Genematrix

REF NR12A

CE

IVD

NeoPlex™ COVID-19 FAST

Multiplex Real-time PCR Reagents for SARS-CoV-2 Detection
For professional *in vitro* diagnostic use only

[INTENDED USE]

The 'NeoPlex™ COVID-19 FAST' Assay is a qualitative *in vitro* test for the simultaneous detection and conf irmation of N gene and RdRp gene in SARS-CoV-2 causing COVID-19 from Respiratory specimens* based on real-time reverse transcription polymerase chain reaction(RT-PCR) assay. This test kit is intended for pro fessional use.

* Respiratory specimens including : Nasopharyngeal swab, Oropharyngeal swab, Nasopharyngeal and Oropharyngeal sw ab Sputum, Bronchoalveolar lavage fluid(BAL), Saliva

[KIT CONTENTS] 96 Tests /Kit

Contents	Volume(96T)	Storage condition	Shelf life
COVID-19 FAST PPM	500 µL x 1 Vial	Upper limit -20 ℃	12 months
FAST RT Master Mix	500 µL x 1 Vial		
COVID-19 FAST Positive Control (PC)	100 µL x 1 Vial		
DW (RNase-free Water)	1 mL x 1 Vial		

[Compatible Instruments]

- CFX96 Real-Time PCR Detection System (Bio-Rad, Cat No.185-5096)
- Gentier96 Real-time PCR System (Xi'an TianLong Science and Technology)
- Rotor-Gene Q 5plex HRM (Qiagen, Cat No. 9001580)
- Applied Biosystems™ 7500 (Fast) Real-time PCR Instrument system (Thermo Fisher Scientific, Cat No. 4351105)
- Applied Biosystems™ 7500 Real-time PCR Instrument system (Thermo Fisher Scientific, Cat No. 4345241)
- Applied Biosystems™ Quantstudio5 (Thermo Fisher Scientific, Cat No. A28134)

[Nucleic acid Extraction]

Manufacturer	Instrument (Cat No.)	Extraction Kit (Cat No.)
Qiagen	N/A (Manual)	QIAamp DSP Viral RNA Mini Kit (61904)
LG Chem	AdvanSure E3 System (YETS0001EG)	AdvanSure NA EX Kit (RPE0001K01)
Roche Life Science	Roche MagNA Pure 96 system (06 541 089 001)	DNA and Viral NA Small Volume Kit (06543588001)
Hanwool TPC	NC-15 PLUS (HWTD-01-48)	AlphaPrep™ Viral DNA/RNA Extraction Kit (VDR-B096V)
Qiagen	QIAcube Connect (9002864)	QIAamp DSP Viral RNA Mini Kit (61904)

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[Additional required equipment and materials]

- 0.2 ml 8-Tube PCR Strips without Caps, low profile, white (Bio-Rad, Inc., Cat No. TLS0851)
- Optical Flat 8-Cap Strips for PCR Tubes (Bio-Rad, Inc., Cat No. TCS0803)
- MicroAmp™ Optical 8-Tube Strip, 0.2-mL (Cat No. 4316567)
- MicroAmp™ Optical 8-Cap Strip (Cat No. 4323032)
- MicroAmp™ Fast 8-Tube Strip, 0.1-mL (Cat No. 4358293)
- Strip Tubes and Caps, 0.1ml (Cat No. 981103)
- 0.2ml 8-Tube Strip, Ultrathin wall, with flat optical cap, white (DN Biotech (Hong Kong) Limited, Cat No. 3121103)
- Pipettes set, P2/P10, P20, P200, and P1000 aerosol barrier tips
- Micro Centrifuge, Vortexer mixer
- Disposable powder-free gloves

⚠ Use PCR plate strip caps only. Do Not use PCR plate sealing film.

[KIT STORAGE AND STABILITY]

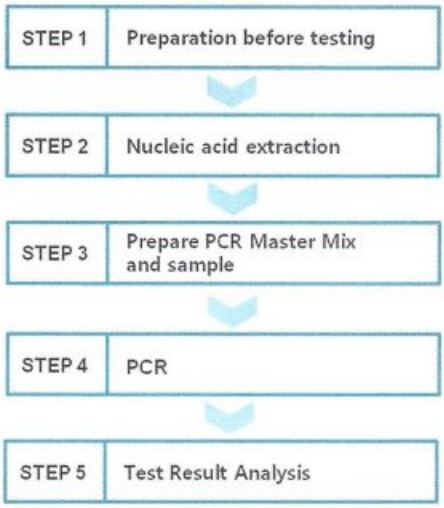
- Store the kit below -20℃.
- Kit materials are stable until the expiration date printed on the label under un-opened condition.
- Kit's shelf life is twelve **(12)** months.
- Please use the reagents within four **(4)** weeks after opening.

