Genomictree
(주)지노믹트리

Biomarker-Based Molecular Diagnostics for Early Cancer Detection

KOSDAQ (228760)

Investor Relations 2019

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EarlyTect®
Powered by Novel DNA Biomarker

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01
Prologue

EarlyTect® Cancer Series

1. Company Overview

- Focusing on methylation biomarkers for 20 years

BIOMARKER-Based Molecular Diagnostics Company
Specialist in **EARLY CANCER** Detection (IVD)
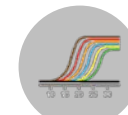
Genomictree

Best-in-class

Novel Biomarker Discovery Engine for Early Cancer Detection

First-in-class

Possession of Innovative Biomarkers
High Sensitivity & Specificity

Best-in-class

High Sensitivity Biomarker Detection Method

Contribute to Improving the Quality of Healthy Life and Reducing of Total Medical Costs

PROBLEM: Shortage of Medical Budget

- **Rapidly increasing healthcare expenses by country**
- **Shortage of national healthcare budget**

  🇺🇸 **Healthcare Reform**

  🇪🇺 **P4 (Prevention-Predictive-Personalized-Participation)**

  🇨🇳 **Insurance Subscription / Payment Structure Reform**

  🇰🇷 **Moon Jae-in Care**

- Percentage of Healthcare Expenditure to GDP by Country

China
Korea 7.7%
Spain
UK
Italy
Japan
Canada
Germany
France
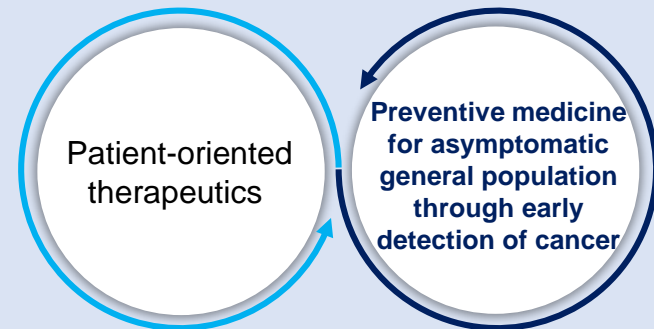USA 17.2%

0   5   10   15   20%

*Source: The World Bank

Unmet Needs

Increase of Cancer Incidence Rate in Aging Society

Increased Demand for Preventive Medicine through Early Detection of Cancer
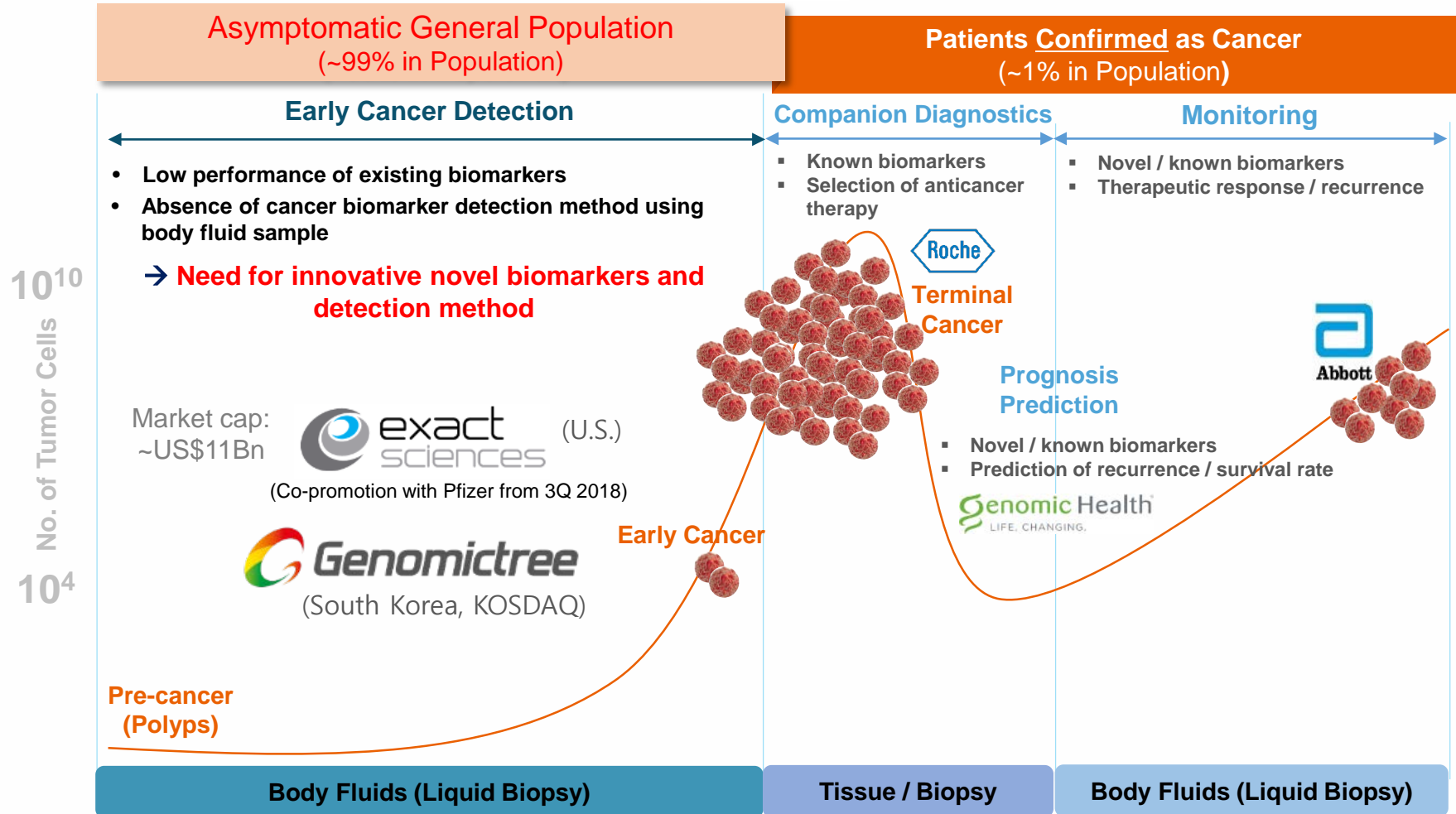
Patient-oriented therapeutics

Preventive medicine for asymptomatic general population through early detection of cancer

GOAL
- **Mitigate the increase of healthcare expenditure rate**
- **Maintain healthy life quality**

EarlyTect®
Powered by Novel DNA Biomarker

Emerging Blockbuster Market

Existing Cancer Diagnostics Market

Asymptomatic General Population (~99% in Population)	Patients Confirmed as Cancer (~1% in Population)

Early Cancer Detection	Companion Diagnostics	Monitoring
• Low performance of existing biomarkers • Absence of cancer biomarker detection method using body fluid sample → **Need for innovative novel biomarkers and detection method**	▪ Known biomarkers ▪ Selection of anticancer therapy	▪ Novel / known biomarkers ▪ Therapeutic response / recurrence

Roche

Terminal Cancer

Market cap: ~US$11Bn

exact sciences (U.S.)

(Co-promotion with Pfizer from 3Q 2018)

Prognosis Prediction

▪ Novel / known biomarkers
▪ Prediction of recurrence / survival rate

Abbott

Genomictree
(South Korea, KOSDAQ)

Early Cancer

genomicHealth
LIFE. CHANGING.

Pre-cancer (Polyps)

No. of Tumor Cells

10^{10}

10^4

Body Fluids (Liquid Biopsy)	Tissue / Biopsy	Body Fluids (Liquid Biopsy)

Remains as unexplored field due to absence of early cancer detection biomarkers and detection technology

Worldwide IVD (In Vitro Diagnostics) Sales : Top 10 Companies & Total Market (2017-2024)

Ranking	Company	Sales (US$ mn)		CAGR	Market Share		Ranking Changes 2017-24
		2017	2024	2017-24	2017	2024	
1	Roche	10,276	14,159	+4.7%	19.5%	17.8%	-
2	Abbott Laboratories	5,616	10,120	+8.8%	10.7%	12.7%	+1
3	Danaher	5,840	8,290	+5.1%	11.1%	10.4%	-1
4	Siemens Healthineers	4,705	6,036	+3.6%	8.9%	7.6%	-
5	Thermo Fisher Scientific	3,241	4,232	+3.9%	6.2%	5.3%	-
6	Becton Dickinson	2,849	4,044	+5.1%	5.4%	5.1%	-
7	Sysmex	2,301	3,579	+6.5%	4.4%	4.5%	-
8	bioMerieux	2,091	3,377	+7.1%	4.0%	4.2%	-
9	Ortho-Clinical Diagnostics	1,800	2,101	+2.2%	3.4%	2.6%	-
10	**EXACT Sciences**	**266**	**1,781**	**+31.2%**	**0.5%**	**2.2%**	**+14**
	Top 10	38,984	57,719	+5.8%	74.1%	72.5%	
	Other	13,638	21,842	+7.0%	25.9%	27.5%	
	Total Industry	52,622	79,561	+6.1%	100.0%	100.0%	

*Source: Evaluate, September 2018 Excludes Glucose Test System which are included in diabetic care classification

EarlyTect®
Powered by Novel DNA Biomarker

In Vitro Cancer Early Detection Method
A molecular diagnostics method to detect cancer at early stage by measuring biomarkers from body fluid (Liquid Biopsy: Blood, Urine, Stool, Sputum etc.)

