

Stay Healthy and Happy with Green Cross Laboratories



Pioneering Better Healthcare with History of Innovation

25th October, 2018



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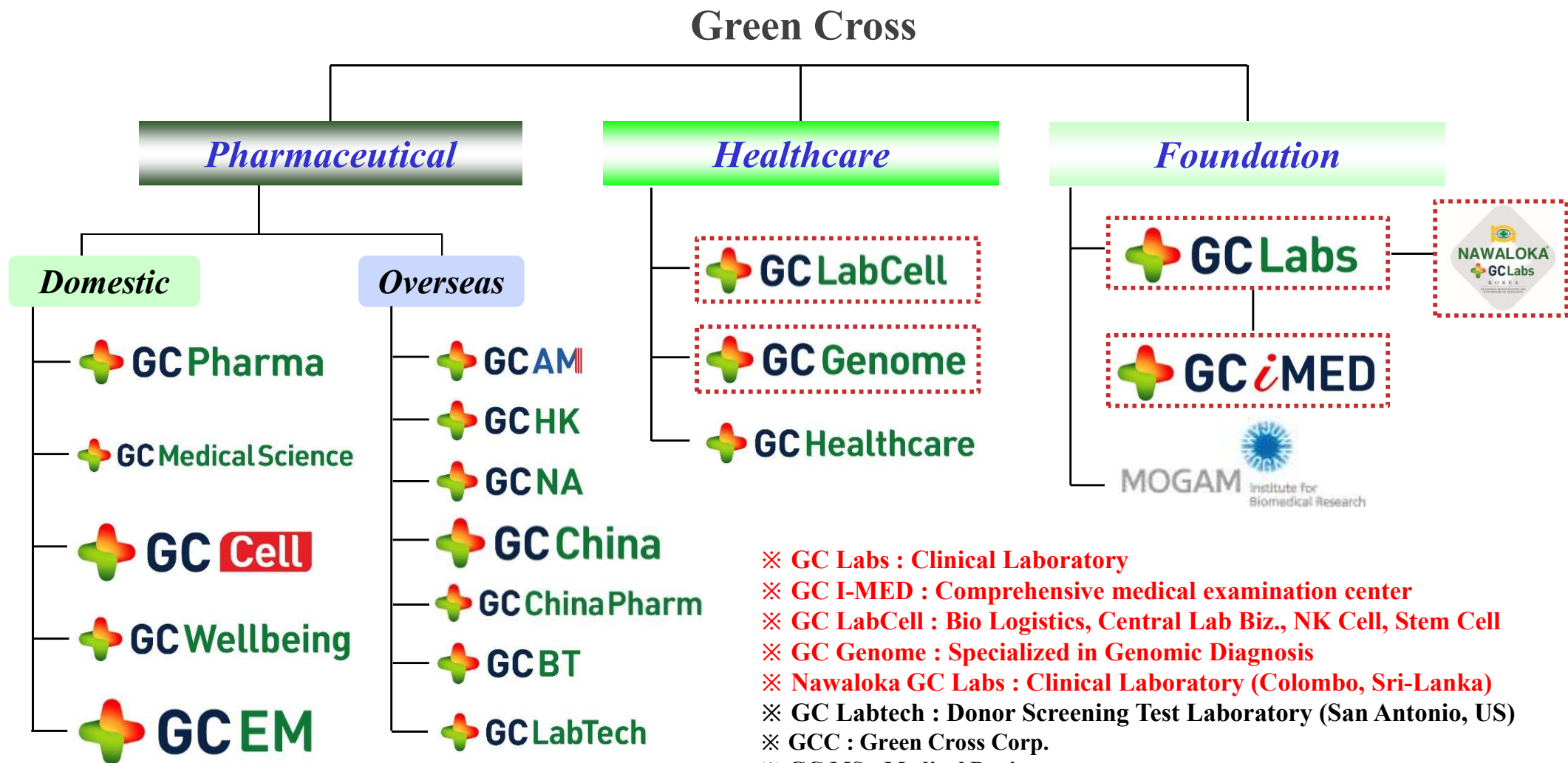
2. Test Area