[WARNINGS AND PRECAUTIONS]

1. This device is intended for *in vitro* use only. Do not use the device for other purposes.
2. Wear personal protective equipments, such as gloves and lab coats when handling NeoPlex™ COVID-19 FAST and/or specimens.
3. Do not smoke, drink or eat while handling NeoPlex™ COVID-19 FAST and/or samples.
4. Please be careful when handling samples to prevent infections of user and/or indirect contact to a perso n. Sample contains a risk of infections and unknown diseases.
5. Do not use reagents from different lots or from different tubes of the same lot.
6. If you do not frequently inspect the product, keep a kit in a refrigerator for a certain amount of time. Do not freeze/thaw over four times. Repeated frozen/thawed product may result in false negative and false positive results.
7. Be careful not to contaminate the product when extracting nucleic acid, amplifying PCR product, using po sitive control (PC, Positive Control). The use of filter tips is recommended to prevent contamination of t he product.
8. It is recommended that the sample or the positive control (PC, Positive Control) contained in the product to be frozen and stored separately from the freezer storing the product.
9. Use the sterilized consumable laboratory supplies. Do not reuse it.

10. Add the extracted nucleic acid sample and positive control (PC, Positive Control) into the reaction soluti on in a space separate from the PCR reaction solution preparation space.
11. Before using, read this instruction for use carefully.
12. Use calibrated measuring tools. (e.g. pipette)
13. Please check the expiration date before using the reagent.
14. Keep Positive Control separately when using to avoid contamination.
15. Before starting the PCR, make sure the lid is closed properly.
16. Dispose the product in accordance with local or national regulations.
17. Please consult with doctor about the test results.

[TEST PROCEDURE]



STEP 1. Preparation before testing

1) Preparation before testing

A. Prepare all the devices and reagent before use.

B. Place the kit on ice when thawing components and preparing PCR Master Mix.

C. After preparing PCR Master Mix, place them on ice.

⚠ Do not freeze/thaw over four times.

2) Specimen Collection, Transportation and Storage

A. Specimens for use: Respiratory specimens

B. Store specimens at 2~8 °C for no longer than seventy two (72) hours. For pro-longed storage, Freeze under -70 °C condition.

C. Extracted nucleic acids should be stored at -70 °C or lower.

D. Transportation of clinical specimens must comply with local regulations for the transport of etiologic agents.

⚠
- Use only the specimen type listed in the instruction manual.
- The specimen volume should be above 0.5ml.
- Wear eye protection, laboratory coats and disposable gloves when handling specimens.
- Specimens should be stored under the storage conditions above. Otherwise, the wrong test results can be obtained.
- Sample information should be recorded to avoid confusion.

STEP 2. Nucleic acid extraction

Nucleic acid should be collected from a fresh specimen to ensure suitable Nucleic acid quality and quantity.

After pre-treatment, nucleic acid extraction can be done by automated purification system or using manual prep kits (QIAamp DSP Viral RNA Mini Kit or equivalent). In that case, Sample volume is 200㎕ and Elution volume is 40㎕. Automatic nucleic acid extraction kits validated for use with the NeoPlex™ COVID-19 FAST can be used. The nucleic acid extraction should be performed according to the Nucleic acid extraction kit manufacturer's instructions as below.

Instrument	Extraction Kit	Manufacturer	Sample volume	Elution volume
Roche MagNA Pure 96 system (06 541 089 001)	DNA and Viral NA Small Volume Kit (06543588001)	Roche Life Science	200 ㎕	50 ㎕
QIAcube Connect (9002864)	QIAamp DSP Viral RNA Mini Kit (61904)	Qiagen	200 ㎕	50 ㎕
NC-15 PLUS (HWTD-01-48)	AlphaPrep™ Viral DNA/RNA Extraction Kit (VDR-B096V)	Hanwool TPC	200 ㎕	50 ㎕
AdvanSure E3 System (YETS0001EG)	AdvanSure NA EX Kit (RPE0001K01)	LG Chem	200 ㎕	100 ㎕

1) Pre-treatment of the Specimen

BAL, Naso/Oropharyngeal swab	Sputum
Place the specimen at room temperature	Place the specimen at room temperature
Prepare the sample by vortexing for 20 seconds before use.	Add saline or PBS to the specimen (1 of specimen: 2 of saline or PBS) and vortex it for 1 minute.
	Leave it at room temperature for 20 minutes.
	Vortex it for 30 seconds

2) For nucleic acid extraction, follow the manufacturer's protocol.

We recommend QIAamp DSP Viral RNA Mini Kit or equivalent nucleic acid extraction kit/automatic machine for nucleic acid extraction.

STEP 3. Prepare PCR Master Mix and sample

1) Prepare the PCR Master Mix

Contents	Volume per test
COVID-19 FAST PPM	5ul
FAST RT Master Mix	5ul
DW (RNase-free Water)	5ul
Total Volume	15ul

Note : Calculate the required amount of each reagent based on the number of reactions (samples + controls).

