LabTurbo™ AIO COVID-19 RNA Testing Kit

Automated workflow for SARS-CoV-2 nucleic acid detection
Catalog: AIOQS3480

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Intended Use

LabTurbo™ AIO COVID-19 RNA Testing Kit is a real-time reverse transcription polymerase chain reaction (RT-PCR) diagnostic product for SARS-CoV-2 RNA detection. The nasopharyngeal swab from individuals suspected of COVID-19 were provided by healthcare following local sampling standard. **LabTurbo™ AIO COVID-19 RNA Testing Kit** for COVID-19 detection has been validated, but FDA's independent review of this validation is pending.

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The positive detection result represents that SARS-CoV-2 RNA has been identified. Laboratories are required to report all positive results to the appropriate public health authorities. The **LabTurbo™ AIO COVID-19 RNA Testing Kit** does not preclude the chance of false positive result. Please contact your healthcare provider to determine how best to care for you based on the test results, medical history, and your symptoms.

The Negative results could not fully exclude the infection of SARS-CoV-2. Additional clinical observations, epidemiological information, and traveling history are recommended for comprehensive evaluation. It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that a patient could possibly still have COVID-19 even though the test is negative. If this is the case, the healthcare provider will consider the test result together with symptoms, possible exposures, and geographical location of places recently traveled in deciding on care.

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Product Description

LabTurbo™ AIO COVID-19 RNA Testing Kit contains oligonucleotide primers and dual-labeled hydrolysis probes (TaqMan®) and control material used in RT-qPCR for the *in vitro* qualitative detection of 2019-nCoV RNA in respiratory specimens. It uses one set of SARS-CoV-2 specific primer pair and probe that specifically recognize SARS-CoV-2 RNA sequence (N1 gene) and is designed to achieve high sensitivity (LOD 20 copies/ml) in the examination. The kit includes **RNA Extraction Control (EC)** for the confirmation of the RNA extraction, reverse transcription, and qPCR procedure for individual samples in batch operation. Furthermore, the **Internal Control (IC)** is provided in the kit to validate cells that were collected from sampling. They are provided in two individual reaction tubes including N1 gene detection in target tube I (1) and EC/IC detection in control tube III (3). Furthermore, the **Positive Control (PC)** is provided in the kit to validate the RT-qPCR and the buffer CCEB is used as no template control (NTC) and negative control (NC). The controls have to be included in each batch testing.

The kit should be stored at -20^{o}C and the number of freeze-thaw is no more than three times and shipped on wet ice. The storage condition of all the components in the kit after open is at 4~8^{o}C for 6 days. The mixtures prepared from components for target tube 1 and control tube 3 can be stored at 4^{o}C~RT for 48 hours.

The kit can be used with LabTurbo™ AIO SP-qPCR System (LabTurbo AIO) and LabTurbo™ Viral DNA/RNA extraction kit for fully automated workflow from viral RNA extraction of NP swab, reaction setup, RT-qPCR, to CT result and report. It can also be used with other extraction systems and equipment with proper testing performance validation regulated by relative authorities.

TaqMan®is registered by Roche Molecular Systems Inc.

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Warnings and Precautions

In all test procedure, well laboratory training is essential to guarantee the test accuracy and safety. Independent area is needed to prevent contamination and false positive results. Inactivation step of specimens is required and must be handled under biosafety hood.

1. The **LabTurbo™ AIO COVID-19 RNA Testing Kit** has been validated, but FDA's review of this validation is pending.
2. Specimen sampling and processing should be performed according to the Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19. (https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html)
3. Personal protective equipment is recommended.
4. All patient specimens and wastes should be considered biohazardous, and sterilization is needed after testing.
5. RNase and DNase free pipette tips with aerosol barriers are recommended to handle infectious specimens.
6. Avoid swallowing or contacting skin and eye with **Proteinase K/Lysis/Wash Buffer**. If accidental swallowing or contact occur, flushing with tap water and medical care are needed.

