VitaPCR™

credo DIAGNOSTICS

VitaPCR™ SARS-CoV-2 Gen 2 Assay

For use with the VitaPCR™ Instrument

For nasopharyngeal (NP) or oropharyngeal (OP) swab specimens

For *in vitro* diagnostic use only

INTENDED USE

The VitaPCR™ SARS-CoV-2 Gen 2 Assay performed on the VitaPCR™ Instrument is a rapid molecular *in vitro* diagnostic test utilizing a real-time reverse transcription polymerase chain reaction (RT-PCR) amplification technology for the qualitative detection of Coronavirus Disease 2019 (COVID-19) viral RNA in nasopharyngeal (NP) or oropharyngeal (OP) swabs from patients with signs and symptoms of respiratory infection.

Results are for the presumptive identification of SARS-CoV-2. The definitive identification of SARS-CoV-2 infection requires additional testing and confirmation procedures in consultation with public health or other authorities for whom reporting is required. The diagnosis of SARS-CoV-2 infection must be made based on history, signs, symptoms, exposure likelihood, and other laboratory evidence in addition to the identification of the SARS-CoV-2.

Rapid molecular assays that identify the target virus from patients infected with SARS-CoV-2 can aid in effective control of the global outbreak. SARS-CoV-2 infection is not precluded by negative results. Results should not be used as the sole basis for diagnosis, treatment or other patient management decisions.

The VitaPCR™ SARS-CoV-2 Gen 2 Assay is intended for use by all Healthcare Professionals.

SUMMARY AND EXPLANATION

Coronavirus Disease 2019 (COVID-19) is an acute respiratory illness caused by infection with the SARS-CoV-2, which was initially reported to WHO in Wuhan, China on December 31, 2019. The SARS-CoV-2 is from the same family of viruses as Severe Acute Respiratory Syndrome (SARS), and is spread from person to person. Virus-laden droplets from an infected person can be transmitted through nose, eyes, or mouth of another.

Symptoms of SARS-CoV-2 infection vary, it can cause mild illnesses including a runny nose, sore throat, cough, and fever. In severe cases, it can lead to pneumonia, breathing difficulties or death.

The VitaPCR™ SARS-CoV-2 Gen 2 Assay performed on the VitaPCR™ Instrument is a rapid molecular *in vitro* diagnostic test utilizing a real-time reverse transcription polymerase chain reaction (RT-PCR) amplification technology for the qualitative detection of SARS-CoV-2. The product contains primers, fluorophore-labeled probes and control material used in real time RT-PCR for the *in vitro* qualitative detection of specific SARS-CoV-2 RNA in respiratory specimens.

PRINCIPLE OF THE TEST

The VitaPCR™ SARS-CoV-2 Gen 2 Assay performed on the VitaPCR™ Instrument is a rapid molecular in vitro diagnostic test utilizing a real-time reverse transcription polymerase chain reaction (RT-PCR) amplification technology. It is used for the qualitative detection and discrimination of SARS-CoV-2 viral RNAs in direct nasopharyngeal (NP) or oropharyngeal (OP) swabs from patients with signs and symptoms of respiratory infection who are suspected of COVID-19. The assay is designed for both detections of specific SARS-CoV-2 RNA and universal SARS-like RNA (including SARS-CoV-2, SARS-CoV, bat SARS-like coronavirus), and both detection targets are located on regions of the virus nucleocapsid (N) gene. The assay includes an artificially single strand RNA as internal control (IC) to monitor whole RT-PCR processes.

Detection of target sequences is achieved through real-time measuring cleaved fluorophore-labeled specific SARS-CoV-2 detection probe, universal SARS-like probe, and internal control RNA detection probe following sequence amplification by respectively specific primer pairs. Three fluorescent channels, including FAM™, VIC® and ROX™, are applied to detect specific SARS-CoV-2 RNA, universal SARS-like RNA and IC, respectively. The Reagent Tube is then loaded on the VitaPCR™ Instrument and the turnaround time for analysis of a sample is approximately 20 minutes.