2) Vortex and briefly centrifuge the PCR Master Mix.

3) Place 15μL aliquots of the PCR Master mix into 0.2ml PCR tubes and close the lids.

4) Add 5μl of each nucleic acid sample to its respective tube.

Contents	1 test (Volume)
PCR Master Mix	15ul
Nucleic acid sample	5ul
Total Reaction Volume	20ul

⚠
- It is recommended that the PCR mixture to be prepared just before use.
- Aerosol-resistant filter tips and tight gloves should be used when preparing samples. Take great care to avoid cross contamination.
- Defrost the reagents completely
- Centrifuge the reagent tubes briefly to remove the drops from the inside of the lids.

5) Make the control amplification reactions

- Negative Control(NC): Add 5μl of DW(RNase-free water (divided)) instead of nucleic acid samples to the tube
- Positive Control(PC): Add 5μl of COVID-19 FAST Positive Control(PC) instead of nucleic acid samples to the tube

⚠
- Use a new pipette tip with each different sample.
- Avoid cross-contamination of PCR Master mix and samples with Positive Control.
- Do not label on the cap of the reaction tubes as fluorescence is detected through the cap.
- Centrifuge the PCR tube thoroughly for 30 seconds

STEP 4. PCR

1) Selection of fluorescence channels

Instruments	RdRp gene	N gene	IC
CFX96	FAM	HEX	Cy5
Gentier96	FAM	HEX	Cy5
Rotor-Gene Q	Green	Yellow	Red
ABI 7500(FAST)	FAM	JOE	Cy5
ABI 7500	FAM	JOE	Cy5
Quantstudio5	FAM	VIC	Cy5

2) Setting the PCR protocol

PCR protocol should be set according to the table below.

Segment	Temperature (°C)	Time	Cycles
1	50	5 min	1
2	98	30 sec	1
3	98	1 sec	40
4*	60	15(30) sec**	

* Segment 4: Fluorescence data should be collected during the 60°C incubation step

** Segment 4 : CFX96/Gentier96/Rotor-Gene time 15 sec & ABI 7500(Fast)/ABI7500/Quantstudio5 time 30 sec

STEP 5. Test result analysis

For the analysis of the test result after PCR amplification, take the Ct* result and interpret the according to the following table.

Instruments	Threshold
CFX96	100
Gentier96	200
Rotor-Gene	0.05
ABI 7500 (Fast)	10,000
ABI 7500	10,000
Quant Studio 5	10,000

[INTERPRETATION OF TEST RESULTS]

Control Testing Result Interpretation

All test controls should be examined prior to interpretation of patient results. If the controls are not valid, the patient results cannot be interpreted. Control results should be interpreted according to the criteria outlined below.

Acceptance criteria for a Valid Test

Case	Positive Control	Negative Control	Internal Control	Interpretation
1	+	-	+	Acceptable
2	+	-	-*	
3	+	+	+	Invalid/Re-test
4	+	+	-	
5	-	+	+	
6	-	+	-	
7	-	-	+	
8	-	-	-	

* if the IC is negative, but the positive and negative controls yield expected results, and the patient specimen has at least one target detected. A positive result may be assigned.

Patient Specimen Result Interpretation

For the analysis of the test result after PCR amplification, take the amplification curve (or amplification plot) result. (For CFX96, check the 'Quantitation' tab and ABI 7500(Fast) and ABI7500, GENTIER96, check the 'Analysis' tab, Quant Studio 5, check the 'Result' tab, Rotor-Gene, check the 'Quantitation Analysis' tab) and interpret the result according to the two following interpretation tables. First which describes the individual ta rget gene Ct thresholds, and the second which outlines the patient specimen result interpretation algorithm.

2. Interpretation criteria for result analysis

Target	Dye	Ct *	Interpretation
COVID-19 RdRp gene	Refer to the fluorescence channels table of [Step 4] PCR Selection of fluorescence channel	≤ 40	Positive (+)
		N/A	Negative (-)
COVID-19 N gene		≤ 40	Positive (+)
		N/A	Negative (-)
IC**		≤ 40	Positive (+)
		N/A	Negative (-)

** Ct: threshold cycle value*

** The Internal Control (IC) gene is to monitor the nucleic acid isolation procedure and the possibility of PCR inhibition.

3. Patient Specimen Result Interpretation Algorithm

Case	RdRp gene	N gene	IC	Interpretation
1	+	+	+	SARS-CoV-2 Positive
2	+	-	+	
3	-	+	+	
4	+	+	-	
5	+	-	-	
6	-	+	-	
7	-	-	+	SARS-CoV-2 Negative
8	-	-	-	Invalid/Re-test

[Quality Control]

NeoPlex™ COVID-19 FAST includes COVID-19 FAST Positive Control(PC) as positive control and DW(RNase-free Water) as negative control. For all runs, valid test results must be obtained for both Positive and Negative control. Positive Control result must be Positive (Valid). Negative Control result must be Negative (Valid). If the positive and negative control results are consistently invalid, contact us for technical assistance.

