PaxGenBio

CE IVD

PaxView® SARS-CoV-2 **real-time RT-PCR** Kit

Intended Use

- In vitro diagnostic medical devices: IVDs
- Diagnosis of SARS-CoV-2 infection
- Respiratory specimens such as oropharyngeal or nasopharyngeal swabs

Features & Advantages

- One-step RT-PCR in a single-tube
- Since the human RNase P gene is used as an internal control, it is possible to check whether the test result is accurate or not by monitoring the entire test process such as sample collection, RNA extraction, and RT-PCR
- High sensitivity and high specificity – Limit of detection (LoD) : **1 copy/μl (5 copies/reaction)**
- User-friendly and simple procedure
- Accurate diagnosis regardless of the SARS-CoV-2 Variants (Alpha, Beta, Gamma, Delta, Omicron)
- Result report is served to Lab by providing Report system (Viewer program)

PaxView® SARS-CoV-2 real-time RT-PCR Kit

Product principle

- Real-time RT-PCR
- Targeted genes : RdRp gene and N gene
- The Kit includes the primers and probe set targeting the human RNase P gene that serves as an internal positive control for the validation of whole procedures, including specimen collection, RNA purification, and PCR

* All clinical samples should be tested for human RNase P gene to control for specimen quality and extraction.

(source: CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel_ Effective: 01 Dec 2020)

https://www.fda.gov/media/134922/download

Kit Components

Components	2X RT-PCR PREMIX	PRIMER/ PROBE MIX	POSITIVE CONTROL
Image			
Volume	1000 µl/tube	500 µl/tube	50 µl/tube
tube	1 tube	1 tube	1 tube

Performance Characteristics

Analytical Sensitivity (Limit of Detection)

- Limit of Detection (LoD) : 1 copy/µl (5 copies/reaction)

Precision

- Repeatability within CV 3%
- Reproducibility within CV 2%

Prevention of carry-over contamination

- Preventing carry-over contamination by using UDG

Analytical Specificity (cross-reactivity)

- No cross-reactivity with 26 respiratory pathogens tested

Analytical specificity (interference)

- No interference with 9 interfering substances tested

Real-time PCR machines

- CFX96 Dx system (Bio-Rad)
- 7500 Fast RT-PCR (Thermo Fisher Scientific)

Analysis of Results

Ct. value for controls

Controls	FAM (RdRp)	HEX (N)	Cy5 (IC)
Positive	≤35	≤35	≤35
Negative	No Ct.	No Ct.	No Ct.

Cut-off

Targets	Fluorescence	Ct value	Result
RdRp	FAM	≤40.0	+
N	HEX	≤40.0	+
IC	Cy5	≤40.0	+

Interpretation

Cases	FAM (RdRp)	HEX (N)	Cy5 (IC)	Determination
1	+	+	+	Positive
2	+	+	-	Positive *
3	+	-	+/-	Inconclusive **
4	-	+	+/-	
5	-	-	+	Negative
6	-	-	-	Invalid ***

Note: Cautions for interpretation

* The result is interpreted as positive, when both FAM(RdRp) and HEX(N), even if Cy5(IC) is negative.
** In cases that unable to interpret
- recommend to retest with high specimen concentration
- recommend to do sequencing
*** When invalid, recommend doing total entire procedure from specimen collection

Clinical performance

Medical Device		Comparator		
		Positive	Negative	Total
PaxView	Positive	94	0	94
	Negative	0	190	190
	Total	94	190	284
Clinical Sensitivity		100% x 94/94 = 100% (95% CI: 96.07% - 100%)		
Clinical Specificity		100% x 190/190 = 100% (95% CI: 98.02% - 100%)		

Ordering information

Medel	Cat. No.	Package	Storage	Expiration date
PaxView® SARS-CoV-2 real-time RT-PCR Kit	R0502N	100 tests/Kit	-25 ℃ ~ -15 ℃	12 months

PaxView® SARS-CoV-2 real-time RT-PCR Kit

SARS-CoV-2 Variant Virus Detection Test

■ SARS-CoV-2 Variant Virus Classification and Definition

Name (WHO Label)	Pango Lineage	First Detected	Characteristics compared with SARS-CoV-2
Alpha	B.1.1.7	United Kingdom	82 % increased transmission, 61 % increased mortality
Beta	B.1.351 / B.351.2 / B.351.3	South Africa	50 % increased transmission, Antibody neutralization reaction decrease
Gamma	P.1 / P.1.1 / P.1.2	Brazil	161 % increased transmission, 50 % increased mortality
Delta	B.1.617.2 / AY.1 / AY.2 / AY.3	India	198 % increased transmission, Antibody neutralization reaction decrease
Omicron	B.1.1.529	Botswana	Unknown

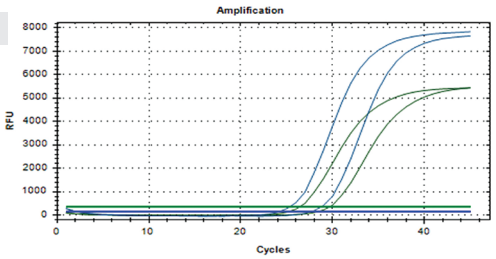
■ SARS-CoV-2 Variant Virus Detection Test

