



Genomadix Cube CYP2C19 System

Operator's Manual

For *In Vitro* Diagnostic Use

R_x ONLY



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NOTE: Throughout this document Genomadix Incorporated, may be referred to as Genomadix, or company and the Genomadix Cube may be referred to as the Cube.

Intended Use

The Genomadix Cube CYP2C19 System is a qualitative *in vitro* diagnostic test for the identification of a patient's CYP2C19 *2, *3, and *17 genotypes determined from genomic DNA obtained from a buccal swab sample.

The Genomadix Cube CYP2C19 System can be used to aid clinicians in determining therapeutic strategy for therapeutics that are metabolized by the cytochrome P450 2C19 gene product, specifically *2, *3, and *17 alleles. This test is not intended to be used to predict drug response or non-response.

Indications For Use

The Genomadix Cube CYP2C19 System is not indicated for stand-alone diagnostic purposes. The information provided from this test may supplement decision making and should only be used in conjunction with routine monitoring by a physician. Clinicians should use professional judgment in the interpretation of results from this test. Results from this type of assay should not be used in predicting a patient's response to drugs for which the drug metabolizing enzyme activity of that allele, or the drug metabolic pathway, has not been clearly established.

The Genomadix Cube CYP2C19 Test Kit is indicated for use with the Genomadix Cube CYP2C19 Platform.

Product Overview

The Genomadix Cube CYP2C19 System is a sample-to-result DNA testing system that uses proprietary technology to integrate DNA extraction and amplification. Genotypes are determined using Polymerase Chain Reaction (PCR) and fluorescent probe detection.

The test protocol is based on the following major processes:

- a. Collection of human genomic DNA via swab(s)
- b. DNA extraction
- c. PCR amplification of extracted DNA
- d. Detection of amplified PCR products via fluorescent oligonucleotide probes
- e. Fluorescent signal detection and analysis (determination of CYP2C19 *2, *3, and *17 genotypes)

NOTE: Steps (b) through (e) are automated by the CYP2C19 System.

THE GENOMADIX CUBE CYP2C19 SYSTEM

Item	Content	Purpose
Platform	Genomadix Cube	Instrument that automates the Genomadix Cube CYP2C19 Test.
	Computer	The user interface (software) for logging in to the CYP2C19 Platform, inputting patient information and other information associated with the test, automatically inputting Cartridge lot numbers, and the instructions for starting a test.
	Barcode scanner	Scans barcode information.
Test Kit	Swabs	Proprietary swabs used to collect a buccal sample from the inside of a patient's cheek and transfer it to the cartridge.
	Cartridge	Contains substances for DNA extraction, PCR amplification, and detection of the CYP2C19 alleles, in three separate tubes. Each tube is specific for the detection of one of the three CYP2C19 loci.

Platform Description

The Genomadix Platform is a real-time reverse transcription (RT)- polymerase chain reaction (PCR) device for the qualitative detection of deoxyribonucleic acid (DNA) or ribonucleic acid (RNA). The Genomadix Cube platform can only be used with Genomadix test kits. The Genomadix platform is not intended to interoperate with other devices, products, or systems on customer networks for normal use/essential performance.

The Genomadix Cube (device) is a multi-well thermal cycler with optical detection capability. The unit has two optical detection channels (labeled as green and red). The device is uniquely identified by a serial number and a Unique Device Identifier (UDI) found on the underside of the Cube.

Materials Provided

Item	Part Number	Content	Quantity
Genomadix Cube CYP2C19 Platform	ASM-00096	Genomadix Cube (ASM-00097)	1
		Computer (ASM-00098)	
		Barcode Scanner (OTS-00223)	



Additional Materials

Components	Part Number	Quantity
CYP2C19 External Control Cartridges	ASM-00099	10
CYP2C19 Training Kits	ASM-00116	5
Swab Kit	ASM- 00103	20

Materials Required - Not Provided

- Genomadix Cube CYP2C19 Test Kit (ASM-00095) is not provided with shipments of the Platform.
- Personal protective equipment.
- Cleaning solutions.

Precautions - General

- For *in vitro* diagnostic use.
- For prescription use only.
- To be used by qualified personnel only.
- The Genomadix Cube CYP2C19 Test Kit was validated using the Genomadix Cube CYP2C19 Platform.
-  It is important to follow the instructions in this manual. Before using this system, system operators are to complete the appropriate training using the software and training materials included with the platform.
-  The Genomadix Cube CYP2C19 Platform includes an electromechanical instrument called the Genomadix Cube. 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 pre-cautions which apply to electrical instruments.
- Do not use any components with visible damage.
- The power supply cord must be inserted into a power outlet with a protective earth contact (ground).
- Only use the supplied power cords or cables. If any of the cables become damaged or inoperable, please contact your distributor for a replacement.

