Strategy to Innovate the Korea Biobank to Effectively Respond to Infectious Diseases

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Strategy to Innovate the Korea Biobank to Effectively Respond to Infectious Diseases

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CONTENTS

ABSTRACT ·····1

I. INTRODUCTION·····4

1. Research Background ····· 4

2. Research Purpose·····6

3. Research Scope and Methodology·····8

II. OVERVIEW OF THE MEDICAL DEVICE INDUSTRY AND IN VITRO DIAGNOSIS MEDICAL DEVICES·····10

1. Medical Device Industry·····10

A. Definition of the Medical Device Industry·····10

B. Characteristics of the Medical Device Industry·····11

2. Overview of *In Vitro* Diagnostic Medical Devices·····12

A. Definition of *In Vitro* Diagnostic Medical Devices·····12

B. The Types and Scope of *In Vitro* Diagnostic Medical Devices·····13

C. *In Vitro* Diagnostic Medical Device Classification·····16

3. Market Size of *In Vitro* Diagnostic Medical Devices·····17

A. Global *In Vitro* Diagnostic Medical Devices Market·····17

B. Domestic *In Vitro* Diagnostic Medical Devices Market·····20

III. THE CONCEPT AND ROLE OF BIOBANK·····33

1. The Term "Biobank" ·····33

A. Human Resources ·····33

B. Definition of Biobank·····34

C. Types of Biobanks·····36

D. Functions of Biobanks ·····37

2. Impact of Biobanks on the Medical Device Industry·····39

A. The Importance of Human Resource Biobanks·····39

B. Effects of the Increasing Importance of Human Resources·····40

C. Market Size of Biobanks for Human Resources·····41

IV. DOMESTIC AND INTERNATIONAL CLINICAL SAMPLE MANAGEMENT STATUS ·····44

1. Status of In Vitro Diagnostic Medical Device Companies·····44

A. Necessity of Clinical Samples and Limitations of Domestic Infection Sample Procurement Methods·····44

B. Lack of Support from Government Agencies·····50

C. Private Sector Efforts (Investment) for Clinical Sample Acquisition·····56

2. Status of Domestic Biobanks·····58

A. Introduction to Domestic Human Biobanks·····58

B. Legal Status of Human Biobanks in South Korea·····78

3. International Biobank Status·····80

A. Global Biobank Status·····80

B. Laws Related to Overseas Biobanks·····88

4. Domestic and International Biobank Survey and Analysis·····91

V. STRATEGY FOR BUILDING A GLOBAL NETWORK OF KOREAN BIOBANK·····93

1. Legal Revisions for Activating Biobanks·····93

2. Clinical Specimen Collection Requires a Conducive Environment ····97

3. Expansion of Global Collaborative Efforts in the Korea Biobank Project·····99

A. Designation of Domestic Collaborative Organizations for Clinical Trials·····99

B. Expansion of International Collaborative Efforts and the Need for New Models·····102

4. The Role of the KBN Portal in Information Exchange in South Korea……105

VI. DISCUSSION……107

VII. CONCLUSION……110

REFERENCES……112

ABSTRACT (IN KOREAN) ……116

LIST OF FIGURES

Figure 1. Graphical representation of the number of biobanking-related publications obtained from PubMed ·····43

Figure 2. Nationwide distribution of the Korea Biobank Network·····59

Figure 3. Korea Biobank Structure·····60

Figure 4. The collection status of human resources·····62

Figure 5. Application procedures for human bioresource distribution·····63

Figure 6. Participating Banks of the Korea Biobank Network·····64

Figure 7. Step-by-step strategy·····106

LIST OF TABLES

Table 1. The types and items of *in vitro* diagnostic medical devices·····14

Table 2. Classification of domestic *in vitro* diagnostic medical device grades·····17

Table 3. The classification of *in vitro* diagnostic medical devices in the European Union ·····17

Table 4. Specific market predictions from different research organization·····18

Table 5. Global *in vitro* diagnostics market value by region, 2020–2029 (million USD) ·····19

Table 6. The size of the domestic medical device market in South Korea for each year (million won, %) ·····21

Table 7. Overview of production performance by year·····21

Table 8. Yearly overview of export performance·····22

Table 9. Top 10 products by production amount in terms of value (thousand won, %) ·····23

Table 10. The top 10 products by export value (USD, %) ·····25

Table 11. Top 10 exporting countries for *in vitro* diagnostic medical devices (USD, %) ·····27

Table 12. South Korean *in vitro* diagnostics market value by product, 2020–2029 (million USD) ·····29

Table 13. South Korean *in vitro* diagnostics market value by technology, 2020-2029 (million USD) ·····30

Table 14. South Korean *in vitro* diagnostics market value by application, 2020–2029 (million USD) ·····31

Table 15. Comparison of biobank definitions by institution·····34

Table 16. Biobanks categorized by sample types·····36

Table 17. Functions and roles of biobanks·····38

Table 18. Domestic private companies establish their own biobanks·····40

Table 19. Effects of increased human resources·····40

Table 20. Cerebrospinal fluid sample procurement status (as of February 23) ·····47

Table 21. Institution-specific pathogen safety management systems and regulations·····48

Table 22. Collaborative organizations for the clinical evaluation of *in vitro* diagnostic medical devices for COVID-19 and other purposes·····53

Table 23. *In vitro* diagnostic medical device rapid clinical evaluation support network·····55

Table 24. Rapid clinical evaluation support system for *in vitro* diagnostic medical devices·····55

Table 25. Role of the institution·····60

Table 26. Statistics criteria as of December 31, 2021·····62

Table 27. Participating organizations in specialized human biobank·····65

Table 28. Innovative biobanking consortium participating institution·····69

Table 29. List of 41 human resource banks·····70

Table 30. Laws related to biobanks in South Korea·····78

Table 31. Summary of overseas biobank status·····86

Table 32. Summary of overseas private biobank status·····87

Table 33. Laws related to overseas biobanks·····89

Table 34. Comparison of domestic and foreign biobanks·····92

ABSTRACT

Strategy to Innovate the Korea Biobank to Effectively Respond to Infectious Diseases

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In the early stages of the COVID-19 outbreak, domestic *in vitro* diagnostic medical device companies developed diagnostic reagents and with the implementation of the "Emergency Use Authorization" by the government, were able to quickly use diagnostic kits. With the sustained growth of infectious disease diagnostic testing products related to COVID-19, *in vitro* diagnostic medical device companies experienced significant growth, and became the key drivers of the medical device industry. However, under the strengthened clinical trials mandated by the *In Vitro* Diagnostic Regulation (IVDR), securing clinical samples has become more important for *in vitro* diagnostic medical devices.

The purpose of this study was to emphasize the significance of obtaining clinical samples for infectious disease research in response to strengthened regulations. Additionally, it highlights the crucial role of government support in providing information on clinical samples collection and offering clinical trial assistance to *in vitro* diagnostic medical device companies.

To accomplish this, the study examined the types and grades of *in vitro* diagnostic medical devices in the medical device industry, domestically and internationally, and highlighted the challenges faced by companies in securing clinical samples through real-world examples. Starting with the terms and concepts of biobanking in various countries, the study investigated its operations, purposes, and institutional and legal advancements to understand the current status of domestic and international biobanks for problem-solving. Lastly, to maximize the utilization of infectious disease clinical samples, the study was concluded by deriving strategic plans for expanding and using domestic and international biobank networks.

Through this research, a step-by-step strategy is proposed to activate domestic biobanks.

First, we propose a legislative amendment by referencing the legal framework of countries with advanced healthcare systems. This amendment aims to facilitate the utilization of clinical samples and activate biobanks by changing the legislative purpose.

Second, there is a need to create an environment that facilitates clinical samples information collection from procurement to use.

Third, we aim to enhance global collaboration in the Korean Biobank Project by designating domestic partners for overseas clinical trials and other collaborative initiatives.

Fourth, we recommend the expansion of specimen collection types within Korea Biobank Network Portal, comprehensive integration of information from all domestic biobanks, and globalization of Korean biobank network portal to enhance its international reach.

Focusing on strengthening ongoing government–private sector collaboration and expanding the domestic biobank network, we propose a national-level strategy for expanding global partnerships with organizations enabling South Korea to successfully lead the future *in vitro* diagnostics market globally.

Key words: *in vitro* diagnostic devices (IVDs), biobank, clinical sample, infectious disease, strategy, government support

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I. Introduction

1. Research Background

During the COVID-19 pandemic, domestic *in vitro* diagnostic medical device companies in South Korea applied their accumulated expertise to rapidly develop diagnostic reagents. In addition, the government implemented an "Emergency Use Authorization" system during the initial stages of COVID-19, thereby facilitating the utilization of *in vitro* diagnostic medical devices (IVDs), such as COVID-19 diagnostic kits, to promptly confirm infections among the public and manage severe cases, including fatalities. These measures demonstrated an exemplary response to the pandemic.

Furthermore, through proactive medical guidance and the introduction of specialized terms such as "molecular diagnostics" and "*in vitro* diagnostics," South Korea managed to overcome the pandemic situation intelligently enough to earn the title of "K-Quarantine."

Interest in South Korea's COVID-19 diagnostic devices expanded further when outstanding performance data on domestically produced COVID-19 diagnostic devices became publicly available in 2020. In March 2021, Seegene (a Korean molecular

diagnostics company) was mentioned alongside renowned companies, including Moderna and Pfizer, as one of the "Top 50 of the World's most innovative companies."[1]

The global reputation of molecular diagnostics companies can be attributed to the continuous growth of South Korea's medical device industry in COVID-19 diagnostic testing categories, enabling the country to maintain a trade surplus for 2 consecutive years.

According to the Ministry of Food and Drug Safety (MFDS), the trade surplus for medical devices reached KRW 3.74 trillion in 2021, an increase of 44% compared to the previous year (KRW 2.60 trillion). The production performance of medical devices in 2021 reached KRW 12.88 trillion, a 27.1% increase compared with the previous year. Among the total production performance of medical devices, IVDs accounted for 33.8%, acting as the main driver for this growth. The production of IVDs increased by 29.7% from the previous year, reaching KRW 4.35 trillion. Furthermore, the export performance of IVDs increased by 26.4% compared to 2020, amounting to approximately KRW 5.32 trillion, accounting for 53.9% of the total medical device exports. This remarkable growth in domestic *in vitro* diagnostic medical device companies has significantly propelled the medical device industry in South Korea.[2]

However, the landscape has evolved in compliance with European Union (EU) regulations on medical devices and the European Parliament and Council's regulations on IVDs [*in vitro* diagnostic regulations (IVDR)], which were implemented on May 26, 2017.[3] The IVDR replace the existing EU directive (98/79/EC) for IVDs, providing a new regulatory framework for introducing, enabling, and servicing IVDs in the European market. Manufacturers have intensified their efforts to secure clinical samples and meet the strengthened regulatory requirements for clinical trials as a result of IVDR implementation.

Although the Food and Drug Administration (FDA) and MFDS undergo clinical performance testing from sample acquisition to clinical trials, the certification process resulting from the IVDR takes longer than that resulting from previous guidelines. Challenges include difficulties in securing clinical samples, differentiation based on device

classes, and software and documentation requirements in the local language in Europe. These challenges increase company expenses, which lengthens the time required to penetrate the European market and generate sales. Consequently, businesses face deteriorating operational conditions because of the complexities, economic burdens, and prolonged timelines associated with entering the European market after the implementation of these regulations.

During CE-IVDD, it was sufficient to provide a self-declaration without extensive clinical verification using clinical samples, which enabled faster market entry and revenue generation in Europe. However, with the transition to IVDR, if the acquisition of clinical samples for conducting clinical trials is not timely, it will pose challenges. This delay could affect regulatory approvals and reduce sales in countries with significant exports.
The challenges posed by IVDR and the increasing difficulty in market adaptation led LG Chem to divest its diagnostic business unit under the Life Sciences Division in April 2023. The Seoul Economic Daily reported that this decision was influenced by concerns that LG Chem was not responding quickly enough to the changes in the diagnostic reagent industry.[4] The decision to divest the diagnostic business unit by well-capitalized large corporations indicates that the challenges of entering the European market for startups and small- and medium-sized enterprises may become more daunting in terms of management and regulatory requirements.

2. Research Purpose

The IVDR 2017/46 of the European Parliament and Council, which replaced the current guidelines (98/79/EC), were enacted on May 26, 2017.[3] Under the *in vitro* diagnostic directive (IVDD) regime, entry into the European market was relatively straightforward with self-declaration. However, with the enhanced regulations, validation through clinical sample usage has become even more critical during performance and clinical trials.

Manufacturers now face increased resource requirements for certification and market entry compared to the previous IVDD system. The South Korean MFDS certification, formerly part of the Consumer Goods Act and currently incorporated into the Medical Devices Act, verifies whether clinical trials were conducted using sufficient clinical samples to confirm their validation. This trend toward strengthening clinical trials for approval is noticeable in various entities worldwide, such as Health Canada, FDA, and Brazilian Health Regulatory Agency.

During the pandemic, government initiatives led the South Korean in vitro diagnostic medical device market to witness significant growth, such as emergency approvals and support for clinical samples, which positively influenced the performance of companies. However, under the strengthened regulations, going forward, only the performance verification of various clinical samples will enable obtaining approvals and sales.

This study aims to clarify the current status of biobanking for clinical sample collection, which is a crucial factor in obtaining approvals. Therefore, it explores countries where biobanking is well-operated and assesses whether their *in vitro* diagnostic medical device markets are active, the purposes they serve, and whether they have more advanced regulatory systems than those in South Korea. Additionally, the utility of domestic biobanks is investigated, and government support programs related to clinical trials and clinical sample acquisition are examined to determine whether they provide practical assistance. If existing government support programs are not significantly beneficial to companies, this study will determine the support necessary for *in vitro* diagnostic medical device companies, which drive the growth of the medical device industry, and present unresolved issues, such as the need for standardized clinical sample information.

Furthermore, this study emphasizes the significance of securing infectious disease clinical samples in light of the enhanced regulations and explains how government support for clinical sample collection information and clinical trials is crucial for *in vitro* diagnostic medical device companies. Therefore, domestic and international biobanking and relevant

regulations are examined. In addition, this study proposes a step-by-step strategy in line with the Medical Device Industry Act and advocates for policy support.

3. Research Scope and Methodology

This study enhances the understanding and emphasizes the importance of IVDs in the medical device industry; explains the definition, types, and scope of IVDs; and examines the market size. To support sustained growth, we address the challenges that *in vitro* diagnostic medical device companies encounter in securing clinical samples using real-world case examples. Considering the legal framework, we domestically and internationally investigate the current status of biobanks involved in the collection, storage, utilization, and provision of clinical samples.

First, we organize the terminologies related to biobanks and human resources, which are used differently by countries and fields. We explain the significance of biobanks and their impact on the medical device industry.

Second, we investigate the current status of *in vitro* diagnostic medical device companies. Through regulatory tightening, clinical trials that use clinical samples have become essential for obtaining certifications domestically and internationally. We assess the limitations of domestic and international sample collection methods and determine whether government support programs are effective for market entry.

Third, we examine the biobanks responsible for collecting, storing, and providing clinical samples, a key element in securing clinical samples for IVD sale. In addition, we investigate the current domestic and international situation of biobanks, assess whether legal and institutional advantages exist abroad, and select organizations with high human resource utilization rates using comparative analysis.

Finally, we draw conclusions by analyzing the current state of clinical sample management

domestically and internationally. Moreover, we demonstrate a strategic plan for utilizing and expanding the domestic and international biobank network to maximize the utilization of clinical samples related to infectious diseases through global collaboration.

By addressing these four aspects, we aim to provide a comprehensive understanding of the challenges and opportunities concerning IVDs in the context of evolving regulations and the significance of biobanks in supporting the medical device industry.

II. Overview of the Medical Device Industry and *In Vitro* Diagnostic Medical Devices

This section presents an overview of the medical device industry, focusing on IVDs and their definitions, types, and scope. Additionally, we will analyze the market size of these devices, focusing on their significance within the medical device industry.

1. Medical Device Industry

A. Definition of the Medical Device Industry

"Medical Device," as defined in Article 2 of the "Medical Devices Act," refers to instruments, machines, devices, materials, software, or similar items that are used alone or in combination to diagnose, treat, alleviate, handle, or prevent human or animal. It also includes products used for diagnosing, treating, alleviating, or correcting injuries or disabilities; products used to inspect, replace, or modify structures or functions; and products used for pregnancy control.[5] However, this concept excludes products governed by the "Pharmaceutical Affairs Act," such as pharmaceutical and nonpharmaceutical products, and assistive devices referred to in Article 65 of the "Act on Welfare of Persons with Disabilities," except for voluntary and auxiliary devices.[6] The term "medical device industry," defined in the "Promotion of the Medical Device Industry and Support for Innovative Medical Devices Act," refers to the industry related to the research, development, manufacturing, import, repair, and distribution of medical devices, as defined in Article 2, Paragraph 1 of the "Medical Devices Act."[7] According to the 2020 Medical Device Analysis Report published by the Korea Health Industry Development Institute, the medical device industry is defined as an interdisciplinary field that integrates various technologies, including clinical medicine, electrical engineering, electronics, mechanical engineering, materials science, and optics, in the design and manufacturing of medical

device products. Ultimately, the medical device industry aims to improve the quality of human life by applying these technologies in healthcare and medicine.[8]

B. Characteristics of the Medical Device Industry

According to the 2020 Medical Device Industry Analysis Report published by the Korea Health Industry Development Institute, the characteristics of the medical device industry can be summarized into five key points.

First, medical devices include several products that have become increasingly complex and diversified as technology advances. They are characterized by interdisciplinary technology integration and application, involving different fields, such as clinical medicine, electrical and electronic engineering, mechanical engineering, materials science, and optics. Medical devices span a broad spectrum, from consumables (e.g., syringes and basic medical supplies) to advanced electronic medical devices. With technological advances, these devices have become more intricate and diverse.[8]

Second, the medical device industry is characterized by small-scale, multiproduct manufacturing. As technology advances, medical devices with diverse product categories have become more complex and diversified. They are distributed through small-scale, multiproduct manufacturing rather than mass production. Consequently, the industry is marked by a trend toward downsizing and sophistication.[8]

Third, the medical device industry is closely associated with government healthcare policies and regulatory systems. As an industry involved in producing products related to human life and health, it directly or indirectly enhances public health and secures health rights. Therefore, government approval and regulation are essential because of their direct use on the human body.[8]

Fourth, the medical device market has limited demand. The primary demand for medical

devices comes from specialized medical institutions specializing in diagnosis and treatment. Therefore, these institutions prioritize the safety and reliability of the products they use. Consequently, healthcare professionals in medical institutions tend to be conservative in their preference for continuous use of existing products. This high degree of conservatism creates relatively high barriers to entry for small- and medium-sized enterprises into the market.[8] Additionally, products with high brand awareness and trust are advantageous in capturing the market. Therefore, proactive investments in new technologies can bring significant advantages when entering the market.[9]

Fifth, continuous investment in research and development is necessary. The medical device industry is capital- and technology-intensive, with a development and production cycle spanning approximately 3–5 years, resulting in a longer return on investment period. Furthermore, the market size of products is relatively small, and the product life cycle is not lengthy, thereby requiring ongoing investment in research and development.[8]

2. Overview of *In Vitro* Diagnostic Medical Devices

A. Definition of *In Vitro* Diagnostic Medical Devices

Article 2 of the In Vitro Diagnostic Medical Devices Act defines IVDs as products used to diagnose the physiological or pathological status of humans or animals by examining specimens originating from humans or animals. These products include reagents, reference or calibration materials, instruments, machines, devices, software, and any medical device defined under Article 2, paragraph 1 of the Medical Devices Act. They are used for various purposes, including diagnosing disease causes, observing disease prognosis, providing information about congenital disabilities, ensuring the safety and suitability of blood and tissues for transfusion or transplantation, predicting treatment responses and outcomes, determining treatment methods, monitoring treatment effectiveness, and detecting side effects.[10]

According to the policy trends report by the Korean Medical Device Safety Information and Analysis Center, diagnostic methods for the human body can be broadly categorized into *in vivo* diagnosis, which examines the inside of the body, and *in vitro* diagnosis, which diagnoses conditions based on substances collected from the body. *In vivo* diagnosis typically uses endoscopy or imaging data obtained from techniques such as radiology and ultrasound to assess the presence and severity of diseases. Conversely, *in vitro* diagnosis relies on biological reactions that involve substances originating from the human body, such as blood, urine, bodily fluids, or saliva, to determine the presence or verification of diseases. In general, IVDs are medical devices that test samples collected from the human body, including reagents and instruments, for disease diagnosis, prognosis assessment, health status evaluation, treatment effectiveness determination, and prevention.[11]

According to Article 2 of the EU IVDR, IVDs mean any reagent medical device, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software, or system, whether used alone or in combination. These devices are intended by the manufacturer to be used *in vitro* for specimen examination, including blood and tissue donations, derived from the human body, solely or principally to provide information on one or more of the following: (a) concerning a physiological or pathological process or state; (b) concerning congenital physical or mental impairments; (c) concerning the predisposition to a medical condition or a disease; (d) determining the safety and compatibility with potential recipients; I predicting treatment response or reactions; and (f) defining or monitoring therapeutic measures. In addition, specimen receptacles can be considered IVDs. “Specimen receptacle” is a device, whether or not of a vacuum type, specifically intended by its manufacturer.[3]

B. The Types and Scope of *In Vitro* Diagnostic Medical Devices

The *in vitro* diagnostic medical device market can be categorized based on different factors, including technology, products, diseases, and end users. However, owing to

overlapping criteria, it is generally divided into subcategories based on “target diseases” or “testing methods.” The categorization based on target diseases includes subdivisions for diseases such as endocrine disorders, cancer, infectious diseases, immune disorders, heart diseases, electrolytes, drugs, urinalysis, pregnancy, and diabetes. In contrast, the categorization based on testing methods divides the market into eight segments: immunodiagnosis, self-blood glucose measurement, point-of-care testing, molecular diagnosis, blood diagnosis, clinical microbiological diagnosis, hemostasis diagnosis, and tissue diagnosis. The MFDS in South Korea uses these categories for IVD management and regulation.[11]

Table 1. The types and items of *in vitro* diagnostic medical devices.

