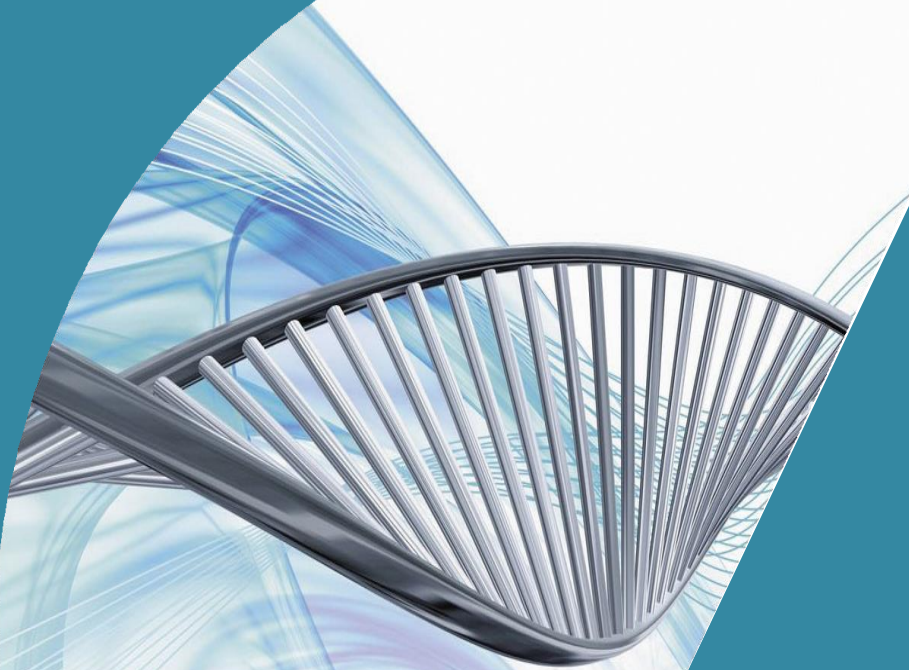


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EuDx™ ufPCR Detection SYSTEM

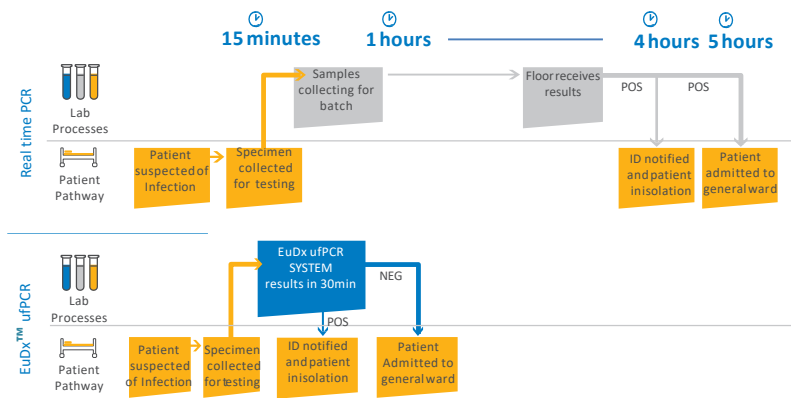


1. EuDx™ ufPCR SYSTEM

1) Overview



2) Impact on patient



Comparison with existing systems

Company Name	EuDiPia(KR)		Cepheid(US)	
Products	EuDx™ ufPCR Flu/RSV		Xpert® Flu+RSV Xpress	
Characteristics	Target	Influenza A(subtype)/B Virus, RSV viral RNA	Target	Influenza A/B Virus, RSV viral RNA
	Specimen	Nasopharyngeal (NP) swab specimens	Specimen	Nasopharyngeal (NP) swab specimens
	Technology	Ultra Fast PCR	Technology	Multiplex real time RT-PCR
Reagent & Equipment Condition	Time of analysis	≤30minutes	Time of analysis	~60min
	Reagent price	Less than US\$20/test (Chip type, Including preconditioning process)	Reagent price	US\$70/test (Cartridge type, Including preconditioning process)
	Commercialization time	2019 4Q	Commercialization time	Released on 2015
	R&D pipeline	Flu/RSV, MDR-TB, PnB, etc.	R&D pipeline	MTB, STD etc.

3) Reagent & system development schedule

Classification	Development product	Development schedule
EuDx™ ufPCR System	Portable and fast ramp time (15 minutes for 30cycles), Reasonable priced fast PCR Device	2016. OCT
EuDx™ ufPCR Flu/RSV Detection Kit	Respiratory virus detection system	KFDA Approval in 4Q 2019
EuDx™ ufPCR MDR TB Detection Kit	Drug-resistant tuberculosis detection system	KFDA Approval in 4Q 2019
EuDx™ ZCD Detection Kit	ZIKA, Chikungunya, Dengue Fever Virus serotype 1,2,3,4 detection system	KFDA Approval in 4Q 2019
EuDx™ ufPCR STI Detection Kit	STI (sexual transmitted infection) detection system	KFDA Approval in 1Q 2020



4) Genechecker Revolution in molecular diagnosis

EuDx™ GENECHECKER



- Patented chip based design provides extremely rapid output
- 30 thermal cycles in 15 minutes
- Patented fluorescence detector enables instant result confirmation
- No needs of electrophoresis
- Innovative and compact design for table-top and portable PCR tasks
- Connection to car power jack enables PCR tasks on site.
- Intuitive control with LED indicated Jog-dial and LCD display
- Innovative and compact design

Why GENECHECKER?

