EN REF PRDICOV-01

Prime CovidDetect Rapid Detection Kit

SARS-CoV-2 (Severe acute respiratory syndrome coronavirus-2) RT-LAMP Kit

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

PRIME DISCOVERIES

EXPLANATION AND SUMMARY

■ Introduction

Acute respiratory infection can be caused by a variety of viruses and bacteria, including SARS-CoV-2 recently introduced. Acute respiratory infection of SARS- 8. CoV-2 outbreak in Wuhan, China has widely spread out into the world since 2019. Common signs of a person infected with SARS-CoV-2 include respiratory symptoms, fever, cough, shortness of breath, and dyspnea. In more severe cases, the infection generates pneumonia, acute respiratory syndrome, kidney failure, or even death. This kit is supportive for the diagnosis of SARS-CoV-2 infection. The tests results are only for clinical reference and cannot be used as a basis for confirming or excluding cases by itself.

■ Intended Use

The Prime CovidDetect Rapid Detection Kit is a reverse transcriptase loop-mediated isothermal amplification (RT-LAMP) assay intended for the qualitative detection of nucleic acid from SARS-CoV-2 in upper respiratory specimens including oropharyngeal and nasopharyngeal swabs, anterior nasal and mid-turbinate nasal swabs, nasopharyngeal washes/aspirates or nasal aspirates as well as bronchoalveolar lavage (BAL) from individuals suspected of COVID-19 by their healthcare provider. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests, or by similarly qualified non-U.S. laboratories.

Results are for the identification of SARS-CoV-2 RNA. SARS-CoV-2 RNA is generally detectable in upper respiratory specimens including oropharyngeal and nasopharyngeal swabs, anterior nasal and mid- turbinate nasal swabs, nasopharyngeal washes/aspirates or nasal aspirates as well as bronchoalveolar lavage (BAL) 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 the disease.

The Prime CovidDetect Rapid Detection Kit is intended for use by qualified and trained clinical laboratory personnel specifically instructed and trained in the molecular biology techniques of real-time PCR/LAMP and in vitro diagnostic procedures.

■ Principle of the Procedure

Prime CovidDetect Rapid Detection Kit is designed according to "WHO interim guidance for laboratory testing for 2019 novel coronavirus (2019-nCoV) in humans" for SARS-CoV-2.

The Prime CovidDetect Rapid Detection Kit uses six LAMP primers for each target genes (ORF1, N, E) for the detection of SARS-CoV-2 RNA, and six LAMP primers for the detection of the human endogenous control 18S RNA (18S ribosomal RNA). The assay features a provided green, fluorescent dye, to be used for each reaction together with the reaction mix.

Both reverse transcription and LAMP reactions take place at 65 °C using an enzyme mixture of reverse transcriptase and Bst (Bacillus Stearothermophilus) DNA polymerase. The LAMP primers are target- specific oligonucleotides, and the intercalating fluorescent dye emits fluorescence detectable in the FAM channel (emission at 520 ±10 nm). The emission signal can be detected by fluorescence readers in RT- PCR systems or plate readers

The increase in fluorescence can be detected without manipulation of the product or opening the reaction tube and can be monitored by the fluorescence reader

Target	Channel
SARS-CoV-2 N/E/ORF1 gene	FAM
Internal control	FAM

KIT CONTENTS

No.	Contents	Quantity	Dosage in each reaction
1	Covid Enzyme Mix	1200 µℓ / vial	4.0 µℓ
2	Primers Mix (Assay)	150 µℓ / vial	0.5 µℓ
3	Primers Mix(Control)	150 µℓ / vial	0.5 µℓ
4	Fluorescent Dye	75 µℓ / vial	0.25 µℓ
5	Positive Control	50 µℓ / vial	-
6	Negative Control	50 µℓ / vial	-
7	Nuclease Free Water	1000 µℓ / vial	-

Instruments for the Kit

ABI 7500 / QuantStudio 3, QuantStudio 5, QuantStudio 6, QuantStudio 7

Materials Required but not Provided

- Micropipette and tip
- PPE (Personal Protective Equipment
- Biohazard Container
- Sample collection tube – Mawi iSWAB-EL Collection Tube (ISM-T-NEL)
- Centrifuge
- PCR Reaction tube
- Vortex Mixer

KIT STORAGE AND STABILITY

All reagents, except for the nuclease free water, are to be stored at -20°C away from UV/sunlight and only thawed when ready to process samples.

