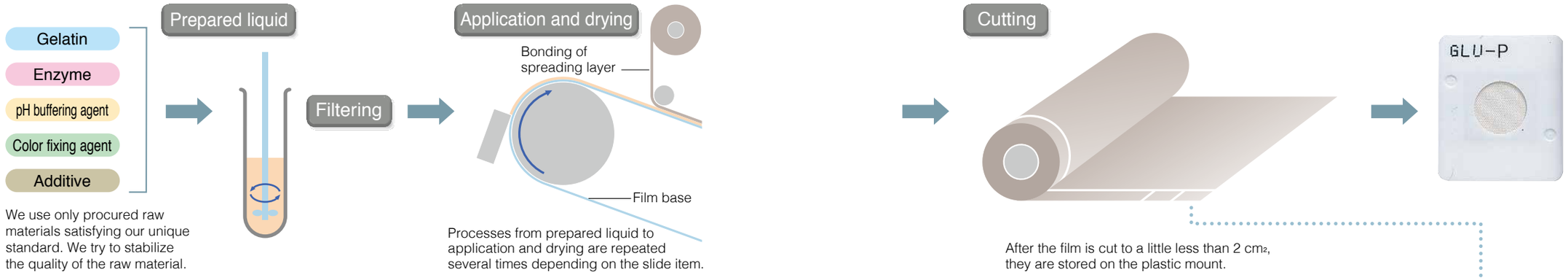
We apply advanced technologies we have cultivated for photo film.

We apply manufacturing technologies of photo film cultivated for over 80 years in manufacturing FUJI DRI-CHEM slides. Technologies include the machining accuracy of the transparent support media (film base) comprising of a multilayer structure and the technology to apply a reagent layer that reacts to the object substance in a sample and a reflection layer that blocks off blood pigments. The world's top level fine chemistry, processing technology and quality control have built a new possibility called dry chemistry in biochemical tests.

"Stabilizing the manufacturing process" brings high precision into reality.

Assuring reliability of measurement data in the biochemical analysis should be the condition to which highest priority should be given. FUJI DRI-CHEM slides have programmed manufacturing processes such as procurement of raw material, prepared liquid, film-based film-forming, application of the reagent layer/reflection layer, drying, bonding of the spreading layer and cutting and manufacturing environment in great detail. Thoroughly "stabilizing the manufacturing condition" stabilizes the quality or establishes high precision. They are compliant with ISO13485.

Film-forming process



Film-forming process

A rolled long strip-shaped film base (transparent support medium) is formed using PET (Polyester) as the raw material. The machining accuracy of this thin film is evenly controlled to 0.1 micron paying due attention to the permeation property and the polarization ratio of light. Multiple layers of a FUJI DRI-CHEM slide are formed by overlapping other layers on this lowest layer.

Prepared liquid process

This is the prepared liquid of the reagent applied on the film base. The type, the mixing ratio, the mixing order, the temperature and the time are strictly programmed by item and layer for gelatin, enzyme, pH buffering agent, color fixing agent and additives and prepared to always show a constant reaction against the object substance in the specimen. As the reagent layer and the reflection layer vary depending on the item and consist of a single layer or multiple layers, the liquid is prepared per layer.

Application process

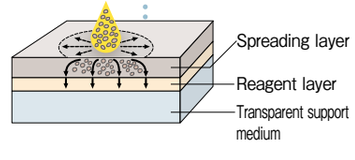
The reagent prepared on the film base running and accurately controlled in a constant speed is applied to 0.1 micron accuracy. This application process and the subsequent drying process are carried out under an indoor condition where light is always kept constant and minute dust particles are kept out.

Drying process

The film applied with the reagent is continuously fed to the drying process. In addition to stabilizing the indoor condition, dry air is finely set to the temperature and humidity per item and layer considering the deactivation of enzymes and then blown. The time to finish drying is accurately controlled by improving the accuracy of the drying process in addition to the prepared liquid and application.

Cutting process

After the spreading layer is bonded, the rolled dry film is set on the slitter (cutting machine). The wide roll is cut in round slices of about 1.2 cm in width and cut again to about 1.3 cm in length direction to form chips as small as approximately 2 cm² or less. These film chips are stored on the plastic mount to protect them and finish a FUJI DRI-CHEM slide.