[TROUBLE SHOOTING]

1. If the Internal control signal is not observed

Potential causes	Solution
Error in specimen collection	If the both target and IC signal were not observed, recollect the specimen
Nucleic acid extraction failure	Read carefully the instruction for use of nucleic acid extraction kit and extract the nucleic acid from specimen again.
Incorrect PCR setting	Repeat the detection procedure with a correct setting
Incorrect PCR cycle or machine temperature	Check the PCR conditions and repeat the PCR under the correct setting if necessary
The fluorescence for data analysis do not comply with the protocol	Select the correct fluorescence for each target listed in this Instruction guide for data analysis
Leaving reagents at room temperature for a long time or incorrect storage condition	Check the storage conditions and the expiration date of the reagents and use a new kit
Presence of inhibitor	Dilute the template nucleic acid in distilled water (10-100x) and repeat the PCR with the diluted nucleic acid (If specimen is still present, restart from nucleic acid extraction procedure)
High load of pathogen's nucleic acid	Dilute the template nucleic acid in distilled water (10-100x) and repeat the PCR with the diluted nucleic acid

2. If signals are observed at the negative control / false positive

Potential causes	Solution
Presence of cross contamination	Decontaminate all surfaces and instruments with sodium hypochlorite or ethanol. Use filter tips during the extraction procedure. Change tips among tubes. Repeat the nucleic acid extraction with the new set of reagents

3. If no signal is observed at the positive control / false negative

Potential causes	Solution
Error in specimen collection	Recollect the specimen
Incorrect storage of the specimen	Recollect the specimen and repeat the whole process. Make sure the product is stored in recommended conditions
Error in nucleic acid extraction	Re-extract the nucleic acid
Incorrect PCR setting	Repeat the PCR with corrected setting
Error in adding nucleic acid to corresponding PCR tubes	Check the sample numbers for nucleic acid containing tubes and make sure to add nucleic acid into correct PCR tubes during detection process.
Incorrect PCR mixture	Check whether all components are added or not (If you use to pre-composed premix, should be reduce sensitivity) Each reagents should be used after homogenization and spin down reagent tube before put the real-time PCR

[PERFORMANCE CHARACTERISTICS]

1 Analytical sensitivity

1.1 Cut-off value

For the cut-off establishment, Ct value was set to be 40 for all targets.

1.2 Limit of Detection (LoD)

This study was conducted to determine the sensitivity by testing respiratory specimens

The proportion of positive results obtained from each concentration was subjected to 95% hit rate by probit analysis, and LoD of each target were obtained by performing 24 times of the tests.

No.	Instrument	Target	Specimen Type	LoD (copies/ul)
1	CFX96	RdRp gene	NPS	8.24
			OPS	8.24
			Sputum	8.34
			BAL	8.24
			NPS+OPS	8.24
			Saliva	8.34
		N gene	NPS	8.63
			OPS	8.79
			Sputum	8.72
			BAL	8.79
			NPS+OPS	8.79
			Saliva	8.72
2	ABI 7500(Fast)	RdRp gene	NPS	8.24
			OPS	8.34
			Sputum	8.14
			BAL	8.34
			NPS+OPS	8.14
			Saliva	8.24
		N gene	NPS	8.63
			OPS	8.72
			Sputum	8.72
			BAL	8.79
			NPS+OPS	8.72
			Saliva	8.72
3	ABI 7500	RdRp gene	NPS	8.43
			OPS	8.24
			Sputum	8.14
			BAL	8.24

			NPS+OPS	8.34
			Saliva	8.34
		N gene	NPS	8.79
			OPS	8.63
			Sputum	8.79
			BAL	8.63
			NPS+OPS	8.79
			Saliva	8.72
4	Quantstudio5	RdRp gene	NPS	8.14
			OPS	8.24
			Sputum	8.34
			BAL	8.34
			NPS+OPS	8.34
			Saliva	8.43
		N gene	NPS	8.79
			OPS	8.79
			Sputum	8.72
			BAL	8.79
			NPS+OPS	8.63
			Saliva	8.72
5	Gentier96	RdRp gene	NPS	8.43
			OPS	8.34
			Sputum	8.34
			BAL	8.34
			NPS+OPS	8.43
			Saliva	8.24
		N gene	NPS	8.63
			OPS	8.63
			Sputum	8.52
			BAL	8.72
			NPS+OPS	8.63
			Saliva	8.63
6	Rotor Gene-Q	RdRp gene	NPS	8.34
			OPS	8.34
			Sputum	8.24
			BAL	8.34
			NPS+OPS	8.24
			Saliva	8.34
		N gene	NPS	8.79
			OPS	8.79

Sputum	8.72
BAL	8.63
NPS+OPS	8.72
Saliva	8.79

2 Analytical Specificity (Interference, Cross reactivity)

Total fourteen (14) substances, endogenous and exogenous source, were studied to determine their interfering effect and no interference reactions was found with the concentration as below.

