



Leisure offers

DEVECAL®

A Health Management Platform That Supports Individuals To Manage Their Own Health



Demecal service consists of an immediate blood separation system that anyone can use anytime, anywhere and a lifetime health management data service.

Health management approach should be in sync with an individual's lifestyle.

The most innovative feature of the service is a "health management program" that is based on an individual's chronological history of test results.

Leisure's goal is to be the "home doctor to 100 million people."

Three Pillars of DEMECAL Service

1 Immediate blood separation device

Capability to conduct blood analysis with ultra-small volume of blood



Demecal Kit has been approved by the Ministry of Health, Labor and Welfare. It is the first combined medical device to be approved by the ministry.

DEMECAL

Approval Number

22600BZX00362000

(Combined medical device)

Lancet (prick finger)

Pipette (absorb blood)

Cylinder with filter (separate blood)

Sealing cap (seal separated blood)



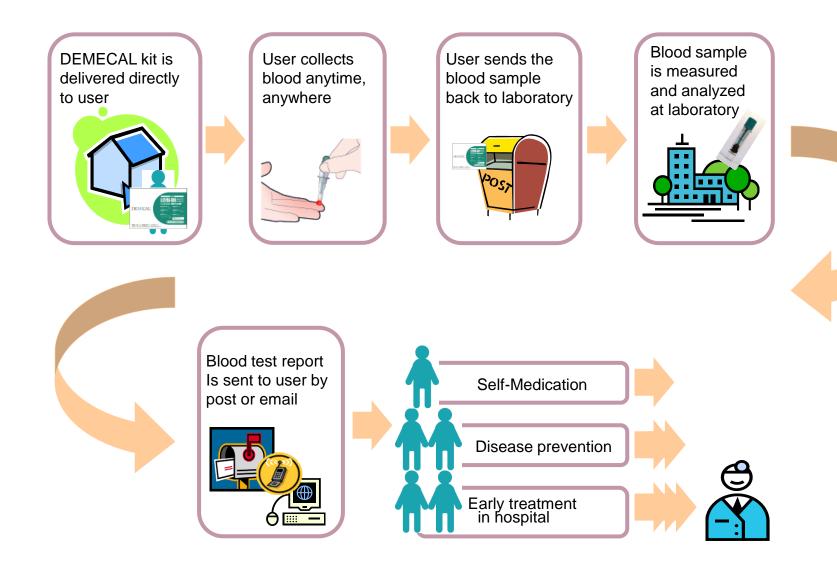
Vial with buffering liquid (mix blood with liquid)

Band-Aid (place over wound)

Alcohol wipe (disinfect finger)



DEMECAL[®]



DEMECAL® Features of DEMECAL SERVICE





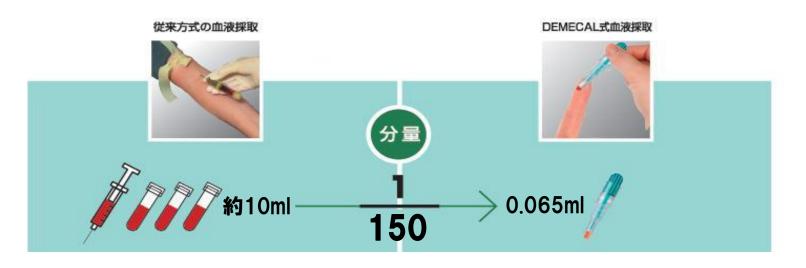
Blood Test Requiring Ultra-small Volume of Blood

Today clinical blood tests are conducted in the following manner

- 1) Doctors, nurses or clinical laboratory technicians collect blood from patients
- 2) Blood is centrifuged to separate plasma
- 3) Serum is placed in a container
- 4) Serum is analyzed by a blood analysis equipment

This method requires approximately three vacuum tubes (10 ml) of blood

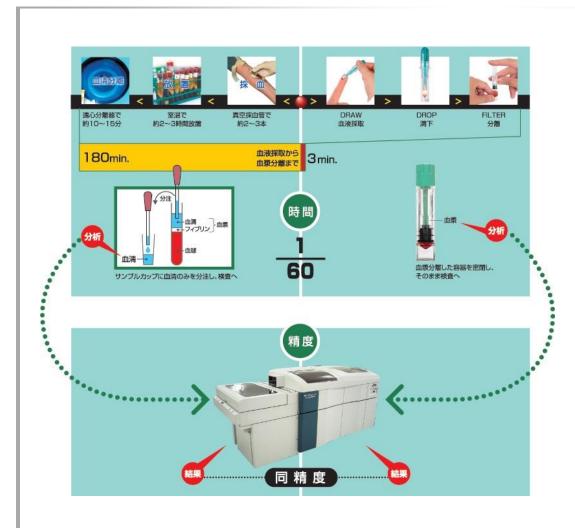
With the Demecal kit, it is possible to separate the plasma by placing 3 to 4 drops of peripheral blood into a cylinder containing a dilution buffering solution and simply pressing a piston equipped with a special filter. This method is proprietary to Leisure, and is the only technology available worldwide that is capable of immediate plasma separation of ultra-small volume of blood at ambient temperature and pressure.







