STANDARD M10 SARS-CoV-2

STANDARD™ M10 SARS-CoV-2

REF M-NCOV-03

INSTRUCTIONS FOR USE

For use with STANDARD™ M10 system

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SD BIOSENSOR

Contents

1. Intended Use

The STANDARD M10 SARS-CoV-2 test is a multiplex real-time RT-PCR test intended for use with STANDARD M10 system for the qualitative detection of nucleic acids from SARS-CoV-2 in nasopharyngeal swab collected from individuals suspected of COVID-19 by their healthcare provider.

Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The STANDARD M10 SARS-CoV-2 test is intended to be performed by trained users in both laboratory and near patient testing settings.

2. Summary and Explanation

Acute respiratory infection can be caused by a variety of viruses and bacteria, including recently introduced SARS-CoV-2. Acute respiratory infection of SARS-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 test results are only for clinical reference and cannot be used as a basis for confirming or excluding cases by itself.

The STANDARD M10 SARS-CoV-2 test is a molecular *in vitro* diagnostic test that aids in the detection and diagnosis of SARS-CoV-2 and is based on widely used nucleic acid amplification technology. The STANDARD M10 SARS-CoV-2 test contains primers and probes and internal control (IC) used in RT-PCR for the *in vitro* qualitative detection of SARS-CoV-2 RNA in nasopharyngeal swab specimens.

[Cartridge Description]

The STANDARD M10 SARS-CoV-2 cartridge is a disposable plastic device that allows performance of fully automated molecular assays by containing all reagents required for the test.

Within the cartridge, multiple steps are automatically performed in sequence using pneumatic pressure to transfer samples and fluids via the chamber to their intended destinations.

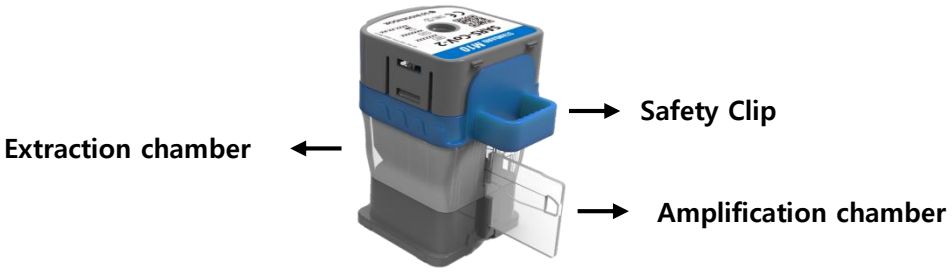

Figure 1. Layout of the STANDARD M10 SARS-CoV-2 cartridge

3. Principle of the Procedure

The STANDARD M10 SARS-CoV-2 test is an automated *in vitro* diagnostic test for qualitative detection of nucleic acid from SARS-CoV-2. The STANDARD M10 SARS-CoV-2 test is performed on STANDARD M10 system.

The STANDARD M10 system automates and integrates sample preparation, nucleic acid extraction reverse transcription polymerase chain reaction (RT-PCR) and detection of the target sequences in various specimens using molecular diagnostic assays. The system consists of the STANDARD M10 Module and the STANDARD M10 Console with preloaded software for running tests and viewing the results. The system requires the use of single-use disposable cartridges that hold the RT-PCR reagents and host the RT-PCR process. Because the cartridges are self-contained, cross-contamination between samples is minimized. For a full description of the systems, see the STANDARD M10 system User Manual.

The STANDARD M10 SARS-CoV-2 test includes reagents for the detection of RNA from SARS-CoV-2 in nasopharyngeal swab specimens. The cartridge is present to control for adequate processing of the sample, nucleic acid extraction and RT-PCR. The sample is first lysed under highly denaturing conditions to inactivate RNases and to ensure isolation of intact viral RNA. Buffering conditions are then adjusted to provide optimal binding of the RNA to the glass fibers. The RNA binds to the glass fibers, and contaminants are efficiently washed away several times using a wash buffer. High-quality RNA is eluted with elution buffer, ready for amplification. The purified nucleic acids is mixed with the lyophilized PCR master beads. And it is denatured under the customized temperature conditions to carry out effective multiplex real-time RT-PCR and amplified according to the PCR conditions.

