

**MobioSense™ COVID-19 Isothermal  
Nucleic Acid Diagnostic Kit  
Catalog No. #COV-INA0-50**

**Instruction for Use**

**Store at –20°C**

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## 1 Intended Use

The MobioSense™ COVID-19 Isothermal Nucleic Acid Diagnostic Kit is a real-time isothermal nucleic acid amplification assay intended for the qualitative detection of nucleic acid from SARS-CoV-2 in upper and lower respiratory specimens including oropharyngeal swabs from individuals who are suspected of having COVID-19 infections.

Results are for the identification of presence of SARS-CoV-2 RNA in individual specimens, which is usually detectable in upper and lower respiratory specimens during the acute phase of infection. In practice, clinical correlation with other diagnostics result is necessary to determine the patient's infection status. Positive results obtained with this kit do not rule out infection by COVID-19.

The Kit is intended for use by qualified or CDC-assigned clinical laboratories with personnel instructed and trained in vitro diagnostic procedures.

## 2 Product Description

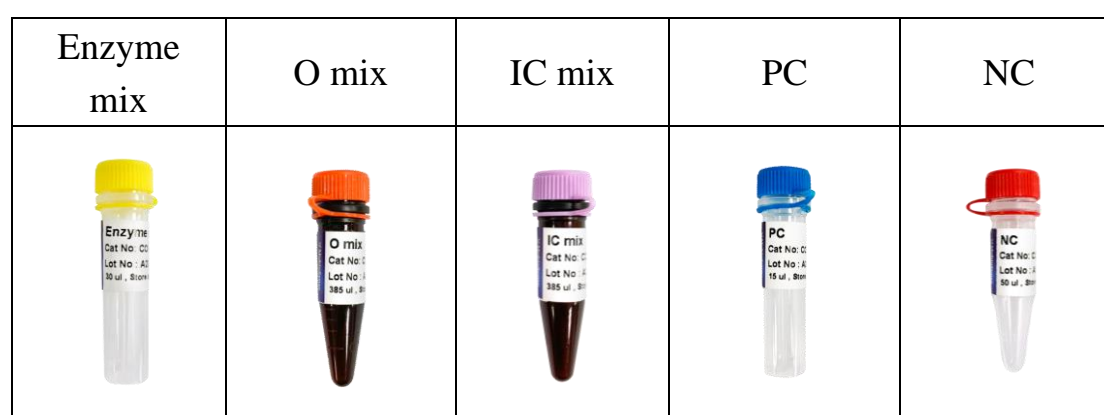
The MobioSense™ COVID-19 Isothermal Nucleic Acid Diagnostic Kit is a real-time loop-mediated isothermal amplification (RT-LAMP) test. The principle of this method is to generate a DNA copy of the viral RNA by reverse transcription and then isothermal amplification of the target region by loop-mediated isothermal amplification (LAMP). The kit uses LAMP primers that target ORF1a for detection of SARS-CoV-2 RNA in the FAM channel and human RNase P for internal control to evaluate the RNA extraction process and real-time PCR performance.

This isothermal reaction can be performed at 60-65°C. The amplification can be monitored in real-time by measuring the increase in fluorescence of DNA binding dyes via a PCR detection system such as ABI QuantStudio 3.

The kit also provides external positive and negative controls. The positive control contains templates of SARS-CoV-2 ORF1a gene and the human RNase P gene fragment. The negative control contains the nuclease-free distilled water.

### 3 Component and Package Specifications

The kit contains reaction buffer, primers, enzyme mix, positive control and negative control.



No.	Label	Part No	Component	Specification	Storage
1	Enzyme mix	COV-INA0-A01	Reverse transcriptase and Polymerase	30 µL /1 vial	-20°C
2	O mix	COV-INA0-A02	ORF1a primer (COVID-19), buffer, dye, dNTP mix	385 µL /1 vial	
3	IC mix	COV-INA0-A03	RNase P primer (human), buffer, dye, dNTP mix	50 µL /1 vial	
4	PC	COV-INA0-A04	Positive control, contains template of ORF1a and RNase P	15 µL /1 vial	
5	NC	COV-INA0-A05	Negative control, Nuclease-free water	50 µL /1 vial	

**Enzyme mix**

The enzyme mix contains reverse transcriptase and polymerase. This mix can be amplified with O mix and IC mix to verify the presence of the targets.