No.	Interfering substance	Concentration	Remark
1	Human Blood	2 % v/v	Endogenous substances
2	mucin	50 µg/ml	
3	Dexamethasone	1.53 µmol/L	Exogenous substances
4	Zanamivir	3.3 mg/ml	
5	Oseltamivir	25 mg/ml	
6	Mupirocin	6.6 mg/ml	
7	Tobramycin	5 µg/ml	
8	Lidocaine	85.3 µmol/L	
9	Eucalyptol	10% v/v	
10	Guaifenesin	15.2 mmol/L	
11	L-Nicotine	6.2 µmol/L	
12	Ethanol	7% v/v	Disinfecting/Cleaning Substances
13	ESwab™ (Copan 482C)	N/A	Transport Medium
14	Rest™ UTM (NobleBio UTM-001B)	N/A	

For analytical specificity, three (3) times of cross reactivity studies used fifty four(54) different pathogens similar with RI-pathogens and other pathogens. As a result, PCR amplification and cross reactivity were not observed with all the pathogens as below.

No.	Manufacturer	Pathogen	Result
1	ATCC	Human coronavrius 229E	No Cross-reactivity
2	Zeptometrix	Human coronavirus OC43	No Cross-reactivity
3	Zeptometrix	coronavirus culture fluid (NL63)	No Cross-reactivity
4	Korean Isolate from clinical sample	Human coronavirus HKU1	No Cross-reactivity
5	BEI	Genomic RNA from Middle East Respiratory Syndrome Coronavirus (MERS-CoV), EMC/2012 Human coronavirus	No Cross-reactivity
6	BEI	SARS Coronavirus, Tor2, Complete Gateway® Clone Set, Recombinant in Escherichia coli	No Cross-reactivity
7	KBPV	Influenza A virus(H3N2)	No Cross-reactivity
8	ATCC	Influenza A virus, A/Virginia/ATCC/2009	No Cross-reactivity
9	ATCC	Influenza B virus, B/Hong Kong/5/72	No Cross-reactivity

10	ATCC	Human respiratory syncytial virus A, Long	No Cross-reactivity
11	ATCC	Human respiratory syncytial virus B, 9320	No Cross-reactivity
12	ATCC	Human parainfluenza virus 1 HPIV-1/C35	No Cross-reactivity
13	ATCC	Human parainfluenza virus 2 HPIV-2/Greer	No Cross-reactivity
14	ATCC	Human parainfluenza virus 3 HPIV-3/C243	No Cross-reactivity
15	KBPV	Parainfluenza virus 4a	No Cross-reactivity
16	KBPV	Parainfluenza virus 4b	No Cross-reactivity
17	KBPV	Human adenovirus 2	No Cross-reactivity
18	ATCC	Quantitative Synthetic Human bocavirus (HBoV) DNA	No Cross-reactivity
19	Zeptometrix	Human metapneumovirus (hMPV) 9 Type A1	No Cross-reactivity
20	Zeptometrix	Human metapneumovirus (hMPV) 3 Type B1	No Cross-reactivity
21	ATCC	Human rhinovirus 1A	No Cross-reactivity
22	ATCC	Human rhinovirus 1B	No Cross-reactivity
23	ATCC	Human Rhinovirus 14	No Cross-reactivity
24	ATCC	Human Coxsackievirus A 21	No Cross-reactivity
25	ATCC	Echovirus 4	No Cross-reactivity
26	ATCC	Echovirus 20	No Cross-reactivity
27	ATCC	Chlamydophila pneumoniae strain J-21	No Cross-reactivity
28	ATCC	Mycoplasma pneumoniae	No Cross-reactivity
29	ATCC	Streptococcus pneumoniae	No Cross-reactivity
30	ATCC	Legionella pneumophila subsp pneumophila	No Cross-reactivity
31	ATCC	Haemophilus influenzae	No Cross-reactivity
32	ATCC	Bordetella pertussis	No Cross-reactivity
33	ATCC	Bordetella parapertussis	No Cross-reactivity
34	ATCC	Moraxella (Branhamella) catarrhalis	No Cross-reactivity
35	Zeptometrix	Streptococcus pyogenes	No Cross-reactivity
36	Zeptometrix	Streptococcus oralis	No Cross-reactivity
37	Zeptometrix	Streptococcus mitis	No Cross-reactivity
38	ATCC	Legionella anisa	No Cross-reactivity
39	Zeptometrix	Legionella longbeachae	No Cross-reactivity
40	ATCC	Haemophilus parainfluenzae	No Cross-reactivity
41	ATCC	Aggregatibacter aphrophilus	No Cross-reactivity
42	ATCC	Haemophilus haemolyticus	No Cross-reactivity
43	Zeptometrix	Bordetella bronchiseptica	No Cross-reactivity
44	Zeptometrix	Bordetella holmesii	No Cross-reactivity
45	Zeptometrix	Pseudomonas aeruginosa	No Cross-reactivity
46	Zeptometrix	Klebsiella pneumoniae	No Cross-reactivity

