Instructions for use

Diagnostics for the Real World

SAMBA III SARS CoV-2 Test

(Simple nucleic acid AMplification Based Assay)

REF 9100-12

IVD

INTENDED USE

The SAMBA III SARS CoV-2 Test is a nucleic-acid based PCR test for the qualitative detection of nucleic acids from SARS-CoV-2 in human respiratory specimens (combined nose and throat swabs) from symptomatic and asymptomatic individuals. The assay is intended for use by professionals and trained operators on the SAMBA III instrument system in clinical and point-of-care settings.

Samples can be collected in selected Universal Transport Medium/ Viral Transport Medium (UTM/VTM) or SAMBA III Specimen Buffer (provided as part of the kit). The SAMBA III Specimen Buffer inactivates the viruses and hence these samples can be handled at the point-of-care; however, samples collected in UTM/VTM will require a BSC II hood following BSL II requirements for preparation of the sample as the viruses will not be inactivated.

DEVICE DESCRIPTION AND TEST PRINCIPLE

The SAMBA III SARS CoV-2 Test is a fully automated (RT-PCR)-based assay run on the SAMBA III instrument system consisting of the SAMBA III Assay Module and the SAMBA III Tablet Module control unit. The SAMBA III Hub Module is also available as an optional accessory for data management. All reagents are pre-loaded in sealed containers and ready to use without any requirement for preparatory activities prior to running the assay.

The SAMBA III SARS CoV-2 Test requires the use of an amplification tube and three (3) cartridges that hold reagents and materials for extraction of viral nucleic acids from the specimen, amplification of the nucleic acid targets and the detection of the amplification products. All the assay steps which take place sequentially within specific cartridges are driven by mechanical movement of the different parts of the Assay Module. Filters are built-in to further prevent cross-contamination and ensure safety of the user.

Sample extraction: The extraction phase of the assay involves the lysis of the viral targets and release of the nucleic acid into solution, which is then captured by a silica membrane column. The bound nucleic acid is washed then eluted from the membrane.

Amplification and Detection: The SAMBA III SARS CoV-2 Test targets sequences and undergo nested real-time multiplexed polymerase chain reaction amplification and detection in the sealed SAMBA III amplification/detection tube. Detection is via an optical system equipped with filters which detect the different fluorescent tags specific for each target and reads the Ct value which is then converted into a result via a pre-determined algorithm in the Assay Module. The assay result is readable in the SAMBA III Tablet Module via a user interface, which can then print results using a Bluetooth printer. Although the assay is qualitative, the number of cycles may be accessed for additional information purposes only. The assay is provided with a built-in internal control (MS2) to serve as a control throughout the assay.

The result is for the detection of SARS-CoV-2 which is generally detectable in respiratory specimens during the acute phase of infection. A positive result is indicative of active infection while a negative result does not preclude SARS CoV-2 and should not be used as the sole basis for patient management decisions. A negative result must be combined with clinical observations, patient history, and epidemiological information.

PREVENTION OF NUCEIC ACID CONTAMINATION

Nucleic acid amplification-based assays are extremely sensitive and at risk of false positive results when contamination occurs. It is highly recommended that the user read the care and maintenance instructions for the SAMBA instrument system and observe good laboratory practice during SAMBA testing and disposal of used test materials.

MATERIALS AND REAGENTS REQUIRED

SAMBA III SARS CoV-2 Test kit (List No. (9100-12)

NOTE: *All reaction tubes and cartridges required to test twelve (12) samples using the SAMBA III SARS CoV-2 Test Kit are packaged in a Kit Box. The kit contains 12 cartridges, each containing dry and liquid materials: S3 SCoV Cartridge 1, S3 SCoV Cartridge 2, S3 SCoV Cartridge 3 and S3 SCoV Cartridge 4. S3 SCoV Cartridge 1& 3 are packed together while S3 SCoV Cartridge 2&4 are packed together in another pouch. Twelve (12) tubes of SAMBA III Specimen Buffer and a bag of 12 sample collection tubes are also provided with the kit. Each Kit Box has enough cartridges and materials to test 12 samples. All cartridges/tubes are for single-use only.*

9100A & 9100C **12 each** **S3 SCoV Cartridge 1 & S3 SCoV Cartridge 3**

Each S3 SCoV Cartridge 1 contains a lyophilized sphere consisting of a PCR master mix of reverse transcriptase, DNA polymerase, buffers, salts, and synthetic oligonucleotide sequences specific to all target nucleic acids/internal control. Each S3 SCoV Cartridge 1 is for single-use only.

Each S3 SCoV Cartridge *3 contains the lyophilized Internal Control material, enzymes, and a filter column. Each S3 SCoV Cartridge 3 is for single-use only.*

9100B & 9100D **12 each** **S3 SCoV Cartridge 2 & S3 SCoV Cartridge 4**

Each S3 SCoV Cartridge 2 contains tubes with the extraction buffers for nucleic acids from swab samples and the detection buffer containing a mixture of salts, treated casein, 0.10% ProClin 300 and 0.15% ProClin 950 and a disposable adapter. S3 SCoV Cartridge 2 is for single-use only.

Each S3 SCoV Cartridge 4 contains pipet tips and syringe components. For single use only.

C19-0125 **12 each** **SAMBA III Specimen Buffer, 2 ml**

Each tube contains 2 ml of SAMBA III Specimen Buffer which includes a detergent that inactivates viruses and bacteria.

Other materials required and provided

C19-0130-12 S3 Sample Collection Tube
C20-0009-12 Transfer pipets, 453 µl

Other materials required but <u>not</u> provided

Flocked, rayon or Dacron swabs with plastic shaft for sample collection.
Pipettor and tips capable of delivering 200µl (When using samples collected in UTM)

Equipment to be ordered separately

I19-0007-AM SAMBA III Assay Module (required)
I19-0007-TM SAMBA III Tablet Module (required)
I19-0007-HM SAMBA III Hub Module and Data management system (optional)
SAMBA printer (optional)

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WARNINGS AND PRECAUTIONS

For *In Vitro* Diagnostic Use Only

Safety Precautions

- *Handle all specimens as though capable of transmitting infectious agents. Note that the SAMBA III Specimen Buffer inactivates SARS CoV-2, hence, these samples can be handled at the point-of-care; however, samples collected in UTM/VTM will require a BSC II hood following BSL II requirements for preparation of the sample.*
- *Wear disposable powder-free gloves, laboratory coat and safety glasses at all times while performing the test. Change gloves as often as possible.*
- *Do not re-use the single-use kit components (e.g. cartridges) under any circumstances.*
- *Read these Instructions for Use and the SAMBA III instrument system User Guides completely before using this product and follow the instructions carefully.*
- *Do not use kit or its components after stated **kit expiry date**.*
- *Dispose of all contaminated materials such as cartridges and tips in accordance with local, state and federal or national regulations.*
- *Do not inhale or swallow any liquid or dry reagents. Avoid contact with skin. Rinse with plenty of water if contact occurs.*
- *Adhere to Good Laboratory Practice (GLP) while running the tests or handling specimens at all times.*
- *Do NOT attempt to open cartridges after use. This can lead to contamination of the laboratory with amplification products.*
- *Clean and disinfect all work surfaces thoroughly with nucleic acid cleaning agent. Freshly prepared 0.5% hypochlorite solution may also be used to clean surfaces and cavities of the SAMBA III Assay Module, followed by distilled water, and 70% ethanol or isopropyl alcohol, then allowed to dry before use.*

S3 SCoV Cartridge 2 contains a mixture of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one, which are components of ProClin. These components are classified per applicable European Community Directives as:

Warning: (see Safety Data Sheet (SDS) for additional details)

Danger: (see Safety Data Sheet (SDS) for additional details)

Hazard statements:

- *H317: May cause an allergic skin reaction*
- *H315: Causes skin irritation*
- *H319: Causes serious eye irritation*

Precautionary Statements Prevention

- *P261: Avoid breathing dust/fume/gas/mist/vapors/ spray*
- *P272: Contaminated work clothing should not be allowed out of the workplace*
- *P280: Wear protective gloves/protective clothing/eye protection/face protection*
- *P264: Wash hands thoroughly after handling*

Precautionary Statements Response

- *P305+P351+P338: If in eyes, rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do; continue rinsing.*
- *P337+P313: If eye irritation persists, get medical advice/attention.*
- *P302+P352: If on skin, wash with plenty of soap and water.*
- *P362, P363: Take off contaminated clothing and wash before reuse.*
- *P333+P313: If skin irritation or rash occurs, get medical advice/attention.*
- *P501: Dispose of contents/container to an approved waste disposal plant*

Reagent storage and handling instructions

- *Store the kit at 2-30°C.*
- *Keep all cartridges/tubes in original packaging until ready for use.*
- *Do not use kit components that show signs of tear or breach of packaging.*
- *Do not use the kit beyond the expiration date printed on the outside of the kit box.*

INSTRUMENT REQUIREMENTS

The SAMBA III SARS CoV-2 Test is performed using the SAMBA III instrument system consisting of the SAMBA III Assay Module (P/N I19-0007-AM) and the SAMBA III Tablet Module *(*P/N I19-0007-TM) and SAMBA III Hub Module (P/N I19-0007-HM) (optional). The SAMBA III instrument system must be set up properly prior to performing the assay. Refer to the appropriate sections on specimen handling and assay procedure described in this document and User Guide of each instrument for detailed operating procedures.