An Internal Control(IC) is also included in the cartridge. The IC is present to control for adequate processing of the sample and to monitor for the presence of potential inhibitor(s) in the RT-PCR reaction. The IC also ensures that the RT-PCR reaction conditions are appropriate for the amplification reaction and that the RT-PCR reagents are functional.
The table below indicates which target is designed to be detected by which channel.

Table 1. Fluorescent channel of each target gene

Target gene	Channel
ORF1ab gene	FAM
E gene	HEX
Internal control	Cy5

4. Materials Provided

The STANDARD M10 SARS-CoV-2 kit contains sufficient reagents to process 10 specimens or quality control samples.

Table 2. Contents of the STANDARD M10 SARS-CoV-2 kit

	Contents	Quantity	Usage in each reaction
1	Cartridge	10	1ea
2	Quick Reference Instructions	1	-

5. Storage and Handling

Store the STANDARD M10 SARS-CoV-2 kit at 2-28℃ (36-82℉). If the cartridge has been refrigerated, perform the test after stabilizing it for 30 minutes at room temperature (20-28°C, 68-82℉). Do not remove the Safety Clip of the cartridge and do not press the cartridge until actual use. Do not use a cartridge that has leaked or is wet. Under these conditions, cartridges can be stored until the expiration date printed on the packaging.

6. Materials Required but Not Provided

- STANDARD M10 system with User Manual
  At least one STANDARD™ M10 Console(11M1011) and one STANDARD™ M10 Module(11M1012)
- Sample collection tools
  COPAN Universal Transport Medium (recommended 3ml of UTM-RT medium)
- Sample transfer pipettes
  - STANDARD™ Fixed volume dropper (600µl) (90DR10)
  - Micropipette with filter tips
- PPE (Personal Protective Equipment)
- External controls (Positive control, Negative control)
  AccuPlex™ SARS-CoV-2 Molecular Controls Kit - Full Genome (SeraCare, 0505-0159) (Optional)
  STANDARD™ M10 SARS-CoV-2 Quality Control Kit (SD Biosensor, Inc, Cat. no. 11COVC10J)

7. Warnings and Precautions

1) This kit is only for *in vitro* diagnosis.
2) Please read the Instructions for Use carefully before testing.
3) Improper specimen collection, transfer, storage, and processing may cause erroneous test results.
4) Do not remove the Safety Clip of the cartridge before use.
5) Do not press the cartridge until actual use.
6) Do not use a cartridge that has leaked or is wet.
7) Do not use the kit after its expiration date.
8) Do not shake, tilt, or invert the cartridge especially after pressing the cartridge to punch the seal. It may yield invalid or false test results.
9) Do not use a cartridge with a damaged barcode label.
10) Do not reuse processed cartridges.
11) Biological specimens, transfer devices, and used cartridges should be considered capable of transmitting infectious agents requiring standard precautions.
12) As this test involves extraction of viral RNA and PCR amplification, care should be taken to avoid contamination. Regular monitoring of laboratory contamination is recommended.
    To avoid contamination of working areas after accidental spills/exposures, a solution of bleach or 70% alcohol should be used where effective for target organisms. A second wiping with sterile water is needed when a corrosive disinfectant, such as bleach, is used. *(ref. LABORATORY BIOSAFETY MANUAL_WHO)*
13) Clinical laboratories should be equipped with equipment and operators in strict accordance with the "Code of Practice for Clinical Gene Amplification Laboratories."

14) When using this cartridge, it should be operated strictly in accordance with the instructions.
15) Follow your institution's environmental waste procedures for proper disposal of used cartridges.