REAGENTS AND MATERIALS

Materials Provided

VitaPCR™ SARS-CoV-2 Gen 2 Assay	
	Sample Collection Buffer: **ORANGE** skrukork inneholdende 4 ml av en lysisbuffer
	Reagensrør: Et lite rør inneholdende et pulver med reagenser. Røret ligger i en sølvfolie fordi det er lys-sensitivt.
	Reagenslokk: Den tynne delen skal ikke berøres og skal ned i reagensrøret.
Quick Reference Guide of VitaPCR™ SARS-CoV-2 Gen 2 Assay	

Materials Required but not Provided

	VitaPCR™ Instrument
	Rack
	Power Adaptor (INPUT: AC 100-240V, 2.0A Max, 50-60Hz. OUTPUT: DC 12V, 5A)
	**Nasopharyngeal Swab** or **Oropharyngeal Swab**: For optimal test performance, ONLY use swabs which meet the CE directive requirements for medical devices. To avoid interference, please do not use swabs with wooden shafts or calcium alginate swabs since the reaction inhibitor might be contained. We strongly recommend the use of flocked swabs or synthetic fiber swabs with plastic shafts.
User Manual of VitaPCR™ Instrument Quick Reference Guide of VitaPCR™ Instrument	

Materials not Provided but purchase separately

	**30 µL Transfer Pipette:** Single-use, disposable plastic component with air bulb head and a small glass capillary tip. It is used to transfer the sample extract from the Sample Collection Buffer to the Reagent Tube.
	**30 µL Fixed Volume Pipette & Filter Tip:** Fixed volume pipettes dispense the same quantity of liquid every time. It is used to transfer the sample extract from the Sample Collection Buffer to the Reagent Tube.

Materials available but purchase separately

External Control	
VitaPCR™ SARS-CoV-2 Gen 2 External Control Set	External Control is available, but not provided in this assay. Please contact your local distributor if needed.

PRECAUTIONS

1. For *in vitro* diagnostic use.
2. Avoid any skin contact with the Sample Collection Buffer. Wear gloves before running the test.
3. Only used with the VitaPCR™ instrument.
4. Treat all specimens as potentially infectious agents. Follow universal precautions when handling samples, this kit and its contents. Please refer to the guidelines for specimen handling.
5. Proper sample collection, storage and transport are essential for correct results. Please only use validated specimen types described in the Intended Use.
6. Patient swabs previously stored in VTM or UTM are not recommended since they will invalidate the test.
7. Do not open the Reagent Tubes foil before running test.
8. Do not use kit after its expiration date.
9. If any assay components are dropped, cracked, found to be damaged or opened when received, DO NOT USE and discard. Do not use scissors or sharp objects to open foil pouches as damage to test pieces can occur.
10. If the Sample Collection Buffer is spilled while opening, clean the work area as per the instructions provided in the device User Manual. Restart the test with a new Sample Collection Buffer if required or suspicious contamination exists.
11. Do not leave anything on the rack and your device after testing. According to the removal instructions described in the device User Manual, dispose items according to your country and local requirements. Follow state or local regulations for proper waste disposal.
12. All kit materials are single-use items. Do not apply on multiple samples.
13. The Reagent Tube contains a lot of viruses' segments after reaction. Please discard it and do not open the lid when the test is done.
14. Rarely, testing samples might contain inhibitors that fail the test. The failure rate is a case-by-case result.
15. The previous positive samples left around work area may cause false positive results. Handle samples under standard lab practices. Clean your device and surrounding surfaces following the User Manual.
16. Visibly bloody samples may interfere the performance of the test.
17. Do not touch the heads of the sample swabs. Contamination may occur and interfere the performance of the test.

QUALITY CONTROL

Internal Control (IC)

The assay contains an internal control that has been designed to control for sample inhibition and assay reagent function. The internal control should be positive in a negative sample and can be negative or positive in a positive sample.

External Positive and Negative Controls

- The positive control consists of an RNA transcript of the SARS-CoV-2 N gene segment which sequence is used for both universal primer/probe and specific primer/probe set target.
- Add 40 µL of the Positive Control into the Sample Collection Buffer of VitaPCR™ SARS-CoV-2 Gen 2 Assay and follow the Test Procedure immediately to perform the positive control test.
- Sample Collection Buffer (SCB) can be used as the negative control and follow the Test Procedure to perform the negative control test.
- The controls are used for quality control testing and for each time receiving new shipment of kits or training a new operator, with local, state and/or federal regulations, accrediting groups or laboratory's standard quality control procedures.
- If external QC testing fails, repeat the test again or contact your local distributor.

