

Spartan **RX**TM

User Manual



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Intended Uses

This Spartan RX CYP2C19 *2 System (or simply Spartan RX System) made by Spartan Bioscience Inc. is for Limited Release only. This device is only to be used by Qualified Investigators.

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1. Introduction

Thank you for choosing to purchase the Spartan RX System. Spartan Bioscience Inc. is committed to bringing fast and accurate DNA analysis to point-of-care applications. This system is designed to provide the user with a patient’s CYP2C19*2 genotype.

This manual is designed for users of the Spartan RX System. The manual includes general information about components of the System, as well as detailed protocol instructions to ensure quality of results.

If there are any questions or concerns that occur during the operation of the system, please contact your Authorized Spartan Dealer at your earliest convenience. In the event your dealer is unable to solve your problem, contact Spartan Bioscience by e-mail at support@spartanbio.com or by telephone from 9am-5pm EST at +1.613.228.7756.

2. Precautions




2.1. General











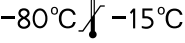


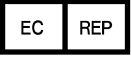


It is important to follow the protocol instructions and complete all necessary training prior to performing the tasks described in this manual. If there is uncertainty or unexpected events, please refer to the protocol instructions, see Section 11: Troubleshooting, or contact your Authorized Spartan Dealer.

Please note that there are some residual risks associated with the use of this System. For information on these risks, please see Section 9.4 of this manual.

2.2. Symbols

Symbols are used throughout the supporting material for the Spartan RX System, including this document, labels, packaging, and instruction guides. Symbols are used as visual signals to point out important information. Below is the legend of symbols used, along with a brief description of their meanings.

	<p>Warning, Risk of Danger – This symbol is used to indicate that non-compliance with the instructions or procedures may lead to physical injury, or even death, or could damage the instrument.</p>
	<p>Important Note – This symbol is used to bring the user’s attention to an important annotation.</p>
	<p>Biohazard – This symbol is used to indicate that certain precautions must be taken when working with potentially infectious material.</p>

	DC (Direct Current)
	This symbol indicates the Manufacturer of the device or system component.
	CE Mark (European Union)
	Caution, Risk of Electrical Shock – This symbol is used to indicate that certain precautions must be taken to avoid electrical shock.
	Do not reuse a product containing this symbol (use the product only once).
	Use until (indicates the expiry date of the product)
	The lot or batch of the product
	Device serial number
	Manufacturing date
	Read the documentation before proceeding.
	The product must be maintained between -80°C and -15°C until immediately before use.
	Protect the product from light.
	Part number or catalogue number.
	Authorized Representative
	Sufficient material for N tests
	In Vitro Diagnostic (indicates the material is an In Vitro Diagnostic or part of an In Vitro Diagnostic Device)

2.3. Electrical

The Spartan RX System contains an Analyzer that is an electromechanical instrument. There is a potential danger of electrical shock or physical injury to the user if the instrument is not used according to the instructions given in this manual. Observe all general safety precautions which apply to electrical instruments.



- The power supply cord must be inserted into a power outlet with a protective earth contact (ground).
- Unplug the power supply cord from the power outlet before cleaning the instrument.
- Only use the supplied power cords or cables. If any of the cables become damaged or inoperable, please contact your Authorized Spartan Dealer for a replacement.
- Do not use the instrument near water or immerse in water.
- The instrument should be operated only with the type of power source indicated on the marking label of the power supply.
- The instrument should be used only with the supplied power supply. If the power supply becomes inoperable, please contact your Authorized Spartan Dealer for a replacement.
- Always plug the power supply into the instrument, and then plug the power supply into the power outlet.
- Do not allow anything to rest on the power cord.
- Do not install the instrument where the cord may be walked upon.
- To reduce the risk of electrical shock, do not disassemble the instrument. Refer servicing to Spartan authorized service personnel.
- Do not overload power outlets because this can result in risks of fire or electrical shock.
- Unplug the power supply cord from the power outlet and refer to Spartan authorized service personnel if one or more of the following conditions exist:
 - The power supply cord or plug is damaged or frayed.
 - Liquid has been spilled onto the instrument.
 - The instrument has been exposed to water.
 - The instrument does not operate normally by following the operating instructions.
- Slots in the front and back of the instrument are provided for ventilation. To protect the unit from overheating, these openings **must not** be blocked and a 15 cm gap must be maintained. Adequate ventilation should be verified at the start of each day.

2.4. Biological

Be aware for your own safety that all biological samples such as buccal material have the potential to transmit infectious diseases. Follow all applicable local, state/provincial, and/or national regulations. Wear appropriate protective clothing and gloves.

If you suspect the instrument may have been exposed to any hazardous material, the instrument must be decontaminated. If you are unsure about suitability of the decontamination or cleaning agent specified in your laboratory decontamination procedure, please contact Spartan by e-mail at support@spartanbio.com or by telephone from 9am-5pm EST at +1.613.228.7756.

Material Safety Data Sheets (MSDS) for the Spartan reaction tubes are available upon request.



After the swab has been used, it may contain infectious agents. Please be sure to safely dispose of the swab shaft. For more information, see Section 9.4 of this document.