The reagents will be shipped frozen in dry ice. If the reagents arrive thawed or not fully frozen, and/or show any abnormality, please contact the manufacturer immediately.

WARNINGS AND PRECAUTIONS

- This kit is only for in vitro diagnosis.
- Please read the product manual carefully before testing
- All instruments used in the experiment should be sterilized
- Improper specimen collection, transfer, storage, and processing may cause errors.

Clinical laboratories should be equipped with equipment and operators in strict accordance with the "Code of Practice for Clinical Gene Amplification. Laboratories." When using this kit, it should be operated strictly in accordance with the instructions; the specimen processing and specimen addition steps must be performed in a biological safety cabinet or other basic protective facilities, and follow the technical requirements of the clinical gene amplification laboratory.

Follow standard precautions. All patient specimens should be considered potentially infectious and handled accordingly. False positive and false negative results can be caused by poor specimen quality, improper specimen collection, improper transportation, improper laboratory processing, or a limitation of the testing technology. The operator should understand the principles of the procedures, including its performance limitations, in advance of operation to avoid potential mistakes. All materials used in one area should remain in that area and should not be moved or used in other areas. After the assay procedures, the workbench and lab supplies should be cleaned and disinfected immediately.

All contents in this package are prepared and validated for the intended testing purpose. Replacement of any of the package contents will affect the testing performance of the kit. Components contained within a kit are intended to be used together. Do not mix components from different kit lots. Prior to beginning each assay, each component must be thoroughly thawed and briefly centrifuged. Avoid repeated freeze-thaw cycles.

Avoid exposure to light of the enzyme mix and primer mix.

SPECIMEN COLLECTION AND PREPARATION

■ Nasopharyngeal swab

- Hold the nasopharyngeal swab close to the nasal septum slowly and deeply to the back of the nasopharynx.
- Rotate it several times to obtain secretions.
- Quickly dip the swab into the specimen collection tube, and discard the tail.
- Tighten the tube cap to seal in case of drying.
- The swab specimens to be tested can be stored for 1 day at room temperature, 4 days at 2-8°C (35.6-46.4°F), and long-term storage below -20°C (-4°F).

■ Oropharyngeal swab

- Use moderate swab to wipe the posterior wall of the pharynx and the tonsils
- on both sides avoiding touching the tongue.
- Quickly dip the swab into the specimen collection tube, and discard the tail.
- Tighten the tube cap to seal in case of drying.
- The swab specimens to be tested can be stored for 1 day at room temperature,
- 4 days at 2-8°C (35.6-46.4°F), and long-term storage below -20°C (-4°F).

■ Anterior nasal swab

- Insert the entire soft end of the swab into the nostril no more than 3⁄4 of an inch (1.5 cm) into the nose. Slowly rotate the swab, gently pressing against the inside of the nostril at least 4 times for a total of 15 seconds. Get as much nasal discharge as possible on the soft end of the swab. Gently remove the swab. Using the same swab, repeat steps 4–6 in the other nostril with the same end of the swab.
- Quickly dip the swab into the specimen collection tube, and discard the tail.
- Tighten the tube cap to seal in case of drying.
- The swab specimens to be tested can be stored for 1 day at room temperature,
- 4 days at 2-8°C (35.6-46.4°F), and long-term storage below -20°C (-4°F).

■ Mid-turbinate nasal swab

- Tilt patient's head back 70 degrees.
- Use a flocked tapered swab. While gently rotating the swab, insert it less than one inch (about 2 cm) into nostril parallel to the palate until resistance is met at turbinates. Rotate the swab several times against nasal wall.
- Remove swab, insert it into the other nostril and repeat the process.
- Quickly dip the swab into the specimen collection tube, and discard the tail.
- Tighten the tube cap to seal in case of drying.
- The swab specimens to be tested can be stored for 1 day at room temperature,
- 4 days at 2-8°C (35.6-46.4°F), and long-term storage below -20°C (-4°F).

ASSAY PROTOCOL

■ Control Materials

A"no template" (negative) control (NC):
Needed to assure there is no cross-contamination and is used to establish a no reaction baseline for the control and the target and is made once per plate. It contains nuclease-free water.

