2022

Smart Diagnostics with Multiplex PCR & Universal Array Technology

PaxGenBio Co., Ltd.

www.paxgenbio.com

Innovative and Chimeric Technologies
Leading to a New World of Healthcare

01. Company Status

General Outline

Company Name	PaxGenBio Co., Ltd.
CEO	Young Suk Park
Date of Establishment	May 1, 2015
Homepage	http://www.paxgenbio.com
Number of Employees	25 employees & related workers (November 2021)
Address	#803~807, 361, Simin-daero, Dongan-gu, Anyang-si, Gyeonggi-do, Rep. of Korea (14057)
Business field	Development and Sales in Convergence Technology of Molecular & Immuno Diagnostic Products
Business Conditions	Manufacture and Wholesale/Retail related to bio-products

Brief History

2015
- May Established(Kyonggi-University, Suwon)
- Aug. Company affiliated research institute certificate (KOITA No. 2015113870)

2016
- Mar. Register as Venture Business of Bio (KIBO)
- Apr. Permission to manufacture medical devices

2017
- Nov. ISO13485 Certificate (TÜV Rheinland, Germany)
- Dec. KGMP Certificate

2018
- Nov. INNO-BIZ Certificate

2019
- Feb. Moved HQ building (Anyang Ace Pyengchon Tower)
- Jul. KGMP & Manufacturing License (Relocation Approval)
- Dec. Minister of SMEs and Startups Award

2020
- May. ULFA patent registration(US)
- Nov. The Korean Biochip Society Technology Award
- Dec. Gyonggi Venture Business Governor's Award
- Designation of Brand K

2021
- Jan. Designation of promising SMEs for export
- Mar. Designated as a G-PASS company
- Dec. Designated as promising SMEs in Gyeonggi-do
- Winning the $1 Million Export Tower
- Selection of BLUE100 company in Anyang

Certificate

Company affiliated research institute certificate | Venture Business of Bio | ISO13485 | KGMP | INNO-BIZ | Brand K | Promising SMEs for Export | G-PASS Company | Promising SMEs in Gyeonggi-do | BLUE100 Company

02. Major Workforce

Composition of highly experienced experts in in-vitro diagnostics

▪ CEO: Young Suk Park

• Education	Bachelor's Degree in Genetic Engineering, Korea Univ. Ph.D. in Biochemistry, Hanyang Univ. Top Researcher Course in Life Science at National Cancer Center
• Experience	Chief of Seoul Clinical Laboratories Head of Bio-core Diagnosis Business Director of LG Life Science Ltd., Diagnosis Research Head of Bioneer Diagnosis Business Reseach Director of Greencross MS

▪ Director of R&D Dept./CTO: Chanhyo Lee

• Education	Bachelor's Degree in Chemistry, Seoul Univ. Ph.D. of Pennsylvania State University
• Experience	Research Director of Bioneer Research Director of Greencross MS

▪ Director of Marketing & Sales Dept. : Youngchai Jeon

• Education	Bachelor's Degree in Biology, Korea Univ.	
• Experience	Greencross MS	Marketing Director Business Development Dept.

▪ Director of Quality Control Dept. : JongHee Choo

• Education	Bachelor's Degree in Chemistry, Yonsei Univ.
• Experience	Severance Hospital Chief of Surgical Inspection in Ajou Univ. Hospital

▪ Director of Management Support Dept. : Euijib Kim

• Education	Bachelor's Degree in Business Administration, Ajou Univ.
• Experience	Samsung-Life Manager of Legal Officer's office

03. R&D Capability

Experts and Facilities for In Vitro Diagnostics Development

▪ Status of Company-Affiliated Research Institute

Classification	Contents
Equipment	38 of PCR, Extraction equipment, etc.
Certificate	Research Institute Certificate (KOITA) Excellence in Employee Invention Promotion(KIPO)


제 2015113870 호

기업부설연구소 인정서

1. 연 구 소 명: (주)팍스젠바이오 기업부설연구소
[소속기업명: (주)팍스젠바이오]
2. 소 재 지: 경기도 수원시 영통구 광교산로 154-42 경기대학교 창업보육센터 6층 609호 (이의동, 경기대학교)
3. 신고 연월일: 2016년 05월 04일
(최초인정일 : 2015년 8월 4일)
※ 변경내역: 명칭기간 변경

미래창조과학부

「기초연구진흥 및 기술개발지원에 관한 법률」 제14조의 2제1항 및 같은 법 시행령 제27조제1항에 따라 위와 같이 기업부설연구소로 인정합니다.

