STANDARD M10 MDR-TB

STANDARD™ M10 MDR-TB

REF M10-MTB-01

INSTRUCTIONS FOR USE

For use with STANDARD™ M10 system

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SD BIOSENSOR

1. Intended Use

STANDARD M10 MDR-TB is a multiplex real-time PCR test intended for use with STANDARD M10 system for the qualitative detection of *M. tuberculosis* complex nucleic acids and drug-resistance mutation in human normal sputum or sputum sediment sample. Positive results of IS*1081* and IS*6110* are indicative of the presence of *M. tuberculosis* complex. Positive results for *rpoB*, *katG* and *inhA* indicate that the detected *M. tuberculosis* complex have drug resistance for rifampicin (RIF) and/or isoniazid (INH). Determining a patient's infection status requires clinical correlation with the patient's medical history and other diagnostic information. Negative results should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. STANDARD M10 MDR-TB is intended to be performed by trained users in both laboratory and near patient testing setting.

2. Summary and Explanation

Tuberculosis (TB) is an infectious disease, which is caused by infection with *M. tuberculosis* complex organisms. It spreads to new hosts through the air from patients who have respiratory tuberculosis disease. Individuals newly infected would get symptoms from TB within weeks to months.

***M. tuberculosis* can cause disease in almost any tissue or organ in human body, such as lungs, kidneys, nerves, and bones. Among them, pulmonary tuberculosis, the lung tissue infection, accounts for the most. TB has different symptoms depending on the organ infected. For example, kidney tuberculosis causes symptoms of cystitis such as hematuria, difficulty urinating, and frequent urination. Spinal tuberculosis causes pain in the lower back. Tuberculous meningitis may cause symptoms such as headache and vomiting. In the case of the most common TB, pulmonary tuberculosis, symptoms such as coughing, chest pain, unintentional weight loss and fever.**

Rifampicin is a semisynthetic derivative of rifamycin B drug extracted from *S. mediterrannei*, and is widely used as the essential drug for the treatment of TB. Rifampicin binds to β-subunit of bacterial DNA dependent RNA polymerase (RNAP) and interferes with the initiation of RNA synthesis. Thus, rifampicin effectively functions as antibiotic by inhibiting essential bacterial activity. Mutation of the *rpoB* gene on the β-subunit causes a decrease the affinity of RNAP for rifampicin, and it causes bacteria to have resistance to rifampicin.

Isoniazid works effectively against active *M. tuberculosis* complex. Isoniazid is a prodrug that is activated by a strong catalase enzyme into acyl radical active form, the enzyme is named catalase-peroxidase (KatG) encoded by the *katG* gene. Active form of the compound disrupts the mycolic acid biosynthesis by inhibiting the NADH-dependent enoyl-acyl carrier protein reductase encoded by *inhA* gene. Mycolic acid is an essential building block of mycobacterial cell wall. Mutations in the *katG* gene and *inhA* gene result in reduction or loss of isoniazid antibacterial activity by inactivation of KatG and structural changes in isoniazid compounds. In the case of multi-drug resistant tuberculosis (MDR-TB), which is resistant to rifampin and isoniazid at the same time, the effect of standard first-line treatment is not adequate. Thus, second-line anti-tuberculosis regimen is needed. For the effective treatment of tuberculosis patients, resistance tests of rifampicin and isoniazid should be performed simultaneously with the diagnosis of *M. tuberculosis* complex.

[Cartridge Description]

STANDARD M10 MDR-TB is a molecular *in vitro* diagnostic assay that aids in the simultaneous detection and differentiation of IS*1081* and IS*6110* genes of *M. tuberculosis* complex strains and *rpoB*, *katG* and *inhA* gene as multi-drug resistant parameter based on nucleic acid amplification technology, real-time PCR. STANDARD M10 MDR-TB cartridge contains bacterial DNA extraction buffers and PCR reagents for the *in vitro* qualitative detection of IS*1081* and IS*6110* genes of *M. tuberculosis* complex strains and *rpoB*, *katG* and *inhA* gene as multi-drug resistant parameter in human normal sputum or sputum sediment sample.