Quality Control					
Control Type	**Control Type External Control Name**	**Used to Monitor**	**specific SARS-CoV-2 RNA**	**universal SARS-like RNA**	**Internal Control**
Positive Control	SARS-CoV-2 N gene segment	Substantial reagent failure including detection primer and probe integrity	+	+	+
Negative Control	Sample Collection Buffer	Reagent and/or environmental contamination	-	-	+

STORAGE AND STABILITY

Store the reagent kit at 5-25°C. The VitaPCR™ SARS-CoV-2 Gen 2 Assay is stable before the expiration date marked on the outer packaging and containers. Ensure all test materials have reached to room temperature before use.

SPECIMEN COLLECTION AND HANDLING

Use freshly collected specimens for optimal test performance. Inadequate specimen collection or improper sample handling/storage/transport may yield wrong results.

For optimal test performance, ONLY use swabs which meet the CE directive requirements for medical devices. To avoid interference, please do not use swabs with wooden shafts or calcium alginate swabs since the reaction inhibitor might be contained. We strongly recommend the use of flocked swabs or synthetic fiber swabs with plastic shafts. Place nasopharyngeal or oropharyngeal swabs collected from patient immediately into Sample Collection Buffer.

Nasopharyngeal swab (NP swab)

Carefully insert the swab into the nostril and pass the swab directly backwards without tipping the swab head up or down. Using gentle rotation, insert the swab into the anterior nares parallel to the palate advancing the swab into the nasopharynx, leave in place for a few seconds, and then slowly rotate the swab as it is being withdrawn. To ensure proper collection, the swab should be passed a distance that is halfway of that from the nose to the tip of the ear. DO NOT USE FORCE while inserting the swab.

Oropharyngeal swab (OP swab, e.g. throat swab)

Swab both the posterior pharynx and tonsils, avoiding the tongue.

SPECIMEN TRANSPORT AND STORAGE

Collected specimens on swab should be tested as soon as possible. If immediate testing is not possible, refer to the following guidelines for transport and storage:

1. Specimen on swab stored at 2℃ to 8℃ up to 24 hours.
2. Specimen eluted in the Sample Collection Buffer (SCB) can be stored at:

- 2℃ to 25℃ up to 7 days (Ideally: 2℃ to 8℃ in the refrigerator).
- For long-term storage, specimens should be frozen at -80℃.

Patient swabs previously stored in VTM or UTM are not recommended since they will invalidate the test.

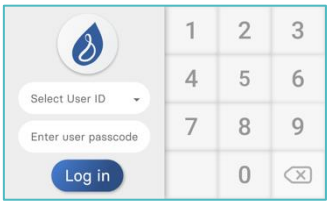
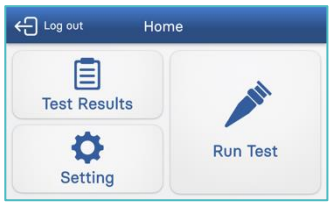
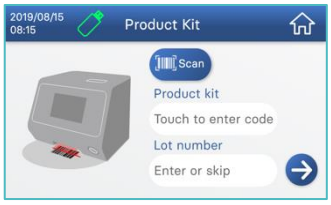
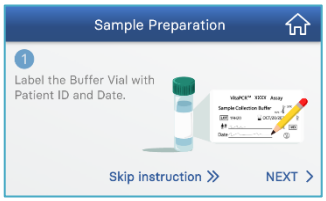
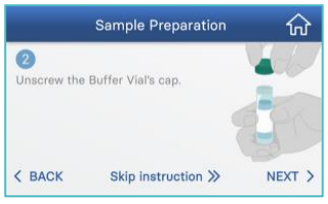
Note: Keep the specimen at temperature as indicated above. Do not freeze and thaw the specimen repeatedly.