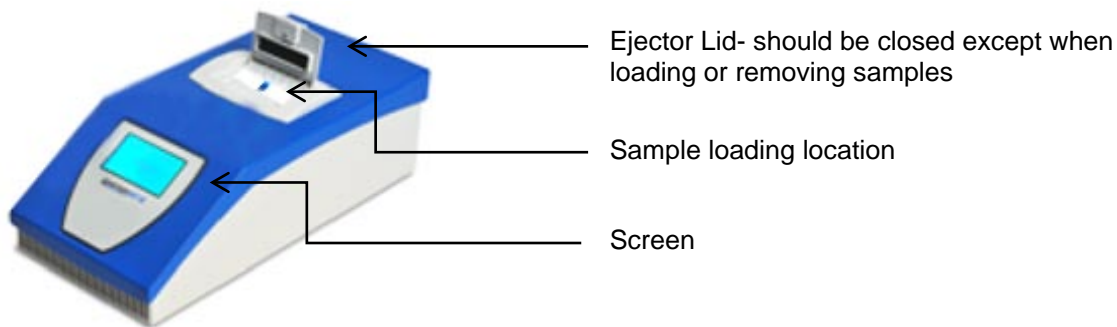
3. Overview of System Hardware and Maintenance

The Spartan RX System consists of a netbook computer, an inkjet printer, an Analyzer device, and their required cables.

3.1. Analyzer

The Analyzer device is a single well thermal cycler with optical detection capability. It is designed to determine an individual's CYP2C19*2 genotype. The device is portable, light-weight, accurate, and robust. The unit has two optical detection channels (green and red) that detect the wild-type and *2 alleles, respectively. The device has been customized to maximize accuracy for this application.

The device is uniquely identified by a serial number on the back.



3.2. Netbook

A netbook computer is part of the System. The netbook serves as a connection between the Analyzer and the printer. Software on the netbook allows the user to log in to the System with a User ID and password. The user may input critical information, such as the Patient ID, which will appear on post-analysis result printouts.

3.3. Printer

Standard A4 or 8.5'x11' sheets of paper will be printed after each patient run is performed. Note that a patient sample run will result in a 1-page report being printed.

3.4. Maintenance



The Analyzer does not require cleaning of any kind. If the instrument becomes dusty, use a dry static-free cloth to clean the surface of the instrument. At no time should solids or liquids be allowed to fall into the sample loading area. If this does happen, or you suspect it has happened, please contact Spartan by telephone from 9am-5pm EST at +1.613.228-7756. As a preventative measure, keep the ejector lid closed at all times, except when samples are being loaded or unloaded.



Slots in the front and back of the instrument are provided for ventilation. To protect the unit from overheating, these openings **must not** be blocked and a 15 cm gap must be maintained. Adequate ventilation should be verified at the start of each day.

The netbook computer does not require maintenance of any kind. The user may clean the screen using a clean, dry, and lint-free cloth.

The printer will require maintenance typical of a commercial printer. Paper outages, paper jams, and toner shortages could occur. Paper and toner levels must be maintained by the user.

4. Equipment Specifications

4.1. Performance Specifications

When used according to the manufacturer’s recommendations, the Spartan RX System has the following performance specifications.

Metric	Performance Specification	Definition
Inconclusive Rate	<7%	Number of times that the test produces an inconclusive result, divided by the total number of tests performed (expressed as a percentage).
Diagnostic Sensitivity*	>98%	Number of *2 true positive results, divided by the sum of *2 true positive and *2 false negative results (expressed as a percentage).
Diagnostic Specificity*	>98%	Number of *2 true negative results, divided by the sum of *2 true negative and *2 false positive results (expressed as a percentage).

* Excludes inconclusive results.

4.2. Instrument Specifications (ratings)

Specification	Min	Typ.	Max	Comments
System Warranty	1 year			
Electrical Compatibility				100 – 240 VA, 50-60 Hz
Max Electrical Power	150W		500W	100W peak for Analyzer 40W peak for netbook 9W or 360W peak (printer choice)
Operating Voltage	11.4V	12.0V	12.6V	12 +/- 5% as per power adapter spec
Operating Current			6.5A	Max current
Operating Temperature	20		25	degrees Celsius
Operating Humidity	20		50	% RH Non-condensing
Operating Altitude	0		2000	meters
System Life (upon arrival)	2 years			

5. Equipment Unpacking and Setup

5.1. Unpacking

The Spartan RX equipment is shipped in two cardboard containers. The containers should be carefully inspected for damage and the carrier immediately notified before taking receipt of the System. Spartan recommends that the unpacking instructions below are fully read and understood before starting the unpacking. If there are any questions or concerns that are not covered by this guide, please contact your Authorized Spartan Dealer at your earliest convenience or Spartan by e-mail at support@spartanbio.com or by telephone from 9am-5pm EST at +1.613.228.7756.

5.2. System Contents

- Analyzer
- Power adapter for Analyzer
- Netbook computer
- Power adapter for netbook
- Printer
- Power adapter for printer
- Netbook – Printer USB cable
- Local power cables
- Ethernet cable
- Spartan RX Quick Guide

5.3. Operating Requirements

- This instrument is designed for indoor use only.
- Operate in ambient temperature between 20°C and 25°C.
- Do not operate in a cold room or a refrigerated area.
- Operate in ambient relative humidity of 20% to 50%.
- These specifications have been calculated for altitudes between 0 and 2,000 meters.
- Ensure adequate front and rear ventilation.

5.4. Setup

When fully set up, the Spartan RX System requires a minimum of 80 cm of desk space and three electrical power outlets (as outlined in the electrical ratings in Section 4.2). The installation is easily completed by following the steps below.

- Remove the Analyzer from the box labeled “1 of 2” and place it upright on the desk. Obtain the Analyzer power adapter and plug it into the wall outlet and the back of the Analyzer. The screen should illuminate in approximately 30 seconds.
- Obtain the Ethernet cable from the Analyzer box and plug one end into the back of the Analyzer.