8. Specimen Collection, Transport, and Storage

Proper sample collection, transportation, and storage are critical to the performance of the test. Improper sample collection, inappropriate sample handling and/or transportation can lead to false results.
Refer to the WHO Laboratory Biosafety Guidance Related to the Coronavirus Disease 2019 (COVID-19).
https://www.who.int/publications-detail/laboratory-biosafety-guidance-related-to-coronavirus-disease-2019-(covid-19)

8.1 Nasopharyngeal swab collection procedure

1) Hold the nasopharyngeal swab close to the nasal septum slowly and deeply to the back of the nasopharynx.
2) Rotate it several times to obtain secretions.
3) Remove the swab from the nasopharynx and place it into the specimen collection tube, and discard the tail.
4) Tighten the tube cap to seal in case of drying.
5) The swab specimens can be stored for 1 day at room temperature, 6 days at 2~8°C (36~46℉), and 6 months storage below -70°C (-94℉).

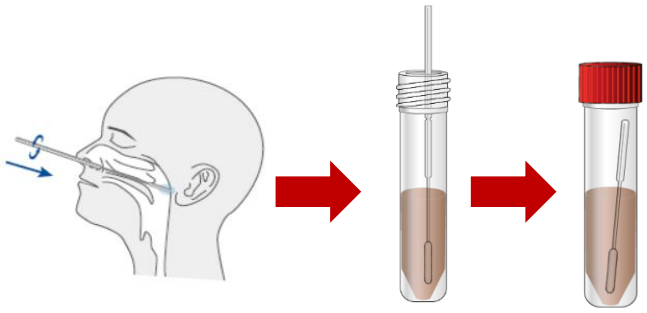

Figure 2. Nasopharyngeal swab collection

9. Procedure

9.1 Starting the STANDARD M10 system

Note	For the detailed instructions, refer to the STANDARD M10 system User Manual. If you have scanned the cartridge barcode in the STANDARD M10 and the software version is not compatible, a 'Not Supported Device' error message appears. Update the software before proceeding with the test.

1) Turn on the STANDARD M10 system.
2) Check the STANDARD M10 Console and the STANDARD M10 Module is connected and functional.

Figure 3. Power connection

3) Enter the User ID and Password on the Log In screen of the STANDARD M10 Console and click the Log In button.
4) Touch the STANDARD M10 Module to run on the Home screen.
(The door of the selected STANDARD M10 Module will automatically open for cartridge loading.)

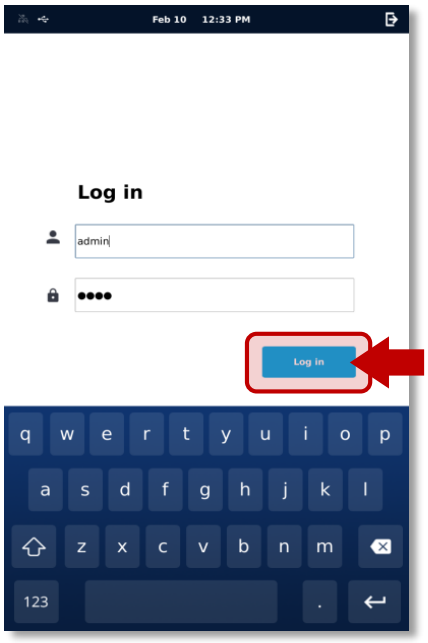

Figure 4. Log In screen

Figure 5. Home screen, Status of M10 module

5) Enter a Patient ID by scanning the barcode or using virtual keyboard on the M10 Console screen.
(Patient ID is optional. You can turn off the Patient ID option from the 'Settings'.)
6) Enter a Sample ID by scanning the barcode of the specimen or using virtual keyboard on the M10 Console screen.
Make sure that the specimen tube cap is firmly closed when scan the ID barcode printed on the specimen tube.
(For quality control test, tick the QC check box)

Figure 6. Entering Sample ID

Figure 7. Scanning a cartridge

7) Scan the STANDARD M10 SARS-CoV-2 cartridge to be used. The STANDARD M10 Console automatically recognizes the assay to be run based on the cartridge barcode.

Note	If you have scanned the cartridge barcode in the STANDARD M10 and the expiration date has expired, An 'Expired Device' error message appears. Check validity period and test with unexpired cartridges.