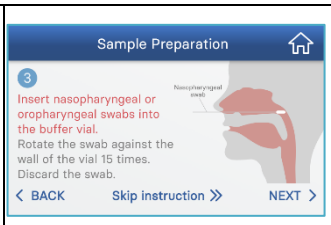
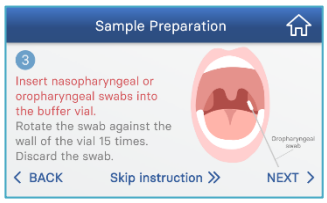
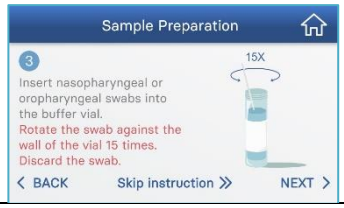
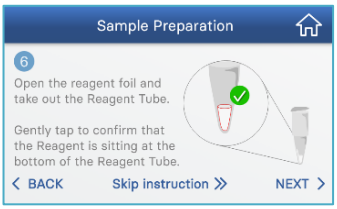
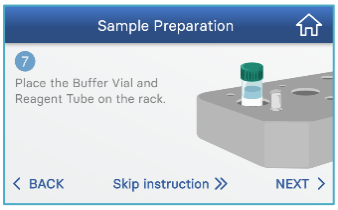
TEST PROCEDURE

Before testing with VitaPCR™ SARS-CoV-2 Gen 2 Assay:

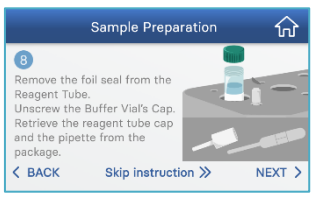
- Allow all samples to reach room temperature.
- Allow all test materials to reach room temperature.

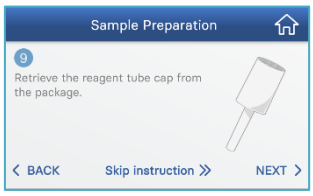
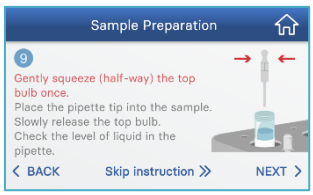
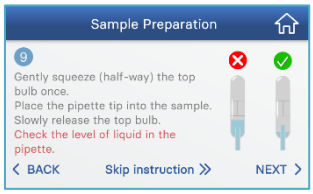
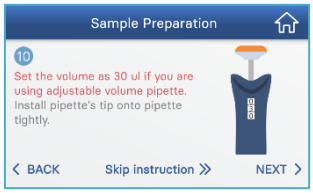
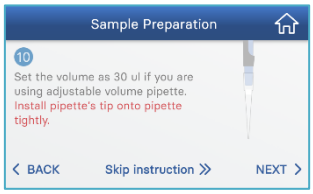
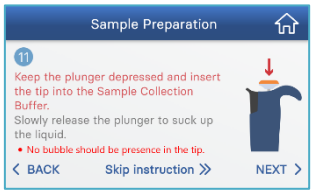
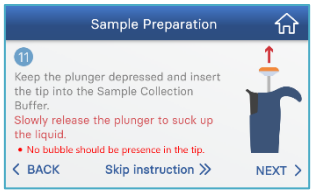
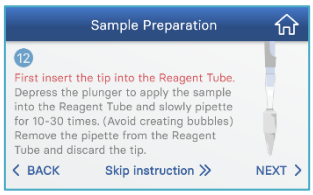
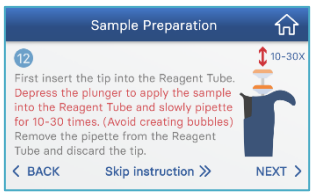
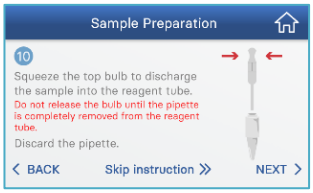
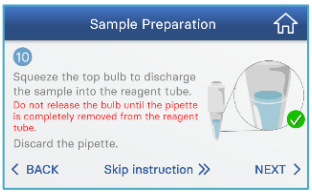
For best results, direct nasopharyngeal or oropharyngeal swabs should be tested immediately after collection.

Place VitaPCR™ instrument on a flat surface. Turn on VitaPCR™ Instrument by pressing the power button in the front of the instrument.	
Select User ID. Enter User Passcode. Press 'Log in'.	
Press 'Run Test'.	
Scan the barcode on the reagent package using the built-in barcode scanner on the lower front side of VitaPCR™ instrument.	
Scan or key in Patient ID. Confirm the Product Kit and Patient ID.	
1. Label the Buffer Vial with patient ID and date.	
2. Unscrew the Buffer Vial's cap.	