Type	Code	Detailed items
Reagents for blood tests	(D01000)	· Blood cell test reagent · Reagent for leukocyte analysis · Erythrocyte sedimentation rate test reagent · Blood cell staining test reagent · General reagent for blood coagulation tests · Blood coagulation test reagent, blood clot test reagent
Reagents for blood transfusion tests	(D02000)	· ABO·RhD blood type test reagent · Reagent for blood type tests other than ABO·RhD · Reagent for blood clot tests for transfusion
Reagents for urine or stool tests	(D03000)	· Chemical test reagents for urinalysis · Fecal occult blood test reagents
Reagents for immunochemistry tests	(D04000)	· Immunochemistry test reagents · Blood gas analysis test reagents · Cardiac disease marker test reagents

		· Therapeutic drug concentration test reagents · Narcotics and toxic substance metabolism test reagents · Tumor marker immunoassay test reagents · Endocrine substance test reagents · Congenital abnormality test reagents · Genetic metabolic disease test reagents · Autoimmune disease test reagents · Allergy test reagents · Immunoassay test reagents for nonblood and nontransplant tissue · Immunoassay test reagents for blood and transplant tissue · HIV, HBV, HCV, and HTLV immunoassay test reagents · HIV, HBV, HCV, and HTLV blood type and Rh test reagents · High-risk infectious agent immunoassay test reagents · Low-risk infectious agent immunoassay test reagents
Reagents for clinical microbiology tests	(D05000)	· Microbial staining and culture reagents · Drug susceptibility and resistance microbial test reagents · Drug susceptibility and resistance marker test reagents
Reagents for molecular genetic tests	(D06000)	· Genetic disease test reagents · Tumor-related genetic test reagents · Drug genetic test reagents · Nonblood and nontransplant tissue genetic test reagents · Blood and transplant tissue genetic test reagents · HIV, HBV, HCV, and HTLV genetic test reagents · HIV, HBV, HCV, and HTLV genetic type test reagents · High-risk infectious agent genetic test reagents · Low-risk infectious agent genetic test reagents

		· Genetic material extraction reagents
In vitro diagnostic test kits	(D07000)	· Personal *in vitro* diagnostic test reagents · Personal immunochemical test papers II (Old) · Personal *in vitro* diagnostic test reagents I
Reagents for pathological tests	(D08000)	· Staining reagents for cell and tissue pathology examination I · Staining reagents for cell and tissue pathology examination II · Staining reagents for cell and tissue pathology examination III · Staining reagents for nucleic acid *in situ* hybridization I · Staining reagents for nucleic acid *in situ* hybridization II · Staining reagents for nucleic acid *in situ* hybridization III
Other reagents for tests	(D09000)	· Control material for miscellaneous test reagents

※ Source: The Ministry of Food and Drug Safety.

C. *In Vitro* Diagnostic Medical Device Classification

The MFDS classifies IVDs into a four-tier system based on their individual and public safety assessment criteria. The safety assessment criteria include the intended use and precautions, user expertise, significance of diagnostic information, and impact of diagnostic test results. Devices are classified into four tiers depending on the level of risk, with higher risks receiving higher tier classification. Most *in vitro* diagnostic medical device reagents fall into the third tier. The COVID-19 diagnostic reagents are classified as fourth tier. The higher the tier classification, the more critical the performance evaluation through clinical specimen usage.

Table 2. Classification of domestic *in vitro* diagnostic medical device grades.

Grades	Hazardousness	Type
First grade	Low hazard	Reagents for, for example, general agar and genetic extraction reagents
Second grade	Moderate hazard	Immunological assay reagents, among others
Third grade	Moderate hazard	Reagents for influenza infection diagnosis, tumor examination reagents, among others
Fourth grade	High hazard	Blood screening reagents for blood type confirmation, specific reagents for, for example, HIV, HBV, and HCV

※ Source: The Ministry of Food and Drug Safety.

Table 3. The classification of *in vitro* diagnostic medical devices in the European Union.

Grades	Hazard level
Class A	Low-hazard products
Class B	Products with low-to-moderate hazard
Class C	Products with high hazard to individuals but low hazard to public health
Class D	Products with high hazard to both individuals and public health

3. Market Size of *In Vitro* Diagnostic Medical Devices

A. Global *In Vitro* Diagnostic Medical Devices Market

The global diagnostic medical device market size was approximately $73.4 billion (around 85.5 trillion Korean won) in 2019, demonstrating an average annual growth rate of 4% over the past 5 years. This market represents nearly 18% of the global medical device market, which is approximately $444.7 billion (around 491 trillion Korean won). Imaging devices and *in vitro* diagnostic devices predominantly dominate the market, each with a size of around $29.5 and $29.8 billion, respectively, accounting for 80% of the diagnostic medical device market. According to market research agencies, such as Allied Market

Research, Global Information, Inc., and Markets and Markets, it is expected to grow at an annual rate of approximately 4%, reaching an estimated size of around $91 billion by 2025.

According to market data from the U.S. business consulting firm Frost & Sullivan, the total revenue for the global *in vitro* diagnostics market was around $99.22 billion as of 2021, with an average annual growth rate of 6.9%. It is anticipated to grow to approximately $138.3 billion by 2026.[12,13]

Table 4. Specific market predictions from different research organizations.

Market research agency	**Forecast period (years)**	**CAGR (%)**	**Estimated Market Size (million** USD)		
			25 years	26 years	27 years
Allied Market Research	20–27	4.8	-	-	91,000
Global Information	21–26	4.9	-	91,200	-
Markets and Markets	21–25	2.6	96,000	-	-
Frost & Sullivan	21–26	6.9		138,300	

※ Source: Allied Market Research, *In Vitro* Diagnostics Market by Product & Service 2020–2027, 2021.

※ Source: Global information, inc., *In Vitro* Diagnostics Market-Growth, Trends, COVID-19 Impact, and Forecasts (2021–2026), 2021.7.

※ Source: Markets and Markets, *In Vitro* Diagnostics Market by Product & Service-Global Forecast to 2025, 2020.

※ Source: Frost & Sullivan market data processing.

※ CAGR: compound annual growth rate.

After the pandemic, an investigation of the market reports for 2023 shows that the market was already significantly influenced by COVID-19 in 2020. In addition, the compound annual growth rate (CAGR) will not be very high until 2029.

In 2023, according to MAGNA Intelligence's data of "Leading *In Vitro* Diagnostics Country Markets," the *in vitro* diagnostics market was valued at $112,518.8 million in 2020 and is projected to reach $113,081.5 million by 2029, exhibiting modest growth at a CAGR

of 0.09% from 2021 to 2029. North America is expected to be the largest contributor to this market, with a value of $37,248.6 million in 2020. It is anticipated to reach $37,135.8 million by 2029, with a minimal CAGR of 0.00%. Meanwhile, the Asia–Pacific region is expected to experience the highest growth rate, reaching $28,068.2 million by 2029 with a CAGR of 0.20%. North America and Europe collectively accounted for approximately 63.1% of the *in vitro* diagnostics market in 2020, with North America contributing around 33.1% of this share. Asia–Pacific and Europe are projected to witness significant growth rates at CAGRs of 0.20% and 0.07%, respectively, throughout the forecast period. As of 2020, these two regions combined accounted for roughly 54.6% of the total *in vitro* diagnostics market and are expected to increase to 54.8% by 2029.[14]

Table 5. Global *in vitro* diagnostics market value by region, 2020–2029 (million USD).

Region	2020	2021	2022	2023	2024	2025
North America	37,248.6	37,130.6	37,039.2	36,974.2	36,935.6	36,923.1
Europe	33,800.3	33,715.7	33,655.2	33,618.7	33,606	33,617.2
Asia–Pacific	27,660.8	27,627.1	27,613.1	27,168.7	27,643.9	27,688.9
Latin America, Middle East, and Africa	13,809.1	13,788.3	13,777.4	13,776.2	13,784.8	13,803.2
Total	112,518.8	112,261.7	112,084.8	111,987.8	111,970.3	112,032.3

Region	2026	2027	2028	2029	CAGR%
North America	36,936.9	36,976.5	37,043.1	37,135.8	0.00%
Europe	33,652.2	33,711.2	33,794.3	33,901.6	0.07%
Asia–Pacific	27,753.6	27,838.3	27,943.1	28,068.2	0.20%
Latin America, Middle East, and Africa	13,831.4	13,869.5	13,917.7	13,975.9	0.17%

Total	112,174.1	112,395.9	112,698.1	113,081.5	0.09

※ Source: primary research, secondary research, Magna Information Centre.

B. Domestic *In Vitro* Diagnostic Medical Devices Market

(A) Status by Year

The domestic *in vitro* diagnostics market has exhibited rapid growth after COVID-19. *In vitro* diagnostics in the domestic diagnostic medical device market account for approximately 52.1%, representing half of the market. The demand in domestic and international markets has increased significantly. According to the Korea Food and Drug Administration, the medical device trade balance was KRW 3.8 trillion in 2022 and KRW 3.7459 trillion in 2021. This analysis indicates that COVID-19 diagnostic testing-related items have been the main drivers of this trend.

Based on data from the Korea Food and Drug Administration for 2022 (Tables 9 and 10), the proportion of IVDs in the total medical device production and exports is significant: approximately 54% in 2021 (KRW 5.32 trillion out of KRW 9.87 trillion) and 44% in 2022.

After examining the top 10 production and export items (Tables 11 and 12) and the top three export items by continent, the following products stand out: “high-risk infectious gene testing reagents,” “high-risk infectious immunological test reagents,” and “infectious agent diagnostic immunological test reagents.”

Regarding the top export destinations, in 2021, Germany and Italy accounted for approximately 42% of the total. However, exports to countries outside of Europe, such as the USA, Taiwan, Japan, and Brazil, increased in 2022.[15]

Table 6. The size of the domestic medical device market in South Korea for each year (million won, %)

Category (year)	Production (A)	Exports (B)	Imports (C)	Trade balance (E)	Market size (F)	Import market share (G)	Market growth rate (%)
2018	6,511,135	3,972,317	4,279,057	−306,739	6,817,874	62.76	10
2019	7,279,384	4,324,479	4,849,005	−524,526	7,803,910	62.14	14.46
2020	10,135,785	7,831,490	5,227,399	2,604,091	7,531,694	69.41	−3.49
2021	12,883,106	9,874,643	6,125,684	3,748,960	9,134,146	67.06	21.28
2022	15,737,442	10,174,528	6,315,254	3,859,273	11,878,169	53.17	30.04

※ Trade balance (E) = (B) − (C), Market size (F) = (A) − (B) + (C), Import market share (G) = (C)/(F) × 100.
※ Exchange rate for converting export and import amounts ($ to KRW): Based on the annual average exchange rate set by the Bank of Korea.
※ Source: Ministry of Food and Drug Safety, 2022 Medical Device Production and Export/Import Performance Statistics.

Table 7. Overview of production performance by year.

Category (year)	*In vitro* diagnostic medical devices							
	Number of companies	Growth rate	Number of items	Growth rate	Growth rate Personnel	Growth rate	Production amount (million won)	Growth rate
2018	-	-	-	-	-	-	-	-
2019	-	-	-	-	-	-	-	-
2020	349	-	2,985	-	14,572	-	3,354,929	-
2021	411	17.77	3,208	7.47	15,386	5.59	4,350,145	29.66
2022	442	7.54	3,273	2.03	15,942	3.61	6,042,342	38.9

Category (year)	Total medical devices (general + *in vitro* diagnostics)							
	Number of companies	Growth rate	Number of items	Growth rate	Growth rate personnel	Growth rate	Production amount (million won)	Growth rate
2018	3,425	4.33	15,082	1.53	61,464	6.72	6,511,135	11.81
2019	3,570	4.23	15,705	4.13	64,470	4.89	7,279,384	11.8
2020	3,887	8.88	16,568	5.5	80,317	24.58	10,135,785	39.24
2021	4,085	5.09	17,433	5.22	84,915	5.72	12,883,106	27.11
2022	4,176	2.23	17,778	1.98	89,333	5.2	15,737,442	22.16

※ As of May 2020, changes were implemented in the statistical data collection process due to the enactment of the *In Vitro* Diagnostic Medical Devices Act.

※ Number of enterprises: companies reporting production among manufacturing enterprises.

※ The number of personnel in medical devices (general + *in vitro*) is calculated by including the personnel count from general and *in vitro* diagnostic companies, leading to duplication in the total count.

※ Source: Ministry of Food and Drug Safety, 2022 Medical Device Production and Export/Import Performance Statistics.

Table 8. Yearly overview of export performance.

Category (year)	*In vitro* diagnostic medical devices								
	Number of companies	Growth rate	Number of items	Growth rate	Growth rate personnel	Growth rate	Export amount (thousand USD)	Growth rate	Converted amount (million won)
2018	-	-	-	-	-	-	-	-	-
2019	-	-	-	-	-	-	-	-	-
2020	128	-	1,545		7,644	-	3,568,657		4,211,194
2021	137	7.03	1,663	7.64	7,373	−3.55	4,649,436	30.29	5,320,907
2022	130	−5.11	1,720	3.43	9,167	24.33	3,536,201	−23.94	4,568,595

Category	Total medical devices (general + *in vitro* diagnostic)								
Year	Number of companies	Growth rate	Number of items	Growth rate	Growth rate personnel	Growth rate	Export amount (thousand USD)	Growth rate	Converted amount (million won)
2018	979	5.16	6,692	2.87	31,732	9.05	3,610,213	14.1	3,972,317
2019	1,003	2.45	7,208	7.71	34,876	9.91	3,709,929	2.76	4,324,479
2020	1,060	5.68	7,498	4.02	39,060	12	6,636,575	78.89	7,831,490
2021	1,090	2.83	7,913	5.53	42,264	8.2	8,628,513	30.01	9,874,643
2022	1,102	1.1	8,084	2.16	48,137	13.9	7,875,326	-8.73	10,174,528

※ The statistical reporting method changed because of the implementation of the *In Vitro* Diagnostic Medical Devices Act in May 2020.

※ Number of enterprises: companies that reported export performance among manufacturing companies.

※ The conversion rate for export amounts from USD to KRW is based on the annual average exchange rate provided by the Bank of Korea.

※ The number of personnel in medical devices (general + *in vitro*) is calculated by including the personnel count from general and *in vitro* diagnostic companies, leading to duplication in the total count.

※ Source: Ministry of Food and Drug Safety, 2022 Medical Device Production and Export/Import Performance Statistics.

Table 9. Top 10 products by production amount in terms of value (thousand won, %).

No.	Classification number	Korean items	2021		
			Production value	Rate (%)	Rank
1	K05030.01	High-risk infectious agent immunodiagnostic reagents	2,012,459,599	15.62	1

2	C20030.01	Dental implant abutment	1,444,681,676	11.21	2
3	K05000	Infection pathogen diagnostic immunological reagent	274,364,376	2.13	7
4	N05030.01	High-risk pathogen genetic testing reagent	1,153,384,883	8.95	3
5	A26380.01	General ultrasound imaging diagnostic device	569,278,828	4.42	4
6	C20040.01	Dental implant superstructure	551,898,493	4.28	5
7	B04230.01	Tissue restoration biomedical material	301,160,333	2.34	6
8	C21010.01	Dental implant surgical equipment	209,281,338	1.62	10
9	A77030.01	Daily disposable soft contact lenses	216,081,192	1.68	9
10	A26430.08	Medical imaging acquisition device	191,622,434	1.49	11
		Subtotal	6,924,213,152	53.7	
		Total	12,883,105,830	100	

No.	**Classification number**	**Korean items**	**2022**			**Increase or decrease (%)**
			Production value	**Rate (%)**	**Rank**	
1	K05030.01	High-risk infectious agent immunodiagnostic reagents	3,031,443,999	19.26	1	50.63
2	C20030.01	Dental implant abutment	1,835,608,871	11.66	2	27.06
3	K05000	Infection pathogen diagnostic immunological reagent	1,441,503,050	9.16	3	425.4
4	N05030.01	High-risk pathogen genetic testing reagent	856,901,253	5.44	4	-25.71

5	A26380.01	General ultrasound imaging diagnostic device	663,347,573	4.22	5	16.52
6	C20040.01	Dental implant superstructure	602,318,340	3.83	6	9.14
7	B04230.01	Tissue restoration biomedical material	395,767,532	2.51	7	31.41
8	C21010.01	Dental implant surgical equipment	274,857,015	1.75	8	31.33
9	A77030.01	Daily disposable soft contact lenses	231,825,605	1.47	9	7.29
10	A26430.08	Medical imaging acquisition device	225,025,294	1.43	10	17.43
Subtotal			9,558,598,532	60.7		38.05
Total			15,737,442,191	100		22.16

※ Ratio: the production amount of the respective product item in a given year relative to the total production amount for that year.

※ Rank: the ranking of the respective product item in terms of production amount among all product items for that year.

※ Increase/decrease (%): the percentage change in production for the respective product item from the previous year.

※ Source: Ministry of Food and Drug Safety, Statistics on the Production and Export–Import of Medical Devices in 2022.

Table 10. The top 10 products by export value (USD, %).

No.	**Classification number**	**Korean items**	**2021**		
			Export amount	**Rate (%)**	**Rank**
1	K05030.01	High-risk infectious agent immunodiagnostic reagents	2,650,942,441	30.72	1
2	K05000	Infection pathogen diagnostic immunological reagent	421,505,158	4.89	4
3	A26380.01	General ultrasound imaging	491,654,884	5.7	3

		diagnostic device			
4	C20030.01	Dental implant abutment	362,110,689	4.2	5
5	N05030.01	High-risk pathogen genetic testing reagent	915,540,442	10.61	2
6	B04230.01	Tissue restoration biomedical material	261,925,775	3.04	6
7	A31020.04	Stereoscopic optical image acquisition device	118,340,813	1.37	13
8	A77030.01	Daily disposable soft contact lenses	185,920,934	2.15	8
9	A11010.03	Dental cone beam computed tomography X-ray device	138,657,519	1.61	12
10	J14010.01	Personal blood glucose test strip	151,939,967	1.76	10
		Subtotal	5,698,538,622	66	
		Total	8,628,513,481	100	

No.	**Classification number**	**Korean items**	**2022**			**Increase or decrease (%)**
			Export amount	**Rate (%)**	**Rank**	
1	K05030.01	High-risk infectious agent immunodiagnostic reagents	1,760,983,729	22.36	1	−33.57
2	K05000	Infection pathogen diagnostic immunological reagent	842,802,243	10.7	2	99.95
3	A26380.01	General ultrasound imaging diagnostic device	535,861,977	6.8	3	8.99
4	C20030.01	Dental implant abutment	470,988,145	5.98	4	30.07
5	N05030.01	High-risk pathogen genetic testing reagent	371,337,334	4.72	5	−59.44
6	B04230.01	Tissue restoration biomedical material	292,511,257	3.71	6	11.68
7	A31020.04	stereoscopic optical image	181,556,019	2.31	7	53.42

		acquisition device				
8	A77030.01	Daily disposable soft contact lenses	179,098,282	2.27	8	−3.67
9	A11010.03	Dental cone beam computed tomography X-ray device	149,164,439	1.89	9	7.58
10	J14010.01	Personal blood glucose test strip	149,070,795	1.89	10	−1.89
		Subtotal	4,933,374,220	62.6		−13.43
		Total	7,875,326,330	100		−8.73

※ Ratio: the export amount of the respective product item in a given year relative to the total export amount for that year.

