REF CV002

GenePro

SARS-CoV-2 Test

Instructions for Use

IVD

Rx Only

The Symbols Glossary is provided on page 33 of this booklet.

For use under Emergency Use Authorization (EUA) only

Please visit us at www.gencurix.com

Manufactured By

Gencurix GMP

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TABLE OF CONTENTS

LIST OF IN-TEXT TABLES

1 GENEPRO SARS-COV-2 TEST PRODUCT INFORMATION

1.1 Intended Use

GenePro SARS-CoV-2 Test is a real-time RT-PCR in vitro diagnostic test intended for the qualitative detection of RNA from SARS-CoV-2 in human nasopharyngeal swab, oropharyngeal swab, anterior nasal swab, and mid-turbinate swab specimens as well as nasopharyngeal wash/ aspirate, nasal aspirate and bronchoalveolar lavage (BAL) specimens obtained from individuals suspected of COVID-19 by their healthcare provider. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be evaluated in combination with clinical observations, patient history, and epidemiological information.

GenePro SARS-CoV-2 Test is intended for use by qualified clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures. GenePro SARS-CoV-2 Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

1.2 Summary and Explanation of the Test

GenePro SARS-CoV-2 Test is a qualitative test on the Applied Biosystems™ QuantStudio™ Dx (QSDx) with version 1.0.3 software (Thermo Fisher Scientific) and CFX96™ Dx System (CFX96) with version 3.1 software (Bio-Rad) systems for the detection of the 2019 coronavirus (SARS-CoV-2) RNA in human nasopharyngeal swab, oropharyngeal swab, anterior nasal swab, and mid-turbinate swab specimens as well as nasopharyngeal wash/ aspirate, nasal aspirate and bronchoalveolar lavage (BAL) specimens. An Internal control (human RPP25 gene) is used to monitor all stages of the test process. The GenePro SARS-CoV-2 Test includes a positive control material that is used for quality control and may be used for laboratory verification.

1.3 Principle of the Procedure

The GenePro SARS-CoV-2 Test is a real-time RT-PCR test. The primer and probe sets are designed to detect RNA from the SARS-CoV-2 in human nasopharyngeal swab, oropharyngeal swab, nasal swab, and mid-turbinate swab specimens as well as nasopharyngeal wash/ aspirate, nasal aspirate and bronchoalveolar lavage (BAL) specimens from patients who are suspected of COVID-19.

1.4 Materials Provided

The GenePro SARS-CoV-2 Test contains the components outlined in Table 1, which is sufficient for 100 tests and stable for up to 12 months from the manufactured date. Reagents should not be used past the expiration date.

Table 1: GenePro SARS-CoV-2 Test - Components Provided

Component	Description	Volume	Vials	Storage Condition
Oligo Mix (OM)	Primers pairs (forward and reverse) and probes for Orf-1ab and E gene of SARS-CoV-2 and human RPP25 gene	100 µL	1	-30°C to -10°C
Reaction Mix A (R-A)	Reaction buffer containing DNA polymerase, reverse transcriptase, dNTPs and MgSO4	250 µL	1	
Reaction Mix B (R-B)	Reaction supplements (MgSO4 and BSA)	100 µL	1	
Positive Control (2 x 10^4 copies/ µL) (PC) (See dilution instructions in Section 1.6 below)	Recombinant RNA containing sequences of Orf-1ab and E gene of SARS-CoV-2 and human RPP25 gene	10 µL	1	
Internal Control (1 x 10^4 copies/µL) (IC) (See dilution instructions in Section 1.6 below)	Recombinant RNA containing human RPP25 gene sequence	25 µL	1	
Controls Dilution Buffer (DB)	1X Tris-EDTA, pH 8.0	1000 µL	1	

Note: The Positive Control included in the GenePro SARS-CoV-2 Test is at high concentration. Dilute the PC with Controls Dilution Buffer 360 times before use.

1.5 Materials Required but Not Provided

Table 2 summarizes the materials required for testing but not provided with the GenePro SARS-CoV-2 Test.

Table 2: GenePro SARS-CoV-2 Test – Required Materials Not Provided

Components	Supplier	Cat. No.
Real Time PCR Instrument with Software		
QuantStudio™ Dx Real-Time PCR Instrument	Thermo Fisher Scientific	4479890
QuantStudio™ Dx Software (version 1.0.3)	Thermo Fisher Scientific	4484392
CFX96™ Dx System	Bio-Rad	1845097 and 1841000
CFX Manager (version 3.1)	Bio-Rad	1845000 and 12007917
Viral RNA Isolation		
QIAamp® DSP Viral RNA Mini Kit	QIAGEN	61904
QIAamp® Viral RNA Mini Kit	QIAGEN	52904 and 52906
QIAcube Connect	QIAGEN	9002840
Sample tube CB	QIAGEN	990382
Reagent bottle rack	QIAGEN	-
Reagent bottles, 30 mL	QIAGEN	990393
Rotor adapters	QIAGEN	990394
Shaker Rack Plugs	QIAGEN	9017854
1000 µL filter-tips	QIAGEN	990452
MagMAX™ Viral/Pathogen Nucleic Acid Isolation Kit	Thermo Fisher Scientific	A42352 and A48310
KingFisher™ Flex System	Thermo Fisher Scientific	5400630
KingFisher™ Flex 96 Deep-Well Heating Block	Thermo Fisher Scientific	24075430
KingFisher™ Deepwell 96 Plate	Thermo Fisher Scientific	95040450
KingFisher™ 96 KF microplate	Thermo Fisher Scientific	97002540
KingFisher™ 96 tip comb for DW magnets	Thermo Fisher Scientific	97002534
100% Ethanol	AS	
Nuclease-Free Water	AS	

Laboratory Equipment		
Laboratory Freezers (-30 to -10°C)	AS	
Centrifuge with a rotor for microplates	AS	
Microcentrifuge	AS	
Vortexer (or equivalent)	AS	
Single and multichannel adjustable pipettors (1 µL to 1000 µL)	AS	
Cold block (or ice)	AS	
Consumables		
MicroAmp® Optical 384-Well Reaction Plate with Barcode	Thermo Fisher Scientific	4309849, 4326270 and 4343814
MicroAmp® Optical 384-Well Reaction Plate	Thermo Fisher Scientific	4343370
MicroAmp™ Fast Optical 96-Well Reaction Plate with Barcode, 0.1 mL	Thermo Fisher Scientific	4346906 and 4366932
MicroAmp™ Fast Optical 96-Well Reaction Plate, 0.1 mL	Thermo Fisher Scientific	4346907
MicroAmp® Optical Adhesive Film	Thermo Fisher Scientific	4311971 and 4360954
Hard-Shell Low-Profile 96-Well Skirted PCR Plates (White/White)	Bio-Rad	HSP9655
Microseal 'B' PCR Plate Sealing Film, Adhesive, Optical	Bio-Rad	MSB1001
Nonpyrogenic & RNase/DNase free microtubes (1.7 mL)	AS	
Sterilized filtered pipette tips (1 µL to 1000 µL)	AS	

'AS' indicates that any suppliers.

1.6 Control Material(s)

1.6.1 Negative Control

The negative control (NC) uses the Controls Dilution Buffer to confirm the absence of contamination throughout the test process from viral RNA isolation to real-time RT-PCR amplification and is used once in each test.

