

# Detection Kits

for Molecular Diagnostics

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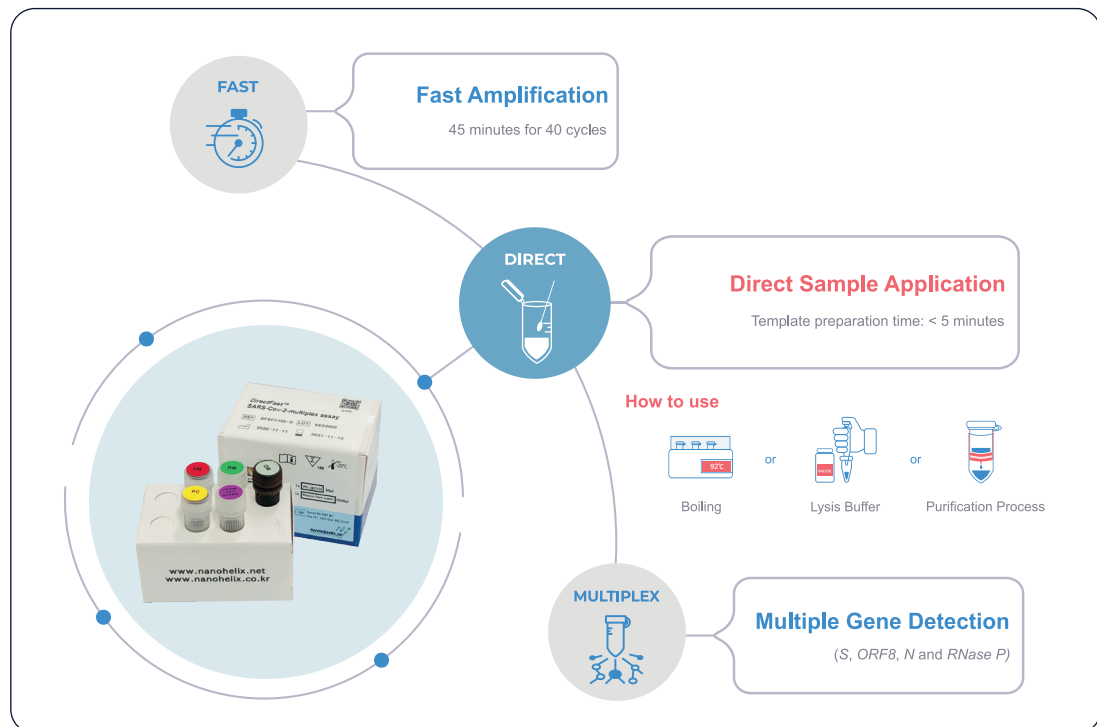
# SARS-CoV-2 Multiplex assay

- Direct, fast, reliable and multiple gene detection for SARS-CoV-2
- **DIRECT**: Applicable to both the purified RNA and unpurified specimen
- **FAST**: 50 minutes [5 minutes for sample preparation + 45 minutes/40 cycles for qRT-PCR]
- **RELIABLE**: 4 target detection for SARS-CoV-2(S, ORF8, N) and Human(RNase P)
- UDG system: Prevention of carryover contamination



**DirectFast™ SARS-CoV-2 Multiplex assay**, a probe-based real-time RT-PCR kit, is designed for 'DIRECT' and 'FAST' detection of SARS-CoV-2 RNA. Crude RNA samples prepared by a lysis buffer(NAExDB) or heating, as well as purified RNA, can be used as templates for this assay without compromised detection sensitivity and accuracy. This kit's fast reaction completes the real-time RT-PCR cycles within 1 hour(45-50 minutes for 40 cycles).

The target multiplicity(ORF8, N, S genes of SARS-CoV-2) lowers the risk of false-negative results induced by mutations of viral RNA. Additionally, this assay contains a heat-labile UDG and dUTP system to prevent carryover contamination.



## Performance Characteristics

### ■ Applicable Real-Time Instruments & Fluorescence Channels

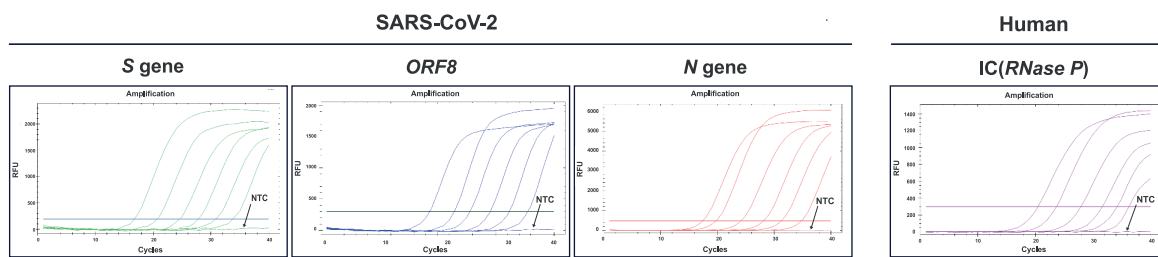
Instrument	Target			
	S	ORF8	N	IC(RNase P)
Bio-Rad CFX96	FAM	HEX	Texas Red	Cy5
ABI 7500(Fast)	FAM	JOE	Texas Red	Cy5

### ■ Analytical Sensitivity

Instrument	S	ORF8	N
Bio-Rad CFX96	10 copies/ $\mu$ l <sup>※</sup>	10 copies/ $\mu$ l	10 copies/ $\mu$ l
ABI 7500(Fast)	10 copies/ $\mu$ l	10 copies/ $\mu$ l	10 copies/ $\mu$ l

※ Concentration of SARS-CoV-2 genomic RNA spiked in a nasopharyngeal swab collection (in UTM). After spiking, SARS-CoV-2 RNA were purified from swab collection sample. 3  $\mu$ l of purified RNA were used in the reaction for the validation of sensitivity detection of SARS-CoV-2.

### ■ Analytical Data



**Fig. Sensitive detection of SARS-CoV-2 with DirectFast™ SARS-CoV-2 Multiplex assay.** SARS-CoV-2 viral RNAs were spiked into the nasopharyngeal swab collections (in UTM) at the concentration of  $10^6 \sim 10^1$  copies/ $\mu$ l. RNAs were prepared from each spiked sample according to the IFU of this product. Each 3  $\mu$ l of the purified viral RNA was used for the detection of SARS-CoV-2 as a template. The reactions were performed on a real-time PCR instrument, Bio-Rad CFX96.

## ■ Clinical Performance

Final results		Reference kit <sup>a</sup>		Total
		Positive	Negative	
<i>DirectFast</i> <sup>TM</sup> SARS-CoV-2 Multiplex assay	Positive	40	0	40
	Negative	0	40	40
Total		40	40	80
* PPA(Positive Percent Agreement): 100% [95% CI: 91.24-100 %] * NPA(Negative Percent Agreement): 100% [95% CI: 91.24-100 %] <sup>a</sup> A commercial kit approved in FDA-EUA was used as the reference kit				

## ■ Detection Result

Case	IC	S	ORF8	N	Interpretation
1	+/-	+	+	+	SARS-CoV-2 Detected
2	+/-	Two of three +			SARS-CoV-2 Detected
3	+/-	One of three +			Inconclusive
4	+	-	-	-	SARS-CoV-2 Not Detected
5	-	-	-	-	Invalid/Retest

## Product Information

Product	Size	Cat. No.
<i>DirectFast</i> <sup>TM</sup> SARS-CoV-2 Multiplex assay (Research Use Only)	100 tests	DFSCV100

# SARS-CoV-2 & Flu Detection Kit

- Fast and simultaneous detection of SARS-CoV-2 and influenza A, B
- **FAST:** 45 minutes/40 cycles for real-time RT-PCR
- 3 targets for SARS-CoV-2(*ORF1ab/ORF8/ORF3a*) and 2 targets for influenza(*InfA/InfB*)
- UDG system: Prevention of carryover contamination



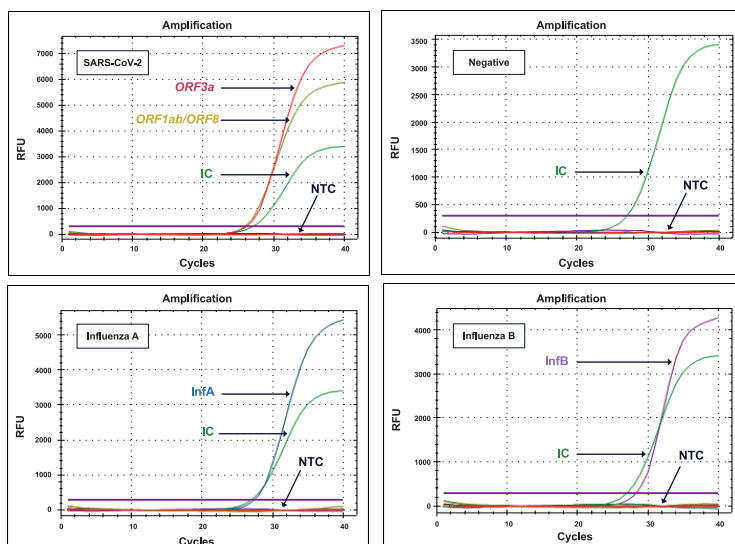
**HelixDtec™ SARS-CoV-2 & Flu Detection Kit** is a fast multiplex real-time RT-PCR kit designed for the simultaneous detection of SARS-CoV-2 and influenza A/B. This kit detects influenza virus A and B together with 3 different targets(*ORF1ab/ORF8/ORF3a*) of SARS-CoV-2, providing accurate and comprehensive detection. To prevent the carryover contamination of amplified products, this assay uses dUTP and heat-labile UDG enzymes.

