# INSTRUCTIONS FOR USE

## QuantiVirus™ SARS-CoV-2 Test Kit

For Real Time RT-qPCR test

Rx Only

IVD

For Emergency Use Authorization (EUA) only

**CATALOG NUMBER**

DC-11-0007 (24 Reactions)
DC-11-0008 (48 Reactions)
DC-11-0009 (480 Reactions)

**COMPANY**

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# CONTENTS

# PART 1. INTENDED USE

The QuantiVirus™ SARS-CoV-2 Test kit is a real-time RT-PCR test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in nasal swabs, nasopharyngeal swabs, oropharyngeal swabs, and sputum 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, to perform high complexity tests.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in sputum and 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 infective status. Positive results do not rule out bacterial co-infection with other viruses. 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-2infection 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 QuantiVirus™ SARS-CoV-2 Test kit is intended for use by qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and *in vitro* diagnostic procedures. The QuantiVirus™ SARS-CoV-2 Test kit is only for use under the Food and Drug Administration's Emergency Use Authorization.

## PART 2. PRODUCT DESCRIPTION

The QuantiVirus™ SARS-CoV-2 Test kit is a real-time reverse transcription polymerase chain reaction (RT -qPCR) test that includes the assays and controls for a real-time RT-PCR test for the qualitative detection of RNA from SARS-CoV-2 in nasal swabs, nasopharyngeal swab, oropharyngeal swab, and sputum specimens from patients who are suspected of COVID-19.

Extracted RNA is reverse-transcribed and amplified in a single reaction. Three genes of the SARS- CoV-2 (Figure 1) including N, Orf1ab and E genes are targeted in the qRT-PCR assay. Primers and TaqMan probes designed for conserved regions of the SARS- CoV-2 virus genome allow specific amplification and detection of the viral RNA from all strains of SARS-CoV-2 from respiratory specimens. The Human RNase P gene is used as Internal control to monitor viral RNA extraction efficiency and assess amplifiable RNA in the samples to be tested.

**Figure 1. SARS-CoV-2 Genome Structure**

# PART 3. COMPONENTS AND STORAGE

## 3.1 Kit Components

QuantiVirus™ SARS-CoV-2 Test kit includes the following components:

- One step RT-qPCR Master mix
- 3 sets of Primers/ Probes specific to different SARS CoV-2 genomic regions and primers/probe for human RNase P gene.
- A Positive control (PC), Extraction control (EC) and a No Template control (NTC)

The QuantiVirus™ SARS-CoV-2 Test kit is available in 3 pack sizes – 24 reactions kit, 48 reactions kit and 480 reaction kit. Individual components and their descriptions are listed in Table 1 below.

## 3.2 Shelf-Life

Final storage of kits is proposed at -25°C to -15°C. Based on individual component shelf life, the approximate shelf life of the kit is estimated to be 12 months. Do not use expired reagents from the kit.

**Table 1. Kit components**

**Pack-Size: 24 Reactions**

| Name of Component | Part # | Description | Pack Size: 24 reactions kit | Label Volume for each vial | Storage Temp |
|---|---|---|---|---|---|
| **5x Primer/probe mix** | 1008133 | **Primer/probe Mix A (N gene):** N gene primers and probes | 1 vial | 48 µL | -25°C to -15°C |
| | 1008143 | **Primer/probe Mix B (Orf1ab gene):** Orf1ab gene primers and probes | 1 vial | 48 µL | -25°C to -15°C |
| | 1008153 | **Primer/probe Mix C (E gene):** E gene primers and probes | 1 vial | 48 µL | -25°C to -15°C |
| | 1008163 | **Primer/probe Mix D (Human RNase P gene):** Human RNase P gene primers and probes | 1 vial | 48 µL | -25°C to -15°C |
| **One step qRT-PCR master mix** | 1008183 | TaqPath 1-step Multiplex Master mix | 1 vial | 240 µL | -25°C to -15°C |
| **Positive Control (PC)** | 1008203 | Synthetic DNA templates for N, Orf1ab and E genes ($1x10^4$ copies/µL) | 1 vial | 24 µL | -25°C to -15°C |
| **Extraction Control (EC)** | 1008193 | *In vitro* transcribed RNA ($1x10^5$ copies/µL) | 1 vial | 50 µL | -25°C to -15°C |
| **No Template Control (NTC)** | 1008213 | Nuclease-Free Water | 1 vial | 480 µL | -25°C to -15°C |

**Pack-Size: 48 Reactions**

| Name of Component | Part # | Description | Pack Size: 48 reactions kit | Label Volume for each vial | Storage Temp |
|---|---|---|---|---|---|
| **5x Primer/probe mix** | 1008132 | **Primer/probe Mix A (N gene):** N gene primers and probes | 1 vial | 96 µL | -25°C to -15°C |
| | 1008142 | **Primer/probe Mix B (Orf1ab gene):** Orf1ab gene primers and probes | 1 vial | 96 µL | -25°C to -15°C |
| | 1008152 | **Primer/probe Mix C (E gene):** E gene primers and probes | 1 vial | 96 µL | -25°C to -15°C |
| | 1008162 | **Primer/probe Mix D (Human Rnase P gene):** Human Rnase P gene primers and probes | 1 vial | 96 µL | -25°C to -15°C |
| **One step qRT-PCR master mix** | 1008182 | TaqPath 1-step Multiplex Master mix | 1 vial | 480 µL | -25°C to -15°C |
| **Positive Control (PC)** | 1008202 | Synthetic DNA templates for N, Orf1ab and E genes ($1x10^4$ copies/µL) | 1 vial | 40 µL | -25°C to -15°C |
| **Extraction Control (EC)** | 1008192 | *In vitro* transcribed RNA ($1x10^5$ copies/µL) | 1 vial | 80 µL | -25°C to -15°C |
| **No Template Control (NTC)** | 1008212 | Nuclease-Free Water | 1 vial | 960 µL | -25°C to -15°C |