Finding the needle in the haystack

3 Factors

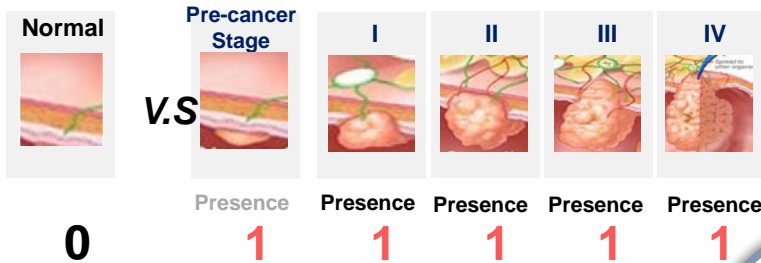| *Clinical Validity*	*Analytical Validity*	*Analytical Validity*
Cancer-specific biomarkers (First-in-class)	**Biomarker detection technology (Best-in-class)**	**Reaction instrument (PCR equipment)**
High sensitivity and specificity	**High sensitivity selective DNA amplification method**	**High throughput analysis**

When sensitivity / specificity is satisfied, in vitro early cancer detection kit is successful

EarlyTect®
Powered by Novel DNA Biomarker

- Aberrant change exists in the **early** stage of tumorigenesis
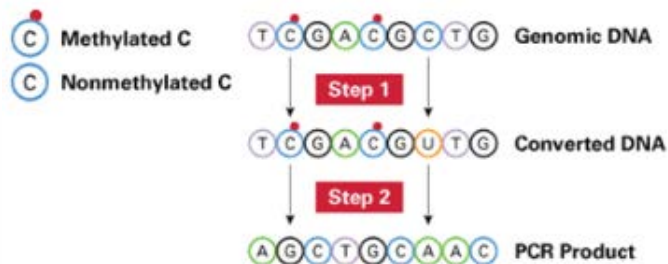- **Constantly** maintained **regardless of clinical stage**

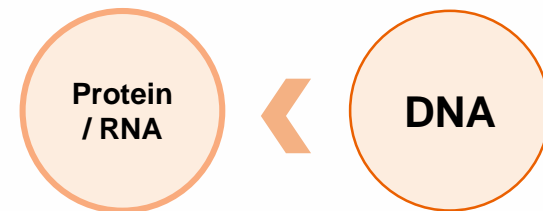| Normal	Pre-cancer Stage	I	II	III	IV
	V.S				
	Presence	Presence	Presence	Presence	Presence
0	**1**	**1**	**1**	**1**	**1**

- **High cancer specificity**

Normal tissue-specific methylation pattern → Cancer-specific aberrant methylation pattern

Biomarkers

Healthy individuals   Cancer patients
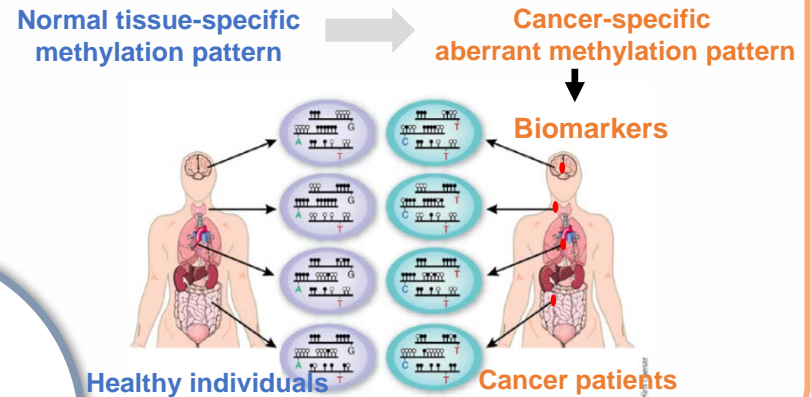
DNA Methylation

- Possible to amplify by PCR when **minute amount** of DNA methylation biomarkers exist in body fluids

© Methylated C
© Nonmethylated C

T C G A C G C T G   Genomic DNA
Step 1
T C G A C G U T G   Converted DNA
Step 2
A G C T G C A A C   PCR Product

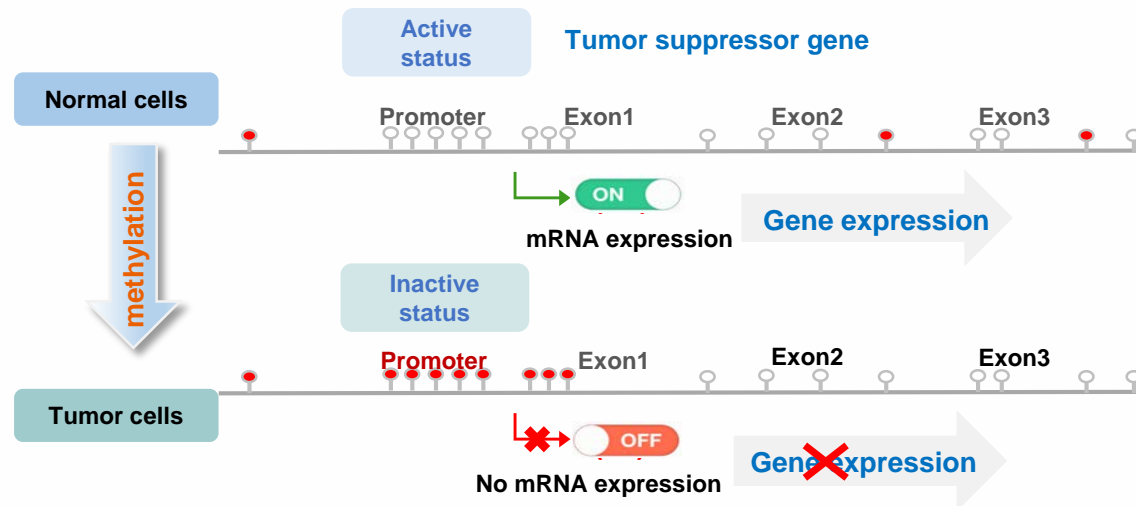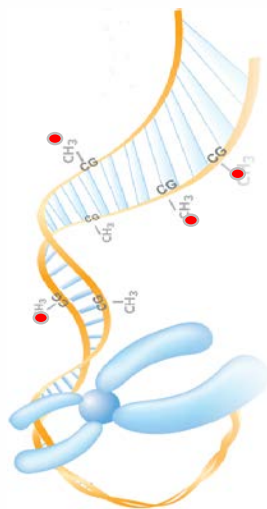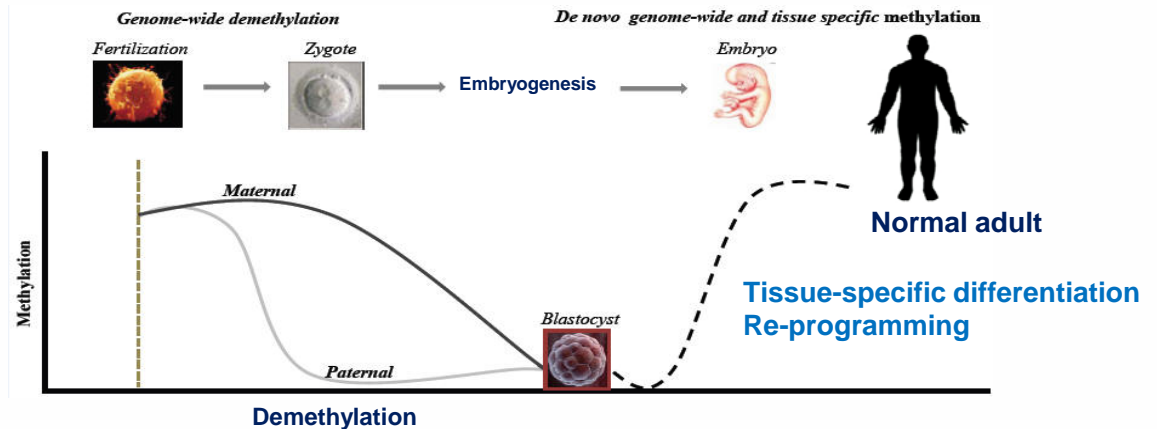- **High detection stability in body fluids**