- Do not use the Genomadix CYP2C19 Platform near water or immerse it 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 distributor 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 stepped on.
- Do not overload power outlets because this may result in risks of fire or electrical shock.
- Unplug the power supply cord from the power outlet and refer to Genomadix authorized service personnel if one or more of the following conditions exist:
 - The power supply cord or plug is damaged or frayed.
 - Liquid has spilled onto the instrument.
 - The instrument has been exposed to water.
 - The instrument does not operate normally following the operating instructions.
- Refer to the Troubleshooting section of this document in the event a problem is encountered.
- Do not connect any external accessory (USB stick, cell phone, etc.) or storage devices to the laptop, or Cube as it could impact product performance.
- The installation of any additional software or applications onto the Genomadix supplied laptop is prohibited.
- Do not plug/insert any personal or non-Genomadix provided accessories into the Laptop or Cube.
- To reduce the risk of electrical shock, do not disassemble any part of the Genomadix platform. Please contact technical support if you are having any issues.
- In environments with high density electromagnetic fields or areas that are susceptible to elevated levels of ESD discharge the operator may experience a temporary loss of essential performance which can be recovered by the operator. This is normal and expected for this type of equipment.
- The Genomadix CYP2C19 Platform is not authorized for use in moist or wet environments.
- The Genomadix CYP2C19 Platform (system) is not authorized to be used with any type of flammable gasses (anesthetics) or oxygen rich environments.
- If any component becomes damaged or inoperable, please stop use immediately, and contact your distributor for a replacement.
- The laptop and cube each contain a rechargeable lithium-Ion battery. Lithium-Ion batteries are potentially hazardous and can present a serious fire hazard if damaged, defective, or improperly used.

Maintenance

The Genomadix Cube does not require maintenance. There are no user-serviceable parts, and it does not require in-field calibration or service. The Positive System Control (PSC) is designed to detect a change in performance of either the platform or Test.

General Cleaning

If the instrument becomes dusty, use a dry static-free cloth to clean the surface of the instrument. Solids or liquids should not be allowed to fall into the cartridge loading area at any time because they could interfere with the optical detection apparatus. As a preventive measure, keep the lid closed at all times, except when samples are being loaded or unloaded.

Slots in the back of the instrument are used for ventilation. To protect the unit from overheating, these openings must not be blocked, and a 10 cm gap must be maintained. Adequate ventilation should be verified at the start of each day.

The computer does not require maintenance. You may clean the screen using a clean, dry, and lint-free cloth.

In the unlikely event that the instrument has been contaminated with biohazardous material, follow these instructions:

- We recommend you wear disposable gloves when cleaning and disinfecting any surface.
- Turn off (power down) the Cube and/or Laptop you plan to clean.
- Disconnect the supplied power adapters and supplied cables/accessories.
- NEVER spray any liquids directly onto any of the products.
- Using any material other than a lint free cloth or the chemicals listed could cause damage to your product.
- Surfaces must be completely air-dried before turning the device on after cleaning. No moisture should be visible on the surfaces of the product before it is turned on or plugged in.
- **Cleaning Instructions:**
 - **CUBE:**
 1. Moisten a lint free cloth with 10% bleach or 70% ethanol. The cloth should be damp and not dripping wet. Excess moisture should be removed before wiping, or you could damage the product.
 - Moisture entering the inside an electronic product can cause damage to the product
 2. Do not open or clean inside the cube lid.
 3. Gently wipe the moistened cloth on the surfaces to be cleaned.
 4. The outer surfaces of the Cube can also be cleaned with disinfectant wipes containing quaternary ammonium salts or 0.5% hydrogen peroxide.
 5. Air dry before turning on or plugging in.
 - **LAPTOP & ACCESSORIES:**
 1. Moisten a microfiber cloth with a mixture of 70% isopropyl alcohol / 30% water. The cloth should be damp, but not dripping wet. Excess moisture should be removed if the cloth is wet before wiping the product. Using any material other than a microfiber cloth could cause damage to your product.
 2. Gently wipe the moistened cloth on the surfaces to be cleaned. Do not allow any moisture to drip into areas like keyboards, display panels, etc. Moisture entering the inside an electronic product can cause damage to the product. Excessive wiping potentially could lead to damaging some surfaces.
 3. When cleaning a display screen, carefully wipe in one direction, moving from the top of the display to the bottom.
 4. Air dry before turning on or plugging in.
 5. Avoid using any of the following chemicals or products containing these chemicals on the laptop and/or accessories. Using any of the chemicals that are listed below will cause permanent damage to some product surfaces.
 - Any chlorine-based cleaner, such as bleach
 - Peroxides (including hydrogen peroxide)
 - Solvents such as; acetone, paint thinner, benzene, methylene chloride or toluene
 - Ammonia
 - Ethyl alcohol

If you have any issues or concerns about the device, please contact your distributor or Genomadix support.

Cybersecurity

As shipped, the Genomadix Cube CYP2C19 System does not require an external network connection for any aspect of normal product operation (e.g., starting tests, generating, viewing, and exporting results). The product is intended to be used in an environment with physical access controls in place (e.g., card key access).