## Performance Characteristics

### ■ Applicable Real-Time Instruments & Fluorescence Channels

Instrument	Target				
	SARS-CoV-2		Influenza		Human
	<i>ORF1ab &amp; ORF8</i>	<i>ORF3a</i>	<i>InfA</i>	<i>InfB</i>	<i>IC(RNase P)</i>
Bio-Rad CFX96	VIC	Texas Red	FAM	Cy5	Cy5.5
QuantStudio 5	VIC	Texas Red	FAM	Cy5	Cy5.5

## ■ Applicable Real-Time Instruments & Fluorescence Channels



## ■ Analytical Data

Case	Human	SARS-CoV-2		Influenza		Interpretation
	IC	ORF1ab & ORF8	ORF3a	InfA	InfB	
1	+/-	+	+	-	-	SARS-CoV-2 Detected
2	+/-	One of two +		-	-	Inconclusive
3	+/-	-	-	+	-	InfA Detected
4	+/-	-	-	-	+	InfB Detected
5	+	-	-	-	-	SARS-CoV-2 & Flu Not Detected
6	-	-	-	-	-	Invalid/Retest

## Product Information

Product	Size	Cat. No.
HelixDtec™ SARS-CoV-2 & Flu Detection Kit (Research Use Only)	100 tests	SCVFLU100

# SARS-CoV-2 & Omicron Detection Kit

- Fast and simultaneous detection of SARS-CoV-2 and Omicron variant
- **FAST:** 45 minutes/40 cycles for real-time RT-PCR
- Detect 3 regions of
  - 1) SARS-CoV-2 general (conserved regions of *N* & *S* gene)
  - 2)  $\Delta 69-70$  mutation (OS1)
  - 3)  $\Delta 211/L212I/Ins214EPE$  mutation (OS2)
- UDG system: Prevention of carryover contamination

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**HelixDtec™ SARS-CoV-2 & Omicron Detection Kit** is designed to enable quick and simultaneous detection of the Omicron variant in addition to the *N* and *S* genes of SARS-CoV-2.

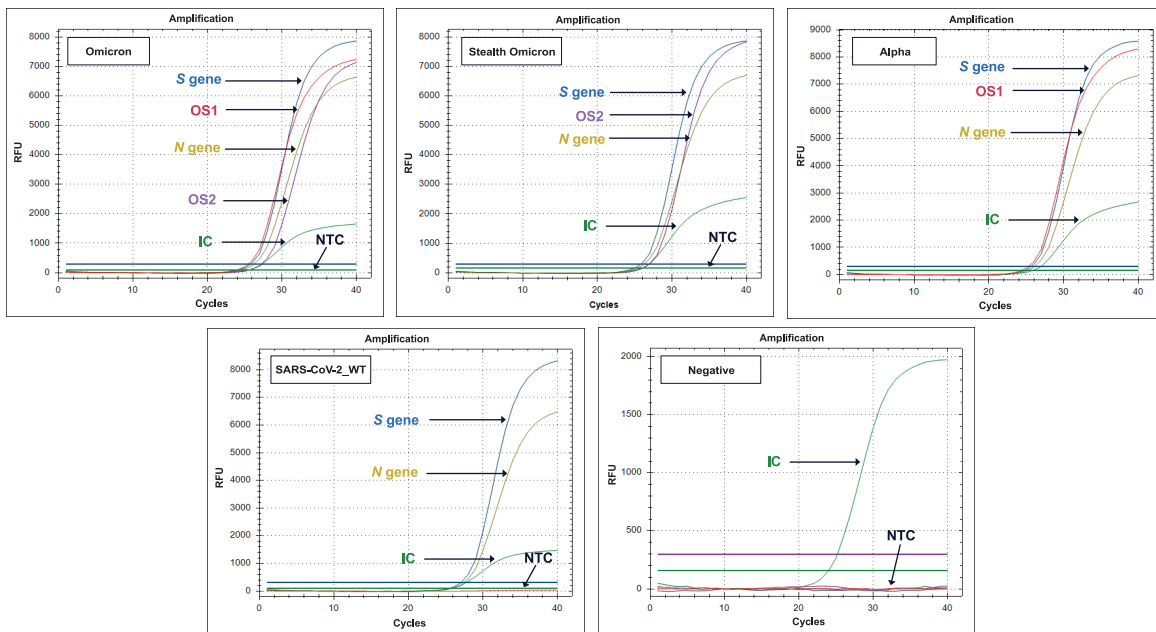
With the application of NanoHelix's fast real-time PCR technology, SARS-CoV-2 infection and the Omicron variant confirmation can be validated within 45 minutes. To prevent the carryover contamination of amplified products, this assay uses dUTP and heat-labile UDG enzymes.

## Performance Characteristics

### ■ Applicable Real-Time Instruments & Fluorescence Channels

Instrument	Target				
	<i>N</i>	<i>S</i>	OS1 ( $\Delta 69-70$ )	OS2 ( $\Delta 211/L212I/Ins214EPE$ )	IC (Human <i>RNase P</i> )
Bio-Rad CFX96	HEX	FAM	Texas Red	Cy5	Cy5.5
ABI 7500	JOE	FAM	Texas Red	Cy5	TAMRA

## ■ Analytical Data



## ■ Detection Result

Case		IC	S gene	N gene	OS1	OS2
SARS-CoV-2	WT/Beta/Gamma/Delta/Lota/Kappa/Lambda/Mu/Zeta variants	+/-	+	+	-	-
	Omicron variant	+/-	+	+	+	+
	Stealth Omicron	+/-	+	+	-	+
	Alpha / Eta variant	+/-	+	+	+	-
Inconclusive		+/-	One of two +		-	-
SARS-CoV-2 Negative		+	-	-	-	-

## Product Information

Product	Size	Cat. No.
HelixDtec™ SARS-CoV-2 & Omicron Detection Kit (Research Use Only)	100 tests	SCVOM100

HelixDtec™

(Research Use Only)

## SARS-CoV-2 Omicron Assay

- Fast differentiation of SARS-CoV-2 Omicron variant
- **FAST:** 45 minutes/40 cycles for real-time RT-PCR
- Detect 4 regions of
  - 1) SARS-CoV-2 general (conserved region of S gene)
  - 2) Δ69-70 mutation (OS1)
  - 3) Δ211/L212I/Ins214EPE mutation (OS2)
  - 4) Q493R/G496S/Q498R/N501Y mutation (OS3)
- UDG system: Prevention of carryover contamination

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**HelixDtec™ SARS-CoV-2 Omicron Assay** is a probe-based real-time RT-PCR kit designed to quickly determine the presence of the Omicron variant in patients who have confirmed infection by any COVID-19 molecular diagnostic test. This kit is designed to scan the three regions of relevant mutations in the SARS-CoV-2 Omicron variant in addition to a conserved region of S gene.