3. Quality Assurance

Biz. model for international project

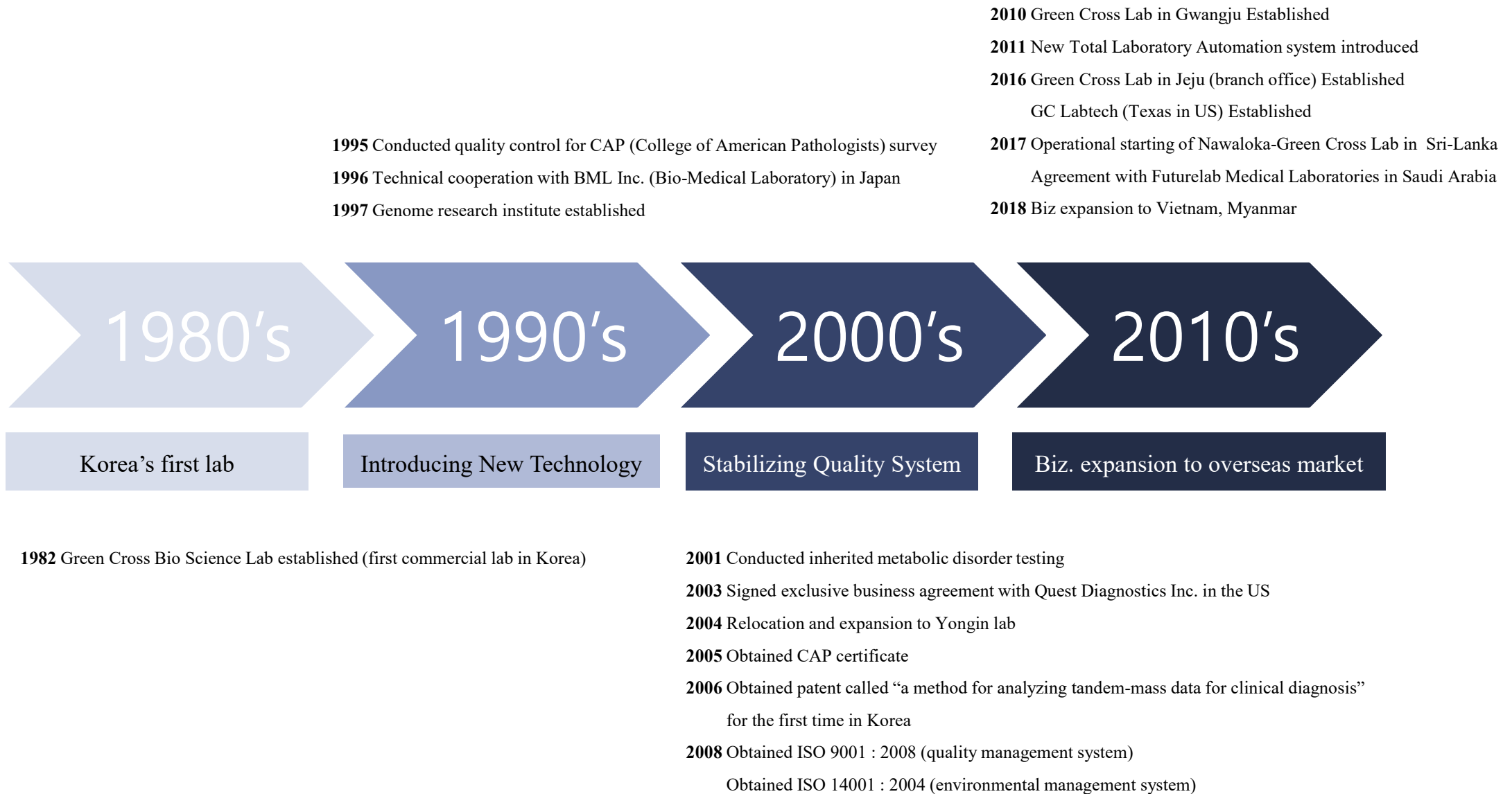


Green Cross Family



- ※ GC Labs : Clinical Laboratory
- ※ GC I-MED : Comprehensive medical examination center
- ※ GC LabCell : Bio Logistics, Central Lab Biz., NK Cell, Stem Cell
- ※ GC Genome : Specialized in Genomic Diagnosis
- ※ Nawaloka GC Labs : Clinical Laboratory (Colombo, Sri-Lanka)
- ※ GC Labtech : Donor Screening Test Laboratory (San Antonio, US)
- ※ GCC : Green Cross Corp.
- ※ GC MS : Medical Devices
- ※ GC Cell : Immune Cell Therapy
- ※ MBRI : Mogam Biotechnology Research Institute
- ※ GCEM : Pharmaceutical Engineering maintenance

GC Labs' History

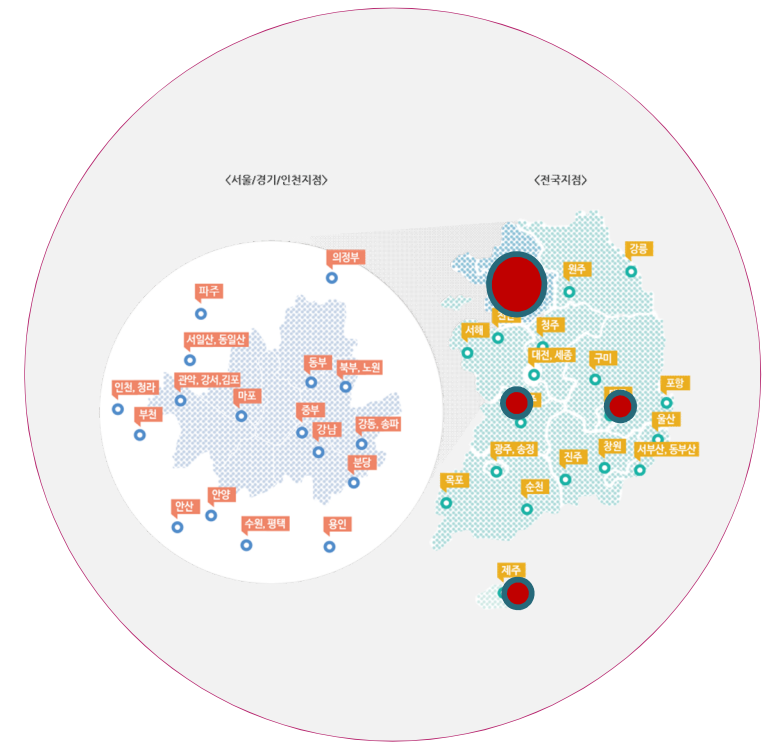


Facilities

- **GC Labs Main (Yongin) Lab**
 - 12,199m²
 - 4-floor building & 2-basements



• Domestic Network



1 Main & 3 Branch Labs
45 Branch offices nationwide

Optimal environment for medical laboratory testing

- Automatic ventilation
- Automatic temperature and humidity control system
- Drain System for medical waste water

Large-capacity UPS, In-house Generator

- Machines are connected with UPS(uninterrupted power supply).
- In-house power generator is ready for 24/7.

Security system

- Using RF cards to store customers' valuable data with the highest level of security

Computer back-up system

- Back up all clinical data in real time by clustering system

Key Facts and Figures

Korea's 1st

Lab participating in the CAP (College of American Pathologists) external quality assessment program in Korea. We aim to become a global standard laboratory for the best quality of tests with international accreditations.

35

Medical Doctors specialized in laboratory medicine and pathology contribute to provide accurate and qualified results.

approx. 4,000

Tests we are performing ranging from routine tests to highly esoteric molecular and genetic assays.

Since 1982

More than 35 years of history.

