FastPlex Triplex SARS-CoV-2 Detection Kit (RT-Digital PCR)
Instructions for Use

Catalog # 02.01.1019
24 Tests/Kit

For Use Under FDA EUA Authorization Only
For *in vitro* Diagnostic (IVD) Use
Rx Only

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A. Intended Use

FastPlex Triplex SARS-CoV-2 Detection Kit (RT-Digital PCR) is a RT-Digital PCR test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in oropharyngeal swabs from individuals who are 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 the 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 upper respiratory specimens during the acute phase of infection. Positive results are indicative of the 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 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 combined with clinical observations, patient history, and epidemiological information.

The ***FastPlex Triplex SARS-CoV-2 Detection Kit (RT-Digital PCR)*** is intended for use by trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and *in vitro* diagnostic procedures. The ***FastPlex Triplex SARS-CoV-2 Detection Kit (RT-Digital PCR)*** is only for use under the Food and Drug Administration's Emergency Use Authorization.

B. Summary and Explanation

An outbreak of pneumonia of unknown etiology in Wuhan City, Hubei Province, China was initially reported to WHO on December 31, 2019. Chinese authorities identified a novel coronavirus (SARS-CoV-2), which has resulted in a pandemic with more than 8 million cases worldwide. Cases of asymptomatic infection, mild illness, severe illness, and deaths have been reported.

The ***FastPlex Triplex SARS-CoV-2 Detection Kit (RT-Digital PCR)*** for Detecting SARS-SARS-CoV-2 is a molecular in vitro diagnostic test that aids in the detection and diagnosis of SARS-CoV-2 and is based on droplet digital PCR technology. The product contains oligonucleotide primers, labeled oligonucleotide probes, and control material used in real-time RT-Digital PCR for the *in vitro* qualitative detection of SARS-CoV-2 RNA in respiratory specimens.

C. Principles and Procedures

The ***FastPlex Triplex SARS-CoV-2 Detection Kit (RT-Digital PCR)*** is a reverse transcription digital droplet polymerase chain reaction (RT-dPCR) test. The SARS-CoV-2 primer and probe set(s) are designed to detect RNA from the SARS-CoV-2 in oropharyngeal swabs from patients with signs and symptoms of infection who are suspected of COVID-19 by their healthcare provider.

This kit employs droplet digital PCR technology combined with Taqman fluorescent probe and provides qualitative detection of SARS-CoV-2. As shown in Figure 1, PCR mix containing target RNA molecules is randomly partitioned into up to 25,000 water-in-oil droplets in nanoliter size. These droplets self-organize to form a monolayer in the reaction chamber located downstream of the droplet generation channels. The water-in-oil emulsions are then subjected to the RT-PCR reaction as the droplets are confined in the chamber. The droplet generation and droplet PCR thermal cycling are both performed using DropX-2000 Sample Prep Station (SG4-2000).

RNA isolated and purified from oropharyngeal swabs is reverse transcribed to cDNA and amplified in one step in the DropX-2000 Digital PCR System. In the process, the probes anneal to their specific target sequence located between the forward and reverse primers. During the extension phase of the PCR cycle, the 5' exonuclease activity of Taq polymerase degrades the probe, causing the reporter dye to separate from the dye quencher, generating a fluorescent signal. With each cycle, additional reporter dye molecules are cleaved from their respective probes, increasing the fluorescence intensity. The SARS-CoV-2 ORF1ab gene probe contains FAM label, the SARS-CoV-2 N gene probe contains HEX label, and RNase P probe contains Cy5 label.

After PCR, Drop-X 2000 DScanner (DS4-2000) images each individual droplet in both bright field and three different fluorescence. After PCR reaction, fluorescent signal from each droplet is acquired. Because of the large number of droplets generated in Suzhou PreciGenome's proprietary microfluidic cartridge, many of the droplets don't contain any target RNA sequence and its fluorescence signal doesn't increase after RT-PCR. In contrast, for those droplets containing at least one copy of a certain target RNA sequence, RT-PCR reaction in this droplet leads to the hydrolysis of the corresponding probe and results in significant increase of fluorescence signal after RT-PCR. In the microfluidic cartridge, droplets self-organize to form a monolayer in the reaction chamber located

downstream of the droplet generation channels. RT-PCR reaction is then performed as droplets are confined in the chamber. The droplet generation and droplet PCR thermal cycling are both performed using DropX-2000 Sample Prep Station (SG4-2000). After PCR, DropX-2000 DScanner (DS4-2000) scans each individual droplet in both bright field and three different fluorescence channels. The DScanner measures the fluorescence intensity of droplets to determine which contain target (positive) and which do not (negative) for each of the targets identified with the SARS-CoV-2 digital PCR Test: ORF1ab, N and RNase P. The DScanner also measures the diameter of each individual droplets based on the brightfield images of the droplets and count the number of total droplets. By using three different probes for ORF1ab gene, N gene and RNase P gene and measuring the fluorescence signal in three different fluorescence channels, the number of positive droplets for each channel (target) are counted. Result interpretation requires a minimum threshold of droplet counts. The next step is to use the number of positive droplets to determine whether the PCR mix has the target RNA.

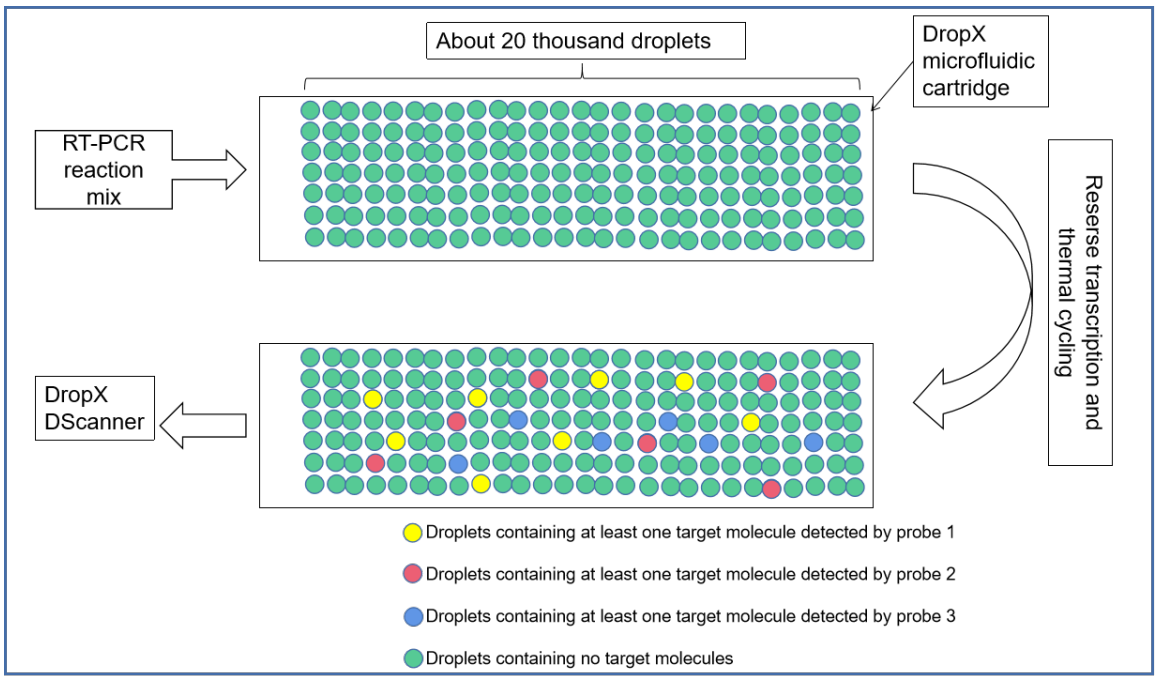


Figure 1. Principle of RT-Digital PCR

For each fluorescence channel, the system counts how many positive droplets there are in each channel. Droplets positive for multiple targets can be distinguished by the fluorescence label and are counted once in each channel. The cutoff for positive results is 3 droplets for each of the given targets/channels based on Poisson statistics and the 95% confidence interval (see, Anal. Chem. 2011, 83, 21, 8158-8168).

The following figure shows ***FastPlex Triplex SARS-CoV-2*** Detection kit workflow.

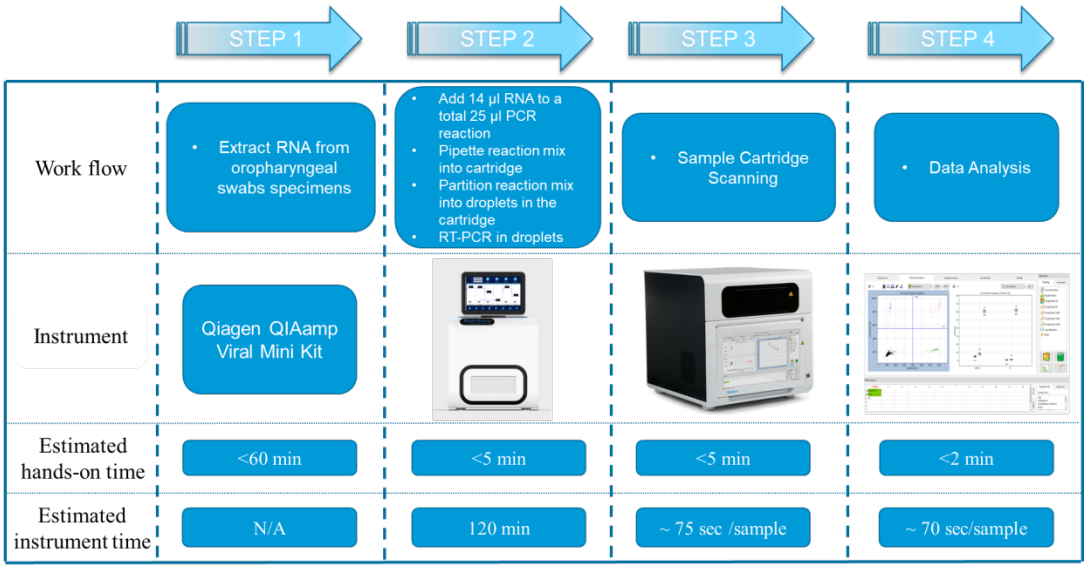


Figure 2. ***FastPlex Triplex SARS-CoV-2 Detection Kit***-Digital PCR Workflow

D. Materials Provided

The following table summarizes the components of ***FastPlex Triplex SARS-CoV-2 Detection Kit (RT-Digital PCR)***