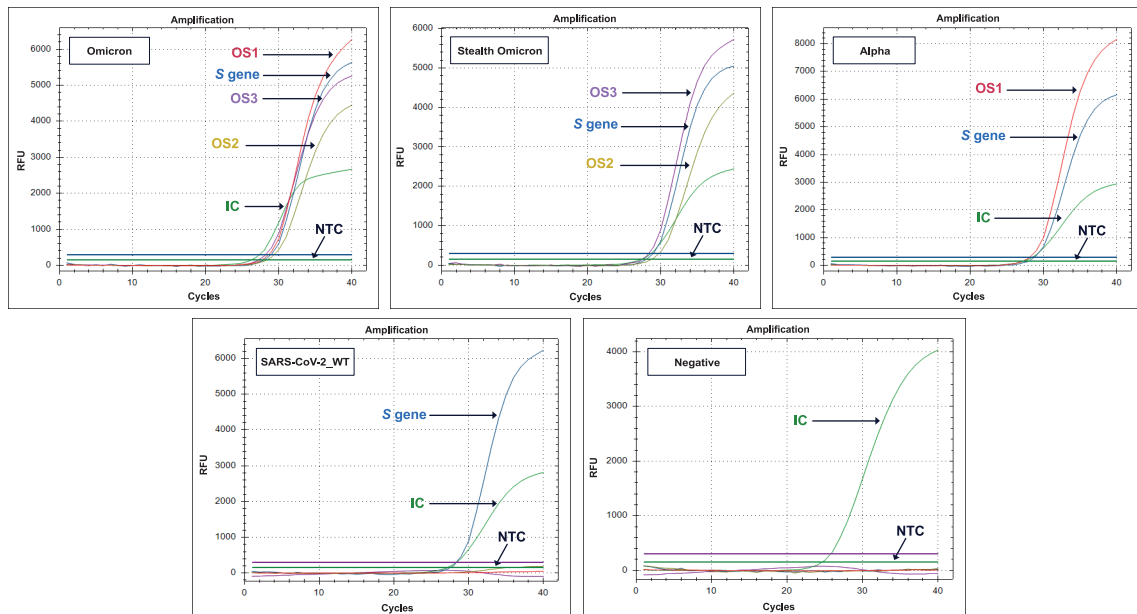
With the application of NanoHelix's fast real-time PCR technology, Omicron variant differentiation can be validated within 45 minutes. To prevent the carryover contamination of amplified products, this assay uses dUTP and heat-labile UDG enzymes.

## Performance Characteristics

### ■ Applicable Real-Time Instruments & Fluorescence Channels

Instrument	Target				
	S	OS1 (Δ69-70)	OS2 (Δ211/L212I/Ins214EPE)	OS3 (Q493R/G496S/Q498R/N501Y)	IC (Human <i>RNase P</i> )
Bio-Rad CFX96	FAM	Texas Red	HEX	Cy5	Cy5.5
ABI 7500	FAM	Texas Red	JOE	Cy5	TAMRA

### ■ Analytical Data



■ **Detection Result**

Case	IC	S gene	OS1	OS2	OS3
<b>SARS-CoV-2</b> (WT/Beta/Gamma/Delta/ Lota/Kappa/Lambda/Mu/Zeta)	+/-	+	-	-	-
<b>Omicron Variant</b>	+/-	+	+	+	+
<b>Stealth Omicron</b>	+/-	+	-	+	+
<b>Alpha/Eta Variant</b>	+/-	+	+	-	-
<b>SARS-CoV-2 Negative</b>	+	-	-	-	-

**Product Information**

Product	Size	Cat. No.
HelixDtec™ SARS-CoV-2 Omicron Assay (Research Use Only)	100 tests	OMCV100

HelixDtec™

(Research Use Only)

## COVID/Flu/RSV Combo Kit

- Simultaneous detection of SARS-CoV-2(*E* and *RdRp* gene), influenza A, B and RSV
- Optional melting curve analysis allows typing of influenza A and B
- UDG system: Prevention of carryover contamination



**HelixDtec™ COVID/Flu/RSV Combo Kit** is a multiplex real-time RT-PCR kit designed for the simultaneous detection of SARS-CoV-2, influenza A/B and RSV(Respiratory Syncytial Virus) in a single tube. This kit more accurately detects SARS-CoV-2 using each probe set for 2 targets(*E* gene and *RdRp* gene). In addition, if necessary, melting curve analysis can be used to identify Influenza A and B. To prevent the carryover contamination of amplified products, this assay uses dUTP and heat-labile UDG enzymes.

### Product Information

Product			Size	Cat. No.
HelixDtec™	COVID/Flu/RSV Combo Kit	(Research Use Only)	100 tests	COVFR100

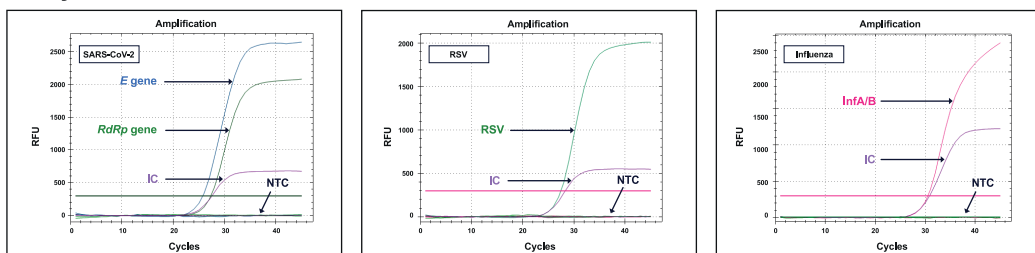
## Performance Characteristics

### ■ Applicable Real-Time PCR Instruments & Fluorescence Channels

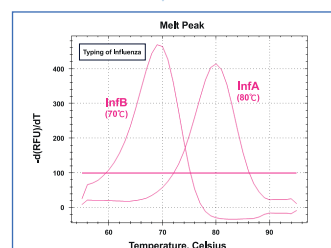
Instrument	Target				
	SARS-CoV-2		Influenza A/B	RSV	IC
	<i>E</i> gene	<i>RdRp</i> gene			
CFX96	FAM	HEX	Cal Red 610	Cy5.5	Cy5

\* IC: Internal Control

### ■ Analytical Data



Optional melting curve analysis for typing of Influenza



**Fig. Example of results in each case**

The graphs show multiplex real-time PCR results in each case. **HelixDtec™ COVID-/Flu/RSV Combo Kit** identifies 2 targets of SARS-CoV-2(*E* and *RdRp* gene), Influenza and RSV in a single reaction(**black** border). According to user's need, typing of Influenza A and B is available using melting curve analysis(**blue** border).

### ■ Detection Result

Case \ Target		IC	SARS-CoV-2		Influenza A/B	RSV
			<i>E</i> gene	<i>RdRp</i> gene		
SARS-CoV-2	Confirmed	+	+	+	-	-
	Inconclusive	+	One positive		-	-
Influenza A		+	-	-	+ (T <sub>m</sub> 79~83°C)	-
Influenza B		+	-	-	+ (T <sub>m</sub> 68~72°C)	-
RSV		+	-	-	-	+
Negative		+	-	-	-	-
Invalid/Retest		-	+/-	+/-	+/-	+/-

\* IC: Internal Control

HelixDtec™

(Research Use Only)

## COVID/Flu/RSV Assay Kit

- Rapid, accurate, and multiplex detection for SARS-CoV-2, Influenza and RSV
- **FAST** assay: 48 minutes/40 cycles for qRT-PCR
- Incorporation of the UDG system to prevent carryover contamination



**HelixDtec™ COVID/Flu/RSV Assay Kit** is a multiplex real-time RT-PCR kit designed for the simultaneous detection and differentiation of SARS-CoV-2, Influenza, and RSV (Respiratory Syncytial Virus) within a single-tube reaction. To ensure precise and reliable detection, the kit utilizes distinct probes for 2 regions of the SARS-CoV-2 virus (*ORF8* and *ORF1ab* gene), wherein both probes are tagged same fluorescence. Influenza A/B and RSV A/B are amplified and detected respectively without subtyping. To prevent the carryover contamination of amplified products, this assay uses dUTP and heat-labile UDG enzymes.

### Product Information

Product			Size	Cat. No.
HelixDtec™	COVID/Flu/RSV Assay Kit	(Research Use Only)	100 tests	SCVFR100

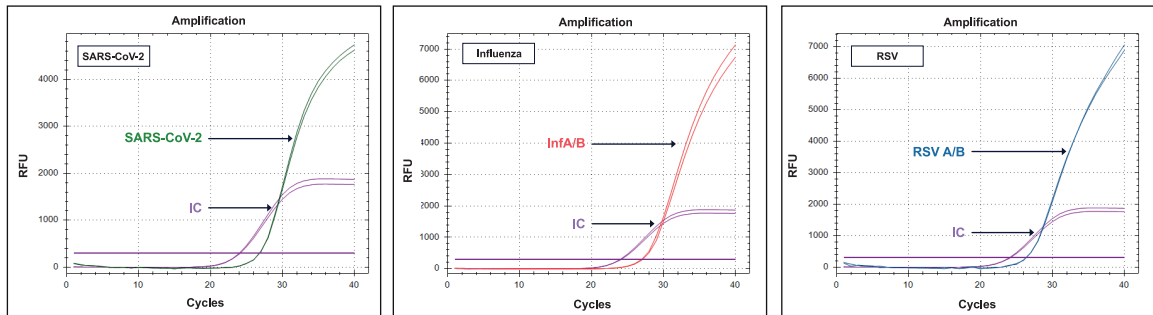
## Performance Characteristics

### ■ Applicable Real-Time PCR Instrument & Fluorescence Channels

Instrument	Target			
	SARS-CoV-2 (ORF8 and ORF1ab)	Influenza A/B	RSV A/B	IC
CFX96	HEX/VIC	Cal Red 610	FAM	Cy5
ABI 7500(Fast) /QuantStudio 5	VIC	Texas Red/ROX	FAM	Cy5

\* IC: Internal Control

### ■ Analytical Data



**Fig. Example of results in each case**

The graphs show multiplex real-time PCR results in each case. **HelixDtec™ COVID/Flu/RSV Assay Kit** identifies two SARS-CoV-2 targets(*ORF8* and *ORF1ab* gene), Influenza and RSV in a single reaction.