**Pack-Size: 480 Reactions**

| Name of Component | Part # | Description | Pack Size: 480 reactions kit | Label Volume for each vial | Storage Temp |
|---|---|---|---|---|---|
| **5x Primer/probe mix** | 1008134 | **Primer/probe Mix A (N gene):** N gene primers and probes | 1 vial | 960 µL | -25°C to -15°C |
| | 1008144 | **Primer/probe Mix B (Orf1ab gene):** Orf1ab gene primers and probes | 1 vial | 960 µL | -25°C to -15°C |
| | 1008154 | **Primer/probe Mix C (E gene):** E gene primers and probes | 1 vial | 960 µL | -25°C to -15°C |
| | 1008164 | **Primer/probe Mix D (Human RNase P gene):** Human **RNase** P gene primers and probes | 1 vial | 960 µL | -25°C to -15°C |
| **One step qRT-PCR master mix** | 1008184 | TaqPath 1-step Multiplex Master mix | 1 vial | 4800 µL | -25°C to -15°C |
| **Positive Control (PC)** | 1008204 | Synthetic DNA templates for N, Orf1ab and E genes ($1x10^4$ copies/µL) | 1 vial | 400 µL | -25°C to -15°C |
| **Extraction Control (EC)** | 1008194 | *In vitro* transcribed RNA ($1x10^5$ copies/µL) | 1 vial | 800 µL | -25°C to -15°C |
| **No Template Control (NTC)** | 1008214 | Nuclease-Free Water | 1 vial | 9600 µL | -25°C to -15°C |

# PART 4. MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT

## A. Reagents for Viral RNA Isolation

- Thermo Fisher PureLink™ viral RNA/DNA mini kit (cat# 122800500)
  *Follow manufacturer's Instructions For Use*

## B. Consumables

- White 0.2 mL DNase-free PCR tubes or plates (96 well) recommended by the instrument manufacturer
- Nuclease-free, low-binding microcentrifuge tubes
- Nuclease-free pipet tips with aerosol barriers

## C. Other Reagents

- Molecular grade DNase/ RNase free water

## D. Equipment

- Applied Biosystems™ QuantStudio 5 Real-Time PCR Instrument (QuantStudio™ Design and Analysis Software v1.4)
  **OR**
  Applied Biosystems™ 7500 Fast Dx Real-Time PCR Instrument (SDS Software v1.4)
- Dedicated pipettes* (adjustable,10-100 µL, 100-200 µL, 1000 µL) for sample preparation
- Dedicated pipettes* (adjustable, 1-20 µL, 10-100 µL, 100-200 µL, 1000 µL) for PCR Master Mix preparation
- Dedicated pipettes* (adjustable, 1-20 µL, 10-100 µL) for dispensing of template RNA/DNA
- 12-channel multichannel pipettor (P-10) for transferring reactions to PCR plates.
- Microcentrifuge
- Benchtop centrifuge* with rotor for 1.5 mL tubes
- Benchtop mini centrifuge with rotor for PCR strips
- Benchtop plate centrifuge
- Vortex instrument
- Compatible 96-well PCR plate
- Compatible clear PCR plate sealer
- Reagent reservoir (holding 25 ml liquid or more)
- Spectrophotometer

**Note**: * Prior to use, ensure that instruments and equipment have been maintained and calibrated according to the manufacturer's recommendations.

# PART 5. WARNING AND PRECAUTIONS

## 5.1. Warnings and Precautions

- For *in vitro* diagnostic use.
- For use under an Emergency Use Authorization (EUA) only.
- For prescription use only.
- Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.
- Handle all specimens as if infectious using safe laboratory procedures. Refer to CDC 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
- Use extreme caution to prevent contamination of PCR reactions with the positive and negative controls provided.
- Minimize exposure of the 4X PCR Master Mix to room temperature for optimal amplification.
- Avoid over exposure of the primer-probe mixes to light for optimal fluorescent signal.
- Use of non-recommended reagent volumes may result in a loss of performance and may also decrease the reliability of the test results.
- Use of non-recommended volumes and concentrations of the RNA/ DNA sample may result in a loss of performance and may also decrease the reliability of the test results.
- Use of non-recommended consumables with instruments may adversely affect test results.
- Do not re-use any remaining reagents after PCR amplification is completed.
- Additional validation testing by user may be necessary when using non-recommended instruments.
- Perform all experiments under proper sterile conditions using aseptic techniques.
- Perform all procedures using universal precautions.
- Wear personal protective apparel, including disposable gloves, throughout the assay procedure.
- Do not eat, drink, smoke, or apply cosmetics in areas where reagents or specimens are handled.
- Dispose of hazardous or biologically contaminated materials according to the practices of your institution.
- Discard all materials in a safe and acceptable manner, in compliance with all legal requirements.
- Dissolve reagents completely, then mix thoroughly by pipetting up and down several times or vertexing if needed.
- If exposure to skin or mucous membranes occurs, immediately wash the area with large amounts of water. Seek medical advice immediately.
- Do not use components beyond the expiration the date printed on the kit boxes.
- Do not mix reagents from different lots.
- Return all components to the appropriate storage condition after preparing the working reagents.
- Do not interchange vial or bottle caps, as cross-contamination may occur.
- Keep all the materials on ice when in use.
- Do not leave components out at room temperature for more than 2 hours.
- Reagents supplied are formulated specifically for use with this kit. Make no substitutions in order to ensure optimal performance of the kit. Further dilution of the reagents or alteration of incubation time and temperature may result in erroneous or discordant data.

The product contains no substances which at their given concentration, are considered to be hazardous to health or environment.

HMIS

| | |
|---|---|
| Health | 0 |
| Flammability | 0 |
| Reactivity | 0 |

## 5.2 Handling and Storage

This kit is shipped on dry ice. If any component of the kit is not frozen on arrival, the outer packaging has been opened during transit, or the shipment does not contain a packaging note or the reagents, please contact DiaCarta or the local distributors as soon as possible.

The kit should be stored at -20 °C immediately upon receipt at -15°C to -25°C in a constant-temperature freezer and must be protected from light. When stored under the specified storage conditions, the kit is stable until the stated expiration date. It is recommended to store the PCR reagents in a pre-amplification area and the controls in a postamplification (DNA template-handling) area. The kit can undergo up to 6 freeze-thaw cycles without affecting performance.

All reagents must be thawed at ambient temperature for a minimum of 30 minutes before use. Do not exceed 2 hours at ambient temperature. The primer and probe mixes contain fluorophore labeled probes and should be protected from light. It is recommended that all reagents should be kept on ice when setting up the assay mixes.

Attention should be paid to expiration dates and storage conditions printed in the box and labels of all components. Do not use expired or incorrectly stored components.

## 5.3. General Considerations

Effective use of qPCR tests requires good laboratory practices, including maintenance of equipment that is dedicated to molecular biology. Use nuclease-free lab ware (pipettes, pipette tips, reaction vials) and wear gloves when performing the assay. Use aerosol-resistant pipette tips for all pipetting steps to avoid cross contamination of the samples and reagents.