2016년 5월 9일

한국산업기술진흥협회장


직무발명보상우수기업 인증서

인증번호 : 제2019-00146호
업 체 명 : (주)팍스젠바이오
대표자명 : 박영석
사업자번호 : 253-87-00041
유효기간 : 2019. 10. 7. ~ 2021. 10. 6.

「발명진흥법」 제11조에 의거하여 위의 기업을 직무발명보상 우수기업으로 인증합니다.

2019년 10월 7일

특 허 청 장

▪ List of Registered Patents

* US Registered/ CN, IN Applied
** ID, CN, IN Applied

Patent No.	Name	State	Date
1020150071945	Method of Detecting Target Nucleic Acid and Kit*	Registered	2015.04.10
1020150162826	Method of Detecting Polymorphism in Sequence and Kit	Registered	2015.11.19
1020160061405	Oligonucleotide containing internal spacers and its purpose	Registered	2017.11.02
1020160158283	Immuno-PCR method using Aptamer	Applied	2016.02.25
1020170102378	Kit for Detecting Tuberculosis and Method of Detecting Tuberculosis by Using it**	Registered	2017.08.11
1020190047768	Kit for Detecting HPV and Method of Detecting HPV by Using it	Registered	2019.04.24
1020200122829	Kit for Detecting RSV, Influenza A&B and Method of Detecting RSV, Influenza A&B by Using it	Applied	2020.09.23
1020210023407	A Composition, Kit for Detecting Prostate-Specific Antigens used in Immuno-PCR and its Application	Applied	2021.02.22
1020210075214	Kit for Detecting SARS-CoV-2 and Method of Detecting SARS-CoV-2 by Using it	Applied	2021.06.10
30-0902658	A Diagnostic Cartridge	Registered	2017.04.07

04. Production Capability

Manufacturing System

▪ Overview of Manufacturing Facilities

Classification	Product/Quality Control Dept.
Manufacturing System	ISO13485 / KGMP System applied
Equipment	26 Clean-room, Dispenser, Fume Hood, etc.
Certificate	▪ Manufacturing medical devices Permitted ▪ ISO13485 (TÜV Rheinland) ▪ KGMP (MFDS)


의료기기 제조 및 품질관리 기준 적합인정서
(Certificate of GMP)

GMP


Certificate

TÜVRheinland

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2050748-1

Organization: PaxGenBio Co.,Ltd.
#803~807, 361, Simin-daero, Dongan-gu,
Anyang-si, Gyeonggi-do, 14057
Republic of Korea

Scope: Design and development, manufacture and distribution of nucleic acid amplification-based molecular diagnostic kits and nucleic acid extraction kits for in vitro diagnosis of infectious diseases

Report No.: 12031532 002
Effective date: 2020-10-30
Expiry date: 2023-10-29
Issue date: 2020-10-16

Masahiro Asami
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

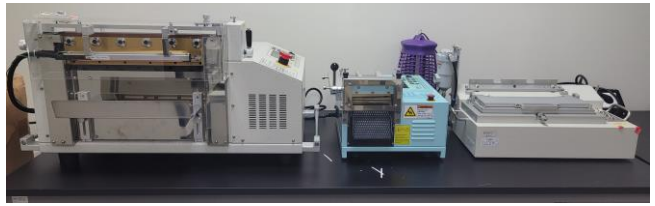
▪ Manufacturing Facilities

Manufacturing Station / Clean Booth

Clean Room Entrance (Air Shower)