## ■ Detection Result

Case \ Target	IC	SARS-CoV-2 (ORF8 and ORF1ab)	Influenza A/B	RSV A/B
SARS-CoV-2 (ORF8 and ORF1ab)	+	+	-	-
Influenza A/B	+	-	+	-
RSV A/B	+	-	-	+
Negative	+	-	-	-
Invalid/Retest	-	+/-	+/-	+/-

\* IC: Internal Control

## ■ Analytical Sensitivity

Instrument	SARS-CoV-2 (HEX/VIC)	Inf A/B (CalRed610)	RSV A/B (FAM)	IC (Cy5)
Bio-Rad CFX96	6 copies/μl	Inf A: 6 copies/μl Inf B: 6 copies/μl	RSV A: 4 copies/μl RSV B: 6 copies/μl	10 copies/μl
ABI 7500 Fast	6 copies/μl	Inf A: 6 copies/μl Inf B: 6 copies/μl	RSV A: 4 copies/μl RSV B: 6 copies/μl	10 copies/μl

※ 5 μl of purified RNA were used in the reaction for the validation of analytical sensitivity.

## ■ Clinical Performance

Final results		Reference kit		
		Positive	Negative	Total
HelixDtec™ COVID/Flu/RSV Assay	Positive	247	0	247
	Negative	0	100	100
	Discordance	2	0	2
	Invalid	1	0	1
	Total	250	100	350

※ PPA(Positive Percent Agreement): 98.8% (247/250) [95% CI: 96.5 – 99.59%]

※ NPA(Negative Percent Agreement): 100.0% (100/100) [95% CI: 96.3 – 100%]

HelixDtec™

(Research Use Only)

## COVID, Flu A/B Assay Kit

- Rapid, accurate, and multiplex detection for SARS-CoV-2, Influenza A and B
- **FAST** Assay: 48 minutes/40 cycles for qRT-PCR
- Incorporation of the UDG system to prevent carryover contamination

”

**HelixDtec™ COVID, Flu A/B Assay Kit** is a multiplex real-time RT-PCR kit designed for the simultaneous detection and differentiation of SARS-CoV-2, influenza A and B within a single-tube reaction.

To ensure precise and reliable detection, the kit utilizes distinct probes for 2 regions of the SARS-CoV-2 virus (*ORF8* gene and *ORF1ab* gene). Influenza A and B are amplified and detected by each specific primer set and probes. To prevent the carryover contamination of amplified products, this assay uses dUTP and heat-labile UDG enzymes.

### Product Information

Product			Size	Cat. No.
HelixDtec™	COVID, Flu A/B Assay Kit	(Research Use Only)	100 tests	COFAB100

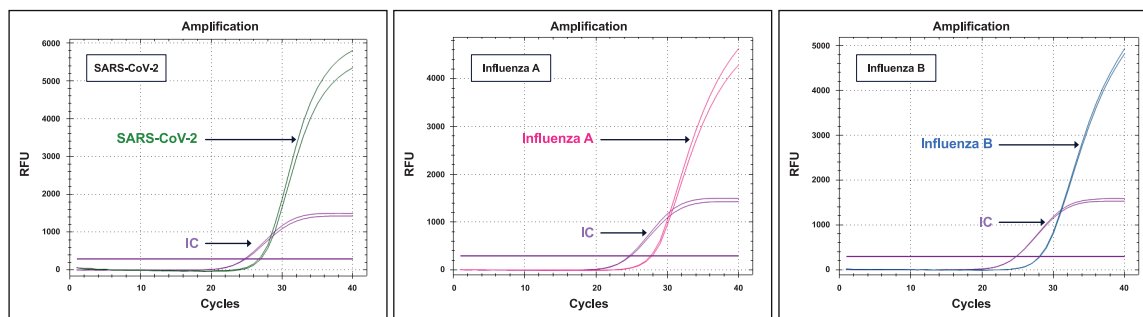
## Performance Characteristics

### ■ Applicable Real-Time PCR Instrument & Fluorescence Channels

Instrument	Target			
	SARS-CoV-2 (ORF8 and ORF1ab)	Influenza A	Influenza B	IC
CFX96	HEX/VIC	Cal Red 610	FAM	Cy5
ABI 7500(Fast) /QuantStudio 5	VIC	Texas Red/ROX	FAM	Cy5

\* IC: Internal Control

### ■ Analytical Data



**Fig. Example of results in each case**

The graphs show multiplex real-time PCR results in each case. **HelixDtec™ COVID, Flu A/B Assay Kit** identifies 2 targets of SARS-CoV-2, Influenza A and B in a single reaction.

## ■ Detection Result

Case \ Target	IC	SARS-CoV-2 (ORF8 and ORF1ab)	Influenza A	Influenza B
SARS-CoV-2 (ORF8 and ORF1ab)	+	+	-	-
Influenza A	+	-	+	-
Influenza B	+	-	-	+
Negative	+	-	-	-
Invalid/Retest	-	+/-	+/-	+/-

\* IC: Internal Control

## ■ Analytical Sensitivity

Instrument	SARS-CoV-2 (HEX/VIC)	Inf A (CalRed610)	Inf B (FAM)	IC (Cy5)
Bio-Rad CFX96	6 copies/μl	6 copies/μl	6 copies/μl	10 copies/μl
ABI 7500 Fast	6 copies/μl	6 copies/μl	6 copies/μl	10 copies/μl

※ 5 μl of purified RNA were used in the reaction for the validation of analytical sensitivity.

# HPV28 Genotyping Kit

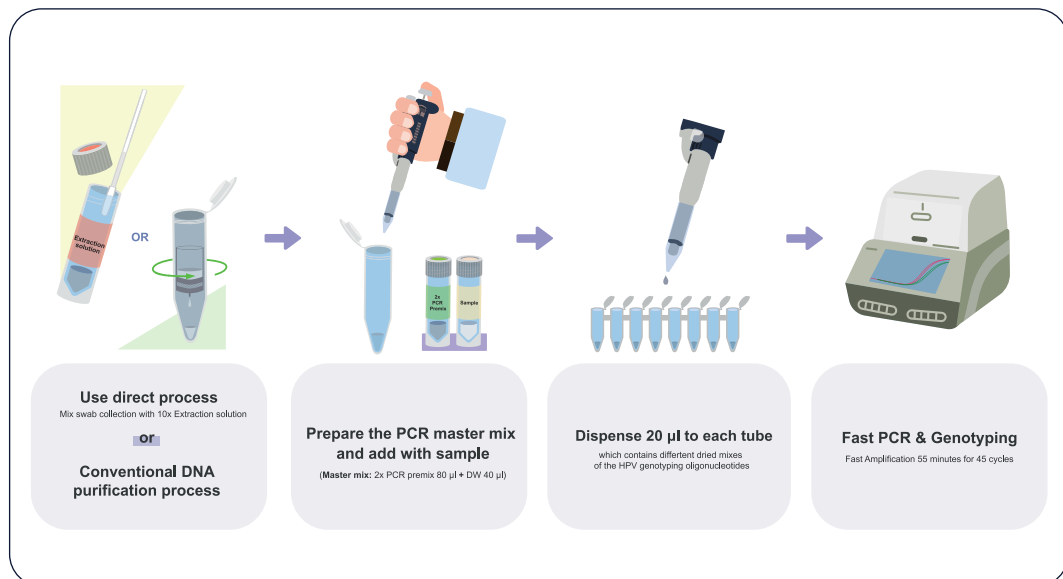
- **DIRECT:** Applicable to both purified DNA and unpurified specimen
- **FAST:** 1 hour[5 minutes for sample preparation + 55 minutes/45 cycles for PCR]
- **28 HPV genotypes(20 high risk, 8 low risk)**
  - 14 high-risk HPV genotypes: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68, 69
  - 6 probable high-risk genotypes: 26, 53, 66, 70, 73, 82
  - 8 low-risk HPV genotypes: 6, 11, 40, 42, 43, 44, 54, 61
- **UDG system:** Prevention of carryover contamination



**DirectFast™ HPV28 Genotyping Kit**, a probe-based real-time PCR kit, is designed for direct and fast detection and typing of human papillomavirus(HPV) DNA.