Prepare the assay mixes in designated pre-amplification areas using only equipment dedicated to this application. Add template RNA/DNA in a separate area (preferably a separate room). Use extreme caution to prevent RNase and DNase contamination that could result in degradation of the template RNA/DNA, or PCR carryover contamination, which could result in a false positive signal.

Reagents supplied are formulated specifically for use with this kit. Make no substitutions in order to ensure optimal performance of the kit. Further dilution of the reagents or alteration of incubation times and temperatures may result in erroneous or discordant data.

# PART 6. SAMPLES & CONTROLS

Patient samples must be collected according to appropriate CDC guidelines. Positive, Extraction control and No Template Controls must be included in every run to accurately interpret patient test results.

**Table 2. Assay controls**

| Control | Used to monitor | Assays |
|---|---|---|
| Positive Control (Synthetic DNA) | RT-PCR reaction | Three genes assay |
| No Template Control (DNase/RNase free water) | Cross contamination for assay procedure | Three genes assay |
| Extraction Control (*in vitro* transcribed RNA) | RNA extraction, reverse transcription and qPCR | RNase P gene assay |

**a. Positive Control (PC)**

A positive control is a mix of synthetic DNA templates for each target of sequences for N, E, and Orf1ab genes of the SARS- CoV2 genome at a concentration of $1x10^4$ copies/µL.

Positive controls must show the appropriate values in FAM channel for the run to be valid. Positive control monitors the function of each assay component.

**b. Extraction control (EC)**

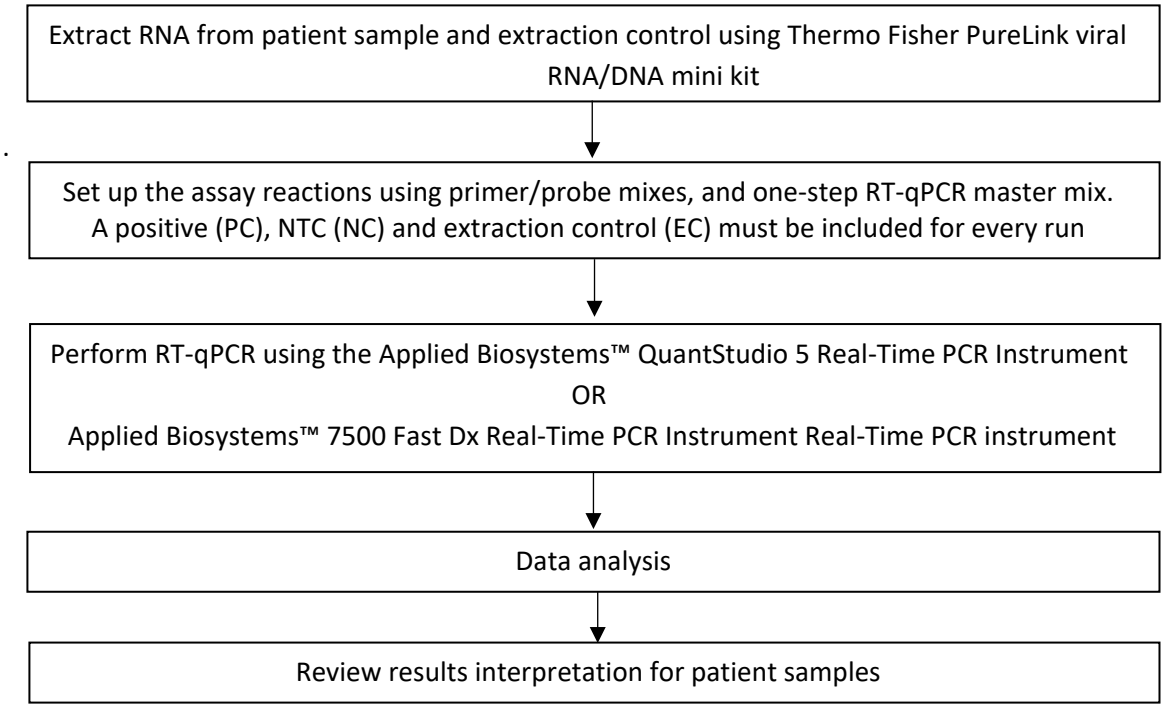
Extraction Control is a ribosomal protein (RP) gene *in vitro* transcribed RNA at $10^5$ copies/µL. The extraction control RP RNA undergoes the full extraction procedure. As the Extraction Control, the RP RNA should be positive for RP gene, but negative for all viral genes (N, E, and ORF 1ab). This control should be run with every batch of extraction.

**c. No Template Control (NTC)**

Nuclease free water is used in place of template. No amplification should be observed in all channels, assuring the absence of contamination during assay set-up.

## PART 7. WORKFLOW

The brief procedure for performing the assay include the following steps:




The workflow begins with nucleic acid extraction from nasopharyngeal swab, oropharyngeal swab and sputum specimens. RNA is isolated and purified from the specimens using the Thermo Fisher PureLink™ viral RNA/DNA mini kit* (Cat# 122800500). The purified nucleic acid is reverse transcribed into cDNA and amplified using the one step QuantiVirus™ SARS CoV-2 test kit using the Applied Biosystems™ QuantStudio 5 Real-Time PCR instrument* or Applied Biosystems™ 7500 Fast Dx Real-Time PCR Instrument*. In the process, the probes anneal to three (3) specific target sequences located between three (3) pairs of unique forward and reverse primers for the following genes:

- N gene
- ORF1ab gene
- E gene

The RNase P primers target the human RNase P housekeeping gene to monitor successful RNA extraction. During the extension phase of the PCR cycle, the 5' exo-nuclease activity of Taq polymerase degrades the probe, causing the reporter dye to separate from the quencher dye, generating a fluorescent signal. With each cycle, additional reporter dye molecules are cleaved from their respective probes, increasing the fluorescence intensity. Fluorescence intensity is monitored at each PCR cycle by the PCR instrument.

**Refer to manufacturer's Instructions for use*

## 7.1. Sample Collection and Handling

Sample collection device is not a part of the assay kit. All testing for COVID-19 should be conducted in consultation with a healthcare provider. We recommend using CDC guidelines for sample collection (Nasopharyngeal swab (NP) /oropharyngeal swab (OP) and sputum) and storage available at link below - https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html

**Nasopharyngeal swab (NP) /oropharyngeal swab (OP) Collection –**

Once the swabs have been collected as per the CDC guidelines above, it is recommended to use Universal Transport Medium (UTM) System (for transportation/ temporary storage of nasopharyngeal and oropharyngeal swabs. Specimen collected in the UTM should be processed within 48 hours from collection and stored at 2-25°C during that time as per the manufacturer's instructions.