Protein / RNA < **DNA**

High structural stability of DNA compared to RNA & protein

*Source: Zhu et al. (2009) Int J Biochem Cell Biol

- The binding of methyl groups to specific site of DNA that determines gene expression is a natural phenomenon that blocks gene expression
- Aberrant DNA methylation induces cancer by inactivating tumor suppressor genes which controls gene expression in response to external stimuli such as smoking and drinking etc. (Baylin&Jones,2011)

Regulation of spatiotemporal gene expression during embryogenesis

Genome-wide demethylation

Fertilization   *Zygote*   **Embryogenesis**   *Embryo*

De novo genome-wide and tissue specific methylation

Normal adult

Methylation

Maternal

Paternal

Blastocyst

Tissue-specific differentiation Re-programming

Demethylation

Active status   **Tumor suppressor gene**

Normal cells

Promoter   Exon1   Exon2   Exon3

ON

mRNA expression   **Gene expression**

methylation

Inactive status

Tumor cells

Promoter   Exon1   Exon2   Exon3

OFF

No mRNA expression   Gene expression

02

Core Competencies

EarlyTect® Cancer Series

Capable of Discovering High Potential Novel High-Performance Biomarkers Efficiently / Continuously

Novel High-Performance Biomarker Discovery Engine

Directly select and capture methylated DNA
Methyl-DNA Capture™
(proprietary development)

Methylated DNA
Truncated-optimized MBD2bt protein

+

Gene expression analysis by DNA microarray
***i*-MAGIC System**

Methylation DB

| Colon Cancer | Bladder Cancer | Lung Cancer | Gastric Cancer | • • • |

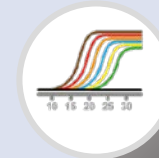**Continue to discover high-performance biomarkers & expand new pipeline**

Expand New Product Pipeline through Discovery of New Biomarkers

Highly Sensitive & Precise Biomarker Detection Technology: LTE-qMSP

Linear Ttarget Enrichment -Quantitative Methylation Specific PCR
Patents filed (domestic & international)
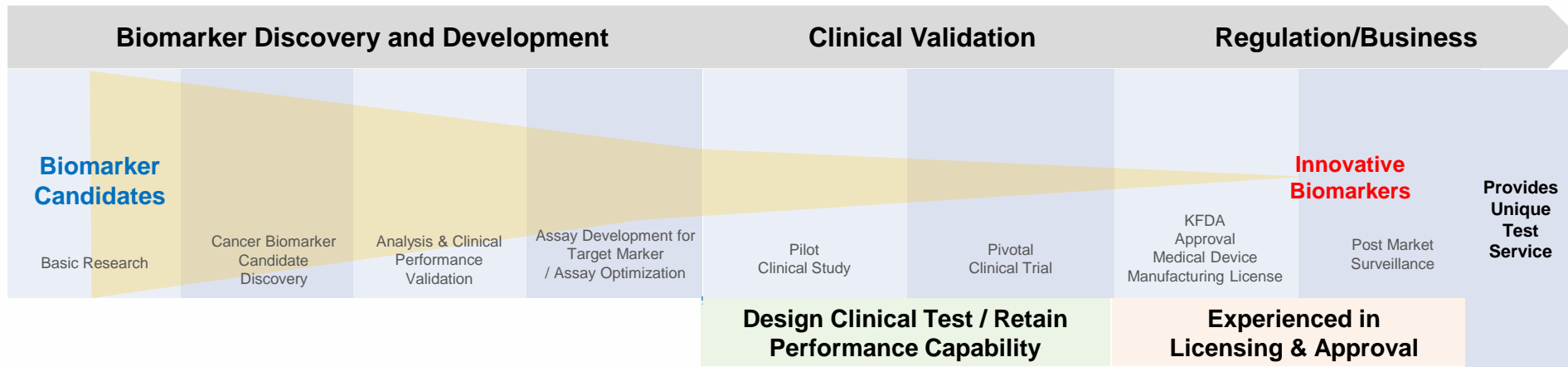
Methylated biomarker DNA   **Control gene DNA**

Highly sensitive biomarker detection from minute amounts existing in body fluid using selective DNA amplification technology

EarlyTect®
Powered by Novel DNA Biomarker

Possess Unique Technology from Biomarker Discovery to Commercialization

Biomarker Discovery and Development	Clinical Validation	Regulation/Business

Biomarker Candidates

Basic Research

Cancer Biomarker Candidate Discovery

Analysis & Clinical Performance Validation

Assay Development for Target Marker / Assay Optimization

Pilot Clinical Study

Pivotal Clinical Trial

KFDA Approval Medical Device Manufacturing License

Innovative Biomarkers

Post Market Surveillance

Provides Unique Test Service

Design Clinical Test / Retain Performance Capability

Experienced in Licensing & Approval

First-in-Class **Possess Cancer-specific Biomarkers**

Syndecan-2 (*SDC2*)
Colorectal Cancer
Methylation Biomarker

PENK
Bladder Cancer
Methylation Biomarker

PCDHGA12
Lung Cancer
Methylation Biomarker

→ **EarlyTect® Cancer Series Product Line**

Best-in-Class **Possess Biomarker Detection Technology**

LTE-qMSP
Selective DNA Amplification technology

Best-in-Class **Possess Biomarker Discovery Engine**

Methyl-DNA Capture™ + Microarray
+
i-MAGIC System

Early Cancer Detection Technology: EarlyTect® Cancer Series Products

EarlyTect® Colon Cancer	EarlyTect® Lung Cancer	EarlyTect® Bladder Cancer

EarlyTect® Colon Cancer

- Cancer type: colorectal cancer
- Subject: asymptomatic general population
- Biomarker: *SDC2* methylation
- Specimen: stool
- Intended use: early detection of patients who should undergo colonoscopy
- Status: KFDA approval (Class III IVD) Granted international patents

EarlyTect® Lung Cancer

- Cancer type: lung cancer
- Subject: patients with pulmonary nodules
- Biomarker: *PCDHGA12* methylation
- Specimen: blood (serum)
- Intended use: early detection of patients with high-risk lung cancer
- Status: Ongoing pivotal clinical trial for KFDA approval (Class III IVD) Granted International patents

EarlyTect® Bladder Cancer

- Cancer type: bladder cancer
- Subject: hematuria patients
- Biomarker: *PENK* methylation
- Specimen: urine
- Intended use: triage of hematuria patients who will undergo cystoscopy
- Status: development Granted International patents

**Technology for Early Detection of CRC
EarlyTect® Colon Cancer
(Stool-based)**

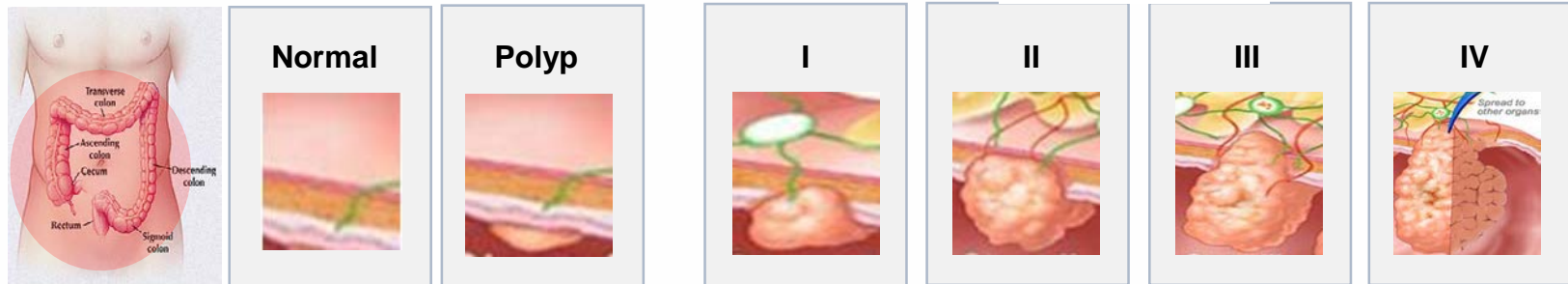**KFDA approval for IVD (Class III)
(Aug 28, 2018)**