3. Insert nasopharyngeal or oropharyngeal swabs into the buffer vial. Rotate the swab against the wall of the vial **at least 15 times**. Discard the swab.	  
4. Screw the Buffer Vial's cap.	
5. Invert the Buffer Vial **10 times**. Place the Buffer Vial on the rack.	
6. Open the reagent foil and take out the Reagent Tube. Gently tap to confirm that the Reagent is sitting at the bottom of the Reagent Tube.	
7. Place the Buffer Vial and Reagent Tube on the rack.	

Chose the one you use.

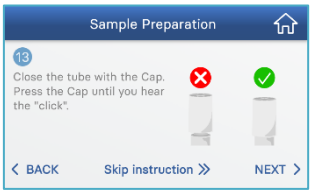
30 µL Fixed Volume Pipette & Filter Tip		**30 µL Transfer Pipette**	
8. Remove the foil seal from the Reagent Tube. Unscrew the Buffer Vial's Cap.		8. Remove the foil seal from the Reagent Tube. Unscrew the Buffer Vial's Cap. Retrieve the reagent tube cap and the pipette from the package. Please be careful NOT to touch the bottom of pipette tip.	

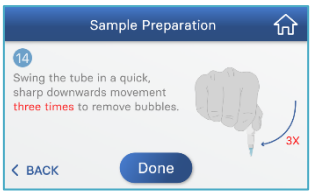
9. Retrieve the reagent tube cap from the package.		9. Gently squeeze (half-way) the top bulb once. Place the pipette tip into the sample. Slowly release the top bulb. Check the level of liquid in the pipette.	 
10. Set the volume as 30 µL if you are using adjustable volume pipette. Install pipette's tip onto pipette tightly.	 		
11. Keep the plunger depressed and insert the tip into the Sample Collection Buffer. Slowly release the plunger to suck up the liquid. ***No bubble should be presence in the tip.***	 		
12. First insert the tip into the Reagent Tube. Depress the plunger to apply the sample into the Reagent Tube and slowly pipette for 10-30 times. Remove the pipette from the Reagent Tube and discard the tip. ***Note: Avoid Creating Bubbles***	 	10. Squeeze the top bulb to discharge the sample into the reagent tube. Do not release the bulb until the pipette is completely removed from the reagent tube. Discard the pipette.	 

13. Close the tube with the Cap.

    Press the Cap until you hear the “click”.

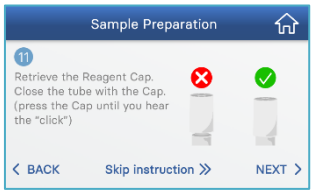
14. Swing the tube in a quick sharp downwards movement three times to remove bubbles.

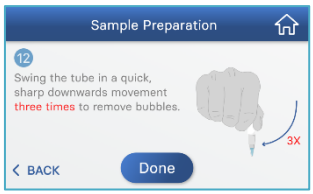




11. Retrieve the Reagent Cap. Close the tube with the Cap. (press the Cap until you hear the “click”)
12. Swing the tube in a quick, sharp downwards movement **three times** to remove bubbles.

Note: After transfer the Sample Collection Buffer into Reagent Tube, the test should be started immediately.

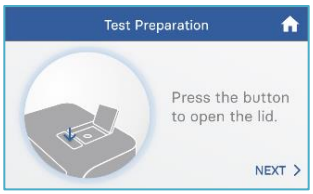


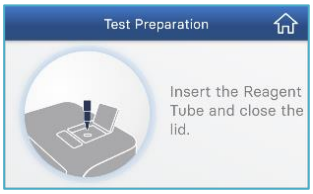


Press the button to open the lid.

Insert the Reagent Tube and close the lid.

Press ‘Run’ to start the reaction.





Verify the process percentage on VitaPCR™ screen is increasing. Progress bar turns blue while reaction is ongoing.

Note:

- ***The screen will continue to display percentage until 100% complete. The VitaPCR™ will beep at the end of test processing.***
- ***The lid will be locked during reaction. Do not try to re-open the VitaPCR™ lid until the display indicates the test is complete.***
- ***To abort the test, press ‘End Run’ and wait for the instruction on the screen.***
- ***Do not move or unplug the VitaPCR™ while the test is processing.***

Result Interpretation:

Note: Press the ‘New Test’ to start a new test.