The laptop runs Windows 10 IoT Enterprise 1809 and has the following cybersecurity controls in place:

- Windows Firewall and Virus & Threat Protection
- Ability to enable Windows full disk encryption.
- Patient identifiers are stored in an encrypted file on the computer.

- Windows Quality Updates will be applied if connected to the public internet. Genomadix has a plan in place to validate Windows Quality Updates for use in this product.
- The product is shipped with a preconfigured Windows user with default passwords configured.
 - The user will NOT be able to perform the following actions:
 - Connect to an external network
 - Connect to Wi-Fi
 - Access the internet
 - Install third-party software
 - Uninstall Software
 - Create additional users

Please note the following recommendations for Cybersecurity:

- It is recommended to change default passwords.
- Genomadix cannot recover any lost Windows passwords.
- Only one user can use the software on a laptop at a time. If multiple users are configured, each user must log out of Windows before another user can use the software.
- Genomadix cannot recover any information from the laptop if full disk encryption is enabled and the password is lost.

Electronic Interfaces

Communication

The laptop has an RJ45 Ethernet connector jack, and an internal Wi-Fi adapter, both of which are disabled in software.

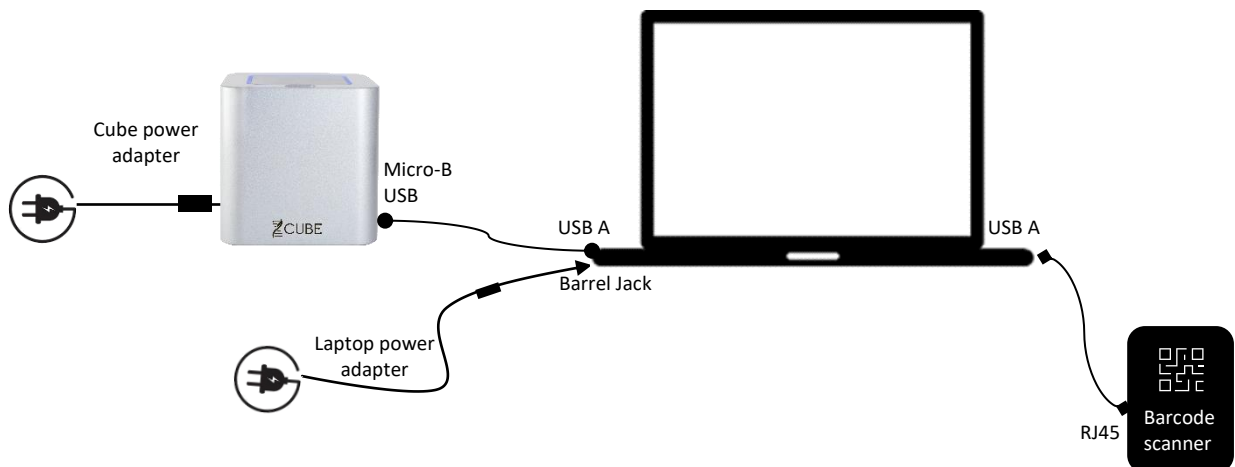
The laptop also has USB ports required for use of the product. The barcode scanner and Genomadix Cube must be connected using USB. The Genomadix Cube has a single micro-USB connector to connect to the laptop directly. Each Genomadix Cube will appear as a network interface on the laptop, and the software and Cube will communicate using HTTPS.

Connection Type	Required for Normal Function	Purpose	Ports
Ethernet over USB	Yes	Communicating with Cube(s)	UDP Inbound/Outbound Port 5353 TCP Outbound Port 8080 and 8081

Connectivity

Only use the Genomadix supplied power adapters, power cords, and cables. If any become damaged or inoperable, please contact your distributor for a replacement.

Note: the use of third-party unapproved USB hubs or any other accessory is strictly prohibited.



Ongoing Support

- Genomadix has a plan in place to validate Windows Quality Updates with the Genomadix CYP2C19 platform
- Genomadix has a plan in place to monitor for on-going cybersecurity threats
- Genomadix will provide software updates to the Genomadix CYP2C19 product
- Genomadix can provide a Software Bill of Materials (SBOM)

Please contact Genomadix Support or visit www.genomadix.com/support for more information, including how to receive notification of updates, mitigations, or other cybersecurity information.

Included Off the Shelf Software

The laptop included in the product contains off the shelf software pre-installed. Users must not install other software onto the laptop, upgrade existing off the shelf software, or remove any existing pre-installed off the shelf software.