Stability during Transportation and Highprecision Analysis



Separating the plasma immediately after drawing blood using the immediate plasma separation device developed by Leisure allows the specimen to maintain its integrity during transportation.

Analysis is conducted by reliable analyzers utilized in conventional blood test centers.

Leisure's patented technologies that consist of immediate plasma separation device and ultra-small volume quantitative blood analyses are the foundation to ensure accuracy.



CRMLN CERTIFICATION

CHOLESTEROL REFERENCE METHOD LABORATORY NETWORK

Certificate of Traceability

This certifies that

LEISURE, INC. Tokyo, Japan

has documented traceability to the National Reference System for Cholesterol by performing a direct comparison with the cholesterol reference method using fresh human specimens which cover the National Cholesterol Education Program medical decision points. This analytical system is representative of the manufacturer's product and has demonstrated the ability to meet the NCEP's performance criteria for accuracy and precision. The comparison shows that the performance of this analytical system is as follows:

Among-run %CV	Average %Bias	Total Error
0.50	170	2601

The comparison was performed with

Osaka Medical Center for Health Science and Promotion Osaka, Japan

The system evaluated was:

Instrument: JEOL JCA-BM2250 Wako Multi Calibrator Lipids

Lot#: KJ 110 Set point: 220 mg/dL

Cholesterol reagent: Wako T-CHO L H Lot #'s: R1: KJ978; R2: KM036 Matrix: Plasma

Date of evaluation: February 18, 2005

Date of expiration: February 18, 2007

CRMLN Laboratory Director Takashi Shinangto

The CDC (Centers for Disease Control and Prevention) is a federal agency under the Department of Health and Human Services in the USA that assumes a leading role in promoting health. It provides reliable information that contributes to decisions related to health and is a key player in developing activities targeted to disease prevention and health promotion.

As the effects of lipids on cardiovascular disease have become more evident, accuracy of lipid tests has become even more important. It is, therefore, imperative to standardize lipid measurement. The CRMLN (Cholesterol Reference Method Laboratory Network) an international organization set up by the guidance of the CDC has continuously undertaken such standardization. The CRMLN is a network centered around the CDC which was requested by the WHO to standardize measurement of lipids. The CRMLN has standardized laboratories located in 10 facilities across 8 countries and is accepted as the model for international collaboration for clinical testing.

The CRMLN issued certificate is proof of accuracy assurance for manufacturers of reagents and laboratories. Test results using reagents by such manufacturers and laboratories are deemed to be highly reliable. Demecal's measurement of lipids using Leisure's immediate plasma separation technology and ultra-small volume blood analysis method was the first to meet international standards using ultra-small volume of blood,



Laboratory Dedicated to Demecal

Demecal's tests are conducted at a dedicated laboratory located in Yamanashi Prefecture called "The Demecal Healthcare Research Center" (DHRC).

DHRC is registered with the Yamanashi Prefecture as a clinical laboratory that meets the regulations established by the Health, Labor and Welfare Ministry (Registered Clinical Laboratory No.16). Furthermore, DHRC has received the highest possible grade by the Integrated Accuracy Assurance Committee of the Japanese Association of Medical Technologists that annually evaluates the facility's accuracy management.

DHRC has the capacity to handle three million specimens per annum.