※ Rank: the ranking of the respective product item in terms of export amount among all product items for that year.

※ Increase/decrease (%): the percentage change in exports for the respective product item from the previous year.

※ Source: Ministry of Food and Drug Safety, Statistics on the Production and Export–Import of Medical Devices in 2022.

Table 11. Top 10 exporting countries for *in vitro* diagnostic medical devices (USD, %).

No.	**Country Code**	**Country names**	**2021**		
			Export amount (USD)	**Rate (%)**	**Rank**
1	US	USA	94,418,698	2.65	9
2	TW	Taiwan	10,770,214	0.3	54
3	JP	Japan	17,486,724	0.49	37
4	CA	Canada	138,903,496	3.89	6
5	DE	Germany	1,285,800,059	36.03	1
6	IT	Italy	244,695,368	6.86	4
7	SG	Singapore	300,238,544	8.41	3
8	VN	Vietnam	366,728,711	10.28	2
9	BR	Brazil	53,542,212	1.5	17

10	AU	Australia	58,057,125	1.63	16
	Subtotal		2,570,641,151	72.03	
	Total		3,568,656,969	100	

No.	Country Code	Country names	2022		Rank	Increase or decrease (%)
			Export amount (USD)	Rank (%)		
1	US	USA	588,222,271	12.65	1	522.99
2	TW	Taiwan	480,618,058	10.34	2	4,362.47
3	JP	Japan	386,134,122	8.3	3	2,108.16
4	CA	Canada	346,434,616	7.45	4	149.41
5	DE	Germany	235,891,059	5.07	5	−81.65
6	IT	Italy	104,935,249	2.26	6	−57.12
7	SG	Singapore	103,178,726	2.22	7	−65.63
8	VN	Vietnam	78,905,791	1.7	8	−78.48
9	BR	Brazil	77,684,344	1.67	9	45.09
10	AU	Australia	77,211,913	1.66	10	32.99
	Subtotal		2,479,216,149	53.32		−3.56
	Total		4,649,435,647	100		30.29

※ Ratio: the export amount of the respective exporting country in a given year relative to the total export amount for that yea

※ Rank: the ranking of the respective exporting country in terms of export amount among all exporting countries for that year.

※ Increase/decrease (%): The percentage change in exports for the respective exporting country from the previous year.

※ Source: Ministry of Food and Drug Safety, Statistics on the Production and Export–Import of Medical Devices in 2022.

(B) Projected Market Size

Table 12. South Korean *in vitro* diagnostics market value by product, 2020–2029 (million USD).

Product	2020	2021	2022	2023	2024	2025
Instruments	409.4	412	414.9	418.2	421.7	425.4
Reagents	2,102.1	2,088.8	2077	2,066.6	2,057.8	2,050.4
Services	101.8	104.9	108.1	111.3	114.6	118
Total	2,613.3	2,605.7	2,600	2,596.1	2,594.1	2,593.9

Product	2026	2027	2028	2029	GAGR (%)
Instruments	429.5	433.9	438.7	443.7	0.90%
Reagents	2,044.5	2,040.1	2,037	2,035.4	−0.32%
Services	121.5	125.1	128.7	132.5	2.97%
Total	2,595.6	2,599.1	2,604.4	2,611.6	0.03%

※ Source: Primary Research, Secondary Research, Magna Information Centre.

The South Korean in vitro diagnostics market was valued at $2,613.3 million in 2020 and is expected to reach $2,611.6 million by 2029, with a projected growth rate of 0.03% from 2021 to 2029. The reagents segment is anticipated to be the primary contributor to this market, reaching $2,035.4 million by 2029, reflecting a CAGR of −0.32%. In addition, the services segment is expected to grow to $132.5 million by 2029, showing the highest CAGR of 2.97%. In 2020, the reagents and instruments segments collectively accounted for approximately 96.1% of the South Korean *in vitro* diagnostics market, with reagents representing 80.4% of that share. During the forecast period, services and instruments segments are projected to experience significant growth rates with CAGRs of 2.97% and 0.93%, respectively. Currently, the combined share of these two segments is estimated to be around 19.6% of the overall South Korean *in vitro* diagnostics market in 2020, which

may reach 22.1% by 2029.[14]

Table 13. South Korean *in vitro* diagnostics market value by technology, 2020–2029 (million USD).

Technology	2020	2021	2022	2023	2024	2025
Immunoassay	263.6	268.8	274.1	279.6	285.2	291.1
Hematology	434.9	427	419.3	412.1	405.1	398.4
Clinical chemistry	697.5	690.2	683.4	677.1	671.4	666.1
Molecular diagnostics	940.4	940.4	941.2	942.6	944.7	947.4
Coagulation	142.1	143.4	144.8	146.2	147.8	149.5
Microbiology	103.3	105.4	107.6	109.8	112.1	114.4
Other technologies	31.5	30.6	29.6	28.7	27.9	27
Total	2,613.3	2,605.7	2,600	2,596.1	2,594.1	2,593.9

Technology	2026	2027	2028	2029	CAGR%
Immunoassay	297.2	303.5	310	316.8	2.08%
Hematology	392	385.8	379.9	374.3	−1.63%
Clinical chemistry	661.2	656.9	653	649.5	−0.76%
Molecular diagnostics	950.8	954.9	959.7	965.2	0.32%
Coagulation	151.3	153.2	155.2	157.4	1.17%
Microbiology	116.9	119.4	122	124.8	2.13%
Other technologies	26.2	25.4	24.6	23.8	−3.06%
Total	2,595.6	2,599.1	2,604.4	2,611.6	0.03%

※ Source: primary research, secondary research, Magna Information Centre.

The South Korean in vitro diagnostics market value was $2,613.3 million in 2020 and is projected to reach $2,611.6 million by 2029, with a CAGR of 0.03% from 2021 to 2029.

The molecular diagnostics segment is expected to be the largest contributor to this market, reaching $965.2 million by 2029, with a CAGR of 0.32%. In addition, the microbiology segment is anticipated to grow to $124.8 million by 2029, exhibiting the highest CAGR of 2.13%. In 2020, the molecular diagnostics and clinical chemistry segments are collectively projected to account for approximately 62.7% of the South Korean *in vitro* diagnostics market, with the former representing 36.0% of that share. During the forecast period, the microbiology and immunoassay segments are also expected to experience significant growth with CAGRs of 2.13% and 2.08%, respectively. Currently, the combined share of these two segments is estimated to be around 14.0% of the overall South Korean in vitro diagnostics market in 2020, which is projected to reach 16.9% by 2029.[14]

Table 14. South Korean *in vitro* diagnostics market value by application, 2020–2029 (million USD).

Application	2020	2021	2022	2023	2024	2025
Infectious Disease	1,505.2	1,495	1,486	1,478	1,471	1,465.1
Diabetes	260.6	260.2	259.9	259.9	260	260.3
Oncology	236.8	237.8	238.9	240.2	241.7	243.4
Cardiology	197.1	196.2	195.5	194.9	194.4	194.1
Nephrology	140.2	140.7	141.4	142.1	143	143.9
Autoimmune disease	103.4	104.3	105.1	106.1	107.1	108.2
Drug testing	79.9	80.1	80.5	81	81.5	82.1
Other application	90.2	91.4	92.7	94	95.4	96.8
Total	2,613.3	2,605.7	2,600	2,596.1	2,594.1	2,593.9

Application	2026	2027	2028	2029	CAGR%
Infectious disease	1,460.3	1,456.5	1,453.7	1451.9	−0.37%
Diabetes	260.8	261.4	262.3	263.3	0.15%

Oncology	245.2	247.2	249.4	251.7	0.71%
Cardiology	193.9	193.8	193.9	194.1	−0.14%
Nephrology	145	146.1	147.4	148.8	0.70%
Autoimmune disease	109.4	110.7	112	113.5	1.06%
Drug testing	82.7	83.4	84.2	85	0.75%
Other application	98.3	99.9	101.6	103.4	1.55%
Total	2,595.6	2,599.1	2,604.4	2,611.6	0.03%

※ Source: primary research, secondary research, Magna Information Centre.

The South Korean *in vitro* diagnostics market was valued at $2,613.3 million in 2020 and is expected to reach $2,611.6 million by 2029, with a modest CAGR of 0.03% from 2021 to 2029. The infectious disease segment is projected to be the primary contributor to this market, amounting to $1,451.9 million by 2029, albeit with a slight CAGR decline of −0.37%. The autoimmune disease segment is anticipated to reach $113.5 million by 2029, showing the highest CAGR of 1.06%. In 2020, the infectious disease and diabetes segments are collectively estimated to represent approximately 67.6% of the South Korean in vitro diagnostics market, with the former accounting for 57.6% of that share. During the forecast period, the autoimmune disease and drug testing segments are anticipated to experience notable growth, with CAGRs of 1.06% and 0.75%, respectively. At present, these two segments are estimated to constitute approximately 7.0% of the overall South Korean in vitro diagnostics market in 2020, which is projected to increase to 7.6% by 2029.[14]

III. The Concept and Role of Biobanks

Given the growth in biotechnology, various terms such as biobank, human-derived materials, and human resources are currently used in different contexts. Each country may have slightly different meanings for these terms according to its bioethical and medical regulations. Therefore, this investigation begins with defining and conceptualizing these terms. Subsequently, biobank types, functions, and their impact on the healthcare industry are presented.

1. The Term "Biobank"

The term "biobank" is a portmanteau of "bio," referring to life or living organisms, and "bank," meaning a storage or repository. In South Korea, it was initially referred to as a "gene bank." However, it was later revised to "human-derived material bank" under the amended "Act on Life Ethics and Safety," which took effect on January 1, 2013. This term describes repositories that store biological materials derived from the human body, such as cells, tissues, or genes. These human-derived materials are actively used in medical research, pharmaceuticals, and biotechnology. Consequently, the government has shown increased policy interest and support in this field.[16]

A. Human Resources

According to Article 2 of the Regulations on the Operation and Management of the National Central Human Resources Bank of the Korea Centers for Disease Control and Prevention, the term "human resources" refers to clinical and epidemiological information collected from individuals and human-origin materials, as defined in Article 2, paragraph 11, of the Bioethics and Safety Act. This comprises tissues, cells, blood, body fluids, and other human components collected or extracted from the human body or separated from

them, including serum, plasma, chromosomes, DNA, RNA, and proteins, along with genetic information analyzed from them.[17]

Furthermore, human resources are utilized in various fields, such as target identification, biomarker discovery, development of platforms for evaluating the efficacy and safety of new drug candidates, development of biosimulation technologies, disease diagnostics (e.g., COVID-19 test kits), advancement of cutting-edge medical technologies, healthcare and medical technology assessments, and enhancement of treatment guidelines.

B. Definition of Biobank

Biobanks are defined in various ways by different countries, institutions, and research papers.

Table 15. Comparison of biobank definitions by institution.

Country/institution	Published papers	Definition
OECD	Guidelines on Human Biobanks and Genetic Research Databases (2009)	Structured collection of human biological samples, information derived from these samples, and associated data for use in genetic research.
England/ UK Biobank Ethics and Governance Council	What is a biobank? Differing definitions among biobank stakeholders	The most robust contemporary definition of "biobanks" is rich collections of data plus biospecimens specifically developed as resources for research. The term "biobank" is normally used for repositories intended for use in research rather than diagnostic purposes.
Germany/	Opinion:	Collections of samples of human bodily

National Ethics Council	Biobanks for Research	substances that are or can be associated with personal data and information on their donor.
OBBR/ NCI	Biobankonomics: Developing a Sustainable Business Model Approach for the Formation of a Human Tissue Biobank	It stores biological samples and corresponding data for academic, government, industrial, and research purposes. It is essentially a repository for biological samples used in research or commercial activities, including drug discovery and validation.
England/ Visiongain	Biobanking for Medicine, Technology Industry Market 2014-2024	These places collect and store human resources, enabling them for researchers and others for research purposes. They vary in scale and scope, each with their unique characteristics.
USA/ FasterCures	Biobanking on Trust: The Future of Research with Human Biological Materials	These places collect, store, and process biological samples and distribute associated data.
Oxford	Dictionary	A large collection of biological or medical data and tissue samples amassed for research purposes.
Korea	Bioethics and Safety Act	These institutions collect, store, and distribute human resources (human-derived materials) and associated epidemiological and clinical information, lifestyle data, such as exercise, diet, and sleep, and life log information.
	KBN homepage	These institutions collect and manage human resources (human-derived materials) used as research materials and

provide them to researchers.

※ Source: Sujin Bae, Current Status and Issues of the Korean Biobank Management System, Bioethics Forum Volume 3, Issue 2 (2014), partial processing.

C. Types of Biobanks

According to the type of samples collected, biobanks can be classified into disease biobanks, which collect human biological specimens and information related to specific diseases, and population biobanks, which secure samples from the general population for various research purposes. Alternatively, biobanks can be categorized based on the type of human resources collected, such as blood, tissues, cells, or organ-specific biobanks. In addition, biobanks can be described according to the sample type handled here (Table 16).[18]

Table 16. Biobanks categorized by sample types.

Types	Explanation
Tissue biobanks	Tissue biobanks use tissue samples obtained from surgeries or autopsies and fixated for histological examination. The optimum temperature should be maintained at −80°C.
Blood biobanks	Blood (serum, plasma, or cells) is usually collected in test tubes containing preservatives and other additives and subjected to analysis in a biobank. This may include biochemical analysis (serum) or DNA analysis (plasma). For short-term preservation, blood components should be preserved at (−20°C), whereas for long-term storage, a temperature of (−80°C) should be maintained.
Cell biobanks	Cellular material is essential for biomedical research. Cell cultures are collected and stored in cell biobanks. Major cell biobanks include the American Type Culture Collection, Cell Cultures GmbH, and Korean Cell Line Bank. These cell repositories provide cellular material for biomedical research.
Organoid biobanks	Organoids are miniorgans cultivated from different types of stem cells. They

	are self-organizing and similar in structure and function to real organs. Consequently, they can be used in biomedical research and regenerative medicine.
Digital biobanks	Digital biobanks enable the integration of data obtained from biospecimens with data from research institutions or clinical data. Alongside the establishment of digital biobanks, standard operating procedures are developed for sample collection, storage, and processing. Digital biobanks provide qualitative biological samples and information that can be used to plan for future research programs. They can also be used in retrospective studies. Digital biobanking networks can advance cooperation between research institutions and reduce the high cost of collecting and maintaining biomaterials.
Population biobanks	A population biobank is a large repository comprising thousands of biological specimens collected from a specific population that may or may not have an underlying pathology. However, biobanks must obtain informed consent from all participants. Furthermore, they must inform the participants about how their genetic information will be shared or used in research. The participants have the right to decide whether they wish to be informed about the research results and may withdraw their consent at any time.

Furthermore, biobanks are categorized as public and private based on the operating entity. Private biobanks can be further divided into nonprofit and commercial, which aim for profit by commercializing research results derived from human resources or receiving funds from companies for profit.

D. Functions of Biobanks

Biobanks are facilities dedicated to collecting, preserving, and managing biological samples and related information. These samples are primarily obtained from human tissues, blood, DNA, and cells and are utilized for research and medical purposes. Biobanks play a crucial role in advancing scientific research and medical innovation. Their primary functions and roles are summarized in Table 17.

Table 17. Functions and roles of biobanks.

Function	Role	Contribution
Collecting biological information	Collecting various types of biological information, such as blood, tissue, and cells	Utilized for medical research and the development of medical devices
Collecting and preserving genetic information	Understanding genetic causes and biological mechanisms.	Providing personalized healthcare services.
Preserving genetic resources for various species	Enhancing the survival prospects of endangered species by conserving their genetic resources.	Food, pharmaceutical, and medical device industries, among others.
Big data analysis	Analyzing collected data using artificial intelligence technology.	Extracting new information related to diseases, prevention, diagnosis, and treatment, which can be utilized to develop medical devices.
International collaboration	Possessing various resources through global collaboration.	Contributing to international research and industries (providing samples to overseas entities is also possible).

These functions collectively contribute to scientific progress and advancements in healthcare, making biobanks indispensable components of the modern biomedical landscape.

2. Impact of Biobanks on the Medical Device Industry

A. The Importance of Human Resource Biobanks

The healthcare industry is undergoing considerable changes because of multiple factors, such as an aging population, climate change, and advancements in science and technology. Consequently, the healthcare industry is shifting toward precision medicine, which involves analyzing unique genetic, clinical, and lifestyle information for each patient to determine accurate treatment targets and provide optimal personalized medical care. A wealth of data, including genomic, clinical, and individual lifestyle information, are necessary to enable precision medicine. In this context, the development of precision medicine depends on the availability of comprehensive data, including genomics and clinical information, to analyze and tailor treatments to specific patients effectively. The growth of new pharmaceuticals and diagnostic technologies has increased the demand for preventive, diagnostic, and treatment services, emphasizing individual health maintenance.[19] Accordingly, information derived from human resources is increasingly in demand and is critical for developing relevant medical industry technologies and market leadership.

The use of biobanks by pharmaceutical and biotechnology companies for storing and managing clinical trial samples has grown, and global clinical trials conducted by biopharmaceutical companies have recently increased.

Furthermore, regulatory authorities have tightened regulations around drug approvals. They may require reevaluation and additional clinical trials involving biospecimens to ensure the efficacy and safety of pharmaceuticals. Biopharmaceutical companies are proactively storing clinical trial samples to mitigate the risks of delays, potential issues, and drug approval failures.

The growing importance of human biospecimens has increased companies' establishment of private biobanks. However, no private biobanks are currently dedicated to managing

infectious pathogens in South Korea.

Table 18. Domestic private companies establish their own biobanks.

Private companies	Name	Major samples	Utility
Hecto Healthcare	GOLDBIOME	Feces (stool)	Extraction and analysis of gut microbiota (microbiome) to treat patients with intestinal diseases
COREE (Subsidiary of Hanmi Pharmaceutical)	Mother and Child and Beyond	Human-derived samples	Research institutions for expectant mothers and newborns
Seoul Clinical Laboratories	SCL Biobank	Human-derived samples (exact information unavailable)	International research collaboration

B. Effects of the Increasing Importance of Human Resources

In the research report on the expansion plan for the National Biobank's human resources management facility, four effects are explained (Table 19).[19]

Table 19. Effects of increased human resources.

Effect	Expectation
Creation of added value	Drug development is costly and time-consuming, with a low success rate. However, when successful, it ensures substantial profits through market exclusivity, such as patent rights, and creates significant added value.
Cost savings in national healthcare	Drug development can significantly reduce national healthcare expenses.
Social welfare impact	The market for the elderly population expands with the advent of an ultra-aging

	society. There is a growing demand for the development of therapeutic technologies for the elderly and those with chronic illnesses, leading to sustained growth.
Health security network effect	Among the medically vulnerable population, such as elderly individuals living alone, particularly those aged 60 and above with multiple chronic conditions, the burden of medical expenses can be reduced. The health security network can be strengthened by preventing diseases.

Similar to pharmaceuticals, diagnostics reagents can contribute to society by predicting diseases. Consequently, they enable early diagnosis and prevention during the early stages of disease development. The rapid development of diagnostic reagents can result in social welfare benefits, reduced national healthcare costs, and capturing high-added value through market leadership. These positive effects can be realized by establishing a system that ensures a steady supply of high-quality samples that can be used with confidence at any time.

C. Market Size of Biobanks for Human Resources

Zion Market Research reports that the global biobanking market, which accrued revenues of 48,020 (million USD) in 2018 and is anticipated to garner earnings of approximately 67,982 (million USD) by 2025, is set to grow at a CAGR of nearly 4.7% from 2019 to 2025.[20]

Biobanks have experienced substantial growth because of the increased interest in biological samples and their growing demand among scientists and medical professionals. The increasing significance of personalized medicine and medical research has sparked a surge in the demand for biospecimens necessary for drug discovery and development, disease research, and other medical applications. This global trend has contributed to the rapid growth of the biobanking market worldwide.

