

Rapid Capture[®] System User Manual



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1 Introduction

Thank you for choosing the Rapid Capture System (RCS). We are confident it will become an integral part of your laboratory.

Before using the RCS, it is essential that you read this user manual carefully and pay particular attention to the safety information. The instructions and safety information in the user manual must be followed to ensure safe operation of the instrument and to maintain the instrument in a safe condition.

1.1 About this user manual

The RCS Software controls the RCS and this user manual provides information for the user to perform RCS-automated testing of *digene*[®] Hybrid Capture[®] 2 (HC2) DNA tests.

This user manual provides information about the Rapid Capture System in the following sections:

- Introduction
- Safety Information
- General Description
- Installation Procedures
- Operating Procedures
- Maintenance
- Troubleshooting
- Technical Specifications
- Appendices

The appendices contain the following information:

- Technical Data
- Changing the Washer Boat
- Waste Electrical and Electronic Equipment (WEEE)
- FCC Declaration
- Warranty Clause

1.2 General information

1.2.1 Technical assistance

For technical assistance and more information, contact QIAGEN Technical Services.

Website: support.qiagen.com

When contacting QIAGEN Technical Services about errors, please have the following information ready:

- Rapid Capture System serial number, type, and version
- Error code (if applicable)
- Timepoint when the error occurred for the first time

- Frequency of error occurrence (i.e., intermittent or persistent error)
- Copy of log files

1.2.2 Policy statement

It is the policy of QIAGEN to improve products as new techniques and components become available. QIAGEN reserves the right to change specifications at any time. In an effort to produce useful and appropriate documentation, we appreciate your comments on this user manual. Please contact QIAGEN Technical Services.

1.3 Intended use of the instrument

The RCS is a general use semi-automated pipetting and dilution system that can be used with approved or cleared *digene* HC2 DNA tests for high-volume sample-throughput testing.

User intervention is limited to sample preparation, RCS deck setup, loading of specimen racks onto the RCS deck and chemiluminescent signal detection and result reporting. The Rapid Capture System is intended for professional use.

Note: Not all *digene* HC2 DNA tests have been validated for use on the RCS. Check the instructions for use for the *digene* HC2 DNA test of interest to determine if the assay and/or sample type you wish to place on the RCS deck has been validated for the RCS.

1.3.1 Cybersecurity Actions

- Ensure that only authorized users have access to the computer in which the *digene* HC2 System Software is installed.
- Ensure that an antivirus software is installed on the computer in which the *digene* HC2 System Software is installed.
- Only connect trusted hardware and devices to the computer in which the software is installed.
- Ensure that any exported or printed data is stored appropriately.

1.3.2 Requirements for instrument users

The table below shows the level of training and experience required for transportation, installation, use, maintenance and servicing of the RCS.

Type of task	Personnel	Level of competence and experience
Transportation	Approved carrier	Appropriately trained, experienced and approved by QIAGEN
Installation	QIAGEN Field Service employees or QIAGEN-trained personnel	Trained, certified and authorized by QIAGEN
Routine use	Laboratory technicians or equivalent	Appropriately trained, experienced, and familiar with the use of computers and automation in general
Routine maintenance	Laboratory technicians or equivalent	Appropriately trained, experienced, and familiar with the use of computers and automation in general
Servicing and semi-annual preventive maintenance	QIAGEN Field Service employees or QIAGEN-trained personnel	Trained, certified and authorized by QIAGEN

1.3.3 Operating software

The RCS Software is installed on the computer hard disk and utilizes the Microsoft® Windows® 7 or later Operating System, which makes the software easy to learn and simple for day-to-day use.

The following table describes the terms used when naming features of the software.

Term	Description
Box	An item in a dialog box which can be checked or unchecked.
Button	An item in a dialog box or toolbar, which the user clicks in order to execute something.
Dialog box	A box that appears temporarily and displays information or requires input from the user.
Dialog field	An item in a dialog box where the user can type in or select something. Note: Some fields are inactivated or simply display numerical or textual information.
Drop-down list	A list of items that appears when the user clicks a menu or the downward arrow appearing in some dialog fields
Graphic	A picture displayed in the software to represent the instrument or a feature of the instrument.
Icon	A small graphic either on the desktop or in the file manager, which represents a file, application or folder.
Menu	An item in the menu bar which the user clicks to display a drop-down list. A menu is also a list of items which are displayed when the user clicks the mouse.
Panel	A clearly marked area of a window or dialog box containing a particular group of information.
Parameter	Something that is specified by the user. A parameter is specified by checking/unchecking boxes and entering/selecting values in dialog fields.
Radio button	A circle in a dialog box, which can be selected or deselected.
Subpanel	A subdivision of a panel.
Tab	A feature in a window that resembles a file tab and contains a particular subset of information.
Window	A primary user interface of the software.
Wizard	A sequence of windows or dialog boxes, which guide the user through a procedure.

The following table describes the terms used to describe the operation of the software.

Term	Description
Check	Move the pointer over a box and click the left mouse button to display a check mark.
Click	Move the pointer over a button or tab and click the left mouse button.
Click and drag	Move the pointer over an item, hold down the left mouse button, pull the pointer and item to a new location and release the mouse button.
Deselect	Move the pointer over a radio button and click the left mouse button to unselect the radio button.
Double-click	Move the pointer over an item and click the left mouse button twice in quick succession.
Highlight	Move the pointer over an item and click the left mouse button to highlight the item. Note: Multiple items are highlighted in the software by holding either the Ctrl or Shift keys on the keyboard and selecting the desired items.
Right-click	Move the pointer over an item and click the right mouse button.
Select	Move the pointer over an item in a drop-down list or over a radio button and click the left mouse button to make a selection.
Uncheck	Move the pointer over a box and click the left mouse button to remove the check mark.

1.4 Materials required

Note: Only use accessories supplied by QIAGEN.

- RCS instrument
- Power Cord
- RS-232 Cable (cat. no. 9233583)
- Wash Bottle (cat. no. 9022179)
- Waste Bottle (cat. no. 9022181)
- System Liquid Bottle (cat. no. 9013248)

1.5 Materials required but not provided

- PC System (cat. no. 9003090)
- HCS Laser Printer (cat. no. 9023211 (120V) and 9023212 (240V))
- USB Printer Cable (cat. no. 9023213)
- HCS MST Vortexer (cat. no. 6000-5021 (120V) and 6000-5022 (240V))
- *digene* Specimen Rack and Lid (cat. no. 6000-5018)
- Conversion Rack and Lid (cat. no. 6000-5017)
- Specimen Collection Tubes (cat. no. 6000-5000)
- Dura Sealing Film (cat. no. 6000-5003)
- Reagent Troughs (cat. no. 6000-5008)
- Reagent Troughs Lids (cat. no. 6000-5010)
- Disposable Tips (cat. no. 6000-5006)
- Drop-on Caps (cat. no. 6000-5007)
- Extra Long Pipette Tips (cat. no. 5075-1011)
- *digene* HC2 System Software (cat. no. 9024225, 9024226, 9024228, and 9024230)

2 Safety Information

This user manual contains information about warnings and cautions that users must follow to ensure safe operation of the RCS and to maintain the instrument in a safe condition.

The following types of safety information appear in this user manual.

WARNING 	The term WARNING is used to inform you about situations that could result in personal injury to you or others. Details about these circumstances are provided to avoid personal injury to you or other persons.
---	--

CAUTION 	The term CAUTION is used to inform you about situations that could result in damage to the instrument or other equipment. Details about these circumstances are provided to avoid damage to the instrument or other equipment.
---	---

The guidance given in this manual is intended to supplement, not supersede, the normal safety requirements prevailing in your country.

Please be aware that you may be required to consult your local regulations for reporting serious incidents that have occurred in relation to the device to the manufacturer and/or its authorized representative and the regulatory authority in which the user and/or the patient is established.

Before using the instrument, it is essential to read this user manual carefully and to pay particular attention to any instructions it contains concerning hazards that may arise from the use of the instrument.

Note: Operators of this instrument must be trained in both general laboratory safety practices and the safety requirements specific to the RCS. If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

2.1 Proper use

Use the instrument only as specified by the operating instructions in this user manual so that you do not impair or damage the built-in safety features of the instrument. Follow good safety practices when operating the instrument.

WARNING 	Risk of inaccurate test results Always change gloves after handling the Waste Bottle, quick-disconnect fittings or liquid waste. Contamination of work areas with alkaline phosphatase can affect test results.
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<p>WARNING</p> 	<p>Risk of inaccurate test results</p> <p>Make sure the Waste Bottle is empty, as the overflow of the Waste Bottle can cause alkaline phosphatase contamination.</p> <p>Contamination of work areas with alkaline phosphatase can affect test results.</p>
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<p>WARNING</p> 	<p>Risk of inaccurate test results</p> <p>Make sure the System Liquid Bottle and Wash Bottle are full prior to the start of the RCS run.</p> <p>Insufficient volume of reagents for the run can result in inaccurate test results.</p>
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<p>WARNING</p> 	<p>Risk of inaccurate test results</p> <p>Wait for the instrument prompt before loading the specimen rack on the RCS deck.</p> <p>If the specimen rack is loaded on the RCS deck prior to the prime and flush of system lines, contamination can occur because of splashing; contamination can result in inaccurate test results.</p>
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<p>WARNING</p> 	<p>Risk of inaccurate test results</p> <p>When starting a run, do not check the same for all tests box in the Start run dialog box.</p> <p>Checking this box will affect reagent volume addition and result in inaccurate test results.</p>
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<p>WARNING</p> 	<p>Risk of inaccurate test results</p> <p>Make sure the correct number of samples is entered for the appropriate microplate.</p> <p>Testing an empty microplate well can clog the plate washer manifold and result in inaccurate test results.</p>
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<p>WARNING</p> 	<p>Risk of inaccurate test results</p> <p>Make sure all microplate wells tested contain liquid.</p> <p>Testing an empty microplate well can clog the plate washer manifold and result in false-negative test results.</p>
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<p>WARNING</p> 	<p>Risk of inaccurate test results</p> <p>For high-risk HPV testing, make sure only RCS-specific protocols provided by QIAGEN are used when creating plate layouts in the assay analysis software.</p> <p>Using the incorrect protocol could result in false-negative test results.</p>
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<p>WARNING</p> 	<p>Risk of inaccurate test results</p> <p>Do not concurrently print a test results report while measuring a microplate.</p> <p>Printing test result reports while measuring a microplate can slow assay processing on the RCS and result in inaccurate test results.</p>
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<p>WARNING/ CAUTION</p> 	<p>Risk of personal injury and material damage</p> <p>Improper use of the RCS may cause personal injuries to the user or damage to the instrument.</p> <p>The RCS must only be operated by qualified personnel who have been appropriately trained.</p>
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<p>CAUTION</p> 	<p>Risk of material damage</p> <p>Syringes are glass. Use caution when handling.</p>
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<p>CAUTION</p> 	<p>Risk of material damage</p> <p>Only QIAGEN Field Service employees or personnel trained by QIAGEN may service or repair the instrument.</p>
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<p>CAUTION</p> 	<p>Damage to the instrument</p> <p>Remove all items from the RCS deck.</p> <p>Items remaining on the RCS deck may result in damage to the instrument.</p>
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2.2 Electrical safety

The RCS does not pose uncommon electrical shock hazards to operators if it is installed and operated without alteration and is connected to a power source of the required specifications.