**ORF1a mix (O mix)**

O mix can be amplified with the enzyme mix to verify the presence of SARS-CoV-2 RNA.

**Internal control (IC mix)**

The IC mix contains primer to detect the human RNase P gene. This internal control is intended to evaluate the RNA extraction process. Each clinical sample should be examined with both the O mix and IC mix. A negative result could only be made when its IC is positive but it fails to amplify the ORF1a gene.

**Positive control (PC)**

The positive control contains synthetic DNA from SARS-CoV-2 ORF1a and the human RNase P. This control can be amplified together with O mix and the enzyme mix. The amplification signal can be detected in the FAM channel.

**Negative control (NC)**

The negative control contains nuclease-free water. No signal should be detected within 20 min while running the NC control.

**4 Storage and Handling Requirement**

- ◆ All reagents must be stored at -20°C (including un-opened and in-use product).
- ◆ Use the reagents within 6 months once opened.
- ◆ Place Enzyme mix on bio-cooler or cold box during the whole procedure. Perform the pipetting procedure ASAP, and put enzyme mix back to -20°C.
- ◆ Completely thaw the reagents except for the enzyme.

- ◆ Place all reagents on ice (Enzyme mix should be on bio-cooler) during the whole test procedure.
- ◆ Vortex and spin down briefly before each use.

## **5 Additional Materials and Equipment**

The kit does not include sample collection kits, RNA extraction reagents and real-time PCR detection instruments. Components required for the identification of SARS-CoV-2 RNA but not provided with the kit include:

### **5.1 Sample collection/Storage/Shipping**

- ◆ Sampling swab.
- ◆ Transport medium.
- ◆ Storage medium.

### **5.2 RNA Extraction kit**

RNA extraction kit: QIAamp Viral RNA Mini Kit (Catalog #52904/52906).

**5.3 Real-time PCR detection system** : ABI QuantStudio 3 qPCR machine.

### **5.4 Protection**

Biosafety cabinet in a Biosafety Level 2 (BSL-2) lab, protective gloves, coat, eye-protection goggles.

### **5.5 Instrument and Supplies**

- ◆ Pipette.
- ◆ Tips (nuclease-free).
- ◆ Microcentrifuge.
- ◆ Microcentrifuge tubes (nuclease-free).
- ◆ Rack.
- ◆ Sterilized gloves.
- ◆ Sanitizing reagent like 70-75% ethanol.

- ◆ Tissue.
- ◆ Ice cooler.
- ◆ Disposable powder-free gloves.

## 6 Warnings and Precautions

- ◆ Please read the user guide carefully before use.
- ◆ For *in vitro* diagnostic use only.
- ◆ Sample and assay waste must be disposed of in accordance with local regulations.
- ◆ Setting up a PCR-specific space while conducting this test is recommended.
- ◆ Report positive results to relevant public health authorities and transport the clinical specimens to appointed health authorities for further confirmation.
- ◆ Avoid opening the PCR tube after amplification as this may lead to contamination.
- ◆ Use DNAZap™ or similar detergents to degrade contaminating DNA and RNA from surface.
- ◆ Store all reagents at -20°C and prepare aliquots for several tests and away from UV/sunlight.
- ◆ Avoid use if the kit is contaminated with clinical samples.
- ◆ Use nuclease-free and sterilized single-use micro filter tips.
- ◆ All test material and clinical samples are infectious biomedical wastes. Waste disposal should be conducted in accordance with applicable local regulations.
- ◆ If any abnormality is observed, stop the experiment and consult technical support.

## 7 Sample Collection, Handling and Storage

### 7.1 Sample collection

Refer to authorities like CDC suggested specimen types including oropharyngeal swab. Store the samples at 2°C to 8°C for up to 72 hours. If delay in shipping or extraction is expected, samples should be stored at

-70 to -90°C. For more details, please refer to authorities like the CDC.

## 7.2 Sample transportation

Specimens must be properly packaged and store at 2°C to 8°C, shipping to the lab on ice packs within 72 hours.

Specimens should be storage at -70°C if the RNA extraction is postponed. For more details, please refer to the current edition of the Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19).

<https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html>

## 7.3 Rejection criteria:

Specimens should be rejected before the test if:

- ◆ the specimens were stored at 2°C to 8°C for more than 72 hours.
- ◆ the specimens were stored or shipped without sufficient volume (less than 1mL)
- ◆ the label was damaged or cannot be read or does not have the corresponding document for identification.