Flagship product

High Medical Costs

- Cancer mortality rate ranked **second** in the world
- About 60% of patients are detected at **late stage**
- Average treatment cost per patient : up to KRW 150 mil. (US), up to KRW 30 mil. (South Korea)

Clinical Stage

Normal | Polyp | I | II | III | IV

❖ **~10 years** >> **Early Detection** >> Improved Quality of Life & Treatment Cost Savings

Survival Rate

Treatment Cost
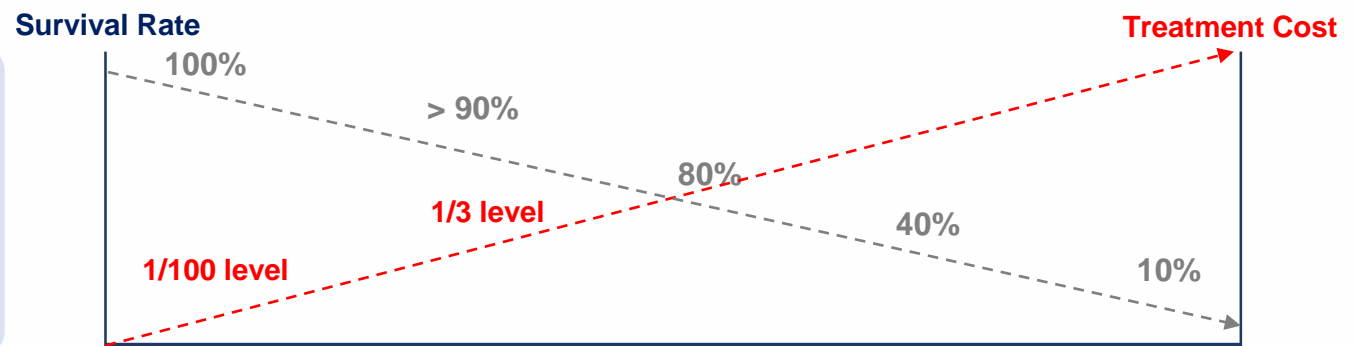
Survival Rate & Treatment Cost

100%
> 90%
80%
40%
10%

1/3 level
1/100 level

Current Screening Tools for CRC Early Detection

Colonoscopy (Gold Standard)

- High invasiveness, inconvenience
- Low participation rate due to bowel preparation (worldwide average of less than 30%)

CRC Incidence Rate & Mortality Rate Remain High

FOBT / FIT

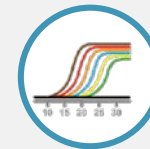- Low sensitivity to early CRC (less than 50%) and polyps (≥ 1.0 cm; less than 20%)

Unmet Needs

- Increase in participation rate of colonoscopy screening
- Increase in early CRC detection

Evidence-based early CRC detection

in vitro early detection technology utilizing biomarkers

EarlyTect® Colon Cancer (KGMP Production)

Stool Sample Collection / Storage / Delivery / Pre-treatment / Reaction Process / Test Process

Stool Collection Kit (1~2g)

Stool Preservation Solution (Self-Development)

Delivery (Room Temperature)

DNA Extraction GT Stool DNA Kit (Class I Medical Device)

Bisulfite Treatment

Real time PCR
- SDC2, Control
- Duplex PCR

Data Result Analysis

Negative(-)

3 years Interval

Positive(+)

Recommend Colonoscopy

- Single stool collection: no restriction on diet or medication
- Real time PCR test / analyze within 8 hours, minimum training required

04. Central Service Lab (In Operation)

| Area	1,432.16 m² (2-story building)
Examination Capacity	170,000 tests/ year (340,000 tests using 2 shift rotation)
Sales Capability	KRW 17 billion ~ 34 billion / year

Establishment of Infrastructure for Examination Process of Early Cancer Detection Products

Specimen Pre-treatment → **DNA Extraction** → **Bisulfite Treatment** → **Real time PCR** → **Data Analysis**
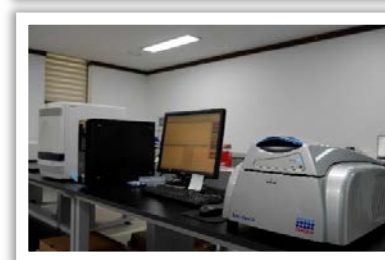
CRC Biomarker: Syndecan-2 Methylation

EarlyTect®
Powered by Novel DNA Biomarker

Innovative CRC Biomarker Discovery Utilizing Unique Biomarker Discovery Engine

Comprehensive Analysis of Methylation Patterns in Normal Colorectal Tissue VS Colorectal Tumor Tissue

Unmet Needs

Healthy Individuals

Cancer Patients

○ CpG

● mCpG

Chr.8 Chr.8
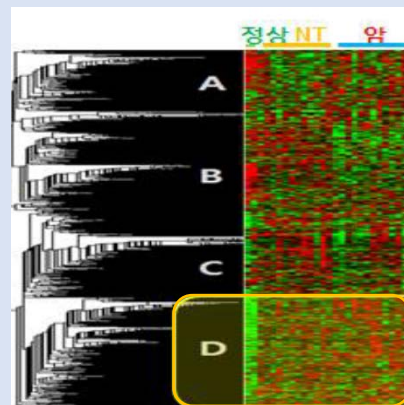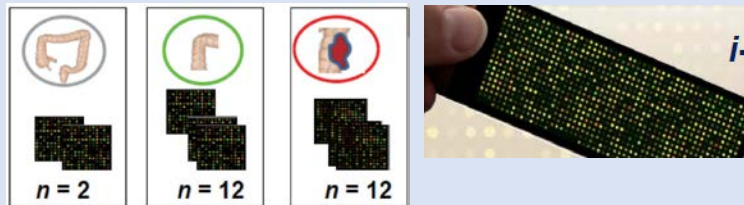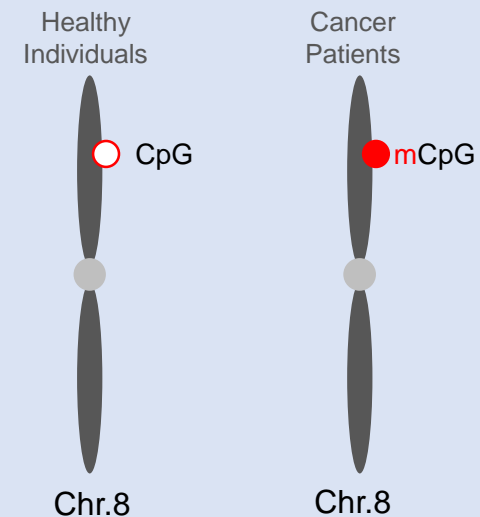
Promoter | UTR | *SDC2*

CpG island

Involvement in Cell Proliferation, Cell Migration, Intercellular Interaction

Established the Clinical Validity for Early CRC Detection in Tissue

[Frequency of positive SDC2 methylation (%)]

Normal Tissues **Polyp Tissues** **CRC Tissues**

I   II   III   IV: Clinical Stage

0%   **96%**   **97%**

97%   **97%**   **98%**   **94%**
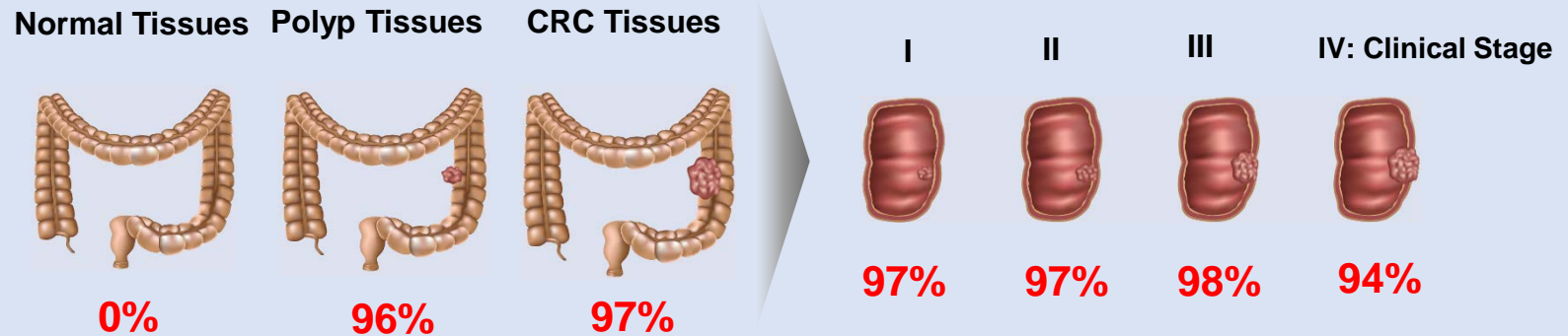
CRC Tissues (*n* = 320)
(J. Mol. Diag. 2013;15(4):498-507)