1.6.2 Positive Control

The positive template control (PC) is a mixture of the in vitro transcribed RNAs containing target sequences of Orf-1ab and E genes and human RPP25 gene, needed to set thresholds

and to evaluate the real-time RT-PCR process. It is provided at high concentration (2x 10^4 copies/μL) per each target gene and measured once in each run at 3-5x LoD concentration (300 copies/reaction).

① Prepare the Positive Control – Dilute the Positive Control (2x 10^4 copies/μL) 360 times using the Controls Dilution Buffer

i. Pipet 18 μL of Controls Dilution Buffer into a microcentrifuge tube, then add 2 μL of Positive Control (1:9 dilution). Vortex well, then centrifuge briefly.

ii. Pipet 175 μL of Controls Dilution Buffer into a second microcentrifuge tube, then add 5 μL of the dilution prepared in the previous step (1:35 dilution). Vortex well, then centrifuge briefly.

1.6.3 Internal Control

The internal control (IC), also serves as an extraction control, is an in vitro transcribed RNA containing target sequence of human RPP25 gene and is needed to monitor the entire test processes from viral RNA isolation to real-time RT-PCR amplification. It is provided at high concentration (1x 10^4 copies/μL) and 1,000 copies are spiked into each individual sample before RNA isolation. The IC is isolated with viral RNA and is detected by a CY5 fluorescent dye modified probe for each sample. The cut-off Ct value is 31. If RNA from each sample has the Ct value lower than 31, it is regarded as viral RNA isolation is passed, while if the Ct value is equal to or higher than 31, it is regarded as viral RNA isolation is failed.

The internal control (IC) should be loaded into each sample prior to viral RNA isolation.

① Prepare the Internal Control (IC) - Dilute the Internal Control (1x 10^4 copies/μL) 20 times using the Controls Dilution Buffer

- Pipet 285 μL of Controls Dilution Buffer into a microcentrifuge tube, then add 15 μL of the Internal Control (1:19 dilution). Vortex well, then centrifuge briefly.

② Add 2 μL of the diluted Internal Control into each sample.

③ Controls dilution buffer (DB) is used as the negative control in each process from viral RNA extraction to PCR amplification without adding the IC.

1.7 Warnings and Precautions

1.7.1 General Precautions

- This product is for in vitro diagnostic use under an Emergency Use Authorization only and for Prescription Use Only.
- This test has not been FDA cleared or approved; the test has been authorized by FDA under an Emergency Use Authorization (EUA) for use by laboratories certified under the

Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

- This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
- Positive results are indicative of the presence of SARS-CoV-2 RNA.
- Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.
- GenePro SARS-CoV-2 Test are for use with Applied Biosystems™ QuantStudio™ Dx (QSDx) with version 1.0.3 software (Thermo Fisher Scientific) and CFX96™ Dx System (CFX96) with version 3.1 software (Bio-Rad) systems.
- Always check the expiration dates. Do not use after the expiration dates.
- Bleach introduced in a sample may damage nucleic acids in the sample, which may lead to a false negative result.
- Specimens should be collected and handled with appropriate universal infection control precautions.

1.7.2 Safety Precautions

- Wear appropriate Personal Protective Equipment (PPE) including (but not limited to) disposable clean powder-free gloves. Protect skin, eyes, and mucus membranes. Change gloves often when handling reagents or samples.
- Handle all samples and waste materials as if they were capable of transmitting infection agents. Observe safety guideline such as those outlined in:

  - CDC/NIH Biosafety in Microbiological and Biomedical Laboratories and CLSI M29-A3. Reagents can be irritating or harmful if swallowed, aspirated, or absorbed into the skin, eyes, or mucous membranes. Keep reagents away from skin, eyes, or mucous membranes and never ingest or swallow them.

  - CLSI Document M29 Protection of Laboratory Workers from Occupationally Acquired Infections

  - Refer to Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with 2019-nCoV (https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html).
- Follow your institution's safety procedures for handling biological samples.
- Dispose of materials used in this assay, including reagents, samples, and used buffer tubes, according to federal, state, and local regulations.
- Use all disposable items only once and do not reuse them.

If a reagent is in contact with skin, eyes, or mucous membranes, wash it immediately with large amount of water and seek doctor's advice. If inhaled, move to fresh air and seek medical advice. If symptoms persist, call a physician. If swallowed, rinse the mouth with water and seek medical advice.

1.7.3 Laboratory Precautions

Preventing Organism Contamination

- Due to the sensitive nature of the GenePro SARS-CoV-2 Test, it is important to guard against contamination of the sample or work area by carefully following the testing process outlined in this instruction document including these guidelines:

  - Do not handle samples in a biosafety cabinet which is used for SARS-CoV-2 culture or immunofluorescence testing.

  - Prior to processing samples, thoroughly clean both the work area and equipment with a suitable cleaner such as freshly prepared 70% ethanol or a similar disinfectant. To avoid residue buildup and potential damage to the sample or interference from disinfectants, wipe disinfected surfaces with water as needed.

  - Always change gloves and clean the work area between samples.

Preventing Amplicon Contamination

A common concern with PCR-based assays is a false positive result caused by contamination of the work area with PCR amplicon. Adhere to the following guidelines to prevent amplicon contamination:

- Discard used kits in a biohazard container immediately after the run has completed.
- Avoid excessive handling of kits after test runs.
- Change gloves after handling a used kit
- Avoid exposing kits or sample injections vials to sharp edges or anything that might cause a puncture.
- Prepare the Positive Control (PC) in a separate area from the reagents handling area.
- Change gloves after diluting the Positive Control (PC).
- Change gloves after loading the Internal Control (IC) into each patient specimen prior to extraction as well as after addition of the Positive Control (PC) to the PCR plate to avoid contamination.
- Clean thoroughly after loading the Internal Control (IC) into patient specimens as well as after addition of the Positive Control (PC) to the PCR plate to avoid contamination.

1.7.4 Precaution Related to Public Health in the United States

Local, state, and federal regulations for notification of reportable diseases are continually updated and include a number of organisms/viruses for surveillance and outbreak investigations. Laboratories are responsible for following their state and/or local regulations and should consult their local/or state public health laboratories for clinical sample submission guidelines.

1.8 Reagent Storage, Handling, and Stability

- GenePro SARS-CoV-2 Test and components should be stored at -30 to -10°C.
- Avoid storage of any materials near heating vents or in direct sunlight.
- All kit components should be stored and used together. Do not use components from one kit with those of another kit. Discard any extra components from the kit after use.
- Do not pool reagents from the different kits or lots.

2 SPECIMEN COLLECTION, VIRAL RNA ISOLATION, AND STORAGE

2.1 Specimen collection, transport, and storage

Collect the swab samples according to appropriate laboratory guidelines. Transport and store the samples at 2-8°C for up to 72 hours after collection.

Please refer to the Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Patients Under Investigation for the 2019 Novel Coronavirus (2019-nCoV) provided by the CDC, www.cdc.gov.

- Samples can be stored at 2-8°C for 72 hours after collection prior to extraction. If samples need to be transported, maintain 2-8°C on ice packs for overnight shipment.
- For longer term storage than 72 hours, unextracted samples can be stored at ≤-70°C. If samples need to be transported, maintain ≤-70°C on dry ice for overnight shipment.
- Extracted nucleic acids can be stored at ≤-70°C. If samples need to be transported, maintain ≤-70°C for overnight shipment.

