# SARS-CoV-2 Test Kit (Real-time PCR)

# Instructions for Use

This package insert must be read carefully prior to use and should be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

REF 801300/801301

48 Tests per Kit

For *In Vitro* Diagnostic (IVD) Use

For Emergency Use Authorization Only

For Prescription Use Only

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## 1. INTENDED USE

The SARS-CoV-2 Test Kit (Real-time PCR) is an in vitro diagnostic real-time reverse transcription-PCR assay intended for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal/oropharyngeal swabs, anterior/mid-turbinate nasal swabs, nasopharyngeal washes/aspirates or nasal aspirates, and bronchoalveolar lavage (BAL) specimens from individuals suspected of COVID-19 by their healthcare provider. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

Results are for the identification of SARS-CoV-2 RNA which is generally detected in 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.

Testing with the SARS-CoV-2 Test Kit (Real-time PCR) is intended for use by qualified laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures. The SARS-CoV-2 Test Kit (Real-time PCR) is only for use under the Food and Drug Administration’s Emergency Use Authorization.

## 2. SUMMARY AND EXPLANATION

The SARS-CoV-2 Test Kit (Real-time PCR) is a molecular in vitro diagnostic test that uses Taqman probe-based technology for the qualitative detection of SARS-CoV-2. The product contains oligonucleotide primers, labeled oligonucleotide probes, and control material used in real-time RT-PCR for the in vitro qualitative detection of SARS-CoV-2 RNA extracted from respiratory specimens.

## 3. PRINCIPLE OF THE PROCEDURES

The SARS-CoV-2 Test Kit (Real-time PCR) is a multiplex, Taqman probe-based one-step reverse transcription polymerase chain reaction (RT-PCR), which enables simultaneous qualitative detection of ORF1ab and a region of the N gene that are specific for SARS-CoV-2 as well as a non-human internal control (Armored RNA for *SUC2*) in one reaction. For ease of storage and transportation, the amplification reagent is designed as a pre-distributed dry reagent (lyophilized).

## 4.

The SARS-CoV-2 Test Kit (Real-time PCR) comprises two catalog numbers (801300 and 801301), each with reagents for 48 tests, components are tabulated below.

1) Catalog No.: 801300

| COMPONENTS | | MAIN INGREDIENT | QUANTITY | STORAGE |
|---|---|---|---|---|
| Amplification Reagents | SARS-CoV-2 RT-PCR Tube | Primers, probes, dNTPs, MMLV Reverse Transcriptase, Taq polymerase | 8 tests / strip (6 white strips*) | 2-8°C, away from light |
| Control Reagents | SARS-CoV-2 Internal Control | Armored RNA for *SUC2* | 51 tests / tube (1 tube) | 2-8°C, away from light |
| | SARS-CoV-2 Positive Control | Armored RNA for ORF1ab and N | 10 tests / tube (1 tube) | 2-8°C, away from light |
| | SARS-CoV-2 Negative Control | No template control (Tris buffer) | 10 tests / tube (1 tube) | 2-8°C, away from light |
| Transparent Replacement tube cap | | / | 6 strips of tube caps | N/A |

2) Catalog No.: 801301

| COMPONENTS | | MAIN INGREDIENT | QUANTITY | STORAGE |
|---|---|---|---|---|
| Amplification Reagents | SARS-CoV-2 RT-PCR Tube | Primers, probes, dNTPs, MMLV Reverse Transcriptase, Taq polymerase | 8 tests / strip (6 transparent strips*) | 2-8°C, away from light |
| Control Reagents | SARS-CoV-2 Internal Control | Armored RNA for *SUC2* | 51 tests / tube (1 tube) | 2-8°C, away from light |
| | SARS-CoV-2 Positive Control | Armored RNA for ORF1ab and N | 10 tests / tube (1 tube) | 2-8°C, away from light |
| | SARS-CoV-2 Negative Control | No template control (Tris buffer) | 10 tests / tube (1 tube) | 2-8°C, away from light |
| Transparent Replacement tube cap | | / | 6 strips of tube caps | N/A |

**Note:** Do not interchange reagents from one kit lot to another.

*There are two types of RT-PCR tubes, which are specific for the Bio-Rad CFX96™ Real-Time

System and Applied Biosystems™ QuantStudio 3 real-time PCR thermal cycler, respectively. Therefore, there are two corresponding catalogue numbers including Cat. No.: 801300 for the Bio-Rad CFX96™ Real-Time System and Cat. No.: 801301 for the Applied Biosystems™ QuantStudio 3 real-time PCR thermal cycler.

## 5. INSTRUMENT

The SARS-CoV-2 Test Kit (Real-time PCR) was validated for use with the Applied Biosystems™ QuantStudio 3 real-time PCR thermal cycler with QuantStudio™ Design & Analysis Software v1.4.3 and the Bio-Rad CFX96™ Real-Time System with CFX Manager™ Software v3.1 that contains FAM, HEX/JOE, and ROX detection channels.

## 6. MATERIALS REQUIRED BUT NOT PROVIDED

- Disposable powder-free gloves, lab coat and protective goggles
- Magnetic stand
- Adjustable pipettes and sterile filtered pipette tips, 1.5 mL and 2.0 mL microcentrifuge tubes
- Vortex mixer
- Hand-held centrifuge for 8-tube Strips as well as 1.5 mL microcentrifuge tubes
- The Virus RNA Extraction Kit (Cat. No.: 602101) from Xiamen Zeesan Biotech Co., Ltd.
  or the Lab-Aid Virus RNA Extraction Kit (Cat. No.: 606204) on the automated Lab-Aid 824s Nucleic Acid Extraction System with Software v1.0.3 (Cat. No.: 501207) from Xiamen Zeesan Biotech Co., Ltd.