Established Clinical Validity Using Stool-based Biomarker Detection Method: KFDA approval (Class III)

Two Independent Clinical Trials: Confirmed High Replicability

Pilot Clinical Trial Results (n = 93)

- Total Sensitivity = 90%, Early Cancer (I – II) Sensitivity = 86%
- Total Specificity = 90.9%
- Cutoff C_T 40

Pivotal Clinical Trial Results (n = 585)

- Total Sensitivity = 90%, Early Cancer (0 – II) Sensitivity = 89%
- Total Specificity = 90%
- Cutoff C_T 40 (1/2 algorithm)

Pilot trial bar chart — Sensitivity / Specificity (%) vs CRC Stage:

	N	NA	I	II	III	IV
Value	90.9	42.9	83.0	91.0	85.0	100
n =	22	21	14	21	13	12

CRC Stage
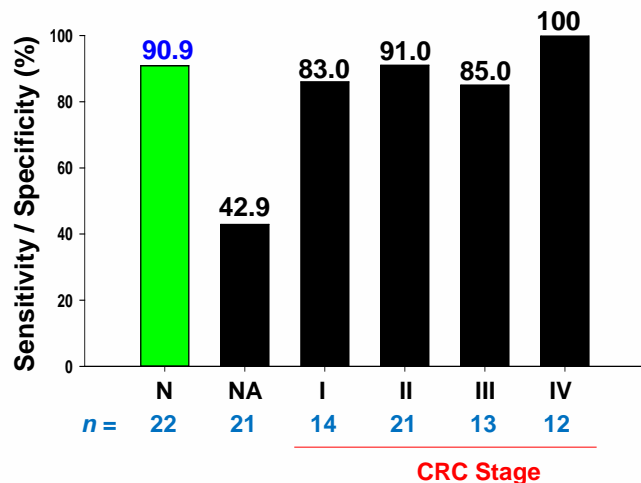
- **N: Normal Person, No Colonoscopy**
- **NA: Non-advanced adenomas (< 1.0 cm)**

Feasibility of quantifying *SDC2* methylation in stool DNA for early detection of colorectal cancer
Clinical Epigenetics, 2017;9:126.

Pivotal trial bar chart — Sensitivity / Specificity (%) vs CRC Stage:

	NED	HOP	NA	AA	0	I	II	III	IV	GC	LC
Value	90.0	26.7	24.4	66.7	100	85.5	91.4	89.6	100	30.4	30.0
n =	245	18	41	3	3	55	70	96	21	23	10

CRC Stage

- NED: No evidence of disease on colonoscopy,
- HOP: Hyperplastic or other polyp,,
- NA: Non-advanced adenomas (< 1.0 cm),
- AA: Advanced adenomas (≥ 1.0 cm),
- GC: Gastric cancer
- LC: Liver cancer

Published in Clinical Epigenetics, 2019;11(1):51

06-1. Global Competitiveness (versus Exact Sciences)

EarlyTect®
Powered by Novel DNA Biomarker

exact sciences   **VS**   **Genomictree**

exact sciences		Genomictree
USA	**Country**	South Korea
1995	**Established**	2000
NASDAQ	**Listed**	KOSDAQ(2019.03)
Whole Stool	**Specimen**	1~2 g of Stool
2x methylation markers (NDRG4,BMP3) + KRAS 7 mutations + FIT (Fecal Immunochemical Test)	**Biomarker Gene**	SDC2 methylation Duplicate reactions
CRC 92% Polyp (≥ 1.0 cm) 42%	**Sensitivity**	CRC 90% Polyp (≥ 1.0 cm) ~50%
87%	**Specificity**	90%
~26 hours	**Test Duration**	~8 hours
US FDA approval (PMA) (2014)	**Certification and Approval**	KFDA approval (Class III) (2018)
List price : $650 Revenue per test: ~$490	**Test price**	List price: up to KRW 200K (domestic) Revenue per test: KRW 100K(domestic)

Global Competitiveness (versus Exact Sciences)

EarlyTect®
Powered by Novel DNA Biomarker

exact sciences	VS	Genomictree
Whole Stool **License-In** *KRAS* Gene Mutations (7 sites)　　FIT　　DNA Methylation *NDRG4*, *BMP3* No patent　　Polymedco　　MDx Health　　Mayo Clinic	**First-in-class Biomarker**	**1~2g of Stool** **Proprietary Development:** **Patent Granted** **DNA methylation** *SDC2*
License-In **QuARTS** **Invader probe** **Allele Specific PCR**	**Best-in-class Detection Technology**	**Proprietary Development:** **Patent Granted** **LTE-qMSP** **TaqMan Probe** **LTE-QMSP PCR**
PCR Equipment **Roche / AB 7500 / Qiagen**	**Detection Instrument**	**PCR Equipment** **Roche / AB 7500 / Qiagen**
Cologuard (FDA) **Up to US$ 650** **(Insurance coverage 80%)** **Limited to US market**	**Competitiveness**	**EarlyTect CRC (KFDA)** **When entering US, about ~US$350** **(target insurance coverage up to 100%)** **High global scalability**

Provide Diverse Benefits to Both Patient and Physician

Patient: Increased Early Diagnosis	● **High confidence: increase compliance with colonoscopy for confirmation of positive patients** ● **Increase in early detection probability of CRC or polyps due to high compliance: expect significant reduction in medical expenses and improvement in quality of life**
Physician: Increased Revenue Generation	● **Increase of patients undergoing colonoscopy due to increased compliance** ● **Positive patients may have polyps or CRC, and treatment results in revenue** ● **Hospitals without Colonoscopy can Benefit from Additional Medical Income without Additional Investment (in Korea)**

Technology for Early Detection of Lung Cancer (LC)
EarlyTect® Lung Cancer
(Blood-based)

Ongoing Pivotal Clinical Trial for K-FDA Approval (Class III)

EarlyTect®
Powered by Novel DNA Biomarker

No LC early detection tool

Unmet Needs

Low-dose chest CT scan

Patients with pulmonary nodules (prevalence can be as high as 25%) (more than 95% are false positives)

Early detection of high-risk LC patients

Follow-up Test
- Bronchoscopy with bronchial wash: Sensitivity up to 30%
- Sputum cytology: sensitivity up to 35%
- Lung biopsy: high Invasiveness / high-risk
- CT follow-up test: radiation

•EarlyTect® Lung Cancer
(**Ongoing Pivotal Clinical Trial for Approval**)

- Cancer type: lung cancer (early detection)
- Subject: patients with pulmonary nodules
- Biomarker: *PCDHGA12* methylation
- Specimen: blood (serum)
- Patent granted: South Korea, US, Europe, China and Japan

"Ranked #4 in total cancer incidence rate (South Korea) by 11.3%"
5 year relative survival rate 26.7%

PCDHGA12 Methylation Positivity (%)

n = 80, Patients

10%

100%

89.5%

95.0%

Healthy control

I

III

IV
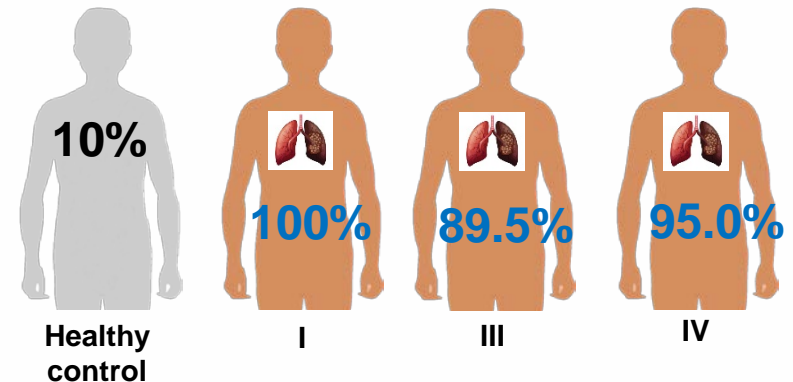
Competitiveness of LC Early Detection Product