35million

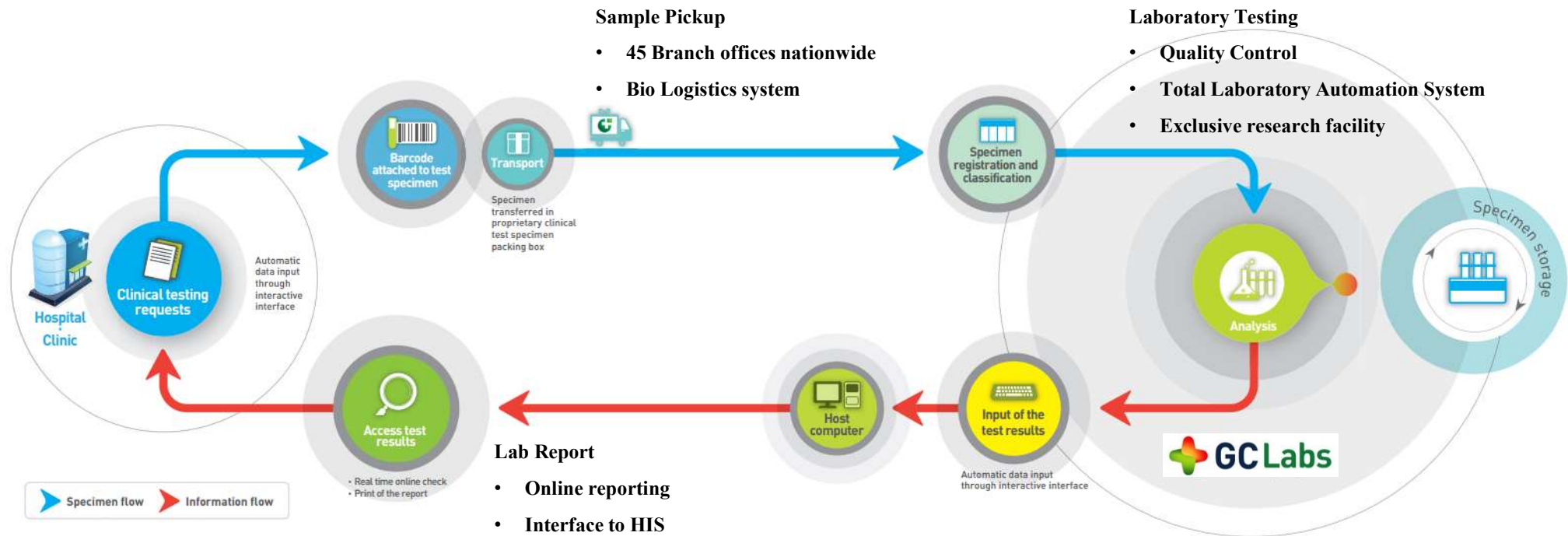
Number of analysis per annum are being performed in GC Labs.

651

Proficiency Tests performed

In the CAP (College of American Pathologists) external quality assessment program('17).

GC Labs' Specimen & Information Flow



- Specimen Monitoring System (by own LIS)
- TAT(Turn Around Time) Management
- e-Reporting
- Two Way Interface-Automatic data process
- Protecting patients' personal information

GC Labs' Testing Services

Laboratory Medicine

Korea's First and Largest Total Laboratory Automation System (TLA)

This system has helped us to offer rapid and accurate test results 24 hours a day, maximizing efficiency by cutting down on turnaround time and lowering laboratory error rates



GC Labs' Testing Services

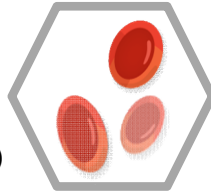
Laboratory Medicine

Hematology

Total Laboratory Automation System

- Handling large quantities of samples rapidly and accurately

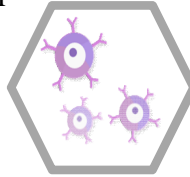
- Peripheral blood tests
- Bone marrow tests
- Blood coagulation tests
- Flow cytometry tests (lymphocyte subset test, PNH study)



Immunology

The Greatest Number of Immunologic Test Items in Korea to Diagnose Various Diseases

- Allergic
- Autoimmune
- Endocrine
- Infective
- Thrombotic
- Tumor markers
- Immunoglobulins
- Free light chains
- PRA (panel reactive antibody) and DSA (donor specific antibody) tests by Luminex technology for organ transplantation
- Bone metabolism
- Urea breath test
- Therapeutic drug monitoring



General Chemistry

Accurate and Rapid Results for The Widest Range of Tests associated with Various Diseases, Syndromes and Conditions