## 8 Assay procedure

### 8.1 Summary

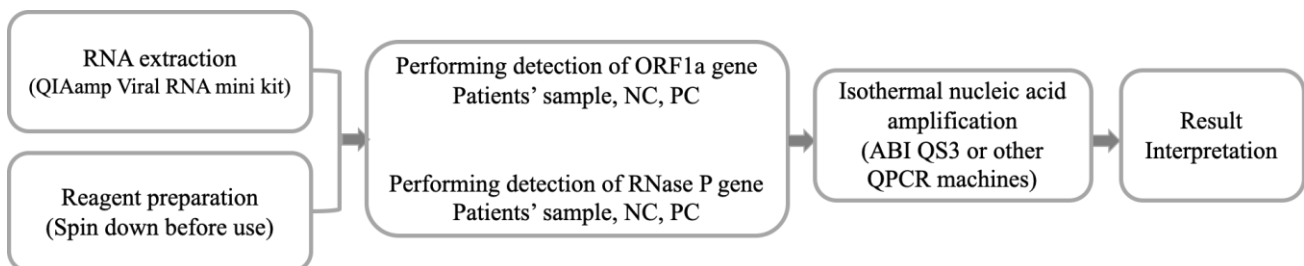


Figure1. Testing procedure for MobioSense™ COVID-19 Isothermal Nucleic Acid Diagnostic Kit.

## 8.2 Extraction of viral RNA

This kit has been validated with the QIAamp Viral RNA mini kit (#52904 or 52906). The extraction kit requires 140  $\mu\text{L}$  of sample input and yield 60  $\mu\text{L}$  of purified nucleic acid. After extraction, stored the extracted RNA in  $-70^\circ\text{C}$  freezer for later use.

## 8.3 Reagent preparation

1. Clean all working spaces and equipment with 5-10% bleach and 75% ethanol before each test to decrease the risk of nucleic acid cross-contamination.
2. The O mix, IC mix, NC and PC should be thawed on ice.
3. All reagents should be kept on ice during the whole test.
4. Spin down all reagents briefly before use to avoid drop remains on the side or top of the PCR tube.

## 8.4 Experimental setup

1. Set up ORF1a and RNase P amplification run.

Each sample and controls (PC and NC) must run both ORF1a and RNase P amplifications. The following shows the reagent composition of each run and always keep reagents on ice during experiments.

ORF1a premix ( for each sample )	
Enzyme mix	0.3 $\mu\text{L}$
O mix	7.7 $\mu\text{L}$
total	8 $\mu\text{L}$



RNase P premix ( for each sample )	
Enzyme mix	0.3 $\mu$ L
IC mix	7.7 $\mu$ L
total	8 $\mu$ L

Example: total 30 clinical samples to be tested + 1 positive control + 1 negative control = total 32 reaction mix / well needed.

ORF1a premix (30 clinical samples +1 NC+1 PC)		
	each	X32
Enzyme mix	0.3 $\mu$ L	9.6 $\mu$ L
O mix	7.7 $\mu$ L	246.4 $\mu$ L
total	8 $\mu$ L	256 $\mu$ L

RNase P premix (30 clinical samples +1 NC+1 PC)		
	each	X32
Enzyme mix	0.3 $\mu$ L	9.6 $\mu$ L
IC mix	7.7 $\mu$ L	246.4 $\mu$ L
total	8 $\mu$ L	256 $\mu$ L

1. Pipet 8  $\mu$ L of ORF1a or 8  $\mu$ L of RNase P reaction mix into each well in a PCR plate or reaction tubes (for example: ABI QuantStudio 3 compatible 8-tube strips and 96-well plates).
2. Pipet 2  $\mu$ L of clinical samples (extracted RNA) or 2 $\mu$ L of control (PC/NC) to each well in a PCR plate or reaction tube. At least one positive control and one negative control need to be included in each run. Filer tips and loading the sample in a hood are highly recommended to avoid possible contamination.
3. Seal the reaction plate with appropriate adhesive films or close the reaction tubes with lids.
4. Place the plates and tubes into a real-time PCR machine and start a run.

