VIASURE

Real Time PCR Detection Kits

by CerTest BIOTEC

SARS-CoV-2

Handbook for the following references:

VIASURE *SARS-CoV-2* Real Time PCR Detection Kit 6 x 8-well strips, low profile, 48 reactions	**VS-NCO206LE**
VIASURE *SARS-CoV-2* Real Time PCR Detection Kit 6 x 8-well strips, high profile, 48 reactions	**VS-NCO206HE**
VIASURE *SARS-CoV-2* Real Time PCR Detection Kit 12 x 8-well strips, low profile, 96 reactions	**VS-NCO212LE**
VIASURE *SARS-CoV-2* Real Time PCR Detection Kit 12 x 8-well strips, high profile, 96 reactions	**VS-NCO212HE**
VIASURE *SARS-CoV-2* Real Time PCR Detection Kit 96-well plate, low profile, 96 reactions	**VS-NCO213LE**
VIASURE *SARS-CoV-2* Real Time PCR Detection Kit 96-well plate, high profile, 96 reactions	**VS-NCO213HE**

For Emergency Use Authorization (EUA) only

For *in vitro* diagnostic use only

For Prescription Use only

Contents

ENGLISH

1. Intended use

VIASURE *SARS-CoV-2* Real Time PCR Detection Kit is a real-time RT-PCR test intended for the qualitative detection of RNA from the SARS-CoV-2 in nasopharyngeal (NP) and nasal swab specimens from individuals suspected of COVID-19 by their healthcare provider. VIASURE SARS-CoV-2 Real Time PCR Detection Kit is for use only under Emergency Use Authorization (EUA) in the US laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests, or by similarly qualified non-U.S. laboratories.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in nasopharyngeal and nasal swab 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 positive results to the appropriate public health authorities.

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

The VIASURE *SARS-CoV-2* Real Time PCR Detection 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 VIASURE *SARS-CoV-2* Real Time PCR Detection Kit is only for use under the Food and Drug Administration's Emergency Use Authorization (EUA).

2. Summary and Explanation

Coronavirus are enveloped non-segmented positive-sense RNA viruses and belong to *Coronaviridae* family. There are six coronavirus species known to cause human diseases. Four viruses (229E, OC43, NL63 and HKU1) cause common cold symptoms and the other two (severe acute respiratory syndrome coronavirus (SARS-CoV) and Middle East respiratory syndrome coronavirus (MERS-CoV)) are zoonotic and producing more severe complications. SARS-CoV and MERS-CoV have caused more than 10,000 cumulative cases in the past two decades, with mortality rates of 34% MERS-CoV and 10% SARS-CoV.

In December 2019, some people that worked at or lived around the Huanan seafood market in Wuhan, Hubei Province, China, have presented pneumonia of unknown cause. Deep sequencing analysis of the respiratory samples indicated a novel coronavirus, which was named firstly 2019 novel coronavirus (2019-nCoV) and lately SARS-CoV-2.

Human-to-human transmission of the SARS-CoV-2 has been confirmed, even in the incubation period without symptoms, and the virus causes severe respiratory illness like those SARS-CoV produced. Although the pneumonia is the principal illness associated, a few patients have developed severe pneumonia, pulmonary edema, acute

respiratory distress syndrome, or multiple organ failure and death. Centers of Disease Control and Prevention (CDC) believes that symptoms of SARS-CoV-2 may appear in as few as 2 days or as long as 14 days after exposure, being the most common fever or chills, cough, fatigue, anorexia, myalgia and dyspnea. Less common symptoms are sore throat, nasal congestion, headache, diarrhea, nausea and vomiting. Loss of smell (anosmia) or loss of taste (ageusia) preceding the onset of respiratory symptoms has also been reported. Older adults and people who have severe underlying medical conditions like heart or lung disease or diabetes seem to be at higher risk for developing more serious complications from COVID-19 illness.

Diagnosis of SARS-CoV-2 is performed detecting conventional causes of pneumonia early and detected by next-generation sequencing or real-time RT-PCR methods. Several assays that detect the SARS-CoV-2 have been are currently available, such as China CDC (gene targets, *ORF1ab* and *N*), *Charité* – Germany (gene targets, *RdRP* and *E*) or US CDC (three targets in *N* gene).

CDC recommends upper respiratory tract specimens (nasopharyngeal (NP) swab, oropharyngeal (OP) swabs, nasal mid-turbinate swab, nasal swab, nasopharyngeal wash/aspirate or nasal wash/aspirate (NW) specimens collected mainly by a healthcare provider) and/or lower respiratory specimens (sputum, endotracheal aspirate, or bronchoalveolar lavage in patients with more severe respiratory disease) for the identification of SARS-CoV-2. In addition, other clinical specimens as blood, urine and stool may be collected to monitor the presence of the virus.

3. Principle of the procedure

VIASURE *SARS-CoV-2* Real Time PCR Detection Kit is designed for the diagnosis of SARS-CoV-2 in nasopharyngeal (NP) and nasal swab specimens. The detection is done in one step real time RT format where the reverse transcription and the subsequent amplification of specific target sequence occur in the same reaction well. The isolated RNA target is transcribed generating complementary DNA by reverse transcriptase which is followed by the amplification of a conserved region of *ORF1ab and N genes* for SARS-CoV-2 using specific primers and a fluorescent-labeled probe.

VIASURE *SARS-CoV-2* Real Time PCR Detection Kit is based on the 5´ exonuclease activity of DNA polymerase. During DNA amplification, this enzyme cleaves the probe bounded to the complementary DNA sequence, separating the quencher dye from the reporter. This reaction generates an increase in the fluorescent signal which is proportional to the quantity of target template. This fluorescence can be measured on Real Time PCR platforms.