See “Appendix A – Technical Data,” for power requirement details.

Basic electrical hazard awareness is essential to the safe operation of any system. Elements of electrical safety include, but are not limited to, the following:

- Do not disconnect any electrical connection while the power is on.

Note: Although putting the power switch in the off position removes power to all electromechanical systems, mains voltage is delivered to the instrument until the power cord is separated from the appliance inlet (disconnecting device) located in the lower left corner on the rear panel of the instrument.

- Keep liquids away from all connectors of electrical components.
- Keep the floor dry and clean under and around the RCS.
- Use only approved power cords and electrical accessories, such as those supplied with the instrument, to protect against electric shock.
- Connect power cords only to properly grounded outlets.
- Do not touch any switch or outlet with wet hands.
- Switch the instrument off before disconnecting the AC power cord.
- Switch the instrument off and separate the power cord from the appliance inlet (disconnecting device) before cleaning liquid spills.
- Make sure the safety shield is in place before operating the instrument.
- Do not breach the space defined by the shield while the instrument is in use, except when directed to do so by the RCS Software.

<p>WARNING</p> 	<p>Electrical hazard</p> <p>Any interruption of the protective conductor (earth/ground lead) inside or outside the instrument or disconnection of the protective conductor terminal is likely to make the instrument dangerous.</p> <p>Intentional interruption is prohibited.</p> <p>Lethal voltage inside the instrument</p> <p>When the instrument is connected to line power, terminals may be live and opening covers or removing parts is likely to expose live parts.</p>
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WARNING 	Electrical hazard Serious injury from electrical shock can result by attempting to service RCS electrical components. QIAGEN Field Service employees and personnel trained by QIAGEN must perform all maintenance, unless otherwise specified in this user manual.
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The AC line fuse (slow blow) compartment is located below the power switch on the rear of the instrument.

Important: Only qualified and authorized personnel should replace fuses. Call QIAGEN Technical Services for service.

CAUTION 	Damage to the instrument Damage to the instrument can result from power failure during a run. QIAGEN recommends connecting the RCS to an uninterruptible power supply.
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2.3 Environment

CAUTION 	Damage to the instrument The RCS equipment should not be located near a heat source or exposed to direct sunlight.
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2.4 Waste disposal

Wastes may contain certain hazardous chemicals or contagious/biohazardous materials and must be collected and disposed of properly in accordance with all national, state, and local health and safety regulations and laws.

For disposal of Waste Electrical and Electronic Equipment (WEEE), see "Appendix C – Waste Electrical and Electronic Equipment," page 87.

2.5 Biological safety

WARNING 	Biohazardous substances The materials used with this instrument may contain biohazardous substances. When using the instrument, follow Universal Precautions regarding potentially infectious material.
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Refer to the applicable *digene* HC2 DNA test instructions for use for additional warnings and precautions related to reagents and specimens.

Use safety laboratory procedures as outlined in publications such as Biosafety in Microbiological and Biomedical Laboratories, HHS (www.cdc.gov/od/ohs/biosfty/biosft.htm).

2.6 Hazardous substances

<p>WARNING</p> 	<p>Hazardous substances</p> <p>When working with chemicals, always wear a suitable lab coat, disposable gloves and protective goggles. For more information, please consult the appropriate safety data sheets (SDSs). These are available online in convenient and compact PDF format at www.qiagen.com/safety where you can find, view and print the SDS for each QIAGEN kit and kit component.</p> <p>The materials used by this instrument may contain hazardous substances. For further information, see the instructions for use provided with the kit.</p> <p>For disposal of laboratory waste, follow all national and local health and safety regulation and laws.</p>
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2.7 Mechanical hazards

The robotic arm can exert enough force to be a pinch hazard.

The computer keyboard must be placed within reach of the RCS to ensure access to the Esc key on the RCS computer keyboard. The Esc key is considered an emergency stop mechanism.

<p>WARNING</p> 	<p>Risk of personal injury</p> <p>Do not remove the safety shield from the instrument. Do not breach the space defined by the shield while the instrument is in use, except when directed to do so by the RCS Software.</p>
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<p>WARNING</p> 	<p>Risk of personal injury</p> <p>Do not wear clothing or accessories that could catch on the RCS. In the event of a mechanical jam or other instrument problems, immediately contact QIAGEN Technical Services for assistance.</p>
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<p>WARNING</p> 	<p>Moving parts</p> <p>Do not reach into the instrument during instrument operation. Moving parts during operation can cause bodily harm.</p> <p>Stop the operation of the instrument before reaching into the RCS deck.</p>
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<p>WARNING</p> 	<p>Risk of personal injury</p> <p>Do not place any part of your hand under a disposable tip while pulling down to remove it. Placing your hand under a disposable tip while removing it may result in injury to the user.</p>
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<p>WARNING/ CAUTION</p> 	<p>Risk of personal injury and material damage</p> <p>Do not attempt to lift or move the RCS. The RCS weighs over 68 kg (150 lbs.).</p> <p>Contact QIAGEN Technical Services for assistance.</p>
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<p>WARNING/ CAUTION</p> 	<p>Risk of personal injury and material damage</p> <p>Do not reach onto the RCS deck while the instrument is running unless the system has paused and displayed a dialog box indicating user-intervention is required.</p> <p>Reaching onto the RCS deck at any other time during a run may result in injury to the user and/or an aborted run.</p>
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<p>CAUTION</p> 	<p>Damage to the instrument</p> <p>Make sure all required microplates, including required lids, are loaded on the RCS deck before starting a run. Missing microplates or lids will cause the robotic plate handler to crash.</p> <p>A crash may require the restart of the run and/or damage the RCS.</p>
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2.8 Heat hazard

<p>WARNING</p> 	<p>Risk of personal injury</p> <p>Avoid contact with the hybridization incubator.</p> <p>Allow the hybridization incubator to cool before touching as the incubator reaches a temperature of 65°C.</p>
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2.9 Maintenance safety

Perform the maintenance as described in "Maintenance," page 56. QIAGEN charges for repairs that are required due to incorrect maintenance.

WARNING 	<p>Risk of personal injury</p> <p>Users must wear lab coats, powder-free gloves and safety goggles when performing the cleaning procedure.</p>
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WARNING 	<p>Moving parts</p> <p>Do not reach into the instrument during instrument operation. Moving parts during operation can cause bodily harm.</p> <p>Stop the operation of the instrument before reaching into the RCS deck.</p>
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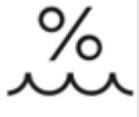
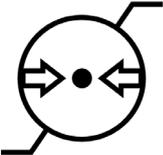
WARNING/ CAUTION 	<p>Risk of personal injury and material damage</p> <p>QIAGEN Field Service employees or personnel trained by QIAGEN must perform all maintenance, unless otherwise specified in this user manual.</p>
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2.10 Symbols on the instrument

The following table describes symbols and labels that may be found on the instrument, on labels associated with the instrument or in this user manual.

Symbol	Location	Description
	On the instrument	General warning sign
	On the instrument	Warning, dangerous voltage
	In this user manual	Warning, biological hazard
	In this user manual	Caution, hot surface
	Type plate on the instrument, instrument box label, and the front cover of this user manual	CE mark for European Conformity

Symbol	Location	Description
	Type plate on the instrument, instrument box label, and the front cover of this user manual Type plate on the instrument and instrument box label	In vitro diagnostic medical device
	Type plate on the instrument and instrument box label	RCM mark for Australia/New Zealand, former A-Tick mark (supplier identification N17965)
	Type plate on the instrument and instrument box label	RoHS mark for China (the restriction of the use of certain hazardous substances in electrical and electronic equipment)
	Type plate on the instrument and instrument box label	Waste Electrical and Electronic Equipment (WEEE)
	Type plate on the instrument and instrument box label	Serial number
	Type plate on the instrument, instrument box label, and the front cover of this user manual Type plate on the instrument and instrument box label	Manufacturer
	Type plate on the instrument and instrument box label	Consult instructions for use
	Type plate on the instrument and instrument box label	FCC mark of the United States Federal Communications Commission
	On the instrument	Warning, crushing hazard: hand
	Type plate on the instrument and instrument box label	Global Trade Item Number
	Type plate on the instrument, instrument box label, and the front cover of this user manual	Catalog number
	Cover of the user manual and instrument box label	Authorized representative in the European Community
	Instrument box label	Fragile, handle with care

Symbol	Location	Description
	Type plate on the back of the instrument and instrument box label	Unique device identifier (UDI)
	Instrument box label	Relative humidity
	Instrument box label	Barometric pressure
	Instrument box label	Temperature range
	Front cover of this user manual	Material

3 General Description

The RCS is a robotic microplate processor comprised of microprocessor-controlled components. All operations of the RCS are directed by software residing on the hard drive of a required computer that is connected to the RCS via an RS-232 interface.

The system is powered by a line voltage sensing switching-type power supply, and all power is distributed through the system at 240 volts AC or less.