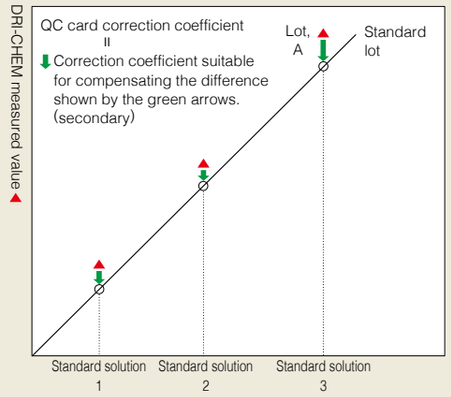
Clinical Chemistry Analyzer

Features of FUJI DRI-CHEM system

FUJI DRI-CHEM QC card system

About calibration

While test reagents should be manufactured with the same degree of quality, in fact, when judged from the point of view of biochemical tests, which require a high degree of precision, there are slight differences between the lots for each reagent. This is why it is necessary to calibrate the measuring equipment when using different lots, or in other words, correct or compensate for the differences between lots.



FUJI DRI-CHEM does not need calibration

Each individual package of FUJI DRI-CHEM comes with a magnetic memory card (QC card) that contains the correction coefficients so that each lot will be corrected to the measured values of a standardized lot. When slides from different lots are used, calibration is performed automatically merely by inserting the QC card into the analyzer beforehand.

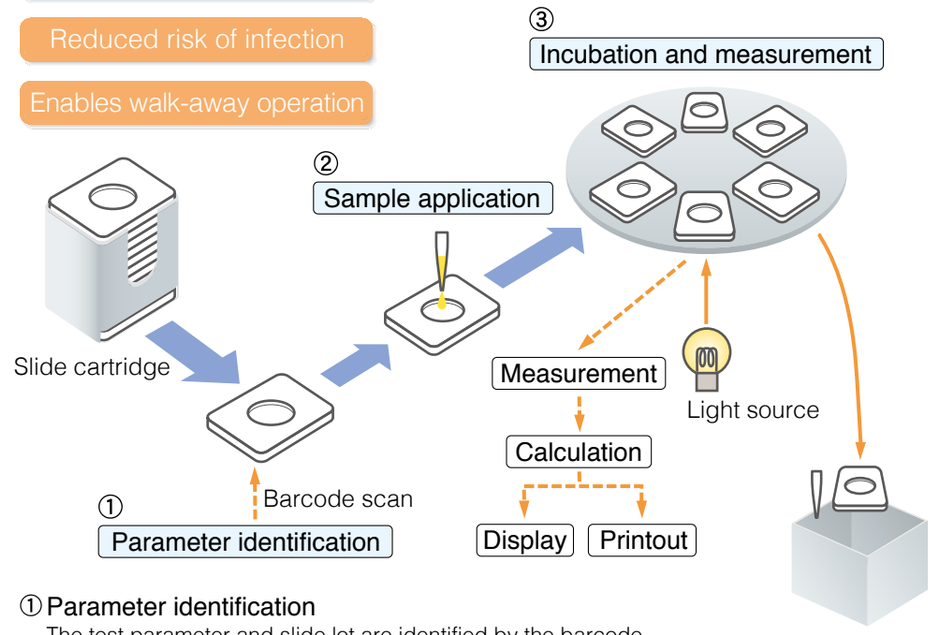
Automated Measurement for Faster, More Accurate, and Safer Testing

FUJI DRI-CHEM uses automated measurement at the device side to provide the key features needed in testing, “simplicity and speed”. Once the START key is pressed, the entire process is automated until the results are displayed. This automated process is faster and more accurate than manual processes, and it minimizes potential contact with samples for reducing the risk of infection by pathogens. This system also enables the operator to leave the test site to perform other operations.

Faster and more accurate

Reduced risk of infection

Enables walk-away operation



① Parameter identification

The test parameter and slide lot are identified by the barcode or 2D dot code printed on the back of the slide. (The sample application amount, measurement wavelength, reaction time, and other information are also loaded at the same time.)

② Sample application

A predetermined amount of sample is applied to the slide quickly and accurately.

③ Incubation and measurement

The sample is incubated for a certain reaction time at 37°C (98.6°F), which is nearly the temperature of the human body, and measured at a specific wavelength, and the calculated measurement results are displayed and printed out.