VIASURE *SARS-CoV-2* Real Time PCR Detection Kit contains in each well all the components necessary for real time PCR assay (specific primers/probes, dNTPS, buffer, polymerase and retrotranscriptase) in a stabilized format. The assay can use an Extraction Control (EC) which can be introduced into each sample at the lysis buffer stage of the extraction process. This control can be used to monitor the extraction process and/or discard the inhibition of the polymerase activity. *ORF1ab* gene is amplified and detected in FAM channel, *N* gene is amplified and detected in ROX channel and the Extraction control (EC) in VIC channel.

4. Reagents provided

VIASURE *SARS-CoV-2* Real Time PCR Detection Kit includes the following materials and reagents detailed in Tables 1, 2 and 3. Based on the commercial presentation and the Real Time PCR platform used, the stabilized PCR reaction mix could be placed inside different wells and could be marketed on multiple formats. Table 1 includes materials and reagents to be used with 8-well strips compatible devices. Table 2 includes materials and reagents to be used with 96-well plate compatible devices.

Reagent/Material	Description	Colour	Amount
SARS-CoV-2 8-well strips	A mix of enzymes, primers probes, buffer, dNTPs and stabilizers in stabilized format	White	6/12 x 8-well strip
Rehydration Buffer	Solution to reconstitute the stabilized product	Blue	1 vial x 1.8 mL
SARS-CoV-2 Positive Control	Non-infectious synthetic lyophilized cDNA	Red	1 vial
Extraction Control	Non-infectious nucleic acid lyophilized	Green	1 vial
Negative control	Non template control	Violet	1 vial x 1 mL
Water RNAse/DNAse free	RNAse/DNAse free water	White	1 vial x 1 mL
Tear-off 8-cap strips	Optical caps for sealing wells during thermal cycling	Transparent	6/12 x 8-cap strip

Table 1. Reagents and materials provided in VIASURE *SARS-CoV-2* Real Time PCR Detection Kit with Ref. VS-NCO206LE and VS-NCO206HE, VS-NCO212LE and VS-NCO212HE.

Reagent/Material	Description	Color	Amount
SARS-CoV-2 96-well plate	A mix of enzymes, primers probes, buffer, dNTPs and stabilizers in stabilized format	White	1 plate
Rehydration Buffer	Solution to reconstitute the stabilized product	Blue	1 vial x 1.8 mL
SARS-CoV-2 Positive Control	Non-infectious synthetic lyophilized cDNA	Red	1 vial
Extraction Control	Non-infectious nucleic acid lyophilized	Green	1 vial
Negative control	Non template control	Violet	1 vial x 1 mL
Water RNAse/DNAse free	RNAse/DNAse free water	White	1 vial x 1 mL
Tear-off 8-cap strips	Optical caps for sealing plate during thermal cycling	Transparent	12 x 8-cap strip

Table 2. Reagents and materials provided in VIASURE *SARS-CoV-2* Real Time PCR Detection Kit with Ref VS-NCO213LE and VS-NCO213HE.

5. Reagents and equipment to be supplied by the user

The following list includes the materials that are required for use but not included in the VIASURE *SARS-CoV-2* Real Time PCR Detection Kit.

- Real Time PCR instrument (thermocycler): Applied Biosystems QuantStudio™ 12K Flex Real-Time PCR System, 96-well block.

- Automated nucleic acid extraction system and materials: the MagNA Pure 96 Instrument (Roche Molecular Systems), the MagNA Pure 96 DNA, Viral NA Small Volume Kit (using Viral NA Plasma ext lyse SV protocol) (Roche) and the MagNA Pure 96 External Lysis Buffer (Roche).
- Collection and transport system: Universal transport medium (UTM), and saline solution (0.9 % sodium chloride).
- Laboratory freezers: - 30°C to - 10°C and/or ≤ –70°C.
- Centrifuge for 1.5 mL tubes and PCR-well strips or 96-well plate (if available).
- Vortex.
- Micropipettes (0.5-20 µL, 20-200 µL).
- Filter tips.
- Powder-free disposable gloves.

6. Transport and storage conditions

- The kits can be shipped and stored at 2-40°C until the expiration date which is stated on the label.
- Once the positive control has been re-suspended, store it at -20°C. We recommend separating it in aliquots to minimize freeze and thaw cycles. Positive control has been validated as still being stable after 6 freeze-thaw cycles.
- Keep components away from sunlight.

7. Warnings and Precautions

- The product is indented 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 (including training on the Real Time PCR instrument (thermocycler) and Nucleic acid extraction system).
- For *In Vitro* Diagnostic Use under the Emergency Use Authorization (EUA) only. For Prescription Use only. Carefully read this entire package insert.
- Do not use past expiration date.
- Do not use reagents if the protective pouches are open or broken upon arrival.
- Do not use reagents if desiccant is not present or broken inside reagent pouches.
- Do not remove desiccant from reagent pouches once is open.
- Close protective pouches of reagents promptly with the zip seal after each use (if available, Ref. VS-NCO213LE, and VS-NCO213HE). Remove any excess air in the pouches prior to sealing.
- Do not use reagents if the foil has been broken or damaged.
- Do not mix reagents from different envelopes and / or kits and / or lots and / or another supplier.
- Protect reagents against from humidity. Prolonged exposure to humidity may affect product performance.
- Design a unidirectional workflow. It should begin in the Extraction Area and then move to the Amplification and Detection Area. Do not return samples, equipment and reagents to the area in which the previous step was performed. Use separate areas for the preparation of patient samples and controls to prevent false positive results.
- Always avoid microbial and ribonuclease (RNase)/deoxyribonuclease (DNase) contamination of reagents. The use of sterile RNase/DNase-free disposable aerosol resistant or positive displacement pipette tips is recommended.

