A Real-Time PCR (qPCR) Assay for Detection of 2019 Novel Coronavirus (COVID-19)

Instruction for Use
***ab*TES™ COVID-19 qPCR I Kit**
Kit Version: 1.1

REF 300142 (100 Reactions)

Store at -25 °C to -15 °C

AITbiotech Pte Ltd, 25 Pandan Crescent #05-15, TIC TECH Centre, Singapore 128477

EC REP EMERGO EUROPE, Prinsessegracht 20, 2514 AP The Hague, The Netherlands

For use on Bio-Rad CFX96, ABI7500/7500 FAST and *ab*CyclerQ Only

1. Pathogen Information

Coronavirus disease 2019 (COVID-19) is a disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)[4]. SARS-CoV-2 is a single-stranded, positive-sense RNA virus which is capable of person-to-person transmission. COVID-19 has spread to more than 20 countries within a month it was declared a pandemic on March 11, 2020[1]. It is genetically highly related to SARS and MERS coronaviruses[2].
So far, seven coronavirus species including COVID-19 are known to infect human. Four viruses, including 229E, OC43, NL63 and HKU1, typically cause a mild cold. However, people infected with the other three, including SARS, MERS and COVID-19, may develop acute and severe respiratory diseases, fever, cough and even death[3].

2. Test Description

The *ab*TES™ COVID-19 qPCR I Kit is a qualitative real-time polymerase chain reaction (qPCR) kit which enables simultaneous detection of two COVID-19- specific signature regions from its non-structure polypeptide (*orf1a*) in a single reaction. It also includes detection of human housekeeping gene, GAPDH, as an **Internal Control (IC)** to identify possible PCR inhibitions from sample processing.

The kit contains all the necessary PCR reagents for rapid, sensitive, and specific detection using target-specific primers and double-labelled hydrolysis probes. This kit has been validated on samples extracted from sputum, nasopharyngeal and throat swabs.

3. Storage Conditions

IMPORTANT!
- **Improper storage conditions may compromise product performance.**
- **Do not exceed three freeze-thaw cycles.**

The components of *ab*TES™ COVID-19 qPCR I Kit should be stored in the dark, between -25°C and -15°C in a **NON**-frost-free freezer. Frost-free freezers go through freeze-thaw cycles to remain frost-free and may cause accelerated degradation of enzymes and nucleic acids. Avoid repeated thawing and freezing (max 3 times) as this may lower the sensitivity. If reagents will be used intermittently, it is suggested to keep the reagents frozen in aliquots.

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(65) 6778 6822 • sales@aitbiotech.com • www.aitbiotech.com

4. Kit Components

Table 1. *ab*TES™ COVID-19 qPCR I Kit components.

Tubes	Components	Volume
1	2x RT-PCR Reaction Mix	1000 µL
2	RT/ *Taq* Enzyme Mix	100 µL
3	Primer/Probe Mix	200 µL
4	COVID-19 Positive Control	50 µL
5	Nuclease-free Water	450 µL

5. Materials and Devices Required but not Provided

- Appropriate Real-time thermal cycler
- Benchtop centrifuge with a rotor for 2 ml tubes
- Plate centrifuge, if using a 96-well plate
- Vortex mixer
- Disposable powder-free gloves
- Nucleic acid extraction kit
- Pipettes (adjustable) and pipette tips with filter (disposable)
- Desktop centrifuge with rotor
- 96-well PCR plates/ 0.1 mL (Bio-Rad CFX96 & ABI7500/7500 FAST)/0.2 mL (*ab*CyclerQ) optical PCR tube
- 96-well PCR plate optical sealing film/ optical qPCR cap
- Ice box/cooling block

6. General Precautions

- Proper aseptic technique should always be used.
- Always work in RNase-free environment.
- Do not exceed three freeze-thaw cycles.
- Do not use the kit after its expiration date.
- Improper storage conditions may compromise product performance.
- Wear disposable gloves, laboratory coats and eye protection when handling samples and reagents. Wash hands thoroughly thereafter.
- Highly recommended to use disposable pipette tips with filter.
- Always select the pipette with the lowest volume possible and the matching filter tip
- Always treat samples as biohazardous and infectious.
- Decontaminate and dispose of all potentially infectious materials in accordance with local and national regulation.