Table 1. ***FastPlex Triplex SARS-CoV-2 Detection Kit*** components

Item No.	***Components***	***Specifications and Quantities***	***Reactions/Tube***
1	SARS-CoV-2 1-step RT-Digital PCR Detection Mix	240 µl×1	24
2	SARS-CoV-2 1-step RT-Digital PCR Enzyme Mix	24 µl×1	24
3	SARS-CoV-2 negative control	140 µl×3	3
4	SARS-CoV-2 positive control	140 µl×3	3

E. Material Required But Not Provided

- RNA extraction reagents: QIAamp Viral RNA Mini Kit [Qiagen, (50)-Cat. #52904 or (250)-Cat. #52906].
- Instrument: DropX-2000 digital PCR system (Suzhou PreciGenome Cat # 01.07.2003); and the associated microfluidic cartridge (Suzhou PreciGenome Cat # 04.01.2002)

Table 2. **Instrument, software and consumables required but not provided in** the ***FastPlex Triplex SARS-CoV-2 Detection Kit (RT-Digital PCR)***

Product Name	Catalog Number
DropX-2000 Sample Prep Station (SG4-2000)	01.03.2001
DropX-2000 DScanner (DS4-2000)	01.02.2002
Microfluidic Cartridge	04.01.2002
Cartridge Gasket	04.02.1000
DropX-2000 digital PCR Oil	02.01.0001
VaporLock	02.01.0002
GeneCount Software V1.61.0508	N/A

- **Additional tools and consumables:**
  - Micropipettes (2 or 10 µL, 200 µL and 1000 µL)
  - Racks for 1.5 mL microcentrifuge tubes
  - -20°C cold blocks
  - Molecular grade water, nuclease-free
  - 10% bleach (1:10 dilution of commercial 5.25-6.0% hypochlorite bleach)
  - DNAZap™ (Ambion, cat. #AM9890) or equivalent
  - RNAse Away™ (Fisher Scientific; cat. #21-236-21) or equivalent
  - Disposable powder-free gloves and surgical gowns.
  - Aerosol barrier pipette tips
  - 1.5 mL microcentrifuge tubes (DNase/RNase free)
  - Vortex mixer
  - Microcentrifuge

F. Warnings and Precautions

- For use under FDA Emergency Use Authorization only.

- Federal Law restricts this device to sale by or on the order of a licensed practitioner.
- For *in vitro* diagnostic use only (IVD).
- 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 laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 U.S.C. §263a, that meet the 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.
- Follow standard precautions. All patient specimens and positive controls should be considered potentially infectious and handled accordingly.
- Do not eat, drink, smoke, apply cosmetics or handle contact lenses in areas where reagents and human specimens are handled.
- Handle all specimens as if infectious using safe laboratory procedures. Refer to Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with SARS-CoV-2 https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html. Dispose of hazardous or biologically contaminated materials according to the practices of your institution.
- Please read the instructions carefully prior to operation.
- Samples must be collected, transported, and stored using the exact procedures and conditions recommended by the swab manufacturer and in this package insert. Improper collection, transport, or storage of specimens may impact the performance of this test.
- False positive and false negative results can be caused by poor specimen quality, improper sample collection, improper transportation, improper laboratory processing, or a limitation of the testing technology.
- Negative results do not preclude infection with SARS-CoV-2 virus and should not be used as the sole basis for treatment or other patient management decision.
- Separate laboratory areas, dedicated to performing predefined procedures of the assay, are required. a) 1st Area: Preparation Area—Prepare testing reagent: b) 2nd Area: Sample processing—Process the specimen and controls: c) 3rd Area: Amplification Area—PCR conducted.
- All materials used in one area should remain in that area and should not be moved or used in other areas. After the assay procedures, the workbench and lab supplies should be cleaned and disinfected immediately.

• All contents in this package are prepared and validated for the intended testing purpose. Do not replace any of the package contents as this will affect the testing performance of the kit.

• Components contained within a kit are intended to be used together. Do not mix components from different kit lots.

• Filter plugged nuclease free pipette tips are required and should be replaced after the addition of each reagent or sample.

• Centrifuge tubes in the assay should be DNase/RNase-free.

• All used consumables should be disposed of in compliance with local, state and federal regulation.

G. Reagent Storage, Handling, and Stability

• Store all reagents at -20°C in the dark when not in use.

• Use the reagents within 30 days once opened.

• Completely thaw the reagents before use; spin briefly before use.

• Do not freeze/thaw cycles for reagents more than 3 times.

• The reagents should be transported in a sealed foam box with ice packs or add dry ice.

H. Controls Materials

Controls - Positive, Negative (Extraction) and No Template Controls provided with the test kit include:

I) SARS-CoV-2 negative control: The SARS-CoV-2 negative control is used as an extraction and amplification control and monitors contamination of test reagents with SARS-CoV-2 RNA as well as proper reverse transcription and amplification of the RNase P targets. Positive and negative are defined based on a cutoff of <3 positive droplets (i.e., a maximum of 2 positive droplets). It should report negative results for ORF1ab and N genes (number of positive droplets less than 3), except for RNase P. If any of the ORF1ab or N genes are positive in the negative control, then the RT-Digital PCR run is invalid. If the SARS-CoV-2 negative control generates negative results of RNase P (Cy5), which is less than 3 positive droplets, it indicates the failure of RNA extraction. The specimen is required to be re-processed.

II) SARS-CoV-2 positive control: The positive control material is provided at a concentration at 1000 copies/mL. The positive control is used to monitor whether the RT-digital PCR process works properly and is used in each detection run. The positive control should be positive for the ORF1ab gene (equal or more than 3 FAM positive droplets), the N gene (equal or more than 3 HEX positive droplets) and the RNase P gene targets (equal or more than 3 Cy5 positive droplets). If the results are not positive, the RT-Digital PCR run is invalid. Positive and negative are defined based on a cutoff of 2 positive droplets.

III) NTC control (no template control) is used to detect any reagent or environmental contaminations. The NTC should be negative for ORF1ab (FAM), N (HEX) and RNase P (Cy5). If NTC shows any positive results, it indicates contamination of reagents or samples. All sample results need to be invalidated and results must not be reported. It is recommended to decontaminate the PCR lab and use a new box of un-opened reagent before repeating sample testing.

I. Collection, Storage and Shipment of Specimens

- Adequate, appropriate specimen collection, storage, and transport are important in order to obtain sensitive and accurate test results. Training in correct specimen collection procedures is highly recommended to assure good quality specimens and results. CLSI MM13-A may be referenced as an appropriate resource.

- Specimen collection: Refer to Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Patients Under Investigation (PUIs) for 2019 Novel Coronavirus (2019-nCoV) https://www.cdc.gov/coronavirus/2019-nCoV/guidelines-clinical-specimens.html. Swab specimens should be collected using only swabs with a synthetic tip, such as nylon or Dacron® and an aluminum or plastic shaft. Calcium alginate swabs are unacceptable and cotton swabs with wooden shafts are not recommended. Place swabs immediately into sterile tubes containing 2-3 ml of viral transport media or universal transport media. Follow specimen collection devices manufacturer instructions for proper use.

- Specimen Transportation: Specimens must be packaged, shipped, and transported according to Department of Transportation (DoT) and consistent with shipping recommendations from CDC for SARS-Cov-2 specimens. Specimens should be shipped at 2-8ºC (on ice packs) or lower (dry ice), overnight.

- Specimen Storage:

  - Upon receipt, specimens can be immediately processed or stored at 2-8°C for up to 72 hours after collection. For longer term storage, store specimens at -70°C or lower.

  - Extracted nucleic acid should be stored at 4°C if it is to be used within 4 hours, or -70°C or lower if stored longer than 4 hours. Avoid repeated freeze-thaw cycles.

J. Laboratory Procedures

a) Equipment Preparation:

Clean and decontaminate all work surfaces, pipettes, centrifuges, DropX-2000 system and other equipment prior to use. The following decontamination agents may be used: 10% bleach, 70% ethanol, or DNAzap™ or RNase AWAY® to minimize the risk of nucleic acid contamination.