- Follow Good Laboratory Practices. Wear protective clothing, use disposable gloves, goggles and mask. Do not eat, drink or smoke or apply cosmetic products in the working area. Once you finish the test wash your hands.
- Specimens must be treated as potentially infectious and/or biohazardous, as well as all the reagents and materials that have been exposed to the samples and they must be handled according to the national safety regulations. Take necessary precautions during the collection, transport, storage, handling, and disposal of samples.
- Samples and reagents must be handled in a biological safety cabinet. Use personal protective equipment (PPE) consistent with current guidelines for the handling of potentially infectious samples. Dispose of waste in compliance with local, state, and federal regulations.
- Regular decontamination of commonly used equipment is recommended, especially micropipettes and work surfaces.
- Consult safety data sheets, upon request.
- Consult each Real Time PCR instrument's reference manual for additional warnings, precautions and procedures.
- Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.
- Modifications to assay reagents, assay protocol, or instrumentation are not permitted, and are in violation of the product Emergency Use Authorization.

8. Test procedure

Briefly, the workflow begins with nucleic acid extraction from nasopharyngeal and nasal swabs (upper respiratory specimens) collected in Aptima® Multitest Swab Specimen Collection Kit (HOLOGIC), UTM, and saline solution that arrive in the testing site. Nucleic acids are isolated and purified from the specimens using the MagNA Pure 96 External Lysis Buffer and MagNA Pure 96 DNA and Viral NA Small Volume Kit (using Viral NA Plasma ext lys SV protocol) (Roche Molecular Systems). Nucleic acid isolation can be performed via an automated process using MagNA Pure 96 Instrument (Roche Molecular Systems). The purified nucleic acid is reverse transcribed into cDNA and subsequently amplified using the VIASURE *SARS-CoV-2* Real Time PCR Detection Kit and the following instrument: Applied Biosystems QuantStudio™ 12K Flex Real-Time PCR System, 96-well block. Fluorescence intensity is monitored at each PCR cycle. The data are analyzed by the software of the used real time PCR equipment itself according to manufacturer´s instructions.

8.1. Specimen collection, transport and storage

The VIASURE SARS-CoV-2 Real Time PCR Detection kit has been validated on nasopharyngeal and nasal specimens collected with synthetic fiber swabs with plastic and placed immediately into a sterile transport tube containing Universal transport medium (UTM), or saline solution (0.9 % sodium chloride) and nasal swabs collected with Aptima® Multitest Swab Specimen Collection Kit (HOLOGIC).

Patient samples must be collected, transport and storage according to appropriate laboratory guidelines. For details, refer to the CDC guidelines (Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19) (website https:// www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html).

8.2. Sample preparation and RNA extraction

Perform the sample preparation according to the recommendations appearing in the instructions for use of the extraction kit. The following automated nucleic acid extraction system and materials, MagNA Pure 96 Instrument (Roche Molecular Systems) using MagNA Pure 96 External Lysis Buffer and MagNA Pure 96 DNA and Viral Nucleic Acid Small Volume Kit (following the Viral NA Plasma ext lys SV protocol) were validated. For RNA extraction from nasopharyngeal and nasal swabs, use a specimen input volume and nucleic acid elution volume of 100 µL.

If the Extraction Control is used to monitor nucleic acid isolation and as PCR inhibition control, add 5 µl of the EC to the specimen and/or lysis buffer mixture (clinical specimen, as well as, positive control and/or negative control). Close each tube and vortex for 10 seconds.

If the Extraction Control is used only as a PCR inhibition control, 1µl of the EC should be added to the reconstituted Reaction-Mix.

8.3. Controls

VIASURE *SARS-CoV-2* Real Time PCR Detection Kit includes the following controls for a multiplex real-time RT-PCR test for the qualitative detection of RNA from SARS-CoV-2:

- **Extraction Control** (EC) contains a defined copy number of a non-infectious DNA molecule to perform 96 extractions. The EC is used to control the entire run process and is needed to monitor the extraction process, to identify possible RT-qPCR inhibition and to confirm the integrity of the reagents of the kit. The extraction control should be added to each specimen, prior to the extraction process. Detection of the Extraction control is not required for samples that are positive for SARS-CoV-2. The Extraction control must be detected in all samples that are negative for SARS-CoV-2 targets (See Result interpretation).

- **SARS-CoV-2 Positive Control** (PC) consists of a non-infectious synthetic lyophilized cDNA that contains high copy number of both SARS-CoV-2 genomic regions targeted by the assays (conserved regions of *ORF1ab* and *N* genes), enough to perform 20 reactions. The Positive Control is used to monitor RT-qPCR reaction setup and reagent integrity, and is needed to validate the reaction, and accurately interpret patient test results. At least, one positive control must be included in each run at RT-qPCR reaction setup in the reserved well for positive control.

- **Negative Control** (NC)("no template control") is used to monitor cross-contamination during RNA extraction and/or reaction setup, and is needed to validate the reaction, and accurately interpret patient test results. It contains sufficient material to perform 96 extractions. At least, one negative control must be included in each run at RT-qPCR reaction setup in the reserved well for negative controls.

8.3.1. Lyophilized extraction control

Recommendation is to open and manipulate the Extraction Control (EC) in pre-PCR laboratory area away from the lyophilized positive control. Reconstitute the lyophilized Extraction Control (green vial) adding 500 µL of Water RNAse/DNAse free (white vial) supplied and vortex thoroughly.

Once the Extraction Control has been re-suspended, store it at -20°C. Recommendation is to separate it in aliquots to minimize freeze and thaw cycles.

Note: The Water RNAse/DNAse free vial must be utilized first to reconstitute the lyophilized Extraction Control in pre-PCR laboratory area, and subsequently, it can be used for reconstitute the lyophilized *SARS-CoV-2* Positive Control in an area away from the other components.