The software-controlled functions and equipment mechanisms include:

- Sample pipetting to microplate
- Reagent addition
- Microplate washing
- Incubation
- Mixing
- A robotic handler transports the microplates between functional stations and moves plate lids and reagent trough covers
- Motion control of the four pipet tips and microplate transport is accomplished with 8 DC servomotors utilizing optical shaft encoders for position and velocity control
- Fluid handling is accomplished with 4 stepper motor syringe drives, 2 DC diaphragm pumps, and a DC peristaltic pump
- An orbital 4 plate shaker is stepper motor driven, as are the X carriage and Z manifold axis of the plate washer
- The hybridization incubator is firmware controlled and regulates each of 5 chambers to 65°C
- Each hybridization incubator chamber contains a DC motorized drawer that extends to enable loading and unloading of the microplates.
- Automatic scanning of plate bar codes and export to the *digene* Microplate Luminometer software (only available with the RCS bar code upgrade)

To accomplish semi-automation of *digene* HC2 DNA tests, the following 6 procedural steps of the manual method can be performed by the RCS:

- Sample pipetting
- Reagent dispensing
- Microplate handling
- Microplate mixing
- Microplate incubation
- Microplate washing

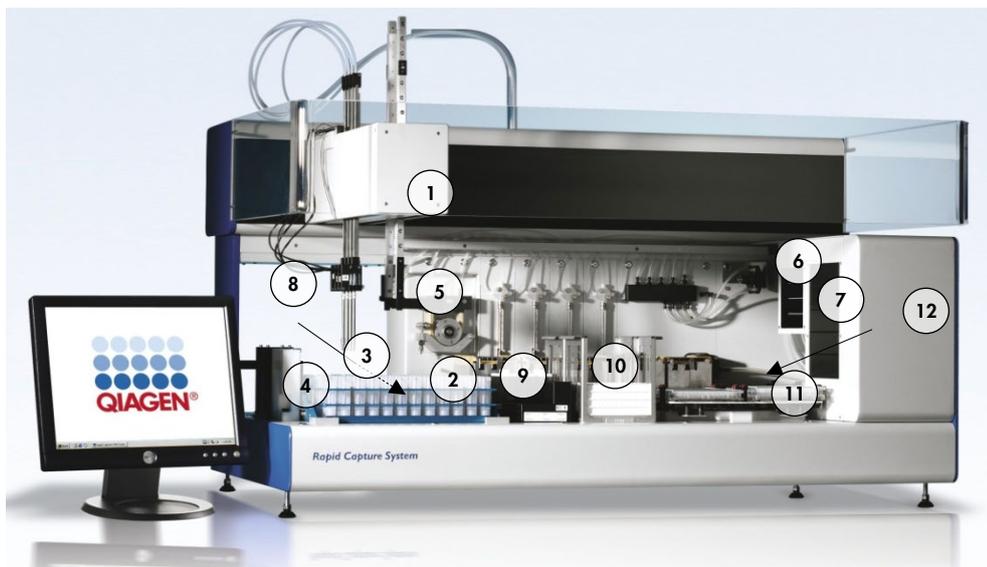
Denaturation of the specimens in preparation for testing with the *digene* HC2 DNA tests is performed independently of the RCS. In addition, amplified chemiluminescent signal detection and result reporting are performed using the off-line luminometer system (common to both the manual and RCS methods) utilizing the *digene* assay analysis software. Microplate mixing, incubation and washing are performed by the same type of equipment used as separate bench top accessories for the manual method of the tests; however, this equipment is integrated on the RCS deck.

Each of the HC2 procedural steps is performed in the same sequence as the manual test procedure. The RCS deck allows for the staggered processing of up to 4 microplates, each plate containing samples and the required assay calibrators and quality controls. The operator prepares the samples according to the instructions stated in the *digene* HC2 DNA Test Instructions for Use. After loading the racks onto the RCS deck, the operator returns at a set time to retrieve the microplate and perform the detection step. The amplified signal generated is detected in a separate chemiluminescent plate reader and the results are calculated and reported using the *digene* assay analysis software. Instructions for the luminometer are available in the user manual provided with the instrument.

3.1 Hardware components

The base unit of the RCS is comprised of:

- The instrument chassis sub-assembly (the base chassis, deck supports, mechanical deck, side and top panels, safety shield and tubing guide)
- The electrical sub-assembly (the power supply, printed circuit boards (PCBs), shielding, connectors and fuses)



- | | | | |
|---|---|----|-------------------------|
| 1 | Robotic arm | 7 | Hybridization incubator |
| 2 | Syringe pump and peristaltic pump modules | 8 | Pipetting position |
| 3 | Tip adapters | 9 | Reagent trough rack |
| 4 | Tip rinse station and drain | 10 | Stacker A and Stacker B |
| 5 | Robotic plate handler | 11 | Plate shaker |
| 6 | Ambient temperature plate shaker | 12 | Plate washer |

3.1.1 Robotic arm

All X/Y/Z/V (V=VariSpan) movements of the robotic arm are driven by DC motors with encoders. Each tip adapter can move independently of the others in the Z direction (up and down). The tip adapters are mounted on the Y slide, which moves front to rear (Y direction) inside the robotic arm. The robotic arm is mounted on the X slide located inside the instrument casing and moves left and right (X direction).

The RCS is equipped with VariSpan — the variable spacing of the tip adapters. This is achieved by the VariSpan motor, which is also used to vary the range of the robotic plate handler.

3.1.2 Sample processor

The Rapid Capture Robotic Microplate Processor features 4 sampling tips carried by the robotic arm. Each tip is connected to the 4-port valve of a precision syringe pump module and can aspirate, dispense, and dilute at most positions on the instrument's work surface. The RCS software controls pipetting sequence, volumes and pipetting modes.

3.1.3 Syringe pump and peristaltic pump modules

The syringe pump is a microprocessor-controlled syringe with a 4-port valve that connects to the syringe, peristaltic pump, tip adapters and System Liquid Bottle. Liquid is fed into the syringe from the System Liquid Bottle and the tip adapters are flushed via the peristaltic pump. All parts that come into contact with liquid are made of inert materials, such as stainless steel, fluorinated ethylene propylene (FEP), etc.

Each tip adapter has a dedicated syringe pump, controlling the aspiration and dispensing functions of the tip adapter.

The 4-channel peristaltic pump is used to supply system liquid used to flush the tubing at an average flow rate of 2 ml per second per channel.

3.1.4 Tip adapters

The RCS has 4 tip adapters carried by the robotic arm. Each tip adapter is connected to the 4-port valve of a precision syringe pump module and can aspirate, dispense and dilute at most positions on the RCS deck.

Each tip adapter features independent movement in the Z direction, while the span movement of tip adapters (Y direction) is variable. This feature is known as VariSpan.

The RCS uses 300 µl conductive disposable tips and automatically detects the presence of disposable tips. If disposable tips are not detected after 5 attempts, the system will pause, and an audible alert will notify the operator.

3.1.5 Liquid level detectors

Each tip adapter is equipped with a liquid level detector, which enables the detection of ionic solutions upon contact. The liquid level detectors monitor changes in capacitance between the disposable pipet tip and the RCS deck.

The liquid level detector is used to detect an insufficient amount or total absence of quality controls, calibrators and reagents; the liquid level detectors are not activated during sample transfer. When the disposable pipet tip touches the liquid surface, this sudden change in capacitance immediately generates a detection signal. If insufficient volume is detected, the system will immediately stop and display a dialog box, allowing the user an opportunity to replenish any liquids.

QIAGEN cannot guarantee proper functioning of the liquid level detectors if the equipment used to contain the quality controls, calibrators and reagents is not supplied by QIAGEN.

Important: Because the liquid level detector cannot identify what material causes a change in capacitance, it is imperative that the tips do not touch any surface (e.g., foam on top of the meniscus) except the liquid to be detected.

3.1.6 Tip rinse station and drain

The system lines and tip adapters are flushed at the tip rinse station. When the tip adapters are positioned in the tip rinse station, deionized or distilled water from the System Liquid Bottle is aspirated by the peristaltic pump and forced through each tip adapter. The flow is dispensed into the tip rinse station moat and down the drain. Any air bubbles in the system lines or tip adapters are purged. Tubing takes the waste fluid from the drain to the Waste Bottle.

3.1.7 Robotic plate handler with integrated plate grippers

The manipulative plate grippers, which are an integrated part of the robotic plate handler, are used to transport microplates and microplate lids between positions and modules, such as the ambient temperature plate stacker, the hybridization incubator, pipetting positions, the plate shaker and the plate washer.

The VariSpan motor is used to vary the spread of the 2 plate grippers and it has an independent Z motor and drive.

Microplates are loaded manually onto the RCS deck (in Stacker A and the plate shaker) and are delivered by the robotic plate handler to defined positions when the run is started.

3.1.8 Ambient temperature plate stacker and hybridization incubator

The fixed ambient temperature plate stacker houses microplates and microplate lids at a few degrees above room temperature during room temperature incubations. The 5-drawer automatic hybridization incubator tower is temperature controllable from approximately 5°C above ambient temperature to 65°C in graduations of 0.1°C.

The hybridization incubator consists of 5 drawers protected from ambient temperature and light by motor-driven, spring-loaded doors. The door is opened and closed by the action of the motor/drawer; the robotic plate handler delivers and retrieves the microplate from the individual drawer.

3.1.9 Pipetting position

For pipetting steps, the robotic plate handler carries the microplate to the pipetting position, a permanent plate mounted on the RCS deck surface. Pipetting position 1 and pipetting position 2 are designed for regular dimension microplates and/or microplate lids. The robotic plate handler will always deposit the correct microplate in the appropriate pipetting position, provided the microplates were placed in the proper locations during RCS deck setup.

3.1.10 Reagent trough rack

The reagents used during testing are contained in reagent troughs, with trough lids, and placed in the reagent trough rack. The reagent trough rack has space for the placement of 5 reagent troughs and 1 space to hold the trough lid, defined as the lid park, while the reagent is removed. During testing, the robotic plate handler removes the trough lid and places it in the lid park. After the trough lid is removed, the tip adapters, with disposable tips attached, pipet the reagent from the reagent trough.

3.1.11 Stacker A and Stacker B

The capture microplates (in a stack with one microplate lid on the top of the stack) used during testing are placed in Stacker A. During testing, used hybridization microplates are stacked in Stacker B after the samples have been transferred to the capture microplates. Each stacker accommodates up to 4 microplates.

3.1.12 Syringes

All sample transfer operations and reagent additions are performed using 500 μ l syringes operated by pumps. The following specification is based on pipetting normal saline solution (0.9% NaCl with deionized or distilled water): at 10% of full stroke and up to the maximum pipetting volume of the syringe, the CV is equal to or less than 1%. When pipetting low volumes of a viscous solution (i.e., 25 μ l of Probe Mix), a maximum CV of 5% is expected.

3.1.13 Plate shaker

The plate shaker is used for mixing after reagent additions and for shaking during incubation. The plate shaker accommodates up to 4 microplates. The plate shaker has 4 shake positions with specially designed clamps that secure the combination of a microplate and a microplate lid. The orbit has a 1.5 mm diameter and a speed of 1100 ± 50 rpm.

3.1.14 Plate washer

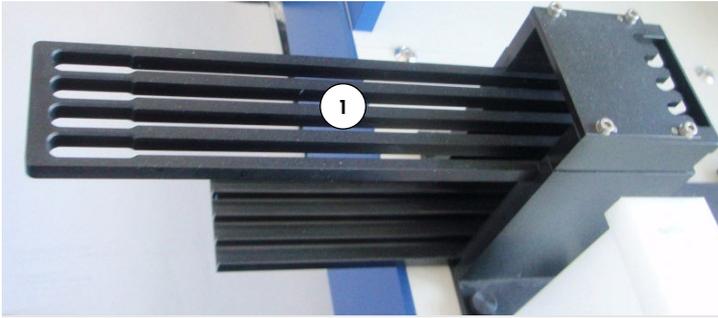
The RCS has a modular plate washer with an 8-channel wash head for flexibility and speed. The plate washer utilizes aspiration and dispensing pumps, a solenoid valve manifold and a restriction valve to control liquid pressure. The plate washer can function independently of other RCS functions due to the multitasking capabilities of the system. The Wash Bottle supplies the plate washer.