INTERPRETATION OF RESULTS AND REPORTING

The table below lists the expected results for The VitaPCR™ SARS-CoV-2 Gen 2 Assay.

Detection of specific SARS-CoV-2 RNA	Detection of universal SARS-like RNA	Internal Control	Result	Interpretation
+	+	±	**Positive**	SARS-CoV-2 RNA Detected. (Both specific SARS-CoV-2 RNA and universal SARS-like RNA are detected.)
+	-	±		SARS-CoV-2 RNA Detected. (The universal SARS-like RNA not detected might be caused by low viral load in the specimen or the accumulation of mutation over time.)
-	+	±	**Presumptive Positive**	Presumptive Positive for SARS-CoV-2 RNA. (The specific SARS-CoV-2 RNA not detected might be caused by low viral load in the specimen or the accumulation of mutation over time.) Sample should be retested. For samples with a repeated Presumptive Positive result, additional confirmatory testing may be conducted, if it is necessary to differentiate between SARS-CoV-2 and SARS-CoV-1 or other SARS-like coronaviruses currently unknown to infect humans, for epidemiological purposes or clinical management.
-	-	+	**Negative**	SARS-CoV-2 RNA Not Detected.
-	-	-	**Invalid**	RT-PCR inhibition or reagent failure. Collect a new sample and Repeat testing.

NOTE:
Due to the molecular evolution of SARS-CoV-2, there is an inherent risk for any PCR based test system that accumulation of mutations over time may lead to false negative results.

DEVICE CLEANING

We recommend cleaning the VitaPCR™ Instrument each day after use.

Procedure:

1. Unplug the power cord from the wall outlet and VitaPCR™.
2. Close the lid.
3. Using 70% ethanol or a germicidal disposable wipe, gently wipe the outer surfaces of VitaPCR™, removing any dust.

NOTE: Do not press the wipe against the open vents of VitaPCR™ Instrument.

4. Using a new cloth, wipe the front of VitaPCR™ twice top to bottom, then twice left to right. Follow this step for the back, top and bottom of VitaPCR™.
5. Do not let liquid gather around any opening. Make sure no liquid enters your device.
6. Allow the unit to dry for at least 10 minutes and check it's all dry before re-connecting the power cord for the AC Adapter.

LIMITATIONS

- The performance of the VitaPCR™ SARS-CoV-2 Gen 2 Assay is determined by the procedures described in this document. Failure to follow the instruction may alter test performance.
- The VitaPCR™ SARS-CoV-2 Gen 2 Assay is for use with nasopharyngeal or oropharyngeal swab specimens.
- Improper collection, storage or transport of specimens may lead to false negative results.
- Test results should also be considered with the patient's medical history, clinical signs and symptoms, and the results of other diagnostic tests.
- As with other tests, negative results do not preclude SARS-CoV-2 infections and should not be used as the sole basis for patient management decisions.
- False negative results may occur if the levels of viruses are lower than the detection limit.
- False negative results may occur if there are mutations in the regions targeted by the test.
- The presence of inhibitors in the sample can lead to invalid results.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity (Limit of Detection)

LoD studies determine the lowest detectable concentration at which ≥ 95% (19/20) of the replicates were positive. The recombinant virus containing SARS-CoV-2 RNA (Seracare, AccuPlex SARS-CoV-2, Material Number 0505-0129) was serially diluted in simulated clinical matrix for the LoD determination study. AccuPlex SARS-CoV-2 was spiked into the Sample Collection Buffer (SCB) consisting of negative clinical matrix to mimic clinical specimen. Negative clinical matrix is created from the NP or OP specimens collected from patient individuals, stored at -20℃ in a clean, dry, tightly sealed plastic tube for up to 24 hours before testing. Samples perform standard operation procedure with the VitaPCR™ SARS-CoV-2 Gen 2 Assay according to the instructions for use.

This data demonstrates that the VitaPCR™ SARS-CoV-2 Gen 2 Assay detects 1.0 copies/µl of SARS-CoV-2 recombinant virus with a confidence ≥95%. This concentration therefore serves as the limit of detection.