## 7.2. Viral RNA Isolation

The QuantiVirus™ SARS-CoV-2 Test kit uses Thermo PureLink™ Viral RNA/DNA Mini Kit (Cat. 12280050) for RNA isolation (follow manufacturer's IFU for details). It is recommended to use 200 uL starting material for RNA isolation. Prior to RNA extraction, spike 2 uL of Extraction control (EC) from the QuantiVirus™ kit into 198 uL sterile RNase-free water (or E3 from Thermo PureLink™ Viral RNA/DNA Mini Kit). Process the spiked Extraction control and clinical sample for viral RNA isolation according to the manufacturer's instructions. It is suggested to elute RNA in 30-50 uL of E3 in the elution step.

Up to 5.5 µL of the extracted RNA can be used in 1 reaction. After RNA isolation, use spectrophotometer to check the RNA concentration, make sure the A260/A280 value is ~ 2.0. Use extreme precautions to handle RNA samples to prevent RNA degradation caused by RNases, follow general lab safety protocol and use precautions for handling RNA. Use DEPC treated water, containers and consumables. Store extracted RNA at -80°C if not using immediately.

## 7.3. Preparation of Reagents and Assay Mixes

1) Thaw all primer and probe mixes, Positive Control, Nuclease-Free Water and 4X qRT-PCR Master Mix provided.
2) Thaw all reaction mixes at room temperature for a minimum of 30 minutes.
3) Keep all thawed reagents on ice.
4) Vortex all components except the PCR Master Mix and Primer and Probe Mix for 5 seconds and perform a quick spin.
5) The RT-qPCR Master Mix and Primer/probe mix should be mixed gently by inverting the tube a few times.

Prior to use, ensure that any precipitate in the RT-qPCR Master Mix is re-suspended by pipetting up and down multiple times. Do not leave kit components at room temperature for more than 2 hours. The PCR reactions are set up in a total volume of 10 µL/reaction. Table 3 shows the component volumes for each 10 ul reaction.

**Table 3. Assay components and reaction volume**

| Components | Volume/Reaction |
|---|---|
| 4X RT - qPCR Master Mix | 2.5 µL |
| Primer and Probe Mix | 2 µL |
| RNA sample or Controls* | Sample - 5.5 µL<br>Controls - add 2 µL of controls and add 3.5 µL of nuclease free water to make 5.5 µL volume |
| Total Volume | 10 µL |

For accuracy, 4x PCR Master Mix, primers and probes should be pre-mixed into assay mixes as described in Table 4 below.

**Preparation of Assay Mixes**

Assay mixes should be prepared just prior to use. Label a micro centrifuge tube (not provided) for each reaction mix, as shown in Table 4. For each control and virus detection reaction, prepare sufficient working assay mixes for the RNA samples, one Positive Control, one extraction control and one Nuclease-Free Water for No-Template Control (NTC), according to the volumes in Table 4. Include reagents for 1 extra sample to allow sufficient overage for the PCR set-up. The assay mixes contain all of the components needed for PCR except the templates (sample or controls).

**Table 4. Preparation of assay mixes**

| | Volume of 4X PCR Master Mix | Volume of Primer and probe Mix |
|---|---|---|
| **Mix A** | 2.5 µL x (n+ 3+ 1) | 2 µL x (n+ 3+ 1) |
| **Mix B** | 2.5 µL x (n+ 3+ 1) | 2 µL x (n+ 3+ 1) |
| **Mix C** | 2.5 µL x (n+ 3+ 1) | 2 µL x (n+ 3+ 1) |
| **Mix D** | 2.5 µL x (n+ 3+ 1) | 2 µL x (n+ 3+ 1) |

n = number of reactions (RNA samples), + 3 is for 3 controls. Prepare enough for 1 extra sample (+1) to allow for sufficient overage for the RT-qPCR set-up.

A reaction mix containing all reagents, except for the RNA sample or control templates, should be prepared for the total number of samples and controls to be tested in one run. The Positive Control (PC), Extraction Control (EC) and No Template Control (NTC) should be included in each run.

## 7.4. Suggested Run Layout

For each reaction, add 4.5 µL of the appropriate assay mix to the plate or tubes. Add up to 5.5 µL of template.

The assay has been validated on the following PCR instruments -

| PCR Instrument | Manufacturer | Data Analysis Software |
|---|---|---|
| QuantStudio 5 Real-Time PCR Instrument | Applied Biosystems™ / Thermo Fischer | QuantStudio™ Design and Analysis Software v1.4 |
| Applied Biosystems™ 7500 Fast Dx Real-Time PCR Instrument | Applied Biosystems™ / Thermo Fisher | SDS Software v1.4 |

**Table 5a. Suggested plate layout (384 wells plate)**

| | | 1 | 3 | 5 | 7 | 9 | 11 | 13 | 15 | 17 | 19 | 21 | 23 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **A** | Mix A | NTC | EC | S1 | S2 | S3 | S4 | S5 | S6 | S7 | S8 | S9 | PC |
| **B** | Mix A | S10 | S11 | S12 | S13 | S14 | S15 | S16 | S17 | S18 | S19 | S20 | S21 |
| **C** | Mix B | NTC | EC | S1 | S2 | S3 | S4 | S5 | S6 | S7 | S8 | S9 | PC |
| **D** | Mix B | S10 | S11 | S12 | S13 | S14 | S15 | S16 | S17 | S18 | S19 | S20 | S21 |
| **E** | Mix C | NTC | EC | S1 | S2 | S3 | S4 | S5 | S6 | S7 | S8 | S9 | PC |
| **F** | Mix C | S10 | S11 | S12 | S13 | S14 | S15 | S16 | S17 | S18 | S19 | S20 | S21 |
| **G** | Mix D | NTC | EC | S1 | S2 | S3 | S4 | S5 | S6 | S7 | S8 | S9 | PC |
| **H** | Mix D | S10 | S11 | S12 | S13 | S14 | S15 | S16 | S17 | S18 | S19 | S20 | S21 |
| **I** | Mix A | S22 | S23 | S24 | S25 | S26 | S27 | S28 | S29 | S30 | S31 | S32 | S33 |
| **J** | Mix A | S34 | S35 | S36 | S37 | S38 | S39 | S40 | S41 | S42 | S43 | S44 | S45 |
| **K** | Mix B | S22 | S23 | S24 | S25 | S26 | S27 | S28 | S29 | S30 | S31 | S32 | S33 |
| **L** | Mix B | S34 | S35 | S36 | S37 | S38 | S39 | S40 | S41 | S42 | S43 | S44 | S45 |
| **M** | Mix C | S22 | S23 | S24 | S25 | S26 | S27 | S28 | S29 | S30 | S31 | S32 | S33 |
| **N** | Mix C | S34 | S35 | S36 | S37 | S38 | S39 | S40 | S41 | S42 | S43 | S44 | S45 |
| **O** | Mix D | S22 | S23 | S24 | S25 | S26 | S27 | S28 | S29 | S30 | S31 | S32 | S33 |
| **P** | Mix D | S34 | S35 | S36 | S37 | S38 | S39 | S40 | S41 | S42 | S43 | S44 | S45 |

PC: Positive Control, EC: Extraction Control, NTC: No-Template Control (water), S1-S45: Samples 1-45, up to 93 unknown samples

Table 5a is a suggested plate set-up for a single experiment analyzing up to **93 unknown samples**.