The USA, UK, Japan, and South Korea have collaborated to establish biobanks to collect and secure human-derived samples and related information for researchers, aiming to implement precision medicine. Consequently, the global biobanking market is growing, particularly in the development of therapies for chronic diseases, such as cancer, cardiovascular conditions, neurological disorders, and immune-related diseases.

Samples stored in biobanks are used for various purposes, including research, therapy development, clinical trials, and drug discovery. Figure 1 shows the number of biobanking-related publications obtained from PubMed, exhibiting an upward trend related to human-derived samples collected from biobanks over time, starting in 2003. These publications cover various topics, including cancer, informed consent, ethics, biomarkers, genomics, public health, personalized medicine, and pharmacogenomics, indicating the growing interest in biobanking and its significance in these fields.[21]

The rise in biobanking-related publications reflects the increasing importance of biobanks in promoting scientific research and medical innovations, particularly precision medicine and the development of new therapies and drugs.

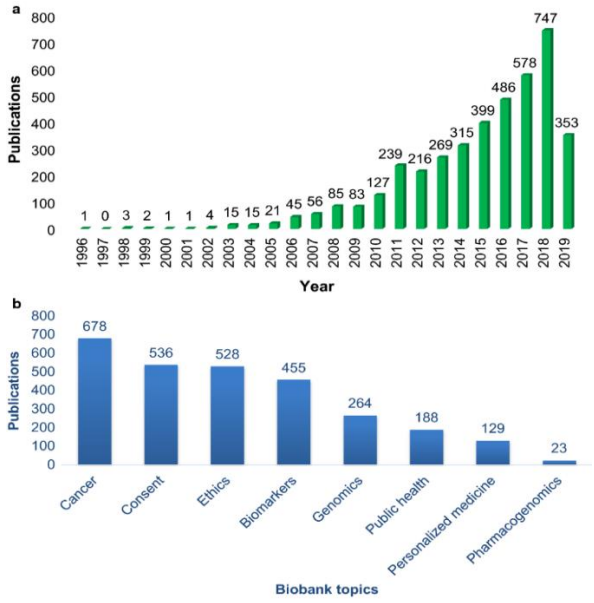

Figure 1. Graphical representation of the number of publications related biobanking obtained from PubMed.

a. Shows the number of publications over time.
b. Shows the number of publications classified for: cancer, consent, ethics, biomarkers, genomics, public health, personalized medicine, and pharmacogenomics (April 8, 2019).

※ Source: J Transl Med. 2019 May 22;17(1):172

IV. Domestic and International Clinical Sample Management Status

1. Status of *In Vitro* Diagnostic Medical Device Companies

A. Necessity of Clinical Samples and Limitations of Domestic Infection Sample Procurement Methods

The rapid development and convergence of genomics and bioinformatics technologies have significantly changed the diagnosis and treatment of human diseases. In particular, techniques related to molecular diagnostic reagents and devices have ushered in an era of fast, accurate, and personalized medical solutions. Furthermore, molecular diagnostic medical devices and their manufacturing have witnessed a continuous rise in demand with increasing public awareness of healthcare and welfare. However, issues related to the utility of medical devices, anomalies resulting from product sensitivity, and the need for product performance verification have been growing.[22]

To prevent these issues, medical device development companies should enhance premarket medical device performance testing to ensure product safety and efficacy, with an emphasis on improving quality. Only through these efforts can a socially safe and reliable environment for the use of medical devices be established. Therefore, clinical performance evaluation is essential in the product development process.

In vitro molecular diagnostic testing medical devices are utilized externally to test samples derived from the human body, such as blood or tissue. They provide information about, for example, disease diagnosis, prognosis, and suitability assessment of blood or tissue. According to the Guidelines for Clinical Performance Evaluation Management of In Vitro Diagnostic Medical Devices by the MFDS, clinical sensitivity and clinical specificity

evaluation criteria for IVDs should include samples derived from humans, such as blood and body fluids.[23]

Generally, performance testing uses residual samples collected with the consent of the sample providers. However, testing can be conducted without written consent when obtaining consent from subjects is practically impossible, when the subjects have no explicit reason to refuse consent, and when testing poses extremely low risks to subjects. However, this should only occur with approval from the Institutional Review Board (IRB) for bioethics.[23]

Therefore, during the development process of molecular diagnostic medical devices for various diseases, performance, including clinical safety and utility, can be verified using residual samples scheduled for disposal. This process should follow appropriate procedures in accordance with relevant regulations and testing institution guidelines. However, collecting and securing clinical sample information may be challenging for development companies.

(A) Difficulties in Collecting and Securing Clinical Sample Information

First, medical institutions typically require personnel to manage and store residual samples scheduled for disposal. Individual research laboratories may not commonly store such residual samples if an official biobank within the institution is not established.

Second, under Article 41 of the Bioethics and Safety Act, biobanks granted permission by the Korea Disease Control and Prevention Agency primarily manage tissues, cells, and blood. The storage and management of samples related to infectious diseases used in diagnostic test reagents are relatively infrequent.

Third, gathering information on rare specimens poses a significant challenge.

Although government agencies may provide sample information through biobanking projects, companies still face difficulty securing sufficient samples, primarily when a single

product target multiple parameters. Obtaining sufficient samples can be challenging. Notably, companies often rely on personal networking to obtain rare samples.

For example, a condition such as viral meningitis, which is characterized by inflammation of the thin membranes (meninges) surrounding the brain and spinal cord, can be caused by viruses, bacteria, mycobacteria, or fungi. Approximately 90% of all cases of viral meningitis are caused by viral infections. Early symptoms can mimic those of a common cold; therefore, an accurate diagnosis is challenging. Meningitis caused by bacteria can be life-threatening, and prompt and accurate diagnosis is essential. The test is typically performed by analyzing cerebrospinal fluid (CSF), but collecting such samples is a complex process.

Even if samples are collected and preserved from patients, they may not be stored in a human-derived sample bank within the hospital. Consequently, information accessibility or sharing might be limited, and there might be uncertainty surrounding the collection period.

In general, for the development of diagnostic kits, clinical sample procurement is performed through retrospective research based on samples obtained from a single institution. However, a prospective leftover clinical study involving multiple tertiary hospitals over one year is conducted for rare samples. Subsequently, the company plans to use retrospective and contrived samples for targets for which sufficient samples have not been obtained. The transition to IVDR imposes stricter criteria for performance testing and clinical trials compared with IVDD. Accordingly, the number of positive and negative samples required has significantly increased. In addition, the necessary diagnostic kits cannot be developed without an adequate supply of clinical samples.

Currently, among domestic companies, there is a CE-IVDD product with 18 targets, including viruses, bacteria, and fungi. However, it requires IVDR transition. The South Korean MFDS mandates reevaluation for IVDs transitioning from general products. Extensive networking efforts were made to secure clinical samples. However, only 8 of the 18 targets have been confirmed, and even obtaining 88 clinical samples to achieve the

standard clinical sensitivity and specificity of 95% is unimaginable. From a company's perspective, collecting information about the country or institution holding the specimen is challenging. Fortunately, given the difficulties in the industry and the field resulting from the response to the COVID-19 crisis, the MFDS (Medical Device Safety Evaluation Division) amended the application period for reevaluation of IVDs (Class 3) transitioning from general products in a notice issued on June 23, 2023 (MFDS Notice No. 2023-306).

Table 20. Cerebrospinal fluid sample procurement status (as of February 23).

Target/institution	A	B	C	D	Total
HSV1	6	20	0	0	26
HSV2	11	20	8	2	41
HHV6	5	20	0	2	27
CMV	0	0	0	0	0
EBV	22	0	20	0	42
VZV	12	0	1	5	18
HEV	0	0	23	0	23
GBS	0	0	0	1	1

※ Source: Seegene Inc.

(B) Individual Legal Considerations for Importing Foreign (Pathogenic) Specimens

When securing clinical samples is challenging domestically, inquiries may be made to overseas hospitals or private institutions with a high incidence of the desired target samples.

These samples can be imported according to customs classification but with specific import requirements. Permission from the Director of the Korea Centers for Disease Control and Prevention is required when the imported samples fall under high-risk pathogens, as specified under Article 22 of the Infectious Diseases Control and Prevention Act.

Additionally, the importation of pathogens into South Korea is subject to various institutional-specific pathogen safety management systems and regulations. These systems and regulations include the Ministry of Agriculture, Food and Rural Affairs' Animal Disease Prevention Act for the management of animal pathogens; the Ministry of Agriculture, Food, and Rural Affairs' Plant Quarantine Act for plant pathogens; the Ministry of Oceans and Fisheries and the National Institute of Fisheries Science's Regulation for the Management of Pathogens in Aquatic Organisms for aquatic animal pathogens; the Ministry of Trade, Industry, and Energy's Biohazardous Materials and Toxic Substances Control Act for biologics and toxins; and the Ministry of Science and ICT's Act on the movement of genetically modified organisms among countries. Therefore, verification of institution-specific pathogen safety management systems and relevant laws is essential for importing pathogens into South Korea.

Table 21. Institution-specific pathogen safety management systems and regulations.

Management target	**Relevant department**	**Related laws**	**Management content**
Contagious pathogens of livestock	Ministry of Agriculture, Food and Rural Affairs (National Veterinary Research and Quarantine Service)	Livestock Contagious Disease Prevention Act	Import, possession, isolation, and transport of pathogens and related substances
Plant pests and diseases	Ministry of Agriculture, Food and Rural Affairs (National Veterinary Research and Quarantine Service)	Plant Quarantine Act	Isolation, preservation, distribution, and management of pathogens and related substance
Pathogens of aquatic organisms	Korea Disease Control and Prevention Agency	Regulations for the Management of Pathogens in Aquatic	Isolation, preservation, distribution, and management of

		Biological Diseases	pathogens and related substance
High-risk pathogens	Ministry of Trade, Industry and Energy	Act on Prevention and Control of Infectious Diseases	Isolation, transport, import, receipt, and preservation, among others, of high-risk pathogens
Biological agents and toxins	Ministry of Science and ICT	Biological Weapons Act	Import, acquisition, possession, manufacturing, and disposal, among others, of biologically active substances and toxins
Genetically modified organisms	Ministry of Science and ICT	Act on the Transboundary Movement of Genetically Modified Organisms, among others.	Import, export, and so on of living modified organisms for research purposes

The growing demand for the biotechnology industry utilizing pathogens, active research for infectious disease defense, and the stimulation of international research and development exchanges have increased the movement, import, and export of pathogens. For example, among the tropical fevers in tropical regions, chikungunya and yellow fever viruses are considered “dual-use items” that can be developed and used as war weapons. Consequently, countries such as the USA and Europe do not permit their export to other countries. However, if the destination country is not subject to export regulations, it is possible to import these materials domestically. Chikungunya virus is classified as a biosafety level 3 pathogen. It can be imported and used in laboratories or facilities with a biosafety level 2 or higher with the approval of the Institutional Biosafety Committee,

which oversees compliance with biosafety regulations. However, a high-risk pathogen handling facility permit is required to obtain approval from the Korea Disease Control and Prevention Agency to import the yellow fever virus.

Owing to the nature of pathogens, they may be abused as biological weapons or bioterrorism. In addition, there is a constant risk of infection and leakage accidents when handling pathogens. Therefore, South Korea has established relevant laws in each ministry to ensure the safe use of pathogens and prevent potential biological Disasters. Such strict management is necessary; however, from a private company's perspective, securing a sample for purchasing a single pathogen is time-consuming and challenging. Several factors should be reviewed before applying.

B. Lack of Support from Government Agencies

(A) Issue of "Optimization Plan for Export Medical Device Approval Management" Due to COVID-19

According to Article 22 of the "In Vitro Diagnostic Medical Devices Act" and the "Regulations on the Approval, Reporting, and Review of In Vitro Diagnostic Medical Devices," IVDs intended for export are excluded from the scope of technical documentation review. However, the MFDS announced an "Optimization Plan for Export Medical Device Approval Management," which included expanded requirements for detailed technical documentation for "Export COVID-19 Diagnostic Medical Devices." This change resulted in a delay of approximately 1 month in the approval process for exporting IVDs, which had previously been approved within approximately 2 weeks. Some companies missed sales opportunities during this period. Given the prominence of K-bio and the quality of domestically produced products during the COVID-19 pandemic, adequate performance validation has been conducted using clinical samples. However, within a short period, especially in a pandemic situation, private companies face difficulty

acquiring and applying infectious samples in experiments.

Even if a product has passed performance tests, performance issues can still arise when it has not been tested using sufficient clinical samples from different ethnicities. Companies also explore various avenues to secure clinical samples. However, acquiring more than 88 samples for each target is challenging and time-consuming to achieve the ideal clinical sensitivity and specificity data of 95% or more.

Technical documentation is crucial for verifying product performance. Regulatory authorities acknowledge the challenges of securing clinical samples. However, ultimately, companies are responsible for securing clinical samples and obtaining approval. Delays in obtaining approval for export products, even after obtaining domestic approval for sales, can result in business losses. Therefore, even with the necessary technology and infrastructure for rapid product development, when clinical samples are difficult to secure, the government should focus more on supporting and establishing the infrastructure and systems for clinical sample procurement.

(B) Clinical Performance and Sample Matching Support Services for *In Vitro* Diagnostic Medical Devices

As of June 2023, official approvals for COVID-19 diagnostic reagents in South Korea, including 56 PCR, 68 antigen, and 24 antibody tests, have been registered, a process of approximately 30 months.[24] By considering research-use-only and laboratory development test diagnostic reagents, several domestic companies that invested in diagnostic reagent development owing to the COVID-19 pandemic are substantial. In the unique circumstances of the pandemic, diagnostic reagents were initially used under emergency use authorizations, and numerous domestic companies completed performance testing using clinical samples. They stored and provided them for research in various institutions to obtain official approval for COVID-19 diagnostic reagents.

Technological innovation has enabled i*n vitro* diagnostic medical device companies to

develop products within a short period. However, securing clinical samples is not necessarily proportional to a company's capabilities. Especially during urgent product development, such as in the case of a pandemic (e.g., an infectious disease outbreak), securing the necessary samples is often impossible without government support when specific variant products emerge in different regions or countries. If we analyze the severity increase in the Gamma, Delta, and Lambda variants, which first emerged in 2019, we observe a mutation trend approximately every 3–5 months. Following the World Health Organization (WHO) classification criteria, these variants were announced on July 19, 2021, to move from "Variants of Interest" to "Alert" status, indicating a need for preparedness. In the context of the pandemic, *in vitro* diagnostic medical device companies monitor potential mutations during the product design phase to ensure accurate diagnostics. However, the In Vitro Diagnostic Medical Devices Act requires "Formal Manufacturing Approval." In addition, clinical trials have not been conducted because of a shortage of clinical samples.

However, the Korea Health Industry Development Institute and the Comprehensive Support Center for the Medical Device Industry contributed to obtaining information about biobanks held by sample-holding institutions and provided sample information. A few companies have received assistance in collecting information about variant viruses because, since March 2020, the Korea Health Industry Development Institute has initiated a matching service project to connect sample-holding institutions and diagnostic reagent development companies, with the aim of supporting clinical evaluations for domestic and international approvals of diagnostic kits for diseases such as COVID-19. The Medical Device Industry Support Center of the Korea Health Industry Development Institute has implemented a program to promote the *in vitro* diagnostic medical device industry. This program seeks to facilitate the distribution of necessary samples for clinical evaluations of companies, establish smooth connections between companies and cooperating medical institutions, and support rapid product validation and clinical evaluations, leading to regulatory approval. Moreover, this program involves securing various samples, such as

respiratory and blood samples, for COVID-19 and other purposes. It also selects and supports four consortia of medical institutions with clinical evaluation capabilities, comprising 11 institutions.

Table 22. Collaborative organizations for the clinical evaluation of *in vitro* diagnostic medical devices for COVID-19 and other purposes.

No.	Institution Name (participating institutions)	Location
1	The Catholic University of Korea. Seoul St. Mary's Hospital (Eunpyeong St. Mary's Hospital, Incheon St. Mary's Hospital)	Seoul, Gyeonggi
2	Myongji Medical Foundation (Soonchunhyang University Seoul Hospital, Ajou University Medical Center)	Seoul, Gyeonggi
3	Gyeongsang National University Changwon Hospital (Chungnam National University Hospital, Chonnam National University Hospital)	Gyeongnam, Daejeon, Jeonnam
4	Kangwon National University Hospital (Hallym University Chuncheon Sacred Heart Hospital)	Gangwon, Chuncheon

※ Source: Korea Health Industry Development Institute's Medical Device Industry Comprehensive Support Center.

Starting in 2022, this program has evolved into the "*In Vitro* Diagnostic Medical Device Rapid Clinical Evaluation Support" project. This project not only facilitates the matching of samples held by domestic clinical trial institutions but also acquires and matches foreign samples for conducting necessary clinical trials for "overseas clinical trial results recognition" and "obtaining approval." As of 2023, it is operated by five lead agencies and 2–3 consortia (Table 23). They follow separate systems for managing sample information,

clinical data, and performance evaluation (Table 24). The application process begins with companies submitting an application to the Korea Health Industry Development Institute. After reviewing the applications, a monthly operational meeting is held to facilitate matching between collaborating medical institutions and companies. Subsequently, detailed arrangements for clinical evaluations and clinical trials are made between the collaborating medical institutions and the applying companies.

However, obtaining adequate high-quality clinical samples (positive and negative) is challenging using multitarget rather than single-target sampling. Additionally, sourcing clinical samples that meet the desired device sampling criteria from a single institution can be difficult. Access to data on human-derived material banks registered in the country is limited; only information from the five lead agencies selected as collaborating institutions is available. From a company's perspective, an integrated information platform is required to search for the types of human resources necessary for development, sample collection methods, storage conditions, and sample quantities and make informed decisions about which institutions to select.

Although no centralized organization currently manages all biobank databases in South Korea, the development of the future information infrastructure will provide the necessary sample information for research and product development. In the context of *in vitro* diagnostic medical device development, biobanks can significantly contribute to expediting market entry by facilitating sample acquisition and reducing the time required for clinical trials. Clinical sample acquisition is a critical factor in sustaining and further enhancing the *in vitro* diagnostics market because it accounts for approximately half of South Korea's medical device market for diagnostics. Accordingly, efforts should be made to create an environment that supports biobank growth and activation.

Table 23. *In vitro* diagnostic medical device rapid clinical evaluation support network.

No.	Lead agency name (consortium)	Location
1	The Catholic University of Korea. Seoul St. Mary's Hospital (Eunpyeong St. Mary's Hospital, Incheon St. Mary's Hospital)	Seoul, Gyeonggi
2	Myongji Medical Foundation (Soonchunhyang University Seoul Hospital, Ajou University Medical Center)	Seoul, Gyeonggi
3	Gyeongsang National University Changwon Hospital (Chungnam National University Hospital, Chonnam National University Hospital)	Gyeongnam, Daejeon, Jeonnam
4	Kangwon National University Hospital (Hallym University Chuncheon Sacred Heart Hospital)	Gangwon, Chuncheon
5	Chungnam National University Sejong Hospital (Inje University Ilsan Paik Hospital, Chosun University Hospital)	Sejong Special Self-Governing City, Gyeonggi-do, Gwangju

※ Source: Korea Health Industry Development Institute's Medical Device Industry Comprehensive Support Center.

Table 24. Rapid clinical evaluation support system for *in vitro* diagnostic medical devices.

Category	***In vitro* diagnostic medical devices support center (medical center)**	***In vitro* diagnostic medical device innovation support platform (Medical device industry comprehensive**	**Manufacturers (developers) of *in vitro* diagnostic devices**

			support center)			
Clinical Evaluation	Sample information	Regular reporting on disease-specific clinical sample storage, management, and sample inventory status	Integrated management of disease-specific clinical sample status information	→	→	Utilize provided samples and clinical data for product development
	Clinical information	Provision of clinical research infrastructure status, clinical research information, and researcher information	Collection and analysis of domestic and international disease-specific clinical research status by analytical method	→	→	
	Performance evaluation	Clinical evaluation consultation and review Conducting clinical performance tests for matched companies	Matching with performance evaluation institutions for sample utilization	←	←	Request for clinical performance evaluation support for developed products

※ Source: Korea Health Industry Development Institute, 2022, business notice.