Note: Specimens must be packaged, shipped, and transported according to the current edition of the International Air Transport Association Dangerous Goods Regulation. Follow shipping regulations for UN 3373 Biological Substance, Category B when sending potential 2019-nCoV specimens.

2.2 Viral RNA isolation

Note: Clean and disinfect all workspaces by wiping with 70% ethanol or a similar disinfectant to prevent contamination of specimens and reagents before the test. Test operators should wear laboratory coats and disposable gloves and be careful not to contaminate the specimens.

Nucleic acids are isolated and purified from samples manually or automatically using the following commercially available viral RNA isolation reagents and instruments (Table 3), according to the manufacturer's instruction.

Table 3: RNA Isolation Protocols

<table>
<tr><th>Reagent</th><th>Instrument</th><th>Input Volume</th><th>Elution Volume</th></tr>
<tr><td>QIAamp Viral RNA Mini Kit</td><td rowspan="2">-</td><td rowspan="3">140 µL</td><td rowspan="3">60 µL</td></tr>
<tr><td>QIAamp DSP Viral RNA Mini Kit</td></tr>
<tr><td>QIAamp Viral RNA Mini Kit</td><td rowspan="2">QIAcube Connect</td></tr>
<tr><td>QIAamp DSP Viral RNA Mini Kit</td><td></td><td></td></tr>
<tr><td>MagMAX Viral/Pathogen Nucleic Acid Isolation Kit</td><td>KingFisher™ Flex System</td><td>200 µL</td><td>80 µL</td></tr>
</table>

① Prepare the Internal Control (IC) - Dilute the Internal Control (1x 10^4 copies/µL) 20 times using the Controls Dilution Buffer
   - Pipet 285 µL of Controls Dilution Buffer into a microcentrifuge tube, then add 15 µL of the Internal Control (1:19 dilution). Vortex well, then centrifuge briefly.

② Pipette 140 µL (QIAGEN extraction methods) or 200 µL (Thermo Fisher Scientific extraction method) of each clinical specimen into the appropriate tubes as per the manufacturer's instructions.

③ Add 2 µL of the diluted Internal Control into each specimen.

④ In each extraction run, include a negative extraction control (Controls dilution buffer (DB)). Note: Do not add the IC to this control.

2.3 Storage Condition

Recommend using the viral RNA immediately after isolation; if not used immediately, freeze extracted RNA at -70°C.

3 TEST PROCEDURE

3.1 Prepare the real-time RT-PCR reactions

Note: Clean and disinfect all workspaces by wiping with 70% ethanol or a similar disinfectant to prevent contamination of specimens and reagents before the test. Test operators should wear laboratory coats and disposable gloves and be careful not to contaminate the specimens.

① Thaw all reagents on ice.

② Vortex and centrifuge briefly all reagents.

③ Prepare the Positive Control – Dilute the Positive Control (2x 10^4 copies/µL) 360 times using the Controls Dilution Buffer

i. Pipet 18 µL of Controls Dilution Buffer into a microcentrifuge tube, then add 2 µL of Positive Control (1:9 dilution). Vortex well, then centrifuge briefly.

ii. Pipet 175 µL of Controls Dilution Buffer into a second microcentrifuge tube, then add 5 µL of the dilution prepared in the previous step (1:35 dilution). Vortex well, then centrifuge briefly.

Note; The positive control preparation should be conducted in a separate area away from the reagent handling area. And it is recommended to change the gloves and clean the area after dilution to mitigate the contamination.

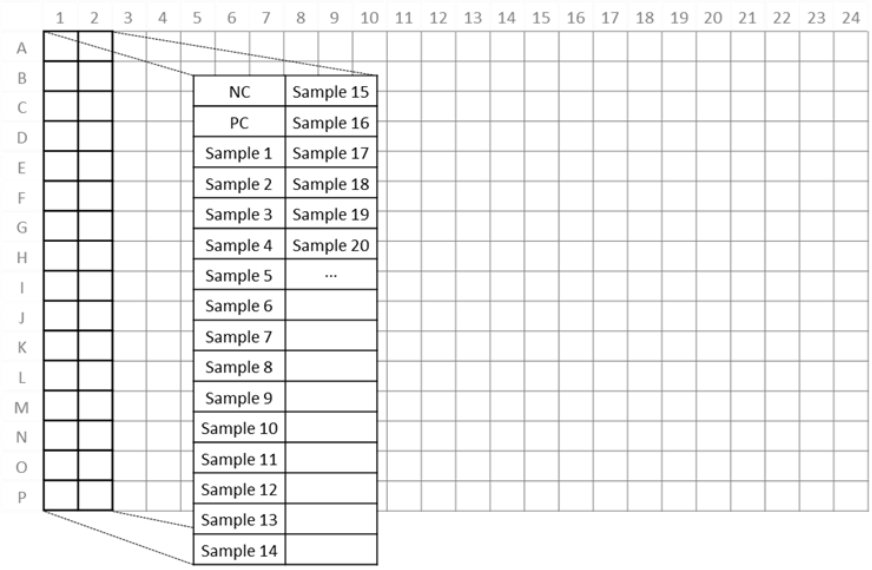
④ Prepare the PCR master mix with consideration to 2 controls and the number of specimens to be tested. Prepare the master mix in a microcentrifuge tube according to the table below.

Component	Volume (µL)/Reaction
Reaction Mix A (R-A)	2.5
Reaction Mix B (R-B)	1
Oligo Mix (OM)	1
Total	**4.5**

⑤ Dispense 4.5 µL of the PCR master mix into each well of a 384-well plate or 96-well plate.

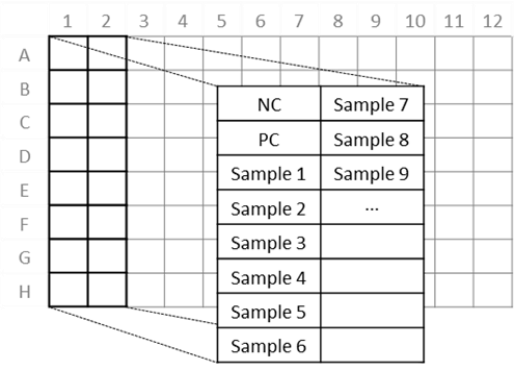
⑥ Add 5.5 µL of negative control (after RNA isolation), the diluted Positive Control, and extracted specimen RNA into the plate, in which the master mix is dispensed. The examples of the dispensation on the plates are shown below.

a. Example of dispensation on the 384-well plate



*MicroAmp Optical 384-Well Reaction Plate with Barcode or MicroAmp Optical 384-Well Reaction Plate for QuantStudio™ Dx

b. Example of dispensation on the 96-well plate



*MicroAmp Fast Optical 96-Well Reaction Plate with Barcode, 0.1 mL or MicroAmp Fast Optical 96-Well Reaction Plate, 0.1 mL for QuantStudio™ Dx

*Hard-Shell Low-Profile 96-Well Skirted PCR Plates (White/White) for CFX96™ Dx

⑦ Seal the plate with a film and centrifuge briefly.

3.2 Run the real-time RT-PCR on QuantStudio™ Dx

① Access QuantStudio Test Development Software to set up an experiment protocol.

