STANDARD M10 vanA/vanB

STANDARD™ M10 vanA/vanB

REF M10-VAN-01

INSTRUCTIONS FOR USE

For use with STANDARD™ M10 system

www.sdbiosensor.com

SD BIOSENSOR

Contents

1. Intended Purpose

STANDARD M10 vanA/vanB is a multiplex real-time PCR test intended for use with STANDARD M10 system for the qualitative detection of *vanA* and/or *vanB* genes in rectal swab specimens in patients at risk of intestinal colonization with vancomycin-resistant *Enterococci* (VRE). This test is designed to aid in the diagnosis of colonization or infection with VRE in patients in healthcare settings. Results are for the identification of *vanA*/*vanB* DNA. Positive results are indicative of the presence of *vanA* and/or *vanB* DNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out virus infection or co-infection with other bacteria. The agent detected may not be the definite cause of disease. Negative results do not preclude VRE 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. This test is intended to be performed by trained users in a laboratory setting and is not intended for use in near-patient testing environments.

2. Summary and Explanation

Enterococcus is a facultative anaerobic Gram-positive bacterium that resides in the gastrointestinal tract and urogenital tract. Because it is relatively mildly toxic, it does not easily develop in healthy people. However, it can cause various opportunistic infections such as urinary tract infections and wound infections in the elderly, immunocompromised patients, and patients hospitalized for long periods of time in hospitals and nursing facilities. Accordingly, symptoms appear in various ways. Common symptoms include fever and chills. In the case of urinary tract infection, there may be a burning sensation when urinating and fever, and in the case of wound infection, pus may be observed and symptoms such as fever may be seen.

Vancomycin-resistant *Enterococci* (VRE) are enterococci that are resistant to glycopeptide antibiotics, including vancomycin. *Enterococcus faecium* and *Enterococcus faecalis* are commonly isolated from clinical specimens. VRE is one of the representative causative agents of healthcare-related infections and can cause nosocomial infections that spread to immunocompromised cancer patients, organ transplant recipients, etc. in hospitals. In particular, the vancomycin resistance genes *vanA* and *vanB* of VRE can be transmitted to other bacteria and cause new multidrug-resistant bacteria, so infection control is very important. Accordingly, rapid and accurate screening is necessary for rapid treatment of infected patients and prevention and surveillance of nosocomial infections.

[Cartridge Description]

STANDARD M10 vanA/vanB is a molecular *in vitro* diagnostic assay that aids in the detection of *vanA* and *vanB* genes based on nucleic acid amplification technology, Real-Time PCR. STANDARD M10 vanA/vanB cartridge contains bacterial DNA extraction buffers and Real-Time PCR reagents for the *in vitro* qualitative detection of *vanA*/*vanB* in rectal swab specimens.

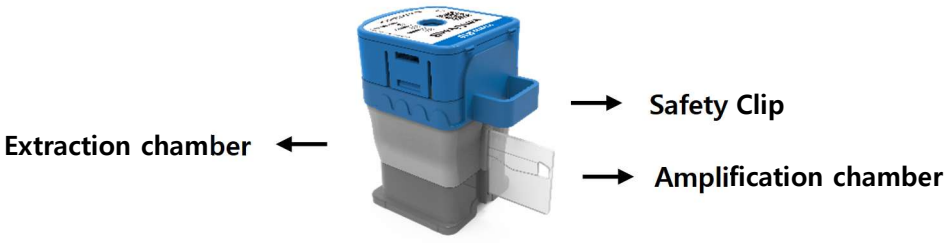

Figure 1. Layout of STANDARD M10 vanA/vanB cartridge

3. Principle of the Procedure

STANDARD M10 vanA/vanB test is an automated *in vitro* diagnostic test for qualitative detection of nucleic acid from individual suspected of vancomycin-resistant *Enterococci* infection. STANDARD M10 vanA/vanB test is performed on STANDARD M10 system.