8.3.2. Lyophilized positive control

SARS-CoV-2 Positive Control contains high copies of the template, the recommendation is to open and manipulate it in a separate laboratory area away from the other components. Reconstitute the lyophilized *SARS-CoV-2* Positive Control (red vial) by adding 100 µL of the supplied Water RNAse/DNAse free (white vial) and vortex thoroughly.

Once the positive control has been re-suspended, store it at -20°C. It is recommended separating it in aliquots to minimize freeze and thaw cycles.

8.4. PCR protocol

Determine and separate the number of required reactions including samples and controls. One positive and negative control must be included in each run for each assay. Peel off protective aluminum seal from plates or strips.

1) Reconstitute the number of wells you need.

Add 15 µL of Rehydration Buffer (blue vial) into each well.

2) Adding samples and controls.

Add 5 µL of Negative Control (violet vial) in the reserved wells for negative control.

Add 5 µL of each RNA sample (eluate from the nucleic acid extraction) in different wells.

Add 5 µL of reconstituted *SARS-CoV-2* Positive Control (red vial) in the reserved wells for positive control.

Add 1 µl of the EC (green vial) to the negative control and positive control wells.

It is recommended to briefly centrifuge the 8-well strips or 96-well plate, or gently tap each strip onto a hard surface to ensure that all the liquids are at the bottom of the tubes.

Load the plate or the strips in the thermocycler.

3) Set up and run the QuantStudio™ 12K Flex Real-Time PCR System (96-well plate).

a. Start the QuantStudio™ 12K Flex Software (v1.2.1), to access the Home screen. There are four menus Tools, Experiment, Run and Analyze.

b. From the Experiment menu, click the Create icon. Click Experiment Properties to access the Experiment Properties screen. Enter or confirm the following:
   - Experiment Name: enter a unique name
   - Block type: 96-Well 0.2-mL Block
   - Experiment type: Standard Curve
   - Chemistry: TaqMan™Reagents
   - Run mode: Standard

c. In the Setup pane on the left side of the screen, there are four tabs. Go through all four tabs the first time that you set up a run.

d. Click Define to access the Define screen. There will be four panels.
   - Define targets. Click New to add targets, enter the Target Name and select the Reporter and Quencher from the respective drop-down menu. Confirm that the reporter dye and the target pairs are correct: FAM (*ORF1ab* gene), ROX (*N* gene) and VIC (Extraction Control (EC)). Quenchers: none.
   - Define samples. Click New to add samples and name them unique.
   - Select the Passive Reference from the drop-down menu: None.

e. Click Assign to access the Assign screen. Use the Assign screen to assign targets and samples to wells in the reaction plate (plate layout).
   - Assign the samples. Select the check box next to the sample to assign to the selected wells. Note: You can assign only one sample to a well.
   - Assign all three targets to each well with samples and controls. Each target can be assigned to one of the following tasks: as U (unknown), S (standard) and N (negative).

f. Click Run Method to access the Run Method screen. Confirm that the Volume is 20 µL, then program the thermocycler following the conditions listed below:

Cycles	Step	Time	Temperature
1	Reverse transcription	15 min	45ºC
1	Initial denaturation	2 min	95ºC
45	Denaturation	10 seg	95ºC
	Annealing/Extension (Data collection*)	50 seg	60ºC

Table 3. PCR protocol

Fluorogenic data should be collected during the extension step (*) through the FAM (*ORF1ab* gene), ROX (*N* gene) and VIC (Extraction Control (EC)). Enable data collection by clicking the camera icon.

g. In the Run tab, click Start Run.
   All experiments are saved in the experiment folder by default. To save in a different folder, click Save As and navigate to the desired location.

9. Result interpretation

All the result of the test should be evaluated by a health care professional in the context of medical history, clinical symptoms, and other diagnostic tests. Check Extraction Control (EC) signal to verify the extraction procedure and/or correct functioning of the amplification mix. The analysis of the controls and samples is done by the software of the used real time PCR equipment itself according to manufacturer´s instructions. Using the following tables 4 and 5 read and analyze the results.

The use of positive and negative controls in each run, validate the reaction by checking the absence of signal in the negative control well and the presence of signal for SARS-CoV-2 in the positive control well. For a valid diagnostic test run, the following control conditions must be met:

Controls	*ORF1ab* gene (FAM)[1]	*N* gene (ROX)[1]	Extraction control (VIC)[2]	Interpretation of Controls
Positive Control (PC)	≤40	≤40	≤32	**Valid**
Negative Control (NC)	≥40 or no signal	≥40 or no signal	≤32	**Valid**

Table 4. Expected Performance of Controls

1 In cases where either or both of the control assays have failed (an amplification signal is observed in the negative control and/or signals absence in the positive control well for any target channel), all results are reported as 'Invalid' and retesting is required.

2 The Extraction Control (EC) should show an amplification signal (Ct ≤32 in control wells (PC and NC)). Differences can be observed in the values of Ct in the extraction controls between the controls and the clinical samples, due to the extraction process.

Assessment of clinical samples test results should be performed after the positive and negative controls have been examined and determined to be valid and acceptable. If one or more controls are not valid, the patient results cannot be interpreted. For interpretation of patient sample results, use the following table:

ORF1ab gene (FAM)	*N* gene (ROX)	Extraction control (VIC)	Interpretation for patients' samples	
≤40	≤40	≤40 or no signal [1]	**Valid**	**SARS-CoV-2 RNA Detected**
≤40 [2]	≥40 or no signal	≤40 or no signal [1]	**Valid**	**SARS-CoV-2 RNA Detected [2]**
≥40 or no signal	≤40 [2]	≤40 or no signal [1]	**Valid**	**SARS-CoV-2 RNA Detected [2]**
≥40 or no signal	≥40 or no signal	≤ 32 [3]	**Valid**	**SARS-CoV-2 RNA not Detected [3]**
≥40 or no signal	≥40 or no signal	≥ 32 or no signal [3]	**Invalid**	**Test Failure – Repeat Testing[3]**

Table 5. Interpretation of patient sample results. Ct values. no signal = no amplification curve.