Figure 1. Layout of STANDARD M10 MDR-TB cartridge

3. Principle of the Procedure

STANDARD M10 MDR-TB is an automated *in vitro* diagnostic test for qualitative detection of nucleic acid from MTB, RIF resistance and INH resistance. STANDARD M10 MDR-TB test is able to perform on STANDARD M10 system.
STANDARD M10 system automate and integrate sample preparation, nucleic acid extraction and amplification, and detection of the target sequences in various specimens using molecular diagnostic assays. The system consists of STANDARD™ M10 Module and 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 PCR reagents and host the 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.
STANDARD M10 MDR-TB includes reagents for the detection of DNA from IS*1081* and IS*6110* genes of *M. tuberculosis* complex strains and *rpoB*, *katG* and *inhA* gene as multi-drug resistant parameter at the same time. 4 probes detect 81 base pair "hot spot" region of *rpoB* gene that can confirm RIF resistance, and probes for *katG* and *inhA* gene determine INH resistance. Therefore, the assay is able to differentiate between the wild-type and mutant sequence in normal sputum or concentrated sputum sediment specimens. The cartridge is present to control for adequate processing of the sample and PCR reaction. The table below indicates which target is designed to be detected by which channel.

Table 1. Fluorescent channel of each target gene

Pathogen	Target gene	Channel
M. tuberculosis	IS*1081*	FAM
	IS*6110*	HEX
M. tuberculosis - RIF	*rpoB*	FAM and/or HEX
M. tuberculosis - INH	*katG*	FAM
	inhA	HEX
Internal control	Internal control (IC)	Cy5

4. Materials Provided

STANDARD M10 MDR-TB contains sufficient reagents to process 10 specimens or quality control samples.

Table 2. Contents of STANDARD M10 MDR-TB

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

5. Storage and Handling

Store STANDARD M10 MDR-TB 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. This kit should be stored at appropriate temperature and kept away from UV/sunlight. 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 label.

6. Materials Required but Not Provided

- **STANDARD M10 system with User Manual**
  At least one STANDARD M10 Console and one STANDARD M10 Module
- **Sample Collection and Transfer Tools**
  - Sample container
  - Screw-capped tube
  - 0.067M Phosphate/H_2O buffer
  - Micropipette with filter tips
  - Pretreatment solution (PS) - STANDARD™ M10 Sputum Pretreatment Kit (Cat.No.: 11PRT10A)
  - Disposable dropper - STANDARD™ M10 Sputum Pretreatment Kit (Cat.No.: 11PRT10A)
  - Pretreatment tool - STANDARD™ M10 Sputum Pretreatment Kit (Cat.No.: 11PRT10A)
- **PPE (Personal Protective Equipment)**
- **Biohazard container**

7. Warnings and Precautions

1) This kit is only for *in vitro* diagnosis.
2) For professionals use only.
3) Please read the Instructions for Use carefully before testing.
4) Improper specimen collection, transfer, storage, and processing may cause erroneous test results.
5) Do not remove the Safety Clip of the cartridge before use.
6) Do not press the cartridge until actual use.
7) Do not use a cartridge that has leaked or is wet.
8) Keep the cartridge away from UV/sunlight and keep dry.
9) Do not use the kit after its expiration date.
10) Do not shake, tilt, or invert the cartridge especially after pressing the cartridge to punch the seal. It may yield non-determinate results.
11) Do not use a cartridge with a damaged barcode label.
12) Do not reuse processed cartridges.
13) All patient samples should be handled as if these samples are infectious.
14) All materials should be considered potentially infectious and should be handled with precautions.
15) As this test involves extraction of bacterial DNA and PCR amplification, care should be taken to avoid contamination. Regular monitoring of laboratory contamination is recommended.
16) Clinical laboratories should be equipped with equipment and operators in strict accordance with the "Code of Practice for Clinical Gene Amplification Laboratories."
17) 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.
18) Follow your institution's environmental waste procedures for proper disposal of used cartridges and unused reagents.

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.

8.1. Specimen collection

Collect normal sputum following your institution’s standard protocol for sample collection and Test normal sputum or concentrated/decontaminated sputum sediment.

Specimen Type :

- Normal sputum treated with Pretreatment solution(PS)
- Sputum sediment treated with Pretreatment solution(PS)

See Table 3 to determine adequate specimen volume when pretreat the two kinds of samples with Pretreatment solution(PS).

Table 3. Requirement of Specimen Volume

	Specimen Type	
	Normal sputum	Sputum sediment
Minimum Sample Volume	0.5 mL	
Specimen to Pretreatment Solution(PS) Ratio	1:2[1)]	

Note: [1)] Basically, Specimen to Pretreatment Solution(PS) ratio is used in a ratio of 1:2, but in case of sputum sample with high viscosity, it can be used up to a ratio of 1:3. Instead, it is possible to change the sensitivity according to the change of the pretreatment process ratio.