- Hepato-biliary-pancreatic
- Cardiovascular
- Renal
- Lipid tests
- Diabetes-related
- Hormones
- Bone metabolism
- Pregnancy-related
- Therapeutic drug monitoring
- Drug intoxication
- Tumor markers
- Electrophoresis
- Immunofixation electrophoresis (IFE)
- Urinalysis

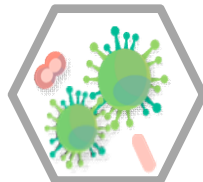


Microbiology

Isolated Area Equipped with Cutting Edge Facilities to Prevent Contamination

- Double doors, air showers, isolated exhaust system

- Isolates and identification of bacteria, mycobacteria tuberculosis, fungi and viruses
- Antimicrobial susceptibility test, following the standards set by the Clinical and Laboratory Standards Institute (CLSI)

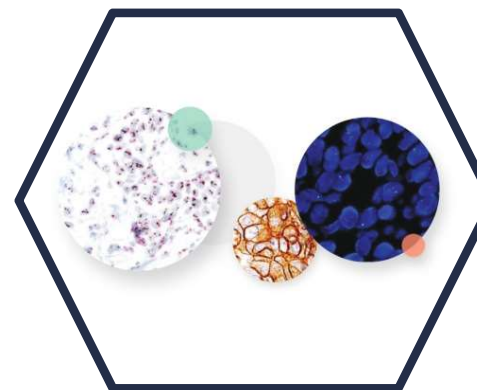


GC Labs' Testing Services

Pathology

Quality Assessments by official organizations including **Korean Society of Pathologists**, **Korean Society of Cytopathology**, **College of American Pathologists**, **UK NEQAS** (National External Quality Assurance Society)

- Immunopathology
- Molecular Pathology
- Histopathology
- Cytopathology
- AI Pathology (R&D)



Special Chemistry (with Institute of Metabolism)

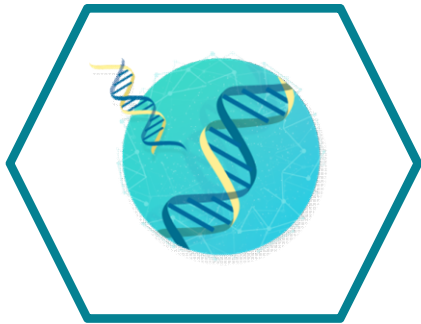
- Neonatal Screening Test
- Metabolic and Nutritional Profiles
- Environmental Toxicant Assay
- Esoteric Enzyme assay
- Pharmacokinetic Study
- **Equipment: LC-MS/MS, GC-MS, HPLC, ICP-MS**



GC Labs' Testing Services

Cytogenetics and Molecular Genetics

PCR, real-time PCR, multiplex PCR, QF-PCR, direct sequencing, pyrosequencing, fluorescent fragment length analysis (gene scan), microarray, MLPA (Multiplex Ligation-dependent Probe Amplification), FISH, etc.



- Cancer-related genetic tests
- Hereditary disease
- Prenatal diagnosis
- Cytogenetics
- Infectious diseases
- Pharmacogenetic tests
- Histocompatibility tests
- Forensic tests

Green Cross Genome


Fulfilling personalized genomic testing throughout lifetime

- Cancer Test : Breast-Ovarian / Colorectal / Hereditary cancer test
- Prenatal & Carrier test : G-NIPT, Wilson disease, Myotonic Dystrophy 1
- Rare Disease : Diagnostic Exome Sequencing (DES)
Chromosomal Microarray
- Other : Pharmacogenetic Test, DTC



Testing Service by GC Genome (Tested by GC Genome)

Pre / Post Natal



G-NIPT Non-Invasive Prenatal Test


Fragile-X Syndrome carrier Screening Test

Wilson Disease Genetic Screening Test

Myotonic Dystrophy I carrier Screening Test

congenital Hearing Loss Genetic Screening Test

Rare Disease (DES : over 6,000 genes)