For example, a total of 30 samples can be planned and loaded into a 96-well plate as follows:

	1	2	3	4	5	6	7	8	9	10	11	12
A	Sample 1				NC		Sample 1				NC	
B	Sample 2						Sample 2					
C	Sample 3						Sample 3					
D	Sample 4			...			Sample 4			...		
E	...			Sample 29			...			Sample 29		
F				Sample 30						Sample 30		
G												
H					PC						PC	

**ORF1a group**
**RNase P group**

### 8.5 Set up real-time LAMP run

After preparing the reaction mixes, set up the running protocol for the ABI QuantStudio 3 real-time PCR detection system. The run protocol and fluorescence channels for the targets are shown in Table 1 and 2.

Table 1. Protocol of the isothermal assay

Device	Temperature	Time	Number of cycles
ABI QuantStudio 3	63°C	60 sec	20

\*Collect fluorescence at the end of each cycle

Table 2. Settings of fluorescence channel

Channel	Target
FAM	COVID-19 ORF1a gene
	Human RNase P gene

## 9 Result Interpretation

### 9.1 Baseline and threshold setting

This kit has been validated using ABI QS3 real-time PCR detection system. Users may set the baseline and adjust the threshold (the level of signal that reflects a statistically significant increase over the baseline) according to the manual of corresponding real-time PCR detection systems.

<https://www.thermofisher.com/tw/zt/home/life-science/pcr/real-time-pcr/real-time-pcr-learning-center/real-time-pcr-basics/real-time-pcr-understanding-ct.html>

### 9.2 Interpretation of quality control

Each experiment should include both NC and PC testing. If the controls are not valid, the results cannot be interpreted.

#### Negative control, NC

The NC reaction should not exhibit a fluorescence growth curve which crosses the baseline within 20 min for the ORF1a gene and the human RNase P gene ( $C_t > 20$ ).

#### Positive control, PC

The PC reaction should yield a positive result with FAM channel for the ORF1a gene ( $C_t \leq 20$ ) and the human RNase P gene ( $C_t \leq 20$ ).

If the values of the controls are invalid, check if the storage conditions, assay set up and execution and equipment settings follow the instructions. For detailed information, please refer to the troubleshooting instructions listed in Section 11 or open a new kit to repeat the test. If the invalid result remains, please contact technical support.

	Negative control (NC)		Interpretation
Target	ORF1a	IC (RNase P)	
Testing Results	Ct>20 (Negative)	Ct>20 (Negative)	Negative control valid
	Other results		Negative control invalid → Batch re-run

	Positive control (PC)		Interpretation
Target	ORF1a	IC (RNase P)	
Testing Results	Ct≤ 20 (Positive)	Ct≤ 20 (Positive)	Positive control valid
	Other results		Positive control invalid → Batch re-run

### 9.3 Interpretation of clinical samples

If the positive and negative controls are conclusive, refer to the following table to determine the infection status of the patient samples.

	Results		
Target	ORF1a	IC (RNase P)	Interpretation
Testing Results	Ct≤ 20 (Positive)	Ct≤ 20 (Positive)	Covid-19 detected
	Ct>20 (Negative)	Ct≤ 20 (Positive)	Covid-19 not detected
	Ct≤ 20 (Positive) or Ct>20 (Negative)	Ct>20 (Negative)	Improper RNA extraction →Perform RNA re-extraction and re-run

## Internal control

The internal control is intended to evaluate the RNA extraction process: if the ORF1a is negative, a positive result from IC (RNase P) can be used to exclude improper nucleic acid extraction from clinical materials; if the result of the IC remains invalid, re-extraction from specimens is recommended. Furthermore, a positive clinical result could be confirmed only when both RNase P and ORF1a show positive. For more details, please refer to Section 11 or contact for technical support if the problem persists.

## 10 Limitations

- ◆ This test is qualitative and does not provide a quantitative value for the viral load in the specimens.
- ◆ The specimens to be tested should be collected, stored and transported according to the suggested guidelines. Inappropriate specimen handling may lead inaccurate results.
- ◆ This kit is compatible with the QIAmp Viral RNA Mini Kit for RNA extraction. Other extraction kits have not been evaluated. Detection of SARS-CoV-2 RNA with this kit has only been validated with the ABI QuantStudio 3 Real-time PCR detection system. Other instruments must be evaluated before use.
- ◆ A false positive may occur if:
  - The viruses are present at a level which is lower than the detection limit of this kit
  - The virus has genomic mutations, insertions, deletions, or rearrangements.
- ◆ For other common problems, please refer to FDA's FAQs on Diagnostic Testing for SARS-CoV-2.