SPECIMEN COLLECTION AND HANDLING INSTRUCTIONS

1. *NOTES:*
    a. *As the SARS CoV-2 is extremely infectious, collect and handle specimens with appropriate PPE prescribed by your institution.*
    b. *Samples collected in SAMBA III Specimen Buffer which inactivates the virus can be handled at the point-of-care; however, samples collected in UTM/VTM will require a BSC II hood following BSL II requirements for preparation of the sample.*
2. Collect specimens from combined nose and throat swabs according to the swab manufacturer's instructions.
3. Flocked, rayon or Dacron swabs with plastic shaft are preferred for collecting respiratory samples. Proper specimen collection, storage, and transport are critical to the performance of this test (see Limitations of the test, page 15).

4. For swab specimens placed in UTM/VTM, proceed to Section A.1.a.
   (NOTE: Remel M4RT and MWE Virocult collection are suitable for use with the SAMBA III SCoV-2 Test diluted at 1:2 in SAMBA III Specimen Buffer. Other transport media have not been validated with the SAMBA III SARS CoV-2 Test, thus, their performance with the assay has not been assessed).
5. For swab specimens placed in SAMBA III Specimen Buffer, proceed to Section A.1.b.
6. For optimum results, however, test samples within the same day of collection. Freezing/thawing of samples should be avoided but if needed for archiving purposes, samples frozen at -80°C for up to 9 months are acceptable for testing with SAMBA III SARS CoV-2 Test.

ASSAY PROCEDURE

READ these instructions for use and the SAMBA III instrument system User Guides carefully before performing the test. Don appropriate PPE according to your institution's health and safety requirements.

The SAMBA III SARS CoV-2 Test is intended to be used only with the SAMBA III instrument system.

- *Do not use kits beyond kit expiration date.*
- *Components within a kit box are intended to be used together.*
- *If necessary, bring the specimens to room temperature (15-30°C) before commencing the assay.*
- *To reduce the risk of nucleic acid contamination, clean and disinfect spills of specimens and reagents by using a detergent solution, followed by a tuberculocidal disinfectant such as 0.5% hypochlorite solution or other suitable disinfectant. For the instruments, follow the care and maintenance procedures before and after use detailed in the User Guide for the SAMBA III Assay Module.*
- *Record of the test results must be kept as per the established protocols of your organization or institution.*

1. **Switch on the SAMBA III Assay Module.** The internal light will illuminate and the status indicator strip on the front of the module will show white and the module number will appear. The AM is now ready for use.
2. **Switch on the SAMBA III Tablet Module.** On the TM select the AM number that you wish to use to run the assay (the Module Number from the front of the AM will be displayed on the TM).

Additional notes:

Set-up the SAMBA III instrument system before starting the assay:

For detailed instructions on how to operate the SAMBA III Assay Module and the SAMBA III Tablet Module, refer to respective User Guide for each instrument prior to use. Laboratory personnel must be trained to operate the SAMBA III instrument system and must follow good laboratory practice. Refer to the **WARNINGS AND PRECAUTIONS in this document prior to preparing specimens.**

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A. SAMPLE PREPARATION

1. **NOTE: Follow your routine procedure for handling swabs including appropriate PPE and BSL requirements.**

    a. **For swabs in Universal / Virus Transport medium (NOTE: Perform the following steps in a BSC II hood and follow BSL II requirements as UTM samples have not been inactivated).**

        i. Mix well and open the lid of the SAMBA III Specimen Buffer (Code C19-0125).

        ii. Using a pipettor and pipette tips capable of dispensing 200µl , transfer 200 µl of the buffer into the Sample Collection Tube (red cap) provided.

        iii. Transfer 200 µl of the sample in transport medium into the same Sample Collection Tube (red cap) provided.

        iv. Mix by pipetting up and down gently three times. Cap the tube and leave the sample for 10 minutes inside the tube prior to use to inactivate the sample.

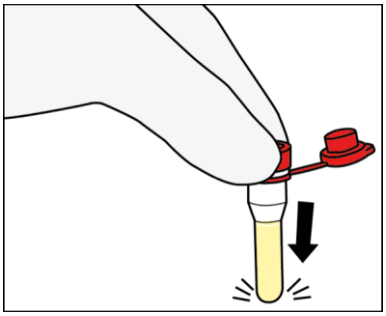
    b. **Sample collection using SAMBA III Specimen Buffer (Code C19-0125)**

        i. Insert the swab into the SAMBA III Specimen Buffer (Code C19-0125) tube and break at the marked point on the shaft. Discard the shaft as potentially infectious material.

        ii. Soak the swab for 10 minutes in the SAMBA III Specimen Buffer.

        iii. Mix the sample by shaking side to side.

        iv. Using the transfer pipet provided with the kit, transfer 400 µl of the inactivated sample into the Sample Collection Tube and cap securely.



2. Proceed to running the assay (Section B).

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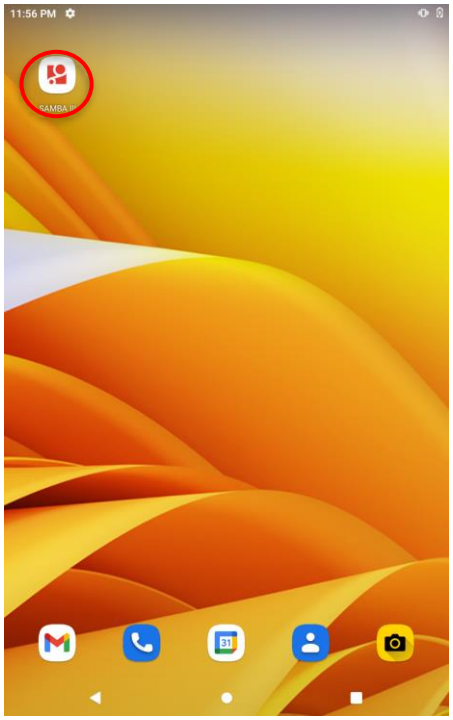
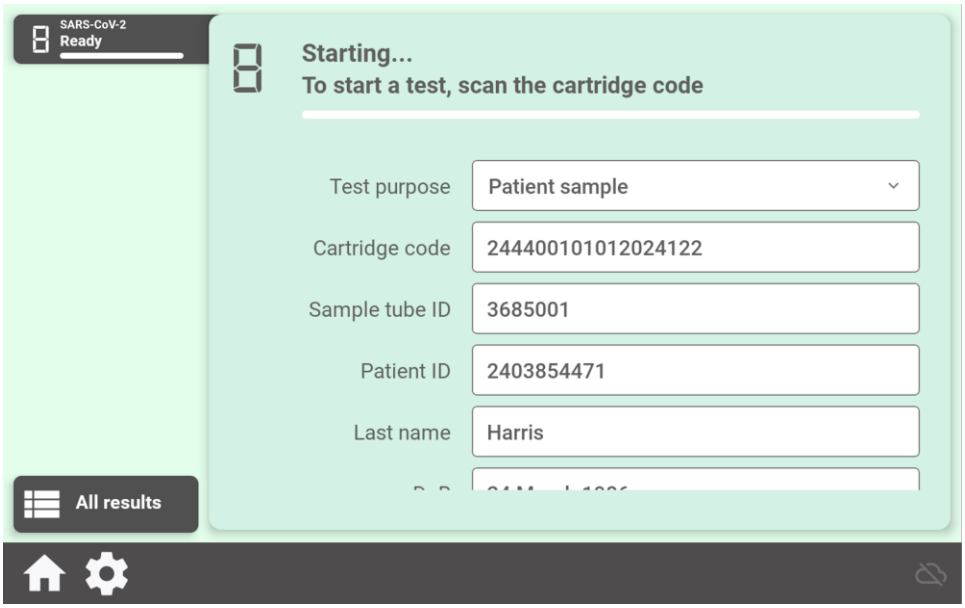
B. RUNNING THE ASSAY USING THE SAMBA III INSTRUMENT SYSTEM

1. Switch on the Tablet and unlock using the PIN or password set for device (Refer to User Guide for SAMBA III Tablet Module for detailed instructions- Doc no C19-0123). Locate the SAMBA III App icon on the Home screen. Tap the SAMBA III icon to launch the App.