STANDARD M10 system automates and integrates 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 Real-Time PCR reagents and host the Real-Time PCR process. Because the cartridges are self-contained, cross-contamination between samples is minimized. For a full description of the systems, see STANDARD M10 system User Manual.
STANDARD M10 vanA/vanB test includes reagents for the detection of *vanA* and *vanB* genes in rectal swab specimens. The cartridge is present to control for adequate processing of the sample and Real-Time PCR reaction.
The table below shows the target that each channel is designed to detect.

Table 1. Fluorescent channel of each target gene

Target	Channel
vanA	FAM
vanB	HEX
Internal control (IC)	Cy5

4. Active Ingredients

- Guanidine Thiocyanate 0.47 g
- Taq DNA Polymerase 110 U/bead
- Target primers and probes 5-20 pmol

5. Materials Provided

STANDARD M10 vanA/vanB contains sufficient reagents to process 10 specimens or quality control samples.

Table 2. Contents of STANDARD M10 vanA/vanB

No.	Contents	Quantity	Usage in each reaction
1	Cartridge	10	1
2	STANDARD™ M10 vanA/vanB Sample Buffer	10	1
3	Nozzle Cap	10	1
4	Quick Reference Instructions	1	-

6. Storage and Handling

Store the STANDARD M10 vanA/vanB at a temperature range of 2-28 °C (36-82 °F). Perform the test after stabilizing all reagents and specimens at 15-30 °C (59-86 °F) for 30 minutes. 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.

7. Materials Required but Not Provided

- STANDARD M10 system with User Manual
  At least one STANDARD M10 Console (Cat. No. 11M1011) and one STANDARD M10 Module (Cat. No. 11M1012)
- Commercially available sterilized transport medium for collecting rectal swab
  - Transport Medium (ASAN, AM608-01)
  - Transystem™ Traditional Bacteriology Transport (COPAN, 134C)
- PPE (Personal Protective Equipment)
- Biohazard container

8. Warnings and Precautions

1) This kit is only for *in vitro* diagnostic use only.
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) All patient samples should be handled as if these samples are infectious.
12) All materials should be considered potentially infectious and should be handled with precautions.
13) 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.
14) Clinical laboratories should be equipped with equipment and operators in strict accordance with the "Code of Practice for Clinical Gene Amplification Laboratories."
15) When using this kit, it should be operated strictly in accordance with the instructions and follow the technical requirements of the clinical gene amplification laboratory.
16) Follow your institution's environmental waste procedures for proper disposal of used cartridges.
17) Any serious incident that has occurred in relation to this kit shall be reported to the manufacturer or its authorized representative, and to the competent authority of the Member State in which the user and/or the patient is established, in accordance with the requirements of Regulation (EU) 2017/746.

9. Chemical Hazards

This kit contains components classified as follows in accordance with the regulation (EC) No. 1272/2008:

*** Hazard Pictogram:** 

*** Signal word:** Danger

*** Hazard statement(s)**

- H314 Causes severe skin burns and eye damage
- H318 Causes serious eye damage

*** Precautionary statements:**

1) Prevention

- P260 Do not breathe dust/fume/gas/mist/vapours/spray.
- P264 Wash hands thoroughly after handling.
- P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.

2) Response

- P301+P330+P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
- P303+P361+P353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
- P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
- P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P310 Immediately call a POISON CENTER or doctor/physician.
- P321 Specific treatment.
- P363 Wash contaminated clothing before reuse.

3) Storage

- P405 Store locked up.

4) Disposal

- P501 Dispose of contents/container in accordance with local/regional/national/international regulation.

10. Specimen Collection, Transport, and Storage

In order to obtain an adequate specimen, follow your institution's guidelines of collecting specimens for M10 vanA/vanB testing.

1. Collect and transfer the rectal swab into the commercially available sterilized transport medium.
2. If the container with the rectal swab is stored and transported at a refrigerated temperature of 2-8 ℃ (36-46 ℉), the specimen can be stored for up to 4 days.
3. Store swab specimen at 15 - 30°C (59 - 86℉). The swab specimen is stable up to 12 hours when stored at 15 - 30°C (59 - 86℉).
4. Store swab specimen at -70℃ (-94℉). The swab specimen is stable up to 24 weeks when stored at -70℃ (-94℉).