After all reagents have been added to the plate, tightly seal the plate to prevent evaporation. Spin at 1000 rpm for 1 minute to mix all the reagents. Place in the real-time PCR instrument immediately.

**Table 5b. Suggested plate layout (96 wells plate)**

| | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| A | Mix A | NTC | NEC | S1 | S2 | S3 | S4 | S5 | S6 | S7 | S8 | S9 | PC |
| B | Mix B | NTC | NEC | S1 | S2 | S3 | S4 | S5 | S6 | S7 | S8 | S9 | PC |
| C | Mix C | NTC | NEC | S1 | S2 | S3 | S4 | S5 | S6 | S7 | S8 | S9 | PC |
| D | Mix D | NTC | NEC | S1 | S2 | S3 | S4 | S5 | S6 | S7 | S8 | S9 | PC |
| E | Mix A | S10 | S11 | S12 | S13 | S14 | S15 | S16 | S17 | S18 | S19 | S20 | S21 |
| F | Mix B | S10 | S11 | S12 | S13 | S14 | S15 | S16 | S17 | S18 | S19 | S20 | S21 |
| G | Mix C | S10 | S11 | S12 | S13 | S14 | S15 | S16 | S17 | S18 | S19 | S20 | S21 |
| H | Mix D | S10 | S11 | S12 | S13 | S14 | S15 | S16 | S17 | S18 | S19 | S20 | S21 |

PC: Positive Control, EC: Extraction Control, NTC: No-Template Control (water), S1-S45: Samples 1-45, up to 93 unknown samples

Table 5b is a suggested plate set-up for a single experiment analyzing up to **21 unknown samples**.

After all reagents have been added to the plate, tightly seal the plate to prevent evaporation. Spin at 1000 rpm for 1 minute to mix all the reagents. Place in the real-time PCR instrument immediately.

## 7.5. Instrument Set-Up

Set up the PCR reaction thermocycling conditions on ABI QuantStudio 5 Real-Time PCR Instrument and ABI 7500 Fast Dx as follows.

### 7.5.1. Selection of Detectors

Assign individual target in each Mix A, B, C, as “FAM”, and Mix D as “HEX”, respectively.

### 7.5.2. Setup the Cycling Parameters for QuantStudio 5 Real-Time PCR Instrument and ABI 7500 Fast Dx as Shown in Table 6

**Table 6. RT-qPCR Cycling Parameters**

| Step | Temperature (°C) | Time (Seconds) | Ramp Rate (°C/s) | Cycles | Data Collection |
|---|---|---|---|---|---|
| **UNG Incubation** | 25 | 120 | 1.6 | 1 | OFF |
| **Reverse Transcription** | 53 | 600 | 1.6 | 1 | OFF |
| **Polymerase Activation** | 95 | 120 | 1.6 | 1 | OFF |
| **Denaturation** | 95 | 3 | 1 | X45 | OFF |
| **Annealing and Extension** | 60 | 30 | 1 | | FAM, HEX |

### 7.5.3. Start the Run

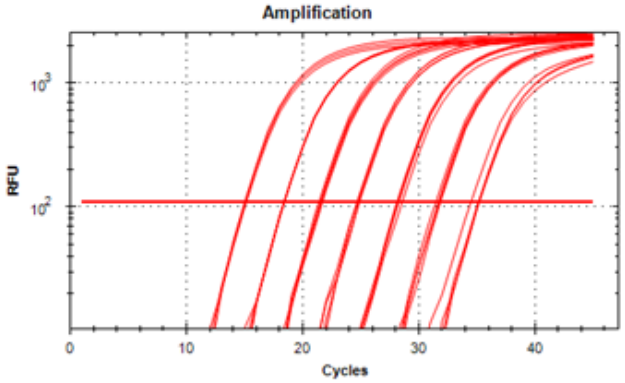
# PART 8. DATA ANALYSIS

## 8.1. Assessment of qPCR Results

Save and analyze the data following the instrument manufacturer ‘s instruction.

Adjust the threshold above any background signal to around the middle of the exponential phase of the amplification curve in the log view (e.g. Figure 2). The procedure chosen for setting the threshold should be used consistently.

**Figure 2. Amplification curve of 10 -fold serial dilution of templates showing the threshold setting**




## 8.2. Assessment of the Assay Run

### 8.2.1. ABI QuantStudio 5

**Controls**

The QuantiVirus™ SARS-CoV-2 test protocol dictates that the controls be analyzed before patient sample results. The kit positive, extraction and no template control Ct values must meet the acceptance criteria in Table 7a below for the assay to be valid. If kit control(s) fail, the test is invalid and needs to be repeated. Patient sample data is analyzed and interpreted only after all the kit controls pass.

**Table 7a. Acceptable Ct values for positive control, extraction controls and No template control**

| Control | | Acceptable Ct | Test valid/invalid |
|---|---|---|---|
| Extraction control | RNase p gene | <36 | Valid |
| Positive control | N gene | <26 | Valid |
| | Orf1 ab gene | <25 | |
| | E gene | <26 | |
| Non-template control | | ≥45 | Valid |

**Samples**

Assessment of the results for each individual assay should be based on the Cq values, according to the criteria outlined in Table 7b below.

**Table 7b. Individual assay results**

| Target | Cut-Off | Result |
|---|---|---|
| Target Virus Gene (A, B, C) | Cq < 38 | POS |
| Target Virus Gene (A, B, C) | Cq ≥ 38 | NEG |
| Rnase P (D) | Cq <36 | Viral RNA input OK |
| Rnase P (D) | Cq ≥36 | Viral RNA input fail |

### 8.2.2. ABI 7500 FAST Dx

**Controls**

The QuantiVirus™ SARS-CoV-2 test protocol dictates that the controls be analyzed before patient sample results. The kit positive, extraction and no template control Ct values must meet the acceptance criteria in Table 8a below for the assay to be valid. If kit control(s) fail, the test is invalid and needs to be repeated. Patient sample data is analyzed and interpreted only after all the kit controls pass.