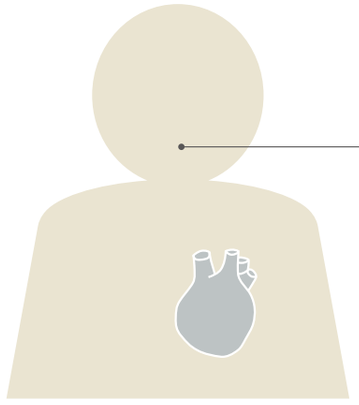
Waste box

After use, slides and tips are automatically dropped into a waste box. This eliminates time-consuming cleanup and minimizes contact with the sample.

Immunological Analyzer

Immunological parameters for infectious diseases

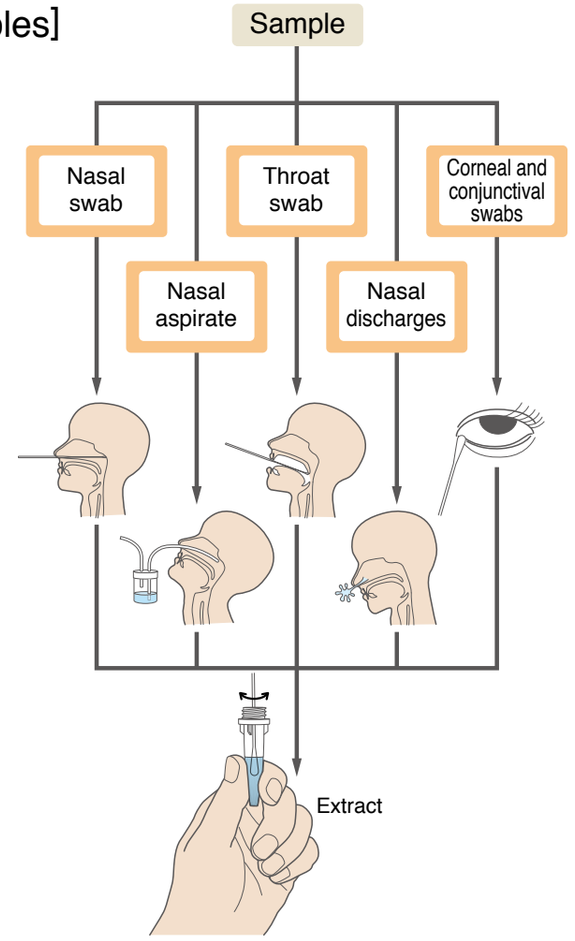
When pathogens such as bacteria or viruses infect people, they multiply in the blood and at the local infected area. These pathogens and biogenic substances (components) are called immunological parameters because antigen-antibody reactions (immunological reactions specific for each component) are used to analyze them. Detection of these immunological parameters helps the diagnosis of some infectious diseases.



Respiratory Illness

FluAB	Influenza virus type A and B antigen
StrepA	Group A beta-hemolytic streptococcus antigen
Adeno	Adenovirus antigen

[Types of samples]



Nasal swab
It is a sample specimen collected by inserting a sterilized cotton swab intranasally and then delicately scrubbing the nasoturbinate with the swab.

Nasal aspirate
It is a specimen collected with an aspirate swab. Collect the nasal aspirate by inserting the aspirate tube in the inner nasal cavity.

Throat swab
It is a specimen collected by inserting a sterilized cotton swab to the throat through the mouth cavity then rubbing the posterior wall of the pharynx and the reddened area of the tonsils.

Nasal discharges
Specimen collected by sneezing onto a tissue paper.

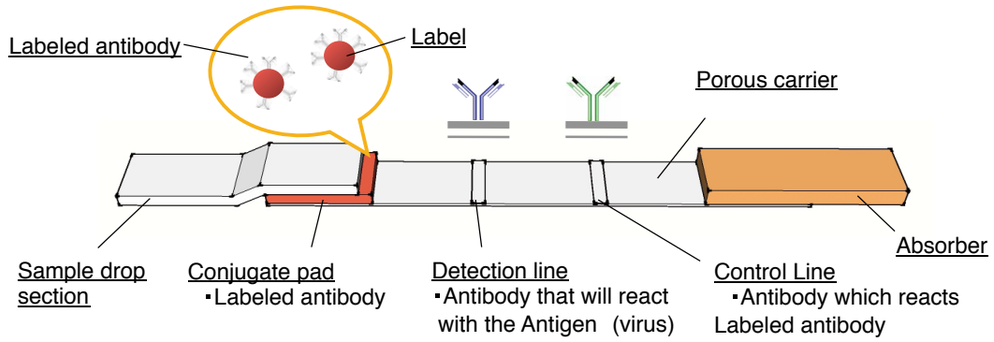
Corneal and conjuctival swabs
It is a specimen collected by strongly rubbing the inflamed part of the cornea several times with a sterilized cotton swab.