② Click Experiment Setup and define run information of each category.

i. Experiment Properties

Setting	Value
Block Type	384-Well or Fast 96-Well (0.1 mL)
Experiment Type	Standard Curve
Reagent	TaqMan® Reagents
Run Property	Fast

ii. Define

- Targets: Add targets and define them according to the table below;

Target Name	Reporter	Quencher
Orf-1ab	FAM	None
E	HEX (or VIC)	None
IC	CY5	None

- Samples: Add samples and name them
- Passive Reference: Select 'None' from the drop-down menu

iii. Assign

- Select wells using Plate Layout of Well Table. Select the check box next to the target and sample to assign to the selected wells.

iv. Run Method

- Reaction Volume Per Well: 10 µL
- Set the thermal profile to the following conditions.

Step	Temperature	Time	Data Collection*	Cycle
UNG Incubation	25°C	2 min	Off	1
cDNA Synthesis	53°C	10 min	Off	1
Pre-Denaturation	95°C	2 min	Off	1
Pre-Amplification	95°C	3 sec	Off	5
	60°C	30 sec	Off	
Amplification and Detection	95°C	3 sec	Off	35
	60°C	30 sec	On	

* Data Collection: Click 'Data Collection' icon ( ) to switch data collection on or off at each step

③ Save the experiment.

④ Click Run in the Experiment Menu pane and click START RUN.

3.3 Run the real-time RT-PCR on CFX96™ Dx

① Access CFX Manager to set up an experiment protocol.

② Click User-defined on Startup Wizard window and define run information of each category.

i. Protocol

- Sample Volume: 10 µL
- Set the thermal profile to the following conditions.

Step	Temperature	Time	Data Collection*	Cycle
UNG Incubation	25°C	2 min	Off	1
cDNA Synthesis	53°C	10 min	Off	1
Pre-Denaturation	95°C	2 min	Off	1
Pre-Amplification	95°C	15 sec	Off	5
	60°C	1 min	Off	
Amplification and Detection	95°C	15 sec	Off	35
	60°C	1 min	On	

* Data Collection: Click 'Data Collection' icon (📷) to switch data collection on or off at each step

- Save the Protocol.

ii. Plate

- Select the Plate Type as BR White in the 'Settings' menu
- Select the Fluorophores; FAM, HEX and CY5
- Select wells using Plate Layout of Well Table and assign the experimental properties.

Setting	Value
Sample Type	Unknown or Positive Control or Negative Control
FAM	Orf-1ab
HEX	E
CY5	IC

③ Click the Run tab and click Start Run.

4 DATA ANALYSIS AND INTERPRETATION

4.1 Data Analysis on QuantStudio™ Dx

Threshold Set Up

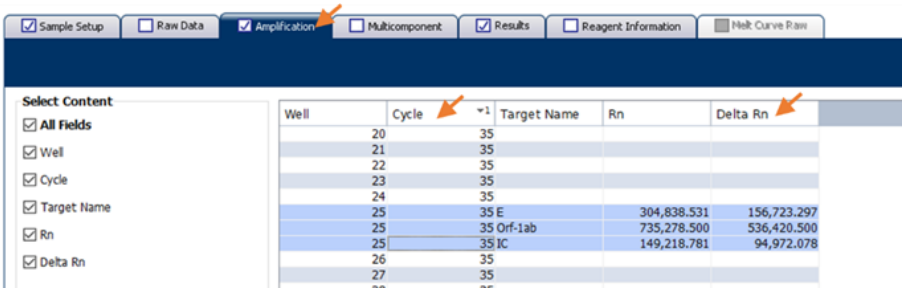
Considering the performance difference in real-time PCR instruments, thresholds for three fluorescence signals (FAM, HEX or VIC, and CY5) are set manually based on the fluorescent value of the positive control for each PCR run.

As applicable for each target, thresholds on QSDx are set as 1/5 of the fluorescent value (delta Rn) of the positive control at the last cycle (cycle 35).

① Check the delta Rn values at the last cycle (35) of the positive control for each target.

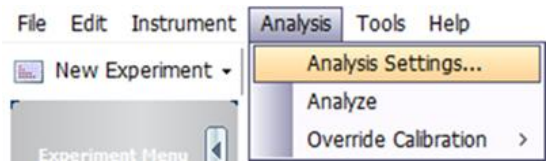
- Click Export in the Experiment Menu pane.

- Click the Amplification tab and check delta Rn values at the Cycle 35 of positive control well



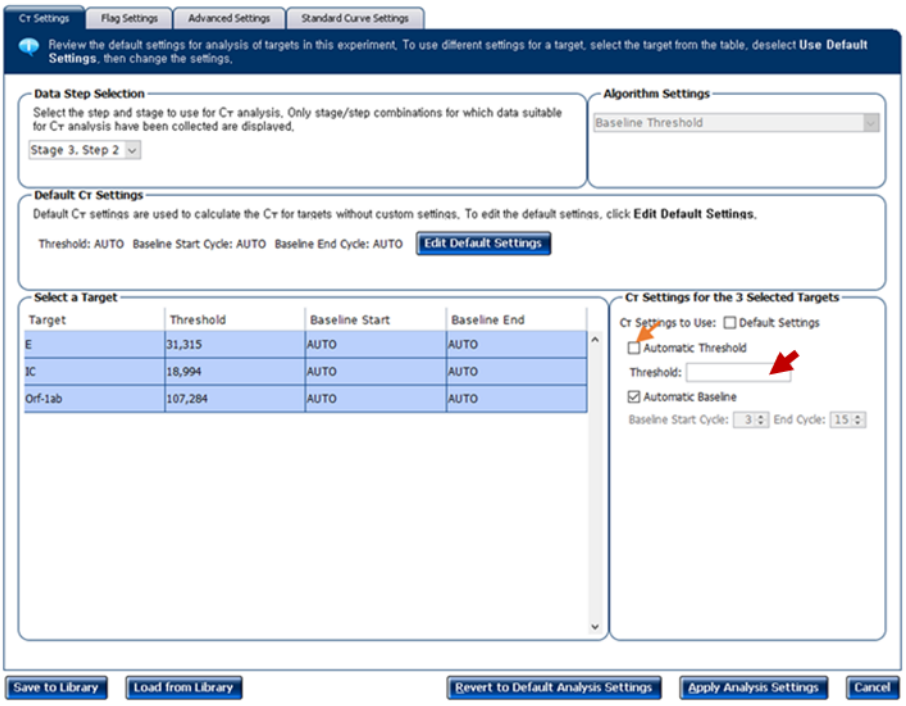
② Set delta Rn value threshold

- Click Analysis in the Experiment Menu pane.
- Click Analysis ▶ Analysis Settings… to open the Analysis Setting dialog box.



- In C_T Settings, select target and deselect Default Settings and Automatic Threshold.

- Enter the threshold value of each target to the 1/5 of delta Rn values at the last cycle (35) of the positive control into the Threshold Box (Red arrow).



- Click Apply Analysis Settings.

③ Move to Well Table and analysis Ct.