2. App will open and display the main Application screen. When App launches, it will attempt to connect to all previously connected Assay Modules.



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3. Using the TM scan the 2D barcode on the S3 SCoV Cartridge 2 and 4 bag to identify the assay type. Carefully remove the cartridges from the bags. Visually inspect each cartridge to ensure foil seals are not perforated and cartridges and tubes are securely clipped.

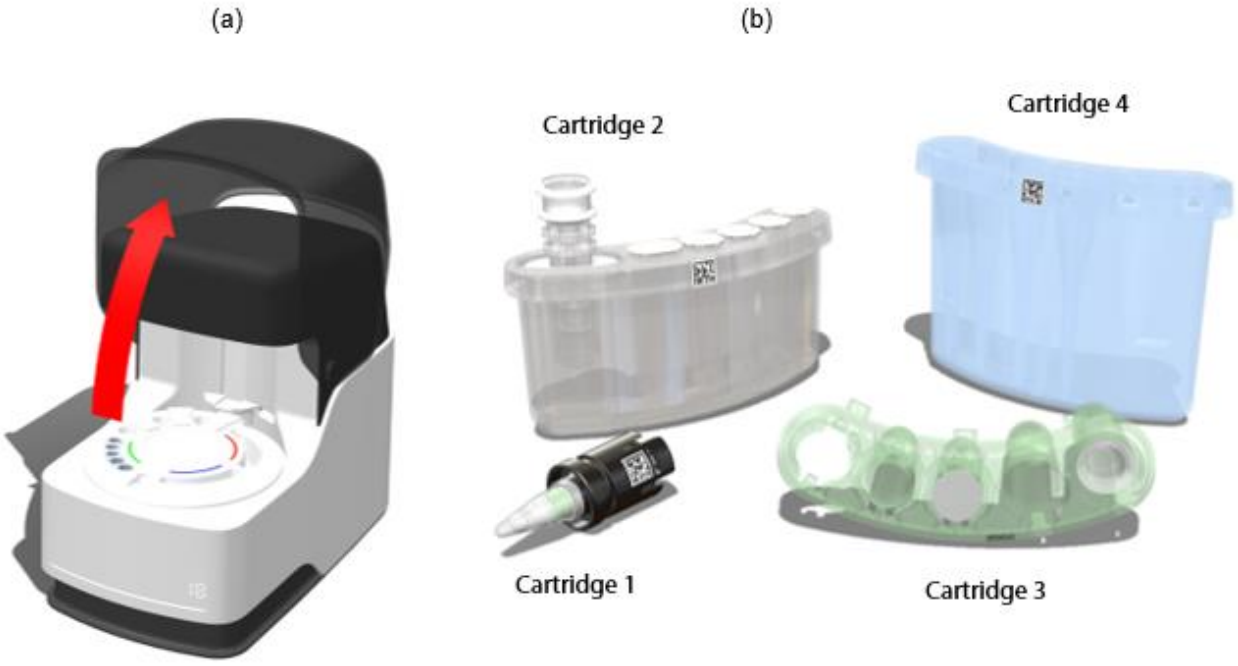
C. Set up the SAMBA III Assay Module.

1. Set up the SAMBA III SARS-CoV-2 Test Cartridges on the SAMBA III Assay Module.
2. Open the kit box and remove a set of 2 bags (combined S3 SCoV Cartridge 1 & S3 SCoV Cartridge 3 and combined S3 SCoV Cartridge 2 & S3 SCoV Cartridge 4).
3. Confirm the contents:

   1 each S3 SCoV Cartridge 1 & 3 (List no. 9100A and list no. 9100C)

   1 each S3 SCoV Cartridge 2 & 4 (List no. 9100B and List no. 9100D)

4. Scan the 2D Barcode on the bag containing S3 SCoV Cartridge 2 and S3 SCoV Cartridge 4.
5. Open the AM lid to its full extent (a), (it will stay open unaided) and inspect the cartridges (b).



6. Load cartridges into the Assay Module following the diagram below:
   - Remove S3 SCoV Cartridge 1 and S3 SCoV Cartridge 3 from the pouch.
   - Insert each of S3 SCoV Cartridge 1 into position 1.
   - Insert S3 SCoV Cartridge 3 into position 3.
   - Remove S3 SCoV Cartridge 2 and S3 SCoV Cartridge 4 from the pouch.
   - Load S3 SCoV Cartridge 2 into position 2.
   - Insert S3 SCoV Cartridge 4 into position 4.
   - Scan the 2D barcode on the Sample Collection Tube containing the sample and load into in the sample holder (see 5 in the figure below):

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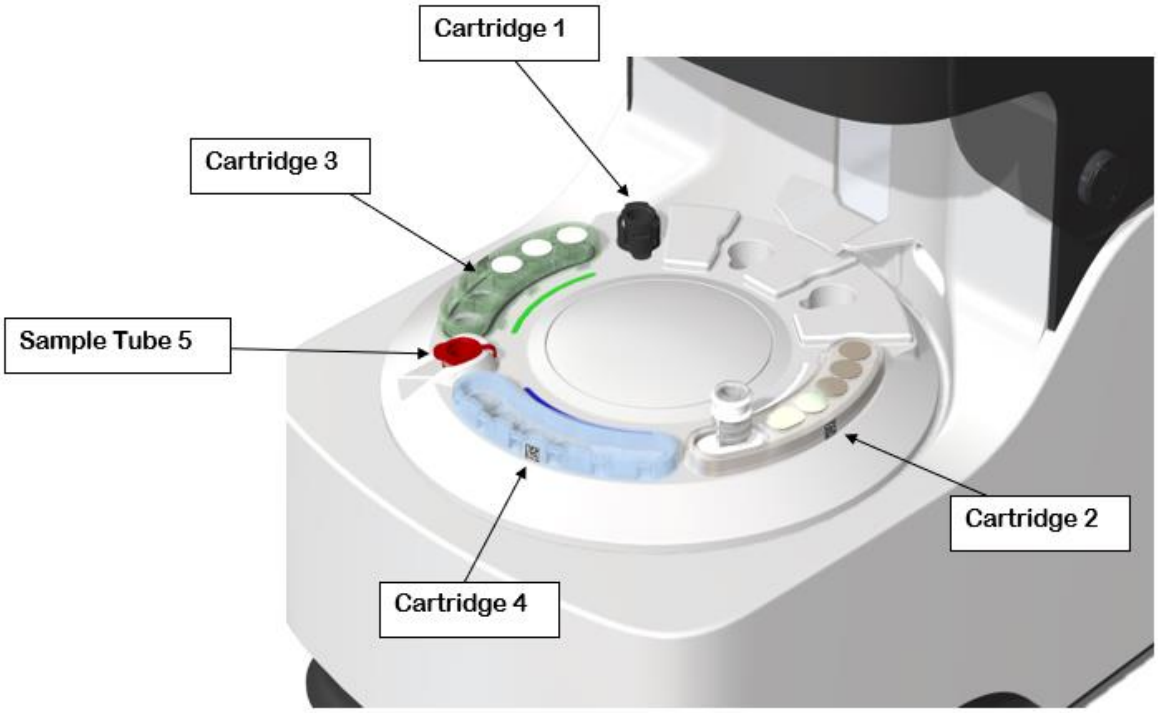
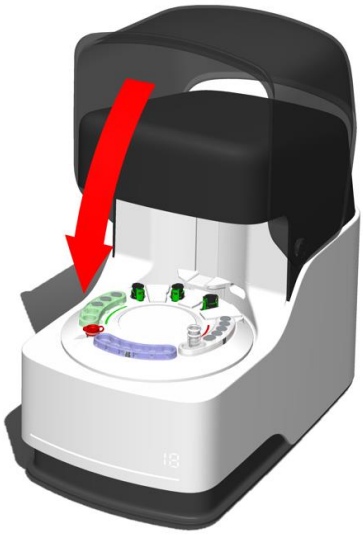


7. Ensure that all cartridges are fully inserted and snugly fit before proceeding. The turret can be rotated if needed to make it easier to load the cartridges. (See the User Guide for Assay Module, Doc No. C19-0122, for details on how to load the cartridges and samples).