## 7. STORAGE AND EXPIRATION DATE

The SARS-CoV-2 Test Kit (Real-time PCR) should be stored at 2~8 °C away from light. The kit is temporarily valid for 12 months.

It is recommended to transport between -18 °C to 37 °C. Production date and expiration date are shown on the package label.

Do not use reagents past their expiration date.

## 8. WARNING AND PRECAUTIONS

1) For in vitro diagnostic use (IVD) only.
2) For Emergency Use Authorization only.
3) For Prescription Use only.

4) The SARS-CoV-2 Test Kit (Real-time PCR) has not been FDA cleared or approved.

5) The SARS-CoV-2 Test Kit (Real-time PCR) has been authorized by FDA under an Emergency Use Authorization (EUA) for use by laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

6) The SARS-CoV-2 Test Kit (Real-time PCR) has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.

7) The SARS-CoV-2 Test Kit (Real-time PCR) is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

8) Operators must be trained and have certain experience. Please read the instructions carefully before using the kit.

9) Follow standard precautions. All patient specimens and positive controls should be considered potentially infectious and handled accordingly.

10) Do not eat, drink, smoke, apply cosmetics or handle contact lenses in areas where reagents and human specimens are handled.

11) Handle all specimens as if infectious using safe laboratory procedures. Refer to Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with 2019-nCoV 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.

12) Please conduct the test operation in strict accordance with the management standards of gene amplification test laboratory: for example, the PCR test shall be strictly divided into different sections; There should be special gloves and pipettes in each district, and they should not be cross-used to avoid contamination; Operators should follow the principle of one-direction from zone one to zone two, and each working area is relatively isolated; The work table and related items for PCR test should be sterilized and disinfected regularly with 1% sodium hypochlorite, 75% alcohol, or 1 mol/L hydrochloric acid (for used pipette tips) or ultraviolet lamp.

13) Consumable items for test operation shall be used in one time and treated aseptically before use.

14) The controls in the kit should be fully thawed before use, well mixed and briefly centrifuged.

Bubbles should be avoided. The PCR reaction tube should be centrifuged instantaneously after adding the template. Avoid shaking the PCR reaction tube before starting the machine and in order to avoid contaminations, pay careful attention to the capped tubes and make sure each tube is sealed tightly.

15) The PCR reaction mixture should be kept away from light; negative control and positive control should be run for each test.

16) Do not mix reagents of different batches. Please use the kit within the validity period.

17) After the reaction, remove the PCR tubes (closed) and put them into a self-sealing (zip) bag and seal tightly, treat as a biohazardous source.

18) Results should be interpreted by a trained professional in conjunction with the patient's history and clinical signs and symptoms, and epidemiological risk factors. 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. The operator should understand the principles of the procedures, including its performance limitations, in advance of operation to avoid potential mistakes.

19) Negative results do not preclude infection with the SARS-CoV-2 virus and should not be the sole basis of a patient treatment/management or public health decision. Follow up testing should be performed according to the current CDC recommendations.

## 9. SAMPLE REQUIREMENTS

**Specimen types:**

- **Upper respiratory tract specimens:** nasopharyngeal swabs, oropharyngeal swabs, anterior nasal and mid-turbinate nasal swabs, nasopharyngeal washes/aspirates or nasal aspirates.
- **Lower respiratory tract specimens**: bronchoalveolar lavage (BALs).

For extraction method of different specimen types, please refer to "Specimen Extraction and Loading" in the test procedure.

Inadequate or inappropriate specimen collection, storage, and transport are likely to yield false test results. Training in specimen collection is highly recommended due to the importance of specimen quality.

**Sample collection:** Collect nasopharyngeal swabs, oropharyngeal swabs, anterior nasal and

mid-turbinate nasal swabs, nasopharyngeal washes/aspirates or nasal aspirates, or bronchoalveolar lavage (BAL) specimens from individuals suspected of having COVID-19 by their healthcare provider. Flocked swabs with plastic shafts in viral transport media/universal transport media are acceptable for processing with the workflow of the SARS-CoV-2 Test Kit (Real-time PCR). Sterile, DNase/RNase free containers without preservative should be used for collection of BALs/washes/aspirates. Specimen collection should avoid possible contamination during collection, storage, and transportation. The specimen should be presumed contagious and be handled according to related regulations.

**Sample storage:** Samples collected in common viral transport medium (swabs) or DNase/RNase free containers without preservative (BALs/washes/aspirates) should be submitted timely for testing. If necessary, specimens can be stored at 4 °C for up to 72 hours if shipping or extraction cannot proceed immediately upon collection/sample receipt. If a delay in processing is expected to exceed 72 hours, then store specimens at -70°C or lower.

**Sample transportation:** Specimens must be packaged and shipped in accordance with the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulations and Guidance of the Centers for Disease Control and Prevention (CDC).

## 10. TEST PROCEDURE

### 10.1 Reagent Preparation (Solution Preparation Area)

a. Take out the aluminum foil bag from the kit, tear the seal, open the self-sealing strip.

b. Open the blister packaging of the SARS-CoV-2 RT-PCR Tube, take out *n* PCR tubes (*n* is determined according to the needs of the current experiment), the remaining reagents should be put back into the aluminum foil self-sealing bag and sealed tightly, and stored at 2~8 °C away from light.

### 10.2 Specimen Extraction and Loading (Extraction Area)

a. The purpose of sample preparation is to extract and concentrate the target nucleic acid (RNA) molecules to make the target accessible for amplification, and to remove potential inhibitors of amplification from the extract. It is recommended that nucleic acids are isolated and purified from nasopharyngeal swabs, oropharyngeal swabs, anterior nasal and mid-turbinate nasal swabs, nasopharyngeal washes/aspirates or nasal aspirates, or bronchoalveolar lavage specimens using the Virus RNA Extraction Kit (Cat. No.: 602101) from Xiamen Zeesan Biotech Co., Ltd., which is a

manual viral RNA extraction kit, or using the Lab-Aid Virus RNA Extraction Kit (Cat. No.: 606204) performed on the automated Lab-Aid 824s Nucleic Acid Extraction System (Cat. No.: 501207) from Xiamen Zeesan Biotech Co., Ltd. The purification procedure for the extraction kit comprises 4 steps: lysis, binding, washing, and elution.