C. Private Sector Efforts (Investment) for Clinical Sample Acquisition

On September 4, 2023, Seegene Inc. published in Springer Nature, a globally recognized British institution with a research community, its “Open Innovation Program powered by

Seegene."[25] They recruited molecular diagnostic experts, scientists, and clinicians with access to samples and aimed to commercialize disease diagnostics using Seegene's patented technology, particularly in syndromic quantitative PCR. Seegene Inc. provided equipment, reagents, and technology free of charge. They offered initiative because numerous individuals may have innovative ideas but lack the technology to bring their products to market, or companies may possess the technology but lack clinical samples. Through this technology-sharing program, we aim to achieve the grand goal of creating a disease-free world.[26]

This project involves 15 specified tasks in which clinical experts and scientists with clinical testable samples participate. In the first round of submissions, Seegene handles the entire product development process, including the development and preapproval stages, excluding clinical trials. In the second round, a free-form task allows individuals with ideas for clinical samples and diagnostic reagent compositions to lead the entire development process from the early stages using Seegene's Digitalized Development System technology. In the final round, with the support of Seegene's technology, candidates take the lead in every stage, from product development to clinical trials and approval. The "Open Innovation Program" aims to develop various products through technology sharing and address legal, regulatory, and time constraints that hinder private companies from independently conducting clinical sample collection, acquisition, and clinical trials. This project serves as a strategic approach to overcome these challenges.

Private companies invest substantial funds, even millions of dollars, in securing and commercializing clinical samples. Using this global project to secure clinical samples for private companies, the government will again recognize the significance of clinical sample collection and preservation. High-quality clinical sample acquisition is essential for the development of the *in vitro* diagnostic medical device industry. This requires collaboration with multiple countries and institutions and institutional support to activate biobanks.

2. Status of Domestic Biobanks

A. Introduction to Domestic Human Biobanks

The domestic biobank business was established in 2008. The National Biobank of Korea, operated under the Korea Disease Control and Prevention Agency, is located in Osong. As of August 31, 2023, 82 domestic human biobanks were granted licenses by the Ministry of Health and Welfare and the Korea Disease Control and Prevention Agency. In 2020, the Korea Biobank Network (KBN, http://www.kbn.re.kr) was established to serve as a national network for human biobanks, overseeing information provision and distribution. The Advanced BioResource Information System (https://www.aris.re.kr), operated by the Ministry of Science and ICT, was opened in 2018. It offers information on life resources and related data in various fields, including animals, plants, microorganisms, human resources, and genomics, which are essential materials for biotechnology research.[27] However, this system is not available for online distribution. To acquire its resources, one can visit the website of the respective institution.

Human biospecimens are collected at the national level through large-scale cohort studies or at clinical sites such as hospitals, where patients have their blood drawn and undergo tissue examinations as part of medical testing. The remaining biological materials are collected after patient consent. According to the status of the KBN project in 2022, the Korea Disease Control and Prevention Agency reported in May 2023 that the KBN supported 465 research projects last year. These projects yielded 139 research papers and 16 patents. Notably, the cumulative number of cases reached 4,562, contributing significantly to healthcare research, chronic disease prediction, the development of diagnostic products, and various aspects of the domestic health and medical industry.[28]

(A) Korea Biobank Network Introduction

KBN is a national biobank network comprising the Korea Centers for Disease Control and Prevention (KCDC) National Biobank of Korea and Human Bioresource Regional

Banks located at 17 university hospitals. KBN collects, manages, and distributes large-scale population-based (National Biobank of Korea) and disease-based (17 regional banks) human bioresources through nationwide networks. The Masan National Tuberculosis Hospital and the Korea Institute of Radiological and Medical Sciences have participated in the network as KBN collaborative hospitals since 2013.[29]

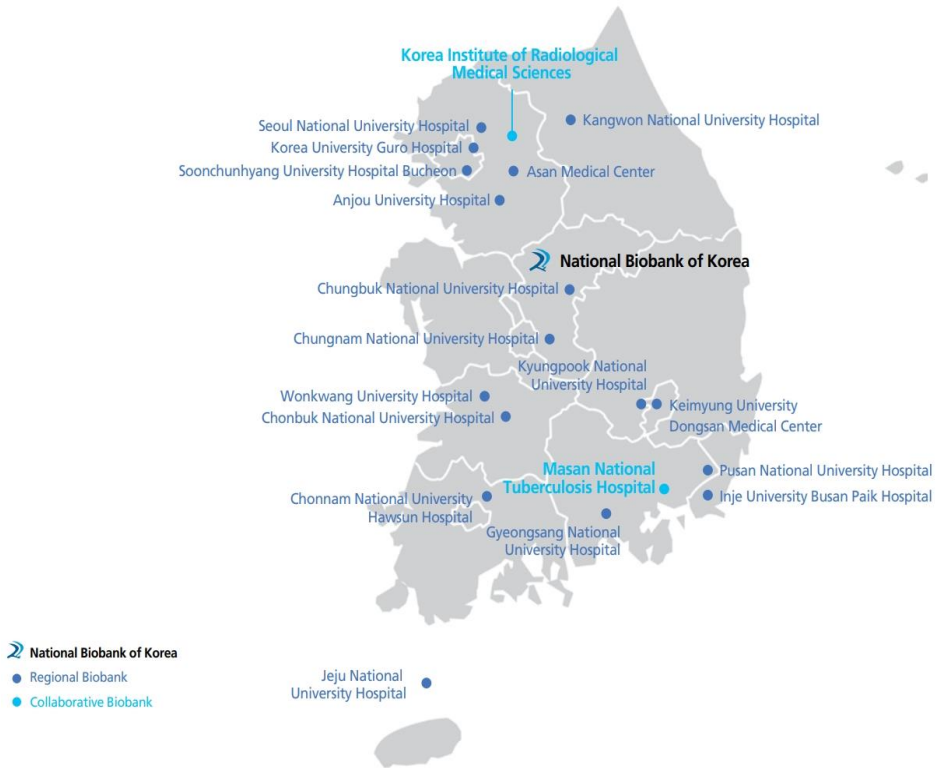

Figure 2. Nationwide distribution of the Korea Biobank Network.

※ Source: J Korean Med Assoc 2021 January; 64(1) 57–65

The Korea Biobank Structure is organized by the Ministry of Health and Welfare (Division of Bioethics Policy), the KCDC Korea National Institute for Health (Division of Biobank

for Health Sciences), Human Bioresource Regional Banks, and Collaborative Hospitals of KBN.[29]

Figure 3. Korea Biobank Structure.

※ Source: KBN homepage.

Table 25. Role of the institution.

Agency	Role
Ministry of Health and Welfare (Division of Bioethics Policy)	· Overall management of National Bioethics Policy · Korea Biobank project-related system support
KCDC KNIH (Division of Biobank for Health Sciences)	· KBN management (National Biobank of Korea management) · Collection, management, and distribution of large-scale population-based human bioresources · Human bioresource management standardization and technology development
Human Bioresource Regional Banks	· Collection, management, and distribution of disease-based human bioresources

	·	Organization and operation of Korea Biobank Council KBN
KBN Collaborative Hospitals	·	Collection, management, and distribution of specialized disease-based human bioresources

※ Source: KBN homepage.

(B) Introduction to Korea Biobank Network Portal

The KBN portal was developed in 2019 through the KCDC's "project to establish a KBN, an open human bioresource sharing platform" (The Catholic University of Korea, College of Medicine, Choi Yeong Jin professors), which has been in operation since March 1, 2020. The KBN portal is the largest shared open platform for disease-based resources owned by KBN regional biobanks. It discloses relevant information to researchers, including disease-based resource status, systematic search, efficient distribution, and utilization outcomes, with the aim of improving the efficient utilization of national disease-based resources.[29]

ⓐ Portal Operation and Human Biospecimen Status

The KBN portal is available without login. Collection Status and Distribution Status are well organized by disease category, sample category, institution, and year. Examining the human resource collection status table of the Korean Human Resources Network on December 31, 2021, 4,136,388 samples have been collected. This number has been continuously increasing since its establishment in 2008.[29]

(unit: individuals)

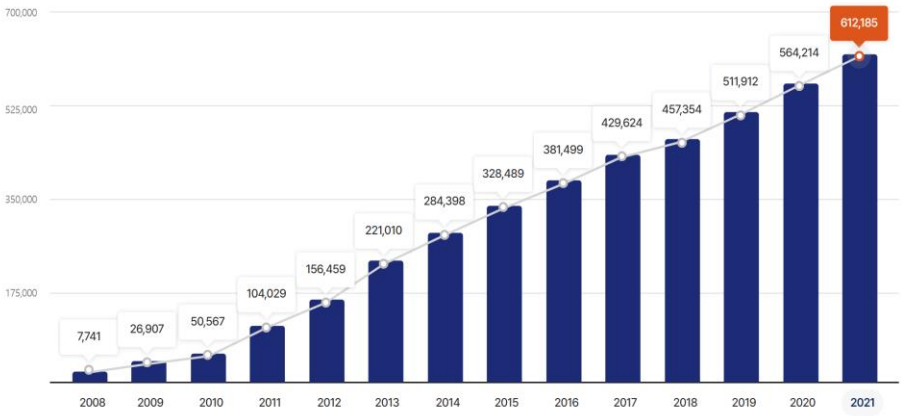

Figure 4. The collection status of human resource.

The collection status of human resources is increasing every year. However, as shown in Table 26, samples are classified into neoplastic and nonneoplastic diseases. It was difficult to confirm the collection status of infected samples in the sample category.

Table 26. Statistics criteria as of December 31, 2021 (unit: vials).

Human bioresource	**Number of vials (sample category)**	**Number of vials (nonneoplastic disease)**	**Ratio (%)**
Plasma	2,727,128	1,410,398	32
Serum	2,500,289	1,392,869	29.3
Tissue	833,041	134,794	9.8
Buffy coat	1,123,653	631,864	13.2
DNA	183,107	99,013	2.1
Others*	1,165,233	610,633	13.7
Subtotal	8,532,451	4,279,571	100%

※ Whole blood, urine, monocytes, erythrocytes, etc.

※ 486,449 vials were collected in 2021.
Serum: 117,553 vials, plasma: 152,591 vials, buffy coat: 78,940 vials, tissue: 32,361 vials, DNA:

6,286 vials, other: 98,718 vials.

※ 126,142 vials were collected for specialized diseases through the Biobank Characterization Support Project in 2021.

ⓑ KNB Portal Human Biospecimen Distribution Methods

Eligibility for specimen distribution is restricted to Korean residents who are research project leaders authorized or exempted by the IRB for life ethics and who are performing research projects. The required documents include an online specimen distribution application, IRB review results, research plans, a human biospecimen usage plan, an agreement form, and a personal information collection and usage consent form. The human biospecimen usage plan must be completed to obtain human biospecimens; it can be submitted online through the KBN portal.[27] The distribution process progresses through several stages: in-progress, application completed, awaiting submission, submission completed, under review, review completed, distribution completed, and utilization concluded. When your research concludes and results are available, you must register your achievements, which can be done through the portal's distribution application status and utilization outcome section.[27]

Figure 5. Application procedures for human bioresource distribution.

※ Source: J Korean Med Assoc 2021 January; 64(1): 57–65.

(C) Introduction to Participating Banks in the Korea Human Resources Bank Network

In 2021, the Korean Biobank Project (KBP) shifted its focus to the fourth phase, transitioning into a specialized support system for human biological resource collection and utilization according to disease characteristics. This phase operated under a centralized bank system, ensuring the acquisition of human resources based on specific disease characteristics, thereby supporting the biohealth industry and research. The KBP worked toward securing disease-specific human biological resources and standardized clinical and epidemiological information. In addition, it collected image data and established a collaborative distribution support system to provide tailored resources to researchers.

Furthermore, the KBP selected ten major disease-focused human biobank centers and two innovative bioresource consortia. These consortia aimed to foster an innovative biobanking ecosystem by encouraging company participation and utilizing support, thus contributing to academic and industrial achievements in biohealth, such as diagnostic kits, digital therapies, and drug development.

Figure 6. Participating banks of the Korea Biobank Network.

※ Source: KBN homepage (as of October 2020).

ⓐ Participating Organizations in the Specialized Support Program for Human Biobanks

Table 27. Participating organizations in specialized human biobanks.

No.	Project name	Specific disease	Category	Organization name
1	Blood, allergic diseases, and healthy volunteer biobank	Blood cancer, hematological disorders, atopic dermatitis, normal individuals	Central Bank	The Catholic University of Korea Seoul St. Mary's Hospital Biobank
			Collaborating Banks	The Catholic University of Korea Yeouido St. Mary's Hospital
				The Catholic University of Korea Uijeongbu St. Mary's Hospital
				The Catholic University of Korea Bucheon St. Mary's Hospital
				The Catholic University of Korea Eunpyeong St. Mary's Hospital
				The Catholic University of Korea Incheon St. Mary's Hospital Biobank
				The Catholic University of Korea St. Vincent's Hospital

				Catholic University Daejeon St. Mary's Hospital
2	Inflammatory bowel disease biobank network establishment and information standardization project	Inflammatory bowel disease	Central Bank	Kyungbuk National University Hospital
			Collaborating Banks	Gyeongsang National University Hospital
				Keimyung University Dongsan Hospital
				Inje University Busan Paik Hospital
3	In-depth clinical epidemiology phenotype-based human biobank characterization project	Glomerular diseases, renal failure	Central Bank	Seoul National University
			Collaborating Banks	Keimyung University Dongsan Hospital
				Kangwon National University Hospital
			clinician	Yonsei University Industry-Academic Collaboration Foundation (Sinchon Severance Hospital)
				Boramae Hospital
4	Oral biobank for overcoming oral diseases and research on systemic diseases	Oral diseases	Central Bank	Seoul National University Dental Hospital
			Collaborating Banks	Yonsei University Dental Hospital
				Apple Tree Dental Hospital
				Pusan National University

				Dental Hospital
5	Next-generation incurable cancer specialized human resource bank subnetwork	Intrahepatic biliary tract cancer, ovarian cancer, pancreatic cancer, lung cancer	Central Bank	Asan Medical Center
			Collaborating Banks	Seoul National University Bundang Hospital
6	Gyeongin region network-based high-quality respiratory allergic disease human resource bank project	Interstitial lung disease, chronic obstructive pulmonary disease, asthma	Central Bank	Soonshunhyang University Bucheon Hospital
			Collaborating Banks	Ewha Womans University Mokdong Hospital
				Hallym University Dongtan Sacred Heart Hospital
			clinician	Individual researcher (4)
7	Establishment of a human resource subnetwork specializing in liver disease and normal groups	Liver cancer, cirrhosis, viral infection, other liver diseases, normal people	Central Bank	Aju University Hospital
			Collaborating Banks	Keimyung University Dongsan Hospital
				Seoul National University Bundang Hospital
				Seoul National University Hospital
8	Support for microbiome research and establishment of a Korean Biobank Network for breast and female reproductive	Female reproductive organ cancer, breast cancer, ductal carcinoma *in situ*, benign breast tumors, breast disorders, pregnancy, childbirth,	Central Bank	Inje University Pusan Paik Hospital
			Collaborating Banks	Inha University Hospital
				Dong-A University Hospital
				Kyungpook National University Hospital

	system precision medicine	postpartum period		Pusan National University Hospital
9	Establishment of a specialized human resource network for healthy control groups and urological tumors based on a two-way human resource collection system	Bladder cancer, kidney cancer, prostate cancer, normal individuals	Central Bank	Chungbuk National University Hospital
			Collaborating Banks	Gyeongsang National University Hospital
				Keimyung University Dongsan Hospital
				Jeju National University Hospital
10	Establishing a next-generation biobank operating platform for precision cancer medical research	Liver cancer, brain tumor, colon cancer, stomach cancer, breast cancer, lung cancer, blood cancer	Central Bank	Hwasun Chonnam National University Hospital
			Collaborating Banks	Chonbuk National University Hospital
				Wonkwang University Hospital

※ Source: KBN portal homepage.

ⓑ Innovative Biobanking Consortium Participating Institutions

The innovative biobanking consortium currently includes only projects related to sarcoma and chronic cerebrovascular diseases. There is a need to establish specialized consortia for infectious diseases, such as respiratory diseases and sexually transmitted infections.

Table 28. Innovative biobanking consortium participating institutions.

No.	Project name	Specific disease	Category	Organization name
1	Innovative biobanking consortium project in the field of sarcoma	Sarcoma	Responsible institution	National Cancer Center
			Consortium organizations (banks, clinicians, and industry)	Chonbuk National University Hospital
				Catholic University Industry-Academic Collaboration Foundation
				Samsung Seoul Hospital
				Celemics Inc.
				Korea Pharmaceutical and Bio Association, AI New Drug Development Support Center
2	Innovative chronic cerebrovascular disease biobank consortium operation project	Chronic cerebrovascular diseases	Responsible institution	Ajou University Industry-Academic Collaboration Foundation
			Consortium organizations (banks, clinicians, and industry)	Samsung Seoul Hospital
				Inha University Industry-Academic Collaboration Foundation
				Department of Neurology, Ajou University Hospital
				Suwon City Happy Mental Health Welfare Center
				Chonnam National University Hospital

	Pusan National University Hospital

※ Source: KBN portal homepage.

ⓒ List of human biobanks

Table 29. List of 41 human resource banks (written as of the end of October 2022).

Affiliated institution	Target disease	Number of samples	Types of collected samples
Gacheon Gil Hospital	Respiratory allergies, asthma, chronic obstructive pulmonary disease, and cancer	Approximately 8,000 individuals	Serum, plasma, buffy coat, tissue (frozen), urine
Catholic University Daejeon St. Mary's Hospital	Blood, allergic disease, and normal group	Approximately 50 individuals	Serum, plasma
Catholic University Bucheon St. Mary's Hospital	Brain tumor, ovarian cancer, endometrial cancer, lung cancer, placenta, etc.	Approximately 1,220 individuals	Tissue, plasma
Catholic University Seoul St. Mary's Hospital	Specialized diseases (blood, allergic diseases, and normal group) and cancer diseases	Approximately 15,000 individuals	Serum, plasma, buffy coat, whole blood, tissue (fresh/frozen, OCT), CSF, urine
Catholic University St. Vincent's Hospital	Blood, allergic disease, and normal group	Approximately 3,000 individuals	Serum, plasma, fresh tissue, OCT tissue, CSF, urine

Catholic University Yeouido St. Mary's Hospital	Specialized diseases (blood, allergic diseases, and normal group) and cancer diseases	Approximately 867 individuals	Tissue (frozen)
Catholic University Eunpyeong St. Mary's Hospital	Blood, allergic disease, and normal group	Approximately 830 individuals	Serum, plasma, tissue, bronchial lavage fluid
Catholic University Uijeongbu St. Mary's Hospital	D10–D36 (benign neoplasm), L00–L99 (disease of the skin and subcutaneous tissue), C15–C26 (malignant neoplasm of the digestive system), C51–C58 (malignant neoplasm of the female reproductive system), C43–C44 (melanoma and other malignant neoplasms of the skin), etc.	Approximately 4,800 individuals	Whole blood, serum, plasma, tissue (fresh/frozen, FFPE, buffy coat), urine
Catholic University Incheon St. Mary's Hospital	Blood, allergic disease, and normal group	Approximately 2,500 individuals	Serum, plasma, buffy coat, whole blood, tissue (fresh/frozen, OCT), CSF, urine, placenta
Kangwon National University Hospital	Neoplastic disease, cancer, nonneoplastic disease, kidney disease, respiratory disease, brain disease, nervous system disease, regional characteristics cohort study	22,708 individuals	Buffy coat, plasma, serum, urine, blood, DNA, tissue, CSF, SVF, BLD, BLF, fluid, AQU, stool, etc.
Kyungpook National University	Inflammatory bowel disease), Crohn's disease, ulcerative colitis	Approximately 50,000 individuals	Amniotic fluid, aqueous humor, ascites, bile, whole blood, bronchoalveolar lavage fluid, buffy coat, DNA, gastric juice,

Hospital			mononuclear cell, nasal wash, primary cell culture, plasma, RBC, RNA, serum, sputum, stool, tissue, urine, vaginal discharge, vitreous humor
Kyungsung University Hospital	Inflammatory bowel disease, urinary tract tumors, premature infants, pediatric and adolescent diseases, coronary artery disease	Approximately 45,000 individuals	Serum, plasma, buffy coat, peripheral blood, CSF, stool, urine, bronchoalveolar lavage fluid, pleural fluid, tissue (fresh/frozen, FFPE)
Keimyung University Dongsan Hospital	Endocrine/metabolic diseases, inflammatory bowel disease, liver disease, neoplastic diseases of the urinary system	Approximately 48,800 individuals	Tissue, fluid, paraffin block, slide, serum, plasma, buffy coat, stool
Korea University Guro Hospital	Tumor diseases (e.g., lung, colon, stomach, and pancreatic cancer), nonneoplastic diseases (e.g., hypertension, stress, and sinusitis)	Approximately 24,000 individuals	Serum, plasma, buffy coat, whole blood, fresh tissue, sputum, saliva, urine, stool, etc.
National Masan Hospital	Tuberculosis	Approximately 4,000 individuals	Sputum, serum, urine, strain
National Cancer Center	Collection and distribution of stomach, colon, breast, lung, liver, and uterine/ovarian cancer, as well as rare cancers, by department (by center)	Biobank approximately 51,803 individuals Normal (cohort) approximately 51,316 individuals	Serum, plasma, buffy coat, DNA, tissue (fresh/frozen, OCT, FFPE), body fluid, CSF, urine, etc.