8.2. Specimen Storage and Transport

Store and transport the specimen refrigerated temperature(2 ~ 8℃), protected from light.

9. Procedure

9.1. Specimen Procedure

9.1.1. Procedure for Normal sputum

1) Prepare the normal sputum in sputum collection container and pretreatment solution(PS).
2) Open carefully the lid of the normal sputum collection container and remove solid particles that may affect the test.
3) Add approximately 2 times the volume of the PS into the normal sputum(normal sputum : PS = 1:2) in the container and secure the lid. If the viscosity is still high, and not liquidized enough for testing despite PS application, add more PS up to a ratio of 1:3.
For example, if normal sputum and PS are used at 0.5 mL and 1.0 mL, respectively, add 0.5 mL of PS to make the final 1:3 ratio.
***Note*: More than 0.5 mL of normal sputum is required for the further steps.**
4) Vortex vigorously twice for 10 seconds to make sure normal sputum and PS are mixed completely.
5) Incubate the sample for 15 minutes at room temperature.

9.1.2. Procedure for concentrated/decontaminated Sputum Sediments

1) Prepare sputum sediment in sputum collection container and 0.067M Phosphate/H_2O buffer.
2) Carefully open the lid of sputum sediment collection container and add 0.067M Phosphate/H_2O buffer for suspension.
***Note*: More than 0.5 mL of suspended sputum sediment is required for the further steps.**
3) Vortex sufficiently until completely suspended, and transfer 0.5 mL suspended sediment to new screw-capped tube using micropipette.
4) Add approximately 2 times the volume of the PS into the suspended sputum (suspended sputum : PS = 1:2) in the tube and secure the lid. If the viscosity is still high, not enough for testing despite PS application, add more PS up to the ratio of 1:3.
For example, if suspended sputum sediment and PS are used at 0.5 mL and 1.0 mL, respectively, add 0.5 mL of PS to make the final 1:3 ratio.
6) Vortex vigorously twice for 10 seconds each and mix suspended sediment with PS.
7) Incubate the sample for 15 minutes at room temperature.

9.2. 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 the test.**

1) **Turn on the STANDARD M10 system.**
2) **Check the STANDARD M10 Console and the STANDARD M10 Module is connected and functional.**
3) **Enter the User ID and Password on the Log In screen of the STANDARD M10 Console and click the Log In button.**

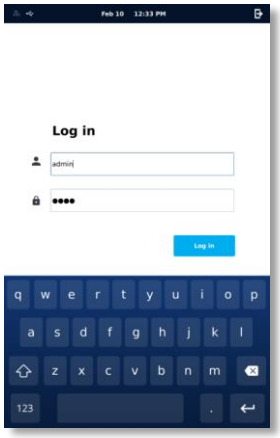

Figure 2. Log In screen

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.)

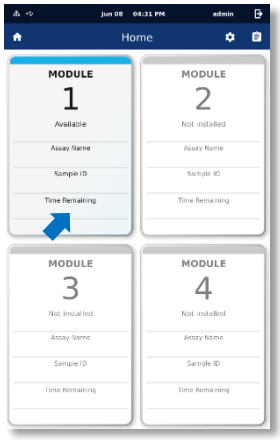

Figure 3. Home screen

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'.)

Figure 4. Entering Patient ID

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 5. Entering Sample ID

7) **Scan STANDARD M10 MDR-TB cartridge to be used. The STANDARD M10 Module automatically recognizes the assay to be run based on the cartridge barcode.**

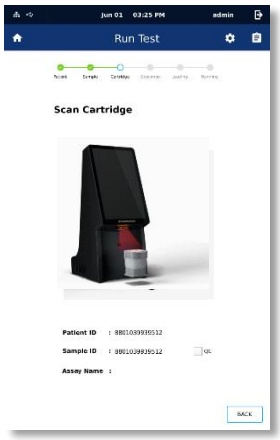

Figure 6. Scanning a cartridge

9.3. Loading a sample into STANDARD M10 MDR-TB 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℉).** **Start the test within 10 minutes of loading the sample into STANDARD M10 MDR-TB cartridge.**
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) **Pierce the sealed cartridge by pressing down the lid until fully engaged into the cartridge groove.**
3) **Open the lid and check that the seal is completely punctured before loading a sample.**
4) **Carefully open the cap of the specimen tube or external control.**
5) **Refer to Figure 8. Transfer appropriate volume of the prepared sample into the barrel of pretreatment tool using disposable dropper with volume indication. Insert and press down the plunger of pretreatment tool, then it will inject 1 mL of the filtered sample into the cartridge.**
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.**