Chromosomal Microarray

Diagnostic Exome Sequencing

- Cardiology
- Coagulation
- Dermatology
- Epilepsy
- Thyroid
- Neuromuscular
- Short Stature/Skeletal
- Lysosomal storage disease
- Inborn error of metabolism
- RASopathies

Pharmacogenetics



Pharmacogenetics Test

DTC Test



gene doctor+

Hereditary Cancer



Hereditary Cancer Genetic Test

Hereditary Cancer Genetic Test

BRCA1&2, TP53 gene mutation

MLH1, MSH2&6, APC Gene Mutation

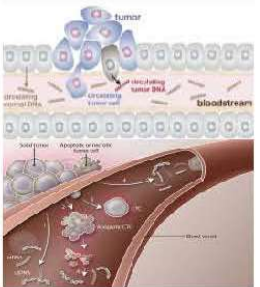
Cancer Health Protector

여성암 지키미

대장암 지키미

Cancer Screening

- ctDNA (Circulating Tumor DNA)
- Solid Tumor



The diagram shows a cross-section of a blood vessel. On the left, a solid tumor is shown with cells shedding DNA into the bloodstream. Labels include 'tumor', 'shedding ctDNA', 'circulating tumor DNA', and 'bloodstream'. On the right, a solid tumor is shown with cells shedding ctDNA into the bloodstream. Labels include 'Solid tumor', 'shedding ctDNA', 'circulating tumor DNA', and 'bloodstream'.

International Accreditation & Certification

GC Labs' quality improvement is based on 35years of knowledge and international standards

- ❖ Domestic Accreditation & Certification
- ❖ International Accreditation & Certification

				
<p>Patent “a method for analyzing tandem-mass data for clinical diagnosis”</p>	<p>CAP(The College of American Pathologists) Accreditation</p>	<p>ISO (International Standardization Organization) 9001</p>	<p>ISO (International Standardization Organization) 14001</p>	<p>CDC NSQAP</p>
				
<p>CDC LSP</p>	<p>CDC EQUIP</p>	<p>NGSP Level 1</p>	<p>Digital PT</p>	<p>G-EQUAS</p>

External Quality Assessment Program

CAP (The College of American Pathologists)

Program	No. of Product Code	No. of Analytes
CAP proficiency test	141	651

CDC (Centers for Disease Control)

Program	Items
LSP Lipid Standardization Program	Cholesterol-Total , HDL Cholesterol, Triglyceride
NSQAP Newborn Screening Quality Assurance Program	Extensive Newborn Screening Test (by MS/MS)
EQUIP Ensuring the Quality of Urinary Iodine Procedures	Iodine

Others

Program	Items
ISBER (DNA purity) International Society for Biological and Environmental Repositories	DNA Quantification and purity, DNA Extraction from Whole Blood RNA Quantification and purity, RNA extraction from Whole Blood Viable PBMC Isolation
G-EQUAS The German External Quality Assessment Scheme for Analyses in Biological Materials	Blood : Cd, Pb, Hg Urine : Cd, Pb, Hg, I, Cotinine, Hippuric acid, Mandelic acid, Methylhippuric acid
PCI Interlaboratory Comparison Program for Metals in Biological Matrices	Blood : Cd, Pb, Hg Urine : Cd, Pb, Hg, Cr, Cu, As, Zn, I
QMEQAS Quebec Multi-Element External Quality Assessment Scheme	Al and others
DEQAS Vitamin D External Quality Assessment Scheme	25(OH) Vit. D
RCPAQAP The Royal College of Pathologists of Australasia Quality Assurance Program	Plasma Metanephrine, Plasma Normetanephrine, Vitamin C, Vitamin B1, Vitamin B6
NGSP Level 1 National Glycohemoglobin Standardization Program	HbA1C

Lab test outsourcing to GC Labs

Providing Lab testing services to overseas institution (for Diagnosis, Clinical Trial)



Process of Test Requisition



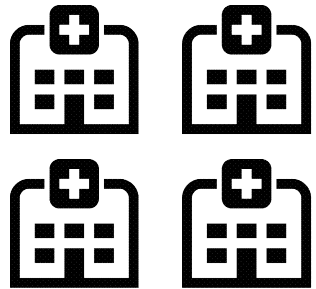
Lab test outsourcing to GC Labs



Test, Academic & MKT Support

- Sample collection is done in hospital or regional lab's collection center

- Sample packaging



(by FedEx, DHL)