The internal control (18S RNA):
Needed to verify the presence of nucleic acid material, test accuracy, performance of the assay, and it should be included in each replicate.

Two positive controls:
The two positive controls (PC) are needed to verify that the assay run is performing as intended and are used once per plate to confirm the proper reaction mix performance and therefore, the successful detection of both target gene (N) and control gene (18S RNA).

■ Reagent Preparation

Prepare the master mix (according to the table below) which contains the oligonucleotide primers targeting the conserved regions of the Sars-CoV-2 (Orf1, E1, N2) or the control sequence (18S RNA), fluorescent dye, enzyme, and nuclease free water. Prepare the master mix based on the estimated number of 2 * N reactions (N Samples) for the Assay Mix (ORF1, E, N) and 2 * N reactions for the control (18S RNA). Pipette 5 µL of master mixture into each well of a 96 or 384-well plate. Cover and transfer the plate into a sample processing area.

Important: 3 Batch Controls should be processed in each batch to ensure reliable results.

Table: Master Mixture Preparation

	Volume Per Reaction in Microliters	Volumes for N patient samples in Microliters (2 rxns for Assay)	Volumes for N patient samples in Microliters (2 rxns for Assay)	Volumes for N patient samples in Microliters (2 rxns for Control)
1	Covid Enzyme Mix	4.0	4.00*(2*(N+3))	4.00*(2*(N+3))
2	Primers Mix (Assay) 20X	0.5	0.50*(2*(N+3))	-
3	Primers Mix (Control) 20X	0.5	-	0.50*(2*(N+3))
4	Fluorescent Dye	0.25	0.25*(2*(N+3))	0.25*(2*(N+3))
5	Nuclease free water	0.25	0.25*(2*(N+3))	0.25*(2*(N+3))

■ RT-LAMP Amplification

- Take 5 µℓ of each of the negative control, patient sample, and positive control, add them to the LAMP mixture dispensed reaction wells.
- Centrifuge at low speed for a few seconds, and place them on the real-time fluorescence quantitative PCR instrument.
- Set the cycle condition below on the PCR instrument for the NA amplification.

Reaction	Temp. (°C)	Time	Cycles
Amplification	65°C	30 seconds	50
	Collect the signals (FAM)		

■ Interpretation of Results

Open the experiment data with the analysis software and perform the Ct analysis according to the instrument manual. An Assay is positive, if Ct value is below cycle 80. See the table below for the result interpretation.

SARS-CoV-2 (ORF1, E, N)	18S RNA	Interpretation
Positive 2/2 Replicates	Positive 2/2 Replicates	SARS-CoV-2 Detected
Negative 2/2 Replicates	Positive 2/2 Replicates	SARS-CoV-2 Non Detected
Negative 2/2 Replicates	Negative 2/2	Failed
Positive or Negative 1/2 Replicates	Positive or Negative ½ Replicates	Inconclusive

Table: Common troubleshooting scenarios

Problems	Possible Causes	Action
No fluorescent signal is detected in any samples, including positive control	Error in the preparation of the master mixture	Ensure the volumes of reagent dispensed during preparation of the master mixture are correct
	Primer degradation	Use a new primer aliquot
	Omitted components	Verify each component and repeat the PCR mixture preparation
	Instrument settings error	Verify the instrument settings are correct
Negative 2/2 Replicates	Carry-over contamination	Change tips between samples, clean pipettes, and use filter tips
	Tube cap not properly sealed	Ensure plates are sealed correctly
	Contamination of the master mixture	Prepare a new master mix and retest samples with RT-LAMP
	Contamination of the preparation area	Clean surfaces and instruments with aqueous detergents, wash lab coats, and replace test tubes and tips in use
Negative 2/2 Replicates	Poor quality of RNA samples	Repeat samples from RT-LAMP
	Not enough volume of RNA samples added	Repeat samples from RT-LAMP
	Pipetting error	Repeat samples from RT-LAMP
Positive or Negative 1/2 Replicates	Contamination in the outer surface of PCR tubes and plate	Repeat samples from RT-LAMP
	Bubbles in wells	Repeat samples from RT-LAMP

NON-CLINICAL PERFORMANCE EVALUATION

The limit of detection (LoD) is defined as the lowest concentration at which approximately 95% of true positive replicates are detected. A preliminary LoD was determined by testing 16 dilution series of 6 replicates per concentration (100,000 copies/ul to 0.1 copies/ul) of quantified heat inactivated SARS-CoV-2 virus (ATCC #VR-1986HK) spiked into real clinical matrix (nasopharyngeal swabs from 10 negative samples collected in Mawi's Buffer cat#ISM-T-NEL). The lowest concentration that gave positive results 100% of the time was defined as preliminary LoD. The preliminary LoD was determined at 80 copies/ µL.