Warning: Do not use bleach when using specimen collection systems containing Specimen collection devices that contain guanidinium isothiocyanate as a stabilizer react with bleach to release toxic cyanide gas.

b) Preparation of the controls:

To avoid contamination, the positive control needs to be prepared in an area separate from the amplification and extraction area. The positive control materials in the kit is provided at a concentration of 1000 copies/mL. The positive control material was prepared by serially diluting stock concentration of 10^7-10^8 copies/mL using oropharyngeal swab matrix (Copan Collection, Transport and Processing Kit UTM 306) down to concentration of 1000 copies/mL.

c) RNA isolation:

Nucleic acids are isolated and purified from oropharyngeal swab specimens using QIAamp Viral RNA Mini Kit, utilizing 140 µL of sample. In the extraction steps all controls, the SARS-CoV-2 positive control, the SARS-CoV-2 negative control (contains RNase P only) and the no template control (water/VTM), are included with 140 µl control material instead of sample and are processed in an identical manner to the sample. Please follow the sample processing steps of the Manufacturer's instructions for use, **EXCEPT** for the Elution. **Perform the elution step using an elution volume of 140 µL AVE buffer.** The extracted RNA can be directly added to the RT-Digital PCR reaction immediately or store at -70°C. Controls are used the same way as the extracted samples (i.e., using 140 µl per extraction and 14 µl of extracted RNA for the PCR reaction) once per sample run.

d) Preparation of digital PCR Reactions

1) Thaw SARS-CoV-2 1-step RT-Digital PCR enzyme mix on ice. Keep the SARS-CoV-2 1-step RT-Digital PCR enzyme mix on ice or cold block all the time during preparation and use, and store it at -20°C immediately after use.
2) Thaw all kit components at room temperature. Vortex all kit components and briefly spin to collect all liquid at the bottom of the tube.
3) If extracted RNA from specimens were frozen, thaw extracted RNA samples on ice or a cold block.
4) Gently vortex RNA extraction sample tubes and centrifuge for 1 minute. After centrifugation, place the RNA extraction sample tubes in the cold rack or on ice.
5) Prepare all PCR mix in an area separate from the RNA extraction.
6) Determine the number of reactions (N is the number of reactions including samples, positive control, negative control and no template control) that will be included in the test.

7) In a 1.5 mL microcentrifuge tubes (DNase/RNase free) prepare the digital PCR mix by adding detection mix and enzyme mix based on Table 4 below. Mix the PCR mix thoroughly by vortex. The remaining reagent must be stored at -20°C immediately.

Table 3. Preparation of Digital PCR mix

Components	Volume [µL]	Final Concentration
SARS-CoV-2 1-step RT-Digital PCR Detection Mix	10µl x (N+1)	1×
SARS-CoV-2 1-step RT-Digital PCR Enzyme Mix	1 µl x (N+1)	1×
Total volume [**µL**]	11 µl x (N+1)	--

8) Centrifuge the digital PCR mix prepared in step 7 for 1 minute to collect contents at the bottom of the tube, and then place the tube in a cold rack.

9) Dispense 11 µL of the digital PCR mix into a 200 µL centrifuge tube. Be sure not to introduce any foam or bubbles into the tubes when aliquoting digital PCR reaction Mix.

10) Add 14 µL of the extracted RNA sample (or positive control or negative control or NTC control) to form a 25 µL of digital PCR reaction mix. Be sure to deposit samples with the pipette directly into the reaction mix in PCR tubes. Mix thoroughly by vortex and centrifuge for 1 minute.

e) Microfluidic cartridge preparation

Microfluidic cartridges and gaskets were placed in a sealable autoclave bag for autoclaving and decontamination (autoclaving is optional). Before loading reagents onto the microfluidic cartridge, remove the cartridge and gasket from the package bag. The microfluidic cartridge is shown in **Figure 3**. Each cartridge can process 4 digital PCR reactions from step d)10) above. There are four sample loading wells (spherical ones) in the cartridge and four oil loading wells (rectangular ones) in the cartridge.

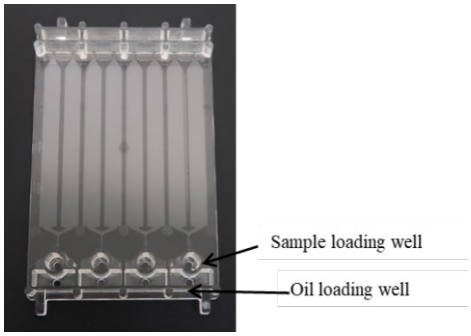


Figure 3. Microfluidic Cartridge

1) Place microfluidic cartridges in the cartridge holder as shown in **Figure 4**. Each cartridge holder holds 4 pieces of microfluidic cartridges.

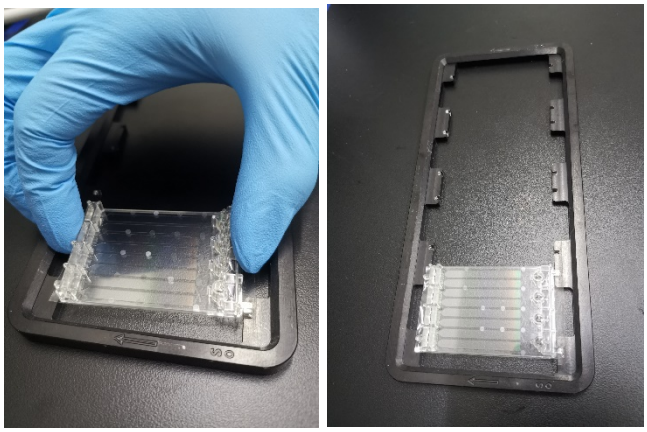


Figure 4. Place microfluidic cartridge on cartridge holder

2) Dispense 75 µL of digital PCR oil into the oil loading wells on the cartridge first. It is important to always dispense oil into cartridge first.

3) Dispense the 25 µL of digital PCR reaction mix from step d)10) above into the sample loading wells.

4) After loading the digital PCR reaction mix, add 10 µL of VaporLock solution on top of the reaction mix.

5) Cover each cartridge with cartridge gaskets at both ends as shown in the **Figure 5** below and transfer cartridge holder with all the cartridges into DropX-2000 sample prep station.

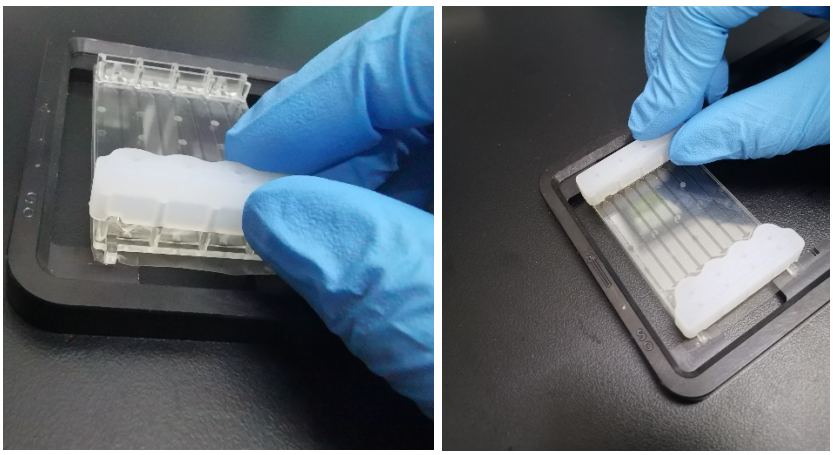


Figure 5. Cover microfluidic cartridge with cartridge gaskets

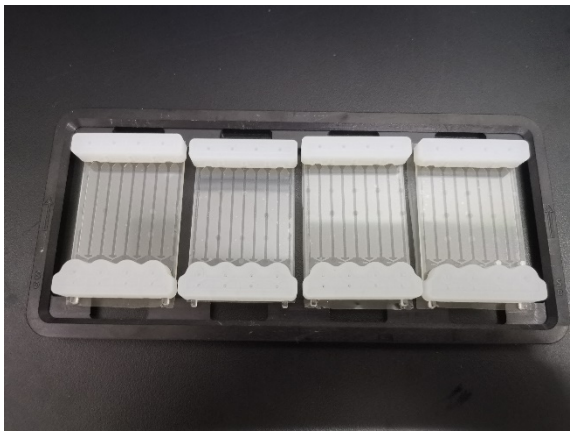


Figure 6. Microfluidic Cartridges in the holder

f) Operation of DropX-2000 Sample Prep Station

Follow the manufacturer's instruction to perform droplet generation and RT-Digital PCR reaction using DropX-2000 Sample Prep Station. Program the instrument and set or load the following instrument settings:

1) Before running the test, users set SARS-Cov-2 RT digital PCR thermal cycling protocol as follows or load the pre-saved protocol using the user interface.

Table 4. SARS-CoV-2 RT-Digital PCR thermal cycling protocol

Steps	Temperature (ºC)	Time (min)	Ramp Rate	Cycles
Reverse transcript	49	20	2°C/s	1
Enzyme Activation	97	12		1
Denaturation	95.3	0.5		40
Annealing- extension	52	1		
Enzyme deactivation	98	10		1
Cool down	20	Infinite		1

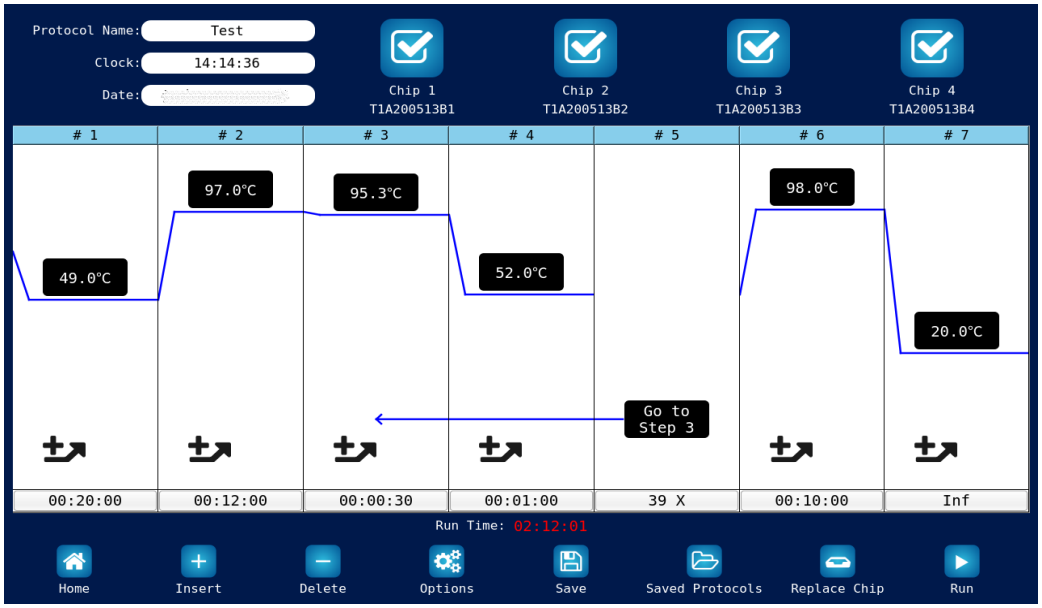


Figure 7. User interface for setting RT-Digital PCR thermal cycling protocol

2) Once the protocol is set, users click the Run button, the door of DropX-2000 Sample Prep Station is opened and the user interface asks users to load the prepared microfluidic cartridges onto the loading dock, close the door and confirm the positions of microfluidic cartridges loaded as shown in the **Figure 8** below.