Ct Value Analysis

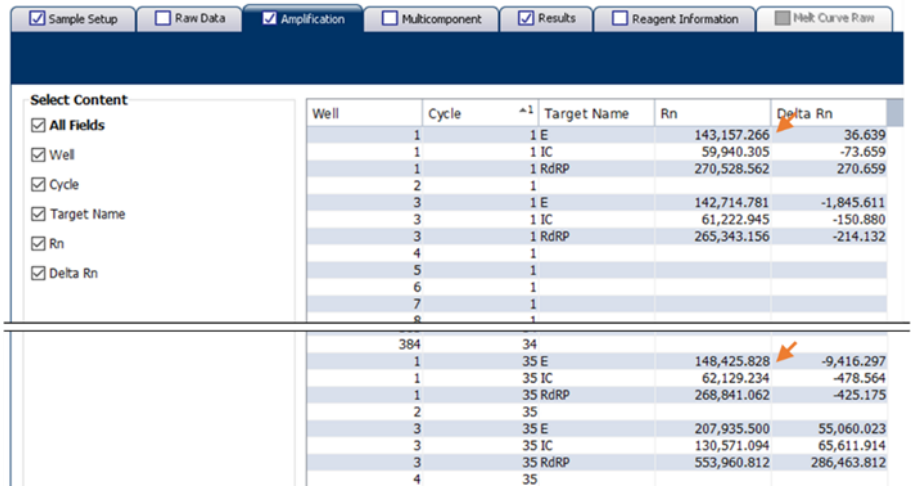
Ct values for three targets are determined at the cycle points where exponential curves meet their threshold. The cut-off Ct value for all target genes is 31.

Table 4: Gene Detection Criteria on QuantStudio Dx™

Target Gene	Orf-1ab	E	IC
Fluorescence	**FAM**	**HEX (or VIC)**	**CY5**
Detected	< 31	< 31	< 31
Not detected	≥ 31	≥ 31	≥ 31

Note; GenePro SARS-CoV-2 Test uses Ct values only of which fluorescent value (Rn) value at cycle 35 (last cycle) is higher than that at cycle 1. For each specimen, Rn values for all targets must be checked as follows;

- *Go to Export ▶ Amplification ▶ check Rn values*



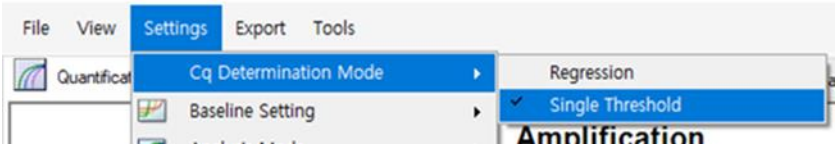
4.2 Data Analysis on CFX96™ Dx

Considering the performance difference in real-time PCR instruments, thresholds for three fluorescence signals (FAM, HEX, and CY5) are set manually by the operator based on the fluorescent value of the positive control for each PCR run.

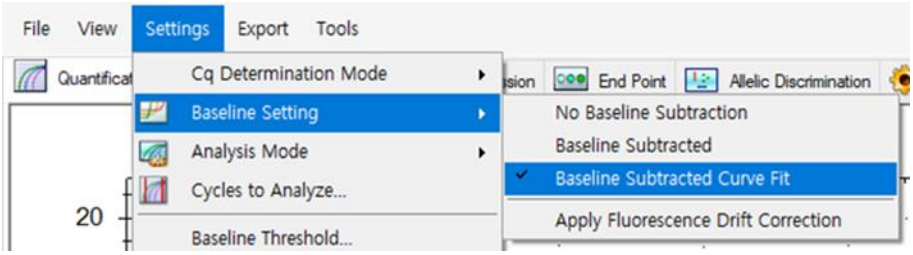
As applicable for each target, thresholds in CFX96 are set as 1/10 of the fluorescent value (RFU; relative fluorescent units) of the positive control at the last cycle (cycle 35).

① Check the RFU at the last cycle (35) of the positive control for each target.

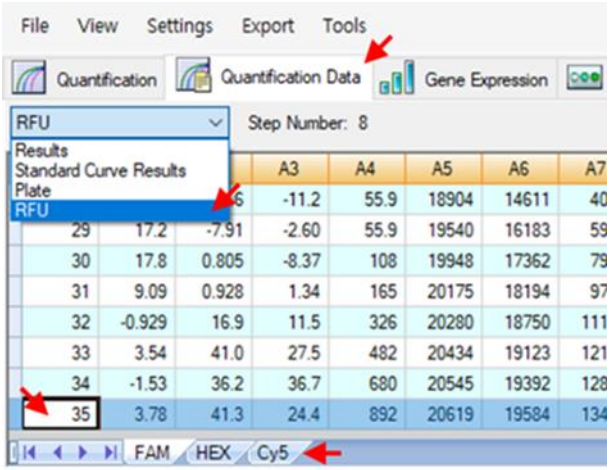
- Select Single Threshold from Cq Determination Mode of Setting Menu



- Select Baseline Subtracted Curve Fit from Analysis Mode of Setting Menu

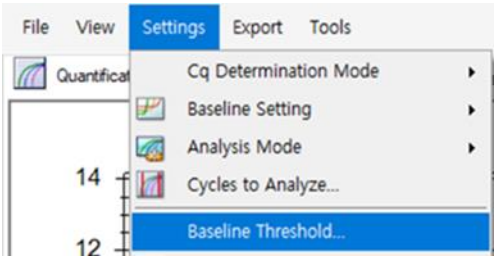


- Move to Quantitation Data Tab and select 'RFU' in the drop box.
- Check the RFU values at the cycle 35 of the positive control well in each fluorescence tab.

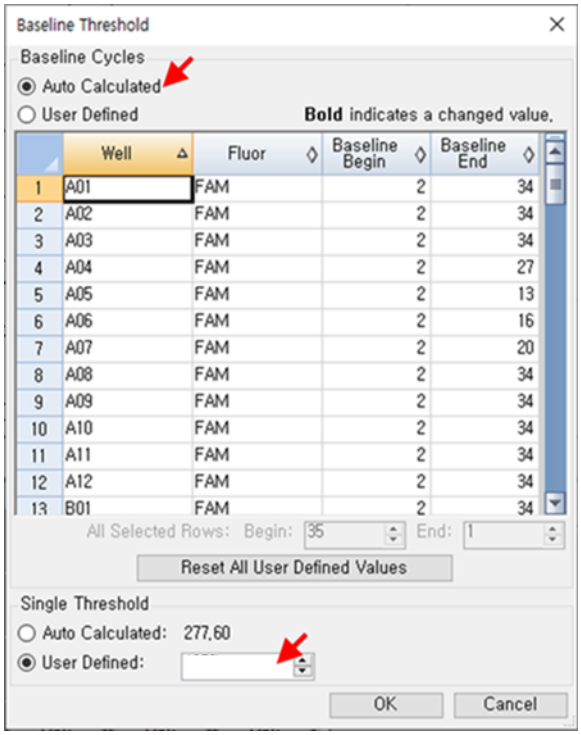


② Set RFU threshold

- Click Baseline Threshold… of Setting Menu



- In the Baseline Threshold Window, Choose Auto calculated as Baseline Cycles and set the Single threshold of each target to the 1/10 of RFU values at the last cycle (35) of the positive control.



- Click OK.

Note; Threshold should be separately set for each of the three target fluorophores (FAM, HEX and Cy5). Change of thresholds is allowed only when a single fluorophore is selected.

③ Move to Quantitation Data Tab and analysis C(t) Values.

Ct Values Analysis

Ct values for three targets are determined at the cycle points where exponential curves meet their threshold. The cut-off Ct value for all target genes is 31.