Dong-A University Hospital	Five major cancers (colon, lung, liver, stomach, and breast) and female reproductive organ diseases	Approximately 5,979 individuals	Tissue, whole blood, serum, plasma, PBMC, urine, sputum, nasal fluid, vaginal discharge/cervical discharge
Pusan National University Hospital	Breast cancer and female reproductive organ diseases	Approximately 58,000 individuals	Serum, plasma, whole blood (X) tissue (fresh/frozen, FFPE, buffy coat, FFNT, FFTT), CSF (X), urine (X), stool (X), vaginal/cervical discharge (X), colon lavage fluid (X), sputum (X), nasal fluid (X), bile juice (X), amniotic fluid (X), aqueous humor (X), ascites (X), bronchoalveolar lavage fluid (X), gastric juice (X), mononuclear cell (X), primary cell culture (X), RBC (X), DNA (X), gDNA (X), RNA (X), vitreous humor (X), MNC
Pusan National University Dental Hospital	Oral disease	Approximately 1,100 individuals	Teeth, saliva, etc.
Seoul National University Bundang Hospital	Normal group, neoplastic disease (lung cancer, breast cancer, pancreatobiliary cancer, colon cancer, brain tumor, head and neck cancer, gynecological cancer, and liver cancer), nonneoplastic disease	Approximately 21,000 individuals	Serum, plasma, buffy coat, whole blood, tissue (frozen), BAL fluid
CHA University Bundang CHA Medical Center	Ovarian cancer (e.g., other female cancer, colon cancer, stomach cancer, lung cancer,	Approximately 3,000 individuals	Tissue, plasma, serum, buffy coat, ascites

	liver cancer, and pancreatic cancer)		
Medical Foundation Apple Tree Dental Hospital	Periodontitis, oral diseases, systemic diseases related to the oral microbiome (diabetes and dementia)	Approximately 287 individuals	Toothpaste, toothbrush, mouthwash
Seoul National University Hospital	Kidney disease, digestive disease, circulatory disease, endocrine disease, nervous system disease, respiratory disease, etc.	Approximately 90,000 individuals	Serum, plasma, blood, buffy coat, RBC, DNA, RNA, cDNA, tissue, urine, CSF, BAL fluid, follicular fluid, ascites, cystic fluid, bone marrow, kidney stone, stool, stool DNA
Seoul National University Dental Hospital	Oral diseases (dental caries, periodontal disease, oral inflammatory disease, oral tumor, jaw bone cyst, salivary disease, etc.)	Approximately 2,000 individuals	Teeth, saliva, plaque, gingival crevicular fluid, oral tissue, dental calculus-derived cells, oral wash, implant, blood (serum, plasma, whole blood)
Seoul Asan Medical Center	Cancer specialized tumor bank	Approximately 80,000 individuals	Plasma, buffy coat, fresh tissue, fluid, bone marrow (MNC) etc.
Bucheon Hospital Affiliated with Soonchunhyang University	Asthma, chronic obstructive pulmonary disease, interstitial lung disease, lung cancer, allergic rhinitis, normal group	Approximately 15,500 individuals	Serum, plasma, buffy coat, DNA, tissue, paraffin block, urine, body fluid (e.g., sputum, broncho-alveolar lavage, plural fluid, and nasal wash), primary cultured cell, peripheral blood mononuclear cell (PBMC)
Seoul Hospital Affiliated with Soonchunhyang University	IPF, asthma, chronic obstructive pulmonary disease, etc.	Approximately 250 individuals	Serum, plasma, tissue (fresh/frozen, FFPE, buffy coat), urine, sputum

Ajou University Industry-Academic Collaboration Foundation	Chronic cerebrovascular disease (e.g., vascular dementia, Alzheimer's dementia, mild cognitive impairment, and subjective cognitive impairment)	1,100 individuals	Serum, plasma, DNA, PBMC, stool, fibroblast
Ajou University Hospital/Ajou University Industry-Academic Cooperation Foundation	1. Liver diseases (liver cancer, cirrhosis, chronic viral hepatitis, other liver diseases). 2. Normal people. 3. Tumor diseases, such as stomach cancer, colon cancer, lung cancer, brain tumor, breast cancer, thyroid cancer, and uterine cancer. 4. psoriasis, Behcet's disease, obstetrics nonneoplastic diseases, such as diseases, gynecological diseases, glomerular diseases, traumatic brain diseases, dementia, asthma, and lupus. 5. Chronic cerebrovascular diseases (e.g., vascular dementia, Alzheimer's dementia, mild cognitive impairment, and subjective cognitive impairment)	20,307 individuals	Buffy coat, serum, plasma, blood, DNA, RNA, tissue, paraffin block, urine, PBMC, stool
Yonsei University Dental Hospital	Oral diseases (e.g., dental caries, periodontal disease, oral inflammatory disease, oral tumor, jawbone cyst, and salivary disease)	Approximately 700 individuals	Teeth, saliva, plaque, gingival crevicular fluid, tumor, soft tissue
Wonkwang	Tumor diseases: colon cancer,	Approximately	Plasma, serum, buffy coat,

University Hospital	breast cancer, lung cancer, stomach cancer, liver cancer, brain tumor, etc.	11,387 individuals	frozen tissue, DNA
Ewha Womans University School of Medicine Mokdong Hospital	Asthma, chronic obstructive pulmonary disease, interstitial lung disease	-	Serum, plasma, buffy coat, etc.
Inje University Busan Paik Hospital	Breast cancer and female reproductive organ diseases	Approximately 39,000 individuals	Serum, plasma, whole blood, tissue (frozen, FFPE), buffy coat, CSF, urine, stool, cervical/vaginal discharge, colon lavage fluid
Inha University Hospital	Tumor disease, liver disease	Collect normal tissue, cancer tissue, and blood resources, approximately 4,500 individuals 68,900 samples *Paraffin block approximately 11,831 individuals 65,900 vials	Serum, plasma, whole blood tissue [fresh/frozen, OCT (X), FFPE, buffy coat, amniotic fluid (X), FFNT (X), FFTT (X)], CSF urine stool vaginal/cervical discharge, colon lavage fluid (X), sputum (X), nasal fluid (X), bile juice, amniotic fluid (X), aqueous humor (X), ascites (X) bronchoalveolar lavage fluid (X), gastric juice (X), mononuclear cell (X), primary cell culture (X), RBC (X), DNA (X), gDNA (X), RNA (X), vitreous humor (X), MNC (X)

Chonbuk National University Hospital	Lung cancer, colon cancer, liver cancer, stomach cancer, breast cancer, leukemia, brain tumor	Approximately 2,122 individuals	Serum, plasma, buffy coat, tissue (fresh frozen tissue/TMA), BM (MNC)
Jeju National University Hospital	Normal people	Approximately 9,832 individuals	Serum, plasma, gDNA, buffy coat, whole blood, tissue, RNA
Chosun University Hospital	Breast, lung, stomach, colon, blood, and liver cancer	Approximately 1993 individuals	Serum, plasma, buffy coat, frozen tissue, bone marrow MNC
Chungbuk National University Hospital	Normal people: prostate cancer, bladder cancer, kidney cancer, cardiovascular disease	52,400 individuals	Tissue, serum, plasma, buffy coat, DNA, PBMC, urine, RNA, AF, PF, PBMC
Korea Institute of Atomic Energy Medicine	Radiation specialization, cancer disease, and normal control group	Approximately 45,000 individuals (including duplicate donor)	Serum, plasma, buffy coat
Hallym University Dongtan Sacred Heart Hospital	Thyroid cancer, colon cancer, lung cancer	Approximately 13,000 individuals	Serum, plasma, buffy, fresh tissue, urine
Hwasun Chonnam National University Hospital	Lung cancer, colon cancer, liver cancer, stomach cancer, breast cancer, leukemia, brain tumor	Approximately 2,000 individuals (year)	Serum, plasma, buffy coat, tissue (fresh/frozen, TMA), MNC

※ Written as of the end of October 2022.
※ Korea Biobank Network homepage.

B. Legal Status of Human Biobanks in South Korea

The National Biobank of Korea operates within the framework of relevant laws and regulations to preserve ethics and safety, prevent harm to human dignity, and operate a transparent and fair biobank based on the regulations for biobank operation.

(A) Laws Related to Biobanks in South Korea

Table 30. Laws related to biobanks in South Korea.

Laws	Related content
Bioethics and Safety Act" (abbreviated name: Bioethics Act).[16]	※ Article 1: Purpose This law regulates matters related to the safeguarding of ethical principles and individual privacy protection, as well as the prevention of actions that infringe upon human dignity and value or that cause harm to human beings when conducting research involving humans, human-derived materials, embryos, genes, or any similar subjects. ※ Related content ・ Scope of human subject research. ・ Establishment and functions of the National Bioethics Review Committee and the Institutional Bioethics Review Committees. ・ Designation of the Bioethics Policy Research Center and specialized institutions. ・ Operation of institutional committees for ethical review. ・ Management and utilization of human-derived materials research. ・ Management and utilization of embryos and stem cells. ・ Establishment procedures for genetic testing and collection and disposal procedures for test subjects' materials, among other matters.
Act on the Acquisition,	※ Article 1: Purpose This law promotes the efficient acquisition and systematic management of

Management, and Utilization of Biological Research Resources.[30]	life science resources and creates the foundation for the development of biotechnology. This aims to improve the quality of life for the citizens and the economic development of the country through sustainable utilization. · The need for the establishment of laws related to the creation and operation of biobanks, as well as the collection, management, and utilization of human-origin resources for the efficient management and operation of domestic human-origin resource biobanks, was reflected in May 2009. · However, no regulations provided a basis for assessing the current status of domestic and foreign biological resources, making it difficult to understand the status of biological resources in South Korea and abroad. Additionally, the absence of a management system for activities, such as transferring biological resources domestically or exporting them overseas, hindered the promotion of domestic and international exchange and utilization of biological resources. · In response to these issues, amendments were made in 2019 to establish a framework for systematically managing and utilizing biological resources by conducting surveys on the current status of biological resources, creating procedures for distribution and export, and addressing various aspects of biological resource management. ※ Related content · Matters related to the acquisition, preservation, management, and utilization of biological resources for research purposes. · Matters related to the promotion and development of fields associated with biological resources.
Personal Information Protection Act [31]	※ Article 1: Purpose This Act aims to protect the freedom and rights of individuals by establishing matters concerning the processing and protection of personal information. It further aims to realize the dignity and value of individuals. ※ Related content · Establishment of a Personal Information Protection Policy

	· Matters concerning the processing of personal information. · Matters concerning the security management of personal information. · Matters guaranteeing the rights of the data subjects. · Matters related to exceptions in processing personal information by information and communication service providers. · Operation of the Personal Information Dispute Mediation Committee. · Matters concerning class-action lawsuits for personal information.

3. International Biobank Status

A. Global Biobank Status

Biobanks, funded mainly by national governments, form part of population health-based research. A list of the world's largest 10 biobanks was first compiled by David Orchard-Webb, Ph.D., in 2018, with updated information available in 2021.[32] The 246th report published by the National Assembly Research Service on April 6, 2022, comprises additional analysis of international biobank usage, including examples from Japan and the USA that use biological specimens, tissues, and logistics.[33] The status of global biobanks was compiled by visiting each biobank's respective website for verification and organization.

(A) Biobank Graz

Biobank Graz, which is publicly funded, was established in 2007 as a nonprofit central research facility of the Medical University of Graz, Austria. Biobank Graz holds the International Organization for Standardization (ISO) certification for quality management systems (9001:2008), storing approximately 20 million samples and associated data. The biobank includes 30 years of collection. Samples are stored semiautomatically or fully automatically to maintain optimal sample quality with fast retrieval rates. With broad informed consent, Biobank Graz distributes samples worldwide to ethically and

scientifically approved research projects from academia, industry, and cooperative studies in biomedical sciences.

(B) Shanghai Zhangjiang Biobank

Zhangjiang Biobank is a commercial biobank located on Li Bing Road in "Zhangjiang Science City," Pudong district, Shanghai, China.

The biobank is projected to reach a storage capacity of 10 million human-derived samples, such as human tissue, cells, blood, and intestinal microflora. It is owned and operated by Shanghai Outdo Biotech Co., Ltd., which aims to establish a "Resource Center" for biological samples of major diseases and a "biological sample virtual information center" to convert products in the research stage into products rapidly. Thus far, four biobank products have been approved by the China Food and Drug Administration, one of which includes an early diagnosis of liver cancer and an early screening kit for self-testing at home. Notably, it shows similar results to blood glucose test strips.

(C) "All of US" Biobank

By enrolling a million or more volunteers, the USA-based "All of Us" research program will have the scale and scope needed to enable research into various diseases—common and rare—and increase understanding of healthy states. This research program is committed to engaging multiple sectors and forging strong partnerships with academic and other nonprofit researchers, patient groups, and the private sector to capitalize on work already underway.

USA has developed a system to trace the history of human-origin cells and tissues. This system investigates the spread of infectious diseases through cells, tissues, and secondary processed products, allowing for appropriate and immediate responses to issues that arise. The USA has established various specialized biobanks in different forms. For example, the Harvard Brain Tissue Resource Center, which received brain tissue donations from 1,474 individuals in 2014, provided more than 140,000 samples not only to researchers in the

USA but also to researchers abroad. This initiative aimed to meet the research demand for overcoming brain and neurological disorders, such as dementia and Alzheimer's disease. In January 2015, the "All of US" Biobank conceptualized the Precision Medicine Initiative, a plan to link genetic information from a million Americans with their medical records, which is currently in progress.[33]

(D) The International Agency for Research on Cancer Biobank

The International Agency for Research on Cancer, which is part of the WHO, aims to promote international collaboration in cancer research. This interdisciplinary agency combines skills in epidemiology, laboratory sciences, and biostatistics to identify cancer causes so that preventive measures may be taken to reduce the disease burden. The International Agency for Research on Cancer Biobank contains 5.1 million biological samples from 562,000 individuals. The European Prospective Investigation into Cancer and Nutrition study contributed over 370,000 individuals and 4 million samples. Approximately 1 million samples were obtained from other collections with nearly 200,000 individuals. Most samples comprise body fluids, including plasma, serum, urine, and extracted DNA.

(E) China Kadoorie Biobank

The China Kadoorie Biobank, previously known as the Kadoorie Study of Chronic Disease in China, was established to investigate the major genetic and environmental causes of common chronic diseases in the Chinese population. During 2004–2008, more than 510,000 adults were recruited from 10 geographically defined regions in China, with extensive data collection by questionnaire and physical measurements and with long-term storage of blood samples for future study. All participants are now closely monitored for death and other health-related outcomes through linkage with established registries and health insurance databases in the study areas. Periodic resurveys should be conducted every few years on approximately 25,000 surviving participants, with repeat interviews, measurements, and blood collection (as in the baseline survey) to assess changes in risk

exposures in the study population.

(F) UK Biobank

UK Biobank is a prominent population-based biobank operating under the support of the National Health Service and a network of 23 research facilities centered around the University of Manchester. It is responsible for collecting and managing human resources and related information. For example, the UK Department of Health, the Medical Research Council, and private companies such as The Welcome Trust jointly launched a large-scale cohort study known as the "UK Biobank Project" (2006–2012). Notably, 64 million pounds was invested in acquiring resources and information from 500,000 individuals aged 40–69, with plans for continued tracking over the following 25 years. This project aims to collect and manage extensive data, including genomic information, to improve the prevention, diagnosis, and treatment of diseases such as cancer, heart disease, diabetes, stroke, eye diseases, and mental disorders.

UK Biobank played a crucial role as a COVID-19 Hub in the context of the pandemic. It conducted five major initiatives: serology research, COVID-19 repeat imaging studies, coronavirus self-test antibody research, coronavirus infection research, and health data integration. These efforts have contributed to taking swift actions to address the global epidemic. UK Biobank provides extensive information about population health and well-being, encouraging broad participation in research. However, UK Biobank allows participation from non-UK residents; therefore, efforts to view infection sample holdings and status may be challenging, as registration requires affiliation with specific institutions and qualifications.

(G) FinnGen Biobanks

A unique study that combines genomic information with digital healthcare data has been launched in Finland. The FinnGen study plans to analyze up to 500,000 unique blood samples collected by a nationwide network of Finnish biobanks to deepen understanding

of the origins of diseases and their treatment. The project is expected to continue for 6 years, with a budget of €59M.

(H) Canadian Partnership for Tomorrow Project Biobank

The Canadian Partnership for Tomorrow Project is Canada's largest group of volunteer research participants (population cohort), built to address key questions about the causes of cancer and chronic disease. Over 300,000 Canadians aged 30–74 years have joined this project. Participants were recruited from five regional cohorts: BC Generations Project, Alberta's Tomorrow Project, Ontario Health Study, CARTaGENE, and Atlantic PATH.

(I) Estonian Biobank

Estonian Biobank is a population-based biobank at the Institute of Genomics, University of Tartu. Its main research directions are to understand the role of genetic, lifestyle, and environmental factors in health and disease. In addition, all its activities are conducted according to the Estonian Human Genes Research Act. All participants signed a broad informed consent form, allowing researchers to use their health and genomics data for various studies upon approval by the Estonian Committee on Bioethics and Human Research. The Estonian Human Genes Research Act enables recontacting and interviewing biobank participants. The rules for accessing data and samples are clear and transparent. The current cohort size is 200,000 individuals (genotyped with genome-wide arrays), reflecting the age, sex, and geographical distribution of the adult Estonian population.

(J) EuroBioBank network

In 2017, the EuroBioBank network comprised 25 rare disease biobank members from nine European countries (France, Germany, Hungary, Italy, Malta, Slovenia, Spain, the UK, and Turkey), Israel, and Canada. EuroBioBank is the first operating network of biobanks in Europe, providing human DNA, cell, and tissue samples as a service to the scientific community studying rare diseases. It is the only network dedicated to rare disease research in Europe. EuroBioBank is the biobank network of RD-Connect. Through the RD-Connect

Sample Catalog, approximately 13,000 new samples are collected each year and 7,000 samples are distributed in Europe and beyond. Currently, the network holds specimens for more than 950 rare diseases.

(K) Japanese Biobanks

Japan centralizes the medical research and development budget, managed by the Japan Agency for Medical Research and Development. This agency provides continuous support for nine focus research areas, including genome medicine, spanning from basic research to product development. To realize personalized medicine, the government developed a large-scale disease-based biobank called Biobank Japan at the University of Tokyo's Institute of Medical Science in 2003. Biobank Japan collects and stores clinical information and human specimens from more than 60 regional hospitals, involving approximately 200,000 patients from 51 disease groups. In addition, the “Genomic Medicine Realization Promotion Council” was established in 2015 to promote genomic medicine. The aim is to utilize the genetic information accumulated in three existing biobanks in research. Since January 2016, they have actively promoted genomic medicine, particularly for cancer patients with limited responses to conventional treatments.[34]

(L) Overseas Private Biobanks

Private biobanks have been established in Europe and the USA. While biobanks for population-based health research funded by governments typically do not hold infectious specimens, private biobanks maintain a diverse range of samples in areas such as oncology, immunology, hematology, infectious diseases, normal tissues, benign conditions, cardiology, dermatology, neurology, and pulmonology. With a global network and access to various sources, private biobanks can provide prospective collection and distribution services even if specific samples are not in their possession. These biobanks contribute to collecting specimens through global networks and connecting and guiding clinical trial facilities, often serving as contract research organizations.

Table 31. Summary of overseas biobank status.