Quality Control

1. Quality control requirements must be performed in conformance with local, state, and federal regulations or accreditation requirements and the user's laboratory's standard quality control procedures. For further guidance on appropriate quality control practices, refer to 42 CFR 493.1256.
2. Quality control procedures are intended to monitor reagent and assay performance.
3. Test all positive controls prior to running diagnostic samples with each new kit lot to ensure all reagents and kit components are working properly.
4. Always include a negative control (NTC or NEC) and all positive controls (PC, EC, IC) in each PCR run for clinical samples to confirm the quality of workflow including specimen collection, RNA extraction, Reaction setup, and RT-qPCR performance.

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Table 1、Kit Contents and Storage

LabTurbo™ AIO COVID-19 RNA Testing Kit (AIOQS3480; 480 reactions)

Component	Description	Quantity	Storage
Primer/Probe mixture I (PM1)	Target tube I mixture (N1 gene)	4 X 200 µl (10 X)	Store at -20 °C for up to one year Ship at 4 to 8°C Store at 4 to 8°C for up to 6 days after open Avoid freeze-thaw cycle for more than 3 times.
Primer/Probe mixture III (PM3)	Control tube III mixture (EC, IC)	4 X 200 µl (10 X)	
Reverse Transcription (RT)	For reverse transcription of tube I mixture and control tube III mixture	4 X 100 µl (20 X)	
PCR Master Mix (MM)	For preparing target tube I mixture and control tube III mixture	4 X 2.0 ml (2 X)	
Extraction Control RNA (EC)	1000 copies/ul	4 X 1.3 ml (50X)	
Positive Control RNA (PC)	1 copy/ul	4 X 40 µl (4-5x LOD)	

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Table 2、Required Materials Not Supplied

Equipment	Description	P/N
LabTurbo™ AIO SP-qPCR Automation System	For sample-to-result nucleic acid testing (nucleic acid extraction, assay setup, RT-QPCR reaction)	A2410, A2420
LabTurbo™ AIO SP-qPCR Dual-Panel Automation System	For sample-to-result nucleic acid testing (nucleic acid extraction, assay setup, RT-QPCR reaction)	AIO48S-144
Laboratory refrigerators 4°C to 10°C	For sample and reagent storage	N/A
Laboratory freezers –10°C to –30°C & ≤ –70°C	For sample and reagent storage	N/A
Laboratory Mixer or Vortex	For sample mixing	N/A
Microcentrifuge	For sample spin-down	N/A
Pipettes (1-1,000 µL)	For liquid handling	N/A
Reagent	**Description**	**P/N**
LabTurbo™ Viral DNA/RNA Extraction AIO Kit	For viral RNA extraction (480 reactions, 500 µl sample input)	AIOLVX500
100% Ethanol	For RNA extraction	N/A
Human Specimen Control (HSC)	For quality control	NA
Consumables	**Description**	**P/N**
PCR 8-Strip Tubes (120) & Caps	For LabTurbo™ AIO SP-qPCR Automation System, 120 strips/case	A0130
LabTurbo™ AIO Robotic Filter Tip 1100 µl (4800)	96 tips/rack, 10 racks/pack, 5 pack/case	S0650
LabTurbo™ AIO Robotic Filter Tip 1100 µl (960)	96 tips/rack, 10 racks/pack, 1 pack/case	S0610
Nasopharyngeal swab	480/pack	S091480
Screw cap tube (2 ml)	480/pack	S092480

Pretreatment Protocol for Nasopharyngeal (NP) Swab Specimens

For specimen sampling, storage, and shipping and handling, please refer to the guidance issued by CDC. (https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html)

Procedure with virus inactivation before using LabTurbo™

Caution: Please handle specimens in biosafety hood!

Step 1: Vortex NP swab specimen with storage buffer for 30 seconds

Step 2: Transfer 0.5 ml of storage buffer of NP swab specimen into a Sample 6-tube Strip or 2 ml screw tube containing 10 µl of BE and 25 µl of proteinase K (The Sample 6-tube Strip, BE,,and proteinase K buffer are supplied in LabTurbo™ Viral DNA/RNA Extraction AIO Kit).