During the sample preparation, when the Virus RNA Extraction Kit is used to extract the sample, add 20 µL of internal control (IC) and 1 mL of specimen to the extraction loading well, and carry out extraction according to the procedures in the instructions manual for the Virus RNA Extraction Kit. When the Lab-Aid Virus RNA Extraction Kit is used to extract the sample, add 20 µL of internal control (IC) and 1.66 mL of specimen to the extraction loading well, and carry out extraction according to the procedures in the instruction manual for use of the Lab-Aid 824s Nucleic Acid Extraction System.

During the extraction process, SARS-CoV-2 virions are disrupted by guanidine isothiocyanate, nucleic acids are captured on the magnetic microparticles, and inhibitors and unbound sample components are removed by washing steps. The bound nucleic acids are eluted off the microparticles with buffer and transferred to a 96 deep-well plate. The nucleic acids are then ready for amplification.

For quality control, 20 µL of SARS-CoV-2 Positive Control and 20 µL SARS-CoV-2 Negative Control are added into different extraction loading wells with 20 µL of SARS-CoV-2 Internal Control. Extraction is started in parallel with the specimens to be tested. The Internal Control (IC) is introduced into each specimen at the beginning of the sample preparation process to demonstrate that the process was completed correctly for each specimen and control. When the Virus RNA Extraction Kit is used to extract the sample, the nucleic acid elution volume is 60 µL. However, 100 µL is the final elution volume when the Lab-Aid Virus RNA Extraction Kit is used. Following extraction, the RNA should be used immediately or stored at -70 °C for use later. When handling the positive control, please take precautions to avoid contamination of the specimen sample. Failure to take proper precautions when handling the positive control could result in a false positive result.

**NOTE: Before the first use of the SARS-CoV-2 Positive Control, SARS-CoV-2 Negative Control, and SARS-CoV-2 Internal Control, 200 µL, 200 µL and 1020 µL of sterilized purified water should be added respectively for dissolution. This is done by vortexing for 20 sec-**

**onds followed by a brief spin. The resuspended assay controls should be stored below -18 °C, frozen and thawed when needed. No more than 5 freeze/thaw cycles should be completed for the controls.**

b. Open the SARS-CoV-2 RT-PCR tubes provided in the kit, discard the tube lids, add 25 µL of sample extracts or SARS-CoV-2 positive / negative control extracts to each PCR tube containing lyophilized reagents, then immediately cover the tubes with the replacement caps included with the kit.

   **NOTE: At least one positive control and negative control are required for each run. The positive control is needed to monitor false negatives and the negative control is needed to monitor false positive results and to ensure that the system has no contamination. The Internal control (Armored RNA for *SUC2*) is needed to monitor false negative results caused by in-tube inhibition and is used to monitor the whole process including sample extraction, reverse transcription, and PCR amplification.**

c. The reaction tubes are subjected to vortexing for 20 seconds followed by a brief spin to remove any air bubbles.

d. Transfer the reaction tubes to the PCR amplification area.

### 10.3 RT and PCR Amplification (Amplification Area)

Reverse transcription of the extracted RNA into cDNA occurs first at 50°C for 15 minutes followed by denaturation. During the amplification process, the probe anneals to a specific target sequence located between the forward and reverse primers. During the extension phase of the PCR cycle, the 5′ 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 Applied Biosystems™ QuantStudio 3 Real-Time PCR thermal cycler (See amplification program below).

The reaction program (reaction volumes are 25 µL; 25 µL of extracted RNA resuspends the lyophilized reagents in the PCR tubes) includes the following:

| Stage | | Condition | Cycle number |
|---|---|---|---|
| PCR Reaction Program | RT reaction | 50°C 15 min | 1 |
| | Pre-degeneration | 95°C 2.5 min | 1 |
| | PCR cycle (Amplification) | 94°C 15 sec | 45 |
| | | 60°C 30 sec (FAM, HEX and ROX channels) | |

## 11. QUALITY CONTROL/ASSAY CONTROL RESULTS

Quality control requirements must be performed in conformance with local, state, and federal regulations or accreditation requirements and the user's laboratory's standard quality control procedures. Quality control procedures are intended to monitor reagent and assay performance. Test the positive control (PC) and negative control (NTC) prior to running diagnostic samples with each new kit lot to ensure all reagents and kit components are working properly. The no template (negative) control and positive control are taken through the entire sample processing procedure, including the extraction. The internal control (*SUC2*) must be spiked into the PC and NTC prior to extraction.

- The NTC is valid if Ct values for the ORF1ab and N targets are not detected (no amplification/fluorescence curve or Ct ≥ 40), and the Ct value for the internal *SUC2* is detected (Ct ≤ 32). The *SUC2* gene is positive in the NTC because this control is spiked in prior to performing the nucleic acid extraction.
- The positive control (PC) is valid if the Ct values for the ORF1ab and N targets are positive (≤ 34 and ≤ 31, respectively), and the internal *SUC2* control has a Ct ≤ 32.