11. Procedure

11.1 Preparing the sample

1. Stabilize all reagents and specimens at 15 - 30 °C (59 - 86 ℉) for 30 minutes before testing.
2. Rectal swab specimens must be processed by following method.
   1) Remove one swab from the specimen transport tube.
   2) Insert the swab into the Sample Buffer, and stir the swab more than 10 times.
   3) Remove the swab while squeezing the sides of the tube to extract the collected specimen from the swab.
   4) Firmly press the Nozzle Cap onto the Sample Buffer tube.
      A. The prepared specimen is used in the process of 11.3.

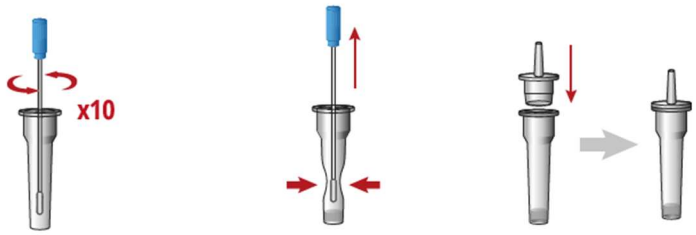

Figure 2. Sample preparation

11.2 Starting STANDARD M10 system

Note	For detailed instructions, refer to 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 STANDARD M10 system.
2) Check STANDARD M10 Console and the STANDARD M10 Module is connected and working.

Figure 3. Power connection

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

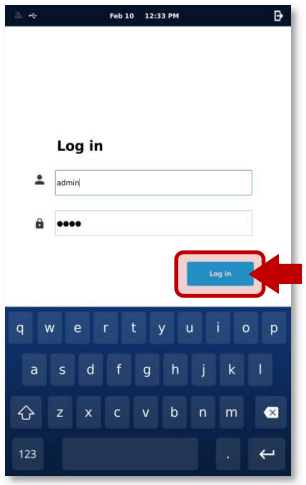

Figure 4. Log In screen

Figure 5. Home screen, Status of M10 module

5) Enter a Patient ID and Sample 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 scanning 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 STANDARD M10 vanA/vanB cartridge to be used. The STANDARD M10 Console will automatically recognize 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.

11.3 Loading a sample into STANDARD M10 vanA/vanB cartridge

⚠ Caution	If the cartridge has been refrigerated, perform the test after stabilizing it for 30 minutes at 20-28 °C (68 -82 °F). Once the sample has been loaded into the cartridge, start the test as soon as possible.
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) Insert the Nozzle of the Sample Buffer tube into the sample loading hole on the cartridge, then squeeze the tube to load the entire specimen into the cartridge. (Sample prepared by the method described in 11.1)

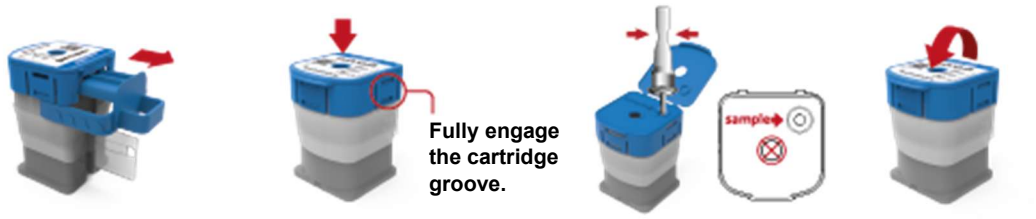

Figure 8. Loading a sample

5) 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.
6) Close the lid.