8. Close the lid.



9. Fill out the mandatory fields on the tablet module.

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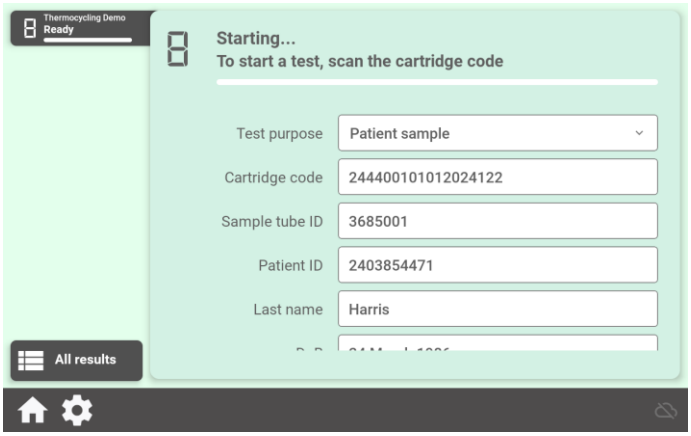
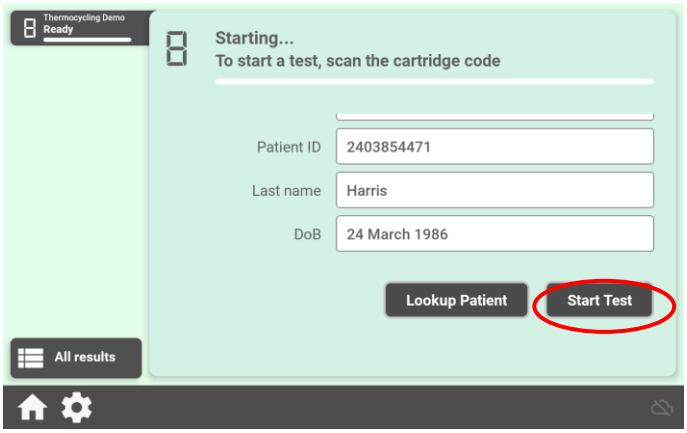
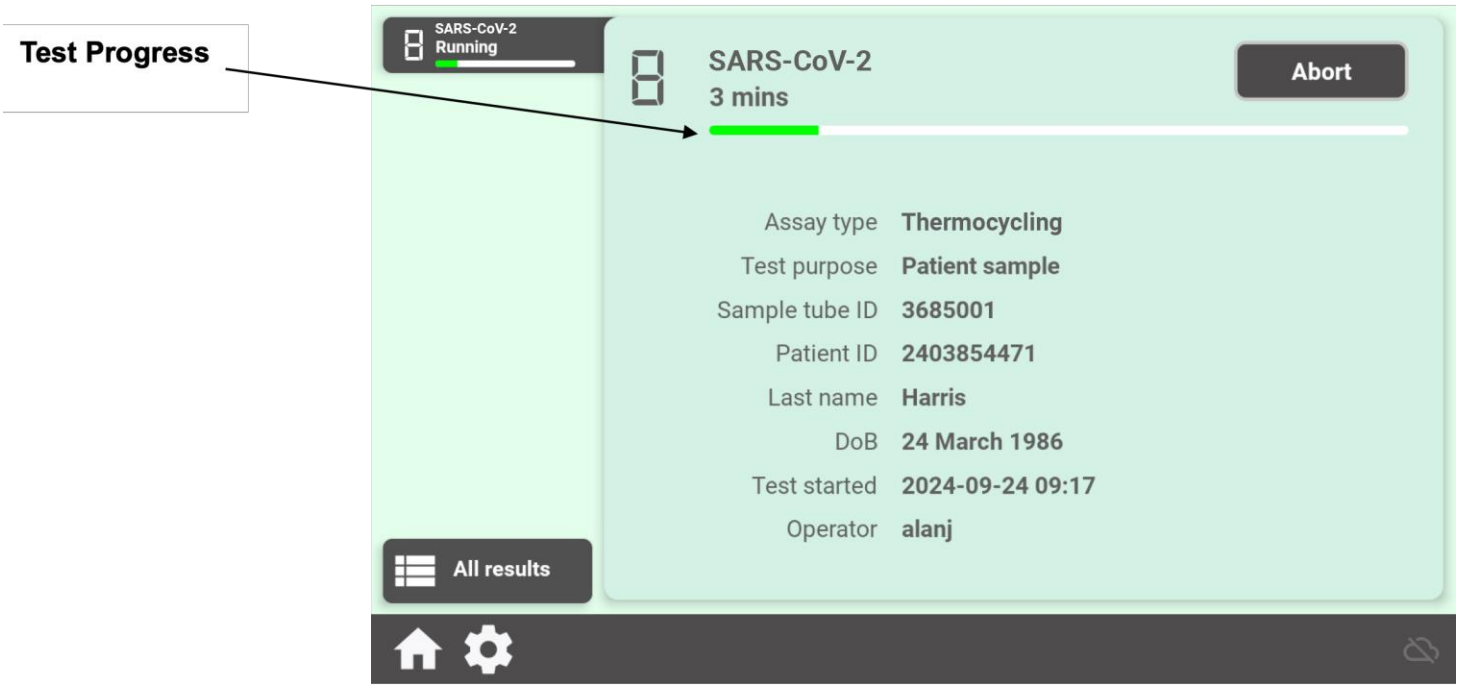
> ⚠ DO NOT OPEN THE LID at any time during a test. This will stop the test and any results will be invalid.
>
> Please refer to the SAMBA III Tablet Module User Guide (C19-0123-EN) for information on how to run a test.

10. The start button will now be available on the Tablet Module. The AM is now ready to begin testing. Press the Start button to proceed.

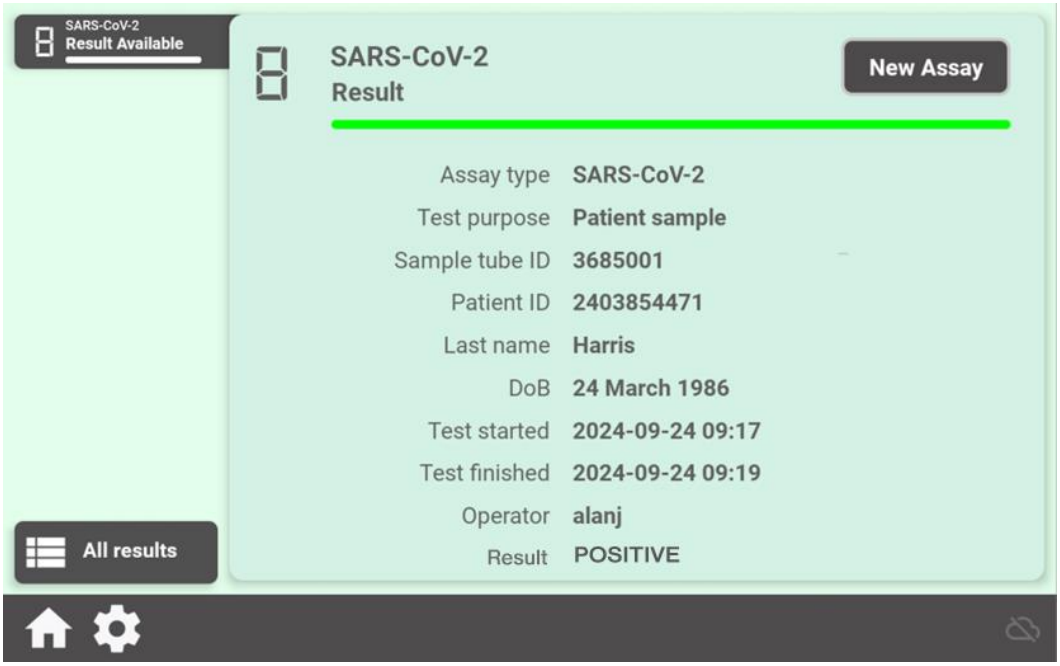




Once the test has started, a Test Progress bar will appear on the screen. The stripe on the front of the Assay Module will change from white to green. The details for the test running will appear on the Test Progress screen on the Tablet Module as shown below. The entire assay will run for approximately **35 minutes**.