Notably, each of the above requirements for the Negative Control and Positive Control should be met in a single test. The controls in the kit must meet the following requirements, otherwise the experiment will be considered invalid. If the controls do not exhibit the expected performance as described, the assay may have been set up and/or executed improperly, or reagent or equipment malfunction could have occurred. Invalidate the run. Nucleic acid extraction should be repeated using residual clinical sample and tested again with the SARS-CoV-2 Test Kit (Real-time PCR). The ranges of Ct values in each test channel (FAM, HEX, ROX) are as follows:

| | Test Channel | | |
|---|---|---|---|
| **Control** | **ORF1ab (FAM)** | ***SUC2* (HEX)** | **N gene (ROX)** |
| SARS-CoV-2 Positive Control | ≤ 34 | ≤ 32 | ≤ 31 |
| SARS-CoV-2 Negative Control | No Ct or ≥ 40 | ≤ 32 | No Ct or ≥ 40 |

## 12. INTERPRETATION OF PATIENT RESULTS

Assessment of clinical specimen test results should be performed after the positive and negative controls have been examined and determined to be valid and acceptable. If the controls are not valid, the patient results cannot be interpreted.

When the above quality control meets the requirements, Ct values of the patient specimens for the ORF1ab, N, and *SUC2* genes can be evaluated according to the following table. For a result to be reported as SARS-CoV-2 positive, both ORF1ab and N targets must be positive (Ct ≤ 37 and CT ≤ 35, respectively).

| **Target Gene** | **Test Channel** | **Critical Ct Value** | **Results** |
|---|---|---|---|
| ORF1ab | FAM | ≤ 37 | + |
| | | > 37 or No Ct | - |
| N | ROX | ≤ 35 | + |
| | | > 35 or No Ct | - |
| *SUC2* | HEX | ≤ 34 | + |
| | | > 34 or No Ct | - |

**Testing Result Scenarios for Patient Specimens**

| **Test Results** | | | **Results** | **Follow-Up Action** |
|---|---|---|---|---|
| **ORF1ab (FAM)** | **N (ROX)** | ***SUC2* (HEX)** | | |
| + | + | +/-* | SARS-CoV-2 positive | Report the result to sender. |
| + | - | +/-* | SARS-CoV-2 presumptive positive | Sample is repeated once using new extracted nucleic acid from residual clinical sample. If the repeated result remains Presumptive Positive, additional confirmatory testing may be conducted, if it is necessary for epidemiological purposes |

| | | | | |
|---|---|---|---|---|
| | | | | or clinical management. |
| - | + | +/-* | SARS-CoV-2 presumptive positive | Sample is repeated once using new extracted nucleic acid from residual clinical sample. If the repeated result remains Presumptive Positive, additional confirmatory testing may be conducted, if it is necessary for epidemiological purposes or clinical management. |
| - | - | + | SARS-CoV-2 negative | Report the result to sender. |
| - | - | - | Invalid | Sample is repeated once using new extracted nucleic acid from residual clinical sample and tested again. Poor RNA yield or RT-PCR inhibition is suspected. If the repeated result is still invalid, report the result to the sender and recommend that a new specimen is collected. |

Note: "+" refers to positive; "-" refers to negative. Expected Ct values for each assay target are shown in the table in Section 12 on page 11.

*Detection of the Internal Control (*SUC2*) in the HEX detection channel is not required for positive SARS-CoV-2 results (ORF1ab + or N +). A high copy number of target-specific gene can lead to reduced or absent *SUC2*.

## 13. LIMITATION OF THE METHOD

1) This assay is for in vitro diagnostic use under FDA Emergency Use Authorization only. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

2) Use of this assay is limited to personnel who are trained in the procedure. Failure to follow these instructions may result in erroneous results.

3) The performance of SARS-CoV-2 Test Kit was established using nasopharyngeal swab and oropharyngeal swab samples. Bronchoalveolar lavage and other swabs (mid-turbinate and anterior nasal)/washes/aspirates are also considered acceptable specimen types for use with the SARS-CoV-2 Test Kit (Real-time PCR) but performance has not been established.

4) PCR product contamination might occur in the laboratory, reagent preparation and cross-contamination of samples and will produce false positive results. The components of the test kit may decline due to improper transportation, storage or inaccurate preparation and will produce false negative results. False negative results may also arise from improper sample collection, deg-

radation of the viral RNA during shipping/storage, using unauthorized extraction or assay reagents, mutation in the SARS-CoV-2 virus and failure to follow instructions for use.

5) Low viral load and excessive degradation in the samples may cause negative results. Thus, a negative result cannot completely exclude the existence of SARS-CoV-2 in the sample and should not be the sole basis of a patient management decision. Follow up testing should be performed according to the current CDC recommendations.

6) Results should be interpreted by a trained professional in conjunction with the patient's history and clinical signs and symptoms, and epidemiological risk factors.

7) Extraction and amplification of nucleic acid from clinical samples must be performed according to the specified methods listed in this procedure. Other extraction approaches and processing systems have not been evaluated.

8) The impacts of vaccines, antiviral therapeutics, antibiotics, chemotherapeutic or immunosuppressant drugs have not been evaluated.

9) Laboratories are required to report all positive results to the appropriate public health authorities.

## 14. CONDITIONS OF AUTHORIZATION FOR THE LABORATORY

The SARS-CoV-2 Test Kit (Real-time PCR) Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website:

https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas.

However, to assist clinical laboratories using the SARS-CoV-2 Test Kit (Real-time PCR), the relevant Conditions of Authorization are listed below:

A. Authorized laboratories[1] using the SARS-CoV-2 Test Kit (Real-time PCR) will include with result reports of the test, 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 the SARS-CoV-2 Test Kit (Real-time PCR) will perform the test as outlined in the Instructions for Use. Deviations from the authorized procedures, including the author-

ized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use the SARS-CoV-2 Test Kit (Real-time PCR) are not permitted.

C. Authorized laboratories that receive the SARS-CoV-2 Test Kit (Real-time PCR) will notify the relevant public health authorities of their intent to run the test prior to initiating testing.

D. Authorized laboratories using the SARS-CoV-2 Test Kit (Real-time PCR) 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 the SARS-CoV-2 Test Kit (Real-time PCR) and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Xiamen Zeesan Biotech Co., Ltd (email: info@zsandx.com 973-941-7857 (USA)/ 0086-592-7615091 (China)) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the test of which they become aware.