GENECHECKER Ultra-Fast PCR System. is an innovative solution for medical device in molecular or genetic diagnosis applications.

This adopts special polymer chip named Rapid chip™ which enables even faster thermal treatment of samples than the case of using conventional PCR tubes.

In addition, GENECHECKER takes the advantage of real-time PCR by integrating high-end fluorescence detection technology in it, which enabled users to visually confirm amplify wells through the computer screen.

Using key technologies integrated in GENECHECKER successfully performs 30 thermal cycles in 15 minutes and lets users confirm the qualitative PCR result with computer screen.

Design Innovation

Design of GENECHECKER is unique and modern. The design effort to eliminate unnecessary features seems to be very simple. Control is intuitively made by jog-dial which enable users to perform most of parameter controls in simple manner. Enjoy innovative design of GENECHECKER Ultra-Fast PCR in your traditional laboratory environment.

How could GENECHECK be born?

Development of GENECHECKER Ultra-Fast PCR instrument was started with several motives.

Researchers were spending too much time and efforts to get a PCR result. Typically, researchers had to spend over 40 minutes for thermal cycling and spend another 40 minutes for electrophoresis, which was quite time consuming process to get a simple PCR result.

Another motivation was to prove that chip-based PCR technology can sufficiently cover the functions of real-time PCR equipment in terms of quality analysis.

We were convinced that targeted performance could be achieved, when this unique chip based PCR concept meets high-end fluorescence detection technology and it is being proven by field evaluations in variety of molecular diagnosis research applications.



General Specification of GENECHECKER™

ITEMS	DESCRIPTION
Description	Precise control of Peltier element
Temperature accuracy	± 0.5°C
Well to well temperature uniformity	± 0.5°C
Temperature stability	± 0.5°C
Ramp up speed	8.0 °C / second
Ramp down speed	8.0 °C / second
Range of temperature setting	20 ~ 99 °C (1.0°C Increment)
Type of sample block	Polymer Based 3-Dimensional Chip
Number of channels	8

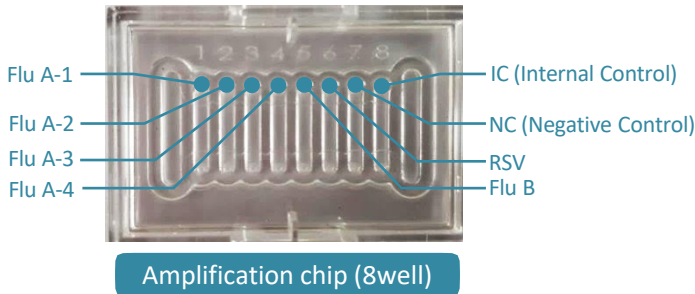
ITEMS	DESCRIPTION
Well volume	10 µL
PCR time	30 Minutes
Necessity of electrophoresis	No (Instant Qualitative Analysis)
Display	Text LCD (4 Lines)
Integrated memory	Saves up to 12 Custom Protocols
Power	AC 110-230V / 50-60 Hz / DC 12V
Computer connection method	USB 2.0A to B (computer-device)
Physical specification	Dimension : 200(w) x 200(d) x 125 (h), Weight : 3.2 kg



2. Product description and components

❖ Name : EuDx™ ufPCR Flu/RSV Detection Kit

1) Chip components



**Use pipet transfer from extraction chip to the amplification chip

Target	Dye
Flu A-1	Eva green
Flu A-2	
Flu A-3	
Flu A-4	
Flu B	
RSV	

Target	Flu A-1: Influenza A Virus Flu A-2: Influenza A Virus subtype, (H1N1)pdm09 Flu A-3: Influenza A Virus subtype, H3 Flu A-4: Influenza A Virus subtype, H5 Influenza B Virus RSV
Specimen	Nasopharyngeal (NP) swab specimens
Amplification Chip	8 well, 1 person – 1 chip
Technology	Ultra Fast PCR
Time of analysis	≤30minutes
Commercialization time	2019

2) Performance characteristics

Analytical sensitivity

Genomic DNA isolated from clinical specimens of influenza virus were diluted in five levels and repeatedly tested three times for each concentration to measure the detection limit (cut-off concentration).

The test results showed 100 % positive detection rates in virus until 100 copies which thus confirmed the product's limit of detection as 100 copies.