During the RCS run, the plate washer dispenses $1.5 \text{ ml} \pm 10\%$ into each microplate well while aspirating from the top of the microplate wells. The flow rate is determined by the dispense pressure of 10 psi and is approximated to be 500 μ l/sec. The microplate wells are then aspirated to a maximum mean residual volume of 7 μ l/well. The fill/aspirate cycle is repeated 6 times.

3.1.15 Tip eject station

The tip eject station extends from the left side of the RCS instrument.

Note: Before using the RCS, a waste container must be positioned below the tip ejection area.



1 Tip eject rail

3.1.16 Power switch and appliance inlet

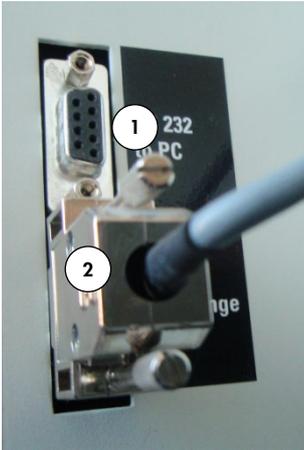
The power switch and power connection are located in the lower left corner on the rear panel of the RCS.



1 Power switch 2 Appliance inlet (disconnect)

3.1.17 System connection

The system connection is in the lower left corner on the rear panel of the instrument.



1 RS-232 interface for connection to computer

2 RS-232 interface for connection to syringe pump

3.1.18 Bottle connections

The bottle connections are on the right side panel of the instrument.



Refer to "Cleaning tubing lines and bottles," page 57, for instructions on how to connect the bottles following cleaning.

3.1.19 System Liquid Bottle, Wash Bottle and Waste Bottle

The RCS is equipped with the following bottles:

System Liquid Bottle

Wash Bottle

Waste Bottle



3.1.20 RCS computer

The RCS must be connected to the computer that is delivered with the RCS. The delivery consists of the computer, keyboard, mouse, monitor and connection cable.

Note: The RCS computer is also used to connect with the *digene* Microplate Luminometer (DML instrument).

3.1.21 RCS Bar Code Reader

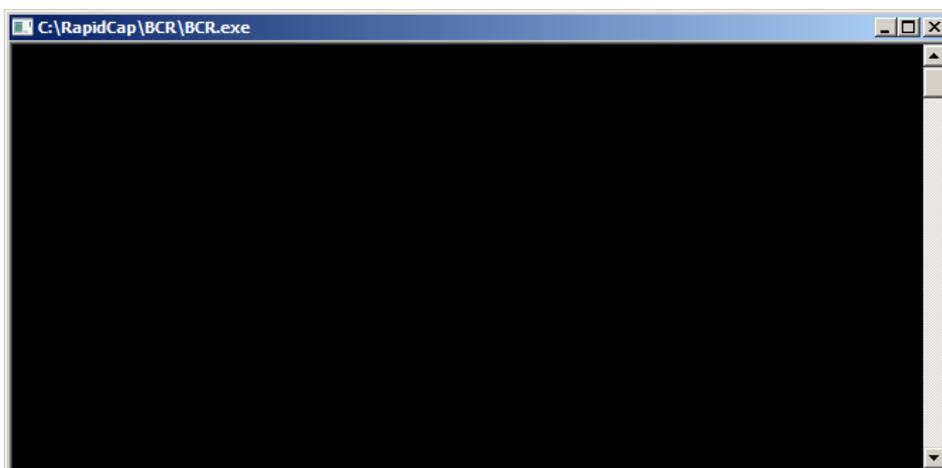
A bar code reader can be added to your RCS. Adding a bar code reader to your RCS will automate the plate tracking from loading to final result analysis. Hybridization and capture microplates supplied by QIAGEN include human-readable text and bar codes that can be read by the RCS Bar Code Reader.

The RCS Bar Code Reader Upgrade Package uses the bar codes on the plate to associate the plate IDs of the hybridization and capture plates processed on the RCS. The capture plate ID is then automatically associated when the hybridization plate ID is created in the *digene* assay analysis software. This allows for seamless plate and sample management.

It is important that users do not switch the sequence of plates on the RCS, for example, during error recovery, so that the correct association between the capture plate and the hybridization plate is maintained. Incorrect plate association could lead to incorrect results.

The RCS Bar Code Reader Upgrade Package includes an application that saves the scanned bar codes for use by the *digene* HC2 System Software. While the bar code scanning application is running, a command window will be displayed.

Example:



Do not close the command window. The window will close automatically after the bar code is saved. If the command window is closed by the user, then the scanned bar code will not be saved.

Important: Only a QIAGEN representative can install the RCS Bar Code Reader Upgrade Package. Do not attempt to install the hardware components, the RCS scripts or the bar code reader software application. Contact QIAGEN Technical Services for assistance.

3.2 Software components

Software components of the RCS include the RCS Software with the bar code reader application and ScriptSelect Software.

3.2.1 Software icons

Software	Icon	Description	Action
RCS Software	 RapidCapture	Rapid Capture System desktop icon	Launches the RCS operating software that controls the instrument.
RCS Software		The Run icon on the RCS Tool Menu bar	Displays the Scripts dialog box.
RCS Software		The Flush System icon on the RCS Tool Menu bar	Flushes the system.
RCS Software		The Park icon on the RCS Tool Menu bar	Moves the robotic arm to the park position.
ScriptSelect Software	 ScriptSelect	ScriptSelect desktop icon	Launches the software to facilitate the selection of the appropriate script for a run. See "Using ScriptSelect Software," page 39.

Note: Additional software applications reside on the RCS computer. These applications control the DML instrument, the LumiCheck Software and the data interface with the Laboratory Information Management System (LIMS). Refer to the respective user manuals for information on these additional software applications.

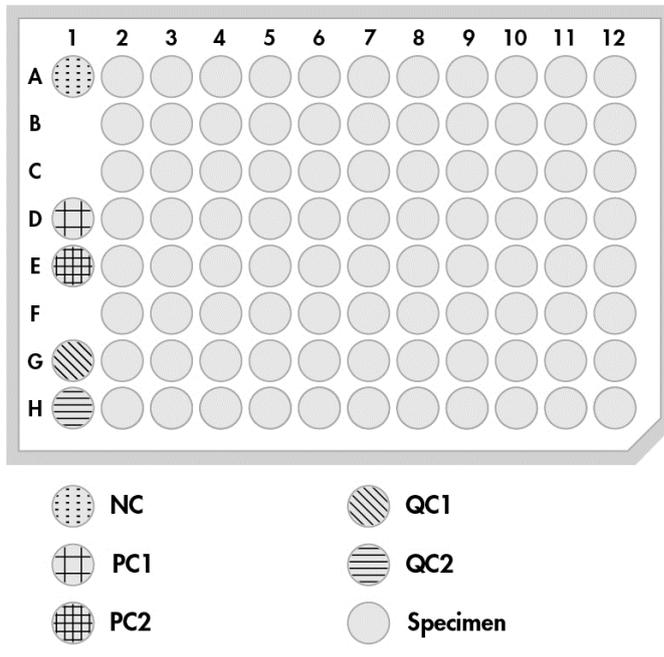
3.3 Additional equipment

3.3.1 MST Vortexer 2 and specimen racks

The Multi-Specimen Tube (MST) Vortexer 2, inclusive of specimen rack and lid accessory components, is required for specimen preparation, processing and denaturation. Each specimen rack is engraved with a serial number on the rack and the lid; when using, the serial numbers of the rack and the lid must match. The following specimen rack designs are available, as follows:

Specimen rack name	Rack color	Intended use
<i>digene</i> Specimen Rack	Blue	Testing of <i>digene</i> specimens
Conversion Rack	Silver	Testing of liquid cytology specimens in 15 ml conical tubes

The following figure of a specimen rack represents a microplate and describes the positions of the calibrators (NC, PC1 and PC2), quality controls (QC1, QC2) and specimens.



3.3.2 The DML instrument and *digene* assay analysis software

The DML instrument and related luminometer software are designed for measuring and analyzing light produced by chemiluminescence from *digene* HC2 DNA tests.

4 Installation, Relocation, and Disposal

4.1 Instrument delivery

Only the equipment and accessories listed have been validated for use with the RCS and are available from QIAGEN.

The following items are delivered with the RCS:

- RCS instrument
- System Liquid Bottle
- Wash Bottle
- Waste Bottle
- Power cord

The following equipment is required to operate the RCS, but may not arrive with the RCS:

- RCS computer including: CPU, keyboard, mouse, Microsoft Windows 7 or later operating system, RCS System Software, ScriptSelect Software
- Monitor
- Printer cable
- RS-232 cables

4.1.1 Equipment required but not supplied

- Uninterruptible power supply (UPS) with a capacity of ≥ 1000 VA, surge suppression, EMI/REI filtering

4.2 Site requirements

CAUTION 	Damage to the instrument The RCS equipment should not be located near a heat source or exposed to direct sunlight.
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The equipment must be located in close proximity to an AC power outlet.

Allow between 30 cm (12 in.) and 61 cm (24 in.) of additional space behind the instrument for servicing and for separating the power cord from the appliance inlet (the disconnecting device located in the lower left corner on the rear panel of the instrument). Make sure the equipment power lines are voltage regulated and surge protected.

The instrument must be placed on a sturdy workbench large enough to accommodate the RCS, System Liquid Bottle, Wash Bottle, and RCS computer. Make sure the workbench is dry, clean, and has additional space for accessories.

Refer to "Appendix A – Technical Data," page 85, for the weight and dimensions of the RCS.

Contact QIAGEN Technical Services for further information about required specifications of the workbench.

- Place the RCS computer keyboard within reach of the RCS to ensure access to the Esc key, which is considered an emergency stop mechanism.
- Locate the RCS such that the user is able to hear the audible alarm, allowing for immediate attention in the event of an error or malfunction.
- Sufficient space must exist to the right side of the instrument on (or near) the workbench to position the System Liquid Bottle and Wash Bottle close to the instrument and on the same level.
- The Waste Bottle must be positioned on a visible, secure spot on the floor, behind the instrument, to prevent spilling.
- Make certain that the space for placing the Waste Bottle is within 1.5 m (5 ft) of the instrument.

4.3 AC power connection

4.3.1 Power requirements

See “Appendix A – Technical Data,” page 85, for details of power requirements.

4.3.2 Grounding requirements

To protect operating personnel, the National Electrical Manufacturers’ Association (NEMA) recommends that the instrument is correctly grounded. The instrument is equipped with a 3-conductor AC power cord that, when connected to an appropriate AC power outlet, grounds the instrument. To preserve this protection feature, do not operate the instrument from an AC power cord outlet that has no ground connection.

4.4 Hardware unpacking, installation, relocation and disposal

QIAGEN Field Service employees or personnel trained by QIAGEN unpack and install the RCS.

If the instrument needs to be moved to a new location, QIAGEN Field Service employees or personnel trained by QIAGEN repack and relocate the instrument.

The responsible body should contact QIAGEN Technical Services for more information about transporting the instrument after delivery and for instructions about eliminating or reducing hazards and/or biohazards resulting from the removing from use, transporting and/or disposal of the instrument.