11. At the end of the test, a summary of the test details and results are displayed on the Test Result screen.



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12. Once the assay is completed, the AM will come to a stop and the status indicator strip on the front of the machine will appear white. The DMS on the TM will also indicate that the test has finished. The test cartridges may now be removed. **Note:** Used cartridges and sample tube are biohazardous and should be disposed of according to the established procedures for such materials.

13. Once all the cartridges and sample tube have been removed, the SAMBA III AM may either be switched off or prepared for another test.

Note: *A record of the test result must be kept with patient records in accordance with the established protocols of your organization or institution. To achieve this, the Test Result screen has 3 buttons- SEND SMS, PRINT and START NEW TEST. Refer to Tablet Module User Guide (Doc No. C19-0125) for details on connecting to Bluetooth printer to print results and uploading test results to the Hub Module). As an option to upload the result to a LIMS, refer to the User Guide for Hub/DM Module (C19-0124).*

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INTERPRETATION OF RESULTS

A. Reading of results

At the end of the assay, one of the following six (6) results appears on the SAMBA III Tablet Module.

Tablet Module read-out	Interpretation of result
SARS CoV-2 Negative	SARS-CoV-2 was not detected.
SARS CoV-2 Positive	SARS-CoV-2 was detected.
Invalid	Repeat testing*
Halted	Repeat testing*
No result	Repeat testing*

**Test needs to be repeated using fresh sample and cartridges. For a repeat invalid result which may be due to inhibitory substances intrinsic to the sample itself or extremely high viral load, sample can be tested using an alternate platform or by carrying out further dilution (e.g. 1:10 using SAMBA III Specimen Buffer or as per the institution's standard o*

QUALITY CONTROL

The Internal Control signal should always serve to verify in the absence of a test line, that each specimen was processed correctly and that no inhibitors of amplification were present. In samples with high organism load, the internal control line may not appear. An external positive control may be run with the SAMBA III SARS CoV-2 Test after routine validation per laboratory standard operating procedure.

Limitations of the Test

For *in vitro* diagnostic use only.

- SAMBA III SARS CoV-2 Test has been validated for qualitative detection of SARS-CoV-2 in combined nasal + throat swab specimens. Test reagents and procedures should be run in conjunction with the SAMBA III instrument system.
- Clinical performance of the SAMBA III SARS CoV-2 Test has only been established in combined nasal and throat clinical specimens according to the requirements of UK Coronavirus Test Devices Approval (CTDA).
- Flocked, rayon or dacron swabs are preferred for collecting respiratory samples. As per current recommendations by Public Health England urethral, pernasal or mini-tip swabs may also be alternatives if standard sized swabs are not available. 'Charcoal' swabs (swabs containing medium) are not suitable. Swabs with wooden polystyrene shafts should be used, as swabs with wooden shafts may contain PCR inhibitors and may also be a safety issue.
- The SAMBA III SARS-CoV-2 Test requires personnel trained on the SAMBA III instrument system to run the instrument and the assay procedures.
- The SAMBA III SARS-CoV-2 Test procedures and instrument system have been designed to reduce the risk of contamination with amplification product. However, contamination from specimens and other sources must be prevented by good laboratory practice and strict adherence to the procedures described in the Instructions for Use.
- Certain nasal sprays have been found to interfere with the SAMBA III SARS-CoV-2 Test. Therefore, it is highly recommended to ask the patient to refrain from using nasal sprays prior to sample collection.

- As with any other *in vitro* diagnostic test, the detection of SARS-CoV-2 is dependent on several factors such as the number of virus present in the specimen, the quality of the specimen, etc. Results from the SAMBA III SARS-CoV-2 Test must be interpreted in conjunction with other clinical and laboratory findings.

PERFORMANCE EVALUATION

The performance characteristics of the SAMBA III SARS-CoV-2 Test were determined using various reference materials including prepared panels and clinical specimens.

WHO First International Standard for SARS-CoV-2 RNA, NIBSC Code: 20/146

Clinical specimens

Microorganisms from the American Type Culture Collection, Zeptometrix and BEI Resources (See Table 2b for details)

Analytical sensitivity (Limit of detection)

The SAMBA III SARS CoV-2 Test was analyzed for its limit of detection using an international standard (WHO First International Standard for SARS-CoV-2 RNA, NIBSC Code: 20/146) diluted in pooled nasal + throat swab specimens collected in UTM or SAMBA III Specimen Buffer. Three lots of reagents were used for LOD determination. A total of 24 replicates per concentration per lot were tested and analyzed by Probit for estimation of LOD. Results are summarized in Tables 1a and 1b.

Table 1a: Limit of Detection using the WHO First International Standard for SARS-CoV-2 RNA, NIBSC Code: 20/146 in SAMBA Specimen Buffer

Concentration (IU/ml)	Log_{10} conc	N	Pos	Pos/N	Probit
300	2.48	24	24	1.00	-
250	2.40	24	24	1.00	-
200	2.30	24	24	1.00	-
150	2.18	24	23	0.96	6.732
100	2.00	24	22	0.92	6.383
50	1.70	24	18	0.75	5.674

Estimated LOD: 135 IU/ml (95% CI: 115 –194)

Using UTM as sample collection buffer, the LOD was estimated using Probit analysis as 245 IU/ml (95% CI: 193-268) (Table 1b).

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Table 1b: Limit of Detection using the WHO First International Standard for SARS-CoV-2 RNA, NIBSC Code: 20/146 in UTM Buffer

Concentration (IU/ml)	Log_{10} conc	N	Pos	Pos/N	Probit
500	2.70	24	24	1.00	-
400	2.60	24	24	1.00	-
300	2.48	24	24	0.99	7.33
200	2.30	24	20	0.83	5.967
100	2.00	24	17	0.71	5.549

Estimated LOD: 245 IU/ml (95% CI: 193-268)

Inclusivity

To assess the analytical reactivity (inclusivity) of the SAMBA III SARS-CoV-2 Test (P/N 9100), variant strains of SARS CoV-2 (Table 1c) were tested in spiked pooled negative nose + throat swab specimens at low concentration (3X LOD) using three lots of reagents (one replicate/lot). All strains of SARS-CoV-2 (four variants) were detected (Table 1c). For the wild type strain, the WHO First International Standard for SARS-CoV-2 RNA, NIBSC Code: 20/146 was used extensively in the analytical performance evaluation.

Table 1c: Analytical reactivity of the SAMBA III SARS CoV-2 Test on SARS CoV-2 variants.

Strain	Source	Accession No.	Lot number	Tablet result interpretation
Heat-inactivated SARS-CoV-2 variant B.1.1.7	ATCC[a]	VR-3326HK	70043248	SARS CoV-2 Positive
Heat-inactivated SARS-CoV-2 variant B.1.351 (Beta)	ATCC	VR-3327HK	70045506	SARS CoV-2 Positive
Heat-inactivated SARS-CoV-2, Omicron variant	ATCC	VR-3347HK	70050282	SARS CoV-2 Positive
Heat-inactivated SARS-CoV-2, Delta variant	ATCC	VR-3342HK	70048932	SARS CoV-2 Positive

[a]*ATCC: American Type Culture Collection, 10801 University Boulevard, Manassas, VA 2011*

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Analytical specificity (Cross-reactivity)

An *in silico* analysis for possible cross-reactivity with related Coronaviruses and other high-risk microorganisms was conducted by mapping primers and probes in the SAMBA III SARS-CoV-2 Test individually to the sequences downloaded from the NCBI database. None of the SAMBA primers nor probes had >80% homology to the following related Coronaviruses: hCoV-NI63, hCoV-229E, hCoV-OC43, MERS-CoV and SARS-CoV nor other microorganisms. When tested in wet format at high organism load, all the five human Coronaviruses tested gave negative results with the SAMBA test.