7. Contamination and Inhibition

- The presence of PCR inhibitors may lead to invalid or false-negative results
- If sample preparation system containing ethanol, make sure any traces of ethanol is eliminated. Ethanol is a strong qPCR inhibitor.
- Do not open reaction tubes/plates after amplification to avoid amplicon contamination.
- Store positive materials (specimens, controls, and amplicons) separately from all other reagents and add to the reaction mix in a separate facility.
- Use sterile pipette tips with filters and replace the tip for every procedure.
- Do not interchange tube as this may lead to cross-contamination.
- Laboratory area can be contaminated with amplicon or specimen if the waste materials are not carefully handled and disposed.

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8. Procedures

⚠ **IMPORTANT!**
- **Be sure read section 6 and 7 before use.**

8.1. Nucleic Acids (NA) Extraction

⚠ **IMPORTANT!**
- **If sample preparation system containing ethanol, make sure any traces of ethanol is eliminated. Ethanol is a strong qPCR inhibitor.**

This kit has been validated on samples extracted from sputum, nasopharyngeal and throat swabs only using NucliSENS® easyMAG® Total Nucleic Acid Extraction Kit, EZ1 Virus Kit and Liferiver RNA Isolation Kit.

Standard NA extraction kits are compatible with this assay but must be validated by the user. Please carry out NA extraction as per instructed in the manufacturer's extraction kit manual.

8.2. PCR Reaction Setup

⚠ **IMPORTANT!**
- **Only use extracted and purified specimen.**
- **Proper aseptic technique should always be used.**
- **Always work in RNase-free environment.**
- **Do not exceed three freeze-thaw cycles.**
- **Do not use the kit after its expiration date.**
- **Before starting an assay, thaw all the components thoroughly at room temperature except for RT/ *Taq* Enzyme Mix as it does not freeze at storage temperature.**
- **Always keep samples and components on the ice during use.**
- **When the components are thawed, mix the components and centrifuge briefly.**
- **Protect Primer/Probe Mix from light.**
- **Always include at least one positive and one negative controls on each run.**
- **Only 96-well PCR plate optical or ultra-clear sealing film/qPCR cap should be used for sealing.**
- **Run sample immediately after PCR reaction setup to prevent degradation of RNA samples.**
- **Always select the pipette with the lowest volume possible and the matching filter tip**
- **Draw up and dispense RT/ *Taq* Enzyme Mix slowly to avoid air bubbles.**
- **Remove excess RT/ *Taq* Enzyme Mix coated on the filter tip.**
- **Do not write on the caps or sealers as this interferes with qPCR detection.**

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Thoroughly thaw all components, mix, and spin briefly. Keep all components and samples on ice. Prepare your PCR reaction based on the following pipetting scheme:

Table 2. Sample reagent preparation calculation for one reaction.

Items	Volume/ rxn
2x RT-PCR Mix	10 µL
RT/ *Taq* Enzyme Mix	1 µL
Primer/Probe Mix	2 µL
Nuclease-free Water	2 µL
RNA Template*	5 µL
Total Volume	**20 µL**

RNA template: replace with 5 µL nuclease-free water for **Negative Ctrl*

Ensure all wells or tubes are tightly sealed. Mix the PCR reaction mix by pipetting up and down or flipping. Always centrifuge briefly to settle tube contents and eliminate large bubble.

8.3. Programming the Real-Time PCR System

*ab*TES™ COVID-19 qPCR I Kit was validated to be used with the following Real-time PCR system. You may need to adjust these conditions for other real-time platforms.

- Bio-Rad CFX96™ Real-Time PCR Detection System
- Applied Biosystems 7500/7500 FAST Real-Time PCR Systems
- *ab*CyclerQ Real-Time PCR System

⚠ **IMPORTANT!**
- **Real-time PCR system must be calibrated before used.**
- **Ensure the reporter dye and detector pairs are correct.**

For general setup and programming of the real-time PCR system, please refer to the respective user manual.
Choose the reporter dye and detector pairs based on Table 3.

Table 3. Reporter dye and detector pairs for COVID-19 qPCR I Kit.

Reporter dye	Detector
FAM	NS1
Texas Red	NS2
HEX/VIC	GAPDH

Set the appropriate PCR cycling condition and the fluorescence is measured at the annealing phase of each cycle.

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8.3.1. Bio-Rad CFX96™ Real-Time PCR Detection System

⚠ **IMPORTANT!**
- **Only use <u>0.1 mL</u> clear, DNA-, RNAse-, and PCR inhibitor-free 96-well plate/PCR tube.**

Table 4. PCR cycling condition for Bio-Rad CFX96™ Real-Time PCR Detection System.

