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COVID-19 TaqMan RT-PCR Kit (N/ORF1ab genes) Dx — Product Insert

REF DxTM67300 CE IVD PIDxTM67300-5

Intended Use

The COVID-19 TaqMan RT-PCR Kit (N/ORF1ab genes) Dx is a real-time RT-PCR test intended for the qualitative detection of RNA from SARS-CoV-2 using a multiplexed TaqMan® fluorescence detection assay (FAM, HEX/VIC and Cy5) in nasopharyngeal swabs, oropharyngeal swabs and saliva samples from individuals suspected of COVID-19 by their healthcare provider or for screening of individuals without symptoms or other reasons to suspect COVID19 infection.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in upper respiratory tract 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. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Any negative results must be combined with clinical observations, patient history, and epidemiological information.

Norgen's COVID-19 TaqMan RT-PCR Kit (N/ORF1ab genes) Dx is intended for use by professional users including clinical laboratory personnel experienced and trained in molecular biology techniques including real-time PCR and in vitro diagnostic procedures.

For *In Vitro* Diagnostic Use

Product Description

Norgen's COVID-19 TaqMan RT-PCR Kit (N/ORF1ab genes) Dx includes 2X One-Step RT-PCR Master Mix, a primer/probe mix, a positive control and a negative control (nuclease-free water). The primer/probe mix contains two SARS-CoV-2 detection targets - N (Nucleoprotein) and ORF1ab (Open reading frame1ab), and the human RNase P transcript (RP - HEX/VIC) as an internal control target to monitor for PCR inhibition, and to validate the quality of the sample and the detection result. The provided N/ORF1ab/RP Positive Control contains an in vitro RNA transcript for the two SARS-related target genes: N gene, ORF1ab gene as well as the human RP gene (internal control).

Norgen's COVID-19 TaqMan RT-PCR Kit (N/ORF1ab genes) Dx was developed and validated to be used with the BioRad CFX96 Touch™ Real-Time PCR Detection System.

Kit Components

Component	Product # DxTM67300 (500 reactions)
N/ORF1ab/RP Primer & Probe Mix Dx	850 µL
N/ORF1ab/RP Positive Control Dx †	500 µL
2X One-Step RT-PCR Master Mix Dx	7 x 1 mL
Nuclease-Free Water (Negative control)	2 x 1.25 mL
Product Insert	1

† Contains an *in vitro* RNA transcript for the three SARS-related target genes.

Storage Conditions and Product Stability

- The COVID-19 TaqMan RT-PCR Kit (N/ORF1ab genes) Dx is shipped on dry ice. The components of the kit should be frozen upon arrival. If one or more of the components is not frozen when the kit is received, or if any of the components have been compromised during shipment, do not use the kit and contact Norgen Biotek for assistance.
- All kit components should be stored at -20°C upon arrival.
- Repeated thawing and freezing (> 3 x) of the Master Mix and Positive Control should be avoided, as this may affect the performance of the assay. If the reagents are to be used only intermittently, they should be frozen in aliquots.
- All reagents can be used until the expiration date specified on their labels.

Customer-Supplied Reagents and Equipment

- Appropriate Real-Time PCR Instrument with FAM, HEX/VIC and Cy5 filter channel
- RNA Purification Kit
    - Performance of Norgen's COVID-19 TaqMan RT-PCR Kit (N/ORF1ab genes) Dx was evaluated using Norgen's Saliva/Swab RNA Purification Kit Dx (Cat# Dx69100)
    - While the kit should be compatible with all RNA purification kits that yield high quality, inhibitor-free RNA, it is up to users to validate the use of alternate RNA purification kits
- Disposable powder-free gloves
- Benchtop microcentrifuge
- Micropipettors
- Sterile pipette tips with filters
- PCR tubes
- Vortex mixer
- PCR reaction preparation station

Quality Control

In accordance with Norgen's ISO 9001 and ISO 13485-certified Quality Management System, each lot of Norgen's COVID-19 TaqMan RT-PCR Kit (N/ORF1ab genes) Dx is tested against predetermined specifications to ensure consistent product quality.

Warnings and Precautions

- Norgen's COVID-19 TaqMan RT-PCR Kit (N/ORF1ab genes) Dx is intended for use by professional users including clinical laboratory personnel experienced and trained in molecular biology techniques including real-time PCR and *in vitro* diagnostic procedures.
- Follow universal precautions. All patient specimens should be considered as potentially infectious and handled accordingly.
- Ensure that a suitable lab coat, disposable gloves and protective goggles are worn when handling specimens and kit reagents.
- Use sterile pipette tips with filters. Use proper pipetting techniques and maintain the same pipetting pattern throughout the procedure to ensure optimal and reproducible values.
- As contamination of patient specimens or reagents can produce erroneous results, it is essential to use aseptic techniques. Pipette and handle reagents carefully to avoid mixing of the samples.
- Do not use supplies and equipment across the dedicated areas of i) specimen extraction, ii) reaction set-up and iii) amplification/detection. No cross-movement should be allowed between the different areas. Personal protective equipment, such as laboratory coats and disposable gloves, should be area specific.
- Store and extract positive material (specimens, controls and amplicons) separately from all other reagents and add it to the reaction mix in a spatially separated facility.
- Dispose of unused kit reagents and human specimens according to local, provincial or federal regulations.

- Do not substitute or mix reagents from different kit lots or from other manufacturers. Do not use components of the kit that have passed their expiration date.
- As with any diagnostic test, results generated using Norgen's COVID-19 TaqMan RT-PCR Kit (N/ORF1ab genes) Dx should be interpreted with regard to other clinical or laboratory findings.
- The presence of PCR inhibitors may cause false negative or invalid results.
- Potential mutations within the target regions of the SARS-CoV-2 genome covered by the primers in this kit may result in failure to detect the presence of the pathogen.
- Good laboratory practice is essential for the proper performance of this kit. Ensure that the purity of the kit and reactions is maintained at all times, and closely monitor all reagents for contamination. Do not use any reagents that appear to be contaminated.
- Ensure that appropriate specimen collection, transport, storage and processing techniques are followed for optimal performance of this test.