Thermo-Hydrostat

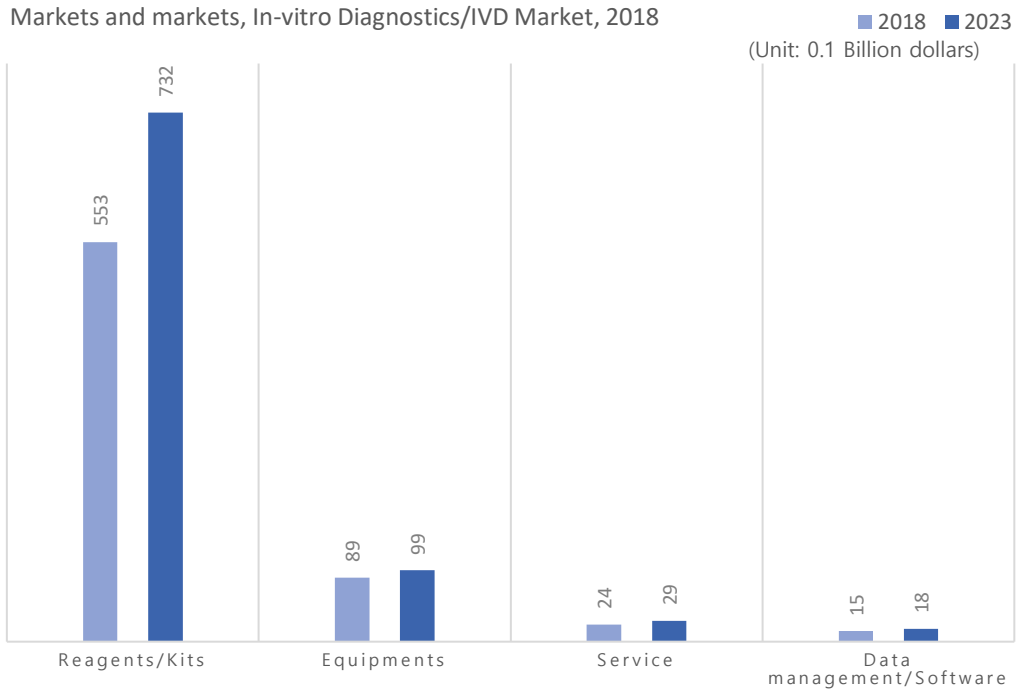
Equipment of ULFA Array Manufacturing



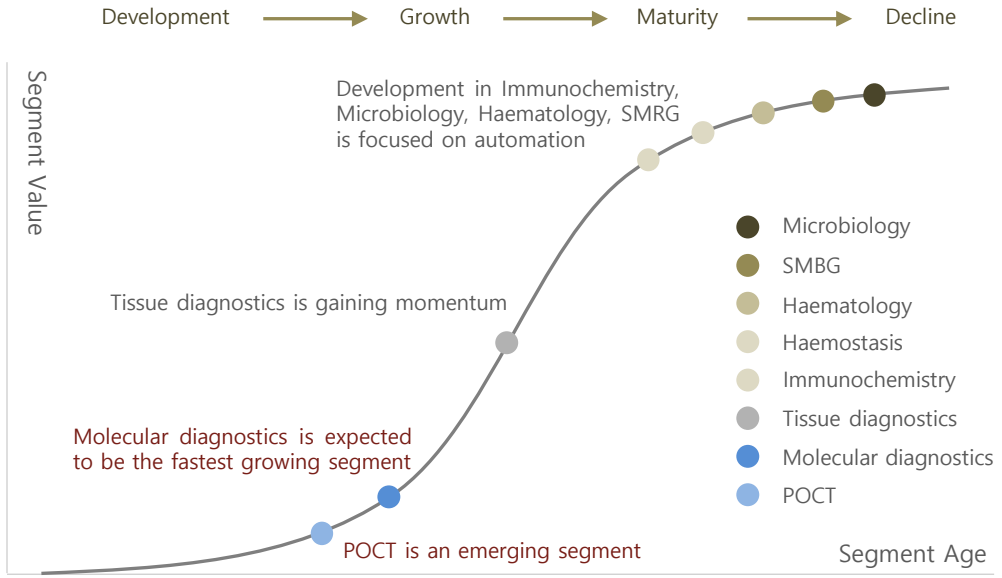
05. In Vitro Diagnosis Market

In Vitro Diagnostics(IVD)	Conducting and interpreting tests related to the diagnosis, follow-up, treatment and prognosis of diseases using human-derived samples (blood, urine, sputum, etc.)
Molecular Diagnostics	Directly examine nucleic acid (DNA or RNA) extracted from human derived samples.
Immuno-Diagnostics	Diagnostic method based on antigen-antibody reaction, examining pathogen-specific antigen or antibody
Global IVD Market	Expected to increase from $60.1 billion in 2018 to $83.2 billion by 2023 with an average annual growth rate of 6.73%

[Reagents & Kits account for 80% of the market]



[Molecular diagnosis & POCT: Highest growth rate]