Use Environment, EMC & EMI Information

Intended Use Environment	Professional Healthcare Facility Environment, designed for indoor use only.
Essential performance (60601-2 Edition 4.1,2020)	Essential performance of the Genomadix Cube is to provide the environmental conditions necessary to enable the duplication of DNA.
Electromagnetic compatibility (EMC)	In environments with high density electromagnetic fields or areas that are susceptible to elevated levels of electrostatic discharge (ESD) the operator may experience a temporary loss of essential performance which can be recovered by the operator. This is normal and expected for this type of equipment.
Electromagnet interface (EMI)	The Genomadix system is intended to be used at locations where the separation distance to third party sensitive radio services is > 30 meters. If these conditions are not met, then the limits for ≤ 20 kVA apply.
Loss of Power during testing	In the event of a power failure while using the equipment the test will be automatically failed and the operator notified of an incomplete test.
Operation in Moist Rich Environments	The Genomadix system is not authorized for use in moist or wet environments
Operation In Oxygen rich or flammable environments	The Genomadix system is not authorized to be used with any type of flammable gasses (anaesthetics) or oxygen rich environments.
Interoperability	The Genomadix Cube CYP2C19 platform is not intended to interoperate with any other equipment and only is intended to be used with supplied accessories.
Wireless/ RF Wireless Communication	The Genomadix Cube CYP2C19 System does not require wireless communication for essential performance and has disabled the ability to connect to a wireless network.
Operating relative humidity (RH) (without condensation)	30% RH to 80% RH NOTE: Drier conditions tend to result in a higher risk of static electricity buildup, which can lead to electrostatic discharges (ESD).
Operating Temperature	18 to 25 degrees Celsius
Supplied Adapter Operating Voltage (V)	Nominal 19V; 24 +/- 5% as per power adapter specification
Supplied Adapter Operating Current (A)	Max 4.75A
Space Requirements	Minimum of 75 x 60 cm of desk space.
Electrical outlet requirement	Two electrical power outlets.
Cube Rear Ventilation	Ensure adequate rear ventilation; 10cm gap must be maintained.

The Genomadix Cube CYP2C19 System conforms to:

- CSA Standard C22.2
- IEC 60601-1-2:2014 + A1:2020
- IEC 61010-1:2017
- IEC 61010-2-010
- IEC 61010-2-101
- Restriction of Hazardous Substances Directive II 2011/65/EU

Equipment Specifications

Genomadix Cube Specifications (Ratings)	
Electrical Compatibility (AC power)	100 – 240 VAC, 50 – 60 Hz
Max Electrical Power (Watts (W))	Minimum 50W, Maximum 200W. 90 W for the Cube
USB Port	5VDC
Storage/transport Temperature	-20 to 40 Degrees Celsius
Storage/transport Humidity	10 – 80% Relative humidity (RH) Non-condensing
Altitude	Max 2000 m
Pollution Degree	2

Equipment Unpacking

Unpacking

The Genomadix Cube CYP2C19 Platform is shipped in one cardboard container. Do not take receipt of the container if you observe any damage. Genomadix recommends that you fully read and understand the unpacking instructions below before you start unpacking the components. If you have any questions or concerns, please contact your distributor.

System Contents (Supplied)

- Genomadix Cube
- Power adapter for Cube (packaged with Cube)
- Computer
- Power adapter for computer (packaged with laptop)
- USB cable for connecting computer and Cube
- Barcode scanner
- USB cable for connecting computer and barcode scanner



Detailed Setup

The setup is completed by following the steps below.


1. Remove the computer from the packaging and place it on the desk. Plug the power adapter into the wall outlet and into the side of the computer.
2. Remove the barcode scanner from the packaging and place it upright on the desk. Attach the cable packaged with the barcode scanner to the back of the Scanner.
3. Plug the free end of the barcode scanner USB cable into the appropriate port on the computer.
4. Remove the Genomadix Cube from the packaging and place it upright on the desk. Plug the Genomadix Cube power adapter into the back of the Genomadix Cube and into the wall outlet.
5. Plug the smaller end of the USB cable into the back of the Genomadix Cube.
6. Plug the larger end of the Genomadix Cube USB cable into the computer.
7. Turn on the Genomadix Cube and computer.
8. The Genomadix Cube CYP2C19 software will automatically launch.
9. You will require the default username and password the first time you log in to the user interface (this can be found on the Login Information Sheet shipped with the platform).
10. Genomadix Inc. recommends that you use a security cable to prevent the Genomadix Cube CYP2C19 Platform from being stolen or transported without your permission. This security cable is not provided with the instrument.

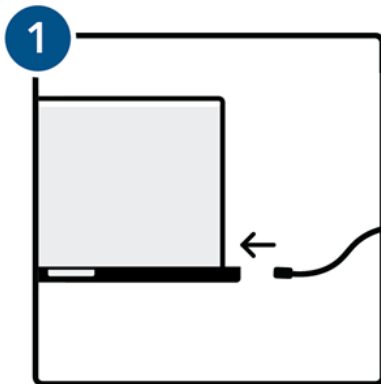
Location of Platform

The Genomadix Cube CYP2C19 Platform should reside in an area that meets the criteria below. Failure to adhere to these constraints may result in poor performance of the Genomadix Cube CYP2C19 Platform.