Assay Limitations

- Norgen's COVID-19 TaqMan RT-PCR Kit (N/ORF1ab genes) Dx performance was established using nasopharyngeal swabs, oropharyngeal swabs and saliva samples. Swab samples were collected using nylon flocked synthetic swabs and were placed into Norgen's Total Nucleic Acid Preservative Tubes Dx (Cat# Dx69200) for storage until RNA isolation. Saliva samples were collected into Norgen's Saliva RNA Collection and Preservation Devices Dx (Cat# 53800) and preserved at room temperature until RNA isolation. **Other specimen types (including sputum) and other preservatives have not been validated with this kit.**
- Norgen's COVID-19 TaqMan RT-PCR Kit (N/ORF1ab genes) Dx performance was established using RNA that was purified with Norgen's Saliva/Swab RNA Purification Dx (Cat# Dx69100). Other RNA extraction methods have not been validated with this kit.
- The following exogenous substances were tested and determined not to interfere with the performance of the kit: nasopharyngeal swabs – blood and mucin; oropharyngeal swabs and saliva – blood, mucin sputum
- The impact of antipyretic analgesics, antitussives, expectorants, antibiotics, antivirals and corticosteroids have not been evaluated.
- **The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.**
- Based on cross-reactivity studies, a positive result from the COVID-19 TaqMan RT-PCR Kit (N/ORF1ab genes) Dx may be indicative of infection with bat coronavirus RaTG13 rather than infection with SARS-CoV-2. However due to the fact that bat coronavirus RaTG13 only infects chiropteran (bat) species, it is very unlikely that a positive result in a human would indicate RaTG13 infection; positive results with the COVID-19 TaqMan RT-PCR Kit (N/ORF1ab genes) Dx are most likely indicative of SARS-CoV-2 infection.
- Do not eat 30 minutes prior to saliva collection.

Instructions for Use

A. Sample Stability and Handling Information

Nasopharyngeal swabs and oropharyngeal swabs should be collected into Norgen's Total Nucleic Acid Preservation Tubes Dx (Cat# Dx69200). Saliva samples should be collected into Norgen's Saliva RNA Preservation Devices Dx (Cat# 53800). The RNA (including viral RNA) in the preserved samples is stable for up to 2 months at ambient temperature without any detectable RNA degradation.

For information on how to safely collect samples please refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19); https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html.

B. Sample Preparation

Testing for COVID-19 should be conducted in consultation with a healthcare provider, and only patients demonstrating symptomatic disease should undergo testing.

Purified RNA is the starting material for Norgen's COVID-19 TaqMan RT-PCR Kit (N/ORF1ab genes) Dx. The quality of the RNA template will have a major impact on the performance of the diagnostic test. The user must ensure that the method used for RNA purification is compatible with PCR technology. We recommend the use of Norgen's Dx series of purification kits for RNA isolation, including **Norgen's Saliva/Swab RNA Purification Dx (Cat# Dx69100).**

If using a different spin column-based sample preparation procedure that includes ethanol-based wash buffers, a column drying step consisting of centrifugation for 3 minutes at 20,000 x g (~14,000 RPM), using a new collection tube, is highly recommended prior to the elution of the RNA. This will help to prevent the carry-over of any ethanol into the purified RNA, as ethanol is known to be a strong inhibitor of PCR. **Ensure that any traces of ethanol from the sample preparation steps are eliminated prior to the elution of the RNA.**

C. TaqMan RT-PCR Assay Preparation

Notes:

- Before use, suitable amounts of all TaqMan RT-PCR components should be completely thawed at room temperature, mixed by gentle vortexing or by pipetting, and centrifuged briefly.
- Work quickly on ice.
- The amount of 2X One-Step RT-PCR Master Mix Dx provided is enough for up to 500 RT-PCR reactions per each target.
- For every TaqMan One-Step RT-PCR run, one reaction containing N/ORF1ab/RP Positive Control Dx and one reaction as a no template control (NTC) must be included for proper interpretation of results. A minimum number of 10 samples are recommended to be tested per run per assay. Table 1 and Table 2 below show an example for the samples and the controls set-up for each assay.

Table 1. Samples and Controls Set-up for One-step RT-PCR Assay

Assay	1	2	3	4	5	6	7	8	9	10	11	12
N/ORF1ab genes/RP	NTC	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	Positive Control

- To avoid any contamination while preparing the TaqMan One-step RT-PCR assay, follow the order outlined in Tables 2, 3 and 4 below to prepare the NTC, Detection Assays and N/ORF1ab/RP Positive control:
  1. Prepare the RT-PCR NTC (Table 2)
  2. Prepare the RT-PCR N/ORF1ab/RP Assay (Table 3)
  3. Prepare the RT-PCR N/ORF1ab/RP Positive Control (Table 4)
- To further avoid contamination, add the components to the PCR tubes in the order shown in the tables below (i.e.: 1) Nuclease-free water; 2) Primer & Probe Mix; 3) Mastermix; and 4) the Sample RNA or Positive Control).

For each TaqMan One-step RT-PCR set, prepare no template control PCR reactions as shown in Table 2 below:

Table 2. TaqMan One-Step RT-PCR NTC Preparation

Reagent	Volume of Reagent Added per Reaction
Nuclease-Free Water	8.5 µL
2X One-Step RT-PCR Master Mix Dx	10 µL
N/ORF1ab/RP Primer & Probe Mix Dx	1.5 µL
Total Volume	20 µL

2. Prepare the RT-PCR reactions for sample detection as shown in Table 3 below.

Table 3. TaqMan One-Step RT-PCR Target Assays Preparation

Reagent	Vol. of Reagent Added per Reaction
Nuclease-Free Water	3.5 µL
2X One-Step RT-PCR Master Mix Dx	10 µL
N/ORF1ab/RP Primer & Probe Mix Dx	1.5 µL
Sample RNA+	5 µL
Total Volume	20 µL

+ The recommended amount of sample RNA to be used is 5 µL. However, 1 µL - 5 µL of sample RNA may be used as template. Adjust the final volume of the RT-PCR reaction to 20 µL using the Nuclease-Free Water provided in case the volume of the sample RNA used is different from the volume shown in Table 4.