Phase	Description	No. of Cycles	Temperature	Duration
1	cDNA synthesis	1	59 °C	10 min
2	Initial Denaturation	1	95 °C	2 min
3	Amplification	45	95 °C	10 sec
			*57.5 °C	15 sec

**Data acquisition at annealing phase*

8.3.2. Applied Biosystems 7500/7500 FAST Real-Time PCR Systems

⚠ **IMPORTANT!**
- **Only use <u>0.1 mL</u> clear, DNA-, RNAse-, and PCR inhibitor-free 96-well plate/PCR tube.**
- **The passive reference dye must be set <u>None.</u>**

Table 5. PCR cycling condition for Applied Biosystems 7500/7500 FAST Real-Time PCR Systems.

Phase	Description	No. of Cycles	Temperature	Duration
1	cDNA synthesis	1	59 °C	10 min
2	Initial Denaturation	1	95 °C	2 min
3	Amplification	45	95 °C	10 sec
			*57.5 °C	30 sec

**Data acquisition at annealing phase*

8.3.3. *ab*CyclerQ Real-Time PCR System

⚠ **IMPORTANT!**
- **Only use <u>0.2 mL</u> clear, DNA-, RNAse-, and PCR inhibitor-free 96-well plate/PCR tube.**

Table 6. PCR cycling condition for *ab*CyclerQ Real-Time PCR System.

Phase	Description	No. of Cycles	Temperature	Duration
1	cDNA synthesis	1	59 °C	10 min
2	Initial Denaturation	1	95 °C	2 min
3	Amplification	45	95 °C	10 sec
			*59 °C	15 sec

**Data acquisition at annealing phase*

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8.4. Data Analysis and Interpretation

⚠ **IMPORTANT!**

- ***ab*TES™ COVID-19 qPCR I Kit is function well if positive control generates sigmoid curve in both FAM and Texas Red channels.**

For general information regarding the data analysis of the real-time PCR system, please refer to the respective user manual. It is advisable to analyze the real time PCR graph at the end of the run to determine the validity of the Ct data.

Assessment of clinical specimen result must perform after positive and negative control are valid. The Ct cut-off value is 40, user must review the amplification curve before final assessment. The interpretation of result is shown in Table 7 and 8.

Table 7. Result interpretation for quality controls.

Quality Control	Observation		Interpretation
	NS1 (FAM)	NS2 (Texas Red)	
No template control	No amplification	No amplification	**Pass**; proceed to specimen analysis
Positive control	Sigmoid curve	Sigmoid curve	
No template control	Sigmoid curve	Sigmoid curve	**Fail**; rerun specimen with positive and negative controls
Positive control	No amplification	No amplification	
Positive control	**Either** NS1 **or** NS2 generates no amplification		

Table 8. Result interpretation for specimens.

Observation			Interpretation
NS1 (FAM)	NS2 (Texas Red)	GAPDH (HEX/VIC)	
Sigmoid curve and Ct value is <40	Sigmoid curve and Ct value is <40	Sigmoid curve	Positive
Sigmoid curve and Ct value is <40	Sigmoid curve with Ct >40 or no amplification	Sigmoid curve	Weak positive*
Sigmoid curve with Ct >40 or no amplification	Sigmoid curve and Ct value is <40	Sigmoid curve	Weak positive*
Sigmoid curve with Ct >40 or no amplification	Sigmoid curve with Ct >40 or no amplification	Sigmoid curve	Negative
Sigmoid curve with Ct >40 or no amplification	Sigmoid curve with Ct >40 or no amplification	No amplification	Invalid test; retest**

** Weak positive means low viral low*

*** First retest must re-extracting RNA from the same specimen. If same result is observed, recollect a new specimen, and repeat the retest.*

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9. Troubleshooting

Table 9. Example of unexpected observations on quality control.