4.5 Uninterruptible power supply

<p>CAUTION</p> 	<p>Damage to the instrument</p> <p>Damage to the instrument can result from power failure during a run. QIAGEN recommends connecting the RCS to an uninterruptible power supply.</p>
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After installation and prior to powering ON the RCS, connect the RCS to a UPS. In the event of a power failure, a UPS allows the RCS to continue operating for at least 30 minutes, enabling user intervention to conclude or terminate a run.

Do not connect the printer provided with the DML instrument directly into the UPS.

4.6 Software installation

The RCS Software is installed on the RCS computer by a QIAGEN Field Service employee or personnel trained by QIAGEN.

The RCS Software is preinstalled on the RCS computer with the *digene* HC2 System Suite 4.4 developed for use with the RCS Bar Code Reader.

4.7 Virus scanners

We are aware of the threat that viruses cause to any computer that exchanges data with other computers. The HC2 System, including the RCS, is intended to be installed in environments where local policies exist to minimize this threat, and where the system is not exposed to the internet. Local policies usually require use of a particular antivirus tool. While the RCS software has been tested on a computer using McAfee® Endpoint Protection Essential for SMB and on a computer using Windows Defender, due to the sheer number of antivirus tools available it is not possible for QIAGEN to predict the possible impact on the system if such a tool is active. The selection of an appropriate virus scanning tool is the customer's responsibility. QIAGEN has not validated the RCS software for use with any antivirus software.

The system administrator should make sure that:

- QIAGEN directories are excluded from virus scanning. For the RCS software, these directories are:
- C:\RapidCap
- C:\Program Files\Selector
- File access is not intercepted by an antivirus scan while the RCS system is in use.
- Updates to the virus database are not performed while the RCS system is in use.
- File scans are not performed while the RCS system is in use.

We strongly recommend disabling antivirus software during laboratory working hours to prevent interference of the antivirus software with the operation of the *digene* HC2 System, including the RCS. The antivirus scanning tasks described above can only be safely carried out when the *digene* HC2 System, including the RCS, is not running; otherwise, there is a risk of an adverse impact on the performance of the system.

5 Powering ON/OFF the RCS

The RCS computer is set up with two administrative user accounts and one standard user account. It is recommended to operate the RCS software under the standard user account.

Note: You cannot change Windows users while the RCS is running.

Details of the user accounts are as follows (passwords are case sensitive):

a. Administrative user account:

- **User ID:** Administrator
- **Password:** *digene*

The system will prompt you to change the password the first time you log in to the Administrator account.

b. Standard user account:

- **User ID:** Welcome
- **Password:** welcome

The Technician user account is intended for use by QIAGEN service personnel.

5.1 Powering ON the RCS

1. Power ON the RCS computer.
2. The welcome screen appears.
3. Click the icon for the appropriate Windows user account.
4. Use the applicable case-sensitive credentials for the Windows operating system to log in.
5. Press the **Enter** key on the RCS computer keyboard.
6. The RCS desktop with icons appears after the password is entered.
7. Confirm that the tip adapters and plate grippers are located in the pipetting positions or the specimen rack loading area (see "RCS deck layout," page 47).
8. If necessary, manually lift the tip adapters and plate grippers, and move the robotic arm to the appropriate location. Lower the tip adapters and the plate grippers to their natural stop point.
9. Make sure there are no miscellaneous items on the RCS deck.
10. Power ON the RCS.

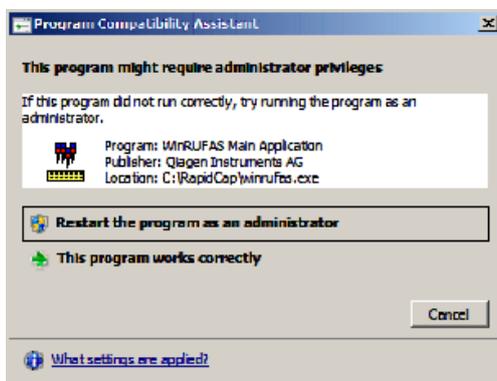
Note: Facing the front of the instrument, the power switch is located on the right-rear of the instrument.
11. Position the RCS computer keyboard so that it is adjacent to the RCS.
12. In the event that the instrument must be stopped immediately, press the **Esc** key on the RCS computer keyboard as an emergency stop mechanism. See "Safety Information," page 12, for additional safety instructions.
13. To launch the RCS Software, double-click the **Rapid Capture System** desktop icon.
14. Alternatively, click the Windows **Start** icon, then **All Programs**, and then **RapidCap**.
15. Click the **Park** icon from the RCS Tool Menu bar.

The tip adapters and robotic plate handler will move slowly to the home position, and the system will initialize all components and signal the hybridization incubator to reach 65°C.

5.2 Powering OFF the RCS

It is recommended that the instrument remain powered ON at all times.

Occasionally, the Windows Program Compatibility Assistant may be displayed when closing the RCS Software. The RCS Software has been validated for use with Windows 7 or later, and this message may be closed by the user by clicking the **X** in the top right-hand corner of the dialog box or by selecting **This program works correctly**.

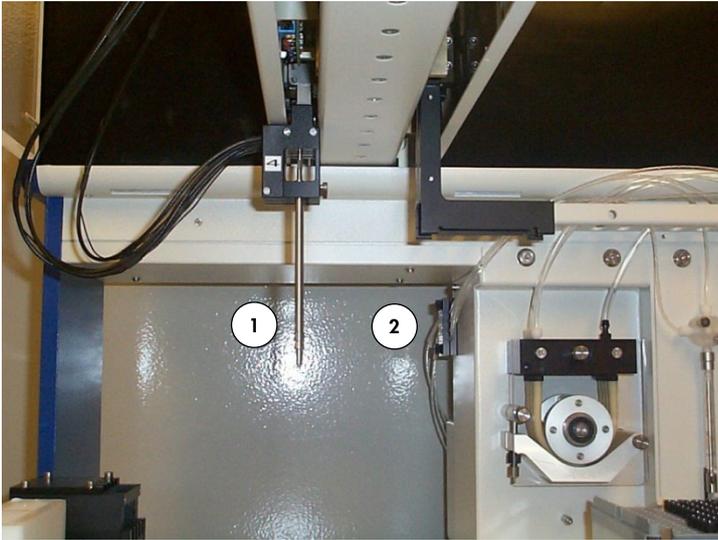


Two people are required to power down the instrument to prevent damage to the tip adapters and the plate grippers. The RCS safely parks the tip adapters and the plate grippers at the end of each script. The power switch is located in the lower-left corner on the rear panel of the instrument.

See also “Powering OFF the RCS following a system interruption,” page 70.

1. The first person supports the tip adapters by placing one hand under the black plastic at the bottom of each vertical bar. Take care not to push or pull on the bars horizontally as their alignment is sensitive.
2. The first person supports the plate grippers from below with the other hand.

Note: This step is not required following completion of an assay, as the plate grippers will already be located close to the RCS deck surface.



1 Tip adapters

2 Plate grippers

3. The second person may now switch OFF the power using the power switch. If there is a microplate in the robotic plate handler, remove it now.
 4. The first person may now guide the robotic arm to the pipetting position using the plate grippers and not the tip adapters. Tip adapters and the plate grippers may now be lowered to the RCS deck.
 5. If there are disposable tips on the tip adapters, it is best to let the RCS unload them by switching the power back on and running the **FLUSH** script (see screenshot on page 74).
 6. If this is not possible due to a malfunction, the tips may be removed individually by pulling straight down on the tip while supporting the black plastic at the bottom of each vertical bar. It is critical that the tip adapters not be pulled horizontally.
- Important:** Users must follow Universal Precautions regarding potentially infectious material. Do not place any part of your hand under a disposable tip while pulling down to remove it.

6 Using ScriptSelect Software

Scripts define the specific set of RCS Software instructions. The script controls the processing sequence required to run a *digene* HC2 DNA test on the RCS. Scripts offer the user flexibility in terms of number of samples, types of specimens and types of *digene* HC2 DNA tests for a specific RCS run. The scripts are generically named for use with multiple *digene* HC2 DNA tests.

ScriptSelect Software assists the user in selecting the script required to perform a *digene* HC2 DNA test on the RCS. It functions by generating a series of screen options in which the user makes the following selections:

- The appropriate *digene* HC2 DNA test
- The number of probes
- The number and type of specimen racks
- The probe configurations

The user must select a script from ScriptSelect Software to add it to the **Run List**.

Note: Some of the scripts are designated for future applications and are not available for current use. When these scripts become available, QIAGEN will supply a password to unlock them. Disclaimers for non-IVD applications as well as statements regarding IVD applications are listed in the Disclaimers: section of the various windows and the "Disclaimers:" section of printouts.

6.1 Installing ScriptSelect Software

ScriptSelect Software is installed on the RCS computer by a QIAGEN Field Service employee or personnel trained by QIAGEN.

6.2 Starting the ScriptSelect Software

Double-click the **ScriptSelect** desktop icon.

The RCS ScriptSelect Software window opens. For more information about this window, see "The ScriptSelect Software main window," page 41.

6.3 Script nomenclature

The correct specimen rack order is always indicated by the script name. In general, if there is a dual assay, the specimen rack for the dual assay is first followed by any other specimen racks of the same specimen type. If a dual assay is not required by the script, then Conversion Racks will always be first followed by *digene* Specimen Racks.

Feature in script name	Definition
C	C refers to microplates processed from a Conversion Rack.
D	D refers to microplates processed from a <i>digene</i> Specimen Rack.
du	du refers to a dual assay.
p	p is a suffix that indicates multiple single-probe assays, signifying a change to a different probe.