Figure 7. Sample Guide screen

7) **Close the lid.**

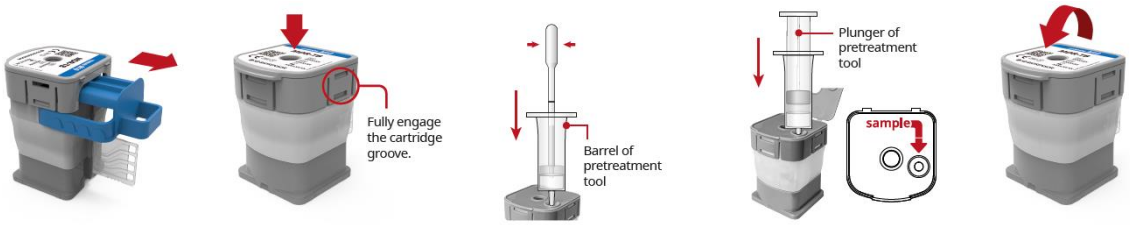

Figure 8. Loading a sample

9.4. Running a test

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.)

Figure 9. Insert Cartridge screen

1) **Close the door completely.**
2) **After confirm the sample and cartridge information, touch the OK button on the screen. (Touch the Reset button to re-input the information.)**

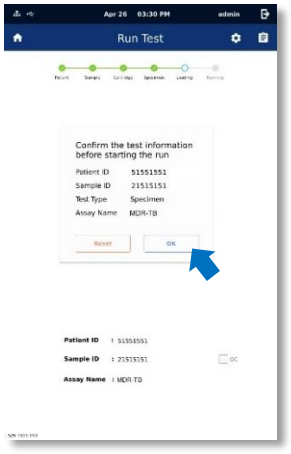

Figure 10. Confirm the test screen

3) Assay starts automatically, and remaining time will appear on the screen.

Figure 11. Running screen

4) When the run is finished, it switches to the Review screen and the result is displayed.
5) Dispose of used cartridges in the appropriate sample waste containers according to your institution's standard practices.
6) 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 STANDARD M10 Console and are clearly shown in the Review screen. STANDARD M10 MDR-TB test provides test results based on the detection of respective gene targets according to the algorithms shown in Table 4.

Table 4. Interpretation of results

Result	MTB		RIF		INH	
	MTB	IC	RIF	IC	INH	IC
MTB Detected RIF Resistance Detected INH Resistance Detected	+	+/-	R+	+/-	R+	+/-
MTB Detected RIF Resistance Detected INH Resistance NOT Detected	+	+/-	R+	+/-	R-	+
MTB Detected RIF Resistance Detected INH Resistance Indeterminate	+	+/-	R+	+/-	Rx	+
MTB Detected RIF Resistance NOT Detected INH Resistance Detected	+	+/-	R-	+	R+	+/-
MTB Detected RIF Resistance Indeterminate INH Resistance Detected	+	+/-	Rx	+	R+	+/-
MTB Detected RIF Resistance NOT Detected INH Resistance NOT Detected	+	+/-	R-	+	R-	+
MTB Detected RIF Resistance NOT Detected INH Resistance Indeterminate	+	+/-	R-	+	Rx	+

MTB Detected **RIF Resistance Indeterminate** **INH Resistance NOT Detected**	**+**	**+/-**	**Rx**	**+**	**R-**	**+**
MTB Detected **RIF Resistance Indeterminate** **INH Resistance Indeterminate**	**+**	**+/-**	**Rx**	**+**	**Rx**	**+**
MTB Not Detected	**-**	**+**	**N/A**	**+**	**N/A**	**+**
Invalid	**-**	**-**	**N/A**	**-**	**N/A**	**-**
Error	**No result**					