EarlyTect®
Powered by Novel DNA Biomarker

Company Name (Country)	Epigenomics (Germany)	Genomictree (South Korea)
Specimen	Plasma DNA	Serum DNA
Amount of Specimen Used	Blood 10 mL	Blood 2 mL
Biomarker Gene	SHOX2, PTGER4 methylation	A novel single gene PCDHGA12 methylation
Sensitivity	**90%**	**92.5% (pilot trial)**
Specificity	**73%**	**90% (pilot trial)**
Price	Unknown	US$150~200 (in Korea)
Test Method (Frequency)	qPCR (triplicate tests)	qPCR (single test)
Regulatory Approval	CE-IVD (2018)	Ongoing pivotal clinical trial (Class III) **(Subject *n* = 547 by 1 institute (KNU hospital) in South Korea)**

Technology for Early Detection of Bladder Cancer (BC) EarlyTect® Bladder Cancer (Urine-based)

In Development

Unmet Needs

Hematuria patients (Approximately 85% of BC patients present with hematuria)

BC prevalence among hematuria patients Micro: ~5%, Macro: ~20%

Cystoscopy is performed for almost all hematuria patients (lack of suitable triage test)

- High invasiveness
- Pain
- Side effects

Need for triage of high-risk patients who will undergo cystoscopy

EarlyTect® Bladder Cancer

- Cancer type: bladder cancer (early detection)
- Subject: patients with hematuria
- Biomarker: *PENK* methylation
- Specimen: urine DNA (10 mL)
- **Patent granted: South Korea, US, Europe, China and Japan**

PENK Methylation Positivity (%)
Pilot study results

n = 574, Hematuria Patients

95% (Survival Rate)
85%
55%
38%
16%

| pTa | pT1 | pT2 | pT3 | pT4 |

6%
84%

Benign Hematuria   **Bladder Cancer**

74% ← **88~100%** →
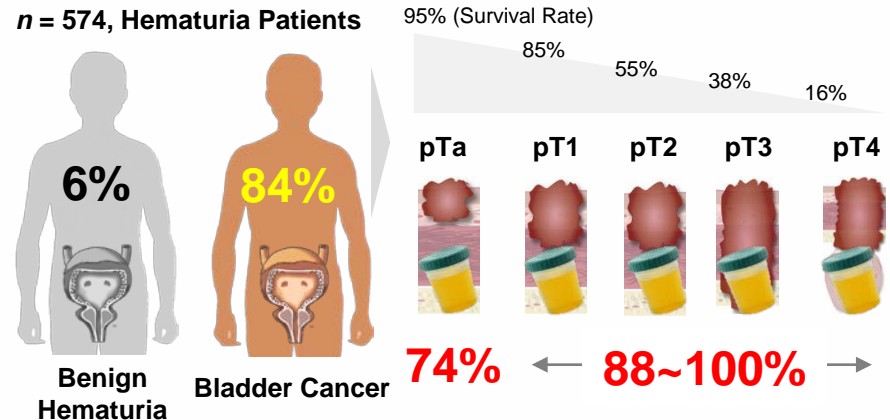
Company Name (Country)	Abbott (USA)		Genomictree (South Korea)
Specimen	Urine	Urine DNA	Urine DNA
Amount of Specimen Used	Less than 1.0 mL	Urine > 30 mL	Urine 10 mL
Biomarker Gene	A single protein marker NMP22	UroVysion 4 chromosome abnormality (3, 7, 9p21, 17)	A novel single gene PENK methylation
Sensitivity	**68%**	**76%**	**84% (Pilot Trial)**
Specificity	**79%**	**85%**	**94% (Pilot Trial)**
Price	Up to US$ 35	Up to US$ 250	US$ $150~200 (in Korea)
Test Method (Frequency)	Rapid kit	FISH	qPCR (single test)
Approval	US FDA Approval (2002)	US FDA Approval (2004)	In development
Remarks	Low accuracy of BC monitoring	High cost of BC recurrence monitoring, complicated analysis of test and data (Not used in domestic)	High accuracy, simplicity

High Entry Barrier of Genomictree's Early Cancer Detection Technology

EarlyTect®
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Secured Intellectual Property

- Domestic patent granted (filed): Total of 49
- Overseas patent granted (filed): Total of 50
- Biomarker patents granted in domestic and in key countries overseas

Difficulty of Technology Replication

- Ingenious biomarker: non-reproducible
- Clinical validation / approval procedure: high level of technical barriers

Countermeasures on Newly Released Products

- Marker discovery ~ verification process: high entry barrier
- Continuously obtain clinical data through post-marketing surveillance

Difficult for second movers to enter the market due to inimitable and high entry barrier

New product release, development of upgrade products and adaptive expansion → Market leader

Main Intellectual Property Status

EarlyTect®
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- **Patenting methylation biomarkers by cancer types: biomarker patents granted in Korea & in key countries worldwide**
- **Assay: patenting open platform / element technology**

- **Colorectal cancer (SDC2): patent granted in South Korea, US, Europe, Japan, China**
- **Bladder cancer (PENK): patent granted in South Korea, US, Europe, Japan, China**
- **Lung cancer (PCDHGA12): patent granted in South Korea, US, Europe, Japan, China**
- **Methylated biomarker detection technology (LTE-qMSP): patent filed in South Korea and PCT application**
- **Base sequence-specific amplification technology (ASRP-multiplex PCR): patent granted in South Korea, US, Europe, China**

(No. of Patents)

Legend: ■ Patent Granted ■ Patent Filed
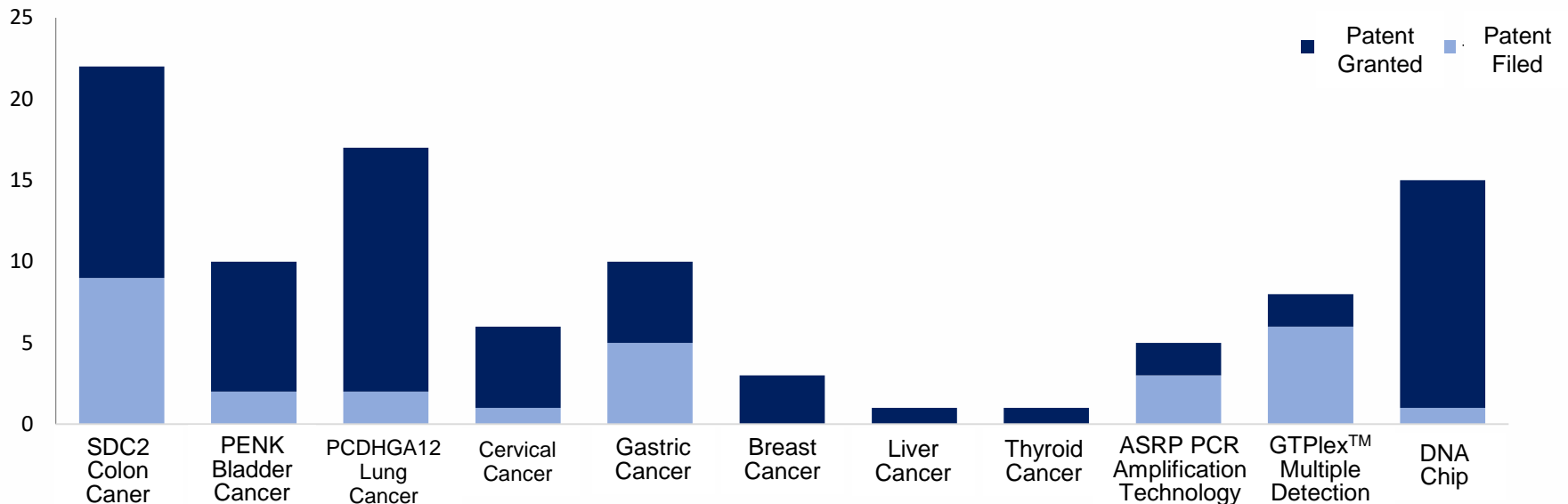
Main Product Development Timeline

Core Platform	2019	2020	2021	2022	2023

Early Detection

Specialized Technology for Isolating Methylated DNA

Methyl-DNA Capture™
+
DNA microarray / NGS

US Entry

EarlyTect® *Colon*

EarlyTect® *Bladder* — K-FDA approval

EarlyTect® *Lung* — K-FDA approval

Selective Amplification Technology of Methylated DNA

LTE-QMSP
Quantitative Methylation Specific PCR

EarlyTect® *Bladder*
BC recurrence (urine)

EarlyTect® *Lung*
LC complementary diagnosis
(bronchial wash)