Crude DNA samples prepared by a lysis buffer(NAExDB) or heating, as well as purified DNA, can be used as templates for this assay without compromising sensitivity and accuracy. This kit's fast reaction completes the real-time PCR cycles within 1 hour.

**DirectFast™ HPV28 Genotyping Kit** simultaneously detects and identifies the 28 distinct HPV genotypes(20 High-risk and 8 Low-risk) in an 8-tube strip. Additionally, this assay contains a heat-labile UDG and dUTP system to prevent carryover contamination.



## Performance Characteristics

- **Technology:** Direct Fast qPCR

- **Analytical Specificity: Human Papillomavirus(HPV)**

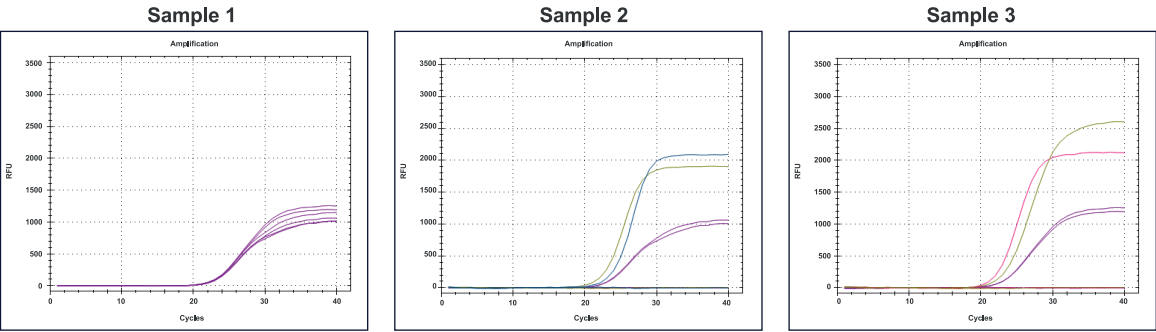
Classification	Type	No.
High-risk type	16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68, 69	14
Probable high-risk type	26, 53, 66, 70, 73, 82	6
Low-risk type	6, 11, Other_1(40, 42, 43), Other_2(44, 54, 61)	8

- **Applicable Real-Time PCR Instrument & Fluorescence Channels**

Instrument	Target			
	High-risk type	Probable high-risk type	Low-risk type	IC(HBB*)
Bio-Rad CFX96	FAM	VIC	Cal Red 610	Cy5
ABI 7500	FAM	JOE	ROX	TAMRA
QuantStudio 5	FAM	VIC	ROX	TAMRA
StepOnePlus™	FAM	JOE	ROX	TAMRA
Rotor-gene Q	FAM	VIC	Cal Red 610	Cy5

\* Internal control:HBB(Hemoglobin subunit beta)

■ Analytical Data



Product Information

Product			Size	Cat. No.
DirectFast™	HPV28 Genotyping Kit	(Research Use Only)	100 tests	HPVR-T100

**RealHelix™**

## ***Pathogenic Amoeba Detection Kit***

- Simultaneous detection of *N. fowleri* and *Acanthamoeba* spp in **singe-tube** reaction
- Probe-based real-time PCR kit
- High specificity: Chemically-modified hot start *Taq* application

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*Naegleria fowleri*(commonly referred to as the "brain-eating amoeba" or "brain-eating ameba"), is a free-living microscopic ameba(single-celled living organism). It can cause a rare and devastating infection of the brain called primary amebic meningoencephalitis(PAM). *Naegleria fowleri* usually infects people when contaminated water enters the body through the nose. Once the ameba enters the nose, it travels to the brain where it causes PAM, which is usually fatal.

*Acanthamoeba* is a microscopic, free-living ameba, or amoeba(single-celled living organism), that can cause rare, but severe infections of the eye, skin, and central nervous system. *Acanthamoeba* can be spread to the eyes through contact lens use, cuts, or skin wounds or by being inhaled into the lungs.

**RealHelix™ *Pathogenic Amoeba Detection Kit*** is a TaqMan® probe-based real-time PCR assay for the simultaneous detection of *Naegleria fowleri* and *Acanthamoeba* spp. in clinical samples.

2x qPCR premix contains hot-start PCR enzyme, dNTPs, buffers, Mg<sup>2+</sup>, and stabilizing agent. The hot-start PCR enzymes provide highly specific amplification of target DNA and minimize side products such as primer dimers. Based on the TaqMan® probe detection principle, the 5'-reporter dye and 3'-quencher dual-labeled oligonucleotide(TaqMan® probe) hybridize on a specific region within the amplified fragment. Target pathogen amplification is detected using FAM and HEX channel.

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## ■ Analytical Data

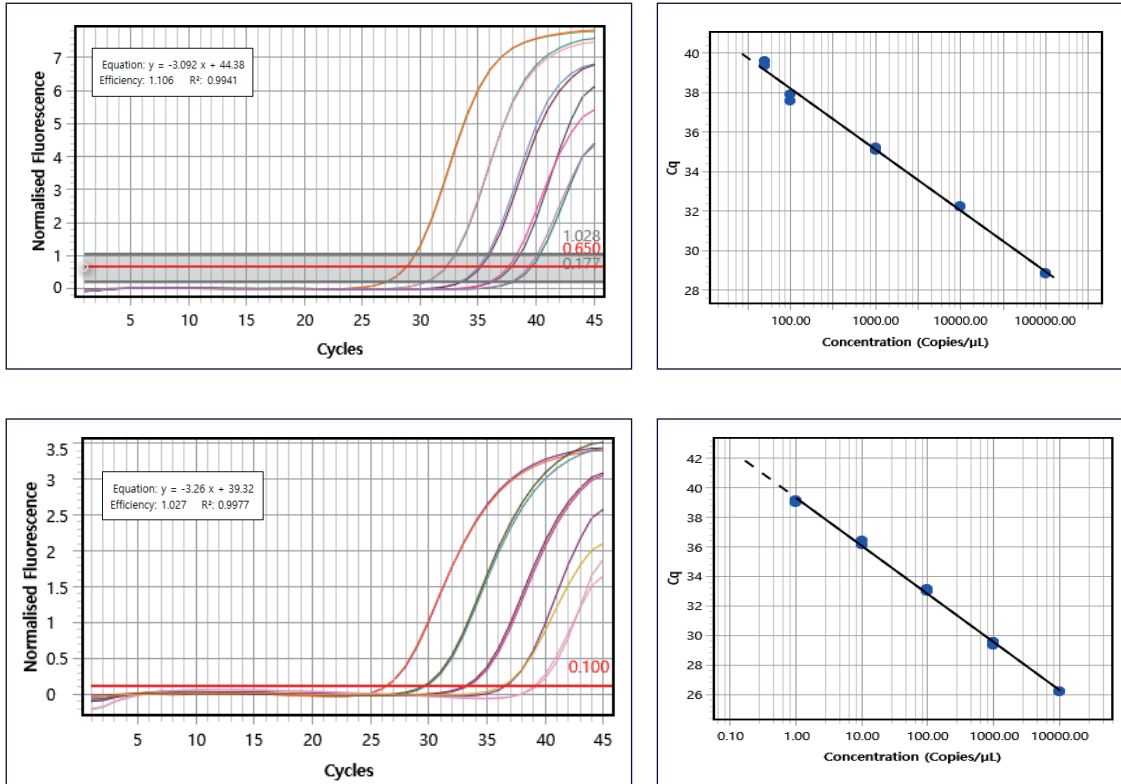


Fig. *Naegleria fowleri* and *Acanthamoeba* PC(plasmid DNA PC) was amplified from serial dilutions of DNA using the RealHelix™ *Pathogenic Amoeba Detection Kit*. 5 point dilution series of PC were obtained when assayed in duplex. Amplification plot and linear regression of *Naegleria fowleri* PC standard curve, respectively, slope: -3.09,  $R^2: 0.994$ (A). Amplification plot and linear regression of *Acanthamoeba* PC standard curve, respectively, slope: -3.26,  $R^2: 0.997$ (B).