9.2 Loading a sample into the STANDARD M10 SARS-CoV-2 cartridge

caution	If the cartridge has been refrigerated, perform the test after stabilizing it for 30 minutes at room temperature (20-28°C, 68-82℉). Once the sample has been loaded into the cartridge, start the test as soon as possible. (within 10 minutes)
Note	False negative results may occur if insufficient sample is added into the cartridge.

1) Remove the Safety Clip located underneath the lid of the cartridge.
2) Press down the cartridge to pierce the seal until fully engaged into the cartridge groove.
3) Open the lid and check that the seal is completely punctured before loading a sample.
4) Mix sample by rapidly inverting the specimen or external control tube 5 times. Carefully open the cap of the specimen tube or external control.
5) Dispense 600µl of the sample into the hole in the lower right corner of the cartridge using a 600 µl of fixed volume dropper or a micro pipette.
6) After a few seconds, Sample Guide screen will automatically change to the Insert Cartridge screen. Touch the Sample Guide screen if you want to skip the guide.
7) Close the lid.

Figure 8. Loading a sample

Figure 9. Sample Guide screen

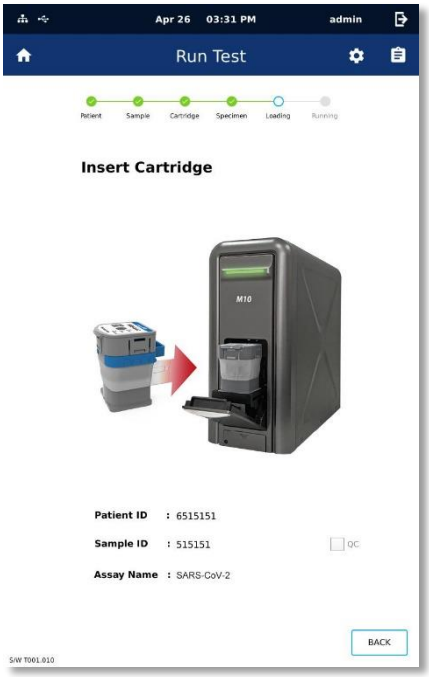

Figure 10. Insert Cartridge screen

9.3 Running a test

1) Load the cartridge on the selected STANDARD M10 Module with the Amplification chamber facing the inside of the module.
   (The status indicator of the selected module will blink green.)
2) Close the door completely.
3) After confirming the sample and cartridge information, touch the OK button on the screen.
   (Touch the Reset button to re-input the information.)

Figure 11. Confirm the test screen

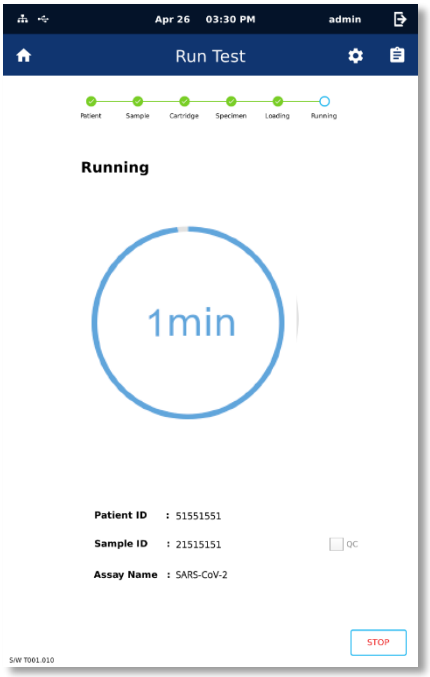

Figure 12. Running screen

4) Assay starts automatically, and remaining time will appear on the screen.
5) If the signal from the target reaches a certain threshold before the full process have been completed, an Early Detection Call function is initiated and it will provide earlier time to results.