## 11 Troubleshooting

### 11.1 Stability

The shelf-life of this kit has been established as 12 months at -20°C or below. Using expired reagents is not recommended and may lead to inaccurate results. Please refer to the latest version of the product manual. More information on the stability of this kit will be included.

### 11.2 Possible mistakes by the operator

Good Laboratory Practices for Molecular Biology Diagnostics (Viana & Wallis, 2011) should be followed when using this product. This product is not intended to be used by untrained personnel. The user must have molecular biology experience and be familiar with proper pipetting techniques to prevent errors such as splashes, crossover contamination and errors in volume selection. Pipette tips must be replaced after each pipetting. Gloves must be replaced often. Equipment such as pipettes and real-time PCR instruments should be calibrated when applicable. Ninety minutes of online training for Good Laboratory Practices for Molecular Genetics Testing (CDC, 2020) is available at the CDC website at the following link: <https://www.cdc.gov/labtraining/trainingcourses/good-lab-practices-molecular-genetics-testing.html>

### 11.3 Invalid or unclear results

#### 11.3.1 Positive control (PC) did not amplify

If the positive control result is invalid, this may be due to:

- ◆ Inaccurate dispensing.
- ◆ Premix buffer or internal control being degraded (inappropriate storage condition).
- ◆ The kit is expired
- ◆ Using the wrong components

### **11.3.2 Negative control (NC) was amplified**

Amplification of SARS-CoV-2 in a non-template control indicates contamination occurring in one or several reagents, the 96-well plate or tubes, or pipetting errors. Under such a situation, all specimens need to be re-tested. If the NTC consistently shows positive amplifications, experiments should stop and identify possible causes for the error. Re-extraction of clinical specimens may be needed. If the cause of the error remains unclear, please contact technical support.

### **11.3.3 Internal control (IC) did not amplify**

Failure of IC may indicate:

- ◆ Degradation of the IC mix or enzyme mix.
- ◆ Presence of PCR inhibitors (ethanol, heparin...etc.).
- ◆ Improper assay execution.
- ◆ Improper reagent storage.

Note: if the repeat test with the same RNA extract remains invalid, repeat the extraction procedure and amplification. If it fails a third time, an investigation should be conducted to identify possible causes for the error. If the cause of the error remains unclear, please contact technical support.

## 12 Performance evaluation

### Limit of detection (LoD)

The LoD analysis establishes the lowest SARS-CoV-2 viral RNA concentrations (genomic copies/ml). A preliminary LoD of SARS-CoV-2 specific target ORF1a was determined using whole viral RNA genome (Twist BioScience #MN908947.3) spiked into a negative clinical sample matrix (extracted by QIAamp viral RNA mini kit.)

Evaluation Item	Sample	Target	LoD		
Limit of detection, LoD	oropharyngeal swab	SARS-CoV2 RNA	*2 Copies/μL		
	Concentration Copies/μL	#GE /reaction	Mean Ct	Ct SD	Positive rate
	10000	1E+05	6.09	0.17	20/20
	1000	1E+04	7.43	0.20	20/20
	100	1E+03	8.95	0.53	20/20
	10	1E+02	10.79	1.4	20/20
	4	4E+01	8.8	0.8	20/20
	2	2E+01	10.41	2.15	20/20
	1	1E+01	14.5	4.13	17/20
	NTC	-	-	-	0/20

Experimental details	
Operator	Personnel instructed and trained in vitro diagnostic procedures.
Assay time	20 minutes
Extraction	QIAamp Viral RNA mini kit (#52904 or 52906)
Target	ORF1a region of SARS CoV-2



Evaluation Item

*In silico* reactivity test BLASTn analysis queries MobioSense™ COVID-19 Isothermal Nucleic Acid Diagnostic Kit primers were performed against reference SARS-CoV-2 genomes in the NCBI database. The simulation results showed the kit may amplify ten different reference SARS-CoV-2 viruses. Detailed results of the *in silico* analysis is shown in the following table.