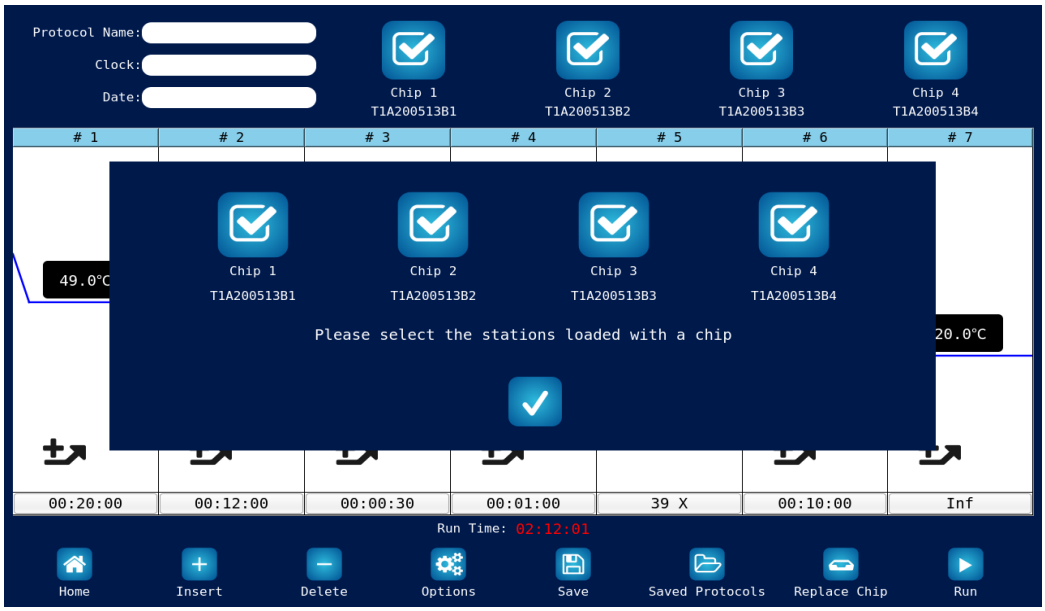


Figure 8. User interface for confirming the positions of microfluidic cartridges loaded.

3) DropX-2000 Sample Prep Station runs droplet generation process after the cartridge is loaded into the instrument.
4) Once the droplet generation process is done, RT-Digital PCR thermal cycling process is carried out automatically without user intervention.
5) While the droplet generation is in progress, prepare the sample settings in the DropX-2000 DScanner per section g below.
6) Upon completion of thermal cycling, an alarm sounds to remind users to transfer microfluidic cartridges from the Sample Prep Station into DropX-2000 DScanner to perform droplets scanning.

g) Operation of DropX-2000 DScanner

After RT-PCR, DropX-2000 microfluidic cartridges are moved into the DropX-2000 DScanner instrument for scanning. For scanning follow the procedural steps below:

1) Programming of Sample/Cartridge Settings

Before the sample cartridges are moved into DScanner for scanning, the information of all the samples should be set up as follows:

i) Setup the samples information in the **Sample Scan** tab. Choose the correct position in sample table on the top of the window based on the corresponding position of sample cartridge placed in the cartridge tray. Then set up the sample information for each sample.

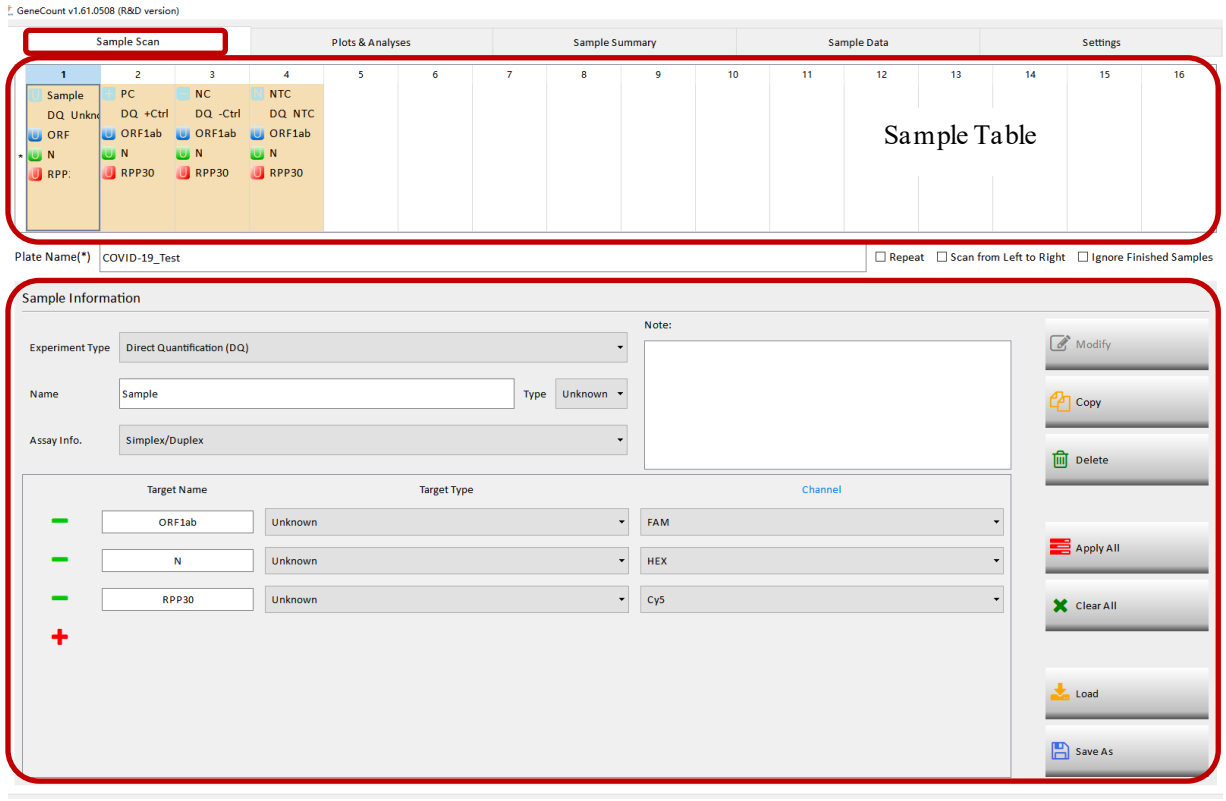


Figure 9. Sample settings for scanning

ii) Select the sample for the run and setup the following:

a. Experiment: Direct Quantification (DQ)

b. Name: Sample ID

c. Type: Unknown

d. Assay Information: Simplex/Duplex

e. Target 1 Name: ORF1ab; Target Type: Unknown; Channel: FAM

f. Target 2 Name: N; Target Type: Unknown; Channel: HEX

g. Target 3 Name: RPP30; Target Type: Unknown; Channel: Cy5

iii) Select the Positive Control Sample (PC) for the run and setup the following:

a. Experiment: Direct Quantification (DQ)

b. Name: PC

c. Type: +Ctrl

d. Assay Information: Simplex/Duplex

e. Target 1 Name: ORF1ab; Target Type: Unknown; Channel: FAM

f. Target 2 Name: N; Target Type: Unknown; Channel: HEX

g. Target 3 Name: RPP30; Target Type: Unknown; Channel: Cy5

iv) Select the No Template Control (NC) for the run and setup the following:

a. Experiment: Direct Quantification (DQ)

b. Name: NC

c. Type: -Ctrl

d. Assay Information: Simplex/Duplex

e. Target 1 Name: ORF1ab; Target Type: Unknown; Channel: FAM

f. Target 2 Name: N; Target Type: Unknown; Channel: HEX

g. Target 3 Name: RPP30; Target Type: Unknown; Channel: Cy5

v) Select the No Template Control (NTC) for the run and setup the following:

a. Experiment: Direct Quantification (DQ)

b. Name: NTC

c. Type: NTC

d. Assay Information: Simplex/Duplex

e. Target 1 Name: ORF1ab; Target Type: Unknown; Channel: FAM

f. Target 2 Name: N; Target Type: Unknown; Channel: HEX

g. Target 3 Name: RPP30; Target Type: Unknown; Channel: Cy5

vi) If any sample setting is changed, click **Modify** button to apply the change to the sample.

vii) After the samples and the plate setup is complete, save a name for the plate by clicking **Save As** button at the right side of the sample information window as shown in **Figure 10**.