Management Company



Demecal Healthcare Research Center 855-24 Komatsu Kasugaicho Fuefuku-shi Yamanashi Japan

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医療関連サービスマーク認定番号:E(7)0802130310

医薬品販売許可番号: 0319030029号

高度管理医療機器販売業:4501190500022号 アメリカ血液バンク協会(AABB)認証施設









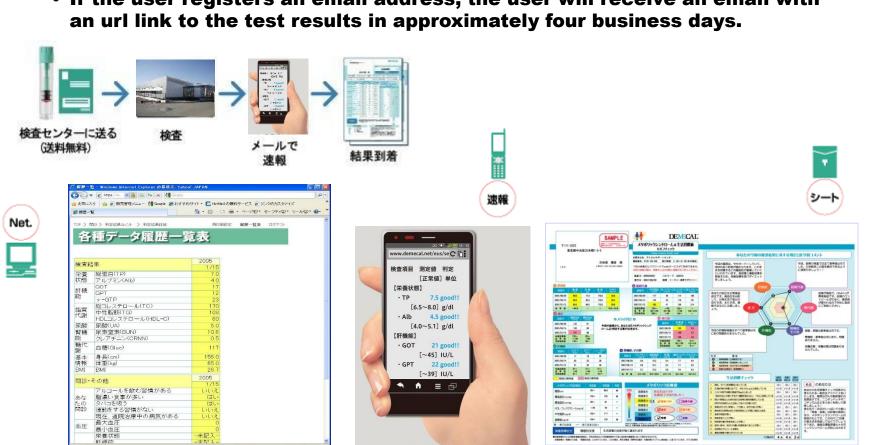
IMS Group

Eil, Inc. is the clinical laboratory arm of IMS Group that operates more than 70 hospitals and medical facilities in Northern Japan and the Kanto Area.



Prompt and Easy to Understand Test Reports

- Test results are sent to the user's registered address in approximately seven business days after the user mails the blood specimen.
- If the user registers an email address, the user will receive an email with an url link to the test results in approximately four business days.



TEST CATEGORIES



Biochemistry

Total protein (TP)

Albumin (ALB)

Asparatateaminotransferase(AST)

Alanineaminotransferase(ALT)

 γ -glutamyltranspeptidase(γ -GTP)

Total cholesterol (T-Cho)

Triglyceride (TG)

High density lipoprotein cholesterol (HDL-Cho)

Low density lipoprotein cholesterol (LDL-Cho)

Blood urea nitrogen (BUN)

Creatinine (CRE)

Uric acid (UA)

Glucose (GLU)

Glycosylatedhemoglobin A1c (HbA1c)

Periodontology

Actinobacillusactinomycetemcomitans(A.a)

Porphytomonasgingivalis(P.g)

Prevotellaintermedia(P.i)

Eikenellacorrodens(E.c)

Tumor Marker

Carcinoembryonicantigen (CEA)

α-fetoprotein (AFP)

Carbohydrate antigen 19-9 (CA19-9)

Carbohydrate antigen 125 (CA125)

Prostate-specific antigen (PSA)

Immunology

Ferritin

Helicobacter pylori antibody

High sensitive C-reactive protein

Anti-p53 antibody (anti-P53)

Pepsinogen I / II

Viral Immunology

Human immunodeficiency virus antibody (HIV)

Hepatitis C virus antibody (HCV)

Hepatitis B virus antibody (HBV)

Other

Adiponectin

PATENTS

JAPAN



Ultra-Small Volume Blood Separation System

(Plasma Separation Device)

Patent No.: 3597837

Title: BLOOD SEPARATING DEVICE AND BLOOD

SEPARATING METHOD

Table-Top Automatic Analysis Machine

Patent No: 3445791

Title: METHOD, DEVICE, AND CARTRIDGE FOR

BIOCHEMICAL ANALYSIS

Ultra-small volume test system

(Leisure Device Testing Procedure)

Patent No: 3698696

Title: BIOLOGICAL SAMPLE PREPARATION, QUANTIFICATION AND

PRESERVATION METHOD

USA



Patent No.: US6936473 B2

Title: METHOD OF PREPARING A BIOLOGICAL SAMPLE FOR QUANTIFICATION

EUROPE



Patent No : EP1221614

Title: METHOD OF PREPARING BIOLOGICAL SAMPLE FOR QUANTIFICATION



KOREA



Patent No: 10-0566124

Title: APPARATUS FOR SEPARATING BIOLOGICAL

SAMPLE

METHOD OF THE SAME

Taiwan



Patent No:I 247615

Title:分離生物様品之装置及分離生物様品之方法

SINGAPORE



Patent No: 135926

特許名称: APPARATUS FOR SEPARATING BIOLOGICAL

SAMPLE

METHOD OF THE SAME

Company Profile



Corporate Name: Leisure, Inc.

Established: May 25, 2000

Capital: ¥881,862,750 (as of May 31, 2016)

Business Purpose: Analysis of Biological Samples and R&D

R&D, Production and Distribution of Medical

Instruments and Device Clinical Testing Service

Production and Distribution of Medical and Health

related Computer Systems

Information Service on the Internet and

Distribution of Information Service

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