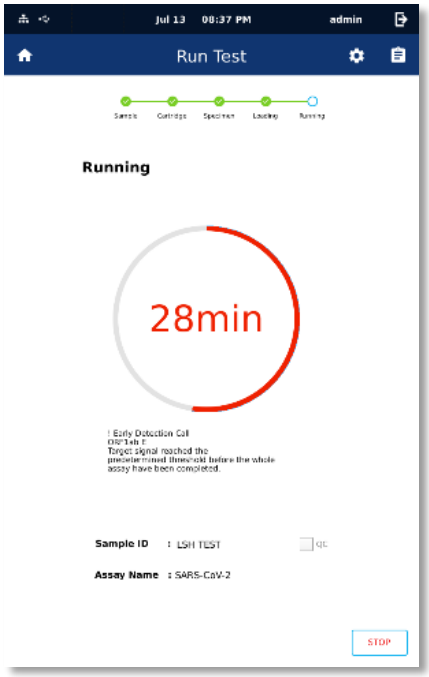

Figure 13. Early Detection Call function

6) When the run is finished, it switches to the Review screen and the result is displayed.
7) Dispose of used cartridges in the appropriate biohazard waste container according to your institution's standard practices.
8) To run another test, touch the Home icon and repeat the process.
(If another STANDARD M10 Module connected to the STANDARD M10 Console is available, you can start a new test while another test is running.)

10. Interpretation of Results

The results are interpreted automatically by the STANDARD M10 Console and are clearly shown in the Review screen. The STANDARD M10 SARS-CoV-2 test provides test results based on the detection of two gene targets according to the algorithms shown in Table 3.

Table 3. Interpretation of results

Outcome (Home screen)	Result (Review screen)	Description
Positive		ORF1ab gene or Both target genes were detected.
Presumptive Positive		Only E gene was detected.
Negative		No target gene was detected.
Invalid		IC signal does not have a Ct within the valid range.
Error		The test failed because either an error occurred or the test was canceled by the user.

Table 4. Description of IC results

Outcome (Summary screen)	Result (Summary screen)	Description
IC Valid		IC has a Ct within the valid range. : The test was completed. Report positive/negative results of pathogens according to the interpretation shown in table 5
IC Invalid		IC does not have a Ct within the valid range. : Pathogens detected as positive shall be reported, but all negative results (tested but not detected) are invalid. Repeat the test
IC Error		The test failed because either an error occurred or the test was canceled by the user. Repeat the test.

Table 5. Interpretation of results

Result	Interpretation
SARS-CoV-2 Positive	SARS-CoV-2 target nucleic acids are detected. • The SARS-CoV-2 signal for the ORF1ab nucleic acid target or signals for both nucleic acid targets (ORF1ab and E) have a Ct within the valid range. • IC: N/A(not applicable); IC may be inhibited and delayed Ct value in case of the sample is SARS-CoV-2 positive at high concentration.
SARS-CoV-2 Presumptive Positive	SARS-CoV-2 nucleic acids may be present. Sample should be retested. For samples with a repeated presumptive positive result, additional confirmatory testing may be conducted, if it is necessary to differentiate between SARS-CoV-2 and SARS-CoV-1 or other Sarbecovirus currently unknown to infect humans, for epidemiological purposes or clinical management. • The SARS-CoV-2 signal for only the E nucleic acid target has a Ct within the valid range. • IC: N/A(not applicable); IC may be inhibited and delayed Ct value in case of the sample is SARS-CoV-2 positive at high concentration.
SARS-CoV-2 Negative	SARS-CoV-2 target nucleic acids are not detected. • The SARS-CoV-2 signals for two nucleic acid targets (ORF1ab and E) do not have a Ct within the valid range. • IC: Valid; IC has a Ct within the valid range.

Result	Interpretation
Invalid	IC does not meet acceptance criteria. Presence or absence of SARS-CoV-2 nucleic acids cannot be determined. Repeat the test. • IC: Invalid; IC and SARS-CoV-2 signals do not have a Ct within valid range.
Error	The test failed because either an error occurred or the test was canceled by the user. Presence or absence of SARS-CoV-2 nucleic acids cannot be determined. Repeat the test.