- Remove the printer from within the box labeled “2 of 2” and place it upright on the desk. Obtain its power adapter and plug it into the wall outlet and the back of the printer.
- Obtain the printer/netbook USB cable from the printer box and connect the appropriate end of the cable into the port on the printer.
- Load the printer with paper and turn the printer on.
- Remove the netbook from within the box labeled “2 of 2” and place it upright on the desk (or on top of the printer as space allows). Obtain its power adapter and plug it into the wall outlet and the back of the netbook. Plug the free end of the printer/netbook USB cable into the appropriate port on the netbook.
- Plug the free end of the Ethernet cable into the Ethernet port of the netbook. Turn on the netbook.
- Log into the netbook. The Spartan RX software should automatically start within 30 seconds (See Section 10 for default password).
- Print a status report (See Section 8.2) to ensure the printer is functioning properly.
- Perform a genotyping test on an individual to ensure that the System is functioning properly.

5.5. Location

The System should be set up in an area that meets the criteria below. Failure to adhere to these constraints may result in poor performance of the Spartan RX System.

- The System must be set up in a location with ambient temperature of **20°C to 25°C** and ambient relative humidity of **20% to 50%**.
- The Analyzer must have adequate front and rear ventilation. To protect the unit from overheating, the openings at the front and rear of the unit must not be blocked and a **15 cm** gap must be maintained.
- The System must be set up in a location that is in close proximity to the patient. **You must be able to start the run within 4 minutes of collecting a patient sample.**

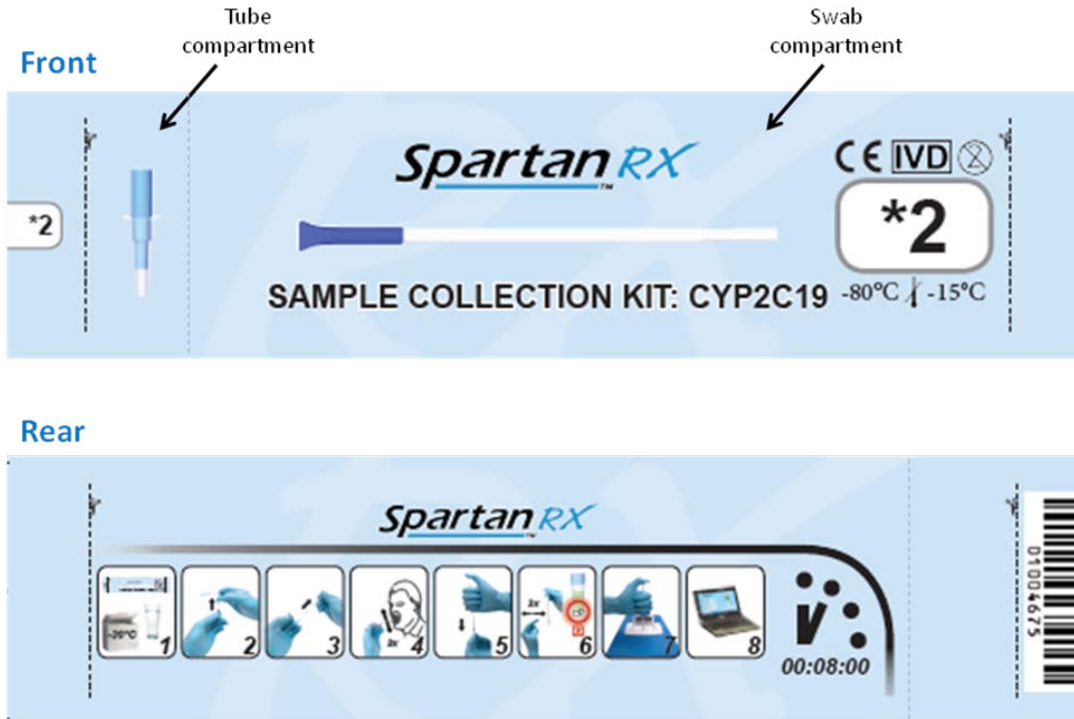
6. Overview of System Consumables

The Spartan RX requires the use of a consumable product called a Sample Collection Kit. This product is described below and its proper use is explained in the protocol (Section 9).

6.1. Sample Collection Kit

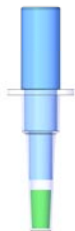
A Sample Collection Kit is required for each patient tested. Each Sample Collection Kit includes the following:

- A laminated pouch with visual instructions and an identification label
- One Spartan swab with blue coloured tip (sealed in the longer pouch compartment)
- One frozen reaction tube (sealed in the shorter pouch compartment)



The swab and tube are removed by tearing off each end of the pouch. Sample Collection Kits must be stored between -80°C and -15°C in a **non frost-free** freezer. Immediately prior to collecting a sample from a patient, the user obtains a Sample Collection Kit from the freezer .

6.2. Reaction Tubes



The Analyzer is designed to work with Spartan reaction tubes. These tubes have been optimized to provide superior performance. Spartan supplies frozen reagents in Spartan tubes, which are sealed in Sample Collection Kit pouches. Each tube consists of the cap (blue plastic), the tube (clear plastic), and the frozen reagents (typically clear but coloured green in the adjacent figure). Tubes must be stored in sealed Sample Collection Kit pouches in a non frost-free freezer at -80°C to -15°C.

Post-run reaction tubes (i.e., a tube used in a Spartan RX System run) must not be opened – this poses a risk of contaminating the work environment with aerosolized or micro-droplet DNA (see Section 9.4).



NOTE: If at any time the product has thawed, it must not be used.

6.3.Spartan Swab



The Spartan swab has been designed and optimized to be used with the Spartan RX System. A Spartan tip (without the tube or reagent) is mounted to the end of each swab and protected by a blue cover. Prior to collecting a sample from a patient the cover is removed and the DNA sample is collected directly on the Spartan tip. The Spartan swab is specially designed to enable easy buccal sample collection and handling. Spartan supplies swabs sealed in Sample Collection Kit pouches.

7.System Consumables Storage and Handling

7.1. Receiving Sample Collection Kits

Sample Collection Kits are shipped on dry ice to keep them frozen. Dry Ice is solidified carbon dioxide and presents hazards to the user.