Table 5: Gene Detection Criteria CFX96™ Dx

Target Gene	Orf-1ab	E	IC
Fluorescence	**FAM**	**HEX**	**CY5**
Detected	< 31	< 31	< 31
Not detected	≥ 31	≥ 31	≥ 31

4.3 Interpretation

Controls Interpretation

A single negative control and single positive control are measured in each run. The run validity is based on the performance of both controls and each run is determined as 'Valid' when both controls meet their criteria. If the controls are not valid, the patient results cannot be interpreted. The negative control is 'valid' if all Ct values of the three target genes are greater than or equal to 31, while the positive control is 'valid' if all Ct values of the three target genes are less than 31.

Table 6: Controls Valid Criteria

Target Gene	Orf-1ab	E	IC	Interpretation
Fluorescence	**FAM**	**HEX (or VIC)**	**CY5**	
Negative Control	≥ 31	≥ 31	≥ 31	Valid
Positive Control	< 31	< 31	< 31	Valid

Patient Samples Interpretation

The Ct value cutoffs for all genes in patient specimens are 31. If the Ct value is calculated as lower than 31, it is determined that the gene detection is positive. The SARS-CoV-2 detection interpretation is as follows;

Note; In the QSDx, the Ct value of which delta Rn value at cycle 35 is higher than that of at cycle 1 is used (Please refer to 4. Data analysis and interpretation - 4.1 Data Analysis on QuantStudio™ Dx).

Table 7: Interpretation of Patient Specimen Results

Orf-1ab	E	IC	Status	Result
Negative	Negative	Negative	Invalid	Invalid*
Negative	Negative	Positive	Valid	SARS-CoV-2 Not Detected
Negative	Positive	Positive or Negative	Valid	Presumptive SARS-CoV-2 Positive+
Positive	Positive or Negative	Positive or Negative	Valid	SARS-CoV-2 Positive

* Repeat test. If the repeat test also results invalid, collect a new specimen.

+ Repeat test. If same results are detected from the repeat test, additional confirmatory testing may be conducted, if it is necessary to differentiate between SARS-CoV-2 and human SARS virus or other Sarbecovirus currently unknown to infect humans, for epidemiological purposes or clinical management. Not detected result for the ORF-1ab gene target may be due to:

1) a sample at concentrations near or below the limit of detection of the test,
2) a mutation in the corresponding target region, or
3) other factors.

5 ASSAY LIMITATION

- The use of GenePro SARS-CoV-2 Test is limited to U.S. laboratories - certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests by prescription only.
- The performance of the GenePro SARS-CoV-2 Test was established using nasopharyngeal/ oropharyngeal specimens. Anterior nasal swabs, mid-turbinate and nasal swabs as well as nasal wash, nasal aspirate, nasopharyngeal wash and BAL specimens are also considered acceptable specimen types for use with the GenePro SARS-CoV-2 Test, but performance has not been established.
- The E gene target of the GenePro SARS-CoV-2 Test may cross-react with the SARS-Coronavirus. SARS-Coronavirus is not known to be currently circulating in the human population, therefore it is highly unlikely to be present in patient specimens.
- Samples must be collected, transported, and stored using appropriate procedures and conditions. Improper collection, transport, or storage of specimens may hinder the ability of the assay to detect the target sequences.
- Extraction and amplification of nucleic acid from clinical samples must be performed according to the specified methods listed in this procedure. Other extraction approaches and processing systems have not been evaluated.
- False-negative results may arise from:

  - Improper sample collection or storage

  - Degradation of the SARS-CoV-2 RNA during shipping/storage

  - Specimen collection after SARS-CoV-2 RNA can no longer be found in the specimen matrix

  - The presence of RT-PCR inhibitors

  - Mutation in the SARS-CoV-2 virus

  - Failure to follow instructions for use
- False-positive results may arise from cross contamination between specimens and RNAs during specimen collection, preparation and handling.
- Negative results do not preclude infection with SARS-CoV-2 virus and should not be the sole basis of a patient management decision.
- Laboratories are required to report all positive results to the appropriate public health authorities.

6 CONDITIONS OF AUTHORIZATION FOR LABS[1]

The GenePro SARS-CoV-2 Test Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas.

However, to assist clinical laboratories using the GenePro SARS-CoV-2 Test, the relevant Conditions of Authorization are listed below.

- Authorized laboratories using the GenePro SARS-CoV-2 Test will include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- Authorized laboratories using the GenePro SARS-CoV-2 Test will perform the GenePro SARS-CoV-2 Test as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents, and authorized materials required to perform the GenePro SARS-CoV-2 Test are not permitted.
- Authorized laboratories that receive the GenePro SARS-CoV-2 Test must notify the relevant public health authorities of their intent to run the test prior to initiating testing.
- Authorized laboratories using the GenePro SARS-CoV-2 Test will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories will collect information on the performance of the GenePro SARS-CoV-2 Test and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Gencurix (technical_support@gencurix.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the test of which they become aware.
- All laboratory personnel using the test must be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit and use the test in accordance with the authorized labeling.
- Gencurix, its authorized distributor(s), and authorized laboratories using the GenePro SARS-CoV-2 Test will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

[1] The letter of authorization refers to, “Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests” as “authorized laboratories.”

7 PERFORMANCE CHARACTERISTICS

7.1 Analytical Sensitivity

The Limit of Detection (LoD) of the GenePro SARS-CoV-2 Test was established by using heat inactivated SARS-CoV-2 virus material provided from BEI Resources (Cat. No. NR-52286, lot number 70033548, 1.16x 10 ^{9} Genomic Equivalent (GE) per mL[2]). The heat inactivated SARS-CoV-2 was diluted into the one or more concentration level(s) in each study and spiked into pooled nasopharyngeal (NP) clinical swab sample matrix in UTM which were determined as SARS-CoV-2 negative. Every replicate in each study was processed individually to include independent viral RNA extraction.

At first, the preliminary LoD study was conducted at five different concentrations levels with five replicate measurements at each concentration using manual QIAamp Viral RNA Mini Kit for extraction and QuantStudio™ Dx (QSDx) for real-time RT-PCR. The results are summarized in Table 8. The preliminary LoD was determined as 5,550 GE/mL (777GE/140 µL, 71 GE/reaction) when both target genes were detected for all replicates tested.

Table 8: Summary of Preliminary LoD Study (QIAamp Viral RNA Mini Kit, QuantStudio Dx)

Test Concentration	Detection Rate			Mean Ct Value		
	Orf-1ab	E	IC	Orf-1ab	E	IC
7,143 GE/mL	5/5	5/5	5/5	28.15	27.77	26.27
5,550 GE/mL	5/5	5/5	5/5	28.91	28.75	26.54
3,964 GE/mL	2/5	4/5	5/5	30.53	30.17	26.67
2,379 GE/mL	0/5	2/5	5/5	-	29.96	26.64
793 GE/mL	0/5	0/5	5/5	-	-	26.76

Based on the result above, three concentration levels around the preliminary LoD were tested in twenty replicates using manual QIAamp Viral RNA Mini Kit for extraction and QuantStudio™ Dx for real-time RT-PCR. The LoD was determined as 840 GE (6 GE/µL, 6,000 GE/mL) when both genes were detected with at least a 95% detection rate. As shown in Table 9, the confirmatory LoD was determined as 6,000 GE/mL (840 GE/140 µL, 77 GE/reaction) when both target genes were detected with at least a 95% detection rate. When confirmatory LoD results are analyzed separately for each of the GenePro SARS-CoV-2 Test targets, the LoD for the Orf-1ab gene target is 5,550 GE/mL and the LoD for the E gene target is 6,000 GE/mL.