3. For each RT-PCR set, prepare positive control RT-PCR as shown in Table 4 below:

Table 4. TaqMan One-Step RT-PCR N/ORF1ab/RP Positive Control Preparation

Reagent	Vol. of Reagent Added per Reaction
Nuclease-Free Water	3.5 µL
2X One-Step RT-PCR Master Mix Dx	10 µL
N/ORF1ab/RP Primer & Probe Mix Dx	1.5 µL
N/ORF1ab/RP Positive Control Dx+	5 µL
Total Volume	20 µL

+ The positive control contains the SARS-CoV-2 N gene, ORF1ab gene and RNase P RNA fragments.

D. COVID-19 TaqMan One-Step RT-PCR Assay Programming

1. Program the thermocycler according to the program shown in Table 6 below.
2. Run one step RT-PCR.

Table 5. COVID-19 TaqMan One-Step RT-PCR Program

One Step RT-PCR Cycle	Step	Temperature	Duration
Cycle 1	Step 1	50°C	20 min
Cycle 2	Step 1	95°C	3 min
Cycle 3 (45x)	Step 1	95°C	15 sec
	Step 2	58°C	30 sec

E. COVID-19 TaqMan One-Step RT-PCR Assay Interpretation

- The Negative Control (NTC – No Template Control) reaction(s) must be negative and not exhibit fluorescence growth curves that cross the threshold line. If there is any amplification with the NTC the run is not valid and no interpretation of SARS-CoV-2 detection can be made. The assay must be repeated.
- The N/ORF1ab/RP Positive Control reaction(s) should produce a positive result with an expected Ct value (< 40.00 Ct) for each target. If the positive control does not provide a positive result the run is not valid and no interpretation of SARS-CoV-2 detection can be made. The assay must be repeated.
- If the NTC and N/ORF1ab/RP Positive Control are exhibiting the correct results, the results of the detection assays can be interpreted as outlined in Tables 6 below.

Table 6. Interpretation of Assay Results

N (FAM)	ORF1ab (Cy5)	RP (HEX)	Result
+	+	+	**Positive**
+	+	-	**Positive**
-	-	+	**Negative**
+	-	+	**Inconclusive Result**
-	+	+	**Inconclusive Result**
-	-	-	**Invalid Result**

- Should a user receive inconclusive results, no diagnostic determination can be made. The user must repeat the test.
- Use of the device in a general, asymptomatic screening population is intended to be used as part of an infection control plan, that may include additional preventative measures, such as a predefined serial testing plan or directed testing of high-risk individuals

F. Performance Evaluation

1. Analytical Sensitivity

A. Initial Study

The analytical sensitivity of the COVID-19 TaqMan RT-PCR Kit (N/ORF1ab genes) Dx was determined by analyzing a dilution series of quantified SARS-CoV-2 RNA heat inactivated viral particles. Contrived nasopharyngeal swabs, oropharyngeal swabs and saliva samples were generated by spiking 5 µL of different concentrations of the viral particles to generate input

samples of variable transcript content. Triplicate samples were tested for each concentration for all 3 samples.

The limit of detection of Norgen's COVID-19 TaqMan RT-PCR Kit (N/ORF1ab genes) from RNA isolated from nasopharyngeal swabs, oropharyngeal swabs and saliva samples is 10 copies per PCR reaction as can be seen in Tables 10, 11 and 12 below.

Table 7. Analytical Sensitivity for Nasopharyngeal Swabs

Copies/PCR reaction	N gene		RP gene		ORF1ab Gene	
	Average Ct Value	SDEV	Average Ct Value	SDEV	Average Ct Value	SDEV
No Spike-in Control	N/A	N/A	27.22	0.12	N/A	N/A
1	41.26	0.93	27.09	0.03	42.28	N/A
5	33.43	0.03	27.08	0.05	35.81	3.10
10	31.78	0.15	27.17	0.10	32.13	0.26
100	28.31	0.25	27.16	0.07	28.56	0.22
1000	24.72	0.14	26.64	0.35	24.78	0.09

Table 8. Analytical Sensitivity for Oropharyngeal Swabs

Copies/PCR reaction	N gene		RP gene		ORF1ab Gene	
	Average Ct Value	SDEV	Average Ct Value	SDEV	Average Ct Value	SDEV
No Spike-in Control	N/A	N/A	26.67	0.22	N/A	N/A
1	38.01	3.93	27.00	0.15	42.34	N/A
5	32.07	0.25	26.79	0.23	32.15	0.63
10	30.85	0.18	26.75	0.10	31.17	0.18
100	28.46	0.68	27.06	0.42	28.16	0.63
1000	24.33	0.11	26.54	0.06	24.12	0.14

Table 9. Analytical Sensitivity for Saliva Samples

Copies/PCR reaction	N gene		RP gene		ORF1ab Gene	
	Average Ct Value	SDEV	Average Ct Value	SDEV	Average Ct Value	SDEV
No Spike-in Control	N/A	N/A	22.68	0.23	N/A	N/A
1	42.05	0.39	22.78	0.32	44.96	N/A
5	34.87	0.52	23.04	0.19	42.54	3.83
10	33.32	0.22	22.84	0.15	33.57	0.40
100	29.21	0.18	22.93	0.11	29.93	0.30
1000	26.67	0.45	23.07	0.16	26.51	0.48

B. Confirmatory Study

The limit of detection of the COVID-19 TaqMan RT-PCR Kit (N/ORF1ab genes) Dx was confirmed using 20 contrived samples of each sample type. Contrived nasopharyngeal swabs, oropharyngeal swabs and saliva samples were generated by spiking heat inactivated SARS-CoV-2 viral particles to 10 copies per PCR reaction. Confirmatory results were acceptable at a 95% confidence interval. This can be achieved when obtaining a minimum of 19 positive samples out of the 20 samples spiked at the limit of detection. As seen in Tables 10, 11 and 12 the limit of detection of Norgen's COVID-19 TaqMan RT-PCR Kit (N/ORF1ab genes) Dx from RNA isolated from nasopharyngeal swabs, oropharyngeal swabs and saliva samples was confirmed to be 10 copies per PCR reaction at a 95% confidence interval.