- Dry Ice is much colder than regular ice and can burn skin similar to frostbite. Avoid contact with skin and eyes. Always handle with insulated gloves.
- Never eat or swallow dry ice.
- Avoid inhaling the carbon dioxide gas that is released as dry ice melts.
- Open the Sample Collection Kit shipping container only in a well-ventilated space.
- Because dry ice can cause carbon dioxide gas to accumulate and build up pressure, do not dispose of dry ice in a sewer, garbage disposal, garbage chute, sink, water, etc.
- Allow leftover dry ice to sublimate or evaporate in a well-ventilated area.



- 80°C / -15°C

It is required that the Sample Collection Kits be placed in a non frost-free freezer at -15°C to -80°C immediately upon receipt. **If it is suspected that the Sample Collection Kits have thawed at any time, they must not be used.** Please contact your Authorized Spartan Dealer for replacements.

7.2.Storage and Stability



Sample Collection Kits should be placed a non frost-free freezer at -15°C to -80°C. If the receiving and storage protocols are followed, the Sample Collection Kits will be stable up to the expiry date marked on the package.



The opacity of the Sample Collection Kit pouch is designed to protect the reaction tube from light. Sample Collection Kit pouches should not be opened until a test is being performed. Exposure of the reaction tubes to light immediately prior to use is acceptable, but the stability of the product will be compromised if the reaction tubes are removed from the pouches prior to testing.

7.3. Verifying a New Lot of Sample Collection Kits

Upon receipt of a new lot of Sample Collection Kits, it is strongly recommended that the user perform a quality control test by performing a single test with a person of confirmed / known genotype. If the lot verification run produces the correct genotype, the lot can be approved and released for use. A newly approved Sample Collection Kit lot number must be added to the Spartan RX system user interface via the “Settings” menu (see Section 10.10). The purpose of this process is to prevent use of an unverified lot of Sample Collection Kits. The Spartan RX System run will not start if a user attempts to input a non-valid Sample Collection Kit lot number.

8. Quality Control

The following steps are designed to ensure accurate and reliable results from the Spartan RX System.

8.1.Training



Each user must undergo a training program under the supervision of qualified Spartan personnel or an approved representative. A training record should be maintained by the System administrator and should be completed and signed before a user is deemed qualified to use the System.

8.2. System Status Checks

The Spartan RX System is configured to perform a series of Status Checks on the optical, thermal, and mechanical subsystems. This series of checks is performed automatically after every patient test and the outcome is displayed on the Spartan RX System user interface as a green check mark (indicating that the Status Check has passed) or a red cross (indicating that the Status Check has failed) – see Section 10.7. Please contact your Authorized Spartan Dealer if a Status Check failure occurs and discontinue use of the System.

Selecting the “Print Status Check” button from the Spartan RX System user interface (see Section 10.6) will print an A4 or 8.5’x11’ paper report in less than 1 minute. A failed Status Check result will display “SYSTEM STATUS - FAILED” on the printed report. A sample of a passed status report is shown below.

```
*****
System Status Check
*****
Unit: 593
Date: 2011/09/30
Time: 14:44:21
Run Identifier: 593-1109261202
System Status Check Identifier: 145260-26125747-3.575339-2.699131

Heating System: PASSED
Cooling System: PASSED
Optical System: PASSED
Flourescence Stability: PASSED
Mechanical System: PASSED

System Status - PASSED
*****
```

8.3. Reaction Tube Lot Tracking by Manufacturer



The reaction tubes in the Sample Collection Kits undergo a quality control analysis at Spartan. To ensure traceability of the reagents, Sample Collection Kits are labeled with a Spartan part number, manufacturing date, and expiry date. The Spartan part number and manufacturing date ensures that there is consistent performance of the reagents from batch to batch. The expiry date ensures that the user does not use consumables which may have inferior performance. **Under no circumstance should the components be used beyond the expiry date.**

8.4. Sample Collection Kit Quality Control Test

It is strongly recommended that a quality control test be performed for each new lot of Sample Collection Kits by testing a person with a confirmed genotype (see Section 7.3). The criterion of acceptance is that the printed result is consistent with the known genotype. It is also strongly recommended that a copy of the lot quality control test printout be stored. New Sample Collection Kit lots should not to be distributed for use until the lot quality control has been completed.

8.5. Software Confirmation and Controls

The netbook software includes the following controls:

- In order to start a test, the user must log in to the netbook computer. Only users who have completed the appropriate training (see Section 8.1) should be given accounts and passwords.
- The software will check to ensure the last Status Check has been successful, and display the status on the screen.
- In order to start a test, the user must enter a valid user ID (see Section 10.1), a valid Sample Collection Kit Lot number (see Section 10.2), and relevant patient information (see Section 10.3). If a patient report already exists for the patient information entered, the user will be prompted to change the patient ID.

9. Spartan RX Test Protocol

Performing a test on the Spartan RX System has a preparation stage and 8 simple steps – these are described in detail below. The 8 steps should take **less than 8 min** to perform.

- The first 4 steps involve preparing the Sample Collection Kit and collecting the patient sample.
STEPS 1 - 4 must be completed within 4 minutes of removing the kit from the freezer.
- The final 4 steps involve mixing and running the patient sample.
STEPS 5 - 8 must be completed within 4 minutes of collecting the patient sample.

PLEASE NOTE THAT ADHERENCE TO THE TIME CONSTRAINTS PROVIDED ABOVE IS CRITICAL FOR OPTIMAL FUNCTIONING OF THE SPARTAN RX SYSTEM.

PERFORMANCE OF THE SYSTEM WILL BE SIGNIFICANTLY IMPACTED IF THE TIME CONSTRAINTS ARE NOT MET.

PREPARATION

Plug in the Spartan RX System Analyzer, netbook, and printer. Ensure that the printer and Analyzer are both connected to the netbook.