Sample	Observation	Potential Cause	Solution
Positive control	Only NS1 or NS2 detected Neither NS1 nor NS2 detected Non-sigmoid curves	• Expired kit • Improper storage condition • Incorrect cycling condition • Improper PCR reaction setup • Faulty real-time PCR system • Sample assigned incorrectly	• Do not use expired kit • Store kit at -25°C and -15°C • Check and rerun with correct cycling condition • Refer section 8.2 for PCR reaction setup • Calibration of real-time PCR system • Ensure sample is assigned accordingly
	GAPDH is detected with typical sigmoid curve	• Contamination	• Repeat qPCR run and investigate the source of contamination (refer section 7).
No template control	NS1, NS2 and/or GAPDH detected	• Contamination from either extracted specimen and/or positive control • Sample assigned incorrectly	• Repeat qPCR run and investigate the source of contamination (refer section 7). • Ensure sample is assigned accordingly
Specimen	Both NS1 and NS2 are detected, but Ct values are vastly different and non-sigmoid curve Either NS1 or NS2 detected at early cycles but with non-Sigmoid curve (GAPDH is detected with typical sigmoid curve)	• Inhibitors present in specimens • Interference from specimens containing some impurities • Interference from substances present inside tubes/strips • Faulty real-time PCR system	• Re-test the specimens • Re-extract RNA to repeat test • If possible, re-collect specimens to extract fresh RNA to repeat test. Be cautious with proper sample collection, transportation, storage, and handling. • Try alternative kit to confirm result. • Calibration of real-time PCR system

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10. Performance Characteristics

10.1 Analytical Sensitivity

Analytical sensitivity (limit of detection) is defined as the lowest concentration at which the assay can detect with a positivity rate of at least 95%.

The analytical sensitivity of the assay was determined by analyzing serial dilutions of *in vitro transcribed* (IVT*)* RNA from 0.002 to 2000 copies/µl for NS1 and NS2. The testing was carried out in either five-replicates (for concentrations ≥10 copies/µl) or seven-replicates (for concentrations <10 copies/µl). The analytical sensitivity was estimated by Probit analysis using SPSS release 16.0.0.

The analytical sensitivities with 95% confidence for both NS1 and NS2 are shown in Tables 10-13.

Table 10. LoD confirmation on the Bio-Rad CFX96™ Real-Time PCR Detection System.

Target	**NS1**		**NS2**	
SARS-CoV-2 IVT RNA concentration	**2.2 copies/µl**		**1.8 copies/µl**	
Sample	**Pos/Neg**	**Ct (FAM)**	**Pos/Neg**	**Ct (Texas Red)**
1	Pos	36.83	Pos	36.30
2	Pos	36.42	Pos	36.86
3	Pos	35.38	Pos	37.55
4	Pos	35.61	Pos	36.52
5	Pos	37.46	Pos	36.19
6	Pos	35.40	Pos	36.13
7	Pos	34.40	Pos	35.49
8	Pos	36.48	Pos	37.35
9	Pos	37.54	Pos	37.32
10	Pos	35.57	Pos	36.24
11	Pos	35.79	Pos	35.74
12	Pos	34.49	Pos	37.05
13	Pos	37.80	Neg	36.06
14	Pos	35.85	Pos	36.81
15	Pos	36.41	Pos	35.29
16	Pos	35.68	Pos	35.42
17	Pos	36.51	Pos	35.28
18	Pos	36.50	Pos	37.28
19	Pos	34.67	Pos	35.26
20	Pos	35.34	Pos	35.02
Statistics	**Mean Ct**	**36.01**	**Mean Ct**	**36.26**
	SD	**0.96**	**SD**	**0.81**
	CV%	**2.69**	**CV%**	**2.23**
	Positive/Total	**20/20**	**Positive/Total**	**20/20**

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Table 11. LoD confirmation on the Applied Biosystems 7500/7500 FAST Real-Time PCR Systems.

Target	**NS1**		**NS2**	
SARS-CoV-2 IVT RNA concentration	**2.2 copies/µl**		**2.2 copies/µl**	
Sample	**Pos/Neg**	**Ct (FAM)**	**Pos/Neg**	**Ct (Texas Red)**
1	Pos	34.16	Pos	34.92
2	Pos	36.59	Pos	37.69
3	Pos	36.40	Pos	36.00
4	Pos	35.45	Pos	36.98
5	Pos	35.14	Pos	35.85
6	Pos	34.56	Pos	36.45
7	Pos	35.70	Pos	35.91
8	Pos	37.90	Pos	38.14
9	Pos	35.76	Pos	37.14
10	Pos	36.03	Pos	36.41
11	Pos	36.15	Pos	37.83
12	Pos	36.01	Pos	35.99
13	Pos	38.36	Neg	-
14	Pos	36.17	Pos	37.28
15	Pos	36.29	Pos	37.83
16	Pos	35.55	Pos	35.62
17	Pos	36.23	Pos	36.23
18	Pos	36.47	Pos	36.52
19	Pos	36.34	Pos	35.39
20	Pos	34.86	Pos	36.5
Statistics	**Mean Ct**	**36.01**	**Mean Ct**	**36.56**
	SD	**0.98**	**SD**	**0.90**
	CV%	**2.73**	**CV%**	**2.47**
	Positive/Total	**20/20**	**Positive/Total**	**19/20**

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Table 12. LoD confirmation on *ab*CyclerQ Real-Time PCR System.