Result	Interpretation
MTB Detected **RIF Resistance Detected** **INH Resistance Detected**	● **The MTB target DNA (IS*1081* and/or IS*6110*) is detected.** ● **RIF mutation in the *rpoB* target sequences has been detected.** ● **INH mutation in the *katG* and/or *inhA* target sequences has been detected.** **- The MTB target and mutation in the *rpoB*, *katG* and/or *inhA* signals have Ct values within the valid range and endpoint above the minimum setting.** **- IC: N/A(not applicable); IC signal can be ignored in case the target gene are positive.**
MTB Detected **RIF Resistance Detected** **INH Resistance NOT Detected**	● **The MTB target DNA(IS*1081* and/or IS*6110*) is detected.** ● **RIF mutation in the *rpoB* target sequence has been detected.** ● **No INH mutation in the *katG* and/or *inhA* target sequences has been detected.** **- The MTB target and RIF mutation in the *rpoB* signals have Ct values within the valid range and endpoint above the minimum setting.** **- INH mutation in the *katG* and/or *inhA* signals does not have a Ct value within the valid range and endpoint above the minimum setting.** **- IC: N/A(not applicable); IC signal can be ignored in case the target gene are positive.** **- IC: Valid; IC signal is detected, since the target gene are not amplified.**
MTB Detected **RIF Resistance Detected** **INH Resistance Indeterminate**	● **The MTB target DNA IS1081 and/or IS6110 is detected.** ● **RIF mutation in the rpoB target sequences has been detected.** ● **INH resistance could not be determined.** **-The MTB target and mutation in the rpoB signals have Ct values within the valid range and endpoint above the minimum setting.** **-IC: N/A(not applicable); IC signal can be ignored in case the target gene are positive.** **-IC: Valid; IC signal is detected, since the target gene are not amplified.**
MTB Detected **RIF Resistance NOT Detected** **INH Resistance Detected**	● **The MTB target DNA (IS*1081* and/or IS*6110*) is detected.** ● **No RIF mutation in the *rpoB* target sequences has been detected.** ● **INH mutation in the *katG* and/or *inhA* target sequences has been detected.** **- The MTB target and INH mutation in the *katG* and/or *inhA* signals have Ct values within the valid range and endpoint above the minimum setting.** **- RIF mutation in the *rpoB* signals does not have a Ct value within the valid range and endpoint above the minimum setting.** **- IC: N/A(not applicable); IC signal can be ignored in case the target gene are positive.** **- IC: Valid; IC signal is detected, since the target gene are not amplified.**

Result	Interpretation
MTB Detected **RIF Resistance Indeterminate** **INH Resistance Detected**	● **The MTB target DNA IS1081 and/or IS6110 is detected.** ● **RIF resistance could not be determined.** ● **INH mutation in the katG and/or inhA target sequences has been detected.** **-The MTB target and mutation in the katG and/or inhA signals have Ct values within the valid range and endpoint above the minimum setting.** **-IC: N/A(not applicable); IC signal can be ignored in case the target gene are positive.** **-IC: Valid; IC signal is detected, since the target gene are not amplified.**
MTB Detected **RIF Resistance NOT Detected** **INH Resistance NOT Detected**	● **The MTB target DNA (IS*1081* and/or IS*6110*) is detected.** ● **No RIF mutation in the *rpoB* target sequences has been detected.** ● **No INH mutation in the *katG* and/or *inhA* target sequences has been detected.** **- The MTB target signal has a Ct value within the valid range and endpoint above the minimum setting.** **- RIF and INH mutations in the *rpoB*, *katG* and/or *inhA* signals do not have a Ct value within the valid range and endpoint above the minimum setting.** **- IC: N/A(not applicable); IC signal can be ignored in case the target gene are positive.** **- IC: Valid; IC signal is detected, since the target gene are not amplified.**
MTB Detected **RIF Resistance NOT Detected** **INH Resistance Indeterminate**	● **The MTB target DNA IS1081 and/or IS6110 is detected.** ● **No RIF mutation in the rpoB target sequences has been detected.** ● **INH resistance could not be determined.** **-RIF mutation in the rpoB signals does not have a Ct value within the valid range and endpoint above the minimum setting.** **-IC: N/A(not applicable); IC signal can be ignored in case the target gene are positive.** ● **-IC: Valid; IC signal is detected, since the target gene are not amplified.**
MTB Detected **RIF Resistance Indeterminate** **INH Resistance NOT Detected**	● **The MTB target DNA IS1081 and/or IS6110 is detected.** ● **RIF resistance could not be determined.** ● **No INH mutation in the katG and/or inhA target sequences has been detected.** **-INH mutation in the katG and/or inhA signals does not have a Ct value within the valid range and endpoint above the minimum setting.** **-IC: N/A(not applicable); IC signal can be ignored in case the target gene are positive.** **-IC: Valid; IC signal is detected, since the target gene are not amplified.**
MTB Detected **RIF Resistance Indeterminate** **INH Resistance Indeterminate**	● **The MTB target DNA IS1081 and/or IS6110 is detected.** ● **RIF resistance could not be determined.** ● **INH resistance could not be determined.** **-IC: N/A(not applicable); IC signal can be ignored in case the target gene are positive.** **-IC: Valid; IC signal is detected, since the target gene are not amplified.**
MTB Not Detected	● **The MTB target DNA (IS1081 and/or IS6110) is not detected.** ● **No RIF mutation in the rpoB target sequences has been detected.** ● **No INH mutation in the katG and/or inhA target sequences has been detected.** **- IC: Valid; IC signal is detected, since the target gene are not amplified.**
Invalid case	● **The MTB target DNA (IS1081 and/or IS6110) is not detected.** ● **No RIF mutation in the rpoB target sequences has been detected.** ● **No INH mutation in the katG and/or inhA target sequences has been detected.** **- IC : Invalid; IC and DNA signals do not have a Ct values within valid range** ● **Repeat test.**
Error	● **The MTB Presence or absence of target nucleic acids cannot be determined.** ● **Repeat test.**