IMPORTANT:

- Follow the System setup instructions in Section 5.4 of this manual.
- Ensure the Analyzer is adequately ventilated (see Section 5.5).



Switch on the printer. Ensure that paper is loaded.



Switch on the netbook, and then log in using the system password. After ~20 seconds, the user interface screen will appear.



When the Spartan RX user interface screen appears on the netbook, verify that the Status Check symbol indicates a pass (green check mark) – see Section 8.2.





If the Status Check has failed (indicated by a red X) discontinue use of the system and contact your Authorized Spartan Dealer.


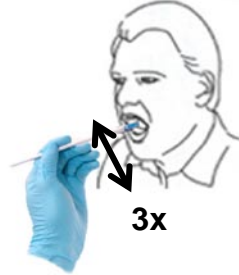



ENSURE THAT THE PATIENT IS READY TO BE SWABBED BEFORE PROGRESSING TO THE FOLLOWING STAGES.

STEPS 1 – 4 – COMPLETE WITHIN 4 MINUTES

Preparing the Sample Collection Kit and collecting the patient sample

<p>1</p>	<p>Put on a pair of gloves, and then obtain one Sample Collection Kit from the freezer.</p> <p>i IMPORTANT:</p> <ul style="list-style-type: none"> - Ensure that the patient has rinsed his/her mouth with water prior to removing the kit from the freezer. - If it is suspected that the tube in the Sample Collection Kit has thawed at any time – <u>do not use the Sample Collection Kit.</u> - If the expiry date is no longer valid – <u>do not use the Sample Collection Kit.</u> 	 <p>The image shows a blue and white pouch for the Spartan RX Sample Collection Kit. The pouch is labeled 'SAMPLE COLLECTION KIT: CYP2C19 -80°C -15°C' and 'CE IVD *2'. Below the pouch is a clear glass filled with water.</p>
	<p>Bring the Sample Collection Kit to the patient.</p> <p>Using gloved hands, remove the swab and tube from the Sample Collection Kit pouch. If the tube has not thawed by this time, thaw it by rolling between your fingertips.</p> <p><i>Tip: When tubes are thawed, the liquid in the tube will appear clear. When tubes are frozen, the liquid will appear opaque.</i></p>	 <p>A close-up image of a hand wearing a blue nitrile glove, holding a white swab and a blue-tipped tube.</p>
<p>2</p>	<p>Using gloved hands, pick up the swab and tube and hold one in each hand.</p>	 <p>An image showing two hands in blue nitrile gloves. One hand holds a white swab, and the other hand holds a blue-tipped tube.</p>
	<p>Remove and discard the cap from the tube. Hold the open tube between your thumb and forefinger.</p>	 <p>An image showing two hands in blue nitrile gloves. One hand is holding the blue cap of the tube, and the other hand is holding the tube between the thumb and forefinger.</p>

<p>3</p>	<p>Still holding the open tube between the thumb and forefinger of one hand, use your other fingers to remove and discard the cover from the swab held in your other hand.</p> <p>i IMPORTANT:</p> <ul style="list-style-type: none"> - The blue end of the swab (after the cover has been removed) will be used to collect a buccal sample from the patient – ensure that it does not contact any surface (e.g., do not put it down on a bench, wipe it against a surface, etc.). 	
<p>4</p>	<p>Using moderate pressure, scrape inside of the patient’s cheek with the blue end of the swab. Scrape the cheek using 3 up and down strokes (i.e., 6 strokes in total).</p> <p>i IMPORTANT:</p> <ul style="list-style-type: none"> - Ensure that you make firm contact with the blue end of the swab on the inside of the cheek. - Visually confirm that the swab tip is wet after sample collection. If excessive saliva is collected (i.e., the swab tip is visibly coated with saliva), we recommend that the kit be discarded and the test repeated (see Section 9.2). 	
<p>STEPS 5 – 8 – COMPLETE WITHIN <u>4 MINUTES</u></p> <p>Mixing and running the patient sample</p>		
<p>5</p>	<p>Grip the swab in your fingers and place your thumb on top, then insert the swab into the tube and push down firmly.</p>	

6

Bring the sample to the Analyzer, then hold the swab **vertically** and **firmly tap** the bottom of the tube **3 times**. Tap using the **tip** of your index finger.



IMPORTANT:

- Tapping should be sufficiently firm to cause the liquid in the tube to move and make contact with the blue tip of the inserted swab. There is usually a bubble at the top of the tube – this bubble should be seen to move slightly down the tube and then back up.
- Avoid excessive force – **do not** dislodge tube from the swab.
- If bubbles form at the bottom of the tube, re-tap the tube again until they move to the top. **Bubbles at the bottom of the tube will cause inaccurate or inconclusive results.**

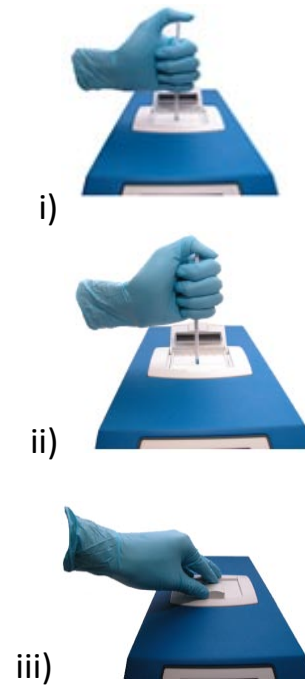
Tip: When tapping the tube, hold the swab at the top. This will help to ensure that the liquid in the tube is mixed sufficiently.



7

Open the lid of the Analyzer

- i. Insert the clear bottom part of the tube into the well. The two tabs on the sides of the tube must be correctly positioned in order for the tube to fit properly into the well.
- ii. Grip the swab shaft tightly with your fingers and place your thumb on top. Push down on the top of the swab with your thumb and slide your fingers upwards. The swab shaft should release from the tube. Only the tube should remain in the Analyzer and the cap should remain in the tube.
- iii. Close the Analyzer lid.