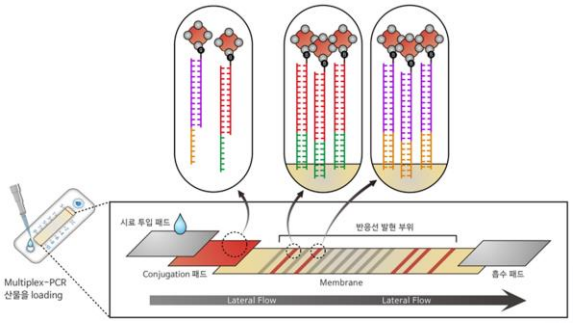


Total IVD Market: Segment Life Cycle Analysis, Global, 2014 (Frost&Sulivan analysis)

06. ULFA array Technology

Rapid Molecular Diagnostic System suitable for Gene Typing for Multiple Pathogen Detection and Companion Diagnostics

▪ MPCR-ULFA array technology



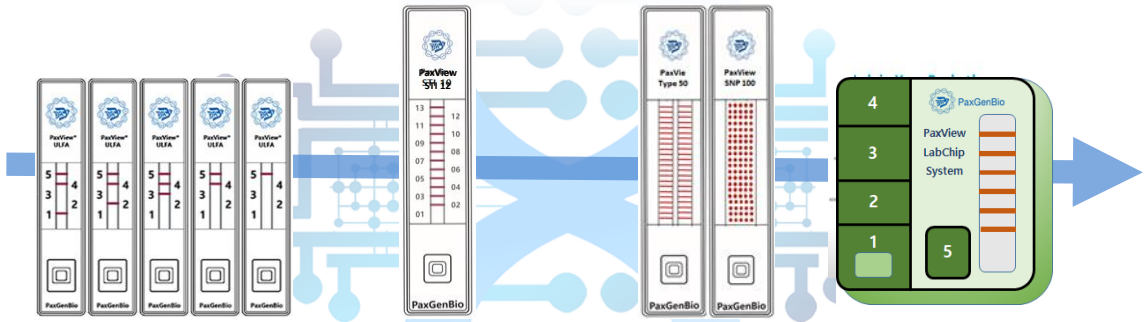
PaxView MPCR-ULFA

Step 1. **Extract Nucleic Acid**

Step 2. **Amplify Nucleic Acid**

Step 3. **Detect Nucleic Acid**

▪ Direction of ULFA array's Development: ULFA → LabChip/POCT



5 lines in 2019 | 13 lines in 2019 | 50~100 lines in 2022 | LabChip/POCT in 2025

▪ ULFA array Movie https://www.youtube.com/watch?v=ZDyGmxk65qU

▪ Ease of use and Market Competitiveness

MPCR (Multiplex PCR)

- Amplify various disease-related genes at the same time
- Able to distinguish various genotypes through one amplification