6.3.1 Examples of script names

Example 1

Script name	Meaning
2C1D	Describes a 3-rack, 3-plate, single-probe script
2C	2 Conversion Racks Microplates 1 and 2 The Probe Mix for microplates 1 and 2 is in position Probe 1
1D	1 <i>digene</i> Specimen Rack Microplate 3 The Probe Mix for microplate 3 is in position Probe 1

Example 2

Script name	Meaning
1Ddu2D	Describes a 3-rack, 4-plate, dual- and single-probe script
1Ddu	1 <i>digene</i> Specimen Rack Microplates 1 and 2 The Probe Mix for microplate 1 is in position Probe 1 The Probe Mix for microplate 2 is in position Probe 2
2D	2 <i>digene</i> Specimen Racks Microplates 3 and 4 The Probe Mix for microplates 3 and 4 is in position Probe 3

Example 3

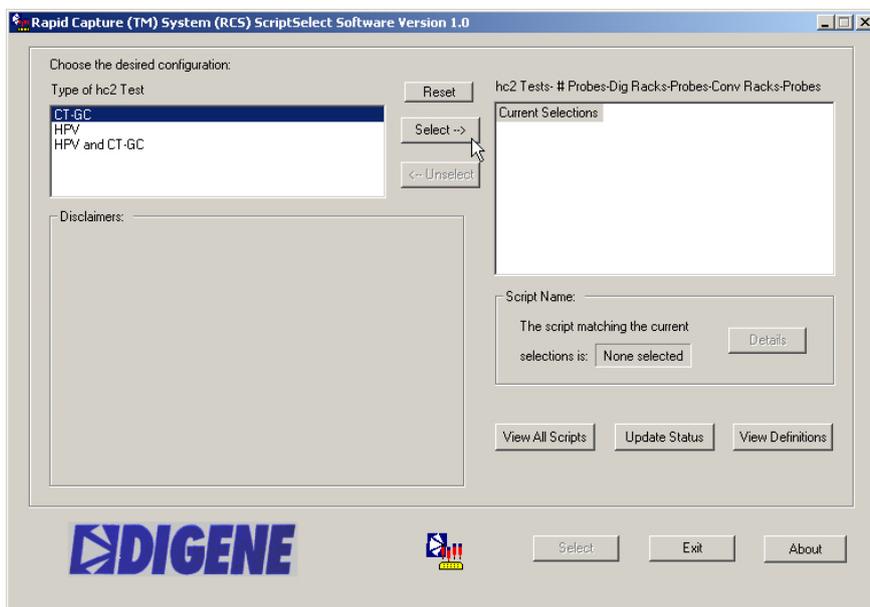
Script name	Meaning
1Cp2Dp	Describes a 3-rack, 3-plate, 2-probe script
1Cp	1 Conversion Rack Microplate 1 The Probe Mix for microplate 1 is in position Probe 1
2Dp	2 <i>digene</i> Specimen Racks Microplates 2 and 3 The Probe Mix for microplates 2 and 3 is in position Probe 2

Example 4

Script name	Meaning
1Ddu	Describes a 1-rack, 2-plate, dual-probe script 1 <i>digene</i> Specimen Rack Microplates 1 and 2 The Probe Mix for microplate 1 is in position Probe 1 The Probe Mix for microplate 2 is in position Probe 2

6.4 The ScriptSelect Software main window

The ScriptSelect Software is operated using the main window.



The following table describes the features of the main window:

Feature	Description
Choose the desired configuration: pane	This panel enables the user to select the appropriate script.
<< name of list box >> in Choose the desired configuration: pa	The name of this list box updates depending on the options selected previously (e.g., "Type of hc2 Test").
Reset button	Click this button to clear all user-selected options in the right list box.
Select --> button	Highlight the appropriate option from the left list box and click this button to move the option to the right list box. Alternatively, double-click the option in the left list box to move it to the right list box.
<-- Unselect button	Highlight the applicable option from the right list box and click this button to remove the option from the right list box. Alternatively, double-click the option to remove it from the right list box. To remove multiple options at a time, double-click the option on the highest level.
hc2 Tests-# Probes-Dig Racks-Probes-Cc	This list box reflects the choices made in the left list box.
Disclaimers: panel	This panel automatically populates with assay-relevant information.
Script Name: panel	This panel provides the name of the script matching the current selections.
The script matching the current selection	This field automatically displays the name of the script that matches the current selections.
Details button	Click this button to open the RCS Script Details dialog box which displays the microplate, specimen rack type and probe script.
View All Scripts button	Click this button to open the RCS SelectScripts: Full Listing of Scripts dialog box.
Update Status button	Click this button to open the Unlock Scripts dialog box that enables the user to unlock a script by entering the password clicking OK .
View Definitions button	Click this button to open the ScriptSelect Definitions dialog box which enables the user to view definitions.
Select button	Click this button to add the script to the Run List . Note: If the script is locked, the Select button is not available.
Exit button	Click this button to close the window.

About button

Click this button to open the **About** dialog box which provides the version of the software.

6.5 Selecting scripts

The ScriptSelect Software provides choices to the user based on previous selections. Menu option screens are bypassed when there is only one option. The software defaults to the appropriate script based on the user's selections.

Use the following instructions to add a script to the Run List.

1. First select a script.

Prompt above list box on left	Action
Type of hc2 Test list box	Select the appropriate test.
Number of Probe(s) list box	Select the appropriate number of probes.
Number of Racks with <i>digene</i> Specimens list box	Select the desired number of <i>digene</i> Specimen Racks to be tested.
Probe Configuration(s) with <i>digene</i> Specimens list box	Select the appropriate probe configuration to be used with the <i>digene</i> Specimen Racks.
Number of Converted Racks list box	Select the desired number of Conversion Racks to be tested.
Probe Configurations(s) with Converted Specimens list box	Select one of the appropriate probe configurations to be used with the Conversion Racks.

When selection is complete, this message appears above the list box on the left:

Script selection is now complete. See highlighted script name and the script name appears in the **Script Name** panel on the right.

2. To add the Script to the **Run List**, click **Select**.

If the script is approved for use, the script is selected and added to the **Run List**.

If the script is not approved for use, the script is not available.

The **RCS ScriptSelect** dialog box opens.

3. Click **OK**.

If the script is approved and available for use, the **ScriptSelect Notice** dialog box appears.

4. Click **Print**.

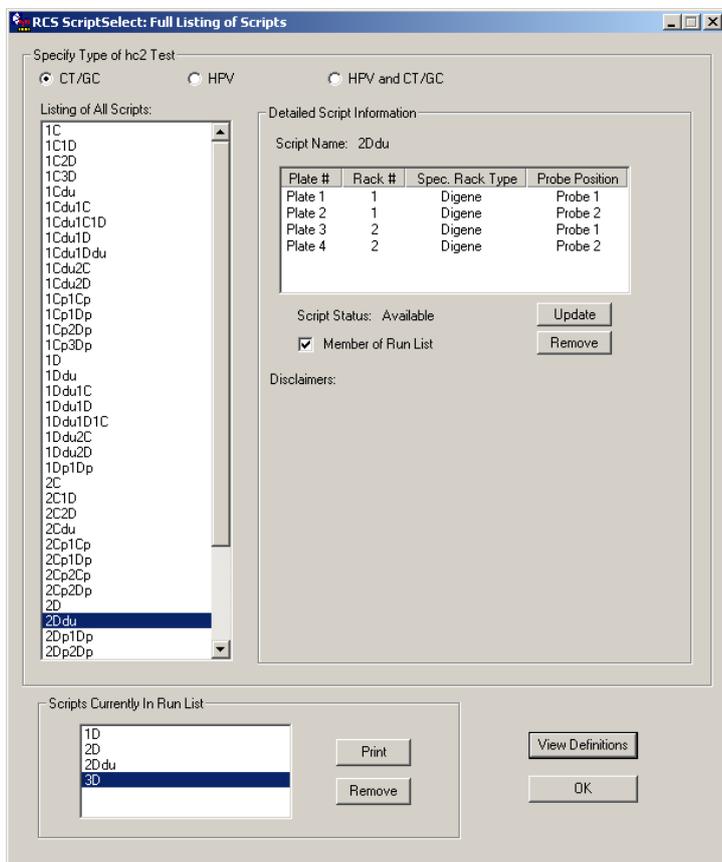
The **Print** dialog box appears. If you do not want to print, click **Cancel**.

5. To print the script information, click **OK**.

6.5.1 Using the View All Scripts button

Click the **View All Scripts** button to open the **RCS ScriptSelect: Full Listing of Scripts** dialog box.

Example:



The following table describes the features of the **RCS ScriptSelect: Full Listing of Scripts** dialog box:

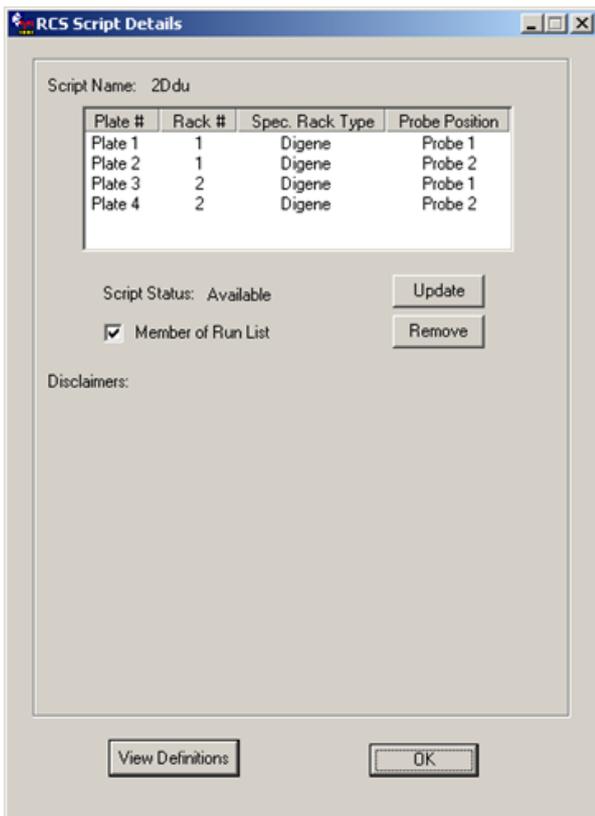
Feature	Description
Specify Type of hc2 Test: panel	This panel provides a list of scripts for the selected test type.
Listing of All Scripts list box	This list box displays a complete list of all scripts installed on the system. Note: To activate the script and add the script to the Run List , double-click the script name in this list box.
Detailed Script Information panel	This panel provides detailed information on the script that is highlighted in the Listing of All Scripts list box.
Script Name: field	This field automatically updates to provide the name of the script that is highlighted in the Listing of All Scripts list box and provides the following information about that script in table format: Plate # Rack # Spec. Rack Type Probe Position
Script Status: field	This field automatically updates to provide the status of the script, as follows: Available – indicates that the script is available for use and can be added to the Run List . Locked – indicates that the script is not available for use and cannot be added to the Run List .
Update button	Click this button to provide the option of entering a password supplied by QIAGEN to change a script’s status from locked to available.
Member of Run List check box	Indicates whether or not the highlighted script in the Listing of All Scripts list box is a member of the Run List .

- Select button** Click this button to add the highlighted script in the **Listing of All Scripts** list box to the **Run List**.
Note: If a script is currently locked, the **Select** button is a grayed-out **Locked button**.
- Script Status: Available
 Member of Run List
- Remove button** Click this button to remove the highlighted script in the **Listing of All Scripts** list box from the **Run List**.
- Script Status: Available
 Member of Run List
- Disclaimers: field** This field automatically populates with assay-relevant information.
- Scripts Currently in Run List panel** This panel lists the scripts that have been added to the **Run List**.
- Print button** Click this button to open the **Print** dialog box to print the appropriate script information.
- Remove button** Click this button to remove the highlighted script in the **Listing of All Scripts** list box from the **Run List**.
- View Definitions button** Click this button to open the **ScriptSelect Definitions** dialog box that enables the user to view definitions.
- OK button** Click this button to close the dialog box.