Table 10. Analytical Sensitivity Confirmation for Oropharyngeal Swabs

Concentration	N gene		ORF1ab		RP Gene	
	Detection Rate	Avg Ct Value	Detection Rage	Avg Ct Value	Detection Rate	Avg Ct Value
1 x LoD	100% (20/20)	32.36	100% (20/20)	32.44	100% (20/20)	27.14

Table 11. Analytical Sensitivity Confirmation for Nasopharyngeal Swabs

Concentration	N gene		ORF1ab		RP Gene	
	Detection Rate	Avg Ct Value	Detection Rage	Avg Ct Value	Detection Rate	Avg Ct Value
1 x LoD	100% (20/20)	32.37	100% (20/20)	32.53	100% (20/20)	25.37

Table 12. Analytical Sensitivity Confirmation for Saliva Samples

Concentration	N gene		ORF1ab		RP Gene	
	Detection Rate	Avg Ct Value	Detection Rage	Avg Ct Value	Detection Rate	Avg Ct Value
1 x LoD	100% (20/20)	31.41	100% (20/20)	32.63	100% (20/20)	21.97

2. Inclusivity / Analytical Specificity

Inclusivity:
BLASTN analysis query alignments were performed with the SARS-CoV-2 N gene and ORF1ab oligonucleotide primer and probe sequences with all publicly available nucleic acid sequences for 2019-nCoV in GenBank to demonstrate the predicted inclusivity of Norgen's COVID-19 TaqMan RT-PCR Kit (N/ORF1ab genes) Dx. All the alignments show 95% identity to the available 2019-nCoV sequences. The alignments for N/ORF1ab show 100% identity to the available 2019-nCoV sequence.

Analytical Specificity (Cross-reactivity):
Cross-reactivity of Norgen's COVID-19 TaqMan RT-PCR Kit (N/ORF1ab genes) Dx was evaluated using both in silico analysis and wet testing against normal and pathogenic organisms

found in the respiratory tract. BLASTN analysis queries of Norgen's COVID-19 TaqMan RT-PCR Kit (N/ORF1ab genes) Dx primers and probes were performed against the database of pathogens in the same genetic family and against organisms that are likely to be in the circulating area, including human sequences. The list of organisms included in the cross-reactivity matching analysis is shown in Table 16 below. Matching was performed using "Complete Genome" sequences in GenBank, using the BLASTN algorithm, with default parameters being changed to Max Target Sequence of 20000, expected threshold of 1000, word size 15, filtering "Low Complexity Regions" and "Mask for Lookup Table" turned on and automatic adjusting of parameters for short input sequences was turned off. The search was limited to sequences with a 100% query cover and percent ID from 80% to 100%.

There is cross-reactivity in the ORF1ab primers/probes to the SARS-CoV database (taxid 694009), however this cross-reactivity is only against one sequence, which is the bat coronavirus RaTG13 (Accession: MN996532.1), the ancestor of the SARS-CoV-2. None of the ORF1ab primers/probe are present together in any of the organisms which are likely to be in the circulating area. Similarly, none of the N primer/probe are present together in any of the organisms which are likely to be in the circulating area. Only RnaseP gene primers/probe aligned to the human sequences. Primers and probes of Norgen's COVID-19 TaqMan RT-PCR Kit (ORF1ab/N genes) Dx align to sequences of the SARS-CoV, but not to sequences of pathogens in the same genetic family, or organisms that are likely to be in the circulating area. As per the kit design, only RnaseP gene primer/probe will align to human sequences.

Table 13: List of Organisms included in the Cross-Reactivity Matching Analysis

Group	Pathogen/Organism
Pathogens in the same genetic family	Human coronavirus 229E
	Human coronavirus OC43
	Human coronavirus HKU1
	Human coronavirus NL63
	SARS-coronavirus
	MERS-coronavirus
Organisms that are likely to be in the circulating area	Actinomycetes: **Contains ALL Actinomycetes subspecies**
	Adenovirus (e.g., C1 Ad. 71)
	Alphacoronavirus: **Contains ALL Alphacoronavirus variants**
	bacteria: Contains entire bacterial database
	Bacteroides oralis
	Bordetella pertussis
	Chlamydia pneumoniae
	Eikenella sp.
	Enterovirus & Rhinovirus
	Epstein-Barr virus (EBV)
	Fungi: Contrains entire fungal database
	Haemophilus influenzae
	Haemophilus parainfluenzae
	Herpes simplex virus 1
	Human adenovirus
	Human metapneumovirus
	Human papillomavirus
	Influenza A virus
	Influenza B virus
	Influenza C virus
	Lactobacillus sp.
	Legionella: **Includes ALL Legionella subspecies**
	Mollicutes: **Includes ALL Mollicutes subspecies**
	Moraxella catarrhalis

	Mycobacterium: **Includes ALL Mycobacterium subspecies**
	Mycoplasma pneumoniae
	Neisseria sp.
	Nocardia sp.
	Parechovirus
	Pneumocystis jirovecii
	Pseudomonas aeruginosa
	Staphylococcus: **Includes ALL Staphylococcus subspecies**
	Streptococcus pneumoniae
	Streptococcus pyogenes
	Streptococcus mutans
	Streptococcus mitis
	Streptococcus viridans
	Parainfluenza virus 1
	Parainfluenza virus 2
	Parainfluenza virus 3
	Parainfluenza virus 4
	Streptococcus salivarius
	Human Orthopneumovirus
	Human respiratory syncytial virus A
	Human respiratory syncytial virus B
	Mycobacterium tuberculosis
	Candida albicans
	Staphylococcus epidermidis
	Adenoviridae: **Includes ALL Adenovirus variants**

To test the analytical specificity of Norgen's COVID-19 TaqMan RT-PCR Kit (N/ORF1ab genes) Dx, the N/ORF1ab/RP Positive Control was used to test the kits specificity against RNA purified from other related pathogens. Amplification was measured by real time RT-PCR.

As can be seen in Table 17 below, only Norgen's N/ORF1ab/RP Positive Control showed amplification for all genes. COVID-19 WA showed amplification of the N gene and the ORF1ab gene targets. None of the remaining pathogens showed amplification with any of the tested genes. Therefore, Norgen's COVID-19 TaqMan RT-PCR Kit (N/ORF1ab genes) Dx can be used to specifically detect, confirm and discriminate COVID-19.