ULFA (Universal Lateral Flow Assay) Array

- Technology capable of genotyping
- Technology that can be applied with POCT due to its convenient usability

07. Comparison of ULFA Array-Related Technologies

PaxGenBio

ULFA array: Rapid/Accurate, Does Not Require Hybridization Equipment ››› Point of Care Testing (POCT) Applicable

Classification	ULFA (Universal array)	Linear Array (Line probe assay)	DNA microarray (DNA chip)
Technology Holder	PaxGenBio 	Roche, Fujirebio Europe 	AGBD, Panagene, Greiner Bio-One (Germany) 
Hybridization Method	DNA-DNA LFA	DNA-DNA Blot	DNA-DNA Blot
Denaturation Process	Unnecessary	Necessary 	Necessary
Hybridization Temperature	Room Temperature	50~60°C 	50~60°C
Reaction Time	10~15 min.	1.5~2.5 hrs. 	1.5~2.5 hrs.
Equipment	Not required	Heater / Incubator 	Heater / Incubator / Scanner 
Possibility of POCT	Possible	Impossible	Impossible
Production Cost	Very low	Middle	High

ULFA array Technology

Easy to develop new products
Easy to mass-produce and quality control
Simple/Easy to use analysis equipment

Existing array Technology

Hard to develop new products
Hard to mass-produce and quality control
Complex/Uncomfortable to use analysis equipment

08. MPCR-ULFA Product Line

Various Multi-Rapid Molecular Diagnostic Kits

- **HPV Molecular Diagnosis Product Line**

PaxView® HPV16/18 MPCR-ULFA Kit

PaxView® HPV16/18/Others MPCR-ULFA Kit

PaxView® HPV 10 Genotyping MPCR-ULFA Kit

PaxView® HPV 20 Genotyping MPCR-ULFA Kit

PaxView® HPV 30 Genotyping MPCR-ULFA Kit *

- **RV Virus Molecular Diagnosis Product Line**

PaxView® SARS-CoV-2 MPCR-ULFA Kit

PaxView® RV 10 MPCR-ULFA Kit *

- **TB Molecular Diagnosis Product Line**

PaxView® TB MPCR-ULFA Kit

PaxView® TB/NTM MPCR-ULFA Kit

PaxView® NTM 6 ID MPCR-ULFA Kit *

PaxView® MDR-TB MPCR-ULFA Kit *

- **STI Molecular Diagnosis Product Line**

PaxView® CT/NG MPCR-ULFA Kit

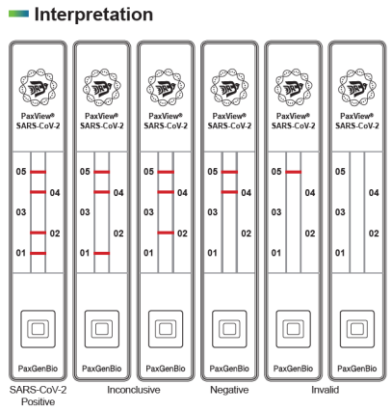
PaxView® CT/NG/TV MPCR-ULFA Kit

PaxView® CT/NG/TP MPCR-ULFA Kit

PaxView® MG/MH/UU MPCR-ULFA Kit

PaxView® HSV1/2 MPCR-ULFA Kit

PaxView® STI 12 MPCR-ULFA Kit *



* Coming soon

09. ULFA array System Pipeline

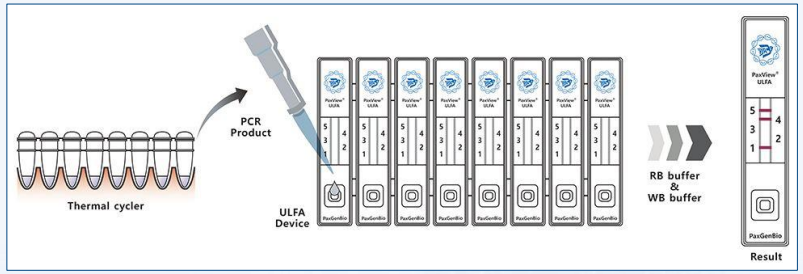
SMART Array Technology Applicable to various Fields