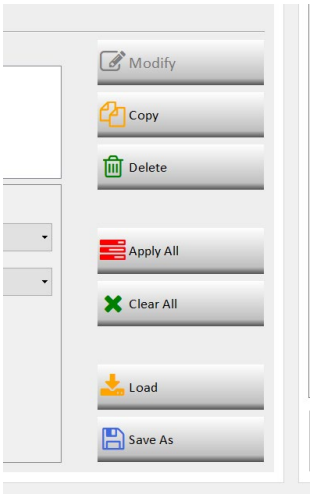
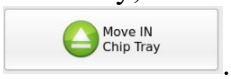


Figure 10. User interface for saving and loading the samples and plate settings.

2) Droplet scanning of the cartridge

i) After completing the DScanner sample program set up, peel off the protective film carefully from the microfluidic cartridge and transfer the microfluidic cartridge with samples to the DropX-2000 DScanner for fluorescent detection of droplets.

ii) Open the cartridge tray by clicking the "**Move OUT Chip tray**" button 

on the right panel of the integrated UI on the touch screen in the front of the instrument. After the cartridges are placed firmly in the tray, move the tray inside the instrument by clicking the "**Move IN Chip tray**" button 

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iii) Click the "**Scan Sample**" 

button from the right-hand panel to begin the droplet scanning process.

iv) During data acquisition the software will display preliminary information of acquired data for the scanned samples. Wait until all the samples are scanned for further analysis. Once the scanning is finished, samples are ready for analysis and users can find the samples listed in **Plate Layout** window as shown in **Figure 11**.

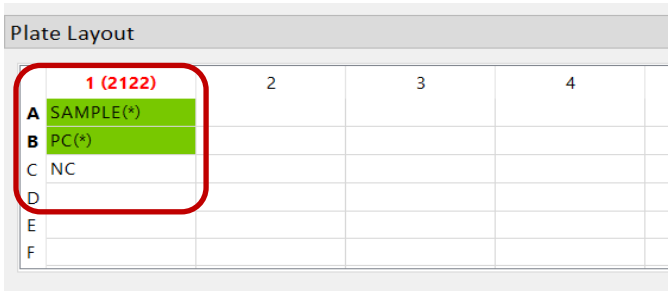

Figure 11. The samples acquired by the scanner are listed in Plate Layout window

3) Disposal of completed cartridges

Following the amplification protocol and droplet reading, microfluidic cartridge should be placed into a sealable plastic bag for disposal.

h) Data Analysis

1) After droplet scanning has been completed, sample data can be directly analyzed in the **Plots and Analyses** tab as shown in **Figure 12**. For analysis of prior data, users can open the *.rxdpcr files to analyze saved samples data by clicking the yellow, folder shaped **Load Sample** icon at the right panel. Samples are analyzed based on the positive template control sample, using the integrated software of the DScanner.

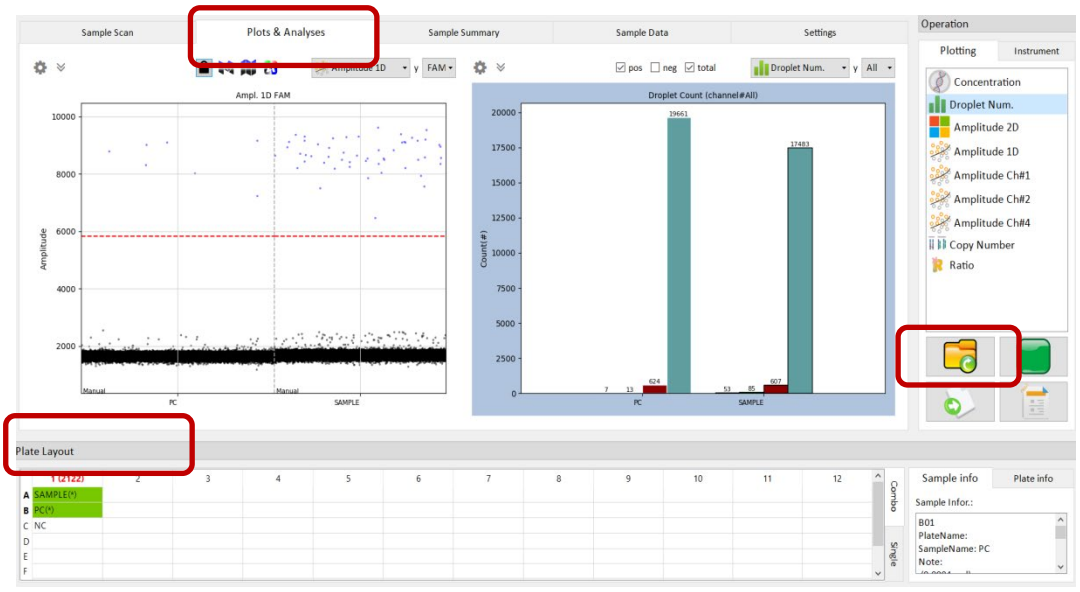

Figure 12. Sample plots and analyses

2) In the **Plate Layout**, select all the samples to be analyzed with the positive control sample (PC) to be analyzed (**Figure 13**). The PC sample is used to set proper threshold for positive clusters of the samples (see step 4 and step 5 below). The threshold is determined by using the halfway between negative droplets and positive droplets of the PC sample.

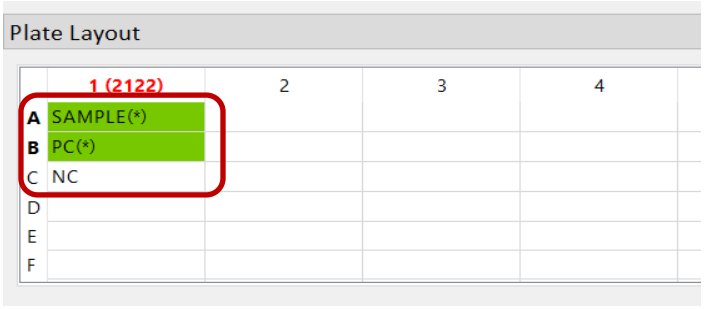

Figure 13. Samples in **Plate Layout** window

3) On the left of the Plots & Analyses tab (**Figure 14**), select Amplitude 1D plot where threshold can be set for different target genes in corresponding fluorescent channels (see step 4 and step 5 below). Select Droplet Num. plot on the right panel to display the positive droplet counts for the target genes. Check pos on the top of the plot to display the positive droplet counts for the samples.

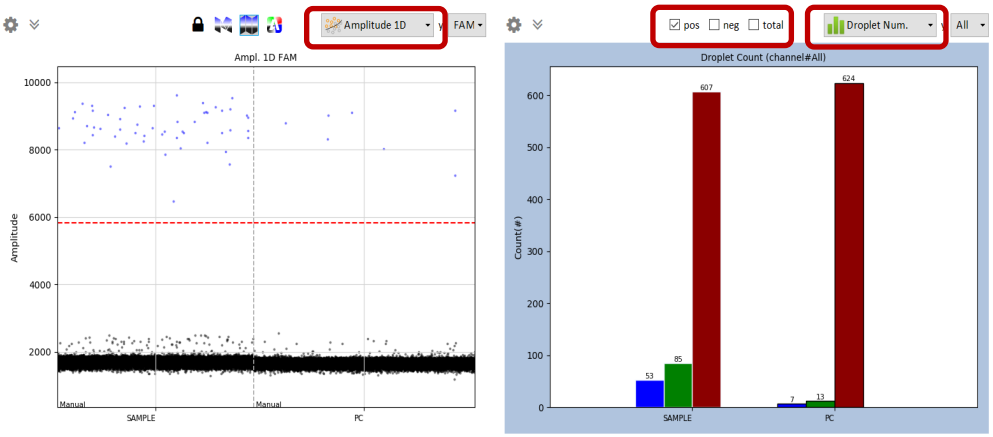

Figure 14. Plots of **Amplitude 1D** and **Droplet Number**

4) Choose FAM channel to analyze ORF1ab gene in the Amplitude 1D plot. Click the gear icon of Multi-Samples Threshold on the top of Amplitude 1D plot.

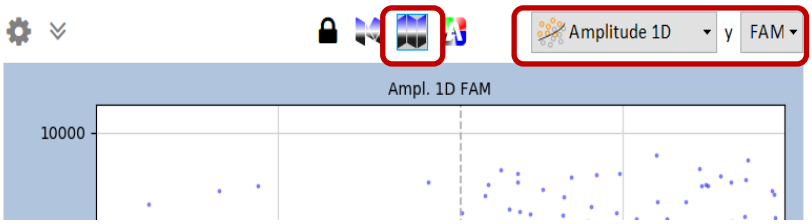

Figure 15. Thresholding in **Amplitude 1D** plot

5) Place a threshold by using the halfway between negative droplets and positive droplets of the positive control sample (PC) on the graph. The number of droplets with a signal higher than the threshold is then counted automatically as positive droplets in the FAM channel.