Major biobanks (URL)	National	Resource collection scale and purpose
Biobank Graz (https://biobank.medunigraz.at)	Austria	· 20 million human-derived samples. · Distribution of samples for academic, industrial, and collaborative research in the field of biomedicine.
Shanghai Zhangjiang Biobank (http://www.shbiobank.com)	China Shanghai	· 10 million human-derived samples. · Genome, transcriptome, proteomics, and other one-stop research platforms.
"All of Us" Biobank (https://www.joinallofus.org/)	USA	· 1 million derived samples. · Research on several diseases, including common and rare diseases.
The International Agency for Research on Cancer Biobank (https://ibb.iarc.fr/)	World Health Organization	· 1.6 million biological samples donated by 562,000 individuals. · Promoting international collaboration in cancer research.
China Kadoorie Biobank (https://www.ckbiobank.org/)	China	· Established to collect blood, medical records, and lifestyle data of 500,000 Chinese individuals and analyze genetic and nongenetic (environmental) causes of chronic diseases. · Over 510,000 participants.
UK Biobank (https://www.ukbiobank.ac.uk)	England	· Blood collection from 500,000 British individuals. · Conduct gene discovery research to overcome cancer and rare diseases.
FinnGen Biobanks (https://www.finngen.fi/en)	Finland	· Collecting blood samples from 500,000 individuals. · The goal is to deepen understanding of the origins and treatment of diseases.

Canada Partnership for Tomorrow Project (https://canpath.ca)	Canada	· Over 300,000 participants · Resolving factors that cause cancer and chronic diseases
Estonian Biobank (https://genomics.ut.ee/en/access-biobank)	Estonia	· Understand the role of genetic, lifestyle, and environmental factors · Current cohort is 200,000 people
EuroBioBank Network (http://www.eurobiobank.org/)	European Union	· A scientific community service dedicated to rare disease research, comprising 25 members from nine European countries (France, Germany, Hungary, Italy, Malta, Slovenia, Spain, the UK, and Turkey), Israel, and Canada. This network researches rare diseases and serves the biomedical field, industry, and collaborative research by distributing samples. · More than 150,000 biological samples · Collection of approximately 130,000 new samples annually
Biobank Japan (https://biobankjp.org/en)	Japan	· Goal of implementing personalized medicine · 260,000 patients

※ Source: David Orchard-Webb (2018). 10 largest biobanks in the world, partial processing.

Table 32. Summary of overseas private biobank status.

Major biobank (URL)	**location**	**Key features**
BocaBiolistics (https://www.bocabio.com)	USA and Europe	· More than half a million samples. · Offers a full range of contract research organization services.
Discovery Life Science (https://www.discoverybiostore.com/s/)	USA and Europe	· Offers a full spectrum of biospecimen solutions.

		· All disease areas: oncology, immunology, hematology, and infectious diseases. · Normal, benign, cardiological, dermatological, neurological, and pulmonological.
Cerba Xpert (https://cerbaresearch.com/)	France	· Largest global PBMC network. · Extended virus biobank services.
Central BioHub (https://centralbiohub.de/)	Germany	· Possession of various specimens, such as infectious diseases. · Hub role with various partnerships.
Audubon (https://audubonbio.com/)	USA	· Offer high-quality human biospecimens. · Quickly growing innovative provider of biomedical research services, including biospecimens and clinical information of the highest quality. · Started in 2016 and since then has grown to a global team of almost 100 specialists working with 120+ sites in 12 countries.

B. Laws Related to Overseas Biobanks

Relevant regulations have been established to establish and operate biobanks and provide a legal framework for the collection and utilization of human-origin materials. The 2020 policy research project report on the expansion plan for the management facilities of the National Central Human Resources Bank reported that various biobank-related laws and regulations have been compiled from different countries.[19]

Table 33. Laws related to overseas biobanks.

Country/ institution	Related laws	Main content
Singapore	· Human Biomedical Research Act, 2015	· Emphasis on the rights and benefits of protecting human specimen donors. · Balancing active research and effective specimen management, establishment, and operation of human tissue banks.
UK	· Human Tissue Act, 2004	· Collection and use of human-derived materials. · Protection of donor rights and personal information privacy.
Island	· Act on Biobank	· Matters related to the establishment and operation of biobanks associated with the deCODE project. · Matters related to the protection of donor rights and personal information privacy. · Government support for securing human-derived materials.
Estonia	· Human Gene Research Act, 2000	· In 2000, the Gene Bank Act was enacted as part of the policy to establish the world's largest gene bank. · The act regulates all matters related to the acquisition and management of genetic resources.
Sweden	· Biobanks in Medical Care Act, 2002	· Detailed provisions for the establishment and operation of biobanks. · Protection of donors' rights and personal information.
Norway	· ACT Relating to Biobanks	· Distinct management of diagnostic, therapeutic, and research biobanks, including their establishment and operation.

			• Regulation of donor rights protection and control and management of biological resource utilization.
Finland	·	Biobank Act, 2013	• Support for research employing human-origin materials while promoting openness in their utilization. • Ensuring the protection of personal information and individual autonomy.
Taiwan	·	Human Biobank Management Act	• Comprehensive legislation for the management and operation of biobanks. • Explicitly specifying the legal protection of identifiable biological samples, derivatives, and related data.
Spain	·	Biomedical Research Act	· Respecting the dignity of human beings and their inherent human rights while regulating biomedical research.
Austria	·	Matters related to the quality and safety of human-origin tissues and cells, as well as regulations concerning tissue banks.	
Denmark	·	Article 312 of the Biobank Act (2003).	
Council of Europe	·	Agreement on the Application of Biology and Medicine for the Protection of Human Rights and Dignity (1997), biomedical research.	
European Commission	·	Directive 2004/23/EC on setting standards for the quality and safety of human tissues and cells used in donation, procurement, testing, processing, preservation, storage, and distribution.	
Netherlands	·	Article 467 of the Civil Code of 1994.	
USA	·	Health Insurance Portability and Accountability Act of 1996.	

※ Source: National Central Human Resource Bank Human Resource Management Facility Expansion Plan Study 2020.

※ Source: The latest foreign legal information for 2023, Issue 1, related to biobanks (country: Singapore), partial processing.

4. Domestic and International Biobank Survey and Analysis

We selected institutions from domestic and international biobanks with a strong track record in information collection, storage, and sample distribution. After analyzing the selected institutions, we provided the ideal direction. The UK Biobank, one of the largest biobanks in the world, demonstrated vigorous research and results. Additionally, we compared it with a commercial biobank, BocaBiolistics, which held different sample types, including infectious disease specimens.

BocaBiolistics is a commercial entity in the USA designed with a well-structured classification of samples by type and collection method. This classification allows for convenient information retrieval when searching for specific samples. Moreover, it boasts a well-established global network, making prospective sample acquisition feasible even when the required clinical samples are not in possession. The UK Biobank, based in the UK, offers distribution to foreigners. However, access to resource information is restricted unless registration scrutiny is passed. In addition, comprehensive management of human-origin material banks based on disease categories, including infectious diseases, and the facilitation of internationalization and advancement are essential in domestic biobanks to enable distribution to domestic and foreign researchers.

Table 34. Comparison of domestic and foreign biobanks.

Country	South Korea	England	USA
Portal name	KBN portal	UK Biobank	BocaBiolistics
URL	www.kbn.re.kr	www.ukbiobank.ac.uk	www.bocabio.com/
Established year	2020 (2012, KBN)	2006	2005
Resources	Government	Government and private	Private
Operating entity	Public biobank	Independent corporation	Private biobanks
Affiliation	Centers for Disease Control and Prevention, National Institute of Health	Medical Research Council	Commercial biobank
Type of biobanks	Population-based (National Biobank of Korea) and disease-based (17 regional banks)	Population-based biobank	Multiple disease-based (e.g., infectious, tropical, cardiovascular, and gastrointestinal diseases and oncology)
Network	17 regional biobanks and 2 collaborative biobanks for human bioresources	23 research facilities centered around the University of Manchester	To collect samples from 5 continents
Online search for bioresources	Available without login	Unavailable without login	Available without login
Online process for distribution	Available	Available	Available
Distribution availability to foreigners	Unavailable	Available	Available
Convenience of sample search	Convenient	-	Convenient
Inventory of infectious diseases	Hard to find	-	Convenient

V. Strategy for Building a Global Network of Korean Biobank

South Korea should initiate legal reforms to establish a successful leadership role in the *in vitro* diagnostics market. The transformation of clinical sample information collection, storage, and management into a well-organized system while ensuring clinical sample availability is a crucial step. Furthermore, expanding the Korea Biobank Project through global collaboration and gradually developing the KBN portal into a global platform are key strategies.

1. Legal Revisions for Activating Biobanks

Reviewing the legal status of advanced healthcare systems in countries and establishing effective regulations while prioritizing patients' rights and protection are necessary for activating domestic biobanks. In 2013, the scope of the application of the Life Ethics Act was expanded in South Korea to include research related to human and human-origin materials. However, the specific details and regulations related to human-origin materials, their operation, obligations of operators or administrators, and supervision are insufficiently regulated, as they are only covered in a separate section. Considering certain aspects of human-origin material-related legislation in Singapore and Finland and suggesting improvement measures is worthwhile to promote domestic biobank activation and standardize sample collection.

Singapore acknowledges the medical industry as a core national industry, as evidenced by its recent foreign legal information about human-origin material banks. It has actively implemented policies to promote the biomedical industry. The Human Biomedical Research Act introduced in 2015 defines human tissues as encompassing all biological materials related to the human body. However, biological materials listed in Schedule 1 of

the Human Biomedical Research Act are excluded. For example, although human-origin materials include DNA and RNA, they are not classified as human tissues because they do not contain human cells. Therefore, the strict regulation under this legislation does not apply to DNA information. Notably, DNA information is treated as pseudonymous. It is not subject to the regulations of the Human Biomedical Research Act because when not linked to personally identifiable information, such as names, DNA information cannot identify individuals on its own. These measures are considered a way to promote research using human genome data.[35]

Singapore introduced the Healthcare Services Act in 2020. This act changed the establishment and licensing of medical support facilities, including medical centers, long-term care institutions, and human tissue banks. The Singaporean government has recognized that the conventional facility-centered licensing system is no longer adequate in the era of advances in medicine and science. This period is characterized by the emergence of non-face-to-face medical care and the proliferation of online healthcare services, which have transformed the traditional healthcare landscape.[35]

Under the Healthcare Services Act, Singapore no longer issues physical facility-based licenses for medical, medical support, and care services. Alternatively, licenses are issued based on the services provided. In June 2023, human tissue banks will operate under this service-based licensing system. Additionally, Article 32 of the Human Biomedical Research Act prohibits commercial transactions involving human tissues. Therefore, human tissue banks are primarily operated by research institutions for nonprofit research purposes.

Research institutions offering human tissue bank services must establish an IRB and form a committee responsible for the operation and management of the human tissue bank. According to Article 6 of the Human Biomedical Research (Tissue Research) regulations, research institutions must designate an individual qualified to serve as the Principal Person in Charge to oversee the activities and missions of the human tissue bank. Furthermore,

they must notify the Ministry of Health at least 30 days before commencing activities involving human tissues and obtain the necessary license.

In particular, with the introduction of the Healthcare Services Act, the role and responsibilities of the service's key personnel have been formalized and strengthened, surpassing the standards set for facilities.[35]

Occupying a leading position in Europe, Finland actively conducts large-scale precision medicine projects and possesses well-established legal and regulatory frameworks in related fields. In addition, the Finnish government has identified healthcare and biohealth as key growth industries for the future. To lead in biohealth technology, Finland has relaxed regulations and supported research and development in these areas.[36]

Finland has acquired extensive experience and technology in various clinical research areas based on its national tendencies, such as the KanTa system for integrated patient medical records, nationwide health information accumulation projects, large-scale clinical studies in chronic diseases, and populations favorable to medical research. Moreover, there has been considerable interest and investment in biohealth, ensuring that its innovative strategies for advancing medical research are legally upheld.[36]

The fundamental Finnish law on information technology is the "Data Protection Act," which came into effect on January 1, 2019. This law replaces the existing Personal Data Act (523/1999) and includes the EU General Data Protection Regulation. It specifies the applicability of Finnish legislation on data protection, including the appointment, organization, and authority of supervisory bodies for data protection issues.

Furthermore, Finland enacted the "Biobank Act" in 2013 to facilitate the collection of genomic data necessary for its ongoing precision medicine initiatives. This law regulates data sources, data centralization, service centralization, and data utilization entities. In May 2019, Finland approved the "Finnish Act on the Secondary Use of Social and Health Data," which has enabled private companies, research institutions, and government agencies to

use the social and health-related information of citizens for various purposes, such as research and development, statistical analysis, and education. According to this law, research institutions and pharmaceutical companies can utilize the biodata provided by the Finnish government for research on health, disease prevention, and new treatment methods.[36]

Unlike other European countries, Finland has made biodata available for secondary use through the "Biobank Act" and the Secondary Use Act. Consequently, these data can be used in scientific and statistical research. Researchers can utilize these data for various purposes, including evaluating specific diseases and postmedication conditions and conducting registry-based research. In line with these legal provisions, Finland launched Findata in April 2020, which is responsible for handling data requests from different institutions. In addition, it assesses data access requests and collects, combines, anonymizes, or pseudonymizes datasets necessary for research. Subsequently, it provides them for research purposes.[36]

The Finnish "Biobank Act" was enacted to support research utilizing human biological samples and tissues. It aims to promote openness in using human biological samples and protect personal information and individual autonomy when handling such materials. Parties interested in establishing a biobank—whether individuals, public institutions, communities, foundations, or other legal entities—can perform this task provided they have the necessary financial and operational means and meet the legal and research-related conditions for maintaining and managing the biobank.[36]

Biobank rights with respect to sample processing are based on consent unless otherwise specified by this law or other laws. When samples are collected or are to be collected for storage in a biobank, for use in biobank research, for providing personal information, for associating information on the individual, for processing information about samples within the scope required by biobank research, or for other matters related to sample and information processing, all of these actions must be based on written consent. Additionally,

individuals have the right to withdraw, modify, prohibit, or restrict the use of their samples for research purposes at any time.[36]

In the legislation on human-derived materials in Finland and Singapore, these materials are not classified as human tissues. The main key legislation in Singapore revolves around issuing licenses based on service activities rather than facility-centered licensing. Finland's Biobank Act comprises six main sections: General Provisions (Chapter 1), Establishment and Operation of Biobanks (Chapter 2), Processing of Personal Data Related to Genetic Samples (Chapter 3), Matters Concerning the National Biobank Register (Chapter 4), Supervision and Compulsory Measures (Chapter 5), and Other Provisions (Chapter 6) (http://site.fingenious.fi/en).[36] The legislative purpose of supporting research involving human-derived materials and promoting openness in their usage is to facilitate research utilizing biobanks, allowing anyone who meets the legal and research-related conditions to establish a biobank. This can serve as a legal requirement for the activation of biobanking and the systematic collection of clinical specimens.

2. Clinical Specimen Collection Requires a Conducive Environment

A systematic sample collection environment should be established to enable standardization of clinical specimen information collection, similar to the requirements for establishing human tissue banks in Singapore, where the responsibility and roles of service operators are strengthened through a service-based licensing system, which promotes the standardization of clinical specimen information collection. This approach could promote the establishment of biobanks by individuals, private entities, and national healthcare institutions once they meet the qualifications of responsible individuals.

Samples collected and stored in personal laboratories that could not be officially utilized could be integrated into biobanks, enabling the organization to conduct clinical trials,

publish research findings, and provide benefits such as submitting research results for publication. This shift could encourage healthcare institutions to choose collection and storage over disposal of remaining specimens after treatment. Institutions setting up biobanks may also be attracted by government participation incentives, tax benefits, the domestic and international supply of clinical specimens, and the opportunity to generate profits.

In the international context, Europe and the USA have already established private biobanks with various sample sources and the ability to provide or distribute stored samples, even prospectively. The cost of providing or distributing samples varies depending on the specimen type, with easily obtained samples, such as urine, costing around €25 and rare samples costing approximately €2,000. According to the "World Biobanking Market" report by Markets and Markets published in May 2023, the global biobanking market is expected to grow from $2.9 billion in 2023 to $5 billion by 2028, with a CAGR of 11.4% projected during the forecast period (2023–2028).[37] However, in the domestic context, if the conditions for establishing private biobanks in South Korea are eased through legal amendments or other means, the number of institutions capable of conducting clinical trials may increase, contributing to the development of the biotechnology industry.

For further promotion of research using clinical specimens, it is necessary to consider a "negative" use review that excludes strict regulation of human-derived materials such as DNA and RNA, which do not include human cells, and categorizes them as nonhuman tissues. Additionally, specimens slated for disposal after medical treatment could be anonymized or deidentified for use in medical research unless individuals object. Currently, when seeking clinical trial approval from the IRB, it is indicated in the submitted documents that residual specimens scheduled for disposal fall under Article 16, "Consent for Human Subject Research" of the "Life Ethics Act." This article allows exemption from obtaining written consent from research subjects for the following cases: obtaining consent is practically impossible during the research process, obtaining consent would seriously impact the feasibility of the study, there are no obvious reasons to presume that research

subjects would refuse consent, and the risk to research subjects is extremely low.[16] The use of a comprehensive consent form for the collection and storage of clinical specimens and the omission of submission of written consent exemption documents for the use of residual specimens can ultimately be identified as a means to streamline operations and contribute to the efficiency of clinical specimen collection and management.

According to the Seoul Medical Tourism website, as of 2019, 320,284 foreign patients (from 190 countries) visited South Korea for various reasons, including health check-ups and plastic surgery.[38] After the legal amendments, the review of comprehensive consent for the use of residual specimens may enable sample acquisition from various ethnicities. The country needs more progressive legal revisions and a conducive environment to facilitate the collection and storage of clinical sample information.

3. Expansion of Global Collaborative Efforts in the Korea Biobank Project

A. Designation of Domestic Collaborative Organizations for Clinical Trials

South Korea requires a special law on collaborative clinical trial designation (pilot project) to secure samples from specific countries or different ethnic groups, particularly European specimens, and to conduct overseas clinical trials.

In vitro diagnostic medical devices, which have shown rapid growth since COVID-19, account for half of the domestic diagnostic medical device market and are growing at an average annual rate of 4% in the global market. *In vitro* diagnostics, driving the activation of the domestic *in vitro* diagnostic medical device market, have become more significant with IVDR implementation, increasing product development time and the importance of performance evaluation and clinical trials using clinical specimens.

Companies develop products that target the global market. However, clinical specimens from specific countries or regions are necessary to cater to specific products for those areas. Obtaining foreign specimens requires Korean researchers to travel abroad to set up equipment, train external researchers, and obtain results. This process incurs a significant amount of time and additional costs compared to obtaining specimens domestically. In addition, specimen availability in regions such as the Americas, Europe, Central and South America, and Southeast Asia could enable interethnic performance evaluations and preemptive adaptation to changes in national interpretation criteria after approval.

The previous description of the challenges encountered by *in vitro* diagnostic medical device companies revealed that companies must confirm regulatory requirements in the exporting country for specific specimens. Import or reimport permits in South Korea require facilities with a biosafety level 2 or higher to handle biological hazards and high-risk pathogens. Companies can focus more on innovative technological development while handling the legal review, permit applications, and clinical trials for specimen import through collaboration with hospitals (institutions) affiliated with the Korea Biobank Project. Currently, two methods can be employed: designating all specialized hospitals for 10 characteristic diseases as collaborating clinical trial institutions and establishing innovation-type biobank consortia for infectious and cerebrovascular diseases, such as the congenital cancer field. As the consortium institutions include specimen banks, clinical professionals, and industry representatives, they can be used by innovative medical device companies and Innovation Medical Device Validation Support Centers in line with the Medical Devices Industry Act.

In November 2020, five university hospitals (Dankook University Hospital, Ajou University Hospital, Gangnam Severance Hospital, Seoul National Dental University Hospital, and Seoul National University Hospital) were selected as Innovation Medical Device Validation Support Centers to support the rapid commercialization of medical devices.[39]

Each hospital has its specialized field, and consortium formation through the main and

subinstitutions is possible. Therefore, utilizing the existing infrastructure can be very beneficial. Based on the willingness to collaborate internationally, the university hospitals selected for clinical trials with ISO14155 and IEC62366 certifications for medical devices have the necessary infrastructure to utilize foreign specimens. Accordingly, companies can validate the importance of clinical samples in cost reduction, time savings, and performance assurance from the product design and validation phase. If such a new regulation (special law) is introduced, one *in vitro* diagnostic reagent can obtain certification from IVDR, FDA, MFDS, Health Canada, and other national authorities and be immediately available for sale.