In addition, *in silico* analysis for possible cross-reactions with all the organisms in Table 2a was conducted by carrying out a BLASTn search for of each of the SAMBA primers and probes against NCBI databases and retrieving all sequences with homologies > 80% (Table 2a).

Table 2a. Percent homology of the SAMBA III SARS-CoV-2 Test primers, capture probes and detector probes with high priority organisms likely in the circulating area.

High priority organisms likely in the circulating area	Primer ORF1ab F	Primer ORF1ab R	Probe ORF1ab P	Primer ORF8 F	Primer ORF8 R	Probe ORF8 P
Adenovirus (e.g. C1 Ad. 71)	<80%	<80%	<80%	<80%	<80%	<80%
Human Metapneumovirus (hMPV)	<80%	<80%	<80%	<80%	<80%	<80%
Parainfluenza virus 1-4	<80%	<80%	<80%	<80%	<80%	<80%
Influenza A	<80%	<80%	<80%	<80%	<80%	<80%
Influenza B	<80%	<80%	<80%	<80%	<80%	<80%
Enterovirus (e.g. EV68)	<80%	<80%	<80%	<80%	<80%	<80%
Respiratory syncytial virus	<80%	<80%	<80%	<80%	<80%	<80%
Rhinovirus	<80%	<80%	<80%	<80%	<80%	<80%
Chlamydia pneumoniae	<80%	<80%	<80%	<80%	<80%	<80%
Haemophilus influenzae	<80%	<80%	<80%	<80%	<80%	<80%
Legionella pneumophila	<80%	<80%	<80%	<80%	<80%	<80%
Mycobacterium tuberculosis	<80%	<80%	<80%	<80%	<80%	<80%
Streptococcus pneumoniae	<80%	<80%	<80%	<80%	<80%	<80%
Streptococcus pyogenes	<80%	<80%	<80%	<80%	<80%	<80%
Bordetella pertussis	<80%	<80%	<80%	<80%	<80%	<80%
Mycoplasma pneumoniae	<80%	<80%	<80%	<80%	<80%	<80%
Pneumocystis jirovecii (PJP)	<80%	<80%	<80%	<80%	<80%	<80%
Candida albicans	<80%	<80%	<80%	<80%	<80%	<80%
Pseudomonas aeruginosa	<80%	<80%	<80%	<80%	<80%	<80%

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High priority organisms likely in the circulating area	Primer ORF1ab F	Primer ORF1ab R	Probe ORF1ab P	Primer ORF8 F	Primer ORF8 R	Probe ORF8 P
Staphylococcus epidermidis	<80%	<80%	<80%	<80%	<80%	<80%
Streptococcus salivarius	<80%	<80%	<80%	<80%	<80%	<80%
SARS-CoV-1	<80%	<80%	<80%	<80%	<80%	<80%
Human coronavirus 229E	<80%	<80%	<80%	<80%	<80%	<80%
Human coronavirus OC43	<80%	<80%	<80%	<80%	<80%	<80%
Human coronavirus HKNI63	<80%	<80%	<80%	<80%	<80%	<80%
SARS-CoV HKU339849	<80%	<80%	<80%	<80%	<80%	<80%
MERS-coronavirus	<80%	<80%	<80%	<80%	<80%	<80%
Corynebacterium diptheriae	<80%	<80%	<80%	<80%	<80%	<80%
Legionella pneumophila	<80%	<80%	<80%	<80%	<80%	<80%
Bacillus anthracis (*Anthrax*)	<80%	<80%	<80%	<80%	<80%	<80%
Moraxella catarrhalis	<80%	<80%	<80%	<80%	<80%	<80%
Neisseria elongata	<80%	<80%	<80%	<80%	<80%	<80%
Neisseria meningitidis	<80%	<80%	<80%	<80%	<80%	<80%
Morbillivirus (Measles)	<80%	<80%	<80%	<80%	<80%	<80%
Varicella zoster (chicken pox)	<80%	<80%	<80%	<80%	<80%	<80%

Wet testing with specific strains of microorganisms (10^6 cells/ml for bacteria and yeast and 10^2-10^5 pfu or $TCID_{50}$/ml for viruses) (Table 2b) in nasal and throat swab specimens in SAMBA III Specimen Buffer showed that SARS-CoV-2 at 3X LoD (450 IU/ml) was detected by SAMBA III SARS-CoV-2 Test in spiked samples. The unspiked samples gave negative results indicating that the assay is specific and confirmed the results from *in silico* analysis.

Table 2b. Specific strains used in wet testing for cross-reactivity.

Microorganism	Source	Accession number	Final concentration tested
Bacteria			
Acinetobacter calcoaceticus	ATCC	23055	10^5/ml
Arcanobacterium haemolyticum	ATCC	9345	10^5/ml
Bordetella avium	ATCC	35086	10^5/ml
Bordetella bronchiseptica	ATCC	10580	10^5/ml
Bordetella hinzii	ATCC	51783	10^5/ml
Bordetella holmesii	ATCC	700052	10^5/ml
Burkholderia orbicola (formerly *B. cepacia)*	ATCC	17762	10^5/ml
Chlamydia trachomatis	Zeptometrix	801775	10^5/ml
Chlamydophila pneumoniae TW-183	ATCC	VR-2282	10^5/ml
Corynebacterium diphtheriae	Zeptometrix	801882	10^5/ml
Corynebacterium striatum	ATCC	BAA-1293	10^5/ml
Enterobacter cloacae	AR Bank	#0038	10^5/ml
Escherichia coli	AR Bank	#0538	10^5/ml
Fusobacterium necrophorum subsp *necrophorum*	ATCC	27852	10^5/ml
Haemophilus influenzae	ATCC	33391	10^5/ml
Haemophilus influenzae	ATCC	49766	10^5/ml
Klebsiella pneumoniae	AR Bank	#0039	10^5/ml
Lactobacillus acidophilus	Zeptometrix	801540	10^5/ml
Lactobacillus plantarum	Zeptometrix	804436	10^5/ml
Legionella (Fluoribacter) bozemanae	ATCC	33217	10^5/ml
Legionella (Fluoribacter) dumoffii	ATCC	33279	10^5/ml
Legionella longbeachae	Zeptometrix	801577	10^5/ml
Legionella (Tatlockia) micdadei	Zeptometrix	801576	10^6/ml
Legionella pneumophila	Zeptometrix	804007	10^6/ml
Leptospira interrogans serovar Copenhageni strain Fiocruz L1-130	ATCC	BAA-1198D-5	0.7 ug/100 µl
Moraxella catarrhalis	ATCC	8176	10^5/ml
Mycoplasma genitalium strain G37, Genomic DNA	ATCC	33530D	16
Mycoplasma orale	ATCC	19524	10^5/ml
Mycoplasma hominis	Zeptometrix	804011	10^5/ml
Mycoplasma pulmonis	BEI	NR-3858	10^4/ml
Mycobacterium tuberculosis, HN878, gamma-irradiated whole cells	BEI	NR-49100	10^5/ml

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Microorganism	Source	Accession number	Final concentration tested
Neisseria elongata	Zeptometrix	801510	10^5/ml
Neisseria gonorrhoeae	ATCC	19424	10^5/ml
Neisseria meningitidis	ATCC	13090	10^5/ml
Proteus mirabilis	ATCC	12453	10^5/ml
Pseudomonas aeruginosa	ATCC	27853	10^5/ml
Serratia marcescens	AR Bank	#0091	10^5/ml
Staphylococcus aureus subsp aureus	ATCC	10832	10^5/ml
Staphylococcus epidermidis	ATCC	29887	10^5/ml
Streptococcus agalactiae	ATCC	13813	10^5/ml
Streptococcus dysgalactiae subsp *dysgalactiae*	ATCC	43078	10^5/ml
Streptococcus pneumoniae	ATCC	BAA-341	10^5/ml
Streptococcus pyogenes	ATCC	19615	10^5/ml
Streptococcus salivarius subsp *salivarius*	ATCC	13419	10^5/ml
Ureaplasma urealyticum	ATCC	27618	10^5/ml
Fungi			
Aspergillus flavus	Zeptometrix	801598	10^5/ml
Aspergillus fumigatus	Zeptometrix	801716	10^5/ml
Candida albicans	ATCC	10231	10^5/ml
Cryptococcus neoformans	ATCC	MYA-4564	10^5/ml
Pneumocystis jirovecii (carinii)	ATCC	PRA-159	10^5/ml
Viruses			
Adenovirus 21 - AV1645	BEI	NR-56500	10^5/ml
Adenovirus Type 31 Culture Fluid (1 mL)	Zeptometrix	0810073CF	10^4/ml
Adenovirus Type 40 Culture species F Strain Dugan Fluid (1 mL)	Zeptometrix	0810084CF	10^3/ml
Coxsackievirus A10	ATCC	VR-168	10^5/ml
Coxsackievirus A21	ATCC	VR-850	10^5/ml
Human Coxsackievirus B1, Conn-5	BEI	NR-58650	10^5/ml
Cytomegalovirus (CMV)	Zeptometrix	0810003CF	10^2/ml
Cytomegalovirus C9209	BEI	ARP-2082	10^5/ml
	ABI Adv Biotech	HFS/CMV C9209-1	
Enterovirus 71 - Tainan/4643/1998	BEI	NR-471	10^5/ml
Epstein-Barr Virus (EBV)	Zeptometrix	0810008CF	10^5/ml
Human Echovirus 30 Strain Bastianni	ATCC	VR-1660	10^5/ml