1 The Extraction Control (EC) shows or not an amplification signal (Ct ≤40 or no signal). Sometimes, its detection is not necessary because a high copy number of the target can cause preferential amplification of target-specific nucleic

acids. Differences can be observed in the values of Ct in the extraction controls between the controls and the clinical samples, due to the extraction process.

2 If only a single positive gene is observed, verify the sigmoid shape of the curve and the intensity of fluorescence. In case of a doubtful interpretation, depending on the available material, it is also recommended to:

a) re-extract and retest another aliquot of the same specimen or,

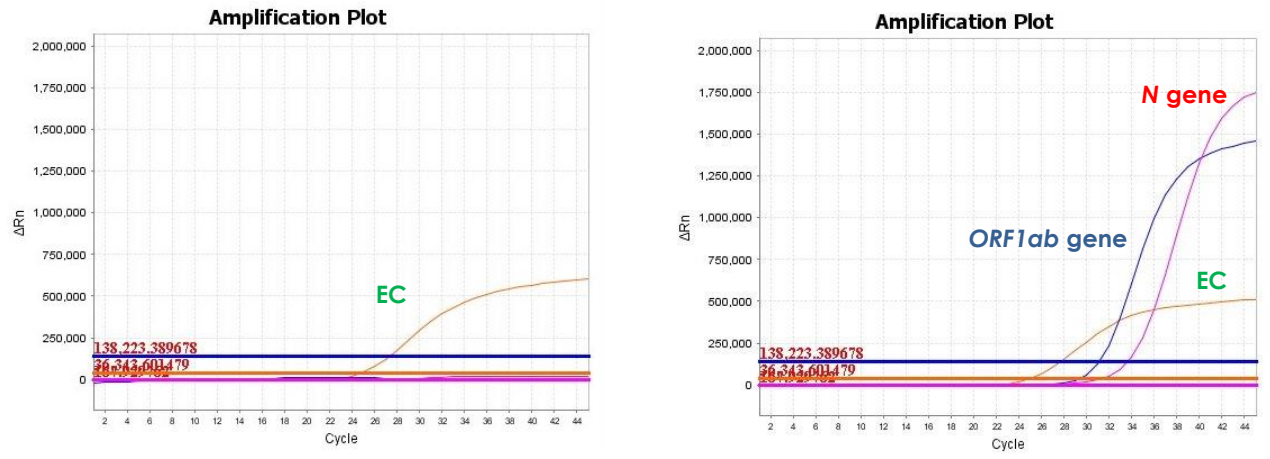
b) repeat RT-qPCR with the same isolated RNA sample, or

c) obtain a new specimen and retest.

3 In the case of SARS-CoV-2 target genes negative, EC must show an amplification signal with Ct less than 32 (Ct value is usually 25±5). If there is an absence of signal or Ct value ≥ 32 of the Extraction Control, the result is considered as 'Invalid', and retesting is required. It is recommended to repeat the RT-qPCR diluting the RNA sample 1:10 and/or 1:100, or re-extract and retest to check for possible failure in the extraction procedure and/or inhibition issues.

In case of a continued ambiguous result, it is recommended to review the instructions for using the extraction process used by the user, to verify the correct performance of each RT-qPCR steps and review the parameters, and to check the sigmoid shape of the curve and the intensity of fluorescence.

Figure 1. Correct run of negative and positive samples run on the QuantStudio™ 12K Flex Real-Time PCR System.



Negative sample **Positive sample**

10. Limitations of the test

- The use of this assay as an *In vitro* diagnostic under the FDA Emergency Use Authorization (EUA) is limited to laboratories that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests.
- The results of the test should be evaluated by a health care professional in the context of medical history, clinical symptoms and other diagnostic tests.
- Although this assay can be used with other types of samples it has been validated only with RNA extracted from nasopharyngeal and nasal swabs.
- Extraction and amplification of nucleic acid from clinical samples must be performed according the specified methods listed in this procedure. Other extraction approaches and processing systems have not been evaluated.

- Extremely low levels of target below the limit of detection might be detected, but results may not be reproducible.
- There is a possibility of false positive results due to cross-contamination by SARS-CoV-2, either samples containing high concentrations of target RNA or contamination due to PCR products from previous reactions.
- There is a possibility of false positive results due to cross-contamination between Extraction Control and *SARS-CoV-2* Positive Control, which contains high copies template, during their reconstitution by adding of Water RNAse/DNAse free (white vial). Each procedure must take place in established order and in a separate laboratory areas.
- The specific primer and probe combinations for detection of the *ORF1ab* and *N* genes used in VIASURE *SARS-CoV-2* Real Time PCR Detection Kit designed for the detection of SARS-CoV-2, do not show significant combined homologies with the human genome, human microflora, or other coronaviruses (with the exception of some *N* and/or *ORF1ab* sequences from SARS-CoV, and other coronaviruses identified in bats and pangolin), which might result in predictable false positive.
- False Negative results may arise from several factors and their combinations, including:
    - Improper specimens' collection, transport, storage, and/or handling methods.
    - Improper processing procedures (including RNA extraction).
    - Degradation of the viral RNA during sample shipping/storage and/or processing.
    - Mutations or polymorphisms in primer or probe binding regions may affect detection of new or unknown SARS-CoV-2 variants.
    - A viral load in the specimen below the limit of detection for the assay.
    - The presence of RT-qPCR inhibitors or other types of interfering substances. The impacts of vaccines, antiviral therapeutics, antibiotics, chemotherapeutics or immunosuppressant drugs used to prevent COVID-19 or used during the treatment of the infection have not been evaluated.
    - Failure to follow instructions for use and the assay procedure.
- A single-gene amplification or even random positive results is suggestive of slightly different amplification yield of the targets regions. Samples with low viral load might result in *N* single-gene amplification. It has been described that *N* gene assay might be more sensitive than the *ORF1ab* gene assay detecting positive clinical specimens. In case of a doubt, it is recommended referring to a reference laboratory for further testing.
- A positive test result does not necessarily indicate the presence of viable viruses and does not imply that these viruses are infectious or are the causative agents for clinical symptoms. However, a positive result is indicative of the presence of targets viral sequences (*ORF1ab* and/or *N* genes).
- 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 SARS-CoV-2 have not been determined. The collection of multiple specimens (types and time points) from the same patient may be necessary to detect the virus.
- If diagnostic tests for other respiratory illnesses are negative and the patient's clinical presentation and epidemiological information suggest that SARS-CoV-2 infection is possible, then a false negative result should be considered, and a re-testing of the patient should be discussed.
- Laboratories are required to report all positive results to the appropriate public health authorities.