Table 14: Pathogens Tested for SARS-CoV-2 Specificity (Nasopharyngeal)

Sample	Final Testing Concentration	N gene	ORF1ab	RNaseP
Positive Control (Norgen)	4×10^6 copies/mL	Positive	Positive	Positive
SARS-CoV-2 (COVID-19 WA)	1.68×10^6 genome copies/mL (2.58×10^7 $TCID_{50}$/mL based on concentration before heat inactivation)	Positive	Positive	Positive
Human cov-229E	1.04×10^6 genome copies/mL	Negative	Negative	Positive
Influenza B virus	3.16×10^6 genome copies/mL	Negative	Negative	Positive

Influenza A virus (H3N2)	1.56×10^8 genome copies/mL	Negative	Negative	Positive
Influenza A virus (H1N1)	2.76×10^7 genome copies/mL	Negative	Negative	Positive
Human cov-NL63	2.72×10^6 genome copies/mL	Negative	Negative	Positive
Human RSV	1.08×10^9 genome copies/mL	Negative	Negative	Positive
Betacoronavirus 1 (OC43)	1.0×10^5 $TCID_{50}$/mL	Negative	Negative	Positive
Human Coronavirus HKU1	2.16×10^6 genome copies/mL	Negative	Negative	Positive
Adenovirus C1 71	4.48×10^8 genome copies/mL	Negative	Negative	Positive
Human Metapneumovirus	1.32×10^6 genome copies/mL	Negative	Negative	Positive
Human Parainfluenza Virus 2	1.6×10^5 $TCID_{50}$/mL	Negative	Negative	Positive
Human Parainfluenza Virus 3	6.4×10^5 $TCID_{50}$/mL	Negative	Negative	Positive
Enterovirus D68	3.56×10^5 $TCID_{50}$/mL	Negative	Negative	Positive
Haemophilus influenzae	4.16×10^6 cfu/mL	Negative	Negative	Positive
Legionella pneumophila	$> 0.8 \times 10^4$ cfu/mL	Negative	Negative	Positive
Streptococcus pneumoniae	1.12×10^6 cfu/mL	Negative	Negative	Positive
Human coronavirus 229E	1.0×10^5 $TCID_{50}$/mL	Negative	Negative	Positive
Human adenovirus 5	1.0×10^7 NIU/mL	Negative	Negative	Positive
Influenza A (H1N1)	1.0×10^5 PFU/mL	Negative	Negative	Positive
Influenza A (H3N2)	1.0×10^5 $TCID_{50}$/mL	Negative	Negative	Positive
Influenza B (Victoria)	2.0×10^6 $TCID_{50}$/mL	Negative	Negative	Positive
Influenza B (Yamagata)	1.39×10^6 $TCID_{50}$/mL	Negative	Negative	Positive
Human respiratory syncytial virus	1.75×10^4 PFU/mL	Negative	Negative	Positive
Chlamydophila pneumoniae	1.0×10^6 IFU/mL	Negative	Negative	Positive
Bordetella pertussis	$> 0.25 \times 10^4$ CFU/mL	Negative	Negative	Positive
Candida albicans	1.0×10^6 CFU/mL	Negative	Negative	Positive
Pseudomonas aeruginosa	1.0×10^6 CFU/mL	Negative	Negative	Positive
Staphylococcus epidermidis	1.14×10^6 CFU/mL	Negative	Negative	Positive
Human parechovirus 2	2.78×10^6 $TCID_{50}$/mL	Negative	Negative	Positive

Corynebacterium diphtheria	1.0 x 10^6 CFU/mL	Negative	Negative	Positive
Legionella longbeachae	1.0 x 10^6 CFU/mL	Negative	Negative	Positive
Leptospira interrogans	Not available	Negative	Negative	Positive
Moraxella (Branhamella) catarrhalis	> 0.25 x 10^4 CFU/mL	Negative	Negative	Positive
Neisseria meningitidis	> 1.0 x 10^4 CFU/mL	Negative	Negative	Positive
Staphylococcus aureus	1.67 x 10^7 CFU/mL	Negative	Negative	Positive

Table 15: Pathogens Tested for SARS-CoV-2 Specificity (Saliva)

Sample	Final Testing Concentration	N gene	ORF1ab	RNaseP
Positive Control (Norgen)	4 x 10^6 copies/mL	Positive	Positive	Positive
SARS-CoV-2 (COVID-19 WA)	1.68 x 10^6 genome copies/mL (2.58 x 10^7 $TCID_{50}$/mL based on concentration before heat inactivation)	Positive	Positive	Positive
Human cov-229E	1.04 x 10^6 genome copies/mL	Negative	Negative	Positive
Influenza B virus	3.16 x 10^6 genome copies/mL	Negative	Negative	Positive
Influenza A virus (H3N2)	1.56 x 10^8 genome copies/mL	Negative	Negative	Positive
Influenza A virus (H1N1)	2.76 x 10^7 genome copies/mL	Negative	Negative	Positive
Human cov-NL63	2.72 x 10^6 genome copies/mL	Negative	Negative	Positive
Human RSV	1.08 x 10^9 genome copies/mL	Negative	Negative	Positive
Betacoronavirus 1 (OC43)	1.0 x 10^5 $TCID_{50}$/mL	Negative	Negative	Positive
Human Coronavirus HKU1	2.16 x 10^6 genome copies/mL	Negative	Negative	Positive
Adenovirus C1 71	4.48 x 10^8 genome copies/mL	Negative	Negative	Positive
Human Metapneumovirus	1.32 x 10^6 genome copies/mL	Negative	Negative	Positive
Human Parainfluenza Virus 2	1.6 x 10^5 $TCID_{50}$/mL	Negative	Negative	Positive
Human Parainfluenza Virus 3	6.4 x 10^5 $TCID_{50}$/mL	Negative	Negative	Positive
Enterovirus D68	3.56 x 10^5	Negative	Negative	Positive