Expand Product Adaptation

EarlyTect® Series
Development of early detection products for new type of cancers
(gastric Cancer / liver cancer / cervical cancer)

Companion Diagnostics

Base Sequence-Specific Nucleic Acid Amplification Technology

ASRP™ Multiplex PCR
Allele-Specific Reactive Primer PCR

AccuraTect™ KRAS — Colorectal cancer

AccuraTect™ EGFR — Lung cancer

Genomictree
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03
Commercialization

USA

120.1 million People

×

Colonoscopy Non-participation Rate

60%

Theoretical Market Size by 2019

$7.2Bn

Europe

159.44 million People

×

Colonoscopy Non-participation Rate

60%

Theoretical Market Size by 2019

$6.4Bn

South Korea

22.5 million People

×

Colonoscopy Non-participation Rate

70%

Theoretical Market Size by 2019

$525MM

Genomictree
EarlyTect® CRC

exact sciences
Cologuard

Assuming **EarlyTect® Colon Cancer** is tested every three years for the population over 45 age, reimbursement is determined by cross-walk, revenue per test is estimated to be $300 in the US, $200 in the Europe and $100 in Korea

Target for 2019: 1) **Develop 800 Providers** (hospitals, health examination centers etc.)
2) Enhance the consumer awareness of EarlyTect

Promote Recommendation for CRC Screening
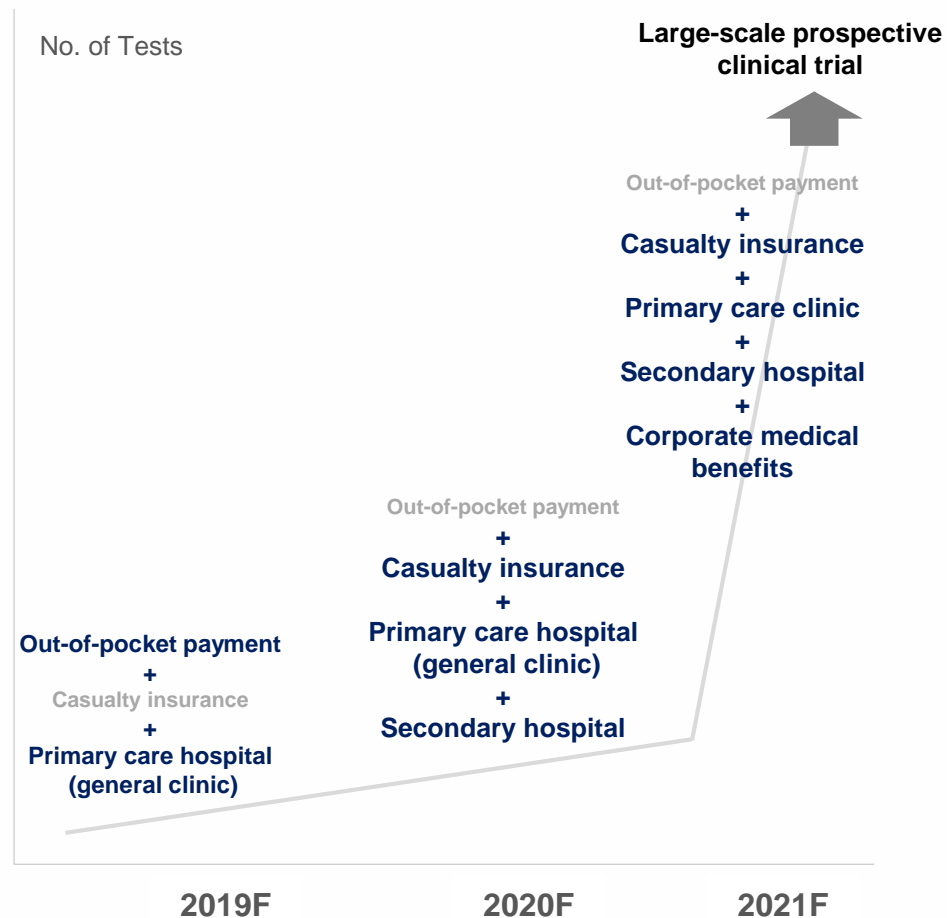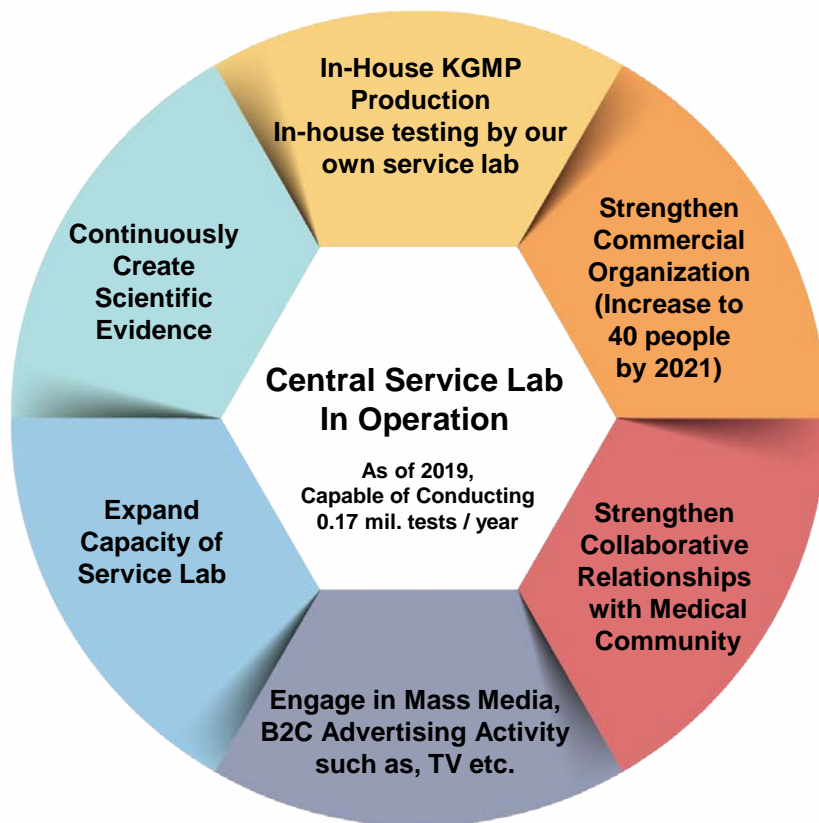
No. of Tests

Large-scale prospective clinical trial

Out-of-pocket payment
+
Casualty insurance
+
Primary care clinic
+
Secondary hospital
+
Corporate medical benefits

Out-of-pocket payment
+
Casualty insurance
+
Primary care hospital (general clinic)
+
Secondary hospital

Out-of-pocket payment
+
Casualty insurance
+
Primary care hospital (general clinic)

2019F   **2020F**   **2021F**

Pie chart labels:
- In-House KGMP Production In-house testing by our own service lab
- Strengthen Commercial Organization (Increase to 40 people by 2021)
- Strengthen Collaborative Relationships with Medical Community
- Engage in Mass Media, B2C Advertising Activity such as, TV etc.
- Expand Capacity of Service Lab
- Continuously Create Scientific Evidence
- **Central Service Lab In Operation** — As of 2019, Capable of Conducting 0.17 mil. tests / year

02-2. Entry Strategy to Recommend Colorectal Cancer Test

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Large-scale Prospective Clinical Trial Plan
Establishment of First Community Advisory Board in Diagnostic Industry

Post market Advisory Board

Hospital	Name	Association
Severance Hospital, Yonsei University Health System	Kim, Nam-Kyu	The Korean Society of Coloproctology, Former Chairman / Coloproctology Research Society
Yongin Severance Hospital, Yonsei University Health System	Han, Yoon-Dae	The Korean Society of Coloproctology / Coloproctology Research Society
Seoul National University Hospital	Jeong, Seung-Yong	Seoul National University Cancer Hospital, Head of Colorectal Cancer Center
Wonju Severance Christian Hospital	Kim, Hyun-Soo	Korean Society of Gastrointestinal Endoscopy, Executive
Graduate School of Public Health Yonsei University	Ji, Sun-Ha	National Health Promotion Institute, Director of Planning

Tertiary Hospital Advisory Board (General Hospital)

Hospital	Name	Association
Kangbuk Samsung Hospital	Park, Dong-Il	The Korean Society of Gastroenterology, Tumor Research Society, Executives
Asan Medical Center	Byun, Jung-Sik	
The Catholic Univ. of Korea Seoul St.Mary's Hospital	Cho, Young-Suk	
Severance Hospital, Yonsei University Health System	Kim, Tae-Il	