Step 3: Incubate at room temperature for 10 minutes.

Step 4: Ready for nucleic acid extraction.

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Guide for the Preparation of Reagents

Precautions

1. Clear and RNase-free dedicated space is needed to prevent contamination. Reagents should avoid direct exposure from light.
2. Each reagent should be mixed by vortex and centrifuge before open.
3. Extraction control, positive control (SARS-CoV-2 template RNA), and no template control (NTC) are necessary for each run of RT-qPCR reaction.

Before running RT-qPCR by **LabTurbo™ AIO SP-qPCR System,** prepare the materials (RT mixture, PCR Master Mix, Primer/probe mixture) in the 2 ml tube; PC and EC template are all ready to use.

Table 3 、Formula of RT-qPCR preparation

Component	Target Tube I	Control Tube III
Reverse transcription (RT) mixture	0.8 µl	0.8 µl
2X PCR Master Mix	8.0 µl	8 µl
Primer/probe mixture I	1.6 µl	-
Primer/probe mixture III	-	1.6 µl
Target Tube I Mixture*	10.4 µl	
Control Tube III Mixture*		10.4 µl
Total Mixture volume for n reaction (+3 are for PC, NC, and dead volume)	10.4 x (n +3)	10.4 x (n +3)
Elution of extraction for each reaction	5.6 ul	5.6 ul
Total volume for each reaction	16 ul	16 ul

***The storage and in-use of Target Tube I Mixture and Control Tube III Mixture is at 4°C~RT for 48 hours**

Table 4 、Conditions for RT-PCR

	RT reaction	Activation	Denature	Anneal & elongation
Temperature (°C)	55	95	95	60
Time (sec)	600	60	10	15
Cycle (s)	1	1	40	

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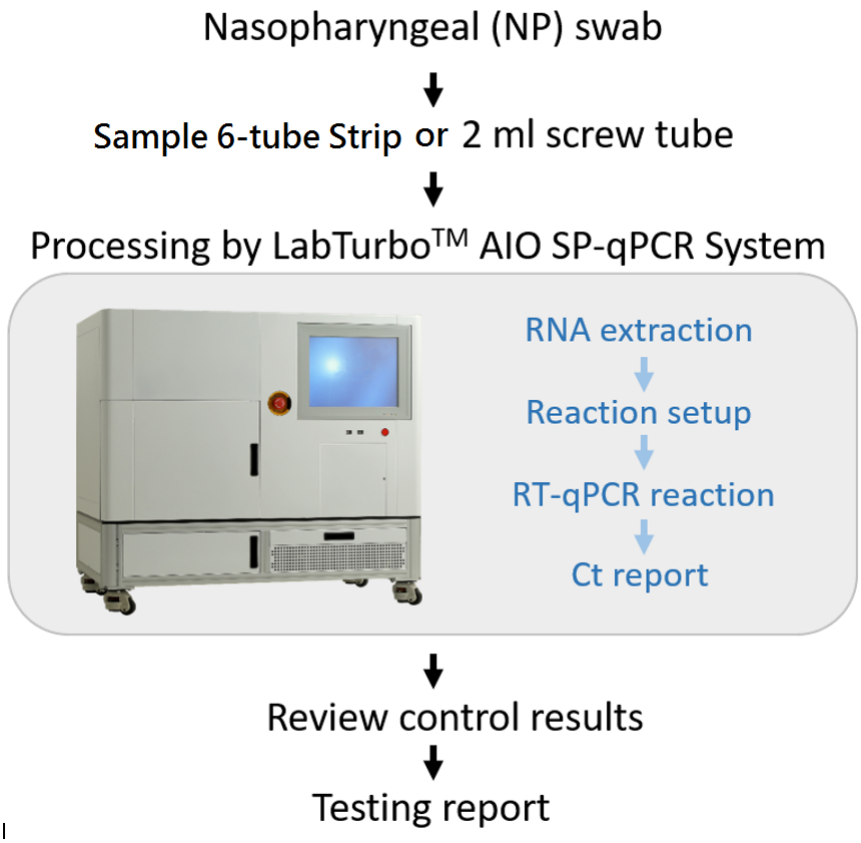
Workflow Using LabTurbo™ AIO SP-qPCR System