11. Conditions of Authorization for Labs

The VIASURE SARS-CoV-2 Real Time PCR Detection 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/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas.

However, to assist clinical laboratories using the VIASURE *SARS-CoV-2* Real Time PCR Detection Kit, the relevant Conditions of Authorization are listed below and are required to be met by laboratories performing the EUA test:

A. Authorized laboratories[1] using the VIASURE *SARS-CoV-2* Real Time PCR Detection Kit will include with result reports of the VIASURE *SARS-CoV-2* Real Time PCR Detection Kit, 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 VIASURE *SARS-CoV-2* Real Time PCR Detection Kit will perform the VIASURE *SARS-CoV-2* Real Time PCR Detection Kit as outlined in the VIASURE *SARS-CoV-2* Real Time PCR Detection Kit 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 perform the VIASURE *SARS-CoV-2* Real Time PCR Detection Kit are not permitted.
C. Authorized laboratories that receive the VIASURE *SARS-CoV-2* Real Time PCR Detection Kit must notify the relevant public health authorities of their intent to run the test prior to initiating testing.
D. Authorized laboratories using the VIASURE *SARS-CoV-2* Real Time PCR Detection Kit 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 test and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and CerTest Biotec S.L. (quality@certest.es) 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 test must be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use the test in accordance with the authorized labeling.
G. JANT PHARMACAL CORPORATION, its authorized distributor(s) and authorized laboratories using the VIASURE *SARS-CoV-2* Real Time PCR Detection Kit 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] For ease of reference, this letter will refer to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests as "authorized laboratories."

12. Quality control

VIASURE *SARS-CoV-2* Real Time PCR Detection Kit contains a positive and a negative control that must be included in each run to correctly interpret the results. Also, the Extraction Control (EC) in each well confirms the correct performance of the technique.

13. Performance characteristics

13.1. Clinical Performance

The clinical performance of VIASURE *SARS-CoV-2* Real Time PCR Detection Kit was retrospective and prospectively evaluated in comparison to two molecular methods that previously have received FDA Emergency Use Authorization, Thermo-Fisher TaqPath™ COVID-19 Combo Kit (EUA-https://www.fda.gov/media/136113/download) or Aptima® SARS-CoV-2 Assay (Panther® System) (Hologic) (EUA-https://www.fda.gov/media/136156/download).

Firstly, a retrospective evaluation was carried out with leftover frozen nasopharyngeal samples collected in UTM or saline solution with synthetic fiber swabs with plastic and nasal swabs collected with Aptima® Multitest Swab Specimen Collection Kit (HOLOGIC), from individuals suspected of SARS-CoV-2 infection by the healthcare provider in the COVID-19 disease endemic region(s). These samples have been previously characterized by Thermo-Fisher TaqPath™ COVID-19 Combo Kit as molecular reference methods. Samples were stored at -80˚C until VIASURE test evaluation was performed. The results were as follows:

VIASURE *SARS-CoV-2* Real Time PCR Detection Kit	**Thermo-Fisher TaqPath™ COVID-19 Combo Kit**		
	+	**-**	**Total**
+	34	1	35
-	0	37	37
Total	34	38	72

Table 6. Comparative results for SARS-CoV-2.

The Positive Percent Agreement (PPA), Negative Percent Agreement (NPA) and Overall Percent Agreement (OPA) for VIASURE *SARS-CoV-2* Real Time PCR detection kit were calculated in relation to the results from the TaqPath™ COVID-19 Combo Kit (Thermo Fisher Scientific) and Aptima® SARS-CoV-2 Assay (Panther® System) (Hologic) as shown in Table 7.

Microorganism	**PPA (%)**	**NPA (%)**	**OPA (%)**
SARS-CoV-2	100 (89.8 to 100)	98.9 (93.7 to >99.9)	99.3 (95.5 to >99.9)

Table 7. PPA, NPA and OPA values for VIASURE *SARS-CoV-2* Real Time PCR detection kit (95% confidence interval).

A second similar prospective evaluation was also performed using leftover nasopharyngeal samples collected in UTM or saline solution from individuals suspected of SARS-CoV-2 infection. These samples were simultaneously

characterized by Aptima® SARS-CoV-2 Assay (Panther® System) (Hologic). Samples were stored at 4˚C until VIASURE test evaluation was performed. The results were as follows:

VIASURE *SARS-CoV-2* Real Time PCR Detection Kit	Aptima® SARS-CoV-2 Assay (Panther® System) (Hologic)			
		+	-	Total
	+	7	0	7
	-	0	57	57
	Total	7	57	57

Table 8. Comparative results for SARS-CoV-2.