Amid the increasing number of companies operating in the *in vitro* diagnostic medical device industry and the accelerating global competition caused by COVID-19, a key way to activate the domestic medical device market is performance verification *via* clinical samples and prioritized market entry for products. Currently, institutions operating or planning to operate biobanks can expand hospital resources, gain international recognition, and enhance service quality and credibility by seeking "ISO 20387:2018" certification. If they operate biobanks with the goal of achieving this certification, their international usability will likely increase. A2LA, the world's largest certification body accredited by the International Laboratory Accreditation Cooperation, granted "ISO 20387:2018" international certification to Seoul Clinical Laboratories' Biobank, a subsidiary of Seoul Clinical Laboratories, in January 2023, the first in Asia and the seventh worldwide to receive this certification.[40] The ISO 20387 assessment criteria conducted by A2LA confirm the operational capability for major biobank activities, such as collection, preservation, storage, distribution, transportation, and disposal, along with the capability to provide human resources and associated data for research and development. As private companies acquire global certifications, national biobanks should comply with these standards.

European samples are required for the European market entry of IVDs; however, the acquisition and utilization of such samples are limited. With the transition to IVDR, maintaining the sales of existing products and reentering the market with improved products necessitate confirming the utility and safety of diverse sample utilization.

Similar to the Letter of Intent signed for the “Korea–US Precision Medicine/MERS Research Cooperation” after confirming cooperation intentions in the development of MERS vaccines and treatments, cooperation agreements should be established between Europe and South Korea. Such agreements can utilize the hospital infrastructure provided by biobanks to expedite product development and achieve market clearance within a short period. This approach aims to create successful cases by leveraging the specific diagnostic product development technology for unique European diseases, along with designated infrastructure and technology partners.

Subsequently, the network of designated collaborative institutions should be expanded using pilot projects to validate this approach. This initiative can yield positive results for healthcare industries in both countries and further foster healthcare industry development.

B. Expansion of International Collaborative Efforts and the Need for New Models

The Ministry of Health and Welfare and the Korea Centers for Disease Control and Prevention are making different attempts to develop international collaborative models. Accordingly, new models are required for international cooperation.

First, the Foundation for Innovative New Diagnostics (FIND) is an international organization dedicated to improving diagnostic conditions for major diseases affecting impoverished countries and supporting the development and certification of diagnostic devices. In pursuit of the global advancement of the *in vitro* diagnostic industry, on May 10, 2023, the Ministry of Health and Welfare identified areas of collaboration. It strengthened cooperation between the Korea Health Industry Development Institute and FIND to support the overseas expansion of Korean diagnostic companies and enhance diagnostic capabilities in low- and middle-income countries through a memorandum of understanding.[41]

Support will be provided through the FIND biobank, comprising over 400,000 samples, to develop diagnostic devices for diseases such as malaria and tropical diseases, for which it is challenging to secure samples in South Korea. FIND is currently designating domestic institutions as clinical trial collaborative partners to alleviate the burden on domestic companies by facilitating overseas clinical trials. FIND plans to utilize the South Korean *in vitro* diagnostic industry to meet global diagnostic demands for poverty-related diseases in low- and middle-income countries. In addition, it aims to support the participation of the South Korean *in vitro* diagnostic industry in international procurement markets.[41] Currently, FIND is conducting an assessment to identify suitable domestic institutions for collaboration, although specific procedures for this collaboration have not yet been established. South Korea has recently witnessed an increase in the incidence of tropical diseases such as Zika, malaria, and other mosquito-borne illnesses, partly due to climate change and travel to Southeast Asia and Africa. Certain samples from the FIND biobank, such as chikungunya and yellow fever viruses, fall under the "dual-use items" category, for which 43 countries have agreed to impose export controls.[42] The "dual-use items" category falls under the "strategic items" category subject to export controls according to the South Korean "Foreign Trade Act" managed by the Ministry of Trade, Industry, and Energy. Specific review criteria may vary depending on the active status of the samples. However, if FIND designates clinical trial collaboration institutions within South Korea, a concrete agreement is required to facilitate the entry of FIND biobank samples with relaxed or no import restrictions. While establishing cooperation procedures between the Korea Health Industry Development Institute and FIND, considering the specific challenges faced by private companies could provide a great opportunity for the South Korean *in vitro* diagnostics industry to leap into the global market, particularly in the context of disease diagnosis in Asia and Africa through the FIND biobank.

Second, the Korea National Institute of Health, part of the Korea Disease Control and Prevention Agency, announced on August 10, 2023, that it would initiate clinical trials for pandemic preparedness against emerging infectious diseases in South Korea through

collaboration with the U.S. National Institute of Allergy and Infectious Diseases. This program, called Strategies and Treatment for Respiratory Infections and Viral Emergencies (STRIVE), is primarily led by the U.S. National Institutes of Health. It focuses on developing treatments for pandemics caused by acute severe respiratory infections, such as COVID-19. Additionally, the Korea National Institute of Health is establishing a national clinical research network to facilitate the participation of South Korean hospitals and researchers in clinical trials, overseeing all stages from trial planning to execution and management.[43]

The Korea National Institute of Health signed a research collaboration agreement with the U.S. National Institute of Allergy and Infectious Diseases in April 2022. This collaboration is part of their ongoing efforts to build a comprehensive national clinical trial cooperation system, which aims to enable smooth participation by domestic hospitals and researchers in clinical trials and coordinate all aspects of clinical trial planning, execution, and management.[43]

Bundang Seoul National University Hospital, Seoul St. Mary's Hospital (Catholic University of Korea), Seoul Asan Hospital, and Chung-Ang University Hospital successfully passed the suitability evaluation for clinical trials in the first half of 2023 to be able to participate in nation-led global clinical research cooperation projects.[43] The increasing interest and efforts made by hospitals with clinical trial institutions and biobanks to obtain qualifications that will enable participation in these international cooperation projects enhance the credibility of domestic institutions, which will yield positive results.

Collaborative efforts between the Ministry of Health and Welfare and the Korea Disease Control and Prevention Agency have enabled medical device companies operating in the *in vitro* diagnostics industry to acquire hard-to-obtain specimens through the FIND biobank and develop products for potential market penetration in Asia and Africa. Initiatives such as the initiation of clinical trials for pandemic preparedness against emerging infectious diseases (e.g., STRIVE) enhance the ability to respond rapidly to infectious diseases,

similar to the development of COVID-19 diagnostic reagents.

Furthermore, private enterprises (e.g., Seegene Inc.), which have pioneered global collaborative technology sharing initiatives for tailored diagnostic reagent development, constantly expand and strengthen these models. South Korea can position itself as a central hub in the global clinical trial cooperation network through ongoing efforts to create and reinforce global collaboration and new cooperative models. If these collaborations and new models are continually developed, the establishment of a global biobank network will provide a substantial foundation for the advancement of the domestic *in vitro* diagnostics industry.

4. The Role of the KBN Portal in Information Exchange in South Korea

The KBN portal has greatly contributed to facilitating information exchange in South Korea. Transformation is necessary to expand the collection of clinical specimen information based on various diseases, including infectious diseases. The portal should integrate information from all human biobanks in South Korea, making it globally accessible, even to foreigners.

The current KBN portal provides statistical criteria (Table 26) showing that “other” specimens account for 13.7%. However, information on infectious disease specimens is difficult to find because of limited historical collection efforts for clinical specimens of infectious diseases. As of August 31, 2023, South Korea had 82 registered human biobanks, 63 of which were not affiliated with the KBN portal.

Expansion of clinical specimen collection for infectious diseases and activation of specimen sharing are required to improve the KBN portal and enhance its role. For database integration, seeking advice from experienced clinical experts is essential to standardize

specimen types, sampling devices, volume, sample collection dates, storage conditions, extraction methods, and terminology and classification methods within the KBN portal. In addition, a standardized user interface should be confirmed to facilitate uniform data input during human biobank registration. Building a standardized and integrated clinical information management system will facilitate the efficient operation of organizations establishing human biobanks. Additionally, companies in need of clinical specimens will benefit from the KBN portal's efficient online information retrieval and distribution system.

Furthermore, if the KBN portal could facilitate specimen sharing with foreigners, similar to biobanks in the UK, Finland, or private banks in the USA and Europe, it would become a vital portal for human resource information exchange. This would establish the "Global Biobank Network of South Korea's Human Biobanks" as a major contributor to health and medical research and support for the medical industry, making it a starting point for various clinical trials and research initiatives in South Korea.

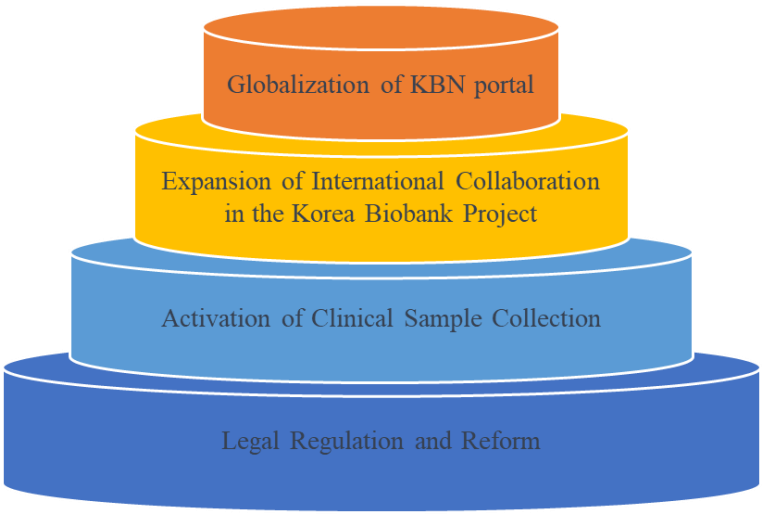

Figure 7. Step-by-step strategy.

V. Discussion

The domestic medical device industry grew substantially in 2021, with a total production output of 12.8831 trillion won. Approximately half of this revenue increase was attributable to *in vitro* diagnostic medical device companies.[2] The unique circumstances of the COVID-19 pandemic witnessed considerable growth to the extent that the general public is now familiar with terms such as "*in vitro* diagnostic medical devices" and "molecular diagnostics." The high growth in IVDs was influenced by government initiatives, such as the "Emergency Use Authorization" system and companies' clinical specimen support programs. However, as the pandemic approaches its final phase, the importance of conducting clinical trials to verify performance using clinical specimens has been emphasized domestically and internationally. With the transition of EU regulations to IVDR, the maintenance and enhancement of sales based on IVDD and the acquisition of regulatory approvals have become increasingly challenging without the availability of various clinical specimens for clinical trials. Compared to CE-IVDD, preparation for market entry into Europe has become time-consuming, resulting in a significant decline in sales for export-oriented countries worldwide.

Seegene's current "Open Innovation Program" aims to overcome its challenges in obtaining the required clinical specimens. It ultimately seeks to access clinical specimens openly through reputable institutions such as Springer Nature. While companies are dedicated to innovative technology development, the government must support the comprehensive technology validation process. Although larger companies have the financial resources necessary to make multifaceted investments, smaller ventures and small- and medium-sized enterprises lack capital; thus, they face difficulty undertaking technology validation. If the government does not provide institutional support for such cases, fostering the progress of medical device technology and reviving the *in vitro* diagnostic medical device industry will be challenging, particularly for smaller ventures and small- and medium-sized enterprises.

This study emphasizes the significance of obtaining clinical specimens for infectious disease research in response to strengthened regulations. In addition, it highlights the crucial role of government support in providing clinical specimen collection information and clinical trial assistance to *in vitro* diagnostic medical device companies. We aim to position the Korea Biobank as a significant contributor to global biobank networks, with a focus on supporting healthcare and medical industry research. Consequently, we intend to establish a forward-looking direction from three perspectives—legal, institutional, and industrial—after assessing the current state of domestic and international biobank operations and conducting legal and regulatory examinations.

First, an environment that can activate analytical performance testing, clinical specimen acquisition, and information collection for clinical trials must be established. This environment should encompass not only human components, such as tissues, cells, and bodily fluids, but also derivatives, such as serum, plasma, chromosomes, DNA, RNA, and proteins. We recommend reclassifying human-derived materials under the Bioethics and Safety Act of South Korea based on the Human Biomedical Research Act, 2015, of Singapore. This reclassification would consider these materials as human-derived, even if they contain DNA or RNA without human cells, thus enabling research using human genome data.[35] Furthermore, the Healthcare Services Act of Singapore issues licenses based on service activities rather than physical facility-based licenses for medical, medical support, and care services. This service-based licensing system will also apply to human tissue banks from June 2023. [35] The Finnish Biobank Act supports research that uses human-derived materials, promotes openness in the use of such materials, and guarantees individual autonomy.[36] The application of a service-based licensing system to biobanking and the relaxation of regulations for the utilization of human-derived materials will contribute to the activation of research activities, thereby enhancing clinical specimen collection and utilization research.

Second, there is a need to expand global collaboration for South Korea Biobank Projects led by the government. Similar to collaborations with Europe, the USA, or organizations

such as FIND, a model should be developed whereby companies can import or access the required infectious specimen resources, along with relaxed regulations, and conduct clinical trials in designated clinical trial facilities within specific domestic hospitals (designated clinical trial institutions). This initiative should be accompanied by ongoing support programs based on successful cases. Given the periodic changes in viruses across hemispheres, having an infrastructure that facilitates the smooth progression from product development to approval and subsequent resale through a single setup can enable South Korean medical devices to lead the global market, increasing market share. Ultimately, South Korea needs a regulatory system to maintain its edge in medical device sales within the *in vitro* diagnostic medical device sector.

Third, while conducting this study, the KBN has not collected several specimens related to infectious diseases. Nonetheless, the KBN portal can serve as a foundational open platform. For maximum utility, the KBN portal should be used to integrate information from all domestic human-origin material banks. Accordingly, researchers can access the required samples in a timely manner through an integrated management system. Additionally, the operating methods should be adjusted to allow foreigners to purchase these materials, as observed in some overseas biobanks. This will solidify the KBN portal's position as an essential portal for information exchange related to human-origin materials.

These measures will contribute to the broader goal of creating a global biobank network, advancing health and medical research, and supporting the medical industry.

While launching the new Peugeot 408 in Korea for the first time, Linda Jackson, CEO of Peugeot, stated at the Peugeot Brand Day in May 2023 that "Korea is a country that leads trends in various industries." In other words, South Korea is a nation that readily embraces innovative challenges and quickly adopts new business models; accordingly, it can lead in any industry. It has a well-developed healthcare industry, and to activate domestic medical devices, we should boldly attempt and challenge necessary changes through regulatory reforms.

VI. Conclusion

The IVD sector constitutes a significant portion of the domestic medical device industry, accounting for approximately 54% in 2021 and 44% in 2022.[15] The increase in the production and trade of genetic test reagents for high-risk infectious diseases, immunodiagnostic reagents for high-risk infectious diseases, and diagnostic immunodiagnostic reagents for infectious agents can be attributed to the impact of the COVID-19 pandemic. In 2021, Germany and Italy represented approximately 42% of total European exports. However, with the transition of European regulations from CE-IVDD to IVDR, an increase in regulatory stringency for clinical trials has been observed, making clinical specimen acquisition a critical component in product development. Companies in the IVD sector, which previously based their European market revenue on CE-IVDD products, face market entry challenges if they are unable to secure the necessary clinical specimens because of the implementation of IVDR. These challenges may result in prolonged market entry timelines and financial difficulties for these companies.

This study aims to provide crucial information and analysis of the establishment of a global biobank network for the *in vitro* diagnostic medical device industry in South Korea, with a primary focus on identifying solutions to the challenge of securing clinical specimens, which is a key factor for maintaining or promoting the *in vitro* diagnostic medical device market. This study investigates how different countries perceive the definitions and roles of biobanks and their current status. Additionally, emphasis is placed on the importance of understanding the legal and regulatory foundations of leading countries in fields related to biopharmaceuticals and personalized healthcare. This understanding is crucial in response to changes in the industry landscape.

The ultimate goal of this study is to propose a phased strategy to promote biobanking in South Korea. This strategy begins with creating an environment conducive to efficient information collection, storage, and management of clinical specimens that can be accessed when needed. The intention is to expand biobanking in South Korea and maximize the use

of clinical specimens for infectious disease research through global collaboration.

First, the study advocates referring to the biorelated laws of Finland and Singapore to facilitate the use of clinical specimens, encourage the establishment of public and private biobanks, and enact legal reforms to invigorate biobanks.

Second, this study encourages the activation of clinical specimen collection by demonstrating that effective clinical specimen storage and information collection can lead to economic benefits. This can encompass direct involvement in clinical trials or providing collection, storage, and supply services.

The third dimension is the internationalization of South Korea's Biobank project. It proposes expanding international collaboration through various means to secure high-quality clinical specimens and designates specific clinical trial collaboration institutions among participating organizations within South Korea's biobank network. This strategy should include regulatory relaxation for specific specimen imports and recognize overseas clinical trials, ultimately reducing the need for domestic companies to conduct trials abroad.

Fourth, this study proposes that the KBN portal should integrate information from all domestic biobanks, including those related to infectious disease specimen collection. This integration, along with increased international cooperation among institutions participating in the KBP, could establish South Korea as a pivotal hub for global biobank information exchange. Rapid development of the integrated management system is crucial in this context.

The government can implement a strategy for expanding the KBP in collaboration with WHO, FIND, and other global partners by strengthening ongoing public–private partnerships and expanding the South Korean Biobank Network. This approach includes designating domestic clinical trial collaboration institutions for overseas clinical trials involving the use of international clinical specimens. Through these strategies, South Korea would lead the global *in vitro* diagnostics market.

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ABSTRACT (IN KOREAN)

감염질환 효과적 대응을 위한 한국인체자원은행 활성화 전략

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코로나 19 발생 초기에 국내 체외진단의료기기 회사는 신속하게 진단 시약을 개발하고, 정부의 '긴급사용승인제도' 시행으로 빠르게 진단키트를 사용할 수 있었다. 코로나 19 관련 감염 진단검사 품목의 지속적인 성장으로 체외진단의료기기 회사는 급격한 성장을 하였다. 하지만 IVDR (*In Vitro* Diagnostic Regulation)에 따른 강화된 임상시험으로 체외진단의료기기에 있어 임상 검체 확보는 더욱 중요 해졌다.

본 연구의 목적은 강화된 규제에 따른 감염병 임상 검체 확보의 중요성을 강조하고, 임상 검체 정보 수집 및 임상 시험에 대한 정부의 지원이 얼마나 중요한지 설명한다.

연구의 방법으로는 의료기기산업에서 체외진단의료기기의 종류, 등급, 국내·외 시장 규모를 조사하여 중요성을 설명하고, 체외진단의료기기 회사의 임상 검체 확보의 어려운 문제점을 실 사례를 들어 설명하였다. 국가별 바이오 뱅킹의 용어와 개념 시작으로 어떻게 운영되는지, 어떤 목적으로

활용되고 있는지, 그리고 제도적, 법률적으로 어떤 발전을 이루고 있는지 조사하여 문제 해결 위한 국내·외 바이오 뱅크 현황을 파악하였다. 마지막으로 감염질환 임상 검체 활용을 극대화하기 위해 국내외 바이오 뱅크 네트워크 확대와 활용 위한 전략적 계획을 결론으로 도출하였다.

본 연구를 통해 국내 바이오 뱅크 활성화 위한 단계적 전략을 제시하고자 한다.

첫째, 해외 선진 의료시스템 갖춘 국가의 법제현황을 참고하여, 임상 검체 활용을 수월하게 하고, 바이오 뱅크 활성화할 수 있도록 법안의 목적을 변경하는 법률 개정을 제안한다.

둘째, 임상 검체 확보에서 사용까지 임상 검체 정보 수집 및 활용이 양지화 되는 환경 마련이 필요하다.

셋째, 해외 감염 검체 이용하는 해외 임상시험을 국내 임상시험 협력기관 지정 등, 한국인체자원은행사업(Korea Biobank Project)의 글로벌 협력을 확대한다.

넷째, Korea Biobank Network Portal 의 검체 수집 종류를 확대, 국내 모든 인체유래물은행의 정보를 통합 관리하며, 글로벌화 한다.

지속적인 민·관 협력을 강화하고, 국내 biobank 네트워크 확대하는데 초점을 맞추어, 국가 차원에서의 글로벌 파트너쉽을 확대하는 전략을 가져 간다면 향후 글로벌 체외진단의료기기 시장에서 한국은 성공적으로 시장을 리드할 수 있다.

핵심어: 체외진단의료기기, 바이오뱅크, 임상 검체, 감염 질환, 전략, 정부지원