11. Quality Control

In accordance with SD BIOSENSOR's ISO-certified Quality Management System, each lot of the STANDARD M10 SARS-CoV-2 is tested against predetermined specifications to ensure consistent product quality. Quality control requirements should be performed in conformance with local, state, and/or federal regulations or accreditation requirements and your laboratory's standard quality control procedures.

12. Performance

12.1 Limit of Detection Test

The Limit of Detection Test of STANDARD M10 SARS-CoV-2 was assessed with two lots of cartridges and five concentration of the heat-inactivated SARS-CoV-2 (2019 nCOV) NCCP 43326/2020/Korea strain ($2.65x10^{-3}$ $TCID_{50}$/ml, $1.33x10^{-3}$ $TCID_{50}$/ml, $6.63x10^{-4}$ $TCID_{50}$/ml, $3.32x10^{-4}$ $TCID_{50}$/ml and $1.66x10^{-4}$ $TCID_{50}$/ml) into pooled negative clinical nasopharyngeal swab matrix. It can be seen that more than 95% of the two genes were detected at the heat-inactivated virus concentration of $6.63x10^{-4}$ $TCID_{50}$/ml, so the LoD was determined to be as $6.63x10^{-4}$ $TCID_{50}$/ml as below.
According to the LoD results, the mean and standard deviation of the Ct value of $6.63x10^{-4}$ $TCID_{50}$/ml was calculated.

- ORF1ab gene : $6.63x10^{-4}$ $TCID_{50}$/ml
- E gene : $6.63x10^{-4}$ $TCID_{50}$/ml

12.2 Interference Test

The Interference Test of STANDARD M10 SARS-CoV-2 was assessed with 10 types of endogenous and exogenous interfering substances. STANDARD M10 SARS-CoV-2 measure a control sample (without interfering substances) and two concentration of SARS-CoV-2 heat-inactive virus (with interfering substances). The test repeated 3 times with one lot for each case. As a result, no interference reaction was observed up to the concentrations below.

Substance		Concentration
Interfering substance	Mucin	0.1 mg/ml
	hemoglobin	10 mg/ml
	dexamethasone	601.2 ng/ml
	zanamivir	3.3 mg/ml
	tobramycin	24 ug/ml
	mupirocin	8.3 mg/ml
	ribavirin	11.1 mg/ml
	Bilirubin	0.05 mg/ml
	Human blood	5%
	Human DNA	10ng/ul
control sample		(no interfering substance)

12.3 Cross-Reactivity Test

The following 38 cross reacting substances were tested 3 times per sample in the dedicated analyzer as one lot. As a result, STANDARD M10 SARS-CoV-2 did not show any cross-reactivity with 38 substances