LabTurbo™ SP-qPCR All-in-one System evolves from the automated membrane-based isolation system (Taigen Bioscience)*. **LabTurbo™ AIO SP-qPCR System** integrates the nucleic acid extraction, reaction setup, RT-qPCR, and Ct report procedure with the use of the **LabTurbo™ AIO COVID-19 RNA Testing Kit**. The detection workflow from RNA extraction to RT-qPCR Ct report can be automatically completed in a single **LabTurbo™ AIO SP-qPCR System**. The **LabTurbo™ viral DNA/RNA AIO extraction Kit** is necessary for automated viral RNA extraction.

*Screening for *Babesia microti* in the U.S.Blood Supply

DNA was extracted with the use of an automated membrane-based isolation system (Taigen Bioscience)

N Engl J Med. 2016 Dec 8;375(23):2236-2245

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Operation of LabTurbo™ AIO SP-qPCR System

LabTurbo™ AIO Viral DNA/RNA Extraction Kit (Cat. No. AIOLVX500) is based on the column-based membrane extraction method. LabTurbo™ AIO SP-qPCR System equips with active reagent vending function. Load the reconstituted reagents in their original bottles to the reagent bottle holders on the system safety door by following the instruction below:

1. Follow the LW1 buffer reconstitute instruction provided on the LW1 reagent label. Add correct amount of absolute EtOH into the bottle and mix well. Place the LW1 bottle on the LW1 bottle holder.

2. Add absolute EtOH to EtOH reagent bottle and place the EtOH bottle on the EtOH bottle holder.

3. Place CCEB bottle (ready to use) on the CCEB bottle holder.

4. Place VXL bottle (ready to use) on the VXL bottle holder.

5. The first bottle is to be left empty.

1. Turn on the machine, then click the **LabTurbo AIO** icon on the desktop to launch the system software.

2. Select the sample numbers and choose the program "**qPCR-COVID19-IC-N-1.5-LVX40-In0.5-E60-QS**", then click "**Next**".

3. Follow the worktable loading check instruction and make sure each consumable is placed correctly, then click "**Next**"

4. Close the safety door. Press "**Start**".

5. When the program finishes, the Ct results will display on the monitor and can be exported.

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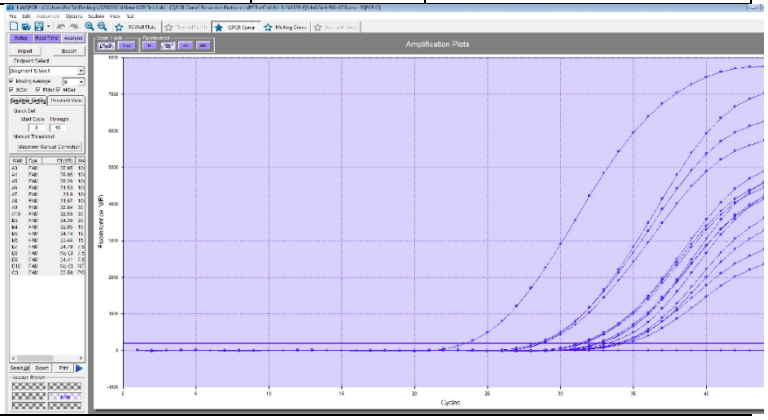
Table 5 Run COVID-19 RNA Testing on LabTurbo™ AIO SP-qPCR System