Outcome (Home screen)	Result (Review screen)	Description
Positive Resistance Detected		MTB positive & RIF and/or INH resistance positive
Positive Resistance NOT-Detected		MTB positive & RIF and/or INH resistance negative
Positive Resistance Indeterminate		MTB positive & RIF and/or INH resistance cannot be determined
Negative		MTB negative
Invalid		Invalid
Error		Error

Result *(Summary screen)*	Description
	MTB positive
	MTB negative
	Resistance detected
	Resistance undetected
	Resistance cannot be determined
	IC valid
	IC Invalid
	Error

Note	**- If the IC is negative and the results for any of the targets are positive, the results for all targets are considered valid. A high copy number of target-specific gene can lead to reduced or absent IC.** **- If an invalid result is confirmed in one or more of the pathogen results, that tests will be invalidated. Please conduct a re-test.** **- If the MTB signal is detected but not strong enough to judge the resistance, Resistance Indeterminate result is possible.**

11. Quality Control

Quality Control procedures are intended to monitor cartridge and assay performance. If the controls are not valid, the patient results cannot be interpreted.
Internal control (IC): Ensures a proper sample has been applied, reagents in the cartridge are well functioning, there were no other interfering factors in the sample, and the procedure was performed correctly. In clinical samples showing positive signal for MTB and the mutations for RIF/INH, the IC is reluctant and is ignored. If the IC fails, where no MTB and/or the mutations are detected, the result is invalid.
External controls should be used in accordance with local, state, and federal accrediting organizations as applicable.

12. Limitations

1) 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.
2) A false negative result may occur if :
   - Sample concentrations is near or below the limit of detection of the test
   - A specimen is improperly collected, transported or handled
   - Inadequate numbers of organisms are present in the specimen
   - Cartridges are exposed to improper environmental factors (temperature / humidity)
3) False positive results may happen from cross-contamination between patient samples, specimen mix-up and/or DNA contamination during product handling.
4) Qualitative detection of positive results in this kit does not indicate the presence of target gene. It is recommended to use other methods confirmation at the same time.
5) This kit only classifies and identifies the *M. tuberculosis* complex, multi-drug resistant (rifampin and isoniazid). 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) Potential mutations within the target regions covered by the primer and/or probes of the test may result in failure to detect the presence of the pathogen.

13. References

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14. Symbols

REF	**Reference number**	LOT	**Batch code**
IVD	***In vitro* diagnostics medical device**	CE	**CE marking - European Conformity**
	**Consult Instructions for Use**		**Manufacturer**
	**Contains Sufficient for <n> Tests**		**Date of manufacture**
	**Caution**	EC REP	**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
MDR-TB

Please contact your
SD BIOSENSOR representative

Manufacturer
SD Biosensor, Inc.
Head office : C-4th&5th, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA
Manufacturing site : 14, Jeungpyeongsandan-ro, Jeungpyeong-eup, Jeungpyeong-gun, Chungcheongbuk-do, 27915, REPUBLIC OF KOREA

Authorized Representative
MT Promedt Consulting GmbH
Ernst-Heckel-Straße 7 66386 St. Ingbert Germany
Phone : +49 6894 581020, Fax : +49 6894 581021

CE IVD

L28MDRENR2 / Issue date : 2023.02

For *In Vitro* Diagnostic Use Only

Any inquiries regarding instructions provided should be addressed to: sales@sdbiosensor.com
or you can also contact us through www.sdbiosensor.com