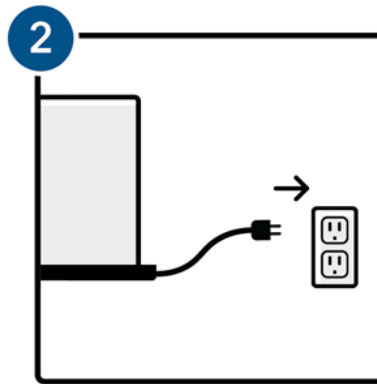
- The Genomadix Cube CYP2C19 Platform must be set up in a location meeting the storage and operating conditions outlined in Use Environment, EMC & EMI Information, and Equipment Specifications.
- The Genomadix Cube must have adequate rear ventilation. To protect the unit from overheating, the openings at the rear of the unit must not be blocked; a 10cm gap must be maintained.

Quick Setup Guide

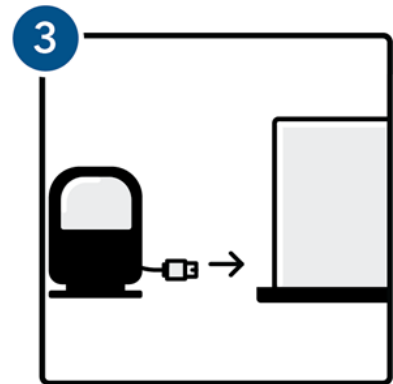
 Before using your Genomadx Cube CYP2C19 System, please carefully read all warnings and safety precautions outlined in this manual.



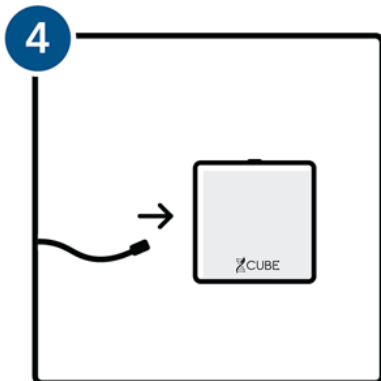
1 Connect the laptop to the computer power cable.



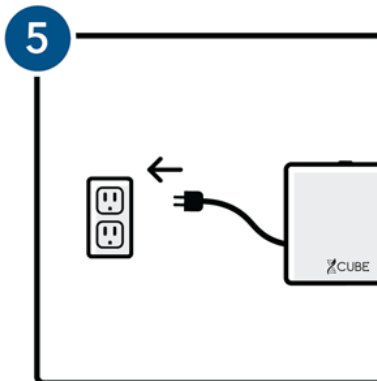
2 Plug the computer power cable into a power receptacle.



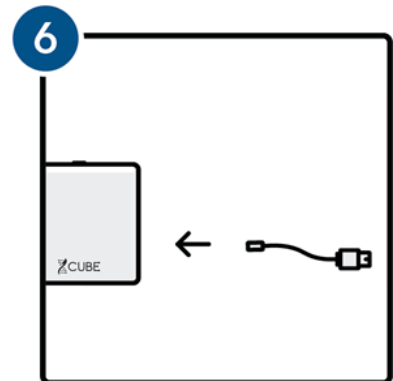
3 Connect the barcode scanner to the computer.



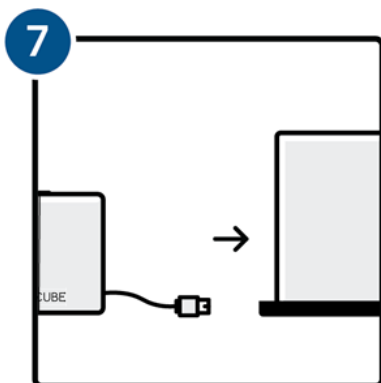
4 Connect the Cube to the Cube power cable.



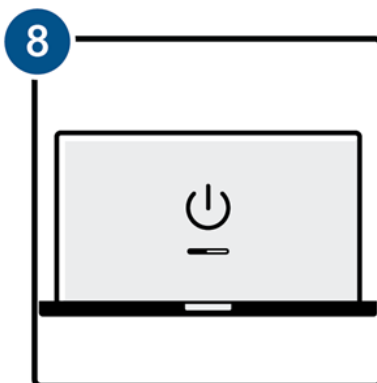
5 Plug the Cube power cable into a power receptacle.



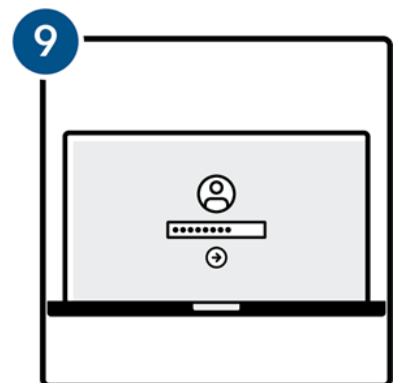
6 Connect the USB Cable to the Cube.