47	Zeptometrix	Acinetobacter baumannii	No Cross-reactivity
48	ATCC	Haemophilus ducreyi	No Cross-reactivity
49	ATCC	Lactobacillus acidophilus	No Cross-reactivity
50	ATCC	Escherichia coli	No Cross-reactivity
51	ATCC	Bacteroides fragilis	No Cross-reactivity
52	ATCC	Enterobacter cloacae	No Cross-reactivity
53	ATCC	Proteus mirabilis	No Cross-reactivity
54	ATCC	Staphylococcus epidermidis	No Cross-reactivity

3 Carry over / Cross-Contamination

This study was performed to evaluate the carry-over and potential cross contamination effect. High concentrated positive sample and negative control sample were cross tested using same PCR instrument, and 100% negative results (64/64)(95% CI: 94.40%-100%) for each negative specimen were determined, respectively.

4 Precision

4.1 Repeatability

Repeatability was assessed by testing for twenty (20) different days, two (2) runs per day, three (3) cycles per run. Targets were set in three (3) levels of concentration, and 100% agreement was found determining the repeatability. The CV criteria, 2%, was met for all test results.

① CFX96

Target	Concentration	Within-run				Between-run				Between - Day			
		N	SD	CV(%)	Positive	N	SD	CV(%)	Positive	N	SD	CV(%)	Positive
RdRp gene	10X LoD	120	0.4	1.3	100%	40	0.3	0.9	100%	20	0.2	0.6	100%
	5X LoD	120	0.5	1.5	100%	40	0.3	0.7	100%	20	0.2	0.5	100%
	2X LoD	120	0.5	1.5	100%	40	0.3	0.7	100%	20	0.2	0.5	100%
N gene	10X LoD	120	0.5	1.4	100%	40	0.3	0.8	100%	20	0.2	0.5	100%
	5X LoD	120	0.5	1.4	100%	40	0.3	0.9	100%	20	0.2	0.6	100%
	2X LoD	120	0.5	1.3	100%	40	0.3	0.7	100%	20	0.2	0.5	100%
NC (DW)		120	-	-	0% (0/120)	40	-	-	0% (0/40)	20	-	-	0% (0/20)

② ABI7500 (Fast)

Target	Concentration	Within-run				Between-run				Between - Day			
		N	SD	CV(%)	Positive	N	SD	CV(%)	Positive	N	SD	CV(%)	Positive
RdRp gene	10X LoD	120	0.5	1.4	100%	40	0.3	0.7	100%	20	0.2	0.6	100%
	5X LoD	120	0.5	1.5	100%	40	0.4	1.0	100%	20	0.3	0.8	100%
	2X LoD	120	0.6	1.6	100%	40	0.3	0.9	100%	20	0.2	0.7	100%
N gene	10X LoD	120	0.5	1.4	100%	40	0.2	0.7	100%	20	0.2	0.5	100%
	5X LoD	120	0.6	1.7	100%	40	0.3	0.9	100%	20	0.2	0.6	100%
	2X LoD	120	0.6	1.6	100%	40	0.3	0.7	100%	20	0.2	0.5	100%
NC (DW)		120	-	-	0% (0/120)	40	-	-	0% (0/40)	20	-	-	0% (0/20)

③ Gentier96

Target	Concentration	Within-run				Between-run				Between - Day			
		N	SD	CV(%)	Positive	N	SD	CV(%)	Positive	N	SD	CV(%)	Positive
RdRp gene	10X LoD	120	0.4	1.3	100%	40	0.2	0.7	100%	20	0.2	0.5	100%
	5X LoD	120	0.6	1.6	100%	40	0.4	1.0	100%	20	0.3	0.8	100%
	2X LoD	120	0.5	1.4	100%	40	0.3	0.7	100%	20	0.2	0.6	100%
N gene	10X LoD	120	0.5	1.4	100%	40	0.3	0.8	100%	20	0.2	0.7	100%
	5X LoD	120	0.6	1.6	100%	40	0.3	1.0	100%	20	0.2	0.7	100%
	2X LoD	120	0.6	1.5	100%	40	0.3	0.9	100%	20	0.2	0.6	100%
NC (DW)		120	-	-	0% (0/120)	40	-	-	0% (0/40)	20	-	-	0% (0/20)