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Microorganism	Source	Accession number	Final concentration tested
Herpes simplex Virus 1 (HSV1)	ATCC	AV-VR-1778	10^5/ml
Human herpes virus 1 (Herpes simplex virus 1 strain H5)	ATCC	VR-260	10^5/ml
Human Herpes Virus 6 (HHV6) Type 6B	Zeptometrix	0810072CF	10^5/ml
Herpes simplex virus Type 2 Culture fluid	Zeptometrix	0810217CF	10^3/ml
Influenza A Virus - Influenza A Virus, A/Puerto Rico/8-MC/1934 (H1N1)	BEI	NR-29022	10^6/ml
Influenza A virus - A/Hong Kong/H090-756-V1(0)/2009 (H3N2)	BEI	NR-44344	10^5/ml
Influenza B virus - B/Taiwan/2/1962	BEI	NR-3181	10^4/ml
Influenza B Virus - B/Sydney/507/2006 (Yamagata Lineage)	BEI	NR-36526	10^4/ml
Measles Virus - MVs/Maryland.USA/18.18 [B3]	BEI	NR-52251	10^4/ml
Measles Virus	Zeptometrix	0810025CF	10^4/ml
Human Metapneumovirus TN/ 83-1211	BEI	NR-22227	10^4/ml
Mumps Virus	Zeptometrix	0810079CF	10^5/ml
Human Parainfluenza Virus 1, HPIV1/FRA/29221106/2009	BEI	NR-48680	10^4/ml
Human Parainfluenza virus 2 - Greer	BEI	NR-3229	10^4/ml
Human Parainfluenza virus Type 4 - M-25	BEI	NR-3237	10^2/ml
Human Parechovirus (HPeV)	Zeptometrix	0810147CF	10^5/ml
Human Respiratory Syncytial Virus - A1998/3-2	BEI	NR-28529	10^5/ml
Human respiratory syncytial virus A2	ATCC	VR-1540	10^2/ml
HCoV-229E	EVAg	011N-03868	10^4/ml
HCoV-NI63	EVAg	011N-03868	10^4/ml
HCoV-OC43	EVAg	011N-03868	10^4/ml
HCoV-SARS-CoV	EVAg	011N-03868	10^4/ml
HCoV-MERS-CoV	EVAg	011N-03868	10^4/ml

ATCC: American Type Culture Collection, 10801 University Blvd, Manassas, VA 20110 USA
BEI: 10801 University Blvd, Manassas, VA 20110 USA
EVAg: UVE-UMR190 Emerging Viral Diseases Medical Faculty, 27 boulevard Jean Moulin - 13385 Marseille cedex 5 - France
AR Bank: Antimicrobial Resistance Isolate Bank (AR Isolate Bank), 1600 Clifton Road, Mail Stop: H17-3, Atlanta, GA 30329-4027 USA
Zeptometrix: 14957 Collection Center Drive, Chicago, IL, 60693-0149 USA

Potential interfering substances

The effect of potentially interfering substances was evaluated on the following panel of commonly used medication for respiratory infection and endogenous substances at low (1%) and elevated (5%) levels: nasal sprays (Beconase, Benacort, Pirinase), Benylin chesty cough, RelonChem Allergy Relief, Nurofen for children, Benylin Night cough, Sudafed Decongestant, Ventolin, Calpol 6 plus, Sterimar, Snuffle babe, Tamiflu and exogenous substances (human blood and human DNA). With the exception of the nasal sprays, which interfered with the SAMBA test at 5%, no interference was observed with the rest of the substances/medications tested in both spiked and unspiked samples at both low and high levels. At 1%, these three nasal sprays did not interfere nor inhibit the detection of the target organisms (Table 3).

Table 3. Testing with potential interfering substances

Name of substance	Active Ingredient(s)	Concentration tested	Inhibition (yes/no)
Control	None	NA	No
Beconase	0.05% Beclometasome diproprionate	5%	Yes
		1%	No
Pirinase	0.05% Fluticasone proprionate	5%	Yes
		1%	No
Benacort	Budesonide 64mg/spray	5%	Yes
		1%	No
Benylin chesty cough	Guaifenesin 50mg/5ml	5%	No
		1%	
RelonChem Allergy Relief	Loratadine 5mg/ml	5%	No
		1%	
Nurofen for children	Ibuprofen 100mg/5ml	5%	No
		1%	
Benylin Night cough	Diphenhydramine 7mg/ml & Levomenthol 0.55mg/ml	5%	No
		1%	
Sudafed Decongestant	Pseudoephedrine hydrochloride 30mg/5ml	5%	No
		1%	
Ventolin	Salbutamol sulfate 2mg/5ml	5%	No
		1%	
Calpol 6 plus	Paracetamol 250mg/5ml	5%	No
		1%	
Sterimar	Sea water isotonic solution	5%	No
		1%	
Snuffle babe	Sodium Chloride 0.9%, Benzalkonium Chloride	5%	No
		1%	
Tamiflu	Oseltamivir 6mg/ml	5%	No
		1%	
Human Whole Blood	N/A	5%	No
		1%	
Human Genomic DNA	108 g/ml	20 g/ml	No
		2 g/ml	

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Specimen stability in SAMBA III Specimen Buffer

The SAMBA III Specimen buffer has been shown to be effective against enveloped viruses as defined in EN 14476:2013 + A2:2019 Annex A when tested after 10-minute exposure. This includes all coronaviruses and SARS-CoV-2. This indicates that the specimens collected in SAMBA III Specimen Buffer from symptomatic individuals may be handled at the point-of-care.

Sample collection media compatibility

Three commonly used specimen transport media were tested for compatibility with the SAMBA III SCoV-2/Flu/RSV Test which shares the same chemistry as the SAMBA III SARS CoV-2 Test: Remel M4RT, MWE Virocult collection media and Copan UTM-RT. All these three media were found suitable for use with the SAMBA III SCoV-2/Flu/RSV Test when diluted at 1:2 in SAMBA III Specimen Buffer, thus similarly suitable for use with the SAMBA III SARS CoV-2 Test. However, only Remel M4RT and MWE Virocult Collection media with clinical specimens were validated in the performance evaluation of the SAMBA III SARS CoV-2 Test.

Reproducibility

Reproducibility of the SAMBA III SARS CoV-2 Test was assessed on three lots of kits using low-level positive (3x LOD), medium-level positive (10x LOD) in pooled nasal+throat swab specimens spiked with SARS CoV-2 (WHO First International Standard for SARS-CoV-2 RNA, NIBSC Code: 20/146) and negative swab samples. The reproducibility assessment was performed in SAMBA III Buffer and in Universal Transport Medium (UTM). Each run included replicates of eight by three operators. As shown in Table 4, 100% agreement was demonstrated from the reproducibility testing on three lots of kits, three levels of inoculum and three operators.

Table 4. Summary of results from reproducibility testing

Sample Media	Virus level	Operator 1 Pre-ML Lot 2	Operator 2 Pre-ML Lot 3	Operator 3 Pre-ML Lot 5	% agreement
SAMBA Specimen Buffer	0	8/8	8/8	8/8	100%
	3X LOD	8/8	8/8	8/8	100%
	10X LOD	8/8	8/8	8/8	100%
Universal Transport Media (UTM)	0	8/8	8/8	8/8	100%
	3X LOD	8/8	8/8	8/8	100%
	10X LOD	8/8	8/8	8/8	100%

Carryover study

Potential cross-contamination was assessed by running alternating samples with high viral load (100,000 IU/mL) and negative samples (0 IU/mL) in five consecutive runs, each run across a single SAMBA III Assay Module and a single SAMBA III Tablet Module. This was repeated across five SAMBA III Assay Modules and five SAMBA III Tablet Modules.