Viral strains	Reference No.	<i>in silico</i> analysis for % identity					The likelihood Of being detected
		Primer 1	Primer 2	Primer 3	Primer 4	Primer 5	
SARS-coronavirus Wuhan-Hu-1	MN908947.3	100%	100%	100%	100%	100%	Can be detected
SARS-coronavirus 2 isolate USA-WA1	MN985325.1	100%	100%	100%	100%	100%	Can be detected
SARS-coronavirus 2 isolate Australia/VIC01	MT007544.1	100%	100%	100%	100%	100%	Can be detected
SARS-coronavirus 2 isolate BRA/SP02	MT126808.1	100%	100%	100%	100%	100%	Can be detected
SARS-coronavirus 2 isolate PER/Peru-10	MT263074.1	100%	100%	100%	100%	100%	Can be detected
SARS-coronavirus 2 isolate HKG/90	MT215195.1	100%	100%	100%	100%	100%	Can be detected
SARS-coronavirus 2 isolate TKYE6968	LC542976.1	100%	100%	100%	100%	100%	Can be detected
SARS-coronavirus 2 isolate HKU-SZ-005b	MN975262.1	100%	100%	100%	100%	100%	Can be detected

SARS-coronavirus 2 isolate SNU01	MT039890.1	100%	100%	100%	100%	100%	Can be detected
SARS-coronavirus 2 isolate HZ-1	MT039873.1	100%	100%	100%	100%	100%	Can be detected

### Evaluation Item

*In silico* specificity  
(Cross-reactivity test)

BLASTn analysis queries MobioSense™ COVID-19 Isothermal Nucleic Acid Diagnostic Kit primers were performed against other coronaviruses and human respiratory viruses in NCBI database. Result of the *in silico* analysis is shown in the following table. No cross-reactivity was observed.

Viral strains	Reference No.	<i>in silico</i> analysis for % identity					The likelihood of being detected
		Primer 1	Primer 2	Primer 3	Primer 4	Primer 5	
Human coronavirus OC43(HCoV-OC43)	AY391777.1	/	/	/	/	/	Will not be detected
Human coronavirus NL63(HCoV-NL63)	NC_005831.2	/	/	/	/	/	Will not be detected
Human coronavirus 229E(HCoV-229E)	NC_002645.1	/	/	/	/	/	Will not be detected
Influenza A	NC_002019.1	/	/	/	/	/	Will not be detected
Influenza B	NC_002208.1	/	/	/	/	/	Will not be detected

Cytomegalovirus	X17403.1	/	/	/	/	/	Will not be detected
Respiratory syncytial virus type B	JN032120.1	/	/	/	30.4%	/	Will not be detected
Human Rhinovirus A	DQ473509.1	/	/	/	/	/	Will not be detected
Measles	NC_001498.1	/	/	/	/	/	Will not be detected
SARS-CoV	NC_004718.3	/	/	/	34.8%	57.1%	Will not be detected
MERS-CoV	KT006149.2	/	/	/	/	/	Will not be detected
HCoV-HKU1	NC_006577.2	/	/	/	/	/	Will not be detected
Adenovirus type 1	AC_000017.1	/	/	/	/	/	Will not be detected
Adenovirus Type 7	AC_000018.1	/	/	/	/	/	Will not be detected
Enterovirus E Type 1	MG571548.1	/	/	/	/	/	Will not be detected
Epstein Barr Virus (Human herpesvirus 4)	NC_009334.1	/	/	/	/	/	Will not be detected
Human parainfluenza type1	NC_003461.1	/	/	/	/	/	Will not be detected
Human parainfluenza type2	AB176531.1	/	/	/	/	/	Will not be detected

Human parainfluenza type3	NC_001796.2	/	/	/	/	/	Will not be detected
Human parainfluenza type4a	KF878965.2	/	/	/	/	/	Will not be detected
Human parainfluenza type4b	EU627591.1	/	/	/	/	/	Will not be detected
Human metapneumovirus Isolate 00-1	AF371337.2	/	/	/	/	/	Will not be detected
Mumps Virus	NC_002200.1	/	/	/	/	/	Will not be detected
<i>Bordetella pertussis</i>	CP011448.1	/	/	/	/	/	Will not be detected
<i>Chlamydia pneumoniae</i>	NC_002491.1	/	/	/	/	/	Will not be detected
<i>Corynebacterium sp</i>	NZ_CP008913	/	/	/	/	/	Will not be detected
<i>Escherichia coli</i>	AE005174.2	/	/	/	/	/	Will not be detected
<i>Hemophilus influenzae</i>	CP000672.1	/	/	/	/	/	Will not be detected
<i>Lactobacillus sp</i>	CP027190.1	/	/	/	/	81.0%	Will not be detected
<i>Legionella spp</i>	CP020894.3	/	/	/	/	/	Will not be detected
<i>Moraxella catarrhalis</i>	CP018059.1	/	/	/	/	/	Will not be detected