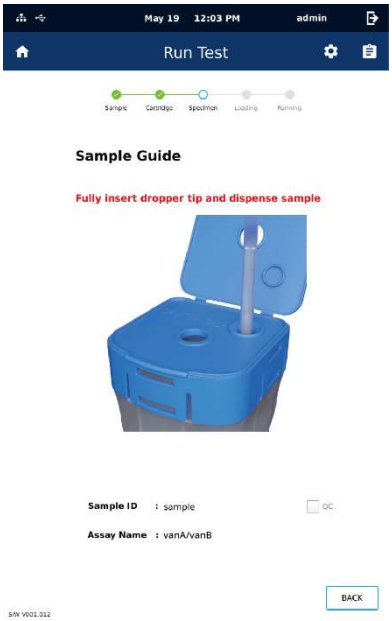

Figure 9. Sample Guide Screen

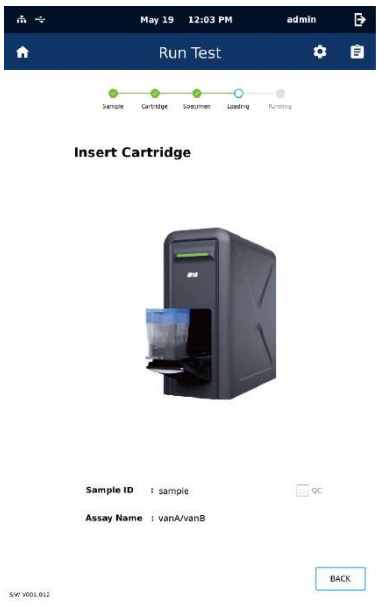

Figure 10. Insert Cartridge screen

11.4 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).
4) Assay starts automatically, and remaining time will appear on the screen.

Figure 11. Confirm the test screen

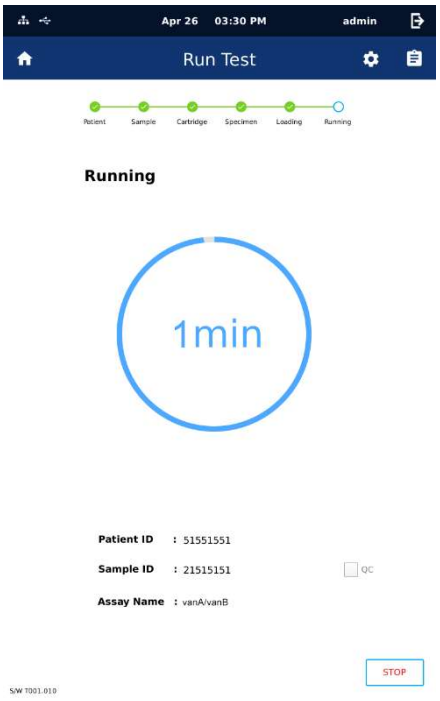

Figure 12. Running screen

5) When the run is finished, it switches to the Review screen and the result is displayed.
6) Dispose the used cartridges in the appropriate biohazard waste container according to your institution's standard practices.
7) 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).

12. Interpretation of Results

The results are interpreted automatically by STANDARD M10 Console and are clearly shown in the Review screen. STANDARD M10 vanA/vanB test provides test results based on the detection of *vanA* and/or *vanB* gene targets according to the algorithms shown in Table 3-6.

Table 3. Summary of results

Result	*vanA*	*vanB*	IC
vanA detected	+	-	+/-
vanB detected	-	+	+/-
vanA/vanB detected	+	+	+/-
vanA/vanB not detected	-	-	+
Invalid	-	-	-
Error	**No result**		

Table 4. Description of results

Outcome (Home screen)	Result (Review screen)	Description
Positive		Target gene is detected.
Negative		Target gene is not detected.

Invalid		All target genes are not detected and IC signal does not have a Ct value within the valid range.
Error		The test failed because either an error occurred or the test was canceled by the user.

Table 5. Description of IC results

Outcome (Summary screen)	Result (Summary screen)	Description
Valid		IC has a Ct within the valid range. : The test was completed. Report positive/ negative results of target according to the interpretation. (If the target is positive, it is displayed as 'Valid' regardless of the IC Ct value.)
Invalid		All target genes are not detected, and IC signal does not have a Ct value within the valid range.
Error		The test failed because either an error occurred or the test was canceled by the user. Repeat test.