7 Connect the USB cable to the computer.



8 Turn on the computer.



9 Log in.

Performing a Test

The first time you set up the Genomadx Cube CYP2C19 Platform, please complete all training activities (see below) and then perform a set of tests and/or controls to ensure that the instrument is performing properly.


Software - User Interface

Introduction

The Genomadx Cube CYP2C19 Software has been pre-loaded on the computer. It will automatically run after you turn on the computer.

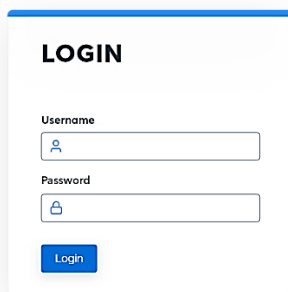
You will require the standard user login and password the first time you log in to the Genomadx Cube CYP2C19 software. This can be found on the Login Information Sheet that was shipped in the platform box. It is recommended that you change the password of this account.

NOTE: If you require administrator access or an administrator account, please contact Genomadx Support at support@genomadx.com. An administrator account is not required for essential performance.

 Users **must not** make any changes to the computer, computer software, or computer operating system.

Login screen

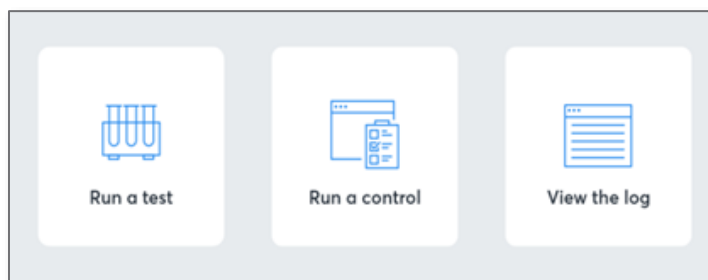
The user login screen automatically appears after you turn on the computer and log in. This screen also appears automatically after a predefined amount of time in the settings. You may log in using a username and password or by scanning a registered login barcode.



The screenshot shows a white login window with a blue header bar. The title "LOGIN" is centered at the top. Below the title, there are two input fields: "Username" with a person icon and "Password" with a lock icon. A blue "Login" button is positioned below the password field.

Main screen

The main screen contains the following items:

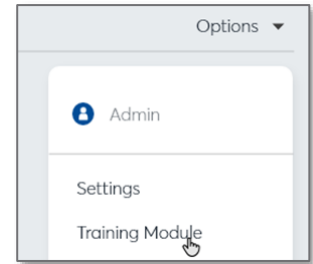


From the main screen you can initiate a test (**Run a test**), initiate a control (**Run a control**), or access previous test results (**View the log**).

Training


Genomadix recommends all users complete the Training Module before performing any tests or controls on the Genomadix Cube CYP2C19 System. The training module comprises a video, a practical walkthrough of the procedure, and a quiz. Upon completion of the Training Module, the user is provided with a certificate of training that may be accessed later by an administrator.

To access the Training Module, select **Options** on the upper right of the main screen and then select **Training Module**. The software will direct you through the various components of the training.



Running a Test

To perform a test on the platform, select **Run a test** and then follow the information on the subsequent screens. After performing the step described on a screen, select **Next** to advance to the next screen/step.

Patient information	By default, there is one field in which the patient information can be either manually entered or scanned in using the barcode scanner. If desired, two additional, optional fields can be included by changing the settings. You must enter information into the first patient information field in order to advance to the next step in the procedure.
Swab collected by	This is an optional field. If an individual other than the user analyzing the specimen on the Genomadix Cube CYP2C19 Platform collects the buccal sample, this person may be identified in the Swab collected by field in the software. This information will appear with the test results.
Notes	This is an optional field. In the Notes box, you may enter up to 500 characters of information that will appear with the test result.
Lot information	<p>Information about the Cartridge or External Control Cartridge lot resides in a 2D barcode (QR Code) on the respective, individual pouch. This information includes expiry date as well as other unique information about the individual lot.</p> <p> Always scan the barcode from the pouch containing the Test or External Control Cartridge being used. If the barcode is damaged or otherwise unscannable, do not scan a barcode from another pouch. The use of incorrect barcodes may cause incorrect or suppressed results. Discard the cartridge and retrieve a new Test Cartridge or External Control Cartridge from your freezer.</p> <p>When a valid Test Kit, External Control Cartridge or Training Cartridge pouch barcode is scanned, the screen will indicate if the cartridge is Valid, Expired, or if there is an incompatibility between the software and the test kit.</p>
Start Test	After advancing through all the workflow screens, you will arrive at a confirmation screen with a button to Start Test . Review the information on the screen to ensure that you have entered all the correct details about the test. Select Edit to revise the associated data, if necessary. To begin analysis of the sample, select Start Test .

Running a Control

To perform an external control using an External Control Cartridge, select **Run a Control** from the main screen. The software will direct you through the procedure, which is similar to a Test but does not require the use of swabs.