Category	No.	Substance	Concentration
Non SARS-CoV-2 coronavirus infections	1	HCoV-OC43	1 x 10^6 $TCID_{50}$/mL
	2	HCoV-229E	1 x 10^5 $TCID_{50}$/mL
	3	HCoV-NL63	1 x 10^5 $TCID_{50}$/mL
	4	MERS-CoV	1 x 10^5 $TCID_{50}$/mL
Non SARS-CoV-2 Viral infections	5	Influenza A (H1N1/NewYork/18/09)	1 x 10^5 $TCID_{50}$/mL
	6	Influenza A_H3N2	1 x 10^5 $TCID_{50}$/mL
	7	Influenza B (B/Taiwan)	1 x 10^5 $TCID_{50}$/mL
	8	Respiratory syncytial virus (RSVA/2/Australia/61)	5 x 10^5 PFU/mL
	9	Respiratory Syncytial Virus Type B (RSV-B)	1 x 10^5 $TCID_{50}$/mL
	10	Rhinovirus A16	1 x 10^5 $TCID_{50}$/mL
	11	Rhinovirus B (strain 1059)	1 x 10^6 $TCID_{50}$/mL
	12	Parainfluenza virus 1	1 x 10^7 $TCID_{50}$/mL
	13	Parainfluenza virus 2	1 x 10^5 $TCID_{50}$/mL
	14	Parainfluenza virus 3	1 x 10^5 $TCID_{50}$/mL
	15	Parainfluenza virus 4A	1 x 10^5 $TCID_{50}$/mL
	16	Parainfluenza Virus_Type 4B	1 x 10^5 $TCID_{50}$/mL
	17	Adenovirus (type 3)	1.54 x 10^7 $TCID_{50}$/mL
	18	Adenovirus Type01 (Species C)	1 x 10^6 $TCID_{50}$/mL
	19	Enterovirus Type 68 Major Group	1 x 10^5 $TCID_{50}$/mL
	20	Human Metapneumovirus(hMPV) 16 type A1	1 x 10^5 $TCID_{50}$/mL
	21	Human Metapneumovirus(hMPV) 3 type B1	1 x 10^5 $TCID_{50}$/mL
	22	Human Cytomegalovirus (HCMV)	1 x 10^5 $TCID_{50}$/mL
	23	Measles virus	1 x 10^5 $TCID_{50}$/mL
	24	Mumps virus	1 x 10^5 $TCID_{50}$/mL
	25	Epstein Barr virus	1 x 10^7 $TCID_{50}$/mL
Exclusivity-Bacteria	26	Mycoplasma pneumonia (Mycoplasma spp.)	1 x 10^5 CFU/mL
	27	Haemophilus influenzae	1 x 10^5 CFU/mL
	28	Moraxella catarrhalis	1 x 10^5 CFU/mL
	29	Bowman Animal bacterium	1 x 10^6 CFU/mL
	30	Pseudomonas aeruginosa	1 x 10^5 CFU/mL
	31	Chlamydia pneumoniae	1 x 10^6 CFU/mL
	32	Streptococcus pyogenes	1 x 10^6 CFU/mL
	33	Bordetella pertussis	1 x 10^6 CFU/mL
	34	Staphylococcus epidermis	1 x 10^7 CFU/mL
	35	Streptococcus salivrius	1 x 10^7 CFU/mL
	36	Neisseria sp	1 x 10^6 CFU/mL
	37	Lactobacillus sp	1 x 10^7 CFU/mL
	38	Corynebacterium sp	1 x 10^8 CFU/mL

12.4 Precision Test

1) Repeatability

Four concentrations of positive heat-inactivated virus were tested by laboratory personnel. Testing is repeated for 5 days, 2 runs every day, 2 replicates per each run. As a result, within Run, Between Run, Between Day satisfy the acceptance criteria with CV < 5% to confirm repeatability.

(1) ORF1ab

Concentration ($TCID_{50}$/ml)	Within-run (%CV)	Between-run (%CV)	Between-day (%CV)
6.63x10^0 $TCID_{50}$/ml	0.82	0.79	0.47
6.63x10^{-1} $TCID_{50}$/ml	0.72	0.73	0.68
6.63x10^{-2} $TCID_{50}$/ml	1.06	1.05	1.04
6.63x10^{-4} $TCID_{50}$/ml	2.90	2.79	2.49

(2) E gene

Concentration ($TCID_{50}$/ml)	Within-run (%CV)	Between-run (%CV)	Between-day (%CV)
$6.63x10^{0}$ $TCID_{50}$/ml	1.34	1.32	0.63
$6.63x10^{-1}$ $TCID_{50}$/ml	0.99	1.02	0.72
$6.63x10^{-2}$ $TCID_{50}$/ml	1.00	0.95	0.91
$6.63x10^{-4}$ $TCID_{50}$/ml	2.90	3.08	2.11

2) Reproducibility

Reproducibility was confirmed by repeating the test twice a day, 2 replicates per each run, using two different instrument for 5 days, by two laboratory personnel with three lots. As a result, it was confirmed that there was reproducibility by satisfying the acceptance criteria with CV < 5% in the evaluation between instruments, between operators and between lots.