**Table 8a. Acceptable Ct values for positive control, extraction control and No template control**

| Control | | Acceptable Ct | Test valid/invalid |
|---|---|---|---|
| Extraction control | RNase p gene | <36 | Valid |
| Positive control | N gene | <26 | Valid |
| | Orf1 ab gene | <26 | |
| | E gene | <26 | |
| Non-template control | | ≥45 | Valid |

**Samples**

Assessment of the results for each individual assay should be based on the Cq values, according to the criteria outlined in Table 8b below

**Table 8b. Individual assay results**

| Target | Cut-Off | Result |
|---|---|---|
| Target Virus Gene (A, B, C) | Cq < 40 | POS |
| Target Virus Gene (A, B, C) | Cq ≥ 40 | NEG |
| Rnase P (D) | Cq <36 | Viral RNA input OK |
| Rnase P (D) | Cq ≥36 | Viral RNA input fail |

## PART 9. INTERPRETATION OF RESULTS

The Positive control, Extraction control and the No Template Control in the kit must function as outlined in tables 7a and 8a above. If the controls do not function as required, the test is invalid. All the samples need to be retested.

**Table 9. Interpretation of the results**

| orf1ab gene | N gene | E gene | RNase P (EC) | Status | Result | Action |
|---|---|---|---|---|---|---|
| NEG | NEG | NEG | NEG | Invalid | NA | Repeat test one more time. If the repeat result remains invalid, consider collecting new specimen. |
| NEG | NEG | NEG | POS | Valid | SARS-CoV-2 Not detected | Report results to healthcare provider. Consider testing for other respiratory pathogens. |
| Two or more positive | | | POS or NEG | Valid | SARS-CoV-2 Detected | Report results to healthcare provider and CDC. |
| One positive | | | POS or NEG | Valid | SARS-CoV-2 Presumptive Positive | Repeat test one more time. If the repeat result remains Presumptive Positive, additional confirmatory testing may be conducted, if it is necessary to differentiate between SARS-CoV-2 and other SARS-like virus currently unknown to infect humans, for epidemiological purposes or clinical management. |

## PART 10. ASSAY LIMITATIONS

1. The performance of QuantiVirus™ SARS-CoV-2 Test Kit was established using nasopharyngeal swab samples. Anterior nasal swabs and mid-turbinate nasal swabs are also considered acceptable specimen types for use with the QuantiVirus™ SARS-CoV-2 Test Kit but performance has not been established. Testing of nasal and mid-turbinate nasal swabs (self-collected or collected by a healthcare provider) is limited to patients with symptoms of COVID-19. Please refer to FDA's FAQs on Diagnostic Testing for SARS-CoV-2 for additional information.

2. 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.

3. Extraction and amplification of nucleic acid from clinical samples must be performed according the specified methods listed in this procedure. Other extraction kits have not been evaluated.

4. If the virus mutates in the rRT-PCR target region, SARS-CoV-2 may not be detected or may be detected less predictably.

5. False Positive results may arise from the contamination during specimen handling or preparation, or between patient samples.

6. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions. Optimum specimen types and timing for peak viral levels during infections caused by 2019-nCoV have not been determined.

7. False Negative results may arise from:
   - Improper sample collection
   - Degradation of the viral RNA during shipping/storage
   - The presence of RT-PCR inhibitors
   - Mutation(s) in the sequence of SARS-CoV-2 virus

## PART 11. CONDITIONS OF AUTHORIZATION FOR THE LABORATORY

The QuantiVirus™ SARS-CoV-2 Test Kit 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/emergency-situations-medical-devices/emergency-use-authorizations
.

However, to assist clinical laboratories using the QuantiVirus™ SARS-CoV-2 Test Kit ("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-EUA-Reporting@fda.hhs.gov) and You (via email: covid19support@diacarta.com or via phone: 510-878-6662, option 4 ) 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-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."

# PART 12. ASSAY PERFORMANCE

The performance characteristics of the SARS-CoV-2 assay were established on QuantStudio 5 Real-Time PCR Instrument and ABI 7500 Fast Dx PCR Instrument.

## 12.1. Analytic Sensitivity and Limit of Detection (LOD)

To determine the Limit of Detection (LoD) and analytical sensitivity of the kit, studies were performed using serial dilutions of analyte and the LoD was determined to be the lowest concentration of template that could reliably be detected with 95% of all tested positive.

LoD of each target assay in the QuantiVirus™ SARS-CoV-2 Test were conducted and verified using SeraCare AccuPlex SARS-CoV-2 Reference Material Kit (Cat# 0505-0126). Non-infectious viral particles from the AccuPlex SARS-CoV-2 Reference Material Kit were spiked in sputum at various concentrations (50 copies/mL, 100 copies/mL, 150 copies/mL, 200 copies/mL and 300 copies/mL) diluted from the stock concentration of 5000 copies/mL. Real-time RT-PCR assay was performed with the provided kit reagents and tested on ABI QS5 and ABI 7500 Fast Dx PCR instruments.

The LOD was confirmed by testing 1xLoD of viral RNA with 20 replicates. The LoD was determined to be the lowest concentration (copies/ml) at which ≥95% (19/20) of the 20 replicates were tested as positive.

### 12.1.1 LoD for ABI QuantStudio 5

The data confirmed the assay analytical sensitivity was **200 copies/mL** for ABI QuantStudio 5.

**Table 10a. Summary of Twenty Replicates for Assay Sensitivity （ABI QuantStudio 5）**

| Target | RNA (copy/mL) | Total | AVE Ct | SD | CV | Positive | Negative | Call Rate |
|---|---|---|---|---|---|---|---|---|
| N GENE | 100 copies/mL | 20 | 33.73 | 0.79 | 0.02 | 20 | 0 | 100% |
| ORF1ab | 100 copies/mL | 20 | 35.13 | 0.87 | 0.02 | 20 | 0 | 100% |
| E GENE | 150 copies/mL | 20 | 37.31 | 1.9 | 0.05 | 18 | 2 | 90% |
| | 200 copies/mL | 20 | 36.77 | 2.0 | 0.05 | 19 | 1 | 95% |

### 12.1.2 LoD for ABI 7500 Fast Dx

The data confirmed the assay analytical sensitivity was **100 copies/mL** for ABI 7500 Fast Dx.