Physician Advisory Board

Hospital	Name	Association
Dr. Park's Medical Clinic	Park, Kun-Tae	Korean Physician's Association, Vice President (President of Seoul District)
JangPyunHan Medical Clinic	Jang, Woong-Ki	Korean Physician's Association, President of Academic
HyunDae Medical Clinic	Lee, Jeong-Yong	Korean Physician's Association, Secretary General
HunHunHan Medical Clinic	Eun, Soo-Hoon	Korean Physician's Association, Director of Public Affairs
Hanyang Rheumatism Clinic	Lee, Seung-Won	Korean Physician's Association, Director of Scientific Committee

03. Overseas Clinical and Advancement Plan

EarlyTect®
Powered by Novel DNA Biomarker

2019	2020	2021

USA

- Establish US corporation and recruit local staff
- FDA clinical design advisory contract
- CRO contract
- FDA Pre-submission

Execute FDA Clinical Trial and FDA Approval

Promote Licensing Out of Technology and Product Sales Rights

Asia

- Establish JV or partnership
- Clinical trial cesign

Execute Clinical Trial

Promote Licensing Out, either Directly or through Partnership

EU
(CE marked)

- Europe regional partnership
- Liaise clinical trial partners
- Clinical trial design

Execute Clinical Trial

Promote Licensing Out, either Directly or through Partnership

04. **Establishment of US Corporation**

Company Name	Promis Diagnostics, Inc.
Initial capital	US$10 million (additional $20 million planned)
Principal office	Pasadena, CA
Mission	- Support and execute US FDA clinical trial - Promote commercialization in North America (including licensing) and manage post contract - Attract foreign investment etc.
Stage	- Clinical trial

Genomictree
(주)지노믹트리

04
Appendix

1. Company Overview

– focusing on the Methylation Biomarker for 20 years

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● General Profile

Company Name	Genomictree, Inc.
CEO	Sungwhan An
Date of Establishment	Oct. 6, 2000
Capital	KRW 10 BN
Listed	KOSDAQ (2019.03)
Net IPO proceeds	~ US$103 MM (F/X $1 : KRW 1,000)
No. of Employees	55
Address	- HQ : 44-6, Techno 10-ro, Yuseong-gu, Daejeon - Seoul office: Miwang Bldg, 364, Gangnam-daero, Gangnam-gu, Seoul
Main Business	• Molecular Diagnostic Business (Early detection of cancer) • Dielectric Analysis Service (DNA Chip, NGS etc.)

● CEO Profile

CEO An, Sungwhan

- Adjunct Professor, Cancer Research Center, Yonsei University College of Medicine
- Former Assistant Professor, Cancer Center, Yonsei University College of Medicine
- Former Post Doctorate, Stanford Univ. Medical Center
- PhD in Molecular Biology, The Univ. of Texas at Austin

● Main HR Breakdown

By Department	R&D	Production / Quality	Diagnostics service	Commercial	Business Mgmt
Total	**17**	**4**	**9**	**18**	**7**

EarlyTect®
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Global Leading Corporation

- Listed at KOSDAQ in March 2019
- Overseas Expansion of Early Cancer Detection Products
- Strengthen Global Competitiveness
- Company Sales Volume of 100 billion

2000~2007

Building R&D Foundation

Oct 2000	Genomictree Inc. established
Feb 2001	Research Institute certified
May 2001	Microarray operation system constructed
Sep 2001	Certified as venture company
Sep 2002	Developed methylation biomarker discovery engine
Nov 2003	Acquired ISO9001 QMS certification
May 2004	Performed project of MOHW (Colorectal cancer)
May 2005	Performed project of MOHW (Lung cancer)
Dec 2005	Secured investment (KDB Capital etc.)
May 2007	Performed project of MOTIE (Bladder cancer)

2008~2014

Establishing Foundation for Commercialization of Core Technology

Aug 2008	Relocated HQ (new building at Tamnip-dong)
Sep 2008	Registered factory (manufacturer of pharmaceutical related products)
Jul 2009	Recognized as Inno-biz: Grade A
Jan 2013	Acquired NET certification
Nov 2013	Awarded at Korea IP Champion Competition
Apr 2014	Medical device manufacturer (MFDS) approved
Apr 2014	EarlyTect GI Syndecan2 Methylation Assay approved
Jun 2014	Acquired KGMP certification (MFDS)
Jul 2014	Secured investment (KB Investment etc.)
Sep 2014	Awarded at Bio IP Technology Golden Bell Competition, Medical device division

2015~2018

Preparing to become Global Molecular Diagnostics Corporation

Feb 2015	Acquired ISO13485 certification
Sep 2015	Named K-Brain Power corporation
Oct 2015	Secured Investment (MAGNA Investment)
Jul 2016	Listed on KONEX (228760)
Sep 2017	Secured investment (KB Investment, SOLIDUS Investment)
Dec 2015	EarlyTect® Colon Cancer CE-IVD
Aug 2018	Secured investment (DAYLI Partners)
Aug 2018	EarlyTect® Colon Cancer manufacturing approved
Oct 2018	Completed construction of molecular diagnosis examination service center

EarlyTect®
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"Details, Every time, Integrity"

Maintain Core Founding Members

Founding Members: R&D / COO

CEO An, Sungwhan
Representative Director
(PhD of The Univ. of Texas at Austin
/ Stanford Univ. Medical Center)

COO Yoon, Chi-Wang
Vice President
(KOLONeENGINEERING
/ KOLON GlOBAL PM)

Director Yoon, Dae-Kyoung
(MS of Pusan National University
/ Samsung Biomedical Research Institute)

Research Director Oh, Tae-Jeong
(PhD of SungKyunKwan University
/ Korea Atomic Energy Research Institute)

PhD Kim, Myung-Soon
(PhD of Chungnam National Univ. College of
Medicine / Samsung Biomedical Research
Institute)

Clinical / Licensing

Professional RA

Yoo, Young-Jun / Lim, Eun-Kyung
(Level 1 License / Chungnam National Univ.)

IT / Bioinformatics

PhD Kim, Chul-Hong
(PhD of Pusan National University
/ Theragen Etex)

R&D

Master's Degree: 4 people
Undergraduate: 1 person

CFO

Ahn, Chan-Ho
(KICPA / BA of Seoul National University)

US FDA Consultant

PhD Kim, Do-Hyun
(10yrs of US FDA experience)

Marketing / Sales Directors

Lee, Yong-Un CCO (MNC Pharm 21 yr)
Director Son, In-Ho (MBA, MNC Pharm 18 yr)
Director Kim, Won-Bong (MNC Pharm 20 yr)

R&D

Master's Degree: 6 people

Examination Service

Clinical Pathologist: 3 people
Procurement: 1 person (Undergraduate)

| 2001 | 2007~2014 | 2015~Present |

EarlyTect®
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Recruitment of Industry-Leading Experts with Marketing Experience in Pharmaceutical Companies
Expansion of Commercial Organization

Chief Commercial Officer	Sales Director	Marketing Director
Lee, Yong-Un	**Kim, Won-Bong**	**Son, In-Ho**
• Major Career **(Total 21 years)**	• Major Career **(Total 20 years)**	• Major Career **(Total 18 years)**
- **MNC Pharmaceutical Company Executive Director, Sales & Marketing**	- **MNC Pharmaceutical Company Executive Lead, Sales & Marketing**	- **MNC Pharmaceutical Company Asia Regional Executive Marketing Lead**
- Novartis	- Novartis	- Novartis
- Sanofi	- Schering	- BMS
- Handok Pharmaceutical		- UCB
- Daewoong Pharmaceutical		

Expect to Expand Business Area at Dun-gok District Science-Business Belt, Daejeon (2021)

EarlyTect®
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Possible to Examine More than 1 Million Tests per year

- **Construction Name:** New Construction of Genomictree Factory, Dungok District

- **Building Owner:** Genomictree Inc.

- **Location:** (Industrial Complex 7-4) Dungok-dong, Yuseong-gu, Daejeon

- **Land Area: 6,050 m² (1,800 pyung size)**

- **Building Profile**
  1) **1st Floor: 2,400 m²**
  2) **2nd Floor: 2,400 m²**
  3) **3rd Floor: 2,400 m²**
  4) **4th Floor: 2,400 m²**

- **Construction Area: 2,436 m²**
- **Ground Floor Total Surface Area: 9,600 m² (2,900 pyung)**

이 종목의 더 많은 IR정보 **확인하기**