	$TCID_{50}$/mL			
Haemophilus influenzae	4.16×10^6 cfu/mL	Negative	Negative	Positive
Legionella pneumophila	$> 0.8 \times 10^4$ cfu/mL	Negative	Negative	Positive
Streptococcus pneumoniae	1.12×10^6 cfu/mL	Negative	Negative	Positive
Human coronavirus 229E	1.0×10^5 $TCID_{50}$/mL	Negative	Negative	Positive
Human adenovirus 5	1.0×10^7 NIU/mL	Negative	Negative	Positive
Influenza A (H1N1)	1.0×10^5 PFU/mL	Negative	Negative	Positive
Influenza A (H3N2)	1.0×10^5 $TCID_{50}$/mL	Negative	Negative	Positive
Influenza B (Victoria)	2.0×10^6 $TCID_{50}$/mL	Negative	Negative	Positive
Influenza B (Yamagata)	1.39×10^6 $TCID_{50}$/mL	Negative	Negative	Positive
Human respiratory syncytial virus	1.75×10^4 PFU/mL	Negative	Negative	Positive
Chlamydophila pneumoniae	1.0×10^6 IFU/mL	Negative	Negative	Positive
Bordetella pertussis	$> 0.25 \times 10^4$ CFU/mL	Negative	Negative	Positive
Candida albicans	1.0×10^6 CFU/mL	Negative	Negative	Positive
Pseudomonas aeruginosa	1.0×10^6 CFU/mL	Negative	Negative	Positive
Staphylococcus epidermidis	1.14×10^6 CFU/mL	Negative	Negative	Positive
Human parechovirus 2	2.78×10^6 $TCID_{50}$/mL	Negative	Negative	Positive
Corynebacterium diphtheria	1.0×10^6 CFU/mL	Negative	Negative	Positive
Legionella longbeachae	1.0×10^6 CFU/mL	Negative	Negative	Positive
Leptospira interrogans	Not available	Negative	Negative	Positive
Moraxella (Branhamella) catarrhalis	$> 0.25 \times 10^4$ CFU/mL	Negative	Negative	Positive
Neisseria meningitidis	$> 1.0 \times 10^4$ CFU/mL	Negative	Negative	Positive
Staphylococcus aureus	1.67×10^7 CFU/mL	Negative	Negative	Positive
MERS-CoV (ZeptoMetrix Culture Fluid)	Not Available	Negative	Negative	Positive
SARS-CoV (ZeptoMetrix NATSARS-ST)	Not Available	Negative	Negative	Positive
Parainfluenza Virus Type 1 (ZeptoMetrix Culture Fluid)	Not Available	Negative	Negative	Positive
Parainfluenza Virus Type 4A (ZeptoMetrix Culture Fluid)	Not Available	Negative	Negative	Positive

3. Precision

A. Initial Study

To generate initial precision data for the COVID-19 TaqMan RT-PCR Kit (N/ORF1ab genes) Dx, contrived nasopharyngeal swab samples were collected and preserved in Norgen's Total Nucleic

Acid Preservative Tubes (Cat. #69200). Nasopharyngeal swabs were chosen due to the fact that they represent the most challenging matrix for isolation and testing. Collected swabs were spiked with 5 µL of one of 3 different concentrations of the N/ORF1ab/RP Positive control to generate input samples of 3 variable transcript content, which resulted in corresponding three ranges of transcript concentration in isolated RNA: High (1,000 copies/µL RNA), Mid (100 copies/µL RNA) and Low (10 copies/µL RNA). RNA was then isolated and used as a template in precision testing, using 5 replicates and performed on 3 instruments over 5 days. Data analysis was carried out by calculating the mean Ct value, standard deviation and coefficient of variation percentage.

Precision was determined as repeatability (one instrument in one day using 5 repeats of each concentration), precision between days (one instrument, 5 days using 5 repeats of each of the 3 concentrations) and precision between instruments (3 instruments, 5 days using 5 repeats of each of the 3 concentration).

3.A.1 Repeatability

Repeatability was measured by analyzing data from one instrument in one day. Data analysis showed consistent results within the same experimental session.

Table 16: Repeatability (one instrument, one day using 5 repeats of each concentration)

Gene	Concentration	N	Mean Value	SDEV	% CV
N Gene	High	5	22.84	0.29	1.29
	Mid	5	26.67	0.17	0.65
	Low	5	30.65	0.17	0.56
ORF1ab	High	5	23.11	0.30	1.28
	Mid	5	25.85	0.25	0.96
	Low	5	30.06	0.12	0.39
RNaseP	High	5	24.06	0.35	1.45
	Mid	5	26.39	0.21	0.78
	Low	5	27.29	0.09	0.34

3.A.2 Precision Between Days

Precision between various experimental sessions was measured by analyzing data from one instrument over 5 days. Data analysis showed consistent results from day-to-day.

Table 17. Precision between days
(one instrument, 5 days using 5 repeats of each of the 3 concentrations)

Gene	Concentration	N	Mean Value	SDEV	% CV
N Gene	High	25	22.76	0.20	0.89
	Mid	25	26.64	0.18	0.67
	Low	25	30.65	0.17	0.55
ORF1ab	High	25	22.73	0.27	1.17
	Mid	25	25.53	0.23	0.88
	Low	25	29.72	0.24	0.81
RNaseP	High	25	24.23	0.31	1.30
	Mid	25	26.58	0.25	0.94
	Low	25	27.61	0.27	0.99

3.A.3 Precision Between Instruments

Precision between instruments was measured by analyzing data from all three instruments over 5 days. Data analysis showed consistent results from the different instruments over time.

Table 18: Precision between instruments
(3 instruments, 5 days using 5 repeats of each of the 3 concentration)

Gene	Concentration	N	Mean Value	SDEV	% CV
N Gene	High	75	22.69	0.07	0.31
	Mid	75	26.57	0.07	0.25
	Low	75	30.63	0.13	0.43
ORF1ab	High	75	22.76	0.10	0.44
	Mid	75	25.58	0.13	0.49
	Low	75	29.91	0.27	0.90
RNaseP	High	75	24.24	0.09	0.38
	Mid	75	26.60	0.13	0.47
	Low	75	27.90	0.35	1.24

B. Final Study

To generate final precision data for the COVID-19 TaqMan RT-PCR Kit (N/ORF1ab genes) Dx, contrived nasopharyngeal swab samples were collected and preserved in Norgen's Total Nucleic Acid Preservative Tubes (Cat. #69200). Nasopharyngeal swabs were chosen due to the fact that they represent the most challenging matrix for isolation and testing. Collected swabs were spiked with 5 µL of one of 3 different concentrations of the N/ORF1ab/RP Positive Control to generate input samples of 3 variable transcript content, which resulted in corresponding three ranges of transcript concentration in isolated RNA: High (1,000 copies/µL RNA), Mid (100 copies/µL RNA) and Low (10 copies/µL RNA). RNA was then isolated and used as a template in precision testing, using 2 replicates and performed in 2 run per day over 20 days. Data analysis was carried out by calculating the mean Ct value, standard deviation and coefficient of variation percentage.