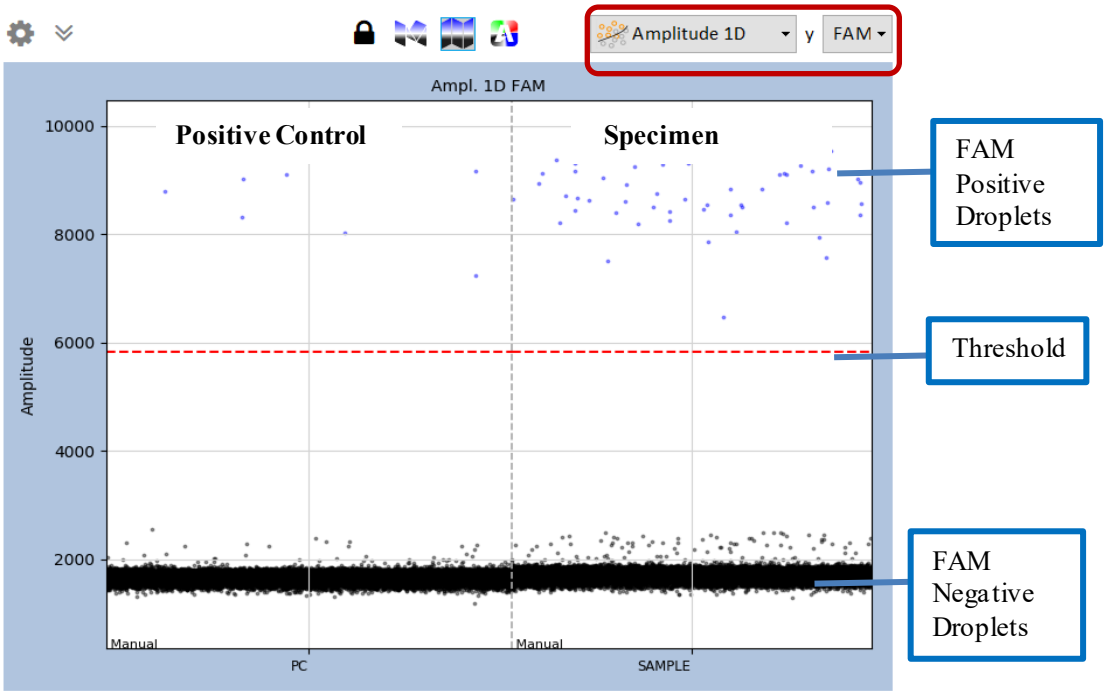

Figure 16. Thresholding specimens in FAM channel

6) This process (Step 3 to Step 5) is repeated for N gene in the **HEX** channel.

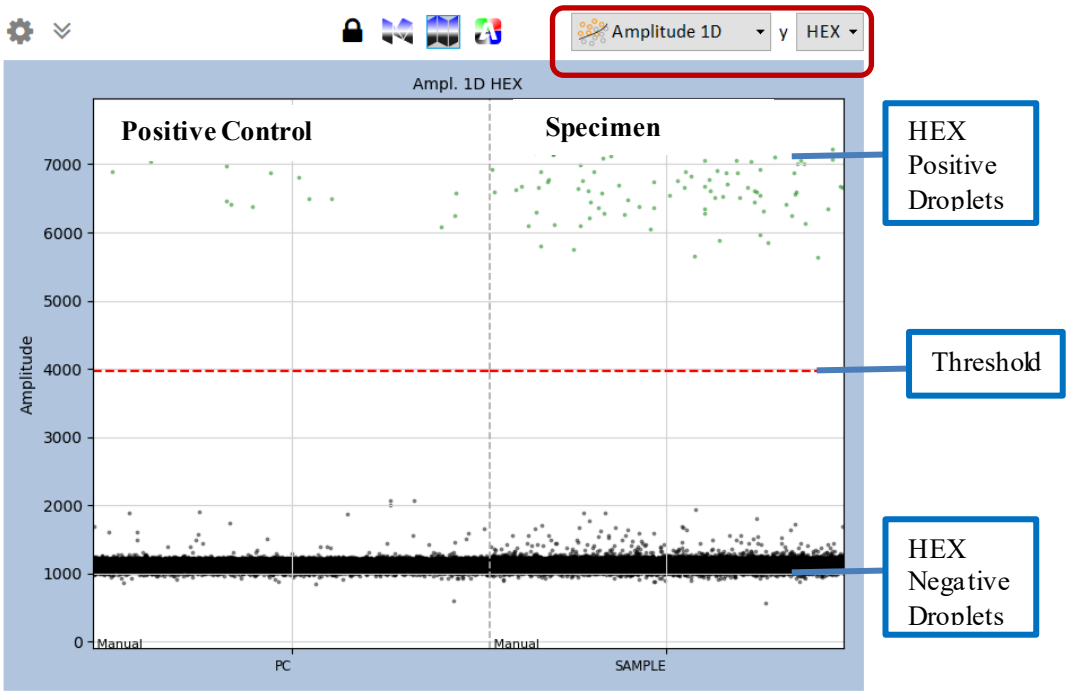

Figure 17. Thresholding specimens in HEX channel

7) This process (Step 3 to Step 5) is repeated for RPP30 gene in the **Cy5** channel.

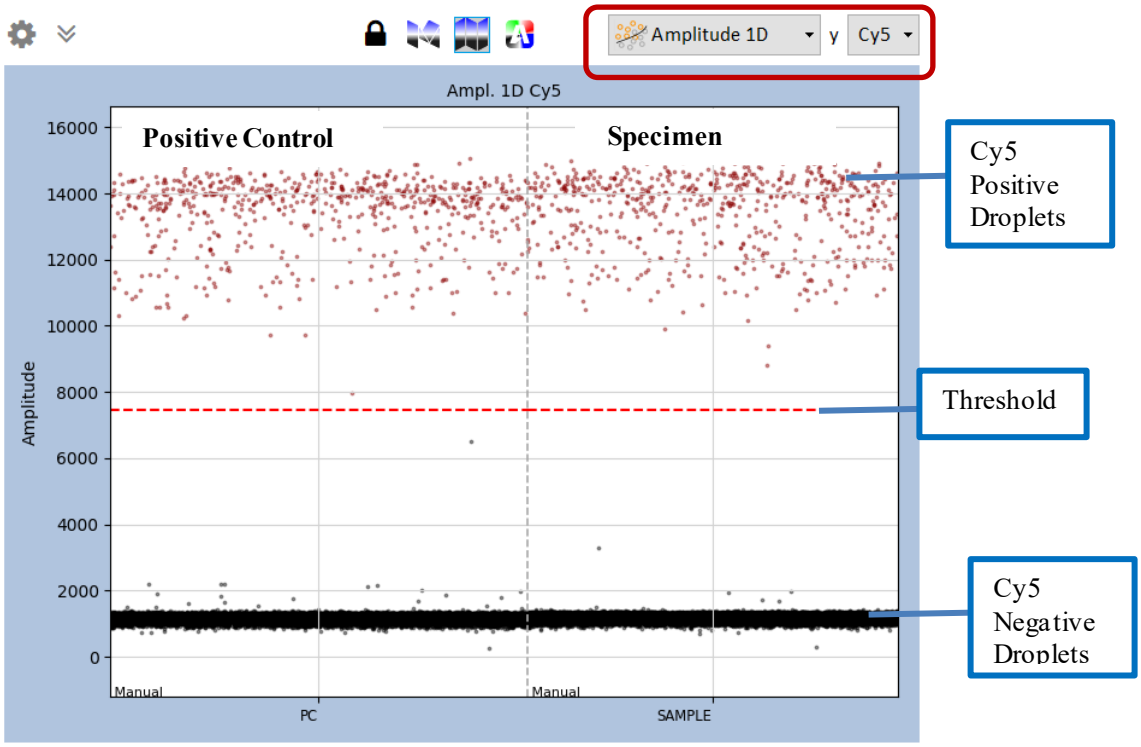

Figure 18. Thresholding specimens in Cy5 channel

8) Quantification results for the ORF1ab, N and RPP30 gene targets are provided as positive droplet counts in the **Sample Data** tab as shown in **Figure 19**. Use the **Export CSV** button on the top of the results table to export data to Excel/CSV file.

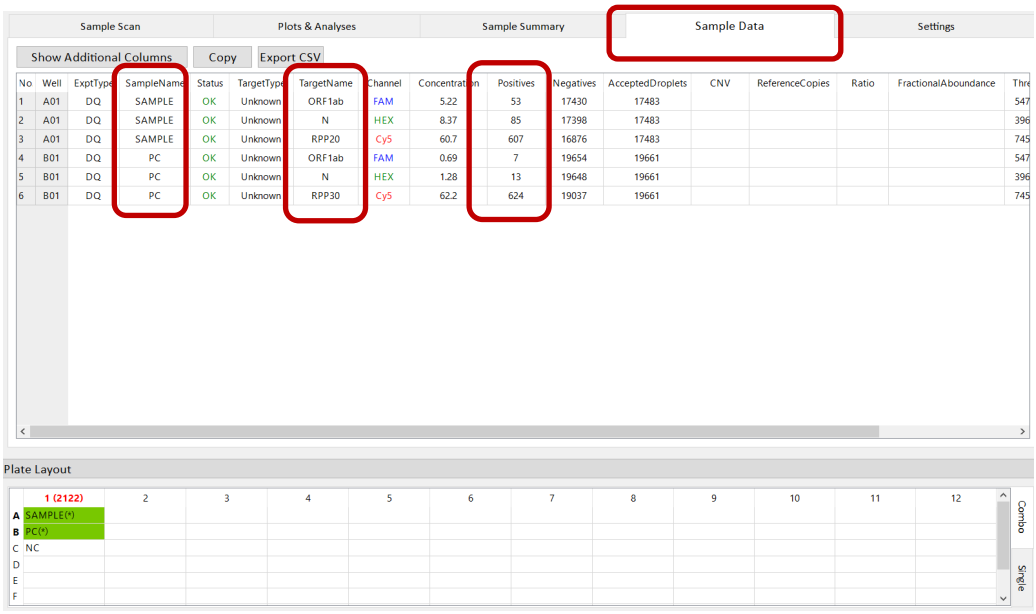

Figure 19. Quantification results of specimens

K. Interpretation of Results

All test controls must be examined prior to interpretation of patient results. If any control does not perform as described below, the run is considered invalid and all specimens must be repeated from extraction step after a root cause is identified and eliminated.