**Table 10b. Summary of Twenty Replicates for Assay Sensitivity （ABI 7500 Fast Dx）**

| Target | RNA (copy/mL) | Total | AVE Ct | SD | CV | Positive | Negative | Call Rate |
|---|---|---|---|---|---|---|---|---|
| N GENE | 100 copies/mL | 20 | 33.73 | 0.79 | 0.02 | 20 | 0 | 100% |
| ORF1ab | 100 copies/mL | 20 | 35.13 | 0.87 | 0.02 | 20 | 0 | 100% |
| E GENE | 100 copies/mL | 20 | 35.59 | 0.95 | 0.03 | 20 | 0 | 100% |

## 12.2. Inclusivity

The QuantiVirus™ SARS-CoV-2 Test kit has been designed to detect publicly available SARS-CoV-2 viral RNA sequences. 102 NCBI and 125 GISAID target sequences were retrived and aligned to identify conserved regions and specific regions of the SARS-CoV-2 genome, where primers and probes were designed for the assay. Alignments were performed with the designed oligonucleotide primer and probe

sequences of QuantiVirus™ SARS-CoV-2 Test kit panel with all publicly available sequences of SARA-CoV-2 in Genbank (about 200 SARS-CoV-2 strains) as of March 19, 2020 to demonstrate the estimated inclusibity of the QuantiVirus™ SARS-CoV-2 Test kit. All the alignments exhibited 100% of identity of design to the available SARS-CoV-2 sequences, suggesting the potential ability of the QuantiVirus™ SARS-CoV-2 Test kit to detect 100% of all the SARS-CoV-2 strains.

In summary, *in silico* analysis of the QuantiVirus™ SARS-CoV-2 Test kit assay design showed that the assay can detect all SARS-CoV2 virus strains and exhibited no cross reactivity with non-SARS-CoV2 species.

## 12.3. Cross-Reactivity

The QuantiVirus™ SARS-CoV-2 Test kit has been designed to detect all publicly available SARS-CoV-2 strains. At the same time, the primers and probes were designed in the SARS-CoV-2 virus specific genome region ensuring the specific detection of the SARS-CoV-2 viral RNA. *In silico* analysis of the SARS-CoV2 assay design were performed and compared to common respiratory flora and other viral pathogens from the same genetic family as SARS-CoV-2 according to the Recommended List of Organisms to be analyzed *in silico* (see Table 12 ) or by Direct wet lab Testing.

**Table 12. List of organisms tested for cross-reactivity by in silico analysis**

| # | Organism | # | Organism |
|---|---|---|---|
| 1 | Human coronavirus 229E | 14 | Rhinovirus |
| 2 | Human coronavirus OC43 | 15 | Enterovirus |
| 3 | Human coronavirus HKU1 | 16 | Chlamydia pneumoniae |
| 4 | Human coronavirus NL63 | 17 | Haemophilus influenzae |
| 5 | SARS-coronavirus | 18 | Legionella pneumophila |
| 6 | MERS-coronavirus | 19 | Mycobacterium tuberculosis |
| 7 | Adenovirus | 20 | Streptococcus pneumoniae |
| 8 | Human Metapneumovirus (hMPV) | 21 | Streptococcus pyogenes |
| 9 | Parainfluenza virus 1-4 | 22 | Bordetella pertussis |
| 10 | Influenza A | 23 | Candida albicans |
| 11 | Influenza B | 24 | Pseudomonas aeruginosa |
| 12 | Enterovirus | 25 | Staphylococcus epidermis |
| 13 | Respiratory Syncytial Virus A | 26 | Staphylococcus salivarius |

Results of *in Silico* analysis demonstrates that there is significant homology between the SARS-coronavirus (MK062184.1) and our assay primer/probes for N gene and E gene. Therefore, the cross reactivity with SARS-coronavirus (MK062184.1) was tested by wet laboratory experiments which did not show any cross reactivity at $10^5$ PFU/mL.

All of other homologies were not significant for the pair of primers and probes in order to predict a *in silico* false positive result.

## 12.4. Clinical Evaluation

### 12.4.1 Clinical Evaluation on ABI QuantStudio 5

Clinical evaluation of the QuantiVirus™ SARS-CoV-2 Test kit was conducted with contrived sputum specimens including 60 positive and 38 negative samples (Table 13a). Sputum samples were mixed with the lysis buffer from the extraction kit at 1:1 ratio before spiking in non-infectious viral particles (SeraCare AccuPlex™ SARS-CoV-2 Reference Material Kit, Cat # 0505-0126).

Sputum samples (20 samples) were contrived with non-infectious viral particles templates at 0.75X LoD (150 copies/mL), 20 samples at 1xLoD (1x200 copies/mL) and 10 sputum samples were spiked with non-infectious virus at 1.5xLoD (300 copies/mL) and another 10 sputum samples were spiked at the concentration of 2.5xLoD (500 copies/mL). Viral RNA was extracted from spiked samples and tested blindly with the QuantiVirus™ SARS-CoV-2 RT-qPCR.

Data show that there is 95% agreement with the spiked sample at 1xLoD (1x200 copies/mL), and 100% agreement at all other concentrations including 300 copies/mL and 500 copies/mL (Table 13a). For negative control, there was one sample excluded due to contamination. The remaining 37 samples were negative.

**Table 13a. Contrived clinical sample evaluation with *in vitro* transcribed RNA (ABI QuantStudio 5)**

| Specimen Type | Viral RNA Spiked | SARS-CoV-2 | | | Performance Agreement | 95% CI |
|---|---|---|---|---|---|---|
| | | Positive | Negative | Total | | |
| viral RNA + sputum | 150 copies /mL (0.75x LoD) | 18 | 2 | 20 | 90% | 69.9-97.2% |
| | 200 copies/mL (1x LoD) | 19 | 1 | 20 | 95% | 76.4-99.1% |
| | 300 copies/mL (1.5x LoD) | 10 | 0 | 10 | 100% | 72.3-100% |
| | 500 copies/mL (2.5x LoD) | 10 | 0 | 10 | 100% | 72.3-100% |
| H2O + sputum | 0 copy/mL | 0 | 37 | 37 | 100% | 90.6-100% |

### 12.4.2 Clinical Evaluation on ABI 7500 Fast Dx

Clinical evaluation of the QuantiVirus™ SARS-CoV-2 Test kit was conducted with contrived sputum specimens including 40 positive and 38 negative samples (Table 13b). Sputum samples were mixed with the lysis buffer from the extraction kit at 1:1 ratio before spiking in non-infectious viral particles (SeraCare AccuPlex™ SARS-CoV-2 Reference Material Kit, Cat # 0505-0126).