8

In the Spartan RX System user interface, enter the patient information and user details in the relevant fields (see Section 10).

Press the green “Play” button to begin the test, You will be prompted with a reminder to ensure that tubes have been tapped before starting the run (see step 6). Press “OK” to confirm and start the run. If samples were not tapped, we recommend that you discard the tube and repeat the test using a new Sample Collection Kit.

After approximately 60 minutes the system will automatically print the test result.

Tip: You can use the tab key or touchpad to navigate between fields. The arrow keys may be used to scroll up and down within each field.



AFTER THE RUN IS COMPLETE – OPEN THE ANALYZER LID AND IMMEDIATELY DISCARD THE TUBE BY PLACING INTO A SEALED BAG.

DO NOT OPEN THE POST-ANALYSIS TUBE
(see Section 9.4 for more information)

9.1.Spartan RX System Result Printout

The printed result of a patient test has two sections. The top section is a summary of the patient test result and the bottom section displays the full details of the Spartan RX System run.

The top section of the result printout displays the following:

- **Patient ID#** - 20 digit alpha-numeric text, entered during the Spartan RX System run setup.
- **Result** – Patient result, which will be one of the following:
 - o ***2 Negative** – The patient is not a carrier of the CYP2C19*2 allele
 - o ***2 Positive** – The patient is a carrier of the CYP2C19*2 allele
 - o **Inconclusive** – The patient test needs to be repeated

The bottom section of the result printout displays the following:

- **Unit** – Spartan RX System identifier
- **Test Complete Time** – Time at which the Spartan RX System run finished
- **Date** – Date of the patient test (YYYY/MM/DD)

- **User** – Username of the person who logged in to the Spartan RX System to begin the run
- **Time Sample Taken** – Time at which the user presses “Begin test”
- **Patient ID#** - Patient ID (20 digit alpha-numeric), entered during the run setup
- **DOB** – Date of Birth of the patient (YYYY/MM), entered during the run setup
- **Run Identifier** – 12-digit alpha-numeric identifier, unique to each Spartan RX System run. The format of the Run identifier is: **Unit-YYMMDDHHMM**

Where:

YYMMDD - Date of the Spartan RX System run

HHMM - Time at which the Spartan RX System run started (24 hour clock)

- **Result** – The detailed patient result, which will be one of the following:
 - **CYP2C19*1/*1** – The patient does not carry any CYP2C19*2 allele
 - **CYP2C19*2/*1** – The patient carries one CYP2C19*2 allele
 - **CYP2C19*2/*2** – The patient carries two CYP2C19*2 alleles
 - **Inconclusive** – The patient test needs to be repeated

9.2. Spartan RX System Interfering Substances

Certain substances present in a patient sample may interfere with the Spartan RX System test result. These interfering substances may be intrinsic or extrinsic to the patient.

Examples of possible intrinsic interfering substances include enzymes, polysaccharides, or other molecules naturally occurring in saliva. The presence of excessive saliva may cause poor results. After swabbing a patient, the blue end of the swab should be visibly wet. If too much saliva is present (i.e., the tip of the swab is fully coated with saliva), we recommend that the user discard the swab and obtain a new Sample Collection Kit. Less saliva can often be collected by asking the patient to swallow his or her saliva before collecting the sample.

Examples of possible extrinsic interfering substances include particles or chemicals originating from food or drink consumed by the patient prior to sample collection. Asking the patient to rinse his or her mouth with water prior to sample collection is required to minimize any effects of intrinsic or extrinsic interfering substances. The patient may swallow or spit the water in conformance with hospital requirements or regulations.

9.3. Spartan RX System Sample Cross-contamination

Due to the design of the Spartan RX System, inaccurate test results caused by cross-contamination are unlikely. Cross-contamination from extrinsic materials entering the reaction tubes is possible (e.g., human cells from the user performing the patient test or the surrounding environment), although this has not been observed in Spartan’s validation studies. To further reduce any risk of this unlikely cross-contamination, it is required that system users wear clean gloves at all times when performing tests.

9.4. System Residual Risks

The Spartan RX System has been designed with the intent to minimize all possible risk associated with the operation of the System. However, some residual risk remains. The following sections describe possible residual risks.

9.4.1 Patient Risks



There is a very remote possibility that the cap may become dislodged from the swab shaft during swabbing. In the event this occurs, it may become a choking risk. Please be aware of this risk and communicate the risk to the patient.

There is a very remote possibility that a patient may obtain a cold or virus from the swab.

There is a very remote possibility that a patient has an allergic reaction to the medical grade Thermoplastic Elastomer (TPE) contained in the swab.

9.4.1 Environmental Contamination Risks

A post-run reaction tube contains a large amount of amplified CYP2C19*2 DNA. If a post-run tube is opened, this amplified DNA may become aerosolized and contamination of the work environment may occur.

NEVER OPEN A POST-ANALYSIS TUBE (I.E., A REACTION TUBE USED IN A SPARTAN RX SYSTEM RUN).

Contamination of the work environment with aerosolized and/or micro-droplets of DNA presents no risk to human health. However, due to the high sensitivity of the Spartan RX System, this type of **contamination may significantly impact performance of the System and can lead to inaccurate genotype outcomes**. Environmental contamination, especially aerosolized DNA, may be difficult to remove and can persist for long periods of time up to years.