The final LoD concentration was confirmed by testing 24 individual replicates at the preliminary LoD as previously described. LoD was defined as the lowest concentration at which more than 95% of replicates were positive. Replicates were called negative if no amplification was detected before cycle 80 of the LAMP reaction. The LoD determination of the Prime COVID-19 Extractionless High Throughput Kit was 80 copies/ µL, which was the lowest concentration of SARS-CoV-2 at which ≥ 95% of replicates were detected.

Table: Limit of Detection of the Prime Discoveries Kit assessed with QuantStudio 5.

Concentration Copies/ul in Primary Samples	ORF1/E/N - (Replicates detected)
1,000	24/24 (100%)
100	24/24 (100%)
80	24/24 (100%)
70	12/24 (91.7%)
50	19/24 (79.1%)
10	11/24 (41.7%)

CROSS REACTIVITY TEST

This study is designed to verify whether cross-reactivity substances have an impact on the performance of Prime CovidDetect Rapid Detection kit or not. Test is performed in 3 replicates for each organism. Prime CovidDetect Rapid Detection Kit did not show any cross-reactivity with related organisms please see table below

Table: Cross-Reactivity/Exclusivity Wet Testing

Organism	Strain	Provider	Catalog #	ORF1/N/E-gene Detected Replicates
Adenovirus 11	Slobitski	ATCC	VR-12	0/3
Adenovirus 5	Adenoid 75	ATCC	VR-5	0/3
Bordetella pertussis	18323 [NCTC 10739]	ATCC	9797	0/3
Candida albicans	NIH 3172	ATCC	14053	0/3
Chlamydophila pneumoniae	TWAR strain 2023	ATCC	VR-1356	0/3
Candida albicans	NIH 3172	ATCC	14053	0/3
Chlamydia pneumoniae	TWAR strain 2023	ATCC	VR-1356	0/3
Enterovirus 70	J670/71	ATCC	VR-836	0/3
Haemophilus influenzae	NCTC 8143	ATCC	33391	0/3
Human parainfluenza virus 4b	CH 19503	ATCC	VR-1377	0/3
Human respiratory syncytial virus	A2	ATCC	VR-1540P	0/3
Human rhinovirus 61	6669-CV39 [V-152-002-021]	ATCC	VR-1171	0/3
Mycobacterium tuberculosis	H37Ra	ATCC	25177	0/3
Mycoplasma pneumoniae	Somerson et al. FH strain of Eaton Agent [NCTC 10119]	ATCC	15531	0/3
Pseudomonas aeruginosa	(Schroeter) Migula (ATCC® 10145™) - [CCEB 481, MDB strain BU 277, NCIB 8295, NCPPB 1965, NCTC 10332, NRRL B-771, R. Hugh 815]	ATCC	10145	0/3
Staphylococcus epidermidis	AmMS 205	ATCC	49134	0/3
Streptococcus pneumoniae	Mu50 [NRS1]	ATCC	700699	0/3

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Table: Cross-Reactivity/Exclusivity Wet Testing (continued)