Table 6. Interpretation of results

Result	Interpretation
vanA detected	*vanA* target DNA is detected. •*vanA* signal has a Ct value within the valid range. • IC: N/A (not applicable); IC is ignored because *vanA* amplification occurred.
vanB detected	*vanB* target DNA is detected. •*vanB* signal has a Ct value within the valid range. • IC: N/A (not applicable); IC is ignored because *vanB* amplification occurred.
vanA and *vanB* detected	*vanA* and *vanB* target DNA are detected. • *vanA* signal and *vanB* signal have a Ct value within the valid range. • IC: N/A (not applicable); IC is ignored because *vanA* and *vanB* amplification occurred.
vanA and *vanB* not detected	*vanA* and *vanB* target DNA are not detected. • IC: Valid; IC has a Ct within the valid range and endpoint above the minimum setting.
Invalid	IC does not meet acceptance criteria. *vanA* and *vanB* target DNA are not detected. Repeat test. • IC: Invalid; IC and DNA 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 target nucleic acids cannot be determined. Repeat the test.

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 perform a re-test.

13. 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 that a proper sample has been applied, the reagents in the cartridge are well functioning, there are no other interfering factors in the sample, and the procedure has been performed correctly. In clinical samples showing positive signal for *vanA* and/or *vanB* gene, the IC is reluctant and is ignored. If the IC fails and no *vanA* and/or *vanB* gene is detected, the result is considered invalid.

External controls should be used in accordance with local, state, and federal accrediting organizations as applicable.

For external controls, it is recommended to use the list below.

- Positive control(PC) : vancomycin-resistant
  1. ATCC* 700221, *Enterococcus faecium (vanA)*
  2. ATCC BAA-2365, *Enterococcus faecalis (vanB)*
- Negative control(NC) : vancomycin-sensitive
  1. ATCC 29212, *Enterococcus faecalis*

*ATCC: American Type Culture Collection

14. Performance

14.1 Limit of Detection Test

To determine the limit of detection (LoD), *Enterococcus faecium* (vanA) and *Enterococcus faecalis* (vanB) strains diluted in a negative rectal swab matrix were used as reference materials. The study was conducted over three days using two reagent lots. For each concentration level, 24 replicates were tested. The LoD was determined using Probit analysis and the results of the LoD study are shown below.

Type	Genotype	LoD (95% CI)
Enterococcus faecium	*vanA*	10.72 cfu/rxn (95% CI $10^{0.83}$ – $10^{1.24}$)
Enterococcus faecalis	*vanB*	56.23 cfu/rxn (95% CI $10^{1.52}$ – $10^{1.99}$)

14.2 Cross-reactivity

To evaluate the cross-reactivity of the STANDARD M10 vanA/vanB, 48 pathogens (viruses and bacteria) that may cause symptoms similar to those of the target pathogen were tested. Each sample was tested in triplicate. As a result, it was confirmed that there was no cross-reactivity between target genes (*vanA* and *vanB*) and all 48 cross-reactive substances.

No.	Organism	Concentration
1	*Acinetobacter baumannii*	$1x10^6$ CFU/mL
2	*MERS-CoV Culture Fluid*	$1x10^5$ $TCID_{50}$/mL
3	*Candida albicans*	$1x10^6$ CFU/mL
4	*Citrobacter koseri*	$1x10^6$ CFU/mL
5	*Clostridium difficile NAP1 toxigenic strain*	$1x10^6$ CFU/mL
6	*Campylobacter coli*	$1x10^6$ CFU/mL
7	*Clostridium perfringens*	$1x10^6$ CFU/mL
8	*Giardia lamblia*	$1x10^6$ Cells/mL
9	*Enterobacter cloacae*	$1x10^6$ CFU/mL
10	*Haemophilus influenzae*	$1x10^5$ CFU/mL
11	*Enterobacter aerogenes*	$1x10^6$ CFU/mL
12	*Enterococcus avium*	$1x10^6$ CFU/mL
13	*Salmonella enterica subsp. enterica*	$1x10^6$ CFU/mL
14	*Enterococcus casseliflavus*	$1x10^6$ CFU/mL
15	*Enterococcus dispar*	$1x10^6$ CFU/mL
16	*Enterococcus durans*	$1x10^6$ CFU/mL
17	*Enterococcus faecalis*	$1x10^6$ CFU/mL
18	*Enterococcus faecalis*	$1x10^6$ CFU/mL
19	*Enterococcus faecium*	$1x10^6$ CFU/mL
20	*Enterococcus faecalis*	$1x10^6$ CFU/mL
21	*Enterococcus faecium*	$1x10^6$ CFU/mL