2016 — 2017 — 2019 — 2022 →

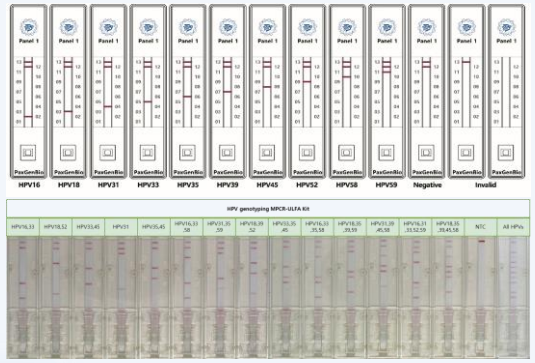
Multiplex MPCR-ULFA

- MPCR-ULFA assay technology optimized
- MPCR-ULFA products launched

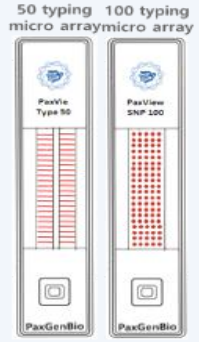
https://www.youtube.com/watch?v=srC0lm-1HRw



13 ULFA assay



50/100 ULFA assay



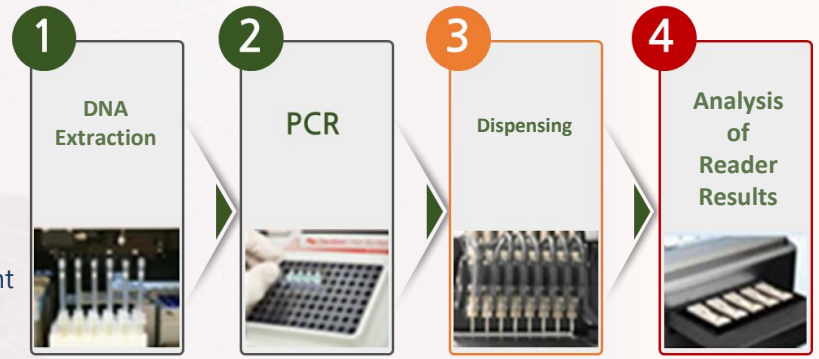
2022 — 2023 — 2025 →

System for POCT

PaxView Station Development

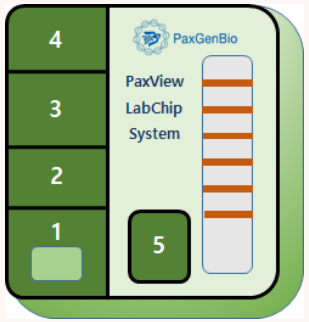
- Extraction/Amplification/Detection integrated system
- Packaging of diagnostic equipment/reagent
- IoT-based information management

System for a Large Laboratory



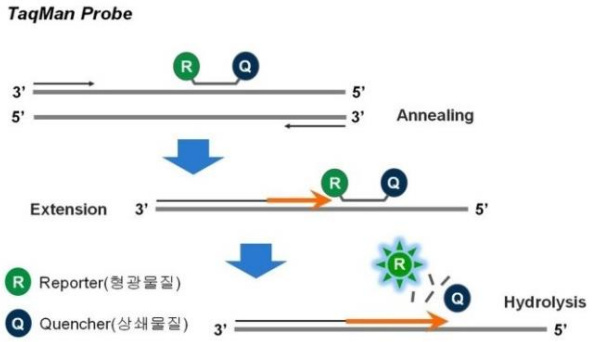
Build a Continuous Automation System

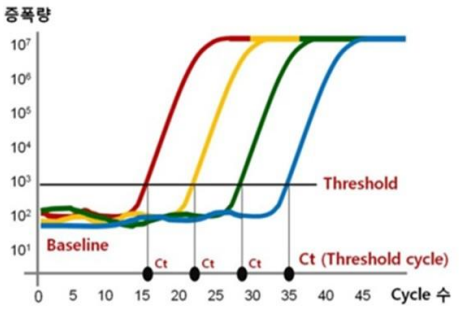
LabChip System for Personal Diagnosis



10. Real-time PCR Technology

- A technology for monitoring an amplified product in real-time
- Using expensive fluorescence analysis PCR equipment
- Capable of 4 multiplex PCR
- High user's convenience