(1) ORF1ab

Concentration ($TCID_{50}$/ml)	Between-instrument(%CV)	Between-Operator(%CV)	Between-Lot (%CV)
$6.63x10^{0}$ $TCID_{50}$/ml	1.69	1.96	1.79
$6.63x10^{-1}$ $TCID_{50}$/ml	1.36	1.47	1.43
$6.63x10^{-2}$ $TCID_{50}$/ml	1.62	1.86	1.25
$6.63x10^{-4}$ $TCID_{50}$/ml	2.21	1.65	1.94

(2) E gene

Concentration ($TCID_{50}$/ml)	Between-instrument(%CV)	Between-Operator(%CV)	Between-Lot (%CV)
$6.63x10^{0}$ $TCID_{50}$/ml	2.08	2.34	1.57
$6.63x10^{-1}$ $TCID_{50}$/ml	1.57	1.49	1.43
$6.63x10^{-2}$ $TCID_{50}$/ml	1.84	1.80	1.01
$6.63x10^{-4}$ $TCID_{50}$/ml	2.73	2.36	2.68

12.5 Clinical Trial

The test results of the STANDARD M10 SARS-CoV-2 were compared with the confirmed results of positive samples and negative samples. The study was conducted using residual specimen stored in nasopharyngeal swab universal transport medium (UTM) after testing, and stored at ≤ -70℃ with storage duration < 12 months. Base on this, calculated the clinical sensitivity and specificity of the medical device for clinical performance test.

Result		Confirmed		Total
		Positive	Negative	
STANDARD M10 SARS-CoV-2	Positive	109	0	109
	Negative	0	120	120
Total		109	120	229

- Clinical sensitivity: 100% (109/109, 95% CI: 96.67% ~ 100%)
- Clinical specificity: 100% (120/120, 95% CI: 96.97% ~ 100%)

13. Limitations

1) If you do not follow procedure, a false negative result may occur.
   - Sample concentrations is near or below the limit of detection of the test
   - A specimen is improperly collected, transported or handled
   - Inadequate respiratory tract organisms are present in the specimen
   - Cartridges are exposed to improper environmental factors (temperature / humidity)
2) False positive results may happen from cross-contamination between patient samples, specimen mix-up and/or RNA contamination during product handling.
3) Performance characteristics of this test have been established with the specimen types listed in the Intended Use Section only. The performance of this assay with other specimen types or samples has not been evaluated.
4) Qualitative detection of positive results in this cartridge does not indicate the presence of live virus.
5) This cartridge 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.
6) Mutations within the target regions of the M10 SARS-CoV-2 test could affect primer and/or probe binding resulting in failure to detect the presence of virus or the virus being detected less predictably.

14. References

1) Characteristics of SARS-CoV-2 and COVID-19. Nature Reviews Micro., 2020, http://doi.org/10.1038/s41579-020-00459-7
2) The species Severe acute respiratory syndrome related coronavirus: classifying 2019-nCoV and naming it SARS-CoV-2. Nature Micro., 2020, Vol. 5, 536-544
3) Clinical management of severe acute respiratory infection when novel coronavirus (nCoV) infection is suspected. Interim guidance. WHO. 2020. http://doi.org/10.2809/1560-7917.ES.2020.25.3.2000045
4) Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR. Euro Surveill., 2020,
5) Diagnosis and treatment of pneumonia caused by new coronavirus (trial version 4) National Health Commission. 2020

15. Symbols

	Reference number		Batch code
	*In vitro* diagnostics medical device		CE marking - European Conformity
	Consult Instructions for Use		Manufacturer
	Contains Sufficient for <n> Tests		Date of manufacture
	Caution		Authorized representative in the European Community
	Note		Keep dry
	Do not re-use		Keep away from sunlight
	Temperature limit		Do not use if packaging is damaged
	Use-by date		

For further information on

STANDARD M10
SARS-CoV-2

Please contact your
SD BIOSENSOR representative

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Manufacturing site : 14, Jeungpyeongsandan-ro, Jeungpyeong-eup, Jeungpyeong-gun, Chungcheongbuk-do, 27915

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CE IVD

For *In Vitro* Diagnostic Use Only

Any inquiries regarding instructions provided should be addressed to: ts@sdbiosensor.com
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