The CFX96™ Dx System and other viral RNA isolation protocols, including QIAamp DSP Viral RNA Mini Kit, QIAcube Connect instrument, and KingFisher™ Flex System with MagMAX Viral/Pathogen Nucleic Acids Isolation Kit, were evaluated by confirming the previously determined LoD through studies at three concentration levels (0.3x, 1x and 3x LoD).

[2] The following reagents was deposited by the Centers for Disease Control and Prevention and obtained through BEI Resources, NIAID, NIH: SARS-Related Coronavirus 2, Isolate USA-QA1/2020, Heat Inactivated, NR-52286.

Table 9: Summary of Confirmatory LoD Study on QSDx (QIAamp Viral RNA Mini Kit)

Test Concentration	Detection Rate			Mean Ct Value		
	Orf-1ab	E	IC	Orf-1ab	E	IC
6,000 GE/mL	20/20	20/20	20/20	28.78	28.01	26.57
5,550 GE/mL	19/20	18/20	20/20	29.76	30.19	27.22
4,764 GE/mL	15/20	13/20	20/20	30.09	30.45	27.01

Detection rates for both SARS-CoV-2 genes were 100% at 1x LoD and 3x LoD concentrations across all conditions, and were less than 95% detection at 0.3x LoD concentration, respectively, implying that the LoD of GenePro SARS-CoV-2 Test is equivalent in the proposed viral RNA isolation protocols and real-time PCR instruments.

Table 10 includes results from a LoD bridging study to evaluate four different QIAGEN extraction methods followed by real-time RT-PCR using the QuantStudio Dx system:

- Manual extraction with QIAamp Viral RNA Mini Kit
- Automated extraction using QIAamp Viral RNA Mini Kit and QIAcube Connect
- Manual extraction using QIAamp DSP Viral Mini Kit
- Automated extraction using QIAamp DSP Viral Mini Kit and QIAcube Connect

Table 10: LoD Equivalence in QIAGEN Products Based Viral RNA Isolation (PCR performed with QSDx)

Test Concentration	Protocol*	Detection Rate			Mean Ct Value		
		Orf-1ab	E	IC	Orf-1ab	E	IC
3x LoD (18,000 GE/mL)	QM	3/3	3/3	3/3	26.33	26.46	26.35
	QA	3/3	3/3	3/3	26.23	26.42	26.78
	QDM	3/3	3/3	3/3	26.28	26.49	26.84
	QDA	3/3	3/3	3/3	26.56	26.61	26.77
1x LoD (6,000 GE/mL)	QM	3/3	3/3	3/3	28.17	28.42	26.65
	QA	3/3	3/3	3/3	27.24	27.19	26.54
	QDM	3/3	3/3	3/3	27.48	27.14	26.94
	QDA	3/3	3/3	3/3	27.63	27.74	26.47
0.3x LoD (1,800 GE/mL)	QM	1/3	0/3	3/3	30.78	-	26.5
	QA	0/3	0/3	3/3	-	-	26.5
	QDM	2/3	2/3	3/3	29.63	30.27	26.93
	QDA	0/3	0/3	3/3	-	-	26.73

**Protocols; QM; QIAamp Viral RNA Mini Kit in Manual, QA; QIAamp Viral RNA Mini Kit with QIAcube Connect (Auto), QDM; QIAamp DSP Viral RNA Mini Kit in Manual, QDA.; QIAamp DSP Viral RNA Mini Kit with QIAcube Connect (Auto)*

Table 11 includes LoD confirmatory testing for the GenePro SARS-CoV-2 Test when performed with real-time RT-PCR on the CFX96™ Dx System and manual extraction using QIAamp Viral Mini Kit.

Table 11: LoD Confirmation, CFX96

Test Concentration	Detection Rate			Mean Ct Value		
	Orf-1ab	E	IC	Orf-1ab	E	IC
3x LoD (18,000 GE/mL)	20/20	20/20	20/20	26.10	25.75	24.52
1x LoD (6,000 GE/mL)	20/20	20/20	20/20	26.54	26.42	24.61
0.3x LoD (1,800 GE/mL)	8/20	17/20	20/20	29.87	29.49	24.76

Table 12 includes LoD confirmatory testing for the GenePro SARS-CoV-2 Test when used with Thermo Fisher KingFisher automated extraction (MagMAX Viral/Pathogen RNA Isolate Kit) followed by real-time RT-PCR with the QuantStudio Dx System.

Table 12: LoD Confirmation for MagMAX

Test Concentration	Detection Rate			Mean Ct Value		
	Orf-1ab	E	IC	Orf-1ab	E	IC
3x LoD (18,000 GE/mL)	20/20	20/20	20/20	27.55	27.70	24.80
1x LoD (6,000 GE/mL)	20/20	20/20	20/20	29.46	29.63	27.26
0.3x LoD (1,800 GE/mL)	10/20	5/20	20/20	30.39	30.53	25.56

7.2 Inclusivity

In silico analysis was conducted and results indicated that GenePro SARS-CoV-2 will detect all analyzed SARS-CoV-2 sequences in NCBI and in GISAID databases available on March 29. 2020.

- The Orf-1ab target had 100% match to all applicable SARS-CoV-2 sequences in NCBI (n = 165) and in GISAID (n = 1812) but three sequences had a single mismatch at i) near 3' end of the forward primer (EPI_ISL_417437), ii) the middle of the reverse primer (EPI_ISL_414468), and iii) the middle of the probe (EPI_ISL_416330).
- The E gene target had 100% match to all applicable SARS-CoV-2 sequences in NCBI (n = 164) and in GISAID (n = 1811) but two sequences had a single mismatch at i) the near 3'

end of the probe (gb|MT039890.1, EPI_ISL_411929), and ii) the near 5' end of the probe (EPI_ISL_416354).

None of the five single base mismatches are predicted to impact the performance.

7.3 Analytical Specificity (Cross-Reactivity)

In silico analysis was conducted for reference sequences in the NCBI database for the organisms that may be present in respiratory specimens and/or have the potential to cross-react with GenePro SARS-CoV-2 gene targets (Table 13). An organism was determined as potentially cross-reactive if the mean homology is greater than 80% between three oligos (primers set and probe) and any applicable sequence in the database.

According to in silico analysis, there is no potential cross-reactivity with organisms except SARS-Coronavirus. The homology of Orf-1ab and E gene targets of the GenePro SARS-CoV-2 Test and SARS-Coronavirus sequence entries were 84.5% and 90%, respectively, implying that the test may cross-react with SARS-Coronavirus.

The potential cross-reactivity with SARS-Coronavirus was further evaluated by wet testing using *in vitro* transcribed RNA containing applicable SARS Coronavirus target sequences. RNA transcripts were spiked at 2x 10^8 copies/mL into individual normal NP swab samples and processed in triplicate. Amplification was not observed for the Orf-1ab gene target; however, the E gene target was detected for all three replicates. The testing results suggest that GenePro SARS-CoV-2 Test will generate detected results for the E gene target for specimens that contain SARS-Coronavirus. Results from this testing are presented in Table 14.