22	*Enterococcus gallinarum (vanC1 strain)*	$1x10^6$ CFU/mL
23	*Enterococcus hirae*	$1x10^6$ CFU/mL
24	*Enterococcus raffinosus*	$1x10^6$ CFU/mL
25	*Enterococcus thailandicus*	$1x10^6$ CFU/mL
26	*Escherichia coli*	$1x10^6$ CFU/mL
27	*Bacteroides fragilis*	$1x10^6$ CFU/mL
28	*Vibrio parahaemolyticus*	$1x10^6$ CFU/mL
29	*Klebsiella oxytoca*	$1x10^6$ CFU/mL
30	*Klebsiella pneumoniae*	$1x10^6$ CFU/mL
31	*Lactobacillus acidophilus*	$1x10^6$ CFU/mL
32	*Candida tropicalis*	$1x10^6$ CFU/mL
33	*Clostridioides difficile (Non toxigenic)*	$1x10^6$ CFU/mL
34	*Morganella morganii*	$1x10^6$ CFU/mL
35	*Parabacteroides distasonis*	$1x10^6$ CFU/mL
36	*Peptostreptococcus anaerobius*	$1x10^6$ CFU/mL
37	*Proteus mirabilis*	$1x10^6$ CFU/mL
38	*Proteus vulgaris*	$1x10^6$ CFU/mL
39	*Staphylococcus aureus (MRSA)*	$1x10^6$ CFU/mL
40	*Staphylococcus aureus (MRSA)*	$1x10^6$ CFU/mL
41	*Stenotrophomonas maltophilia*	$1x10^6$ CFU/mL
42	*Streptococcus agalactiae*	$1x10^6$ CFU/mL
43	*Vibrio alginolyticus*	$1x10^6$ CFU/mL
44	*Gardnerella vaginalis*	$1x10^6$ CFU/mL
45	*Citrobacter freundii*	$1x10^6$ CFU/mL
46	*Leuconostoc mesenteroides subsp. Mesenteroides*	$1x10^6$ CFU/mL
47	*Providencia rettgeri*	$1x10^6$ CFU/mL
48	*Providencia stuartii*	$1x10^6$ CFU/mL

14.3 Interference

A total of 15 endogenous and exogenous interfering substances, which may potentially be present in the specimen, were tested. These substances were diluted to the test concentration using negative rectal swab matrix and evaluated under conditions with and without the addition of interfering substances in both negative and 3X LoD concentration samples, with three replicates per condition. The results confirmed that there was no interference up to the specified test concentrations for the 15 substances listed below.

Type	No.	Interfering Substances	Test concentration
Endogenous	1	Human whole blood	5% v/v
	2	Palmitic acid	2 mg/mL
	3	Stearic acid	4 mg/mL
	4	Mucin	3 mg/mL
Exogenous	5	Mineral Oil	2% v/v
	6	Biotin	0.00351 mg/mL
	7	Metronidazole	0.00072 mol/mL
	8	Imodium (antidiarrheal)	0.00667 mg/mL
	9	Fleet Glycerin suppositories	0.17 mg/mL
	10	Barium sulfate	5 mg/mL
	11	Vancomycin hydrochloride acid	12.5 mg/mL
	12	Bismuth subsalicylate	0.87 mg/mL
	13	Benzalkonium chloride	0.12% w/v
	14	Hydrocortisone	2% w/v
	15	K-Y Jelly (Lubricant)	0.17 mg/mL

14.4 Precision (Repeatability & Reproducibility)

14.4.1 Precision (Repeatability)

The precision study of STANDARD M10 vanA/vanB demonstrated consistent and reproducible performance across all tested concentrations (Negative, 1X LoD, 3X LoD, and 5X LoD), with Within-Run, Between-Run, Between-Day, and Within-Laboratory variability all meeting the acceptance criterion of SD < 2 Ct.