Analytical Sensitivity (Limit of Detection) of detection of specific SARS-CoV-2 region			
RNA Concentration (copies/µl)	**% Replicate Detection**	**Mean Ct**	**Standard Deviation (Ct)**
1.0	100 (20/20)	37.00	1.45
0.5	90 (18/20)	37.94	0.94

Analytical Sensitivity (Limit of Detection) of detection of universal SARS-like region			
RNA Concentration (copies/µl)	**% Replicate Detection**	**Mean Ct**	**Standard Deviation (Ct)**
1.0	100 (20/20)	37.95	1.10
0.5	85 (17/20)	39.47	0.94

In Silico Analysis of Specificity (Cross-Reactivity)

BLASTn analysis was performed with the primer and probe of the VitaPCR™ SARS-CoV-2 Gen 2 Assay against all publicly available nucleic acid sequences in GenBank as of March 06, 2020 . The nucleotide collection consists of GenBank, EMBL, DDBJ, PDB, and RefSeq sequences, but excludes EST, STS, GSS, WGS, TSA, patent sequences as well as phase 0, 1, and 2 HTGS sequences and sequences longer than 100Mb.The search parameters automatically adjust for short sequences and the expect threshold is 1000. The match and mismatch scores are 1 and -3 respectively. The penalty for creating and extending a gap is 5 and 2 respectively.

specific SARS-CoV-2 primer/probe
The forward and reverse primer sequences of specific SARS-CoV-2 RNA showed high sequence homology to Bat coronaviruses. However, the probe sequence showed no sequence homology with SARS coronavirus, bat SARS-like coronavirus and other coronavirus genome (except for bat coronavirus RaTG13), or human genome. Combining primers and probe, there is no prediction of potential false positive RT-PCR results.

universal SARS-like primer/probe
Analysis of the forward and reverse primer and probe sequences of universal SARS-like RNA showed significant homology only to human SARS coronavirus and bat SARS-like coronavirus. Combining primers and probe, there is no significant homologies with human genome, or other coronavirus (except for bat coronavirus RaTG13) that would predict potential false positive RT-PCR results.

In summary, no potential unintended cross reactivity is expected for both targets.

Analytical Specificity (Cross-Reactivity)

Cross reactivity performance of VitaPCR™ SARS-CoV-2 Gen 2 Assay was evaluated by testing the whole organisms or appropriate representative samples listed below. These organisms were tested in three replicates in this study. High level of these organism (i.e., 10^6 CFU/ml for bacteria and 10^5 $TCID_{50}$/ml for viruses) was added into the Sample Collection Buffer with clinical matrix, and then was tested with VitaPCR™ SARS-CoV-2 Gen 2 Assay under the same operating procedure to see if there was any identified false-positive reaction.

No cross reactivity of VitaPCR™ SARS-CoV-2 Gen 2 Assay with the selected organisms was observed at the concentrations tested. By design, SARS coronavirus should be detected by universal SARS-like primer/probe (the results have been illustrated as "Presumptive Positive").

Organisms	Concentration	Detection of specific SARS-CoV-2 RNA	Detection of universal SARS-like RNA
		Result (x/3)	Result (x/3)
Human coronavirus 229E	$1.00x10^7$ $TCID_{50}$/ml	0/3	0/3
Human Adenovirus type 1	$5.62x10^8$ $TCID_{50}$/ml	0/3	0/3
Influenza A/California/7/2009 (H1N1)	$3.16x10^6$ $TCID_{50}$/ml	0/3	0/3
Influenza A/Wisconsin/67/2005 (H3N2)	$3.16x10^7$ $TCID_{50}$/ml	0/3	0/3
Influenza B/Malaysia/2506/2004 (B/Victoria)	$3.16x10^5$ $TCID_{50}$/ml	0/3	0/3
Respiratory syncytial virus (long A)	$1.17x10^5$ $TCID_{50}$/ml	0/3	0/3

Endogenous Interference Substances Study

To demonstrate that designated function of VitaPCR™ SARS-CoV-2 Gen 2 Assay will be operational while the specimen is tested in the presence of common endogenous substances. We tested the interfering substance individually, and spiked 3x LoD positive samples with interfering substance respectively, to reveal if there will be unexpected results. Each test performed three replicates.