④ ABI7500

Target	Concentration	Within-run				Between-run				Between - Day			
		N	SD	CV(%)	Positive	N	SD	CV(%)	Positive	N	SD	CV(%)	Positive
RdRp gene	10X LoD	120	0.0	1.2	100%	40	0.2	0.7	100%	20	0.2	0.5	100%
	5X LoD	120	0.6	1.6	100%	40	0.3	0.9	100%	20	0.2	0.6	100%
	2X LoD	120	0.5	1.4	100%	40	0.3	0.7	100%	20	0.2	0.5	100%
N gene	10X LoD	120	0.4	1.2	100%	40	0.2	0.7	100%	20	0.2	0.5	100%
	5X LoD	120	0.6	1.7	100%	40	0.3	1.0	100%	20	0.2	0.7	100%
	2X LoD	120	0.6	1.5	100%	40	0.3	0.8	100%	20	0.2	0.6	100%
NC (D.W)		120	-	-	0% (0/120)	40	-	-	0% (0/40)	20	-	-	0% (0/20)

⑤ Quant Studio 5

Target	Concentration	Within-run				Between-run				Between - Day			
		N	SD	CV(%)	Positive	N	SD	CV(%)	Positive	N	SD	CV(%)	Positive
RdRp gene	10X LoD	120	0.0	1.3	100%	40	0.2	0.7	100%	20	0.2	0.5	100%
	5X LoD	120	0.6	1.6	100%	40	0.3	0.9	100%	20	0.2	0.6	100%
	2X LoD	120	0.5	1.5	100%	40	0.3	0.8	100%	20	0.2	0.5	100%
N gene	10X LoD	120	0.5	1.4	100%	40	0.3	0.9	100%	20	0.2	0.6	100%
	5X LoD	120	0.6	1.6	100%	40	0.3	0.9	100%	20	0.2	0.6	100%
	2X LoD	120	0.5	1.5	100%	40	0.3	0.8	100%	20	0.2	0.6	100%
NC (D.W)		120	-	-	0% (0/120)	40	-	-	0% (0/40)	20	-	-	0% (0/20)

⑥ Rotor-Gene

Target	Concentration	Within-run				Between-run				Between - Day			
		N	SD	CV(%)	Positive	N	SD	CV(%)	Positive	N	SD	CV(%)	Positive
RdRp gene	10X LoD	120	0.0	1.3	100%	40	0.3	0.8	100%	20	0.2	0.5	100%
	5X LoD	120	0.5	1.5	100%	40	0.3	0.8	100%	20	0.2	0.6	100%
	2X LoD	120	0.5	1.3	100%	40	0.3	0.9	100%	20	0.2	0.6	100%
N gene	10X LoD	120	0.4	1.3	100%	40	0.3	0.8	100%	20	0.2	0.5	100%
	5X LoD	120	0.6	1.7	100%	40	0.4	1.1	100%	20	0.3	0.9	100%
	2X LoD	120	0.6	1.5	100%	40	0.3	0.8	100%	20	0.2	0.5	100%
NC (D.W)		120	-	-	0% (0/120)	40	-	-	0% (0/40)	20	-	-	0% (0/20)

4.2 Reproducibility

The reproducibility study was performed with four different conditions: for Between-lot (3 lots), Between-tester (3 testers), Between-instrument (3 instruments), and Between-site (3 sites). All results showed 100% agreements.

4.2.1 Between-Lot

Target	Titer	Lot 1 (n = 30)			Lot 2 (n = 30)			Lot 3 (n = 30)			Between - lot (n = 90)		
		SD	CV(%)	*(%)	SD	CV(%)	*(%)	SD	CV(%)	*(%)	SD	CV(%)	*(%)
RdRp gene	10X LoD	0.4	1.1	100%	0.5	1.4	100%	0.5	1.4	100%	0.5	1.4	100%
	5X LoD	0.6	1.6	100%	0.6	1.7	100%	0.5	1.6	100%	0.6	1.6	100%
	2X LoD	0.6	1.5	100%	0.5	1.4	100%	0.6	1.6	100%	0.5	1.5	100%
N gene	10X LoD	0.4	1.2	100%	0.4	1.2	100%	0.4	1.3	100%	0.4	1.2	100%
	5X LoD	0.7	1.8	100%	0.6	1.8	100%	0.6	1.6	100%	0.6	1.8	100%
	2X LoD	0.6	1.5	100%	0.6	1.7	100%	0.6	1.5	100%	0.6	1.6	100%
NC (DW)	-	-	100%		-	100%		-	100%		-	100%	

4.2.2 Between-Tester

Target	Titer	Tester 1 (n = 30)			Tester 2 (n = 30)			Tester 3 (n = 30)			Between - tester (n = 90)		
		SD	CV(%)	*(%)	SD	CV(%)	*(%)	SD	CV(%)	*(%)	SD	CV(%)	*(%)
RdRp gene	10X LoD	0.5	1.6	100%	0.5	1.4	100%	0.5	1.5	100%	0.5	1.5	100%
	5X LoD	0.6	1.7	100%	0.6	1.6	100%	0.6	1.6	100%	0.6	1.7	100%
	2X LoD	0.5	1.4	100%	0.5	1.4	100%	0.6	1.5	100%	0.6	1.5	100%
N gene	10X LoD	0.5	1.5	100%	0.4	1.3	100%	0.4	1.3	100%	0.5	1.4	100%
	5X LoD	0.5	1.4	100%	0.6	1.8	100%	0.5	1.4	100%	0.5	1.5	100%
	2X LoD	0.6	1.6	100%	0.6	1.6	100%	0.6	1.7	100%	0.6	1.6	100%
NC (DW)	-	-	100%		-	100%		-	100%		-	100%	