14.4.2 Precision (Reproducibility)

The reproducibility study of STANDARD M10 vanA/vanB demonstrated reliable and consistent performance across different lots, operators, and testing sites, with all results meeting the acceptance criteria of SD < 2 Ct and CV < 5% for negative, 1X LoD, and 3X LoD samples.

14.5 Clinical Performance Study

The clinical performance was evaluated for the qualitative detection of the *vanA* and *vanB* genes associated with vancomycin-resistant *Enterococci* (VRE) in rectal swab specimens. Clinical sensitivity and specificity were determined by comparison with reference methods. A total of 194 rectal specimens for VRE were included in the clinical performance analysis.

1) *vanA*

Clinical sensitivity = 95.31% (61/64) [95% CI: 86.91% - 99.02%]
Clinical specificity = 93.85% (122/130) [95% CI: 88.23% - 97.31%]

Table 7. Summary of the clinical evaluation test results

vanA		**Reference methods**		**Total**
		Positive	**Negative**	
STANDARD M10 vanA/vanB	**Positive**	61	8	69
	Negative	3	122	125
	Total	64	130	194

2) *vanB*

Clinical sensitivity = 98.68% (75/76) [95% CI: 92.89% - 99.97%]
Clinical specificity = 94.92% (112/118) [95% CI: 89.26% - 98.11%]

Table 8. Summary of the clinical evaluation test results

vanB		**Reference methods**		**Total**
		Positive	**Negative**	
STANDARD M10 vanA/vanB	**Positive**	75	6	81
	Negative	1	112	113
	Total	76	118	194

15. Limitations

1) STANDARD M10 vanA/vanB detects the *vanA* and/or *vanB* gene from individual having of suspected vancomycin-resistant *Enteroccoci* (VRE) infection.
2) Performance characteristics of this test have been established with the specimen types listed in the Intended Purpose Section only. The performance of this assay with other specimen types or samples has not been evaluated.
3) A false negative result may occur if :
   - Sample concentrations are near or below the limit of detection of the test.
   - A specimen is improperly collected, transported or handled.
   - Inadequate number of organisms are present in the specimen.
   - Cartridges are exposed to improper environmental factors (temperature / humidity).
4) False positive results may happen from cross-contamination between patient samples, specimen mix-up and/or DNA contamination during product handling.
5) Qualitative detection of positive results in this kit does not indicate the presence of live bacteria. It is recommended to use other methods for confirmation at the same time.
6) This kit only classifies and identifies the *vanA* and/or *vanB* gene. 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.

16. References

1) Matthew L. Faron,a Nathan A. Ledeboer,a,b Blake W. Buchana,b. (2016). Resistance Mechanisms, Epidemiology, and Approaches to Screening for Vancomycin-Resistant Enterococcus in the Health Care Setting. Journal of Clinical Microbiology. Volume 54 Number 10. jcm.asm.org
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17. Symbols

REF	Reference number	LOT	Batch code
IVD	*In vitro* diagnostics medical device		Manufacturer
	Consult Instructions for Use		Date of manufacture
	Contains Sufficient for <n> Tests		Keep dry
	Caution		Keep away from sunlight
	Temperature limit		Do not use if packaging is damaged
	Do not re-use.		Use-by date
EU REP	Authorized representative in the European Community	CE 0123	CE marking – European Conformity
	Not for Near-Patient Testing	CAT	Catalog number
CONTENTS	Kit Contents	Manufacturing site	Manufacturing site
Cartridge	Cartridge	Sample Buffer	Sample Buffer
Nozzle Cap	Nozzle Cap	Quick Reference Instructions	Quick Reference Instructions
UK CA	This product fulfills the requirements of UK MDR 2002	UK REP	Indicates the UK Responsible Person

For further information on

STANDARD M10
vanA/vanB

Please contact your
SD BIOSENSOR representative

L28MABEN3R1 / 2026.06

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Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA

Manufacturing site
14, Jeungpyeongsandan-ro, Jeungpyeong-eup,
Jeungpyeong-gun, Chungcheongbuk-do, 27915, REPUBLIC OF KOREA

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IVD **For *In Vitro* Diagnostic Use Only**

CE 0123 UKCA

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