Precision was determined as repeatability (analysis of all 80 replicates), precision between days (analysis of data generated per each of the 20 days) and precision between runs (analysis of data generated per each of the 40 runs).

3.B.1 Repeatability

Repeatability was measured by analyzing data obtained from all replicates. Data analysis showed consistent results over all data points.

Table 19: Repeatability (one instrument, 80 replicates over 40 runs in 20 days)

Gene	Concentration	N	Mean Value	SDEV	% CV
N Gene	High	40	23.16	0.40	1.74
	Mid	40	26.89	0.31	1.15
	Low	40	30.96	0.46	1.50
RNaseP	High	40	23.75	0.47	1.97
	Mid	40	25.66	0.38	1.48
	Low	40	26.62	0.59	2.21
ORF1ab	High	40	22.09	0.41	1.87
	Mid	40	24.74	0.34	1.37
	Low	40	28.83	0.50	1.73

3.B.2 Precision Between Days

Precision between days was measured by analyzing data generated from the two sessions of each day over 20 days. Data analysis showed consistent results from day-to-day.

Table 20. Precision between days (one instrument, 20 days)

Gene	Concentration	N	Mean Value	SDEV	% CV
N Gene	High	40	23.14	0.34	1.45
	Mid	40	26.82	0.45	1.66
	Low	40	30.81	0.47	1.54
RNaseP	High	40	23.74	0.35	1.49
	Mid	40	25.67	0.36	1.42
	Low	40	26.57	0.57	2.13
ORF1ab	High	40	22.12	0.21	0.96
	Mid	40	24.81	0.28	1.14
	Low	40	28.92	0.30	1.05

3.B.3 Precision Between runs

Precision between runs was measured by analyzing data generated from the 40 runs. Data analysis showed consistent results from run-to-run.

Table 21: Precision between runs (one instrument, 40 runs)

Gene	Concentration	N	Mean Value	SDEV	% CV
N Gene	High	80	23.15	0.38	1.62
	Mid	80	26.86	0.39	1.45
	Low	80	30.88	0.52	1.70
RNaseP	High	80	23.74	0.43	1.80
	Mid	80	25.66	0.38	1.47
	Low	80	26.60	0.60	2.27
ORF1ab	High	80	22.11	0.34	1.56
	Mid	80	24.77	0.33	1.32
	Low	80	28.88	0.61	2.13

4. Accuracy

Clinical evaluation (i.e., accuracy) of the COVID-19 TaqMan RT-PCR Kit (N/ORF1ab genes) Dx was conducted with Clinical Samples (i.e., nasopharyngeal swabs, oropharyngeal swabs and saliva samples) collected from 30 positive and 30 negative donors to generate the Positive Percentage Agreement (PPA), Negative Percentage Agreement (NPA) and overall percentage agreement (OPA) as a measurement of estimated Diagnostic Accuracy. All samples were collected from symptomatic subjects. From each donor, 4 matched samples were collected for a total of 240 samples. Each matched sample set consisted of 1 nasopharyngeal swab and 1 oropharyngeal swab collected into Norgen's Total Nucleic Acid Preservative Tubes (Cat. #69200). The third matched samples were saliva collected into Norgen's Saliva RNA Collection and Preservation Devices (Cat. #53800). The fourth and final samples were a second oropharyngeal swab collected into a Zymo's DNA/RNA Shield Collection Tube (Cat. #R11019-C).

RNA from all samples collected in the Zymo's DNA/RNA Shield Collection Tube (Cat. #R11019-C) were extracted using Zymo's *Quick*-DNA/RNA Viral Magbead Kit (Cat. #R2140). The isolated RNA was validated with a CE marked and FDA approved qRT-PCR SARS-CoV-2 detection kit (Zymo's *Quick* SARS-CoV-2 rRT-PCR Kit, 100 Rxns, Cat. #R3011). RNA from the remaining 90 matched Positive samples (nasopharyngeal, oropharyngeal and saliva samples, collected on Norgen's preservatives) and 90 matched Negative samples (nasopharyngeal, oropharyngeal and saliva samples, collected on Norgen's preservatives) were then isolated utilizing Norgen's Saliva/Swab Total RNA Purification Kit (Cat. #69100). The isolated RNA was used as a template in Norgen's COVID-19 TaqMan RT-PCR Kit (N/ORF1ab genes) (Cat. #TM67300) to detect 3 targets of the kit (N gene, ORF1ab and RP).

As it can be seen in Table 24 below, the various SARS-CoV-2 kit targets can be detected from RNA isolated from the clinical nasopharyngeal swabs, oropharyngeal swabs and saliva samples using Norgen's COVID-19 TaqMan RT-PCR Kit (N/ORF1ab genes), with no detectable viral targets from non-reactive samples.