For each fluorescence channel, the number of positive droplets is used to determine whether this channel is positive or negative according to **Table 5-1**.
Because a positive result is based on the detection of only 3 positive droplets, the total droplet count can significantly impact result generation in low positive samples. Therefore, a minimum droplet count of 16,000 total droplets is required to determine a negative result. All reactions with droplet count below 13,000 have to be repeated.to ensure proper droplet generation. The software warns the user when the number of droplets is below 13,000.

For each channel first determine the following:

Table 5-1. Interpretation of Single Channel Test Results Using the *FastPlex Triplex SARS-CoV-2 detection kit (RT - Digital PCR)* Test

Channel	Positive Droplets	Interpretation
FAM	0-2 positive droplets	Negative
	≥3 positive droplets	Positive
HEX	0-2 positive droplets	Negative
	≥3 positive droplets	Positive
Cy5	0-2 positive droplets	Negative
	≥3 positive droplets	Positive

Continue to the interpretation of controls.

a) *FastPlex Triplex SARS-CoV-2 Detection Kit (RT-Digital PCR)* Controls – Positive, Negative and No template controls

- Negative controls should report positive results for the RNase P target but must report negative results for all SARS-CoV-2 targets (number of positive droplets less than 3 droplets). If any of the ORF1ab or N genes are positive the RT-Digital PCR run is invalid. Positive and negative are defined based on a cutoff of <3 positive droplets (i.e., a maximum of 2 positive droplets). The SARS-CoV-2 negative control is used as an extraction and amplification control and monitors contamination of test reagents with SARS-CoV-2 RNA as well as proper reverse transcription and amplification of the RNase P targets. If the SARS-CoV-2 negative control generates negative results of RNase P (Cy5), which is less than 3 positive droplets, it indicates the failure of RNA extraction. The specimen is required to be re-processed and re-tested.

- The positive control should be positive for the ORF1ab gene (equal or more than 3 FAM positive droplets), the N gene (equal or more than 3 HEX positive droplets) and the RNase P gene targets (equal or more than 3 Cy5 positive droplets). If the results are not positive, the RT-Digital PCR run is invalid.

- NTC control is used to detect any reagent or environmental contaminations. The NTC should be negative for ORF1ab (FAM), N (HEX) and RNase P (Cy5). If NTC shows any positive results, it indicates contamination of reagents or samples. All sample results need to be invalidated and results must not be reported. It is recommended to decontaminate the PCR lab and use a new box of un-opened reagent before repeating sample testing.

Assessment of clinical specimen test results should be performed after the positive, negative and NTC controls have been examined and determined to be valid and acceptable by the criteria listed in **Table 5-2**. If the controls are not valid, the patient results are invalid and cannot be interpreted.

Table 5-2. Expected Results of Controls Used in the *FastPlex Triplex SARS-CoV-2 Detection Kit* (RT-Digital PCR)

Control Type	Control Name	Used to Monitor	Total Droplet Number[1]	Expected Results and Concentration Values		
				SARS-COV-2 ORF1ab	SARS-CoV-2 N	RNase P
Negative	SARS-CoV-2 Negative Template Control (NC)	Assay or extraction reagent contamination	≥ 16000	**Negative** 0-2 FAM positive droplets	**Negative** 0-2 HEX positive droplets	**Positive** ≥3 Cy5 positive droplets
Positive	SARS-CoV-2 Positive Template Control (PC)	Improper assay setup, reagent failure including primer and probe degradation	⩾ 13000	**Positive** ≥3 FAM positive droplets	**Positive** ≥3 HEX positive droplets	**Positive** ≥3 Cy5 positive droplets
Negative Template Control	NTC	Assay or extraction reagent contamination	⩾ 16000	**Negative** 0-2 FAM positive droplets	**Negative** 0-2 HEX positive droplets	**Negative** 0-2 Cy5 positive droplets

[1] For the positive control to be valid it must have ≥13,000 total droplets. For the negative control and the negative template control to be valid they must have ⩾ 16,000 total droplets.

b) Examination and Interpretation of Patient Specimen Results

Only after control samples are determined to be valid, the results of each channel is used to determine whether the sample is positive or negative for SARS-CoV-2 according to **Table 6**. Note that if the Cy5 channel (RNase P) is negative, the sample result is invalid.

To ensure negative results are not generated due to low droplet numbers, a minimum of 16,000 droplet is required to report a negative result.

Table 6. Interpretation of Patient Results Using the *FastPlex Triplex* SARS-CoV-2 Detection Kit (RT-Digital PCR) Test

ORF1ab (FAM Droplets)	N (HEX Droplets)	RNase P （Cy5 Droplets)	Total Droplet Number	Result Interpretation	Report	Action

≥ 3 (Positive)	≥3 (Positive)	≥ 3 (Positive)	≥ 13000	SARS-CoV-2 **Detected**	SARS-CoV-2 **Positive**	Report results
≥ 3 (Positive)	<3 (Negative)	≥ 3 (Positive)	≥ 13000	SARS-CoV-2 **Detected**	SARS-CoV-2 **Positive**	Report results
< 3 (Negative)	≥3 (Positive)	≥ 3 (Positive)	≥ 13000	SARS-CoV-2 **Detected**	SARS-CoV-2 **Positive**	Report results
< 3 (Negative)	<3 (Negative)	≥ 3 (Positive)	≥ 16000	SARS-CoV-2 **Not detected**	SARS-CoV-2 **Negative**	Report results
< 3 (Negative)	<3 (Negative)	≥ 3 (Positive)	< 16000	**Invalid**	**Invalid**	Insufficient droplet generation number to report negative results. Repeat test. If repeat result generates droplet number ≥ 16000, report SARS-CoV-2 Negative.
Any number	Any number	Any number	< 13000	**Invalid**	**Invalid**	Insufficient droplet generation number to report result. Repeat test. If repeat result generates droplet number ≥ 13000, report result based on the criteria listed in first three rows in this table.
≥0 (Positive or Negative)	≥0 (Positive or Negative)	< 3 (Negative)	≥ 13000	**Invalid**	**Invalid**	Re-extract residual patient specimen. If repeat result is invalid, collect new sample and repeat test.

L. Limitations

- The use of this assay as an in vitro diagnostic under the FDA Emergency Use Authorization (EUA) is limited to laboratories that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests.

- Use of this assay is limited to personnel who are trained in the procedure. Failure to follow these instructions may result in erroneous results.
- The performance of ***FastPlex Triplex SARS-CoV-2 Detection Kit (RT-Digital PCR)*** for Detecting SARS-CoV-2 was established using oropharyngeal swabs. Bronchoalveolar lavage samples, nasal swabs, mid-turbinate nasal swabs and nasopharyngeal swabs are also considered acceptable specimen types for use with the ***FastPlex Triplex SARS-CoV-2 Detection Kit (RT-Digital PCR)***
- Negative results do not preclude infection with SARS-CoV-2 virus and should not be used as the sole basis for treatment or other patient management decision.
- False-negative results may arise from:
    - Improper sample collection
    - Degradation of the viral RNA during shipping/storage
    - Inadequate numbers of organisms are present in the specimen
    - 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 during specimen handling or preparation
    - Cross contamination between patient samples
    - Specimen mix-up
    - RNA contamination during product handling
- The effect of vaccines, antiviral therapeutics, antibiotics, chemotherapeutic or immunosuppressant drugs have not been evaluated.
- This test cannot rule out diseases caused by other bacterial or viral pathogens.
- Laboratories are required to report all results to the appropriate public health authorities.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

M. Conditions of Authorization for the Laboratory

The ***FastPlex Triplex SARS-CoV-2 Detection Kit (RT-Digital PCR)*** for Detecting SARS-CoV-2 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/in-vitro-diagnostics-euas.

However, to assist clinical laboratories using the ***FastPlex Triplex SARS-CoV-2 Detection Kit (RT-Digital PCR)*** for Detecting SARS-CoV-2 ("your product" in the conditions below), the relevant Conditions of Authorization are listed below:

A. Authorized laboratories[1] using your product will include with result reports of your product, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

B. Authorized laboratories using your product will use your product as outlined in the Instructions for Use. 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 use your product are not permitted.

C. Authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.

D. Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

E. Authorized laboratories will collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUAReporting@fda.hhs.gov) and PreciGenome, LLC (info@precigenome.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.

F. All laboratory personnel using your product must be appropriately trained in RT-Digital PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.

G. You, authorized distributors, and authorized laboratories using your product 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, "United States (U.S.) laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests" as "authorized laboratories.

N. Performance Characteristics

a) Limit of Detection (LoD) - Analytical Sensitivity

To determine the tentative LoD, negative clinical matrix was prepared by pooling oropharyngeal swabs specimens collected from person negative for SARS-CoV-2. The negative matrix was used to serially dilute SARS-CoV-2 pseudovirus (Fubio, Cat: FNV2001, Lot :20200302) from 71.4 to 1785.7 copies/mL in replicates of four. Replicates were individually processed using the QIAamp Viral RNA Mini Kit according to the ***FastPlex Triplex SARS-CoV-2 detection kit (RT-Digital PCR)*** instructions for use. The tentative LoD was determined to be 571.4 copies/mL.

The tentative LoD was confirmed by testing 20 additional replicates of contrived samples at the preliminary LoD concentration of 571.4 copies/mL. The contrived replicates were prepared and extracted following the same procedure above. The LoD was confirmed to be 8 copies of viral RNA per reaction (571.4 copies/mL) as 95% (19/20) of the replicates were positive. Data are shown in **Table 7**.