6.5.2 Using the Details button

Select a script in the ScriptSelect Software main window and click the **Details** button to open the **RCS Script Details** dialog box.

Example:



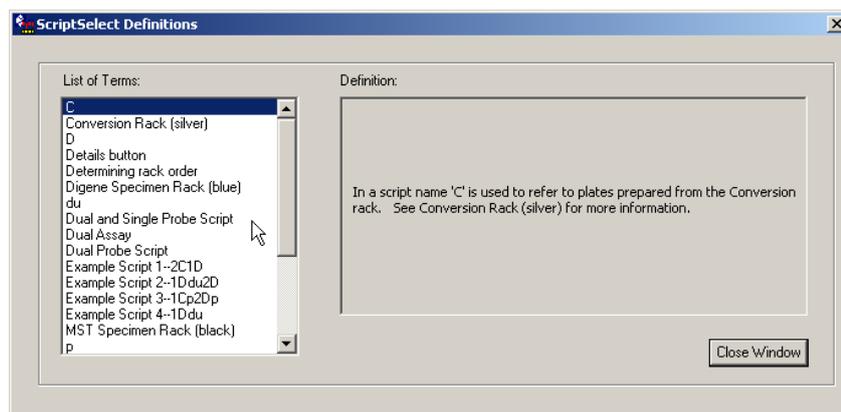
The following table describes the features of the **RCS Script Details** dialog box.

Feature	Description
Script Name: panel	This field provides the name of the selected script.
<< table >>	The table lists the following information for each plate: Plate # Rack # Spec. Rack Type Probe Position
Script Status: field	This field automatically updates to provide the status of the script as either available or locked.
Update button	Click this button to provide the option of entering a password supplied by QIAGEN to change a script's status from locked to available.
Member of Run List check box	Indicates whether or not the script is included in the Run List . If checked, the script is listed in the Run List . If not checked, the script is unavailable in the Run List .
Remove button	Click this button to remove the selected script from the Run List .
Disclaimers: field	This field automatically populates with assay-relevant information.
View Definitions button	Click this button to open the ScriptSelect Definitions dialog box which enables the user to view definitions.
OK button	Click this button to close the dialog box.

6.5.3 Using the View Definitions button

Throughout the ScriptSelect Software, clicking **View Definitions** opens the **ScriptSelect Definitions** dialog box.

Example:



The following table describes the features of the **ScriptSelect Definitions** dialog box.

Feature	Description
List of Terms: list box	This list box contains a list of terms.
Definition: field	This field displays the definition for the term that is highlighted in the List of Terms list box.
Close Window button	Click this button to close the ScriptSelect Definitions dialog box.

7 Performing *digene* HC2 DNA Tests

7.1 Preparing and storing reagents

Strict adherence to reagent usage and limitations specified in the respective *digene* HC2 DNA test instructions for use is critical for reproducible and consistent assay results. Failure to follow the reagent usage requirements may result in invalid assays and inaccurate sample results.

Refer to the respective *digene* HC2 DNA test instructions for use for the following information:

- Specimen types approved for use with the RCS
- Preparation and storage of kit reagents
- Required reagent volumes for performance of the test on the RCS

7.2 Setting up the RCS deck

It is critical that the RCS deck is set up and maintained in the exact manner described in this user manual and no extraneous items are placed on the RCS deck during operation.

Things to do before starting:

- Wear disposable, powder-free gloves during setup.
- Power ON the RCS. See "Powering ON/OFF the RCS," page 36, for additional instructions.

The RCS Software monitors the temperature of the hybridization incubator. The script will not begin until the hybridization incubator reaches the target temperature.

Recommendation: Leave the RCS powered ON at all times.

- Power on the DML instrument at least 1 hour prior to measuring the first capture microplate as the instrument requires a warm-up period.

Recommendation: Leave the DML instrument on at all times.

- Using the *digene* assay analysis software, create the plate layout for each microplate tested.

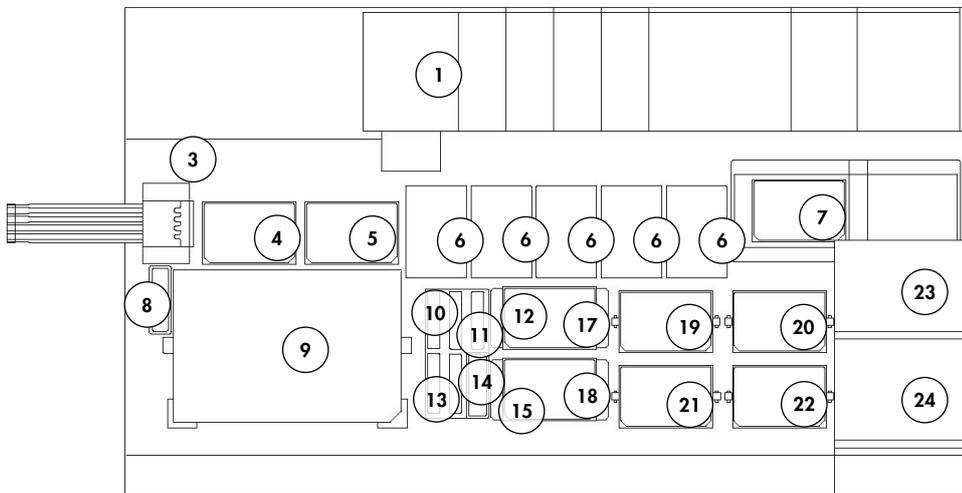
Refer to the respective software user manual and the *digene* HC2 DNA test instructions for use.

Important: The plate layout must correspond to the correct specimen rack and microplate in order to report accurate sample results.

- Check that the silver RCS washer boat is installed in the plate washer. If not, see "Appendix B – Changing the RCS Washer Boat," page 86, for additional instructions.
- Empty the container used to collect disposable tips and empty as often as necessary to make sure that the disposable tips fall completely into the tip eject station.
- Inspect the RCS deck and remove any microplates, lids or other items.

Note: If the hybridization incubator could contain microplates from a previously aborted run, contact QIAGEN Technical Services for assistance in inspecting the incubator.

7.2.1 RCS deck layout



- | | | | |
|----|--------------------------------|----|-----------------------------------|
| 1 | Peristaltic pump | 13 | Probe Mix 3 |
| 2 | Diluter (4) | 14 | Probe Mix 2 |
| 3 | Tip eject station | 15 | Lid park |
| 4 | Pipetting position 1 | 16 | Reagent trough rack |
| 5 | Pipetting position 2 | 17 | Stacker B |
| 6 | Disposable tip rack (5) | 18 | Stacker A |
| 7 | Plate washer | 19 | Shake position 1 |
| 8 | Tip rinse station | 20 | Shake position 2 |
| 9 | Specimen rack loading position | 21 | Shake position 3 |
| 10 | Detection Reagent 2 (DR2) | 22 | Shake position 4 |
| 11 | Detection Reagent 1 (DR1) | 23 | Ambient temperature plate stacker |
| 12 | Probe Mix 1 | 24 | Hybridization incubator |

7.2.2 Loading consumables on the RCS deck

<p>WARNING</p> 	<p>Risk of personal injury</p> <p>Avoid contact with the hybridization incubator.</p> <p>Allow the hybridization incubator to cool before touching as the incubator reaches a temperature of 65°C.</p>
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<p>CAUTION</p> 	<p>Damage to the instrument</p> <p>Remove all items from the RCS deck.</p> <p>Items remaining on the RCS deck may result in damage to the instrument.</p>
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1. Fill all 5 disposable tip racks with disposable tip trays.

When loading the disposable tip tray, the U-shaped notch of the tray must be positioned in the front left of the rack. The tray should snap into place.

Note: If the disposable tip tray is not properly positioned, the tip adaptors may not be able to properly locate the disposable tips. If the tray does not snap into place, contact QIAGEN Technical Services for assistance.

Note: If at any time the quantity of disposable tips is insufficient, the system will pause, display a message, and signal the user with an audible alarm. Load additional disposable tips on the RCS deck.

2. Number the front-facing side of the hybridization microplates 1 through 4, as applicable. Place a microplate lid on each hybridization microplate.

<p>CAUTION</p> 	<p>Damage to the instrument</p> <p>Make sure all required microplates, including required lids, are loaded on the RCS deck before starting a run. Missing microplates or lids will cause the robotic plate handler to crash.</p> <p>A crash may require the restart of the run and/or damage the RCS.</p>
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3. Place the hybridization microplates with lids on the RCS deck in shake position 1 through 4 (see "RCS deck layout," page 47) corresponding to the hybridization microplate number.
4. Orient the hybridization microplates with the A1 well in the back left corner and seat within the guides.
5. Number the front-facing side of the capture microplates 1 through 4, as applicable.
6. If a full capture microplate will not be tested, remove the appropriate number of capture microplate strips or wells, return them to their original Mylar® bag with desiccant pack, seal tightly, and store at 2–8°C.
7. Replace all missing capture microplate wells with RCS microplate well strips.
8. Orienting each capture microplate with the A1 well in the back left corner, stack the capture microplates in numerical order with capture microplate 1 on top.
9. Place a microplate lid on capture microplate 1 only, and place the stack of capture microplates on the RCS deck in Stacker A (see "RCS deck layout," page 47).

Note: We recommend labeling the microplate lid "REMOVE" to increase the visibility of the microplate lid during routine cleaning. A microplate lid remaining on the RCS deck will cause an instrument crash.

<p>WARNING</p> 	<p>Risk of inaccurate test results</p> <p>Always change gloves after handling the Waste Bottle, quick-disconnect fittings or liquid waste.</p> <p>Contamination of work areas with alkaline phosphatase can affect test results.</p>
---	---

<p>WARNING</p> 	<p>Risk of inaccurate test results</p> <p>Make sure the Waste Bottle is empty, as the overflow of the Waste Bottle can cause alkaline phosphatase contamination.</p> <p>Contamination of work areas with alkaline phosphatase can affect test results.</p>
---	---

10. Empty the Waste Bottle, if necessary.

11. Make sure the tubing extending from the instrument to the Waste Bottle does not have any kinks or loops in the tubing path that would prevent the liquid waste from flowing downward.

7.2.3 Loading the reagents on the RCS deck

WARNING 	Risk of inaccurate test results Make sure the System Liquid Bottle and Wash Bottle are full prior to the start of the RCS run. Insufficient volume of reagents for the run can result in inaccurate test results.
---	--

1. Fill the Wash Bottle with prepared wash buffer. Make sure the quick-disconnect fitting clicks securely in place.
2. Make sure the tubing from the Wash Bottle to the instrument is free of kinks and properly connected. Note especially the points where the tubing attaches to the Wash Bottle and the instrument inlet port.
3. Empty the System Liquid Bottle and refill it with deionized/distilled water. Make sure the quick-disconnect fitting clicks securely in place.
4. Make sure the tubing from the System Liquid Bottle to the instrument is free of kinks and properly connected. Note especially the points where the tubing attaches to the System Liquid Bottle and the instrument inlet port.
5. Label the reagent troughs and trough lids, if necessary.