- Used Kit : PaxView® SARS-CoV-2 real-time RT-PCR Kit
- Used Equipment : CFX96 (Bio-Rad)
- Used Specimen : SARS-CoV-2, SARS-CoV-2 variants (Alpha, Beta, Gamma, Delta)
- Specimen Source : NCCP (National Culture Collection for Pathogens) of Korea Disease Control and Prevention Agency
- Test Method : Test with 1/10 serial dilution of each virus

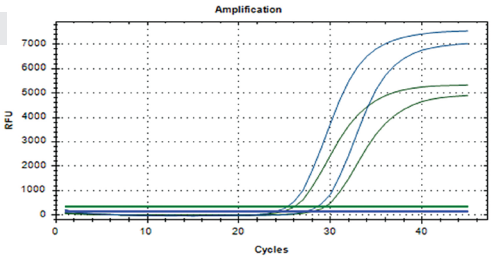
▶Results

Case	SARS-CoV-2		Alpha		Beta		Gamma		Delta	
Target gene	RdRp	N	RdRP	N	RdRP	N	RdRp	N	RdRp	N
1	25.47	25.1	25.36	25.24	25.37	25.06	25.5	24.95	25.18	24.58
2	28.83	28.43	28.84	28.45	28.6	28.22	28.67	28.14	28.54	27.97
3	32.14	31.84	32.37	32.11	31.97	31.54	31.96	31.32	31.88	31.34
4	34.21	34.78	35.56	34.31	35.24	34.85	35.29	34.39	35.14	34.34
5	36.98	37.37	39.12	36.28	36.57	37.25	36.89	37.49	38.38	37.8

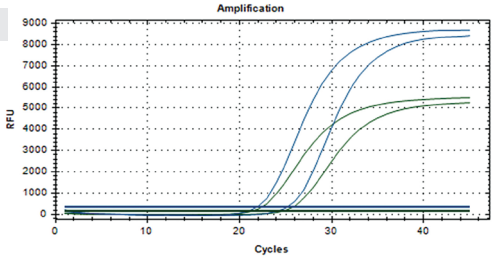
Alpha



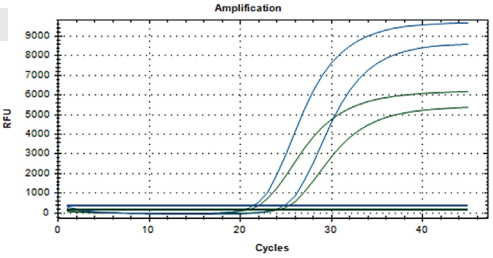
Beta



Gamma



Delta



▶Conclusion

- The test results indicated that PaxView® SARS-CoV-2 real-time RT-PCR Kit detected SARS-CoV-2 and **SARS-CoV-2 variants (Alpha, Beta, Gamma, Delta)**.
- The in silico analysis of primers and probes suggests that PaxView® SARS-CoV-2 real-time RT-PCR Kit would detect SARS-CoV-2 Variants (Alpha, Beta, Gamma, Delta, Omicron, Epsilon, Zeta, Eta, Iota, Kappa, etc.).

Comparison of analytical sensitivity

- Kit : PaxView® SARS-CoV-2 real-time RT-PCR Kit and 4 Kits approved by the MFDS(KFDA)
- Real-time PCR instrument : CFX96 (Bio-Rad)
- Sample : Positive reference materials(Vircell), SARS-CoV-2 influx from china (19B), SARS-CoV-2 UK variant (Alpha), SARS-CoV-2 South Africa variant (Beta)

■ Results

▶ Comparison with Positive reference material

Case		PaxView	A	B	C	D
Positive reference material (Vircell)	200 cp/ul	+	+	+	+	+
	60 cp/ul	+	+	+	+	+
	20 cp/ul	+	+	+	+	-
	6 cp/ul	+	-	+	+	-
	2 cp/ul	+	-	+	+	-
	0.6 cp/ul	+	-	-	-	-
	0.2 cp/ul	-	-	-	-	-

▶ Comparison with SARS-CoV-2 Variants

Case			PaxView	A	B	C	D
SARS-CoV-2 Variants of Concern	SARS-CoV-2 influx from china (NCCP43326)	X 10^{-5}	+	+	+	+	+
		X 10^{-7}	+	+	+	+	+
		X 10^{-9}	+	-	-	-	-
	SARS-CoV-2 UK variant (NCCP43381)	X 10^{-5}	+	+	+	+	+
		X 10^{-7}	+	+	+	+	+
		X 10^{-9}	-	-	-	-	-
	SARS-CoV-2 South Africa variant (NCCP43382)	X 10^{-5}	+	+	+	+	+
		X 10^{-7}	+	+	+	+	+
		X 10^{-9}	-	-	-	-	-

■ Conclusion

- As a result of comparative analysis in positive reference materials, PaxView® SARS-CoV-2 real-time RT-PCR Kit detected positive reference material at a lower concentration than the comparison product → The result of the analytical sensitivity test with positive reference materials indicated that PaxView® SARS-CoV-2 real-time RT-PCR Kit detected the positive reference material at a lower concentration compared to the other kits tested.
- As a result of a comparative analysis in SARS-CoV-2 variants, Kit detected positive reference material at the same or lower concentration than the comparative product. → The result of the sensitivity test indicated that PaxView® SARS-CoV-2 real-time RT-PCR Kit detected the SARS-CoV-2 variants at the same or lower concentration compared to the other kits tested.

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