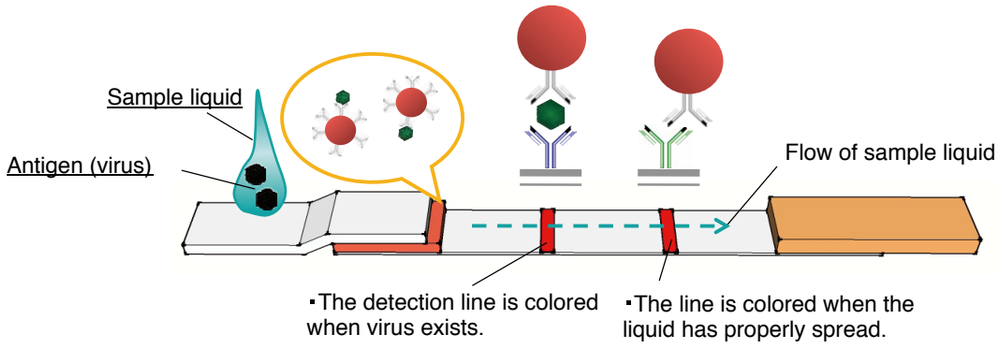
* The type of sample to be used depends on the test item.

Immunological Analyzer

Measurement principle of FluAB

Principle of Immunochromatographic Assay

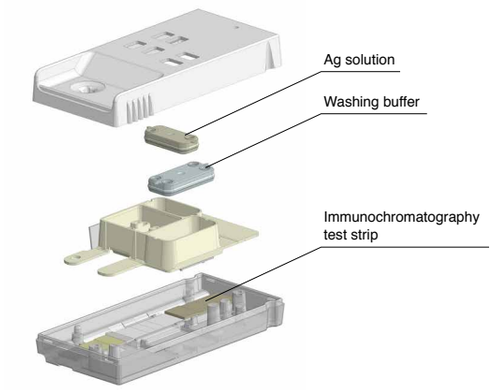


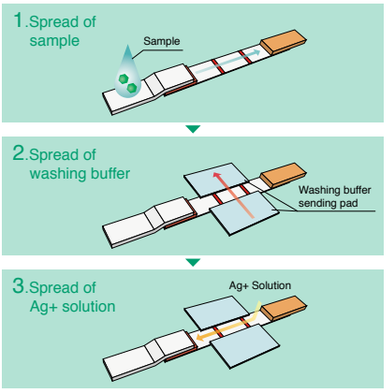


When a sample liquid containing an antigen (virus) is dropped onto the sample drop section, the labeled antibody in the conjugated pad is specifically bound to the antigen. The sample liquid is spread horizontally by the capillary force of the porous carrier and absorbed by the absorber. The detection line on the porous carrier is coated with an antibody that reacts specifically with a virus. The label is fixed to the detection line with the virus sandwiched between the antibody and the labeled antibody. That colors the detection line and indicates that the result is positive.