To avoid contamination of your work environment with aerosolized DNA, the following good work practices should be followed:

- **NEVER OPEN A POST-ANALYSIS TUBE.**
- **DISCARD POST-ANALYSIS TUBES IN A SEALED BAG AS SOON AS POSSIBLE AFTER THE RUN IS COMPLETE.**
- **DO NOT RE-USE GLOVES AFTER HANDLING A POST-ANALYSIS TUBE – DISCARD GLOVES INTO A SEALED BAG ALONG WITH THE POST-ANALYSIS TUBE.**
- **EMPTY GARBAGE CONTAINING SEALED POST-ANALYSIS TUBES ON A WEEKLY BASIS OR MORE FREQUENTLY.**

10. Spartan RX User Interface

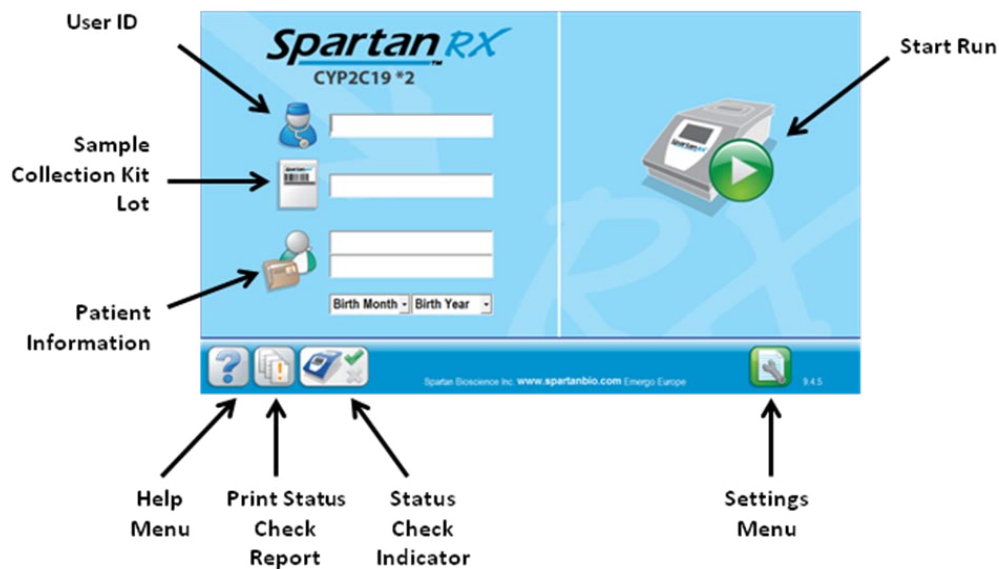
The Spartan RX user interface has been loaded on the netbook and it will automatically run upon login. The user interface allows you to enter patient information and user details.

The Spartan RX System comes preloaded with one User Account with the username “**Spartan**” and the password “**1234**”. This user account has full administrator rights to the netbook. Authorized users can be added to the system (see Section 10.9 below).



Users **must not** make any Operating System changes other than modifications to the user accounts.

The Spartan RX user interface screen is shown below:



10.1. User ID



The user ID is entered in this field – the user ID must correspond to an existing user account (see Section 10.9 for instructions on how to create a new account). The purpose of the user ID is to prevent unauthorized use of the Spartan RX System. Once a user ID is entered, a message box will appear prompting for a password. Entering a valid password will allow the test run to start once the play button is pressed. The run will not start if a non-valid user ID and password is entered.

10.2. Sample Collection Kit Lot



The Sample Collection Kit Lot number is entered in this field – the number must correspond to an existing verified lot (see Section 10.10 for instructions on how to add a new lot to the Spartan RX System). The purpose of the Sample Collection Kit lot is to prevent use of an unverified lot of Sample Collection Kits. The run will not start if a non-valid Sample Collection Kit lot is entered. The system comes pre-loaded with lot number 001.

10.3. Patient Information



Relevant patient information can be entered in these fields. Each line holds up to 20 alphanumeric characters (excluding symbols “#?/\<>”).

10.4. Begin Test



Press the green “Play” icon to begin the Spartan RX System run. A pop-up message will appear asking you to confirm that samples were tapped before placing into the Analyzer. If samples were not tapped, we recommend that you discard the tube and repeat the test using a new Sample Collection Kit.

10.5. Help Menu



Selecting this icon will display helpful information about troubleshooting the Spartan RX System.

10.6. Print Status Check Report



Selecting this icon will print a copy of the Spartan RX System Status Check report (see Section 8.2).

10.7. Status Check Indicator

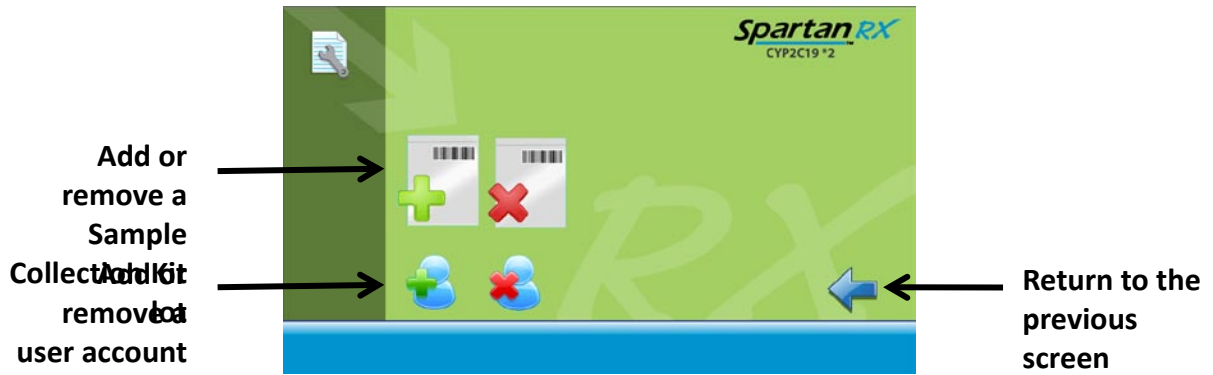


The Spartan RX system performs a Status Check at the end of every run. A green check mark indicates that the Status Check has passed and a red X indicates that it has failed. In the event of a Status Check failure please print the Status Check Report (see Section 10.6 above) and contact your local Authorized Spartan Dealer. Discontinue use of the Spartan RX System.