Analytical specificity

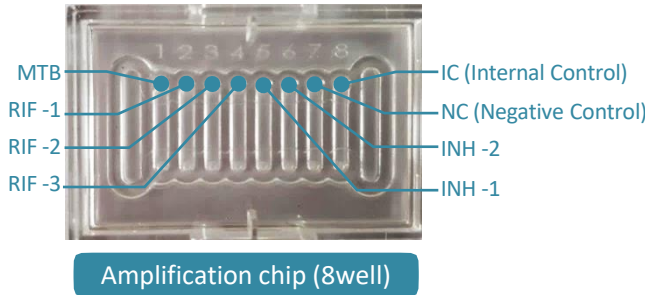
Specificity tests were performed against of human genomic DNA, 2 kinds of PCR (Urea and Hemoglobin) and 6 kinds of antibiotics (Mucin, Mupirocin, Tobramycin, Phenylephrine, Zanamivir and Dexamethasone) were tested.

Interference reaction was not occurred.



❖ Name : EuDx™ ufPCR MDR TB Detection Kit

1) Chip components



**Use pipet transfer from extraction chip to the amplification chip

Target	Dye
MTB	FAM
RIF -1	
RIF -2	
RIF -3	
INH -1	
INH -2	

Target	MTB, RIF(6), INH(2) RIF: S531L, L511P, H526Y, H526D, D516V, D516Y INH: inhA -15->T, katG 315 AGC->ACC
Specimen	Sputum
Amplification chip	8 well, 1 person – 1 chip
Technology	Ultra Fast PCR
Time of analysis	≤40minutes
Commercialization time	2019

2) Performance characteristics

Analytical sensitivity

Cloned DNA, isolated from reference strains of TB (MTB H37Rv, ATCC 27294), RIF resistant strains, and INH resistant were diluted in five levels and repeatedly tested three times for each concentration to measure the detection limit. (cut-off concentration)

The test results showed 100% positive and resistant detection rates in MTB, RIF resistant strains, and INH resistant strains until 100 copies which thus confirmed the product's limit of detection as 100 copies.

Analytical specificity

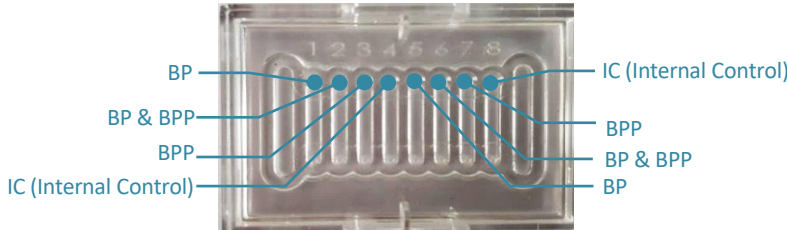
The results of tests on genomic DNAs obtained from 12 kinds of nontuberculous mycobacteria that might work as a cross material during the use of this product and 14 kinds of other pathogenic microorganisms that might migrate into samples showed no cross-reaction.

The results of tests on three kinds of PCR inhibitors (urea, hemoglobin, and blood) and anti-TB drugs (Rifampicin, Isoniazid, Ethambutol, Pyrazinamide, Moxifloxacin, and Levofloxacin) that might hinder the response of this product showed no interfering reaction.



❖ Name : EuDx™ ufPCR Bordetella Detection Kit

1) Chip components



Amplification chip (8well)

**Use pipet transfer from extraction chip to the amplification chip

2 person 1 chip

Target	Dye
BP	Eva green
BP & BPP	
BPP	

Target	<i>Bordetella pertussis</i> , <i>Bordetella parapertussis</i>
Specimen	Nasopharyngeal (NP) swab specimens
Amplification chip	8 well, 2 person – 1 chip
Technology	Ultra Fast PCR
Time of analysis	≤30minutes
Commercialization time	2019 (RUO)

2) Performance characteristics

Analytical sensitivity

Genomic DNA isolated from clinical specimens of *Bordetella pertussis*(DSMZ 5571) , *Bordetella parapertussis*(DSMZ 13415) were diluted in five levels and repeatedly tested three times for each concentration to measure the detection limit. (cut-off concentration)

The test results showed 100 % positive detection rates in DNA until 100 copies which thus confirmed the product's limit of detection as 100 copies.

Analytical specificity

Specificity tests were performed against potential cross-reactants, Genomic DNAs from 35 kinds of different pathogens. Cross reaction was not occurred.

As testing against potential inhibitors of human genomic DNA, 2 kinds of PCR (Urea and Hemoglobin) and 5 kinds of antibiotics (Cotrimoxazole, Azithromycin, Clarithromycin , Moxifloxacin and Levofloxacin) were tested.

Interference reaction was not occurred.



❖ Ordering Information

Product	Unit	Category No.
EuDx™ ufPCR Pn Detection Kit	20 tests	UF04-20T
EuDx™ ufPCR Flu/RSV Detection Kit	10 tests	UF05-10T
EuDx™ ufPCR MDR TB Detection Kit	10 tests	UF06-10T
EuDx™ ufPCR Bordetella Detection Kit	20 tests	UF07-20T



Instrument	Description	Category No.
GENECHECKER™	POCT PCR	UF-150

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