- Registration



- Analysis



- Report back to overseas lab contact person



Collaboration with Overseas Partner

- Partnership with innovative regional lab for providing GC Labs' services
- Academic collaboration
- Establishing extensive technical network with advanced laboratory globally

Academic Support, Education



Global Diagnostics Network

The Global Diagnostics Network



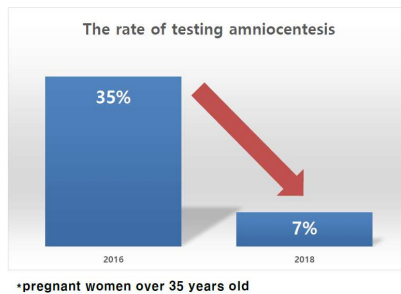
GDN Members

GDN members are some of the world's leading diagnostics companies from every continent, operating at the highest professional standards. Collectively, the GDN is present in countries with over half of the world's population. The founding members of the GDN are:



G-NIPT Background

4. NIPT advantages



Definition of Inborn Errors of Metabolism

- **Single gene defect :**
 - Autosomal recessive / X-linked recessive trait
- **Results in enzyme deficiency ⇒ inherited**
- **Deficiency in Cofactor ⇒ acquired**



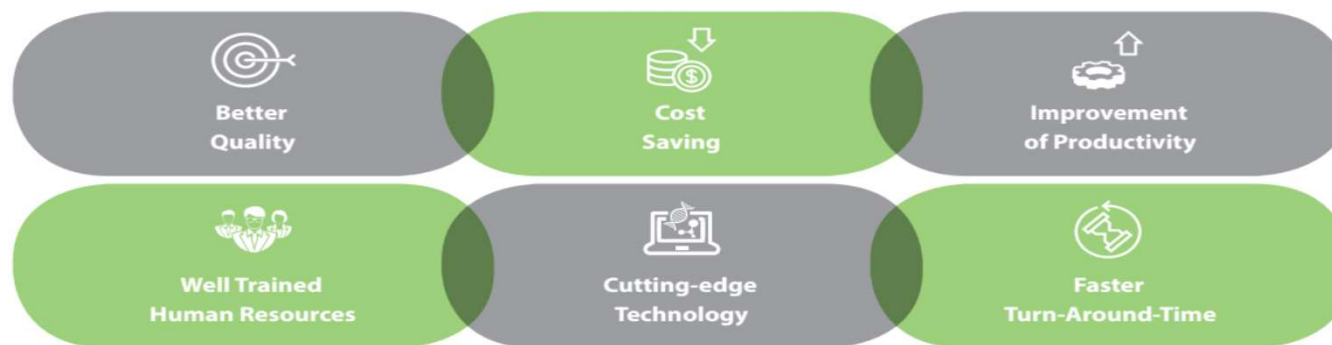
- Increased precursors: **A and B**
 - Lack of the product: **C**
 - Presence of increased amounts of alternate products: **D and E**
- Core indicator for evaluation & monitoring

Lab Operation Consulting Services



Service Scope	
Procurement	Selection of equipment and reagents suitable for each testing
Operation	Facility / Utilization / Automation planning Optimized Lab Information System & Document Management System
Technology	The latest technology information and academic exchanges Technology transfer of in-house developed items
Education	Personnel training and education Seminar for newest technology
Quality Assurance	Setting up internal QA program Helping the preparation for upcoming QC inspection

EXPECTING EFFECTS (including ongoing projects)



JV in Sri-Lanka



Biz Model of NAWALOKA-GREEN CROSS LAB in Sri-Lanka

- Operational start: 01 Apr 2017
- NAWALOKA; Finance, Human Resource and Hardware
- GC Labs; Consulting for lab operation, Technology provider
- Profit sharing system

Inaugural Ceremony (31st Mar 2017)

Auditorium, Nawaloka Hospital, Colombo Sri-Lanka



Thank You



Pioneering Diagnostics