F. All laboratory personnel using the SARS-CoV-2 Test Kit (Real-time PCR) must be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use the SARS-CoV-2 Test Kit (Real-time PCR) in accordance with the authorized labeling.

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

## 15. PERFORMANCE CHARACTERISTICS

### 1) Limit of Detection (LoD):

LoD studies determine the lowest detectable concentration of SARS-CoV-2 at which ≥ 95% of all (true positive) replicates test positive. The LoD was determined by limiting dilution studies using characterized samples.

A preliminary LoD for the SARS-CoV-2 specific targets (ORF1ab region and N target) was determined using SARS-CoV-2 RNA extracted from inactivated virus obtained from the Xiamen Center for Disease Control and Prevention, China. RNA was extracted using the Virus RNA Extraction Kit

from Xiamen Zeesan (Cat # 602101) and quantitated using ddPCR. Clinical, pooled nasopharyngeal swab matrices were screened negative by the Xiamen CDC and spiked with inactivated virus at various concentrations (1000, 500, 400, 300, 200 and 100 copies/mL). Three separate spiked samples prepared at 1000, 500, 400, 300, 200 and 100 copies/mL were tested in triplicate using three lots of reagents on the Applied Biosystems™ QuantStudio 3 Real-Time PCR platform and three separate spiked samples prepared at 400, 300, 200 and 100 copies/mL were tested in triplicate using three lots of reagents on the Bio-Rad CFX96™. The preliminary LoD using nasopharyngeal swab matrix was determined to be 200 copies/mL.

The LoD of the SARS-CoV-2 Test Kit (Real-time PCR) was confirmed using 20 individual extraction replicates consisting of spiked nasopharyngeal swab samples at 500 copies/mL, 200 copies/mL, and 100 copies/mL. Three separate spiked samples prepared at three different concentrations were evaluated using 20 extraction replicates per concentration and three kit lots. Samples at 500 copies/mL, 200 copies/mL, and 100 copies/mL were extracted with the Virus RNA Extraction Kit and tested on the Applied Biosystems™ QuantStudio 3 Real-Time PCR instrument and samples at 200 copies/mL were extracted with the Virus RNA Extraction Kit and tested on the Bio-Rad CFX96™. The lowest target level at which more than 95% of 20 replicates for nasopharyngeal swab specimens produced positive results was 200 copies/mL (Table below).

| **Virus RNA Extraction Kit/ Applied Biosystems™ QuantStudio 3 Real-Time PCR** | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Lot** | **Sample #** | **Concentration (copies/mL)** | **# Detected / Total Tested** | **Detection Rate (%)** | **Mean Ct** | | |
| | | | | | **ORF1ab (FAM)** | ***SUC2* (HEX)** | **N (ROX)** |
| 20013001 | 1 | 500 | 20/20 | 100 | 33.35 | 28.76 | 29.60 |
| | | 200 | 20/20 | 100 | 35.01 | 28.59 | 31.00 |
| | | 100 | 17/20 | 85 | 35.85 | 28.59 | 31.88 |
| | 2 | 500 | 20/20 | 100 | 32.97 | 28.65 | 29.61 |
| | | 200 | 20/20 | 100 | 34.02 | 28.92 | 31.11 |
| | | 100 | 17/20 | 85 | 35.84 | 28.42 | 31.59 |
| | 3 | 500 | 20/20 | 100 | 32.78 | 28.26 | 29.11 |
| | | 200 | 20/20 | 100 | 34.52 | 29.08 | 30.96 |
| | | 100 | 18//20 | 90 | 35.86 | 28.31 | 31.32 |
| 20013101 | 1 | 500 | 20/20 | 100 | 32.89 | 29.01 | 29.21 |
| | | 200 | 20/20 | 100 | 33.59 | 28.79 | 30.14 |
| | | 100 | 17/20 | 85 | 35.34 | 28.22 | 30.90 |
| | 2 | 500 | 20/20 | 100 | 33.05 | 28.54 | 29.67 |
| | | 200 | 20/20 | 100 | 34.40 | 28.83 | 30.90 |
| | | 100 | 15/20 | 75 | 36.34 | 28.28 | 32.07 |

| Virus RNA Extraction Kit/ Applied Biosystems™ QuantStudio 3 Real-Time PCR | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Lot** | **Sample #** | **Concentration (copies/mL)** | **# Detected / Total Tested** | **Detection Rate (%)** | **Mean Ct** | | |
| | | | | | **ORF1ab (FAM)** | ***SUC2* (HEX)** | **N (ROX)** |
| | 3 | 500 | 20/20 | 100 | 33.10 | 28.52 | 29.73 |
| | | 200 | 20/20 | 100 | 34.13 | 28.88 | 31.14 |
| | | 100 | 11/20 | 55 | 36.85 | 28.43 | 32.31 |
| 20013102 | 1 | 500 | 20/20 | 100 | 32.97 | 28.35 | 29.87 |
| | | 200 | 20/20 | 100 | 34.21 | 28.44 | 31.34 |
| | | 100 | 12/20 | 60 | 37.67 | 28.17 | 32.51 |
| | 2 | 500 | 20/20 | 100 | 32.99 | 28.49 | 29.36 |
| | | 200 | 20/20 | 100 | 34.15 | 28.53 | 30.45 |
| | | 100 | 13/20 | 65 | 37.16 | 28.21 | 31.54 |
| | 3 | 500 | 20/20 | 100 | 32.86 | 28.50 | 29.16 |
| | | 200 | 20/20 | 100 | 34.10 | 27.89 | 30.21 |
| | | 100 | 15/20 | 75 | 36.45 | 28.87 | 31.96 |
| **Virus RNA Extraction Kit/Bio-Rad CFX96™ Real-Time System** | | | | | | | |
| **Lot** | **Sample #** | **Concentration (copies/mL)** | **# Detected / Total Tested** | **Detection Rate (%)** | **Mean Ct** | | |
| | | | | | **ORF1ab (FAM)** | ***SUC2* (HEX)** | **N (ROX)** |
| 20013001 | 1 | 200 | 20/20 | 100 | 33.80 | 28.57 | 32.23 |
| | 2 | 200 | 20/20 | 100 | 33.75 | 28.54 | 32.03 |
| | 3 | 200 | 20/20 | 100 | 33.64 | 28.57 | 32.04 |
| 20013101 | 1 | 200 | 20/20 | 100 | 33.39 | 28.17 | 31.79 |
| | 2 | 200 | 20/20 | 100 | 33.15 | 28.19 | 31.72 |
| | 3 | 200 | 20/20 | 100 | 33.01 | 28.12 | 31.66 |
| 20013102 | 1 | 200 | 20/20 | 100 | 32.97 | 28.73 | 31.50 |
| | 2 | 200 | 20/20 | 100 | 33.24 | 28.83 | 31.26 |
| | 3 | 200 | 20/20 | 100 | 32.75 | 28.66 | 31.34 |