## Product Information

Product	Size	Cat. No.
RealHelix™ <i>Pathogenic Amoeba Detection Kit</i>	50 tests	AMQP50

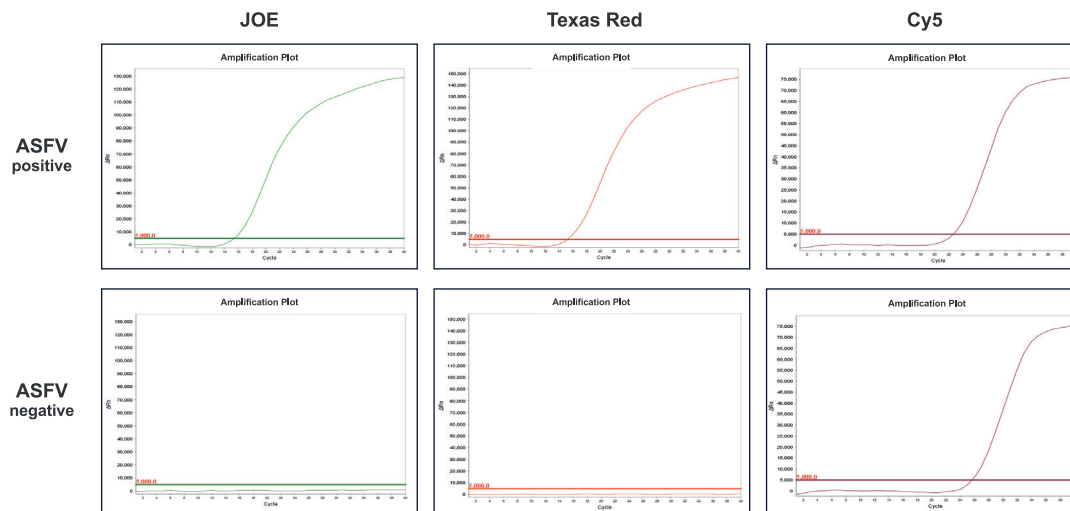
HelixDtec™

## ASFV Real-Time PCR Assay

- Probe-based real-time PCR kit

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**HelixDtec™ ASFV Real-Time PCR Assay** is a multiplex real-time quantitative assay kit that specifically detects the ASFV(African Swine Fever Virus) DNA. The primers and probes are designed to amplify and detect 2 regions of the P72 gene of ASFV to cover the wide range of variant viruses.



### Product Information

Product	Size	Cat. No.
HelixDtec™ ASFV Real-Time PCR Assay	100 tests	ASFV-T100

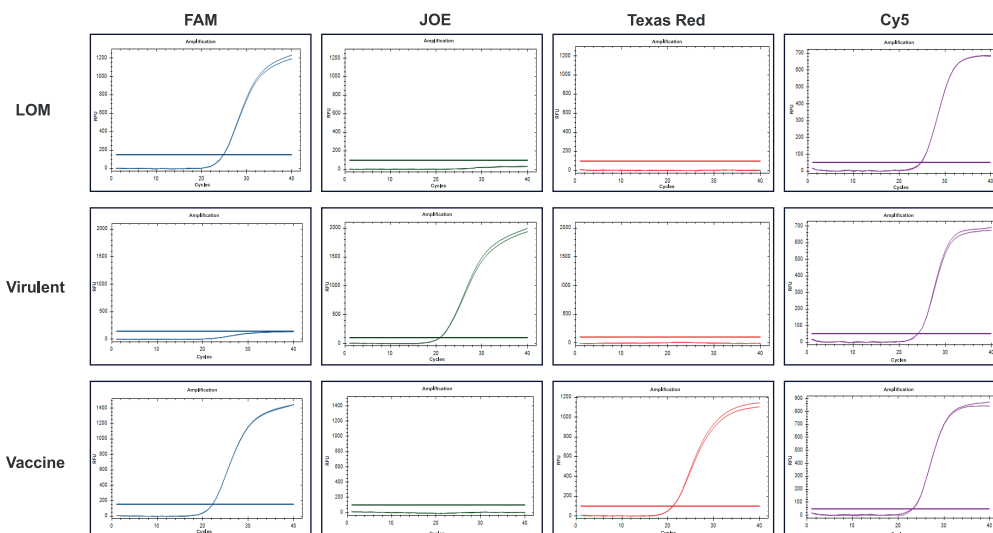
HelixDtec™

## CSFV Detection & Typing Kit

- In a **single-tube** reaction
- Probe-based real-time RT-PCR kit
- Allele-specific PCR-based detection  
: Virulent CSFV & LOM = 5'UTR / live vaccine strain = BVDV Ern

”

**HelixDtec™ CSFV Detection & Typing Kit** is designed to detect CSFV(classical swine fever viruses) and distinguish between the virulent strains and their vaccine strains(LOM and live vaccine strain) in a single-tube reaction using the one-step real-time RT-PCR technology.



### Product Information

Product	Size	Cat. No.
HelixDtec™ CSFV Detection & Typing Kit	100 tests	CSFV-T100

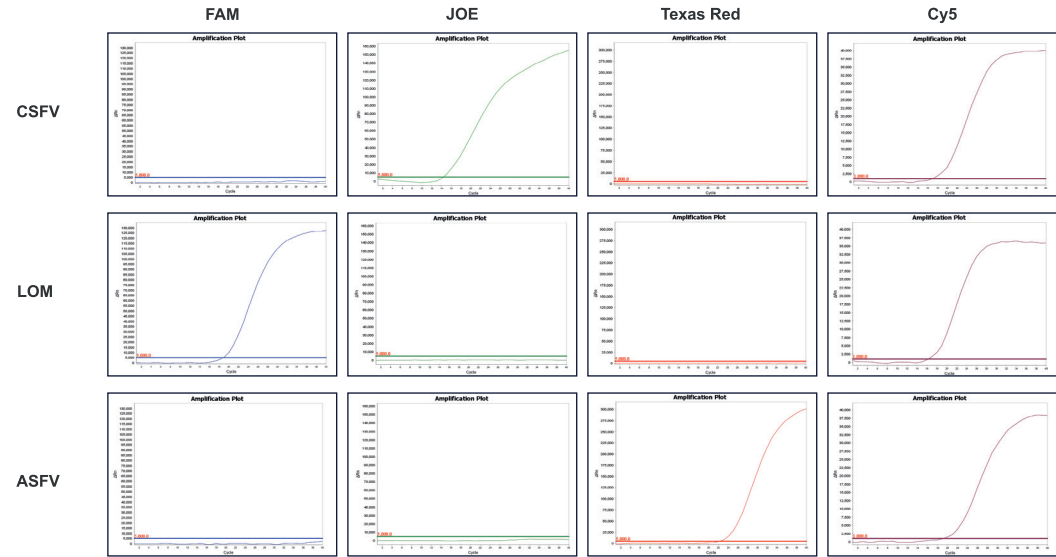
HelixDtec™

# CSFV & ASFV Assay

- In **single-tube** reaction
- Probe-based real-time RT-PCR kit
- Allele-specific PCR-based detection

“

**HelixDtec™ CSFV & ASFV Assay** is a multiplex real-time quantitative assay kit that simultaneously detects the virulent CSFV(Classical Swine Fever Virus) strains and their vaccine strain(LOM) as well as ASFV(African Swine Fever Virus) in a single-tube reaction. In this assay, specific primers and probes amplify and detect the 5' UTR in CSFV RNA and LOM vaccine RNA, and the P72 gene in ASFV DNA.



## Product Information

Product	Size	Cat. No.
HelixDtec™ CSFV & ASFV Assay	100 tests	CASFV-T100

**RealHelix™**

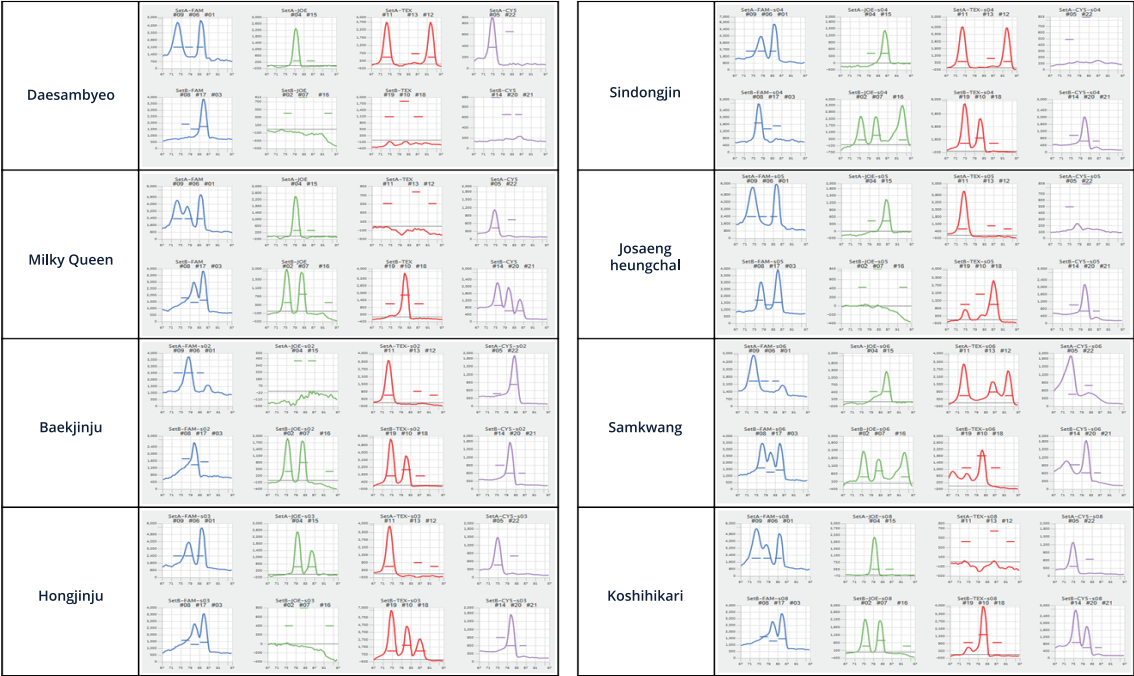
## **Rice-22 FMMA Kit**

- Application of **FMMA technology**
- Detection of 22 nucleotide polymorphisms in two-tube reactions
- Identification of 290 variants of Asian rice(*Oryza sativa*)
- **MULTIPLEX:** Up to 12-plex probe qPCR in a reaction