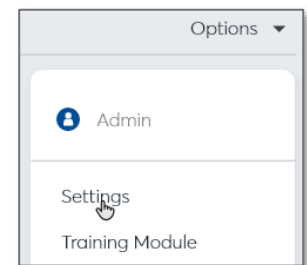
Indicator Light

The light on top of the Genomadix Cube indicates the Cube status. When powering on the Cube, the light ring will briefly appear yellow and then proceed to blue. When performing a test, the following colour coding applies:

Colour	Status
Blue	The Cube is in the standby state
“Breathing” white	A test is in progress
Green	A test has completed
Solid yellow	The test result is inconclusive
Flashing yellow	The Positive System Control has been triggered during a test
Solid red	A system error has occurred

Settings

Only an administrator may change the software settings. These include adding users, setting password requirements, and turning on or off control lockouts. To access the settings, select **Options** on the upper right of the main screen and then select **Settings**.



Help

For troubleshooting information or details about the Genomadix Cube CYP2C19 System, open the **Options** menu in the upper right of the main screen and then select **Help**.

Results, Data Log and Export

At the end of a test or control, you will be shown the test result along with the patient information and other data associated with the assay. From this screen, you have the option to export the result as a portable document format (.pdf) document. Select **Done** to return to the main screen.

The outcome of every test and external control performed on the Genomadix Cube CYP2C19 Platform is stored in the Test Log. The Test Log can be accessed by selecting **View the Log** from the main screen. The Log provides a list of tests that can be sorted and/or filtered by date, operator, swabber (if provided), patient information, or result.

Selecting a test will open a screen identical to the results screen that appears at the end of a test. From this screen you again have the option to export the result as a .pdf document.

Sign Out

After being idle for a predefined time interval (the default is 30 min), the system will automatically log you out of the software. If you wish to log out manually, select **Logout** from the **Options** menu in the upper right of the main screen.

Powering Down the Platform

When not in use, it is recommended that the Genomadix Cube and computer are turned off.

- To turn off the Genomadix Cube, press and hold the button on the back until the light on the top changes colour.
- To turn off the computer, shut it down through the Windows operating system software. Please note that closing the screen does not place the computer in standby mode.

Troubleshooting

Issue Description	Resolution
Computer or Genomadix Cube does not power on.	<ul style="list-style-type: none">• Ensure power is supplied.• Ensure power switch on the computer or Genomadix Cube is in the “On” position.
Unable to log in to computer.	<ul style="list-style-type: none">• Check that the password is correct.• Check that the caps lock button is in the correct position.
Genomadix Cube CYP2C19 Platform will not begin the run.	<ul style="list-style-type: none">• Check that ambient temperature is within the acceptable range of 18°C to 25°C.• Ensure the Genomadix Cube lid is closed.• Check all cables and ensure they are properly connected.
An error code appears during a test.	<ul style="list-style-type: none">• Follow the instructions provided in the warning message that appears.• Contact your distributor, if appropriate.
Test result is “Inconclusive”.	<ul style="list-style-type: none">• Ensure that patient was swabbed correctly—three up-and-down strokes on the inside of the cheek, with sufficient pressure to maintain a bulge in the cheek for all strokes.• Ensure that the Cartridge is used within 15 minutes of retrieving it from the freezer.• Ensure that the swab sample is analyzed within 20 hours of buccal sample collection.
Test results for a single patient are consistently “Inconclusive”.	<ul style="list-style-type: none">• Try swabbing the patient with more force.• On rare occasions (less than 1 in 100 patients), the Genomadix Cube CYP2C19 System may be unable to produce a conclusive result. This may be due to factors intrinsic to the patient, e.g., interfering salivary substances, rare genotype.
Test results for multiple patients are consistently “Inconclusive”.	<ul style="list-style-type: none">• Ensure that the cartridges have not been removed from the freezer for an extended period of time or that the freezer has not had issues that may have caused the reagents to thaw. If the Test Kits have thawed, you will need to obtain new ones.

If an INCONCLUSIVE or PSC result is displayed, collect a new set (second set) of swabs from the same patient to test using a new cartridge.







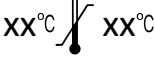





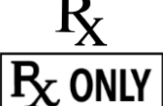
Disposal

There are no user serviceable parts in the device. Repair must occur at the manufacturer's location. There are no special disposal requirements other than standard procedures used for the disposal of electrical and electronic devices. The unit itself does not pose any bio-hazard risks.

Genomadix Inc. supports European Union Directive 2012/19/EU regarding the waste of electrical and electronic equipment (WEEE). As such, final holders and resellers can return the electrical and electronic waste of the Genomadix Cube CYP2C19 System free of charge. Arrangements can be made by contacting your distributor.

Table of Symbols

Symbols are used throughout this document or on the product. The table below lists the symbols and a brief description of their meanings.