Sensitivity, specificity, Positive predictive value (PPV) and negative predictive value (NPV) for VIASURE *SARS-CoV-2* Real Time PCR detection kit were calculated in relation to the results from the Aptima® SARS-CoV-2 Assay (Panther® System) (Hologic), as shown in Table 9.

Microorganism	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
SARS-CoV-2	100 (56.1-100)	100 (92.1-100)	100 (56.1-100)	100 (92.1-100)

Table 9. Sensitivity, specificity, PPV and NPV values for VIASURE *SARS-CoV-2* Real Time PCR detection kit (95% confidence interval).

13.2. Analytical sensitivity

The analytical sensitivity (Limit of detection or LoD) study established the lowest SARS-CoV-2 viral concentration (Genomic Equivalents or GE) that can be detected by the VIASURE *SARS-CoV-2* Real Time PCR Detection Kit at a ≥95% positive rate. The LoD was determined by testing serial dilutions of pooled negative clinical nasopharyngeal swab specimens in UTM spiked with Genomic RNA from SARS-Related Coronavirus 2, Isolate USA-WA1/2020 (BEI Resources; NR-52285) at several concentrations and processed through the VIASURE *SARS-CoV-2* Real Time PCR Detection Kit workflow. A two-phase approach was used to determine the LoD of the VIASURE *SARS-CoV-2* Real Time PCR Detection Kit. In phase I, the preliminary LoD was established by testing 3 replicates at each of 9 serially diluted concentrations (2-fold dilutions, starting at 960 GE/mL and ending at 3.25 GE/mL). In phase II, the preliminary LoD was confirmed by testing 21 replicates.

Finally, the LoD was determined and verified to be 7.5 genome equivalents (GE)/mL).

13.3. Analytical specificity and Microbial Interference

The analytical specificity (cross-reactivity) of the VIASURE *SARS-CoV-2* Real Time PCR Detection Kit was evaluated using both wet testing and *in silico* analysis against normal and pathogenic organisms found in the respiratory tract (Table 10 and 11).

To evaluate the analytical specificity with regards to cross-reactivity, genomic RNA or DNA from the following viruses, bacteria and fungi as well as nucleic acid extracted from pooled nasal washes in UTM and saline solution (Table 10) were tested without the presence of SARS-CoV-2. RNA or DNA samples were tested directly in the PCR

(5 µl of the nucleic acid stock material was used in each Real Time PCR reaction). For other sample types, the nucleic acids were previously extracted using MagNA Pure 96 Instrument. A total of 33 nucleic acids were tested with the VIASURE *SARS-CoV-2* Real Time PCR Detection Kit as described in Section Test procedure.

Cross-reactivity (wet testing)				
Pathogen	**Source**	**Sample Type**	**Stock Concentration (copies/mL)**	**VIASURE Interpretation (SARS-CoV-2 *ORF1ab* and *N* genes)**
Human adenovirus 14 strain de Wit	ATCC® VR-15D™	DNA	2.40E+10	Negative
Bordetella pertussis strain 5374	ATCC® 12742™	Culture	n/a	Negative
Candida albicans strain 3147	ATCC® 10231D-5™	DNA	2.20E+9	Negative
Chlamydophila pneumoniae TWAR strain 2023	ATCC® VR1356™	Culture	n/a	Negative
Enterovirus D68 Strain US/MO/14-18947	ATCC® VR1823D™	RNA	2.08E+10	Negative
Haemophilus influenzae strain Rd	ATCC® 51907D™	DNA	1.14E+10	Negative
Human coronavirus 229E strain 229E	ATCC® VR-740D™	RNA	8.32E+8	Negative
Human coronavirus OC43	ZeptoMetrix® Corporation NATRVP2-BIO	-	n/a	Negative
Human coronavirus NL63	ZeptoMetrix® Corporation NATRVP2-BIO	-	n/a	Negative
Human coronavirus HKU1	ZeptoMetrix® Corporation NATRVP2-BIO	-	n/a	Negative
Human Metapneumovirus 8 Strain Peru6-2003	ZeptoMetrix® Corporation NATRVP2-BIO	-	n/a	Negative
Human parainfluenza virus 3 strain C 243	ATCC® VR-93D™	RNA	1.38E+9	Negative
Human respiratory syncytial virus strain 18537	ATCC® VR-1580D™	RNA	2.27E+9	Negative
Human rhinovirus 17	ATCC® VR-1663DQ™	RNA	5.2E+8	Negative
Influenza A/Virginia/ATCC2/2009 (H1N1)pdm09	ATCC® VR-1737™	Culture	n/a	Negative
Influenza A/Wisconsin/15/2009 (H3N2)	ATCC® VR-1882™	Culture	n/a	Negative
Influenza B/Florida/78/2015	ATCC® VR-1931™	Culture	n/a	Negative
Legionella pneumophila serogroup 1 strain Benidorm 030 E	ATCC® 43108™	Culture	n/a	Negative
Middle East respiratory syndrome coronavirus (MERS-CoV)	ATCC® VR-3248SD™	Quantitative Synthetic RNA	7.4E+7	Negative
Mycobacterium tuberculosis strain TMC 331	ATCC® 35838D-2™	DNA	3.96E+8	Negative
Pseudomonas aeruginosa strain PAO1-LAC	ATCC® 47085D™	DNA	5.00E+8	Negative
Staphylococcus epidermidis strain RP62A	ATCC® 35984D-5™	DNA	3.13E+9	Negative
Streptococcus pneumoniae strain TIGR4	ATCC® BAA-334D™	DNA	5.56E+9	Negative
Streptococcus pyogenes typing strain T1	ATCC® 12344D-5™	DNA	6.12E+9	Negative
Streptococcus salivarius subsp. salivarius strain DSM 13084	ATCC® BAA1024D-5™	DNA	9.60E+9	Negative
Pooled human nasal washes from 10 donors in UTM and saline solution- to represent diverse microbial flora in the human respiratory tract	n/a	n/a	n/a	Negative

Table 10. Reference pathogenic microorganisms and human nasal wash used in the wet testing. *NATtrol™ Respiratory Verification Panel 2 (NATRVP2-BIO) (ZeptoMetrix® Corporation) is a qualitative control. The manufacturer does not provide quantitative values for the organisms in the panel. ATCC: American Type Culture Collection.