<table>
<tr><th>Workflow</th><th colspan="4">Description</th></tr>
<tr><td>Specimen sampling, storage, and shipping and handling</td><td colspan="4">Please refer to the guidance issued by CDC. (https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html)</td></tr>
<tr><td>Pretreatment of NP swab specimen</td><td colspan="4">As described on Page 8</td></tr>
<tr><td>AIO Startup</td><td colspan="4">Turn on AIO instrument & launch system software</td></tr>
<tr><td>AIO Worktable setup</td><td colspan="4">Flowing the guidance displayed on the system software to load the plastic consumables, reagents, Sample ID (by barcode or typing) and specimens,</td></tr>
<tr><td>AIO Start</td><td colspan="4">Press “Start” to initiate the procedure</td></tr>
<tr><td>AIO viral RNA extraction</td><td colspan="4">Input volume: 500 µl
Elution volume: 60 µl</td></tr>
<tr><td rowspan="4">AIO Reaction setup</td><td>Detection tube</td><td>Tube I</td><td colspan="2">Tube III</td></tr>
<tr><td>Target Tube I Mixture</td><td>10.4 µl</td><td colspan="2">-</td></tr>
<tr><td>Control Tube III Mixture*</td><td>-</td><td colspan="2">10.4 µl</td></tr>
<tr><td>Volume of elution product</td><td>5.6 µl</td><td colspan="2">5.6 µl</td></tr>
<tr><td rowspan="4">AIO RT-qPCR reactive condition</td><td>RT reaction</td><td>Activation</td><td>Denature</td><td>Annealing /Elongation</td></tr>
<tr><td>55°C</td><td>95°C</td><td>95°C</td><td>60°C</td></tr>
<tr><td>600 sec</td><td>60 sec</td><td>10 sec</td><td>15 sec</td></tr>
<tr><td>1</td><td>1</td><td colspan="2">40 cycles</td></tr>
<tr><td>AIO qPCR growth curve</td><td colspan="4">  </td></tr>
</table>

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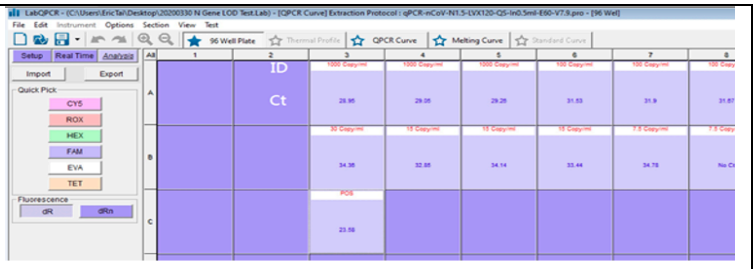
AIO Ct Report



Sample ID	Target Name	Ct (dR)
Sample 1	Coronavirus SARS-CoV-2	30.55
Sample 2	Coronavirus SARS-CoV-2	30.9
Sample 3	Coronavirus SARS-CoV-2	No Ct
Sample 4	Coronavirus SARS-CoV-2	No Ct
Sample 5	Coronavirus SARS-CoV-2	31.04
Sample 6	Coronavirus SARS-CoV-2	30.78

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Results and Interpretation

Each test result should be assessed by positive, negative, and internal control. These control reactions are necessary for each RT-qPCR reaction. In target **tube 1**, FAM signal shows SARS-CoV-2 has been detected. In control **tube-3**, FAM signal shows human cell internal control (IC) gene is detected and Cy5 signal shows RNA extraction control (EC) is detected. The result interpretation principle is as below:

Table 6 Result interpretation and actions

N1 gene	EC	IC	Result	Interpretation and action
Target Tube 1 (FAM)	Control Tube 3 (Cy5)	Control Tube 3 (FAM)		
+	+	+/-	Valid	**SARS-CoV-2 RNA was Detected**
+	-	+	Valid	
-	+	+/-	Valid	**SARS-CoV-2 RNA was not Detected**
-	-	+	Valid	
+	-	-	Invalid	**Repeat extraction and RT-qPCR. If the repeated result remains invalid, consider collecting a new specimen from the patient.** Consult the manufacturer for technical support and report it to regulatory authorities.
-	-	-	Invalid	

N1 gene +: means CT <40; -: means not detected or CT >40；IC +: means CT <40; -: means not detected or CT >40；CT of PC in the range of 29-32；CT of EC in the range of 25-30； NTC should be CT >40 (N.D).