To demonstrate that the Lab-Aid Nucleic Acid Extraction Kit on the Lab-Aid 824s System was an equivalent extraction method to the manual Virus RNA Extraction Kit, LoD studies were performed on both the Bio-Rad CFX96™ platform and the QuantStudio 3 instrument.

For the preliminary range finding study, different dilutions were prepared using SARS-CoV-2 inactivated virus spiked into pooled negative clinical nasopharyngeal swab matrix obtained from the Xiamen Center for Disease Control and Prevention, China. RNA was extracted using the Lab-Aid Virus RNA Extraction Kit on the Lab-Aid 824s Nucleic Acid Extraction System and quantitated using ddPCR. Clinical, pooled nasopharyngeal swab matrices were screened negative and spiked with inactivated virus at various concentrations (1000, 500, 200, and 100 copies/mL). Three separate spiked samples prepared at 1000, 500, 200, and 100 copies/mL were tested using five replicates per

concentration and three lots of reagents on the CFX96™ and the QuantStudio instruments. Confirmation of the final LoD was determined using dilutions of SARS-CoV-2 inactivated virus spiked into pooled negative clinical nasopharyngeal swab matrix. Three SARS-CoV-2 spiked samples at 200 copies/mL and 100 copies/mL were tested using 20 independent extraction replicates at each dilution level with three lots of reagents on the Bio-Rad CFX96™ instrument. Samples at 200 copies/mL were extracted with the Lab-Aid workflow and tested on the QuantStudio 3 (Table below).

| **Lab-Aid Workflow/Bio-Rad CFX96™ Real-Time System** | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Lot** | **Sample #** | **Concentration (copies/mL)** | **# Detected / Total Tested** | **Detection Rate (%)** | **Mean Ct** | | |
| | | | | | **ORF1ab (FAM)** | ***SUC2* (HEX)** | **N (ROX)** |
| 20013001 | 1 | 200 | 20/20 | 100 | 33.73 | 28.49 | 32.04 |
| | | 100 | 17/20 | 85 | 36.21 | 28.18 | 32.51 |
| | 2 | 200 | 20/20 | 100 | 33.56 | 28.47 | 32.14 |
| | | 100 | 19/20 | 95 | 35.66 | 28.19 | 32.71 |
| | 3 | 200 | 20/20 | 100 | 33.56 | 28.43 | 32.03 |
| | | 100 | 20/20 | 100 | 35.55 | 28.20 | 32.43 |
| 20013101 | 1 | 200 | 20/20 | 100 | 33.53 | 27.87 | 31.60 |
| | | 100 | 19/20 | 95 | 35.38 | 27.78 | 32.43 |
| | 2 | 200 | 20/20 | 100 | 33.41 | 27.81 | 31.67 |
| | | 100 | 18/20 | 90 | 35.29 | 27.78 | 32.49 |
| | 3 | 200 | 20/20 | 100 | 33.45 | 27.86 | 31.79 |
| | | 100 | 19/20 | 95 | 35.04 | 27.84 | 32.40 |
| 20013102 | 1 | 200 | 20/20 | 100 | 33.19 | 28.27 | 31.67 |
| | | 100 | 19/20 | 95 | 35.06 | 27.91 | 31.91 |
| | 2 | 200 | 20/20 | 100 | 33.06 | 28.25 | 31.80 |
| | | 100 | 16/20 | 80 | 34.97 | 27.85 | 31.88 |
| | 3 | 200 | 20/20 | 100 | 33.06 | 28.30 | 31.72 |
| | | 100 | 19/20 | 95 | 34.75 | 27.88 | 31.92 |
| **Lab-Aid Workflow/ Applied Biosystems™ QuantStudio 3 Real-Time PCR** | | | | | | | |
| 20013001 | 1 | 200 | 20/20 | 100% | 34.19 | 26.81 | 30.23 |
| | 2 | | 20/20 | 100% | 34.30 | 26.76 | 30.12 |
| | 3 | | 20/20 | 100% | 34.29 | 26.72 | 30.26 |
| 20013101 | 1 | 200 | 20/20 | 100% | 33.97 | 26.75 | 29.99 |
| | 2 | | 20/20 | 100% | 33.95 | 26.77 | 30.13 |
| | 3 | | 20/20 | 100% | 33.59 | 26.72 | 30.24 |
| 20013102 | 1 | 200 | 20/20 | 100% | 35.28 | 27.28 | 30.96 |
| | 2 | | 20/20 | 100% | 34.70 | 26.86 | 30.28 |
| | 3 | | 20/20 | 100% | 33.19 | 26.78 | 30.03 |

The established LoD of the SARS-CoV-2 Assay Kit (Real-time PCR) was 200 copies/mL when using the following combinations of extraction methods and RT-PCR platforms:

- Virus RNA Extraction Kit with the QuantStudio 3 Real-Time PCR System
- Virus RNA Extraction Kit with the CFX96™ Real-Time System
- Lab-Aid automated workflow with the CFX96™ Real-Time System
- Lab-Aid automated workflow with the QuantStudio 3 Real-Time PCR System

**2) Inclusivity:**

Inclusivity was demonstrated by performing an *in silico* analysis of SARS-CoV-2 sequences using the primers and probes of ORF1ab and N gene targets within the assay. A total of 41,121 SARS-CoV-2 full genome sequences were retrieved from GSAID website (updated to 2020-7-15). The mismatches were randomly across the primers and probe regions and reactivity is unlikely to be affected.

| Target | Primer or Probe | Number of Sequences | Percent Homology (# with mismatch) |
|---|---|---|---|
| ORF1ab region | Forward | 41,121 | 99.9149% (35) |
| | Reverse | 41,121 | 99.9490% (21) |
| | Probe | 41,121 | 99.9052% (39) |
| N gene | Forward | 41,121 | 99.9270% (30) |
| | Reverse | 41,121 | 99.8230% (68) |
| | Probe | 41,121 | 99.8640% (56) |

**3) Specificity/Cross-Reactivity**:

Cross-reactivity of the SARS-CoV-2 Test Kit (Real-time PCR) was evaluated using both *in silico* analysis and wet testing against normal and pathogenic organisms associated with the respiratory tract.

***In silico* analysis:** The primers and probes sequences of the ORF1ab and N gene were analyzed using sequences deposited in GenBank. No *in silico* cross-reactivity was found from the organisms in the recommended list (see Table below) except SARS-CoV. Primers sequences of SARS-CoV-2 ORF1ab gene have a 100% homology with that of SARS-CoV, but the ORF1ab probe sequence only shows 76.9% homology with SARS. *In silico* analysis shows the probe will not hybridize with the SARS-CoV sequence, thus the ORF1ab primers/probe set should not cross-react with SARS-CoV.

| Other high priority pathogens from the same genetic family | High priority organisms likely in the circulating area |
|---|---|
| Human coronavirus 229E | Adenovirus (e.g. C1 Ad. 71) |

| | |
|---|---|
| Human coronavirus OC43 | Human Metapneumovirus (hMPV) |
| Human coronavirus NL63 | Influenza A |
| SARS-coronavirus | Influenza B |
| MERS-coronavirus | Influenza C |
| | Enterovirus D68 |
| | Respiratory syncytial virus A |
| | Respiratory syncytial virus B |
| | Rhinovirus |
| | *Chlamydia pneumoniae* |
| | *Haemophilus influenzae* |
| | *Legionella pneumophila* |
| | *Mycobacterium tuberculosis* |
| | *Streptococcus pneumoniae* |
| | *Streptococcus pyogenes* |
| | *Bordetella pertussis* |
| | *Mycoplasma pneumoniae* |
| | *Pneumocystis jirovecii* (PJP) |
| | *Candida albicans* |
| | *Pseudomonas aeruginosa* |
| | *Staphylococcus epidermis* |
| | *Streptococcus salivarius* |

**Wet testing:** The potential cross-reactivity of the SARS-CoV-2 Test Kit (Real-time PCR) was also assessed via wet testing other pathogens (not detected by the kit) that could be associated with clinical respiratory specimens. Each spiked sample was extracted using the Virus RNA Extraction Kit and was tested in triplicate with three lots of the SARS-CoV-2 Test Kit on the Applied Biosystems™ QuantStudio 3 Real-Time PCR System No cross-reactivity of the SARS-CoV-2 Test Kit with the selected microorganisms and human genomic DNA was observed at the concentrations tested. See summary table below.

| Microorganism | Concentration | Result (No. Positive/No. Tested) | Final Result |
|---|---|---|---|
| Human coronavirus 229E | 1.00 x $10^5$ PFU/mL | 0/3 | Negative |
| Human coronavirus OC43 | 1.00 x $10^5$ PFU/mL | 0/3 | Negative |
| Human coronavirus HKU1 | 1.00 x $10^5$ PFU/mL | 0/3 | Negative |
| Human coronavirus NL63 | 1.00 x $10^5$ PFU/mL | 0/3 | Negative |
| SARS-coronavirus | 1.00 x $10^3$ Copies/mL | 0/3 | Negative |
| MERS-coronavirus | 1.00 x $10^3$ Copies/mL | 0/3 | Negative |
| Adenovirus | 1.00 x $10^3$ Copies/mL | 0/3 | Negative |
| human genomic DNA | 50 ng/µL | 0/3 | Negative |
| Parainfluenza virus (type I) | 1.00 x $10^3$ Copies/mL | 0/3 | Negative |