”

**RealHelix™ Rice-22 FMMA Kit** is designed to identify 290 variants of Asian rice(*Oryza sativa*) by detecting their 22 nucleotide polymorphisms in two-tube reactions. The kit's analysis is based on the **Fluorescence-based Multiple Melting Analysis(FMMA)** method developed by NanoHelix Co. Ltd., which can simultaneously analyze up to 12 different targets through multiple amplification and melting analyses in a single reaction using a 4-channel real-time PCR instrument. The data analysis through the provided “Rice-22 FMMA viewer” program conveniently identifies 290 variants of Asian rice commercialized in the market.





## Product Information

Product		Size	Cat. No.
RealHelix™	Rice-22 FMMA Kit	100 tests	RFM-100

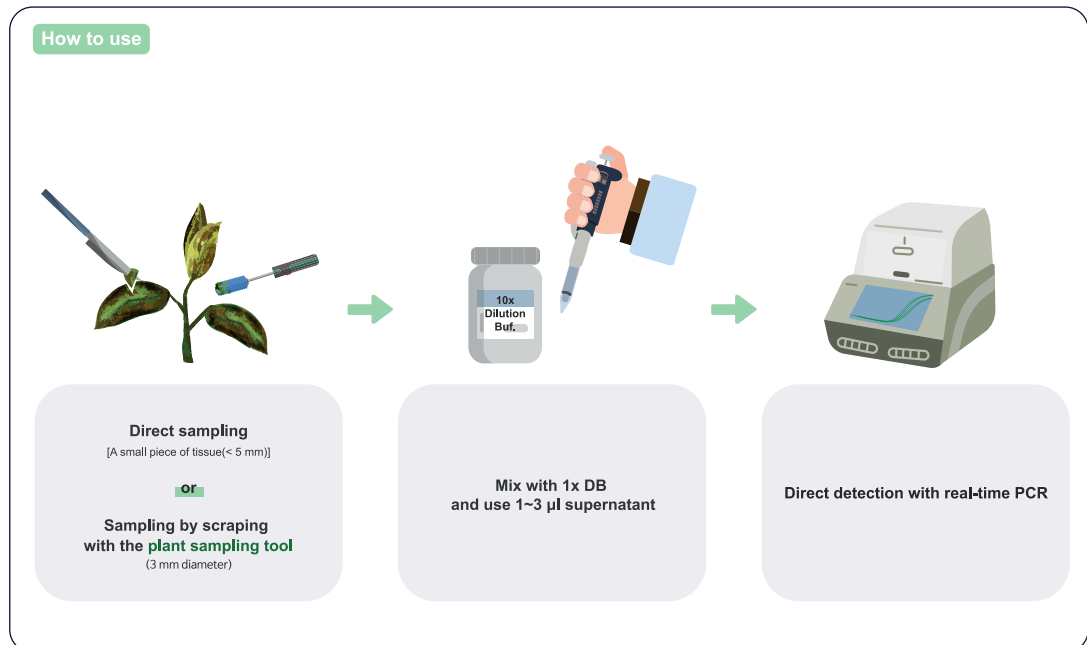
HelixDtec™

## Fireblight/Black Shoot Blight Pathogen Detection Kit

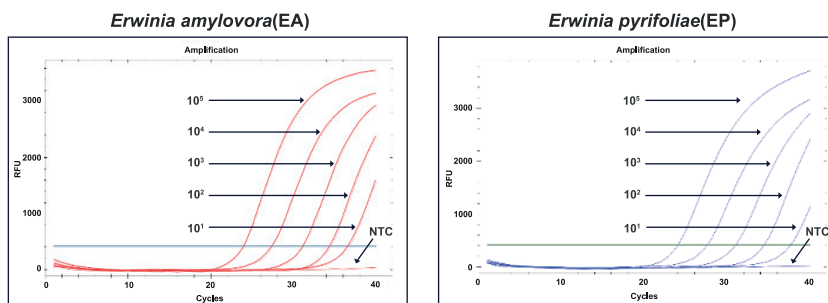
- Simultaneous EA-EP detection in **single-tube** reaction
- Probe-based real-time PCR kit
- Direct real-time PCR
- **FAST:** Sample preparation to detection, 50 minutes

”

**HelixDtec™ Fireblight/Black Shoot Blight Pathogen Detection Kit** is a probe-based fast real-time PCR product that simultaneously detects *Erwinia amylovora*, the major pathogen of fire blight, and *Erwinia pyripolliae*, the main causative agent of black shoot blight, from plant tissues through single-tube reaction. This kit contains a 2x premix including *Taq* DNA polymerase, dNTPs, MgCl<sub>2</sub>, and a unique buffer system to resist various PCR inhibitors from plant tissue samples. Since the 10x Dilution Buffer, a DNA extraction reagent, is included as a product component. Whole processes from DNA extraction to qPCR, can be performed with this product alone.



## ■ Analytical Data



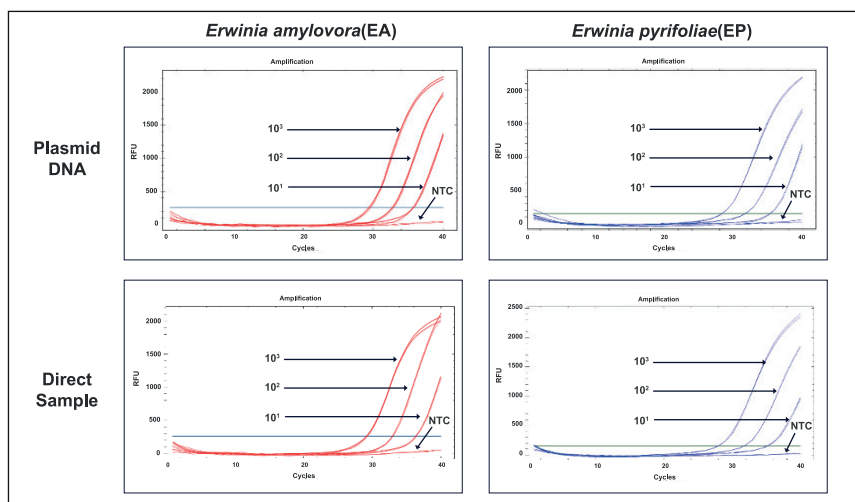
### EA/EP simultaneous detection sensitivity of EAEP-T100

**Template DNA:** Plasmid DNA contains EA- or EP-specific gene ( $10^5 \sim 10^1$  copies of each)

**Primer & probe:** EA- or EP-specific primer and probe set

**Fluorescent dyes:** EA=FAM / EP=JOE

**PCR instrument / Reaction time:** Bio-Rad CFX96/45 minutes



### EA/EP simultaneous detection results using direct plant samples.

**Template DNA:** (Control = Plasmid DNA) Plasmid DNA contains EA- or EP-specific gene

(Test = Direct sample) Add plasmid DNA to the 1x Dilution Buffer contains plant leaf

Plasmid DNA =  $10^3 \sim 10^1$  copies of each

**Primer & probe:** EA- or EP-specific primer and probe set

**Fluorescent dyes:** EA = FAM / EP = JOE

**PCR instrument / Reaction time:** Bio-Rad CFX96/45 minutes

## Product Information

Product		Size	Cat. No.
HelixDtec™	Fireblight/Black Shoot Blight Pathogen Detection Kit	100 tests	EAEP-T100
HelixLab™	Plant Sampling Tool	100 pcs	PST-T100