Table 22: Accuracy of the COVID-19 TaqMan RT-PCR Kit (N/ORF1ab genes) Dx

	Clinical Samples					
	Norgen Nasopharyngeal		Norgen Oropharyngeal		Norgen Saliva Samples	
	Positive	Negative	Positive	Negative	Positive	Negative
Positive of comparator	30	0	30	0	30	0
Negative of comparator	0	100	0	100	0	100
Total	30	100	30	100	30	100
	PPA	NPA	PPA	NPA	PPA	NPA
	100	100	100	100	100	100
	PPA 95% CI	NPA 95% CI	PPA 95% CI	NPA 95% CI	PPA 95% CI	NPA 95% CI
	88.8% - 99.9%	96.3% - 99.9%	88.8% - 99.9%	96.3% - 99.9%	88.8% - 99.9%	96.3% - 99.9%
	Overall Percentage Agreement					
	100		100		100	
	95% CI of Overall Percentage Agreement					
	97.1% - 99.9%		97.1% - 99.9%		97.1% - 99.9%	

5. Robustness

In order to determine robustness of Norgen's COVID-19 TaqMan RT-PCR Kit (Cat.TM67300) the effect of endogenous substances in saliva samples were evaluated. Such endogenous samples include water, mucin and blood. Tubes within each group were used for RNA isolation using 250 uL input after spiking with the heat inactivated SARS-CoV-2 to generate input samples corresponding to a limit of detection (LoD) of 3X. RNA isolation was performed from all samples using Norgen's Saliva/Swab RNA Purification Kit (Cat69100, Lot#599887) and RNA was eluted in 50 uL. Five microliters of the isolated RNA were used as a template in Norgen's COVID-19 TaqMan RT-PCR Kit (N/ORF1ab genes) (Cat. #TM67300) to detect the 3 targets (N gene, Orf1ab targets and RP).

Table 23: Robustness of the COVID-19 TaqMan RT-PCR Kit (N/ORF1ab genes) Dx (Endogenous Substances)

Sample	Substance	ORF1ab		N		RNase P	
		Ave Ct	SDEV	Ave Ct	SDEV	Ave Ct	SDEV
Nasopharyngeal	Water	31.31	0.30	30.36	0.21	23.70	0.25
	Mucin	31.15	0.32	29.60	0.36	24.98	0.16
	Blood	32.19	0.14	30.49	0.38	22.84	0.29
Oropharyngeal	Water	31.50	0.26	28.02	0.06	25.80	0.30

	Mucin	30.67	0.06	30.14	0.14	27.03	0.04
	Blood	32.43	0.38	30.03	0.39	23.27	0.20
	Sputum	30.56	0.28	29.06	0.15	24.51	0.09
Saliva	**Water**	30.74	0.27	28.71	0.36	22.30	0.16
	Mucin	31.69	0.37	29.88	0.40	22.67	0.14
	Blood	31.61	0.04	30.20	0.19	22.59	0.23
	Sputum	32.62	0.48	30.92	0.37	21.58	0.24

In order to determine robustness of Norgen's COVID-19 TaqMan RT-PCR Kit (Cat.TM67300) the effect of exogenous substances in saliva samples were evaluated. Such exogenous samples include eating, drinking, chewing gun, rinsing with mouth wash, brushing teeth, taking cough syrup and smoking. This experiment was done using negative clinical samples spiked with heat inactivated SARS-CoV-2 at 3X LOD. Theses substances did not affect the detection of heat-inactivated SARS-CoV-2 at 3X the limit of detection, with the exception of eating food.

Saliva samples were collected from health donors and preserved in Norgen's Saliva RNA Collection and Preservation Devices (Cat. #RU53800, Lot #596082 and Lot #604858). As it can be seen in Table 25 below, most of the exogenous substances that were tested do not affect the detection of SARS-CoV-2 targets of the kit at 3X the limit of detection, from saliva samples. The only exogenous substance that would affect the detection of SARS-CoV-2 is eating. Which is why it is important to not eat 30 minutes prior to saliva collection.

Table 24: Robustness of the COVID-19 TaqMan RT-PCR Kit (N/ORF1ab genes) Dx (Exogenous Substances)

Condition	ORF1ab		N		RNase P	
	Mean Value	SDEV	Mean Value	SDEV	Mean Value	SDEV
Eating	N/A	N/A	32.10	0.15	22.36	0.43
Drinking	35.48	0.26	32.06	0.03	25.22	0.17
Gum	33.30	0.43	31.53	0.41	23.75	0.12
Mouthwash	33.41	0.20	31.48	0.46	22.51	0.50
Cough Syrup (Benylin)	36.01	1.40	35.84	0.64	23.86	0.05
Cough Syrup (Robitussin)	31.62	0.26	29.39	0.13	27.19	0.07
Toothpaste	34.68	1.09	35.69	1.04	25.08	0.06
Smoking	34.35	0.25	31.11	0.21	23.33	0.41

Product Use Restriction

Norgen's COVID-19 TaqMan RT-PCR Kit (N/ORF1ab genes) Dx is an *in vitro* diagnostic test for the qualitative detection of SARS-CoV-2 specific RNA using a multiplexed TaqMan® fluorescence detection assay (FAM, HEX/VIC and Cy5) in a single one-step RT-PCR reaction. The assay is designed for use with RNA isolated from nasopharyngeal swabs, oropharyngeal swabs and saliva samples collected from individuals with clinical signs/symptoms related to SARS-CoV-2 infection for *in vitro* diagnostic use.

Norgen's COVID-19 TaqMan RT-PCR Kit (N/ORF1ab genes) Dx is intended for use by professional users including clinical laboratory personnel experienced and trained in molecular biology techniques including real-time PCR and *in vitro* diagnostic procedures.

Good laboratory practice is essential for the proper performance of this kit. Ensure that the purity of the kit and reactions is maintained at all times, and closely monitor all reagents for contamination. Do not use any reagents that appear to be contaminated.

Ensure that appropriate specimen collection, transport, storage and processing techniques are followed for optimal performance of this test. The presence of PCR inhibitors may cause false negative or invalid results.

Potential mutations within the target regions of the SARS-CoV-2 genome covered by the primers in this kit may result in failure to detect the presence of the pathogen.

As with any diagnostic test, results generated using Norgen's COVID-19 TaqMan RT-PCR Kit (N/ORF1ab genes) Dx should be interpreted with regard to other clinical or laboratory findings.

The respective user is liable for any and all damages resulting from application of COVID-19 TaqMan RT-PCR Kit (N/ORF1ab genes) Dx for use deviating from the intended use as specified in the user manual.

All products sold by Norgen Biotek are subjected to extensive quality control procedures and are warranted to perform as described when used correctly. Any problems should be reported immediately. The kit contents are for laboratory use only, and they must be stored in the laboratory and must not be used for purposes other than intended. The kit contents are unfit for consumption.

Label Legend

							
Use by	Batch Code	Catalogue Number	Contains sufficient for <n> tests	Manu-facturer	In Vitro Diagnostic Medical Device	Consult instructions for use	Temperature limitation

Authorized Representative

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