| | | | |
|---|---|---|---|
| Influenza A (H1N1) | 1.00 x $10^5$ PFU/mL | 0/3 | Negative |
| Influenza A /(H3N2) | 1.00 x $10^5$ PFU/mL | 0/3 | Negative |
| Influenza B Virus Yamagata | 1.00 x $10^5$ PFU/mL | 0/3 | Negative |
| Influenza B Virus Victoria | 1.00 x $10^5$ PFU/mL | 0/3 | Negative |
| Respiratory syncytial A virus | 1.00 x $10^5$ PFU/mL | 0/3 | Negative |
| Respiratory syncytial B virus | 1.00 x $10^5$ PFU/mL | 0/3 | Negative |
| *Streptococcus pneumoniae* | 1.00 x $10^6$ CFU/mL | 0/3 | Negative |
| *Haemophilus influenzae* | 1.00 x $10^6$ CFU/mL | 0/3 | Negative |
| *Klebsiella pneumoniae* | 1.00 x $10^6$ CFU/mL | 0/3 | Negative |
| *Cryptococcus* | 1.00 x $10^6$ CFU/mL | 0/3 | Negative |
| *Citrobacter* | 1.00 x $10^6$ CFU/mL | 0/3 | Negative |
| *Serratia marcescens* | 1.00 x $10^6$ CFU/mL | 0/3 | Negative |
| *Pseudomonas aeruginosa* | 1.00 x $10^6$ CFU/mL | 0/3 | Negative |
| *Staphylococcus aureus* | 1.00 x $10^6$ CFU/mL | 0/3 | Negative |
| *Staphylococcus epidermidis* | 1.00 x $10^6$ CFU/mL | 0/3 | Negative |
| *Escherichia coli* | 1.00 x $10^6$ CFU/mL | 0/3 | Negative |
| *Acinetobacter baumannii* | 1.00 x $10^6$ CFU/mL | 0/3 | Negative |
| *Candida albicans* | 1.00 x $10^6$ CFU/mL | 0/3 | Negative |
| *Streptococcus pyogenes* | 1.00 x $10^6$ CFU/mL | 0/3 | Negative |
| *Streptococcus salivarius* | 1.00 x $10^6$ CFU/mL | 0/3 | Negative |
| *Streptococcus oralis* | 1.00 x $10^6$ CFU/mL | 0/3 | Negative |

**Interfering Substances**: An interfering substances study was performed to determine if common interferents (both exogenous and endogenous substances) that could be present in respiratory samples would impact device performance. Each interfering substance (See table below) was evaluated at the highest medically relevant concentration (worst case) in the presence of SARS-CoV-2 reference material (nCoV S reference; positive contrived sample consisting of spiked inactivated virus in pooled negative respiratory clinical matrix provided by Xiamen CDC; final concentration 200 copies/mL). Prepared samples with each interfering substance were extracted with the Virus RNA Extraction Kit and one replicate was tested with three lots of kit reagents.

| Interfering Substance | Description/Active Ingredients | Concentration |
|---|---|---|
| Blood | Blood (human) | 2% (v/v) |
| Nasal spray/nasal drops | Oxymetazoline | 15% (v/v) |
| Nasal dermal steroids | Dexamethasone | 5 µg/mL |
| Antiviral drug | Zanamivir | 7.5 mg/mL |
| Antibiotic/nasal ointment | Mupirocin | 10 mg/mL |

The interfering substances study demonstrated that common endogenous and exogenous interferents did not impact the performance of the SARS-CoV-2 Test Kit (Real-time PCR).

**4) Clinical Performance:**

A clinical evaluation study was performed to evaluate the performance of the SARS-CoV-2 Test Kit (Real-time PCR) using nasopharyngeal swab and oropharyngeal swab specimens. A total of 30 frozen positive samples and 30 frozen negative samples that were previously confirmed using an EUA authorized assay were tested with the SARS-CoV-2 Test Kit. Of the 60 clinical samples that were evaluated, 34 specimens were NP swabs and 26 specimens were OP swabs. Samples were extracted using their validated methods, blinded, and randomized for testing.

All 30 positive samples were correctly detected with both SARS-CoV-2 Test Kit (Real-time PCR) and the EUA authorized RT-PCR test. Of the 30 positive specimens, 19 were nasopharyngeal swabs and 11 were oropharyngeal swabs. None of the 30 SARS-CoV-2 negative samples (15 nasopharyngeal swabs and 15 oropharyngeal swabs) were positive. Therefore, both the positive percent agreement and negative result agreement were 100% (30/30) in comparison to the EUA authorized RT-PCR test.

| **Nasopharyngeal Swabs** | | **EUA Authorized Comparator** | | |
|---|---|---|---|---|
| | | **Positive** | **Negative** | **Total** |
| **Zeesan SARS-CoV-2 Test Kit (Real-time PCR)** | **Positive** | 19 | 0 | 19 |
| | **Negative** | 0 | 15 | 15 |
| | **Total** | 19 | 15 | 34 |
| **Positive Percent Agreement (PPA)** | | 19/19; 100% (95% CI 83.18-100%) | | |
| **Negative Percent Agreement (NPA)** | | 15/15; 100% (95% CI 79.61-100%) | | |

| **Oropharyngeal Swabs** | | **EUA Authorized Comparator** | | |
|---|---|---|---|---|
| | | **Positive** | **Negative** | **Total** |
| **Zeesan SARS-CoV-2 Test Kit (Real-time PCR)** | **Positive** | 11 | 0 | 11 |
| | **Negative** | 0 | 15 | 15 |
| | **Total** | 11 | 15 | 26 |
| **Positive Percent Agreement (PPA)** | | 11/11; 100% (95% CI 74.11-100%) | | |
| **Negative Percent Agreement (NPA)** | | 15/15; 100% (95% CI 79.61-100%) | | |

| **Nasopharyngeal and Oropharyngeal Swabs Combined Performance** | | **EUA Authorized Comparator** | | |
|---|---|---|---|---|
| | | **Positive** | **Negative** | **Total** |
| **Zeesan SARS-CoV-2 Test Kit (Real-time PCR)** | **Positive** | 30 | 0 | 30 |
| | **Negative** | 0 | 30 | 30 |
| | **Total** | 30 | 30 | 60 |
| **Positive Percent Agreement (PPA)** | | 30/30; 100% (95% CI 88.43-100.00%) | | |
| **Negative Percent Agreement (NPA)** | | 30/30; 100% (95% CI 88.43-100.00%) | | |

**Key to symbols used in the package:**

| | |
|---|---|
| REF | Catalogue Number |
| IVD | In Vitro Diagnostic Medical Device |
| | Manufacturer |
| 2℃ 8℃ | Store at 2°C ~8°C |
| | Expiration Date |
| | Do Not Reuse |
| | CAUTION |
| | Consult Instructions for Use |
| Σ 48 | Contains Sufficient for 48 tests |

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