4.2.3 Between-Instrument

Target	Titer	Instrument 1 (n = 30)			Instrument 2 (n = 30)			Instrument 3 (n = 30)			Between - Instrument (n = 90)		
		SD	CV(%)	*(%)	SD	CV(%)	*(%)	SD	CV(%)	*(%)	SD	CV(%)	*(%)
RdRp gene	10X LoD	0.5	1.6	100%	0.5	1.4	100%	0.5	1.5	100%	0.5	1.5	100%
	5X LoD	0.6	1.7	100%	0.6	1.6	100%	0.6	1.6	100%	0.6	1.7	100%
	2X LoD	0.5	1.4	100%	0.5	1.4	100%	0.6	1.5	100%	0.6	1.5	100%
N gene	10X LoD	0.5	1.5	100%	0.4	1.3	100%	0.4	1.3	100%	0.5	1.4	100%
	5X LoD	0.5	1.4	100%	0.6	1.8	100%	0.5	1.4	100%	0.5	1.5	100%
	2X LoD	0.6	1.6	100%	0.6	1.6	100%	0.6	1.7	100%	0.6	1.6	100%
NC (DW)	-	-	100%		-	100%		-	100%		-	100%	

4.2.4 Between-site

Target	Titer	Site 1 (n = 30)			Site 1 (n = 30)			Site 1 (n = 30)			Between - site (n = 90)		
		SD	CV(%)	*(%)	SD	CV(%)	*(%)	SD	CV(%)	*(%)	SD	CV(%)	*(%)
RdRp gene	10X LoD	0.5	1.4	100%	0.4	1.2	100%	0.4	1.3	100%	0.4	1.3	100%
	5X LoD	0.6	1.7	100%	0.6	1.6	100%	0.5	1.5	100%	0.6	1.6	100%
	2X LoD	0.6	1.6	100%	0.5	1.3	100%	0.6	1.6	100%	0.5	1.5	100%
N gene	10X LoD	0.5	1.5	100%	0.5	1.4	100%	0.4	1.3	100%	0.5	1.4	100%
	5X LoD	0.6	1.6	100%	0.5	1.5	100%	0.6	1.6	100%	0.6	1.6	100%
	2X LoD	0.5	1.5	100%	0.6	1.7	100%	0.5	1.5	100%	0.6	1.6	100%
NC (DW)	-	-	100%		-	100%		-	100%		-	100%	

5 Clinical evaluation

The clinical study was performed in the clinical laboratory with the specimen collected from various sources, such a hospitals or clinics. The comparable CE-marked product already available on EU market was used as a comparator test. Prior to testing with the NeoPlex™ COVID-19 FAST, the specimens were confirmed with sequencing analysis as a reference method.

The clinical study results were analyzed with 2x2 table, and summarized as below:

Target	Positive Percent Agreement	Negative Percent Agreement
RdRp gene	100% (80/80) [95% CI 95.49-100]	100% (80/80) [95% CI 95.49-100]
N gene	100% (80/80) [95% CI 95.49-100]	100% (80/80) [95% CI 95.49-100]

The results show 100% agreement of NeoPlex™ COVID-19 FAST with the comparator in both reactive and non-reactive specimens.

[LIMITATION OF TEST]

1. Results from this test must be correlated with the clinical history, epidemiological data, and other data of the patient available to the clinician.
2. If you do not use the samples and other specimens described in this manual, you may get inaccurate results.
3. Although the results of this test are negative, it is not advisable to exclude the possibility that the infection is actually present.
4. It is not excluded that this kit shows false positive results due to the presence of cross-contamination.
5. False negative results may occur due to polymerase inhibition. COVID-19 IC may help to identify any substance existing in the specimens interfering with nucleic acid isolation and PCR amplification.
6. This kit is for professional use only. Only trained healthcare provider can use this kit.

NeoPlex™ COVID-19 FAST

Multiplex Real-time PCR Reagents for SARS-CoV-2 Detection
For professional *in vitro* diagnostic use only

[SYMBOLS]

REF	LOT		
Catalogue number	Batch code	Date of manufacture	Use-by date
IVD			
In vitro diagnostic medical device	Upper limit of temperature	Caution	Consult instruction for use
		EC REP	CE
Manufacturer	Contains sufficient for <n> tests	Authorized representative in the European Community	Conformity to European Directive 98/79/EC

CE IVD

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