	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.
	Important Note – This symbol is used to bring the user’s attention to an important annotation.
	Biohazard – This symbol is used to indicate that certain precautions must be taken when working with potentially infectious material.
	This symbol indicates the manufacturer of the device or system component.
	Do not reuse a product containing this symbol (use the product only once).
	Use until (indicates the expiry date of the product).
	Temperature limitations
	Part number or catalogue number.
	Lot number of product(s).
	Device serial number.
	Caution, Risk of Electrical Shock – This symbol is used to indicate that certain precautions must be taken to avoid electrical shock.
	In Vitro Diagnostic (indicates the material is an In Vitro Diagnostic or part of an In Vitro Diagnostic Device).
	For prescription use only.

Residual Risks and Limitations

- The Genomadix Cube CYP2C19 System identifies only the CYP2C19 *2, *3, and *17 alleles, and the corresponding polymorphisms. The test reports only the genotypes for these alleles. Other CYP2C19 alleles, which are rare, or unknown at the time of development of this product, will not be identified by this product. These other alleles may result in either a *1 call (wild-type), a no-call, or a call of a genetically related allele included in this system. A *1 call, or the call of a genetically related allele may result in a phenotype prediction that is different from the phenotype prediction that would be made if the presence of the rare allele were known. When the report lists the combined genotype as wild-type (*1/*1), only the tested alleles (*2, *3, *17) are wild-type.
- The CYP2C19*10 allele is a loss-of-function allele that has a predicted frequency of 0.037% based on the NCBI ALFA database¹. The presence of the CYP2C19*10 allele can interfere with the detection of the CYP2C19*2 allele. A homozygous *10/*10 will result in an inconclusive, while a *2/*10 will result in an incorrect *2 call.
- In samples with inadequate amount of DNA, the presence of the single nucleotide polymorphism (SNP) rs576566073 can interfere with the detection of the CYP2C19*17 allele. The frequency of the rs576566073 SNP is predicted to be 0.048% based on the NCBI ALFA database¹. A homozygous rs576566073 SNP sample may result in an inconclusive, while a *17 sample containing a heterozygous rs576566073 SNP may result in an incorrect *17 call at low DNA concentrations.
- Based upon published information, the genotype information provided by the Genomadix Cube CYP2C19 System may be used by the clinician to predict an individual's CYP2C19 enzymatic activity. Clinicians should use caution and professional judgment in predicting phenotype and adjusting treatment strategy for patients who express *2, *3, and/or *17 alleles. The information provided from this test may supplement decision making and should only be used in conjunction with routine monitoring by a physician. Because of the variability in the knowledge of clinical utility with specific drugs that are metabolized by CYP2C19, clinicians should use professional judgement in the interpretation of results from this test. Results from this type of test should not be used in predicting a patient's response to drugs for which the drug-metabolizing enzyme activity of that allele, or drug metabolic pathway, has not been clearly established.
- Results from the Genomadix Cube CYP2C19 System should be used and interpreted only in the context of the overall clinical diagnosis. Genomadix Inc. is not responsible for any clinical decisions that are taken.
- There is a risk that the swab tip may fall off in the patient's mouth. If this occurs, immediately instruct the patient to remove the tip from their mouth and obtain a new swab kit to collect the sample.
- The Genomadix system is intended to be used at locations where the separation distance to third party sensitive radio services is > 30 meters. If these conditions are not met, then the limits for ≤ 20 kVA apply.
- Only operate the Genomadix Cube CYP2C19 Platform under the following conditions: 18 to 25 Degrees Celsius and 30 to 80% non-condensing, relative humidity.
- In the event of a power failure while using the equipment the test will be automatically stop and the operator notified of an incomplete test.
- Only use the Genomadix supplied power adapters, power cords, and cables. If any become damaged or inoperable, please contact your distributor for a replacement. (Note: the use of third-party unapproved USB hubs or any other accessory is strictly prohibited.)
- Only use the platform (laptop, Cube, cables, and barcode scanner) for Genomadix System purposes.
- Although antivirus software is present on the laptop, patient information is encrypted and the Genomadix platform is not connected to the network, unauthorised devices plugged into the USB port pose a cybersecurity threat to the laptop.
- If unauthorised access to the laptop occurs, the antivirus software cannot prevent a malicious attacker from disabling antivirus. NOTE: Patient information is encrypted and the Genomadix platform is not connected to a network.
- The Genomadix platform is not intended to be used with any other medical devices, or software.

¹ ALFA: Allele Frequency Aggregator. <https://www.ncbi.nlm.nih.gov/snp/docs/gsr/alfa/#alfa-at-a-glance>. Version: release 2, version 20201027095038. Release date 6-JAN-2021. Accessed: 26-OCT-2022

Licenses and Patents

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Molecular Beacon technology is licensed pursuant to an agreement with the Public Health Research Institute (PHRI). This product is sold under license from PHRI.

This product is covered by US Patent Numbers 8,528,777; 8,735,104; 9,593,369 and other patents issued and pending by Genomadix Inc. worldwide.

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