Target	**NS1**		**NS2**	
SARS-CoV-2 IVT RNA concentration	**2.6 copies/µl**		**3.0 copies/µl**	
Sample	**Pos/Neg**	**Ct (FAM)**	**Pos/Neg**	**Ct (Texas Red)**
1	Pos	34.57	Pos	31.53
2	Pos	33.97	Pos	31.26
3	Pos	34.56	Pos	30.36
4	Pos	34.26	Pos	31.81
5	Pos	34.64	Pos	31.63
6	Pos	34.62	Pos	30.79
7	Pos	34.62	Pos	31.09
8	Pos	34.28	Pos	31.26
9	Pos	36.15	Pos	32.48
10	Pos	-	Pos	32.57
11	Pos	34.91	Pos	31.86
12	Pos	35.11	Pos	31.43
13	Pos	32.97	Neg	31.65
14	Pos	34.24	Pos	31.35
15	Pos	34.67	Pos	-
16	Pos	35.83	Pos	31.87
17	Pos	34.80	Pos	32.31
18	Pos	34.46	Pos	31.28
19	Pos	35.09	Pos	31.84
20	Pos	34.45	Pos	31.82
Statistics	**Mean Ct**	**34.64**	**Mean Ct**	**31.45**
	SD	**0.67**	**SD**	**0.55**
	CV%	**1.92**	**CV%**	**1.73**
	Positive/Total	**19/20**	**Positive/Total**	**19/20**

Table 13. Summary of LoD results.

Target	**Detection Channel**	**Real-Time PCR System**	**Analytical Sensitivity (95% confidence)**
NS1	FAM	Bio-Rad CFX96™	2.2 copies/µL
		Applied Biosystems 7500/7500 FAST	2.2 copies/µL
		*ab*CyclerQ	2.6 copies/µL
NS2	Texas Red	Bio-Rad CFX96™	1.8 copies/µL
		Applied Biosystems 7500/7500 FAST	2.2 copies/µL
		*ab*CyclerQ	3.0 copies/µL

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10.2. Analytical Specificity

10.2.1. Inclusivity

The inclusivity of *ab*TES™ COVID-19 qPCR I Kit was evaluated by in silico analysis against 8,494 high-quality complete genome sequences of SARS-CoV-2 published via GISAID (www.gisaid.org) as of April 17, 2020. It turned out that the primers/probes of the kit show homology from 99.71-99.99% as shown in Table 14.

Table 14. Results of the in silico inclusivity analysis.

Primers/probes	Homology
NS1 forward primer	8488/8494=99.93%
NS1 reverse primer	8469/8494=99.71%
NS1 probe (FAM)	8480/8494=99.84%
NS2 forward primer	8493/8494=99.99%
NS2 reverse primer	8488/8494=99.93%
NS2 probe (TxR)	8487/8494=99.92%

10.2.2. Cross-reactivity

The *ab*TES™ COVID-19 qPCR I Kit was tested for potential cross-reactivity against other coronaviruses and some common respiratory infectious pathogens, as listed in Table 15. No cross-reactivity was observed.

Table 15. Organisms that were tested for cross-reactivity.

Organism	Result
MERS Coronavirus	Not Detected
Coronavirus 229E	Not Detected
Coronavirus NL63	Not Detected
Coronavirus OC43	Not Detected
Influenza A	Not Detected
Influenza B	Not Detected
Respiratory Syncytial virus A	Not Detected
Respiratory Syncytial virus B	Not Detected

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10.3. Precision/Reproducibility

The inter-assay (variability between different runs) and intra-assay (variability within one run) precision was determined by performing the assay once per day in five-replicates over a period of two days for one sample (two targets: NS1 and NS2) of different concentrations (total ≥10 reactions per target).