Table 7. LoD Verification Study Results

Nominal concentration (copies/mL)	Number of Replicates Tested	ORF1ab		N		RNase P		Detected Replicates	Detection Rate
		Detected Replicates	Mean positive Droplet Count	Detected Replicates	Mean positive Droplet Count	Detected Replicates	Mean positive Droplet Count		
571.4	20	11	3	19	7	20	747	19/20	95%

b) Inclusivity (Analytical Sensitivity)

Of 1066 published SARS-COV-2 sequences (https://blast.ncbi.nlm.nih.gov/Blast.cgi), the following was observed:

- The ORF1ab forward primer and the N-gene probe demonstrated 100% homology with 1066 published sequences in NCBI GenBank.
- The ORF1ab reverse primer, the ORF1ab probe and the N-gene reverse primer had 100% homology with 1065 of 1066 sequences; one sequence for each, primer and the probe did not yield 100% homology. Each had a single mismatch that – based on the Tm of the annealing temperature and the location in the primer/probe is not expected to impact binding.
- The N-gene forward primer had 100% homology with 1017 out of 1066 published sequences. Of the remaining 49 sequences 16 sequences have a single base pair mismatch in a position that would not impact the primer/probe binding. 32 sequences have a 3 consecutive nucleotide mismatch at the 5' end of the primer but these sequences still have an estimated Tm that is still above the annealing temperature of the test and they are expected to not impact amplification. One sequence was observed that combined the 3 nucleotides mismatch at the 5' end with a single nucleotide m mismatches in the 3' third of the primer. This sequence may fail to be detected.

However, the failure to amplify one of the targets in individual sequences is mitigated by the dual target design of the test. Therefore, all currently published sequences are expected to be detected with the ***FastPlex Triplex SARS-CoV-2 Detection Kit.***

c) Cross-reactivity (Analytical Specificity)

Cross-reactivity of the ***FastPlex Triplex SARS-CoV-2 Detection Kit (RT-Digital PCR)*** was evaluated using both *in silico* analysis and wet testing against normal and pathogenic organisms found in the respiratory tract.

***I) In silico* analysis:**

In silico analysis for possible cross-reactivity with the organisms listed in **Table 8** was performed. With the exception of SARS-coronavirus, no organisms, including other related

coronaviruses, were amplified by either the ORF1ab or N target PCR primers and probes. The results of the *in silico* analysis suggest that the ***FastPlex Triplex SARS-CoV-2 Detection Kit (RT-Digital PCR)*** is specific for SARS-CoV-2.

SARS-coronavirus, a closely related human SARS virus exhibited > 90% homology to the forward primer, probe of ORF1ab target, forward and reverse primer of N target and – based on the *in silico* analysis - would be expected to result in cross-reactivity with the ***FastPlex Triplex SARS-CoV-2 Detection Kit (RT-Digital PCR).*** However, cross-reactivity was not observed in the wet testing (see Table 9 below). The impact of such cross-reactivity is further mitigated through the fact that SARS-CoV virus is not currently circulating.

Table 8. Cross-Reactivity *In Silico* Study (Reference Sequences of Organisms)

Pathogen	GenBank Acc#	Pathogen	GenBank Acc#
Human coronavirus 229E	AF304460.1	A7 Respiratory syncytial virus	U39661.1
Human coronavirus OC43	NC_006213.1	Rhinovirus	NC_009996.1
Human coronavirus HKU1	NC_006577.2	*Chlamydia pneumoniae*	NC_000922.1
Human coronavirus NL63	NC_005831.2	*Haemophilus influenzae*	NC_000907.1
SARS-coronavirus	NC_004718.3	*Legionella pneumophila*	NC_002942.5
MERS-coronavirus	NC_019843.3	*Mycobacterium tuberculosis*	NC_018143.2
Adenovirus (e.g. C1 Ad. 71)	KF268207	*Streptococcus pneumoniae*	NC_003098.1
Human Metapneumovirus (hMPV)	MG431250.1	*Streptococcus pyogenes*	NC_002737.2
Parainfluenza virus 1	NC_003461.1	*Bordetella pertussis*	NC_002929.2
Parainfluenza virus 2	NC_003443.1	*Mycoplasma pneumoniae*	NC_000912.1
Parainfluenza virus 3	KF687319	*Pneumocystis jirovecii* (PJP)	NW_017264775.1
Parainfluenza virus 4	KF483663.1	*Candida albicans*	NC_032089.1
Influenza A	KT388699.1	*Pseudomonas aeruginosa*	NC_002516.2
Influenza B	AF101982.1	*Staphylococcus epidermis*	NC_004461.1

Enterovirus (e.g. EV68)	NC_038308.1	*Streptococcus salivarius*	CP013216.1

***II) Wet-Testing*:**

Wet testing with normal and pathogenic organisms of the respiratory tract was performed to confirm the results of the *in silico* analysis. The organism identified in **Table 9** below were tested with 3 lots of ***FastPlex Triplex SARS-CoV-2 Detection Kit (RT-Digital PCR)*** at the organism concentrations indicated (1 replicate per lot). All results were negative with the internal control target being successfully detected.

Table 9. Wet testing of organisms in negative clinical matrix for cross-reactivity with the *FastPlex Triplex SARS-CoV-2 Detection Kit (RT-Digital PCR)*

Pathogen	Concentration	Fastplex Triplex SARS-CoV- 2 Detection Kit (RT-Digital PCR)			
		Mean FAM Droplets	Mean HEX Droplets	Mean Cy5 Droplets	Interpretation
Influenza A virus (A/Aalborg/INS132/2009(H1N1 (HA-NA)	⩾ 1E+7 Copy/mL	0	0	255	Negative
Influenza A virus (A/Addis Ababa/1514A07305892N/2013(H3N2 (HA-NA)	⩾ 1E+7 Copy/mL	0	0.33	251	Negative
Influenza A virus (A/Anhui/1-DEWH730/2013(H7N9 (HA-NA))	⩾ 1E+7 Copy/mL	0	0	324	Negative
Influenza B virus (B/Yamagata/222/2002 (HA-NA)	⩾ 1E+7 Copy/mL	0	0	279	Negative
Influenza B virus (B/Victoria/1/2014 (HA-M1))	⩾ 1E+7 Copy/mL	0	0	299	Negative
Influenza A virus (A/goose/Guangdong/1/1996(H5N1))	⩾ 1E+7 Copy/mL	0	0	267	Negative
FNV-SARS-ORF1a-N	⩾ 1E+7 Copy/mL	0	0	277	Negative
FNV-SARS-ORF1a-N +SARS-CoV-2 [1]	⩾ 1E+7 Copy/mL	7	8	228	Positive
FNV-MERS-abEN	⩾ 1E+7 Copy/mL	0	0	271	Negative

[1] Testing SARS in the presence of whole genomic RNA extracted from SARS-CoV-2 positive patient (NTHL-20200212) spiked at 2x LoD demonstrated that SARS-CoV-2 is detectable.

d) Clinical Evaluation:

The performance of ***FastPlex Triplex SARS-CoV-2 Detection Kit (RT-digital PCR)*** with oropharyngeal swab clinical samples was evaluated using 170 clinical specimens. Clinical samples were collected by qualified personnel according to the package insert of the collection device. All clinical samples were randomized, blinded, and tested with ***FastPlex Triplex SARS-CoV-2 Detection Kit (RT-digital PCR)*** and a RT-PCR comparator test that is EUA authorized for use with upper respiratory specimens including oropharyngeal swabs. Nucleic acid extraction was performed with the QIAamp Viral RNA Mini Kit. The comparator test was run on the ABI 7500 per instructions. Results are determined based on the manufacturers' instructions.

A total of 168 specimens were available for analysis; 2 specimens was excluded due to an invalid test result (the internal control was negative).

The positive percent agreement (PPA) was 96.30%, 95% CI [90.8%-99.0%] and the negative percent agreement (NPA) was 96.7%, 95% CI [88.5%-99.6%] as shown in **Table 10**.

Table 10. Clinical Evaluation between *FastPlex Triplex SARS-CoV-2 Detection Kit (RT-digital PCR)* and FDA EUA RT-PCR Test

	Comparator Test Positive	Comparator Test Negative	Total
FastPlex Triplex SARS-CoV-2 Positive	104	2	106
FastPlex Triplex SARS-CoV-2 Negative	4	58	62
Total	108	60	168

PPA = 104/108 x 100% = 96.30%, (95% CI: 90.9%-98.6%)

NPA = 58/60 x 100%= 96.7%, (95% CI: 88.6%- 99.1%)

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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 manual extraction using QIAamp Viral RNA Mini Kit [Qiagen, (50)-Cat. #52904 or (250)-Cat. #52906] using Thermofisher Heraeus Pico 17 centrifuge and all extracted samples were tested on DropX-2000 Digital PCR System. The results are summarized in Table 11.

Table 11: Summary of LoD Confirmation Result using the FDA SARS-CoV-2 Reference Panel

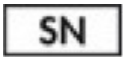
Reference Materials Provided by FDA	Specimen Type	Product LoD	Cross-Reactivity
SARS-CoV-2	Oropharyngeal Swab	$1.8x10^5$ NDU/mL	N/A
MERS-CoV		N/A	ND

NDU/mL = RNA NAAT detectable units/mL

N/A: Not applicable

ND : Not detected

O. Symbols

	Contains reagents sufficient for <N> number of reactions
	Use by
	*In vitro* Diagnostic Device
	Catalog Number
	Lot Number
	Serial Number
	Prescription Use Only
	Temperature Limitations
	Manufacturer
	Keep away from sunlight
	Consult Instructions for use

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References:

1) YF Men, Y Fu, ZT Chen, P.A. Sims, W J Greenleaf and YY Hung. Digital polymerase chain reaction in an array of femtoliter polydimethylsiloxane microreactors. Anal. Chem. 2011, 83, 21, 8158-816.

2) CDC Guidelines for clinical specimen handling: https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html