10.8. Settings Menu



The settings menu allows you to add a new user account and add a new lot of Sample Collection Kits. After selecting this icon and entering the administrator password, the following screen will appear:



10.9. Adding or Removing a User Account



To add a new user, select the icon with the green plus sign, and then enter the new User ID and password. The User ID holds up to 20 alphanumeric characters (excluding symbols “#?/\<>”). To remove an existing user account, select the icon with a red X, and then delete the required account(s).

10.10. Adding a Sample Collection Kit Lot



To add a new Sample Collection Kit lot, select the icon with the green plus sign, and then enter the new lot number. The lot number can be found on the Sample Collection Kit pouch. To remove an existing Sample Collection Kit lot, select the icon with a red X, and then delete the required lot(s). A new lot of Sample Collection Kits should only be added to the system once it has undergone verification (see Section 7.3).

10.11 Return to Main Screen



Selecting this icon will return to the main RX user interface screen. Changes will be automatically saved.

11. Troubleshooting

If problems occur with the Spartan RX System, please contact your Authorized Spartan Dealer or Spartan at +1.613.228.7756. Common troubleshooting solutions are provided below.

Issue Description	Resolution
Patient test result does not print.	<ul style="list-style-type: none"> - Ensure paper tray is not empty. - Ensure power is supplied and all devices are powered. - Ensure netbook is connected to printer.
Status Check fails.	<ul style="list-style-type: none"> - Discontinue use of the Spartan RX System. Please call your Authorized Spartan Dealer and a representative will assist you.
“SYSTEM STATUS - FAILED” on the Status Check printed result.	<ul style="list-style-type: none"> - This indicates that the Analyzer has failed a Status Check. Do not use the unit. Please contact your Authorized Spartan Dealer and a representative will assist you.
Printer / netbook / Analyzer does not power on.	<ul style="list-style-type: none"> - Ensure power is supplied.
Unable to log in to netbook.	<ul style="list-style-type: none"> - Check that the password is correct. Check that the caps lock button is in the correct position.
Spartan RX System will not begin the run.	<ul style="list-style-type: none"> - Ensure Analyzer lid is closed. - Check all cables and ensure they are properly connected. - Ensure a valid User ID and Sample Collection Kit lot number has been entered.
Spartan RX System stalls / will not complete a run.	<ul style="list-style-type: none"> - Ensure ambient temperature is within acceptable range of 20 – 25°C (59 - 77°F). - Ensure relative humidity is within acceptable range of 20 - 50%. - Ensure adequate ventilation of the Analyzer – ensure that there is at least a 15 cm gap surrounding the Analyzer.
Run takes significantly longer than 60 minutes to complete.	<ul style="list-style-type: none"> - Ensure ambient temperature is within acceptable range of 20 – 25°C (59 - 77°F). - Ensure relative humidity is within acceptable range of 20 - 50%. - Ensure adequate ventilation of the Analyzer – ensure that there is at least a 15 cm gap surrounding the Analyzer.
Patient test result is “Inconclusive”.	<ul style="list-style-type: none"> - Sample Collection Kit thawed during storage – repeat patient

	<p>test using a new Sample Collection Kit.</p> <ul style="list-style-type: none"> - Sample Collection Kit expired – check expiry date and repeat patient test using a new Sample Collection Kit. - Patient was not swabbed correctly – ensure that: i) Three up and down strokes are performed; ii) Blue tip of the swab is visibly wet after swabbing, but not coated with saliva. - Protocol time constraints were not met – ensure that: i) Steps 1-4 are completed within 4 minutes; ii) Steps 5-8 are completed within 4 minutes. - Bubbles present at the bottom of the tubes – ensure that any bubbles present at the bottom of the tube are removed by firmly tapping the tube until they move to the top. - Insufficient / improper tapping of tubes – Ensure that tapping is sufficiently firm so that the liquid in the tube moves and makes contact with the blue tip of the inserted swab. - Patient did not rinse his or her mouth with water prior to sample collection – repeat the test. - Ensure temperature is within acceptable range of 20 – 25°C (59 - 77°F). - Ensure relative humidity is within acceptable range of 20 - 50%. - Ensure adequate ventilation of the Analyzer – ensure that there is at least a 15 cm gap surrounding the Analyzer.
<p>Test results for a single patient are consistently “Inconclusive”.</p>	<ul style="list-style-type: none"> - Try swabbing the patient with more force. - On rare occasions (less than 1 in 100 patients), the Spartan RX System may be unable to produce a conclusive result. This may be due to factors intrinsic to the patient, e.g., interfering salivary substances.
<p>Test results for multiple patients are consistently “Inconclusive”.</p>	<ul style="list-style-type: none"> - Sample Collection Kits have thawed at some point during storage - obtain a new batch of Sample Collection Kits. Check that storage location is appropriate (-15°C to -80°C). - If test results are still “Inconclusive” after new Sample Collection Kits have been tested, there may be a problem with the Spartan RX System. Please contact your Authorized Spartan Dealer and a representative will assist you.



12. Proper Disposal of the RX System

Spartan supports European Union Directive 2002/96/EC regarding the waste of electrical and electronic equipment (WEEE). As such, final holders and resellers can return the electrical and electronic waste of the Spartan RX System free of charge. Arrangements may be made by contacting Spartan at +1.613.228.7756 or support@spartanbio.com.

All used components of the Sample Collection Kit, including swab shafts and tubes, should be disposed of as regular waste in accordance with local and national regulations.