For both targets, the qualitative results of all ten reactions were 100% reproducible. The coefficient of variation (CV) of the cycle threshold (Ct) for the intra- and inter-assay precision are shown in Table 16 and 17.

Table 16. Inter-assay precision data showing standard deviation and CV% (calculated from Ct values) at each concentration.

Target	IVT RNA Concentration	2000 copies/µl	200 copies/µl	20 copies/µl	10 copies/µl	5 copies/µl	1.6 copies/µl
NS1	SD	0.12	0.20	0.16	0.32	0.42	0.55
	CV%	0.5%	0.7%	0.5%	1.0%	1.2%	1.6%
NS2	SD	0.08	0.18	0.27	0.37	0.53	0.82
	CV%	0.3%	0.6%	0.9%	1.1%	1.6%	2.3%

Table 17. Intra-assay precision data showing standard deviation and CV% (calculated from Ct values) at each concentration.

Target	IVT RNA Concentration	2000 copies/µl	200 copies/µl	20 copies/µl	10 copies/µl	5 copies/µl	1.6 copies/µl
NS1	SD	0.12	0.17	0.13	0.17	0.42	0.66
	CV%	0.5%	0.7%	0.5%	0.4%	1.3%	1.5%
NS2	SD	0.08	0.20	0.27	0.42	0.40	0.77
	CV%	0.3%	0.7%	0.9%	1.1%	1.6%	2.2%

10.4. Diagnostic Evaluation

To predict the diagnostic evaluation of *ab*TES™ COVID-19 qPCR I Kit at the 95% confidence interval, a total of 112 clinically extracted samples used. The positive samples used in the study are from confirmed COVID-19 cases. This kit has been tested on samples extracted from sputum, nasopharyngeal and oropharyngeal swabs.

The nucleic acids (RNA) were extracted using a commercially available kit such as NucliSENS® easyMAG® Total Nucleic Acid Extraction Kit, EZ1 Virus Kit and Liferiver RNA Isolation Kit. The extracted specimens were tested by the WHO recommended protocol as a reference test.

Table 18. Summary of the result of diagnostic sensitivity and specificity for COVID-19 as below.

Description	*ab*TES™ COVID-19 qPCR I Kit (*n*=112)		Sensitivity/ Specificity
	COVID-19 Positive	COVID-19 Negative	% (95% Confidence Internal)
COVID-19 Positive	65	2*	97 % sensitivity
COVID-19 Negative	0	45	100 % specificity
Total	65	47	

**The Ct values of these two specimens in its original runs was very high, implying the virus load was very low and reported as negative in this evaluation. Moreover, the RNA samples have since then been freeze/thawed repeatedly, possibly causing degradation.*

In summary, abTES™ COVID-19 qPCR I Kit showed 97 % sensitivity and 100% specificity.

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11. Limitations

- The use of this product and its data interpretation is intended for personnel trained in real-time PCR techniques and *in vitro* diagnostics procedures only.
- Appropriate specimen collection, transport, storage, and nucleic acid extraction procedures are required for reliable results.
- As SARS-CoV-2 will mutate over time, and potential mutations will likely occur within the primer/probe regions. These regions are actively monitored against the sequence database available at NCBI and GISAID.

12. Explanation of Symbols

Symbol	Explanation
IVD	*In vitro* diagnostic medical device. *abTES™ COVID-19 qPCR I Kit has received Provisional Authorization from the Health Sciences Authority in Singapore.*
REF	Catalogue number
-25°C -15°C	Store at -25°C to -15°C
	Manufacturer
EC REP	Authorized Representative in the European community
LOT	Lot number
	Use by
Σ	Contains sufficient for <n> tests
	Important

13. References

1. (2020) Coronavirus disease (COVID-19) Pandemic. [Online] WHO. [Accessed 20 April 2020].
2. (2020) 2019 Novel Coronavirus (2019-nCoV), Wuhan, China. [Online] US Centers for Disease Control and Prevention. [Accessed 27 Jan 2020].
3. Zhu N, Zhang D, Wang W, Li X, Yang B et al. A Novel Coronavirus from Patients with Pneumonia in China, 2019. N Engl J Med. 2020; 1-7.
4. (2020) Naming the coronavirus disease (COVID-19) and the virus that causes it [Online] WHO. [Accessed 8 May 2020].

Electronic copy of product insert Soft can be downloaded online from http://aitbiotech.com/covid-19/

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