Organism	Strain	Provider	Catalog #	ORF1/N/E-gene Detected Replicates
Streptococcus pyogenes	Rosenbach (ATCC® 49399™ - QC A62)	ATCC	49399	0/3
Streptococcus salivarius	B2	ATCC	9759	0/3
Human coronavirus		BEI	NL63	0/3
Human coronavirus		BEI	229E	0/3
Human coronavirus, Middle East Respiratory Syndrome Coronavirus (MERS-CoV),	EMC/2012	BEI	NR-50549	0/3
SARS Coronavirus		BEI	NR-3882	0/3
SARS-Related Coronavirus 2		BEI	NR-52286	0/3
A. baumannii	307-0294	ZeptoMetrix	NATPPQ-BIO	0/3
Adenovirus Type 3		ZeptoMetrix	NATRVP-1	0/3
Adenovirus Type 3		ZeptoMetrix	NATPPA-BIO	0/3
Adenovirus Type 31		ZeptoMetrix	NATPPA-BIO	0/3
C. pneumoniae	CWL-029	ZeptoMetrix	NATPPA-BIO	0/3
Coronavirus	229E	ZeptoMetrix	NATRVP-1	0/3
Coronavirus	NL63	ZeptoMetrix	NATPPA-BIO	0/3
Coronavirus	OC43	ZeptoMetrix	NATRVP-1	0/3
Coronavirus	SARS	ZeptoMetrix	NATRVP-1	0/3
E. cloacae	Z101	ZeptoMetrix	NATPPQ-BIO	0/3
E. coli	Z297	ZeptoMetrix	NATPPQ-BIO	0/3
Enterovirus		ZeptoMetrix	NATRVP-1	0/3
H. influenzae	MinnA	ZeptoMetrix	NATPPQ-BIO	0/3
Human Metapneumovirus		ZeptoMetrix	NATRVP-1	0/3
Influenza A	H1	ZeptoMetrix	NATRVP-1	0/3
Influenza A	H1N1 (2009)	ZeptoMetrix	NATRVP-1	0/3
Influenza A	H3	ZeptoMetrix	NNATRVP-1	0/3
Influenza A	H3 A/ Brisbane/10/07	ZeptoMetrix	NATPPA-BIO	0/3
Influenza B		ZeptoMetrix	NATRVP-1	0/3
Influenza B	B/Florida/02/06	ZeptoMetrix	NATPPA-BIO	0/3
K. aerogenes	Z052	ZeptoMetrix	NATPPQ-BIO	0/3
K. oxytoca	Z115	ZeptoMetrix	NATPPQ-BIO	0/3
K. pneumoniae	KPC2	ZeptoMetrix	NATPPQ-BIO	0/3
K. pneumoniae	Z138; OXA-48	ZeptoMetrix	NATPPQ-BIO	0/3
K. pneumoniae	Z460; NDM-1	ZeptoMetrix	NATPPQ-BIO	0/3
L. pneumophila	Philadelphia	ZeptoMetrix	NATPPA-BIO	0/3
M. catarrhalis	Ne 11	ZeptoMetrix	NATPPQ-BIO	0/3
M. pneumoniae	M129	ZeptoMetrix	NATPPA-BIO	0/3
Metapneumovirus	8 PERU6-2003	ZeptoMetrix	NATPPA-BIO	0/3
P. aeruginosa	Z139, VIM-1	ZeptoMetrix	NATPPQ-BIO	0/3
P. mirabilis	Z050	ZeptoMetrix	NATPPQ-BIO	0/3
Parainfluenza virus Type 1		ZeptoMetrix	NATPPA-BIO	0/3
Parainfluenza virus Type 1		ZeptoMetrix	NATRVP-1	0/3
Parainfluenza virus Type 2		ZeptoMetrix	NATRVP-1	0/3
Parainfluenza virus Type 3		ZeptoMetrix	NATRVP-1	0/3
Respiratory Syncytial Virus A		ZeptoMetrix	NATRVP-1	0/3
Respiratory Syncytial Virus B		ZeptoMetrix	NATRVP-1	0/3
Rhinovirus 1A		ZeptoMetrix	NATRVP-1	0/3
Rhinovirus 1A		ZeptoMetrix	NATPPA-BIO	0/3
RSV A2		ZeptoMetrix	NATPPA-BIO	0/3
S. agalactiae	Z019	ZeptoMetrix	NATPPQ-BIO	0/3
COL	COL	ZeptoMetrix	NATPPQ-BIO	0/3
S. marcescens	Z053	ZeptoMetrix	NATPPQ-BIO	0/3
S. pneumoniae	Z022	ZeptoMetrix	NATPPQ-BIO	0/3
S. pyogenes	Z018	ZeptoMetrix	NATPPQ-BIO	0/3

INTERFERENCE TEST

Interfering substances which could be found in respiratory samples endogenously or exogenously were tested to evaluate the extent, if any, of potential assay inhibition. Baseline anterior nasal swabs were collected in triplicate from study volunteers as negative control samples (without potential interfering substance). The study volunteers then used the interfering substances as recommended by the manufacturer of the substance which should represent the relevant dose.