Table 13: In Silico Analysis Microorganism List

High priority pathogens from the same genetic family	High priority organisms
Human coronavirus 229E	Adenovirus
Human coronavirus OC43	Enterovirus
Human coronavirus HKU1	Human Metapneumovirus
Human coronavirus NL63	Human Parainfluenza virus (1/2/3/4)
SARS-Coronavirus (Cross Reacts with E gene target)	Influenza (A/B/C)
MERS-Coronavirus	Respiratory syncytial virus
	Rhinovirus (A/B/C)
	Bacillus anthracis
	Bordetella pertussis
	Candida albicans
	Chlamydia pneumoniae

	Chlamydophila pneumoniae
	Chlamydophila psittaci
	Haemophilus influenzae
	Legionella pneumophila
	Mycobacterium tuberculosis
	Mycoplasma pneumoniae
	Pneumocystis jirovecii (PJP)
	Pseudomonas aeruginosa
	Staphylococcus epidermis
	Streptococcus pneumoniae
	Streptococcus pyogenes

Table 14: Wet Test for Cross-Reactivity

Pathogen	Template	Test Concentration	Mean Ct Value		
			Orf-1ab	E	IC
SARS-Coronavirus	In Vitro Transcribed RNA	2x 10^7 copies/rxn	-	16.84	30.94
			-	16.88	29.89
			-	17.05	-

7.4 FDA SARS-CoV-2 Reference Panel Testing

The evaluation of sensitivity and MERS-CoV cross-reactivity was performed using reference material (T1), blinded samples and a standard protocol provided by the FDA. The study included a range finding study and a confirmatory study for LoD. Blinded sample testing was used to establish specificity and to confirm the LoD. The extraction method and instrument used were QIAamp Viral RNA Mini Kit (manual isolation) and CFX96™ Dx. The results are summarized in Table 15.

Table 15: Summary of LoD Confirmation Result using the FDA SARS-CoV-2 Reference Panel

Reference Material Provided by FDA	Specimen Type	Product LoD	Cross-Reactivity
SARS-CoV-2	Nasopharyngeal (NP) Swab	2.7x 10^3 NDU/mL	N/A
MERS-CoV		N/A	ND

NDU/mL = RNA NAAT Detectable Units/mL

N/A: Not Applicable

ND: Not Detected

7.5 Clinical Evaluation

The clinical performance of GenePro SARS-CoV-2 Test was evaluated by using SARS-CoV-2 negative NP swab samples and contrived SARS-CoV-2 positive samples that were contrived by spiking the heat inactivated SARS-CoV-2 provided from BEI Resources (Cat. No. NR-52286, lot number 70033548, 1.16x 10^9 Genomic Equivalent (GE) per mL) into unique clinical negative NP swab sample matrices.

The following three combinations were tested;

- QIAamp Viral RNA Mini Kit Manual (QIAamp) and QuantStudio™ Dx (QSDx)
- QIAamp Viral RNA Mini Kit Manual and CFX96™ Dx (CFX96)
- MagMAX™ Viral/Pathogen Nucleic Acids Isolation Kit (MagMAX) with KingFisher™ Flex System and QuantStudio™ Dx

As the result, SARS-CoV-2 was not detected from negative samples and all contrived positive samples were interpreted as 'SARS-CoV-2 Positive' for each of the three extraction/PCR method combinations. The standard deviation (SD) of Ct values of SARS-CoV-2 genes were lower than 1 and the coefficient of variation (%, %CV) were less than 5 in contrived positive samples.

Table 16: Clinical Evaluation with QIAamp and QSDx

Clinical Sample	Detection Rate (Detected/Tested)	Target	Ct Value		
			Mean	SD	%CV
Negative*	0/30	Orf-1ab	-	-	-
		E	-	-	-
		IC	24.38	2.00	8.20
2x LoD (12,000 GE/mL)	20/20	Orf-1ab	26.61	0.36	1.35
		E	26.34	0.55	2.09
		IC	24.22	1.95	8.05
5x LoD (30,000 GE/mL)	10/10	Orf-1ab	25.84	0.28	1.08
		E	25.96	0.35	1.35
		IC	24.87	1.41	5.67

**Note; Two of thirty negative specimens were re-tested because they were interpreted as 'invalid' from the first clinical evaluation study. Repeat testing generated 'not detected' results for both specimens.*

Positive Percent Agreement: 30/30 = 100% (CI: 88.7-100%)
Negative Percent Agreement: 30/30 = 100% (CI: 88.7-100%)

Table 17: Clinical Evaluation with QIAamp and CFX96

Clinical Sample	Detection Rate (Detected/Tested)	Target	Ct Value		
			Mean	SD	%CV
Negative	0/30	Orf-1ab	-	-	-
		E	-	-	-
		IC	24.37	2.30	9.44
2x LoD (12,000 GE/mL)	20/20	Orf-1ab	25.52	0.27	1.06
		E	25.74	0.21	0.82
		IC	22.76	1.99	8.74
5x LoD (30,000 GE/mL)	10/10	Orf-1ab	24.41	0.24	0.98
		E	24.59	0.12	0.49
		IC	22.73	1.67	7.35

Positive Percent Agreement: 30/30 = 100% (CI: 88.7-100%)
Negative Percent Agreement: 30/30 = 100% (CI: 88.7-100%)

Additionally, clinical evaluation study was conducted using viral RNA isolated by KingFisher™ Flex System with MagMAX Viral/Pathogen RNA Isolation Kit. 200 µL of 70 individual samples (30 SARS-CoV-2 negative NP samples in PBS and 40 individual contrived positive NP samples in PBS; 20 samples with 1x LoD and 20 samples with 3x LoD) were processed individually (i.e., independent extractions) and with PCR performed using QuantStudio™ Dx.

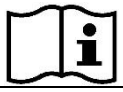
SARS-CoV-2 was detected from all contrived positive samples and was not detected from all negative samples. The standard deviation (SD) of Ct values of SARS-CoV-2 genes were lower than 1 and the coefficient of variation (%, %CV) were less than 5 in contrived positive samples (Table 18).

Table 18: Clinical Evaluation with MagMAX and QSDx

Clinical Sample	Detection Rate (Detected/Tested)	Target	Ct Value		
			Mean	SD	%CV
Negative	0/30	Orf-1ab	-	-	-
		E	-	-	-
		IC	25.36	1.83	7.22
1x LoD (6,000 GE/mL)	20/20	Orf-1ab	29.46	0.51	1.73
		E	29.63	0.48	1.62
		IC	27.26	1.56	5.72
3x LoD (18,000 GE/mL)	20/20	Orf-1ab	27.55	0.55	2.00
		E	27.70	0.53	1.91
		IC	24.80	1.46	5.89

Positive Percent Agreement: 40/40 = 100% (CI: 91.2-100%)
Negative Percent Agreement: 30/30 = 100% (CI: 88.7-100%)

APPENDIX A: SYMBOLS

Symbol	Used for
	For *In Vitro* Diagnostic Medical Device
	Temperature Limitation
	Contains Sufficient for < n > Tests
	Batch Code
	Used by YYYY-MM-DD
	Catalog Number
	Authorized Representative in the European Community
	Caution, Consult Accompanying Documents
	Consult Instructions for Use
	Manufacturer
	For prescription use only

APPENDIX B: CONTACT AND LEGAL INFORMATION

Customer and Technical Support	
Contact Us on the Web: www.gencurix.com Contact Us by Mail: #311, #402, #908, #909, #910, Digital-ro 242, Guro-gu, Seoul, 08394, Republic of Korea	Contact Us by Email: technical_support@gencurix.com Contact Us by Phone: +82 2 7508 2340 Contact Us by Fax: +82 2 2624 7039