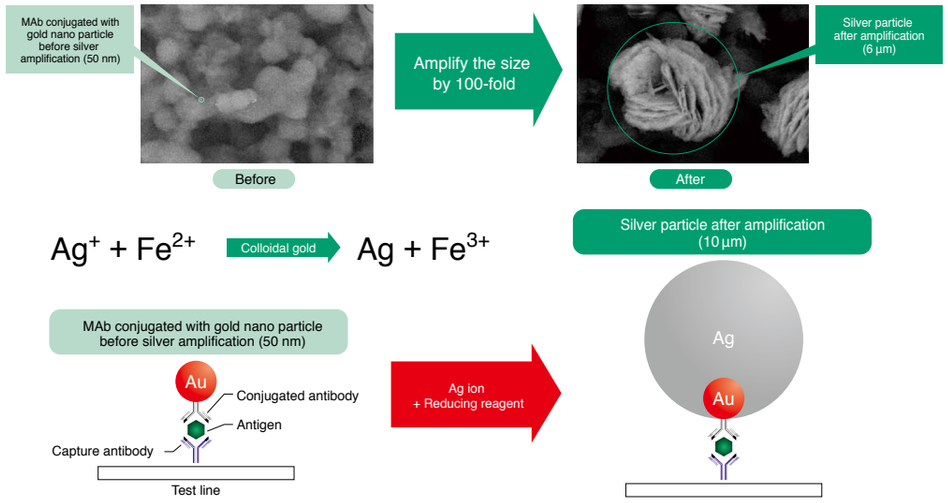
Highly sensitive immunochromatographic detection using silver amplification

Structure of cartridge





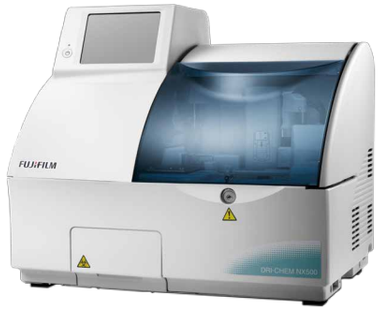
The figure above shows the structure of the IMMUNO AG cartridge FluAB, an influenza virus detection kit. The sample spreads to the test trip like the conventional methods (1). After the spreading and reaction of the sample with the reagents, excess labeled antibodies are removed by washing with buffer (2). This is to prevent false positive results. Next, silver amplification is performed to increase the sensitivity of the detection (3). Reducing agent and silver ions run through the membrane forming silver clusters around the gold particles. The SEM images (below) were taken before and after silver amplification, showing the increase size of the complex after amplification.
Through the silver halide photography technology, the detection sensitivity of the virus has significantly improved. This enables the detection even for samples from the initial onset stage of the disease, where the virus quantity is small.



FUJI DRI-CHEM
Test Lineup

Clinical chemistry analyzer and immunological analyzer tests

FUJI DRICHEM Clinical Chemistry Analyzer



Test parameters and slides

Test parameter				Slide name by sample	
	Category		Parameter name	For plasma and serum	For whole blood
Biochemical test	Enzyme	1	Gamma-glutamyl transpeptidase	GGT-PⅢ	
		2	Glutamate oxaloacetate transaminase	GOT/AST-PⅢ	
		3	Glutamate pyruvate transaminase	GPT/ALT-PⅢ	
		4	Creatine phosphokinase	CPK-PⅢ	
		5	Lactate dehydrogenase	LDH-PⅢ	
		6	Alkaline phosphatase	ALP-PⅢ	
		7	Amylase	AMYL-PⅢ	
		8	Leucine aminopeptidase	LAP-P	
		9	Creatine phosphokinase isozyme MB	CKMB-P	
		10	Cholinesterase	CHE-P	
		11	Lipase	LIP-P	
	General chemistry	1	Glucose	GLU-PⅢ	
		2	Blood urea nitrogen	BUN-PⅢ	
		3	Creatinine	CRE-PⅢ	
		4	Uric acid	UA-PⅢ	
		5	Total cholesterol	TCHO-PⅢ	
		6	HDL cholesterol	HDL-C-PⅢD	
		7	Triglycerides	TG-PⅢ	
		8	Total bilirubin	TBIL-PⅢ	
		9	Direct bilirubin	DBIL-PⅡ	
		10	Calcium	Ca-PⅢ	
		11	Inorganic phosphorus	IP-P	
		12	Total protein	TP-PⅢ	
		13	Albumin	ALB-P	
		14	Ammonia	NH_3-PⅡ (for plasma)	NH_3-WⅡ
		15	Magnesium	Mg-PⅢ	
	Electrolyte	1	Sodium	Na-K-Cl	
		2	Potassium		
		3	Chloride		
Immunological test			C-reactive protein	CRP-SⅢ	
Blood gas			Total carbon	TCO_2-P	

FUJI DRICHEM Immunological Analyzer

Tests parameters for infectious diseases

Parameter name	Cartridge name
Influenza virus type A and B antigen	FluAB
Group A beta-hemolytic streptococcus antigen	StrepA
Adenovirus antigen	Adeno

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