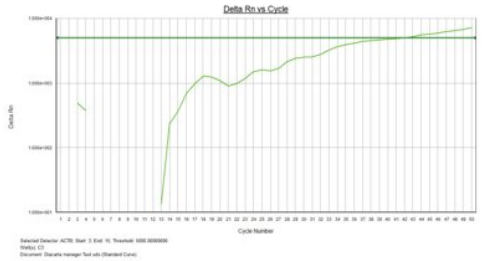
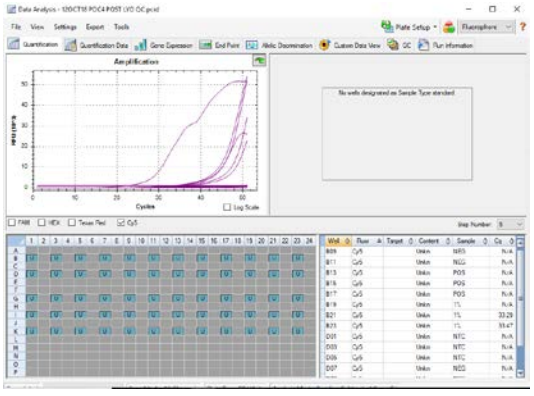
Sputum samples (20 samples) were contrived with non-infectious viral particles templates at 1xLoD (1x100 copies/mL) and 10 sputum samples were spiked with non-infectious virus at 3xLoD (3x100 copies/mL) and another 10 sputum samples were spiked at the concentration of 5xLoD (5x100 copies/mL). Viral RNA was extracted from spiked samples and tested blindly.

Data show that there is 100% agreement with the spiked sample at 1xLoD (1x100 copies /mL), and 100% agreement at all other concentrations including 3xLoD and 5x LoD (Table 13b). For negative control, there was one sample excluded due to contamination. The remaining 37 samples were negative

**Table 13b. Contrived clinical sample evaluation with *in vitro* transcribed RNA (ABI 7500 Fast Dx)**

| Specimen Type | Viral RNA Spiked | SARS-CoV-2 | | | Performance Agreement | 95% CI |
|---|---|---|---|---|---|---|
| | | Positive | Negative | Total | | |
| viral RNA + sputum | 100 copies /mL (1x LoD) | 20 | 0 | 20 | 100% | 83.9-100% |
| | 300 copies/mL (3x LoD) | 10 | 0 | 10 | 100% | 72.3-100% |
| | 500 copies/mL (5xLoD) | 10 | 0 | 10 | 100% | 72.3-100% |
| H2O + sputum | 0 copy/mL | 0 | 37 | 37 | 100% | 90.6-100% |

## PART 13. ASSAY TROUBLESHOOTING

| Problem | Cause | Solution |
|---|---|---|
| Fluorescence signals in No Template Control (NTC), e.g. Cq <= 40<br>  | The positive signal may be caused by contamination during setting-up of the PCR;<br>Or<br>The signal is not true target amplification, but background curves generated by the software of the qPCR instrument. | Repeat the PCR with new reagents. Follow the general rules of GLP in a PCR lab. It is recommended to set up the qPCR reactions in a separate area, where no DNA is handled and with equipment designated for pre-PCR activities. Make sure the workspace and instruments are decontaminated regularly. Ignore the Ct value of NTC if the amplification curve looks not real but background noise. |
| The Positive Control did not meet the criteria set for acceptable values of the virus RNA detection kit. The assay is invalid. | Kit was not stored at the recommended conditions;<br>Or<br>Kit shelf-life expired. | Check the kit label for storage conditions and expiration date and use a new kit if necessary. |
| The edge wells have abnormal amplification curves, resulting in high baseline threshold with incorrect estimation of Ct values.<br>  | Edge wells show high background fluorescence which prevents software from calling Ct values for sample wells. | All wells showing high background fluorescence must be deselected, threshold reset to a lower value and then reanalyzed using user defined threshold setting. |

## PART 14. CUSTOMER AND TECHNICAL SUPPORT

Visit diacarta.com/support for the latest service and support information.

- Product support information
  – Product FAQs
  – Software, patches, and updates
  – Training for many applications and instruments

- Order and web support

- Product documentation
  – User guides, manuals, and protocols
  – Certificates of Analysis
  – Safety Data Sheets (SDSs; also known as MSDSs)

Note: For SDSs for reagents and chemicals from other manufacturers, contact the manufacturer.

Contact:
Email: covid19support@diacarta.com
Phone: 510-878-6662, option 4 (tech support)



1. Thermo Fisher Scientific® QuantStudio™ 5 System
2. Applied Biosystems™ 7500 Real-Time PCR Systems
3. Thermo Fisher Scientific® | PureLink™ ™ RNA Mini Kit
4. Applied Biosystems™ TaqPath™ 1-Step Multiplex Master Mix
5. SeraCare AccuPlex™ SARS-CoV-2 Reference Material Kit

# PART 15. SYMBOLS USED IN PACKAGING

**Symbols used in packaging**

| Symbol | Definition |
|---|---|
| Rx | Prescription Only |
| EUA | Emergency Use Authorization |
|  | In vitro Diagnostic Use |
|  | Catalog Number |
|  | Manufactured By |
|  | Temperature Limitation |
|  | Batch Code |
|  | Expiration Date |
|  | Contains sufficient for <n> tests |
| 1011-11-17 | Date Format (year-month-day) |
| 1011-11 | Date Format (year-month) |

**HMIS**

| | |
|---|---|
| Health | 0 |
| Flammability | 0 |
| Reactivity | 0 |

The product contains no substances which at their given concentration, are considered to be hazardous to health.

## PART 16. REFERENCE

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**CDC guidelines for Sample collection –**
https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html

**FDA EUA guidance –**
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-diagnostic-tests-coronavirus-disease-2019-during-public-health-emergency

**Thermo Fisher viral RNA extraction kit PureLink™ Viral RNA/DNA Mini Kit (Cat# 12280050) Kit for RNA isolation**
https://www.thermofisher.com/order/catalog/product/12280050#/12280050
Catalog Number 12280050 Publication NumberMAN0000562

**QuantStudio 5**
https://assets.thermofisher.com/TFS-Assets/LSG/manuals/MAN0017162_QS5HIDInstrument_UG.pdf
Publication Number MAN0017162

**ABI 7500 Fast Dx**
https://www.thermofisher.com/order/catalog/product/4406985#/4406985
Publication Part Number4406991