Results showed that all the spiked samples gave a positive result while all the unspiked samples gave a negative result indicating that no high viral load samples were observed to be carried over to negative samples when tested with the SAMBA III SARS-CoV-2 Test using the SAMBA III instrument system.

Performance evaluation in clinical specimens

The SAMBA III SARS-CoV-2 Test is provided with its own sample collection buffer, SAMBA III Specimen Buffer (Code C19-0125). In addition, the SAMBA assay can also be used with specimens collected in certain transport/specimen collection buffer such as universal transport medium, thus, the clinical performance of the assay was assessed in both the SAMBA III Specimen Buffer and Universal Transport Media that are commonly used in hospitals.

In this clinical evaluation study, the TaqPath COVID-19 Combo kit was used as the comparator test for SARS-CoV-2. For testing of discrepant results, the SAMBA III, TaqPath COVID-19 Combo and TaqPath COVID-19, FluA/B, RSV Combo kit were repeat-tested simultaneously and the final disposition was based on the repeat test result. The sensitivity, specificity and 95% CI were then calculated using the Medcalc diagnostic test calculator: https://www.medcalc.org/calc/diagnostic_test.php.

Clinical Samples

A. Symptomatic vs asymptomatic

Below is the distribution of specimens from symptomatic and asymptomatic individuals:

Remel M4RT (80) and MWE Virocult Collection media *(213)*

- 98 symptomatic SCoV-2 positive
- 20 asymptomatic SCoV-2 positive
- 2 symptomatic negative (2 SCoV-2-positive by TaqPath COVID-19 Combo Kit)
- 173 asymptomatic negative

SAMBA Specimen Buffer (299)

- 102 symptomatic SCoV-2 positive
- 197 asymptomatic negative

SARS CoV-2 and negative samples were tested in combined nose and throat swab specimens collected into two sample collection buffers: a) Universal Transport Medium UTM) and b) SAMBA SCoV Buffer (shown to be equivalent to SAMBA III Specimen Buffer).

B. Distribution of Ct values (determined by TaqPath assays) for positive clinical samples

Table 5 gives a summary of the number of positive samples per Ct category included in the clinical performance evaluation following the requirements of UK's Coronaviru

Table 5. Distribution of Ct values (determined by TaqPath assays) of positive clinical samples

Ct	UTM samples	SAMBA Specimen Buffer samples
	SCoV-2	SCoV-2
<25	30	39
25-30	31	40
>30	59	23
Total	**120**	**102**

C. Results from testing with SAMBA III SARS-CoV-2 Test and TaqPath

Samples collected in UTM

SARS-CoV-2

In total, 120 SARS-CoV-2 positive combined nose/throat samples collected in UTM from both symptomatic and asymptomatic individuals in the UK were tested both by SAMBA III and TaqPath. Of these, 118 were positive and 2 were negative by SAMBA III. The two negative results gave mean Ct values of 34.75 and 36.04 when tested on TaqPath COVID-19 Combo kit and repeated negative when tested on SAMBA III. The remaining 118 concordant positive samples had Ct values when tested on TaqPath COVID-19 Combo kit of 11.74 –35.67.

Negative Samples

In total, 173 negative combined nose/throat samples collected in UTM from asymptomatic individuals in the UK were tested both by SAMBA III and TaqPath. Of these, all 173 were negative for all targets by SAMBA III and by TaqPath comparator kits.

Samples collected in SAMBA III Specimen Buffer

SARS-CoV-2

In total, 102 SARS-CoV-2 positive combined nose/throat samples collected in SAMBA III Specimen Buffer from symptomatic individuals in the UK were tested both by SAMBA III and TaqPath. Of these, all 102 were positive by SAMBA III. The Ct range for these samples as determined by the TaqPath COVID-19 Combo kit was 12.23 –35.86.

Negative Samples

In total, 197 negative combined nose/throat samples collected in SAMBA Specimen Buffer from asymptomatic individuals in the UK were tested both by SAMBA III and TaqPath. Of these, all 197 were negative for all targets by SAMBA III and by TaqPath comparator kits.

Overall clinical performance

The overall sensitivity and specificity of SAMBA using TaqPath as a comparator test for each viral target is shown in Table 6 below.

Table 6 Clinical performance of the SAMBA III SARS-CoV-2 Test compared to TaqPath COVID-19 test and TaqPath COVID-19, FluA/B, RSV Combo kit

Target	Sample buffer	Number of specimens	+/+	+/-	-/-	-/+	PPA (95% CI)	NPA (95% CI)
SARS-CoV-2	UTM	293	118	0	173	2	98.33% (94.11 –100.00)	100.00% (97.89 –100.00)
	SAMBA III Specimen Buffer	299	102	0	197	0	100.00% (96.45 –100.00)	100.00% (98.14 –100.00)
	All samples	***592***	***220***	***0***	***370***	***2***	***99.10% (96.78 □ 99.89)***	***100.00% (99.01 □ 100.00)***

+/+ concordant positive, +/- SAMBA positive/comparator negative, -/- concordant negative, -/+ SAMBA negative/comparator positive

[1]Ct of samples negative by SAMBA III were 34.75 and 36.04 when tested on TaqPath COVID-19 Combo kit

Equivalency in performance between fresh and frozen specimens

Samples collected in SAMBA III Specimen buffer and tested with the SAMBA III SARS-CoV-2 Test

To assess the performance of the assay on the detection of SARS-CoV-2 in fresh and frozen samples, (30) matched fresh and frozen nasal and throat clinical swab specimens collected into SAMBA III Specimen Buffer and 30 similar specimens collected into UTM were analysed using the SAMBA III SARS-CoV-2 Test kit and TaqPath COVID-19 Combo kit. Results showed that SARS-CoV-2 was detected in all the matched fresh and frozen samples by both SAMBA and the comparator tests (Ct 25.05 –33.96) indicating that SAMBA performs equivalently on fresh and frozen positive samples within a broad range of Ct values.

Shelf-life

Based on the predecessor test and accelerated shelf life study, the shelf life of the kit has been assigned at 6 months when stored at 2-30ºC.

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REVISION HISTORY

Version no.	Brief description of changes	Date approved
4.0	Updated UK rep address to First Floor, Park Central, 40-41 Park End Street Oxford OX1 1JD England, United Kingdom. Corrected code number for accessories listed on page 3 from C19-0130 to C19-0130-12 and C20-0009 to C20-0009-12 as materials are provided in a 12 pack to match the number of tests in a kit. Updates made for completeness, thus risk is low.	20 Aug 2025
3.0	Corrected the number of Remel M4RT and MWE Sigma Virocult UTM specimens on page 25.	27 July 2025
2.0	Added details on safety warnings on pages 3-5 ; updated UTM claims on pages 6 and 24; simplified Tablet Module result on page 17; removed specimen storage claims at 2-8 C and 30 C on page 24, pending clinical sample stability study; added UTM details on clinical SARS CoV-2 specimens tested on page 25; updated symbols on page 29; updated manufacturer address on page 30.	25 July 2025
1.0	Initial release	13 November 2024

ADVICE LINE

For Technical Support, feedback or advice, contact Diagnostics for the Real World Ltd. Customer Service at:

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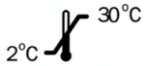
SYMBOLS	Description of Symbol
	Catalogue number
	Batch or Lot code
	**Store at 2-30ºC (Temperature limit)**
	***In vitro* diagnostic medical device**
	Use-by-date (YYYY-MM)
	Consult instructions for use
	Do not use if package is damaged
	Do not re-use
	Warning: (see Safety Data Sheet (SDS) for additional details)
	Danger: (see Safety Data Sheet (SDS) for additional details)
	Manufacturer
	UK Responsible Person who acts on behalf of the non-UK manufacturer in the UK.
	UKCA marking for United Kingdom (except Northern Ireland)
	Keep dry
	Fragile, handle with care
	This way up
	Contains sufficient for <*n*> tests

DRW Diagnostics for the Real World

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