Interfering Substances: Table below for evaluation of interfering substances for the ability to generate false *positive* results:

Potential Interfering Substance	Concentration	Results (Detected x/3)
Mucin	0.05%	0/3
Blood	0.1%	0/3

Interfering Substances: Table below for evaluation of interfering substances for the ability to generate false *negative* results:

Potential Interfering Substance	Concentration	Spike 3xLoD SARS-CoV-2 Results(Detected x/3)
Mucin	0.05%	3/3
Blood	0.1%	3/3

Clinical Performance

Due to the difficulty of obtaining clinical specimens from SARS-CoV-2 infected patients, performance characteristics of the VitaPCR™ SARS-CoV-2 Gen 2 Assay were evaluated using contrived clinical specimens. The recombinant virus containing SARS-CoV-2 RNA (Seracare, AccuPlex SARS-CoV-2, Material Number 0505-0129) was used in this testing. This recombinant virus containing SARS-CoV-2 RNA with known titer was prepared for spiking 30 individual negative NP or OP swab specimens at different concentrations. They were blinded, randomized and spiked into Sample Collection Buffer in which individual negative NP or OP swab specimens were washed. 20 NP or OP swab specimens were spiked at 1.5x LoD, 5 at 3x LoD, and 5 at 5x LoD. Another 30 individual negative NP or OP swab specimens were left un-spiked. In brief, we spiked either NP or OP swab specimens into contrived samples with various concentrations, then proceeded the assay in this section.

All 60 samples were blinded, handed to unbiased operators to analyzed with the VitaPCR™ SARS-CoV-2 Gen 2 Assay to generate the Positive Percentage Agreement (PPA), Negative Percentage Agreement (NPA), and Overall Percentage Agreement (OPA) as a measurement of estimated Diagnostic Accuracy.

Nasopharyngeal (NP) Specimens		**Contrived clinical specimen (Expected result)**	
Variable	**Status**	**Positive**	**Negative**
VitaPCR™ SARS-CoV-2 Gen 2 Assay	Positive	30	0
	Negative	0	30
Positive Percentage Agreement (PPA) (95% CI)[1]		100% (88.4 - 100)	
Negative Percentage Agreement (NPA) (95% CI)[2]		100% (88.4 - 100)	
Overall Percentage Agreement (OPA) (95% CI)[3]		100% (94.0 - 100)	

Note:
1 Positive Percentage Agreement = [True positives / (True positives + False negatives)] *100%
2 Negative Percentage Agreement = [True negatives / (True negatives + False positives)] *100%
3 Overall Percentage Agreement = [(True positives + True negatives) / (True positives + False negatives + True negatives + False positives)] *100%

Oropharyngeal (OP) Specimens		**Contrived clinical specimen (Expected result)**	
Variable	**Status**	**Positive**	**Negative**
VitaPCR™ SARS-CoV-2 Gen 2 Assay	Positive	30	0
	Negative	0	30
Positive Percentage Agreement (PPA) (95% CI)[1]		100% (88.4 - 100)	
Negative Percentage Agreement (NPA) (95% CI)[2]		100% (88.4 - 100)	
Overall Percentage Agreement (OPA) (95% CI)[3]		100% (94.0 - 100)	

Note:
1 Positive Percentage Agreement = [True positives / (True positives + False negatives)] *100%
2 Negative Percentage Agreement = [True negatives / (True negatives + False positives)] *100%
3 Overall Percentage Agreement = [(True positives + True negatives) / (True positives + False negatives + True negatives + False positives)] *100%

CONTACT INFORMATION, ORDERING, AND PRODUCT SUPPORT

For technical and product support, contact email：service@credodxbiomed.com

SYMBOLS

	Do Not Re-Use		Manufacturer
	Consult Instructions for Use		Positive Control
	Caution		Negative Control
	Temperature Limit		Catalogue Number
	Use-By Date		Contains sufficient for <n> tests
	Batch Code		Patient Number
	*In vitro* diagnostic medical device		Keep away from sunlight
	Do not use if package is damaged		Keep Dry
	CE mark		Authorized Representative in the European Community
	WEEE - Electronic equipment marked with this symbol are subject to European Union Directive 2012/19/EU (WEEE), and cannot be disposed of in the municipal waste system		

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