HelixDtec™

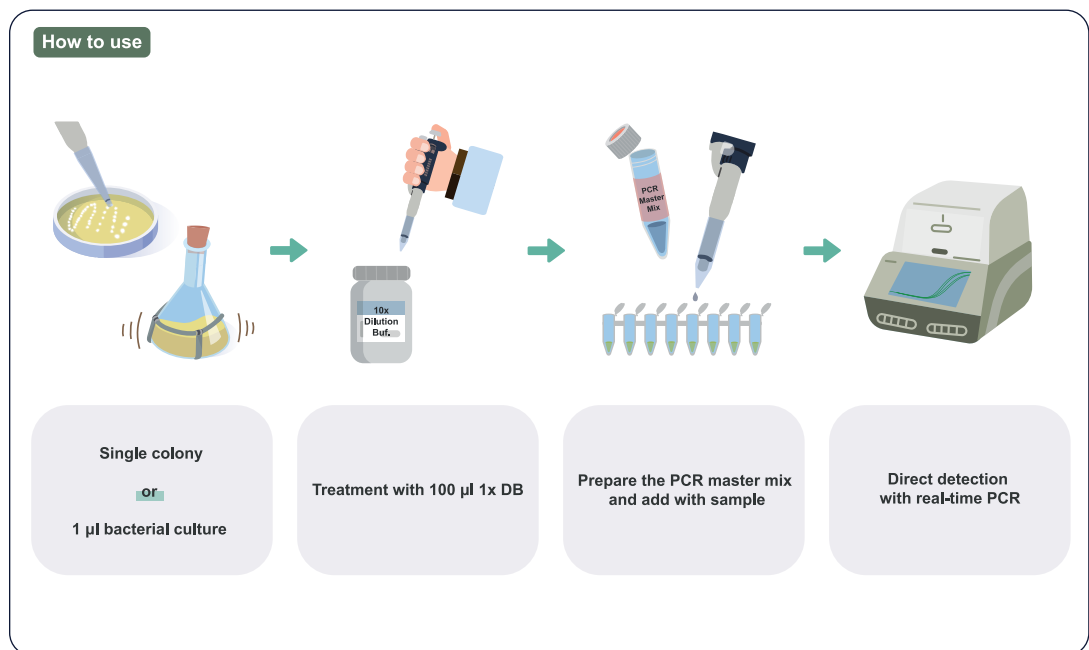
## Fireblight(*E. amylovora*) Dual Detection Kit

- 2 different sets of *E. amylovora*-specific primers
- Probe-based real-time PCR kit
- Direct real-time PCR from bacterial culture or colony
- **FAST**: Sample preparation to detection, 50 minutes

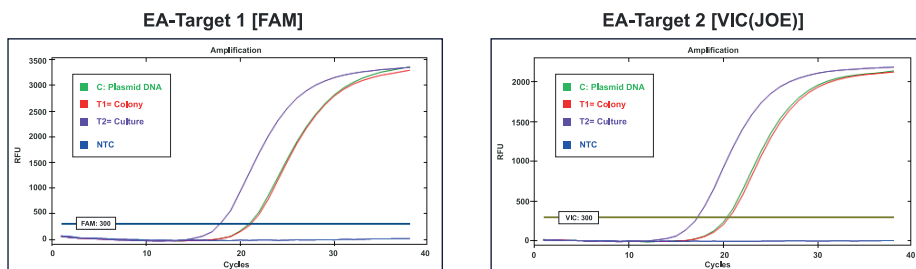
”

**HelixDtec™ Fireblight(*E. amylovora*) Dual Detection Kit** is a probe-based fast real-time PCR product that diagnoses the infection of *Erwinia amylovora*, the main causative agent of fire blight, from a plant-derived bacterial culture or colony with two sets of primers through single-tube reaction.

This kit contains a 2x premix including *Taq* DNA polymerase, dNTPs, MgCl<sub>2</sub>, and unique buffer system to resist various PCR inhibitors from plant tissue samples. Since the 10x Dilution Buffer, a DNA extraction reagent, is included as a product component, whole processes, from DNA extraction to qPCR, can be performed with this product alone.



## ■ Analytical Data



### EA dual detection using EAD-T100

**Template DNA:** Control = Plasmid DNA contains EA-specific gene

Test = 1x Dilution Buffer 100  $\mu$ l treated T1 or T2 sample 1  $\mu$ l

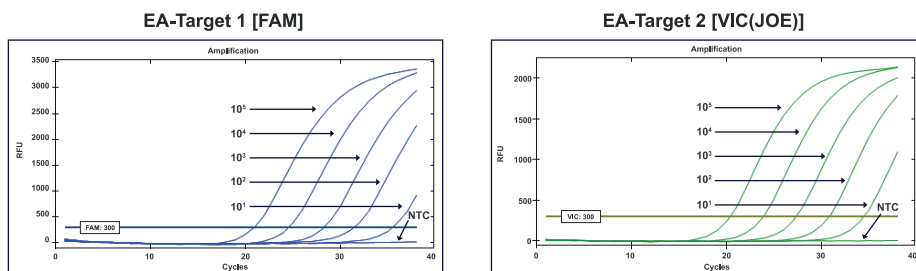
\*T1 = Dispersed single colony in DW 100  $\mu$ l

\*T2 = Bacterial culture

**Primer & probe:** EA-specific primer and probe set

**Fluorescent dyes:** Target 1 = FAM, Target 2 = VIC(JOE)

**PCR instrument / Reaction time:** Bio-Rad CFX96/45 minutes



### EA dual detection sensitivity of EAD-T100

**Template DNA:** Control = Plasmid DNA contains EA-specific gene ( $10^5 \sim 10^1$  copies of each)

**Primer & probe:** EA-specific primer and probe set

**Fluorescent dyes:** Target 1 = FAM, Target 2 = VIC(JOE)

**PCR instrument / Reaction time:** Bio-Rad CFX96/45 minutes

## Product Information

Product	Size	Cat. No.
HelixDtec™ Fireblight( <i>E.amylovora</i> ) Dual Detection Kit	100 tests	EAD-T100

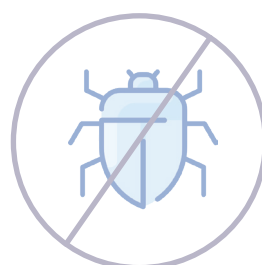
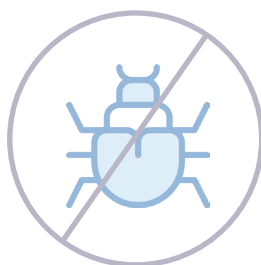
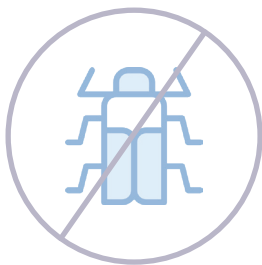
# Rice Planthopper ID LAMP Kit

- **Direct** and **fast** identification of 3 rice-damaging planthoppers by LAMP
- Observable color changing LAMP
- Sensitive and accurate
- Convenient POC testing















The **Rice Planthopper ID LAMP Kit** allows for discrimination of 3 rice-damaging planthoppers; White-backed, Brown and Small brown planthopper.













This kit is based on the Direct-LAMP(loop-mediated isothermal amplification) technology and assays can be done in 30 minutes and does not require the DNA purification process. Amplification of the target can be confirmed by the naked eye through color change after the reaction.



(A)

White-backed planthopper				Brown planthopper				Small brown planthopper			
1~3 instar	4~5 instar	Imago	NTC	1~3 instar	4~5 instar	Imago	NTC	1~3 instar	4~5 instar	Imago	NTC
											

(B)

White-backed planthopper LAMP primer				Brown planthopper LAMP primer				Small brown planthopper LAMP primer			
WBPH	BPH	SPH	NTC	WBPH	BPH	SPH	NTC	WBPH	BPH	SPH	NTC
											

**Fig. The 3 species of rice planthopper were identified using the Rice Planthopper ID LAMP Kit.** Each rice planthopper treated with extraction solution was directly used as a template. Panel (A) shows the successful colorimetric detections regardless of their ages. Panel (B) shows the amplification specificities of the LAMP primer sets.

## Product Information

Product		Size	Cat. No.
HelixDtec™	<i>N.lugens</i> (brown planthopper) LAMP Assay	100 tests	NLLMP-T100
HelixDtec™	<i>L.striatellus</i> (small brown planthopper) LAMP Assay	100 tests	LSLMP-T100
HelixDtec™	<i>S.furcifera</i> (white-back planthopper) LAMP Assay	100 tests	SFLMP-T100



# Who

# We Are

Established in 2008, NanoHelix began by producing research-use enzymes and now manufactures large-scale for molecular diagnostic applications. Utilizing an ICT-based smart factory system with ISO 13485:2016 and GMP facilities, we can produce 5 billion units of *Taq* DNA polymerase annually; equivalent to more than 2 billion PCR tests. NanoHelix continues to develop consistently reliable products, reinforcing our ability to supply 70% of Korea's COVID-19 MDx raw material reagents and putting us at the forefront of the pandemic response. We will maintain our reputation as an exceptional manufacturer and supplier of raw materials for molecular diagnostics and nucleic acid-based MDx kits.

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Contract Manufacturer | Custom Development | OEM Business



# Contact us

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