<i>Mycobacterium tuberculosis (avirulent)</i>	AL123456.3	/	/	/	/	/	Will not be detected
<i>Mycoplasma pneumoniae</i>	CP014267.1	/	/	/	/	/	Will not be detected
<i>Neisseria meningitidis</i>	CP023814.1	/	/	/	/	/	Will not be detected
<i>Neisseria sp</i>	CP022527.1	/	/	/	/	/	Will not be detected
<i>Pseudomonas aeruginosa</i>	CP000438.1	/	84.2 %	/	/	/	Will not be detected
<i>Staphylococcus aureus (Protein A producer)</i>	AP017922.1	/	/	/	/	/	Will not be detected
<i>Streptococcus pneumoniae</i>	CP019299.1	/	/	/	/	/	Will not be detected
<i>Streptococcus pyogenes</i>	AE009949.1	/	/	38%	/	/	Will not be detected
<i>Streptococcus salivarius</i>	CP015282.1	/	/	/	/	71.4%	Will not be detected

**Evaluation Item**

**Specificity (Cross-reactivity test)** In vivo testing against Influenza A (H1N1), Influenza B, human coronavirus (OC43, NL63, 229E), respiratory syncytial virus (RSV), parainfluenza, adenovirus and rhinovirus were evaluated. Each virus was tested using synthetic replicates at a concentration of  $10^9$ pfu/mL. No detectable amplification curve (Ct) was observed after running for 30 min at 63°C, 64°C and 65°C.

SARS and MERS were also tested using synthetic replicates at concentration of  $10^9$ pfu/mL. No detectable amplification curve (Ct) was observed after running for 30 min at 63°C.

**Item**

**Clinical Evaluation (mimic clinical samples)** Clinical evaluation is based on 96 contrived samples from oropharyngeal swabs. Spiked samples were created by serial dilution (1x, 2x, 4x LoD, 20 each) of whole viral RNA spiked into a 96 QIAamp extracted clinical oropharyngeal matrix. Thirty-six samples were used as negative clinical samples.

SARS-CoV 2 Concentration	Results (Hit/Tested)	Concordance rate
1x LoD	19/20	95%
2x LoD	20/20	100%
4x LoD	20/20	100%
Negative	0/36	100%

**Evaluation Item**

**Clinical Evaluation (Real sample)** Clinical evaluation of the kit was conducted with contrived oropharyngeal swabs (5 positive and 5 negative). Clinical testing was performed after extraction by using the QIAamp viral RNA mini kit. The results obtained by using our kit and CDC RT QPCR are summarized in the following table.

Sample number	Age	Gender	Sample type	Clinical symptoms	RT-qPCR assay			MobioSense kit	
					Ct value			Ct (min)	Average estimated concentration*
					RdRp	E	N	ORF1a	(#GE/reaction)
1	20+	male	throat swab	Fever/Muscle pain	23.92	27.69	29.53	<b>7.38</b>	<b>1.14E+04</b>
2	20+	female	throat swab	Fever/Cough	32.33	29.45	34.09	<b>7.61</b>	<b>3.34E+03</b>
3	20+	male	nasopharyngeal swab	Fever/Muscle pain	30.07	26.27	31.3	<b>7.69</b>	<b>2.34E+03</b>
4	20+	male	nasopharyngeal swab	Dry Cough	31.5	29.28	31.69	<b>7.65</b>	<b>1.8E+03</b>
5	20+	female	nasopharyngeal swab	Fever/Cough	35.65	34.55	34.95	<b>9.00</b>	<b>3.0E+03</b>
6	20+	male	throat swab	Fever/Cough	-	-	-	-	-
7	30+	female	throat swab	Fever/Cough	-	-	-	-	-
8	20+	male	throat swab	Fever/Cough	-	-	-	-	-
9	20+	female	nasopharyngeal swab	Fever/Cough	-	-	-	-	-
10	20+	male	nasopharyngeal swab	Fever/Cough	-	-	-	-	-

### 13 Technical support

If you need technical support, please contact :

TEL : +886-2-25175455

E-mail : [contact@mobiosense.co](mailto:contact@mobiosense.co)

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