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Cross Reactivity Testing of SARS-CoV-2 Specific Primer/Probe

In silico analysis of primers and probes in **LabTurbo™ AIO COVID-19 RNA Testing Kit** were analyzed from NCBI database. The following species were included for *in silico* analysis:

Table 7、Inclusivity (analytical sensitivity) for SARS-CoV-2

SARS-CoV-2 strain	Country	N1 gene
GenBank: MT126808.1	BRA	100%
GenBank: MT123290.1	CHN	100%
GenBank: MT093571.1	SWE	100%
GenBank: MT066176.1	TWN	100%
GenBank: MT049951.1	CHN	100%
GenBank: MT163721.1	USA	100%
GenBank: LC534419.1	JPN	100%
GenBank: MT007544.1	ANZ	100%
GenBank: MT066156.1	ITA	100%
GenBank: MT233519.1	ESP	100%

Table 8、*in silico* cross-reactivity analysis for SARS-CoV-2

Strains	**In Silico Analysis for % Identity to SARS-CoV-2 N1 gene priming site By AIO**
Human coronavirus 229E	No alignment
Human coronavirus OC43	No alignment
Human coronavirus HKU1	No alignment
Human coronavirus NL63	No alignment
SARS-coronavirus	65%
MERS-coronavirus	No alignment
Adenovirus	No alignment
Human Metapneumovirus	No alignment

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Parainfluenza virus 1	No alignment
Parainfluenza virus 2	No alignment
Parainfluenza virus 3	No alignment
Parainfluenza virus 4	No alignment
Influenza A	No alignment
Influenza B	No alignment
Influenza C	No alignment
Enterovirus	No alignment
Respiratory syncytial virus	No alignment
Rhinovirus	No alignment
Chlamydia pneumoniae	No alignment
Haemophilus influenzae	No alignment
Legionella pneumophila	No alignment
Mycobacterium tuberculosis	No alignment
Streptococcus pneumoniae	No alignment
Streptococcus pyogenes	No alignment
Bordetella pertussis	No alignment
Mycoplasma pneumoniae	No alignment
***Pneumocystis jirovecii* (PJP)**	No alignment
Candida albicans	No alignment
Pseudomonas aeruginosa	No alignment
Staphylococcus epidermis	No alignment
Staphylococcus salivarius	No alignment

* The target sequences were blasted against NCBI Database and no alignment results were found. No potential unintended cross reactivity is expected based on this *in silico* analysis.

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Performance Characteristics (I)

The Limit of detection (LoD) test was performed by spiking different concentrations of the Heat Inactivated 2019 Novel Coronavirus from ATCC (VR-1986HK™, lot number: 70035039, viral concentration: 1.6 x 10^5 $TCID_{50}$/mL, RNA copy number by ddPCR: 3.75 x 10^5 genome copies/μL) into negative clinical NP swab preservation medium (VTM) of Puritan UniTranz-RT Transport System following the pretreatment protocol described on page 7 to evaluate the lowest viral copy number with 95% detection rate (19 positive detections from 20 contrived samples). The test was performed following the "**Run COVID-19 RNA test on LabTurbo™ AIO SP-qPCR System"** on Table 5.

Information of ATCC Heat Inactivated 2019 Novel Coronavirus lot 70035039: https://www.atcc.org/~/media/Files/Certificates%20of%20Analysis/3/B/4/1/VR-1986HK_70035039.ashx

Table 9 Limit of Detection (LoD) - Analytical Sensitivity:

	N1 gene			
	Concentration			
Repeat	1	2.5	5	10
1	No Ct	31.3	29.97	27.9
2	No Ct	31.01	30.74	28.86
3	No Ct	31.62	29.48	29.07
4	32.79	30.98	29.17	28.36
5	35.43	31.4	30	29.16
Average	32.79	31.2275	29.84	28.5475
Std	N/A	0.2988	0.6844	0.5244
CV	N/A	0.0096	0.0229	0.0184
Detection rate	3/5	5/5	5/5	5/5

The result of LoD for N1 gene is 2.5 copies/ul

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Performance Characteristics (II)