No cross-reactivity of the VIASURE *SARS-CoV-2* Real Time PCR Detection Kit with genomic RNA/DNA of the selected pathogens and with nucleic acid extracted from pooled nasal wash was observed (Table 10). Extraction Control showed amplification in all the samples tested. The microorganism SARS Coronavirus, Parainfluenza virus 1, 2 and 4, *Mycoplasma pneumoniae*, and *Pneumocystis jirovecii*, were not available for wet testing.

In addition to microorganism wet testing, *in silico* analysis was performed to assess the specificity of the assay in relation to the microorganisms listed in Table 11. BLAST (http://blast.ncbi.nlm.nih.gov/Blast.cgi), and Primer-BLAST (http://www.ncbi.nlm.nih.gov/tools/primer-blast) analyses over each primer and/or probe against the sequences from NCBI Genbank Nucleotide Database (https://www.ncbi.nlm.nih. gov/genbank/) available as of May 7, 2020, was performed.

***In silico* Cross-reactivity testing**					
Adenovirus (e.g. C1 Ad. 71)	-	Human coronavirus HKU1	-	Parechovirus	-
Bacillus anthracis	-	Human Metapneumovirus	-	*Pneumocytis jirovecii*	-
Bordetella pertussis	-	Influenza A	-	*Pseudomonas aeruginosa*	-
Candida albicans	-	Influenza B	-	Respiratory Syncytial virus (RSV)	-
Chlamydophila pneumoniae	-	Influenza C	-	Rhinovirus	-
Chlamydia psittaci	-	*Legionella pneumophila*	-	SARS Coronavirus	(3)
Corynebacterium diphtheriae	-	*Legionella non-pneumophila*	-	Bat Coronavirus	(3)
Coxiella burnetii	-	*Leptospira*	(1)	Pangolin Coronavirus	(3)
Enterovirus (e.g. EV68)	-	MERS Coronavirus	-	*Staphylococcus aureus*	-
Haemophilus influenzae	-	*Moraxella catarrhalis*	-	*Staphylococcus epidermidis*	-
Human Bocavirus	-	*Mycoplasma pneumoniae*	-	*Streptococcus pneumoniae*	-
Human coronavirus 229E	-	*Mycobacterium tuberculosis*	-	*Streptococcus pyogenes*	-
Human coronavirus OC43	-	*Neisseria elongata*	-	*Streptococcus salivarius*	-
Human coronavirus NL63	-	*Neisseria meningitidis*	(2)	Parainfluenza 1, 2, 3 and 4 viruses	-

Table 11. Organisms assessed in *in silico* Cross-Reactivity analysis.

Excepting SARS Coronavirus and Bat and Pangolin Coronaviruses, all the analyzed organisms and sequences showed:

- ≤80% homology between one of the full-length primers/probes and any sequence present in the targeted microorganism,
- homologous regions split in several sequence fragments spanning along the organism sequence, making PCR product amplifications unlikely,
- no amplification product resulting in Primer-BLAST analysis or too lengthy (>800 nt) to hinder SARS-CoV-2 amplification and detection. Particularly, *Leptospira* (1) sequences CP021412.1 and CP000348.1 (GenBank ID) align with *N* gene forward primer with 5 mismatches and in resulting product length of 3326 nt and *Staphylococcus aureus* (2) sequence LS483317.1 (GenBank ID) aligns with *ORF1ab* gene reverse primer with 4 mismatches and in resulting product length of 828 nt.

Based on the *in silico* analysis, it is predicted that the assay may cross-react with SARS-CoV, SARS-like coronaviruses, and animal coronaviruses (Bat and Pangolin Coronaviruses) (3), however, the aligned sequences show several mismatches. Besides, these animal coronaviruses have either not been identified in humans before or are considered eradicated, dating the last SARS coronavirus official diagnosis back to 2004. Therefore, the homology of primers and probes sequences to these viruses should cause no interference in the SARS-CoV-2 detection.

13.4. Analytical reactivity

The analytical reactivity (Inclusivity) of VIASURE *SARS-CoV-2* Real Time PCR Detection Kit was evaluated against genomic RNA from SARS-Related Coronavirus 2, Isolate USA-WA1/2020 (BEI Resources), showing positive results.

In silico inclusivity analyses of the primers and probe sequences for the SARS-CoV-2 *ORF1ab* and *N* genes were performed against 1579 SARS-CoV-2 sequences available from GenBank as of May 8, 2020. BLAST analysis showed that *ORF1ab* and *N* gene primers and probes present 100% homology to 99.05% (1564/1579) to NCBI Genbank SARS-CoV-2 published sequences. The misalignments are usually due to incomplete genome sequences.

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15. Symbols for IVD components and reagents

IVD	*In vitro* diagnostic device	Σ	Contains <n> test	REF	Catalogue number		Keep dry		Manufacturer
	Consult instructions for use	LOT	Batch Code (NCO206L-xxx, NCO212L-xxx, NCO213L-xxx)		Use by (yyyy-mm: year and month)		Temperature limitation	EUA	For Use under Emergency Authorization Only
RxOnly	For prescription Use Only								

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