Company	PaxGenBio	SeeGene	SD BioSensor
Kit name	PaxView® SARS-CoV-2 real-time RT-PCR Kit	Allplex SARS-CoV-2 Assay	STANDARD™ M nCoV Real-Time Detection kit
Real-time PCR machine	ABI7500 Fast CFX96	CFX96	ABI 7500 / ABI 7500 Fast / CFX96 / QS 5
Kit component	1) RT-PCR premix 2) Primer/Probe Mix 3) Positive control	1) SARS2 MOM(Oligomixture) 2) EM8(Polymerase, Polymerase buffer) 3) SARS2 PC(Positive Control) 4) RP-V IC2(Internal Control) 5) Rnase-free Water(Distilled)	1) 2019-nCoV Reaction Solution 2) Rtase Mix 3) 2019-nCoV Positive control 4) Negative control 5) Internal control A 6) ROX
Target gene	RdRp, N	RdRp, E, S, N	RdRp, E
Internal control	RNase P (house keeping RNA gene)	MS2 phage	Lentivirus
LoD	1 copy/ul (5 copies/reaction)	5 copies/ul (25 copies/reaction)	0.5 copies/ul (5 copies/reaction)
Features	✓ High sensitivity ✓ User convenience ✓ Can monitor the entire process from sampling to checking the results	✓ Low sensitivity ✓ Complex product composition ✓ User inconvenience ✓ CFX-96 Only	✓ High sensitivity ✓ Complex product composition ✓ User inconvenience ✓ Various equipment applicable

11. Real-time PCR Product Line

Product Line in Possession & Development

- **RV Virus Molecular Diagnosis Product Line**

PaxView® SARS-CoV-2 real-time PCR Kit

PaxView® RV Type real-time PCR Kit

- **HPV Molecular Diagnosis Product Line**

PaxView® HPV16/18/Others real-time PCR Kit

PaxView® HPV 30 Genotyping real-time PCR Kit

- **TB Molecular Diagnosis Product Line**

PaxView® TB/NTM real-time PCR Kit

PaxView® MDR-TB real-time PCR Kit

- **STI Molecular Diagnosis Product Line**

PaxView® CT/NG/TV real-time PCR Kit

PaxView® HSV1/2 real-time PCR Kit

PaxView® STI 12 real-time PCR Kit

12. PaxTech® Molecular Diagnostic Equipment

PaxTech® Brand Products

DNA Extractor (32T)

Electromagnetic Nucleic Acid Extractor

ITEMS	PARAMETER
Capacity	≤48 samples / run customized
Heating temp.	Room temp. to 120 ℃
Reagents	Suitable for magnetic particle method
Prevent contamination	UV light
Network communication	Ethernet(optional)

Thermal Cycler (96T)

Normal Nucleic Acid Amplifier

ITEMS	PARAMETER
Temp. control range of block	4.0 ℃ to 99.9 ℃
Gradient block (12 Row)	Temp. range: 30 ℃ to 99 ℃
Block temp. accuracy	±0.1 ℃
Heat or cooling rate	max. 4.5 ℃/s
Interfaces	USB & Ethernet

ULFA Reader (Prototype)

Automatic Result Analysis Equipment

ITEMS	PARAMETER
Analysis	Automation
Analysis time	≤5 sec.
Result output	Visualizing quantification
Network communication	Mobile device & tablet PC

Innovative and Chimeric Technologies Leading to a New World of Healthcare