The Clinical evaluation testing was performed to evaluate the detection performance in artificial samples. In this study, negative clinical nasopharyngeal swab specimens in VTM of Puritan UniTranz-RT Transport System were collected and spiked with different concentrations of the Heat Inactivated 2019 Novel Coronavirus from ATCC (VR-1986HK™, lot number: 70035039, viral concentration: 1.6 x 10^5 TCID50/mL, RNA copy number by ddPCR: 3.75 x 10^5 genome copies/μL) and EC/IC to obtain specimens of 1x, 2x, and 4x of LoD. The test was performed using the method listed on table 5 "**Run COVID-19 RNA test on LabTurbo™ AIO SP-qPCR System"**. 30 negative clinical nasopharyngeal swab specimens in VTM were used as negative specimens. NTC was used as negative control; N.D.=Not detected.

Table10 Clinical evaluation study in **Primer/Probe Mixture I** (N1 gene) using NP swab sample.

Replicate	Effective copy number in Nasopharyngeal specimens				Acceptance Criteria
	1X LoD 2.5 copies/ul	2 X LoD 5.0 copies/ul	4 X LoD 10.0 copies/ul	Negative specimen	
1	31.34	30.98	30.97	N.D.	Positive Ct < 40 Negative Ct > 40 (N.D.)
2	30.85	32.78	32.43	N.D.	
3	33.28	32.64	30.64	N.D.	
4	33.22	31.09	31.98	N.D.	
5	32.93	30.81	29.09	N.D.	
6	33.69	30.96	30.18	N.D.	
7	31.69	30.9	31.6	N.D.	
8	32.21	31.7	31.17	N.D.	
9	32.04	31.27	32.25	N.D.	
10	32.97	33.23	30.98	N.D.	
11	30.36	30.8	33.36	N.D.	
12	31.25	31.4	30.79	N.D.	
13	32.3	31.01	31.28	N.D.	
14	32.79	30.9	32.45	N.D.	
15	31.57	31.83	32.26	N.D.	

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16	31.63	31.38	31.42	N.D.	
17	33.68	33.18	31.66	N.D.	
18	31.43	30.7	31.34	N.D.	
19	33.01	32.43	33.86	N.D.	
20	31.99	33.31	31.16	N.D.	
21				N.D.	
22				N.D.	
23				N.D.	
24				N.D.	
25				N.D.	
26				N.D.	
27				N.D.	
28				N.D.	
29				N.D.	
30				N.D.	
Average	32.21	31.67	31.54	-	
Standard deviation	0.9528	0.9140	1.0715	-	
CV	0.0296	0.0289	0.0340	-	
Positive samples	**20/20 (100%)**	**20/20 (100%)**	**20/20 (100%)**	**0/30 (0%)**	

Table 11 Clinical evaluation study summary

Concentration (Copies/ul)	Valid results	N1 gene		
		n	Average	Detection rate
2.5	20	20	32.21	100%
5	20	20	31.67	100%
10	20	20	31.54	100%
Negative	30	30	N.D.	N.D.

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Clinical Confirmatory Study

For the clinical validation, 5 positive and 5 negative uncontrived NP swab samples from patients identified by this assay were sent to Bureau of Laboratories of Pennsylvania Department of Health to confirm the testing results. The comparator device uses US FDA EUA granted CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel.

Table 12 Clinical confirmatory study results

		CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel	
		Positive	Negative
LabTurbo™ AIO COVID-19 RNA Testing Kit	Positive	5	0
	Negative	0	5
Positive percent agreement: 5/5 = 100% Negative percent agreement: 5/5 = 100%			

Testing results were confirmed correct without false positive or false negative results from detections using LabTurbo™ AIO COVID-19 RNA Testing Kit.

Limitations

- The LabTurbo™ AIO COVID-19 RNA Testing Kit has been validated, but FDA's independent review of this validation is pending.
- The test was limited for use with nasopharyngeal (NP) swab specimen.
- False negative results might be caused by incorrect specimen sampling, handling, and transportation.
- False positive results might be caused by specimen cross-contamination during sampling or handling and/or RT-qPCR reagents contamination.
- Do not use any expired reagent for testing.

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