Immediately after the substances were used, anterior nasal swabs were collected in triplicate and spiked with viral heat inactivated SARS-CoV-2 (ATCC #VR-1986HK) at 5X LoD. 100 µL of whole blood and mucin were separately added into negative clinical matrix in triplicate and then spiked at 5X LoD. The negative swabs that did not contain potentially interfering substances were also spiked with viral heat inactivated SARS-CoV-2 at 5X LoD. None of the tested substances inhibited or interfered with the performance of the Prime COVID-19 High Throughput Assay. Swabs both with and without the interfering substance yielded expected results

Table: Endogeneous and Exogenous Substances Evaluated for Potential Assay Interference

Substance	Active Ingredient	Concentration	% Agreement with Expected Results
Whole Blood	N/A	5X LoD	100% (3/3)
		Negative	100% (3/3)
Mucin	N/A	5X LoD	100% (3/3)
		Negative	100% (3/3)
Tobacco	Nicotine, Tar, Carbon Monoxide, Formaldehyde, Ammonia, Hydrogen Cyanide, Arsenic, and DDT	5X LoD	100% (3/3)
		Negative	100% (3/3)

CLINICAL EVALUATION

A total of 238 patient samples were processed through the Prime CovidDetect Rapid Detection Kit and compared with RT-qPCR results. The cohort of tested samples included 238 nasopharyngeal swabs (105 positives and 133 negatives). All results generated by the Prime CovidDetect Rapid Detection Kit were concordant with the RT-qPCR results.

Table: Performance of Nasopharyngeal Swabs when Compared to a RT-qPCR Assay.

Nasopharyngeal Swabs		Comparator – EUA Authorized Assays		
		Positive	Negative	Total
Prime COVID-19 High Throughput Assay Result	Positive	105	0	105
	Negative	0	133	133
	Total	105	133	238
Positive Percent Agreement		100% (105/105); 97.14% - 100.00%*		
Negative Percent Agreement		100% (133/133); 97.74% - 100.00%*		

*95% confidence interval. Jovanovic B. D, & Levy, P.S. (1997). A Look at the Rule of Three. The American Statistician, 51(2), 137-139.

QUALITY CONTROL

A negative control and a positive control should be set for each test. The control results should meet the requirements of the following table, otherwise the test is invalid. Check the instrument, reagents and amplification conditions for errors and repeat the experiment.

Table: Data interpretation for quality control validation

Control Type	RT-LAMP		End-Point Fluorescence	
	ORF1, E, N (FAM channel)	18S RNA (FAM channel)	ORF1, E, N (FAM channel)	18S RNA (FAM channel)
Negative	Non-detected or detection ≥ 80 cycles	Non-detected or detection ≥ 80 cycles	Non-detected or detection ≤ 2-fold increase in background fluorescence	Non-detected or detection ≤ 2-fold increase in background fluorescence
Positive	Detection ≤ 80 cycles Positive control for SARS-CoV-2	Detection ≤ 80 cycles Positive control for 18S RNA	Detection ≥ 2-fold increase in background fluorescence Positive control for 18S RNA	Detection ≥ 2-fold increase in background fluorescence Positive control for 18S RNA

LIMITATIONS OF THE KIT PROTOCOLS

- Qualitative detection of positive results in this kit does not indicate the presence of live virus. It is recommended to use other methods for confirmation at the same time.
- This kit only classifies and identifies the SARS-CoV-2, The test results are for clinical reference only. The clinical diagnosis and treatment of patients should be combined with their symptoms, signs, medical history, other laboratory tests and treatment responses considering.
- Although the kit was designed to select relatively conservative fragments for amplification and detection, in theory, it is still not possible to completely avoid missed detection of coronavirus types that may have rare mutations in the conserved regions.

SYMBOLS

Please see symbols used below

REF	Reference number		Consult Instructions for use
LOT	Batch code	IVD	In vitro diagnostic medical device
	Manufacturer		Date of manufacture
	Contains Sufficient for <n> Tests		Temperature limit
	Use-by date		Note
CE	Fulfill the requirements of Directive 98/79/EC on in vitro diagnostic medical devices	EC REP	Authorized representative in the European Community

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