Important: Label the reagent troughs and segregate reagents to prevent possible contamination from run to run. Once labeled, only use reagent troughs with specified reagent.

Recommendation: Maintain two sets of reagent troughs so a clean, dry set is always available for each run.

6. Add the required volume of Probe 1 to the designated reagent trough and place the reagent trough in the back-right position of the reagent trough rack (see "RCS deck layout," page 47). Cover the reagent trough using the corresponding trough lid.
7. If applicable, add the required volume of Probe 2 to the designated reagent trough and place the reagent trough in the front-center position of the reagent trough rack (see "RCS deck layout," page 47). Cover the reagent trough using the corresponding trough lid.
8. If applicable, add the required volume of Probe 3 to the designated reagent trough and place the reagent trough in the front-left position of the reagent trough rack (see "RCS deck layout," page 47). Cover the reagent trough using the corresponding trough lid.
9. Mix the Detection Reagent 1 (DR1) thoroughly; add the required volume to the designated reagent trough, and place the reagent trough in the back-center position of the reagent trough rack (see "RCS deck layout," page 47). Cover the reagent trough using the corresponding lid.

Important: Change gloves after handling DR1 to prevent alkaline phosphatase contamination.

10. Mix the Detection Reagent 2 (DR2) thoroughly; add the required volume to the designated reagent trough, and place the reagent trough in the back-left position of the reagent trough rack (see "RCS deck layout," page 47). Cover the reagent trough using the corresponding trough lid.

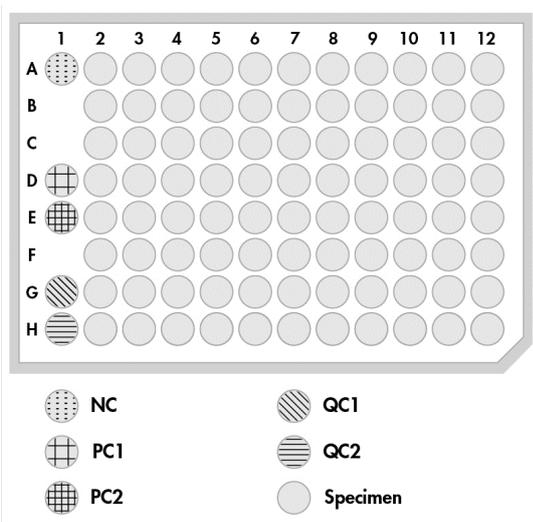
Note: The RCS employs liquid level detection when dispensing reagents from the reagent troughs to a capture or hybridization microplate. In the event of insufficient volume, the system will pause, display a message, and signal the user with an audible alarm. The user can then place the filled reagent trough on the RCS deck or add additional reagent, as appropriate.

7.2.4 Preparing the specimen rack

<p>WARNING</p> 	<p>Risk of inaccurate test results</p> <p>Wait for the instrument prompt before loading the specimen rack on the RCS deck.</p> <p>If the specimen rack is loaded on the RCS deck prior to the prime and flush of system lines, contamination can occur because of splashing; contamination can result in inaccurate test results.</p>
---	--

If the denatured calibrators, quality controls or specimens have been stored, allow them to thaw to 20–25°C. If the denatured calibrators, quality controls or specimens have been stored in a specimen rack with caps, remove and discard the caps from the tubes.

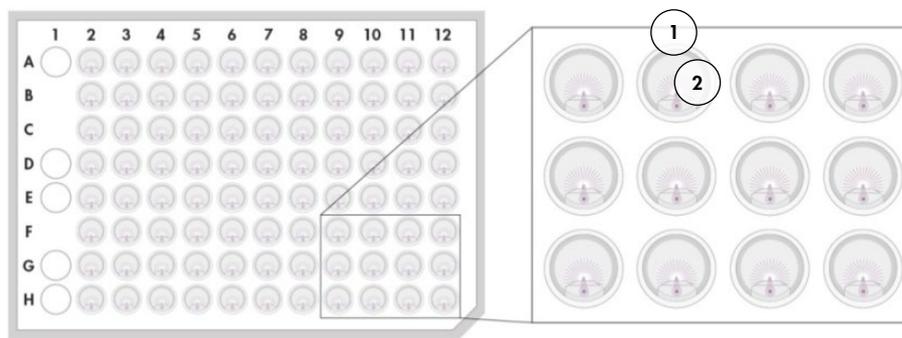
1. Vortex the specimens using one of the following methods:
 - If in a specimen rack, cover the tubes with DuraSeal™ tube sealer film and secure the rack lid on the specimen rack. Vortex for 10 seconds on the MST Vortexer 2.
 - With a cap on the tube, vortex each tube individually for 5 seconds.
2. If the specimens are in a specimen rack, immediately place the specimen rack on the bench top and release the latches. Lift the rack lid approximately 1 cm, and move gently left to right to release any tubes that may have adhered to the DuraSeal tube sealer film. Remove the rack lid by lifting it straight up until it clears the specimen rack. Carefully peel the DuraSeal tube sealer film from the rack lid and discard.
3. If the specimens have caps, remove the caps from the tubes. For each specimen rack tested, make sure the denatured calibrators, quality controls and specimens are in the positions in the appropriate specimen rack, as follows:
 - Negative Calibrator (NC) in the A1 position
 - Positive Calibrator 1 (PC1) in the D1 position
 - Positive Calibrator 2 (PC2) in the E1 position (used only for dual-assay testing)
 - Quality Control (QC1) in the G1 position
 - Quality Control (QC2) in the H1 position
 - Specimens in the remaining available specimen rack positions



The RCS pipets the calibrators and quality controls into column 1 of the hybridization microplate. On the hybridization microplate, the RCS places the NC replicates in A1, B1, C1; the PC replicates in D1, E1, F1; the QC1 in G1; and the QC2 in H1.

Important: The *digene* assay analysis software will report the calibrator and quality control results to verify the assay run based on their location. The correct placement of the calibrators and quality controls in the specimen rack and the correct *digene* assay protocol selection are essential for valid assay results.

4. For each specimen containing a collection device, place a drop-on cap onto each tube. Make sure the shaft of the collection device is trapped between the tab of the drop-on cap and the side of the tube. The drop-on caps must be oriented so the tab is closest to the user as they face the specimen rack.



Drop-on cap and *digene* Specimen Rack

Brush stem

7.3 Starting the RCS run

7.3.1 Flushing the tubing

Flush the RCS with deionized/distilled water by running the FLUSH script. Make sure all air bubbles are removed from the system lines and liquid is not dripping from the tip adapters. Failure to complete a system flush may result in the improper dispensing of aliquot volumes.

7.3.2 Selecting the script

<p>WARNING</p> 	<p>Moving parts</p> <p>Do not reach into the instrument during instrument operation. Moving parts during operation can cause bodily harm.</p> <p>Stop the operation of the instrument before reaching into the RCS deck.</p>
---	---

1. In the RCS Software, click the **Run** icon.

Alternatively, select **Script/Run Script**.

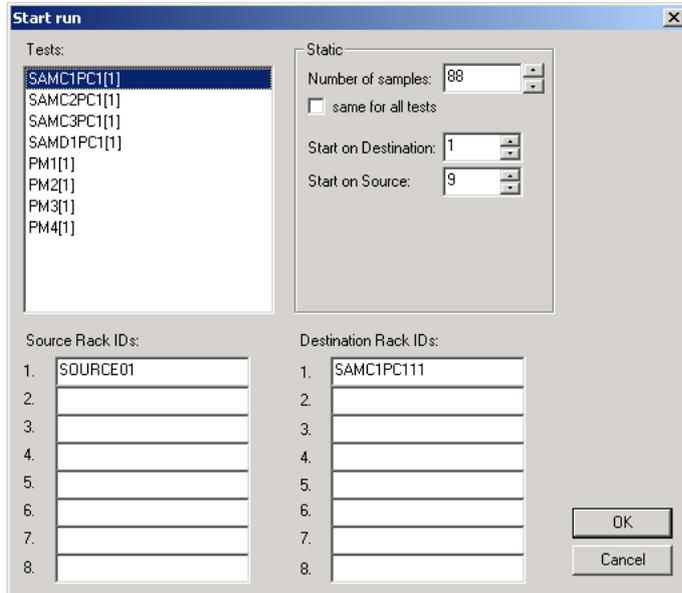
The **Scripts** dialog box appears, listing the scripts available.

2. Highlight the appropriate script for the run and click **OK**.

Note: See "Selecting scripts," page 42, for instructions to select the correct script and add it to the **Run List**.

The **Start run** dialog box appears.

Example:



<p>WARNING</p> 	<p>Risk of inaccurate test results</p> <p>When starting a run, do not check the same for all tests box in the Start run dialog box.</p> <p>Checking this box will affect reagent volume addition and result in inaccurate test results.</p>
---	--

<p>WARNING</p> 	<p>Risk of inaccurate test results</p> <p>Make sure the correct number of samples is entered for the appropriate microplate.</p> <p>Testing an empty microplate well can clog the plate washer manifold and result in inaccurate test results.</p>
---	---

Highlight the desired SAMXXPC1[1] in the **Tests** list box.

- In the **Static** panel, enter the number of samples, excluding calibrators and quality controls, for the corresponding hybridization microplate in the **Number of samples** dialog field.

The default is a full microplate of 88 samples.

Note: The letter immediately after **SAM**, either **C** or **D**, indicates a microplate processed from either a rack of converted specimens or a rack of *digene* specimens.

Note: The numerical value immediately after the specimen type, 1 thru 4, indicates the microplate order as determined by shake position.

- Repeat for each additional microplate, as applicable.
- Highlight the desired PMX[1] from the **Tests** list box.
- In the **Static** panel, enter the number of samples, including calibrators and quality controls, for the corresponding hybridization microplate in the **Number of samples** dialog field.

PM = SAM + 8

The default is a full microplate of 96 samples.

7. Repeat for each additional microplate, as applicable.

Note: The "X" in "PMX[1]" indicates the microplate order as determined by shake position.

8. Click **OK** to begin the script.
9. At the prompt, input the probe type used for the RCS run and click **OK**.

A printout with the selected script and probe type is generated.

10. All on-board components will initialize.

7.3.3 Loading the specimen racks

1. At the script alert about loading the RCS deck, confirm the disposable tip racks, hybridization microplates with lids, capture microplates with one lid and filled reagent troughs are on the RCS deck in the correct positions (see "RCS deck layout," page 47). Click **OK**.

The system lines will prime and flush.

2. If applicable and at the script alert, confirm that the drop-on caps are on those specimens containing collection devices. Click **OK**.
3. At the script alert about specimen rack loading, place the specimen rack for microplate 1 on the RCS deck with the notched corner of the specimen rack in the right front and positioned within the guides. Click **OK** to begin sample transfer.
4. At the script alert about completion of specimen rack transfer, remove the specimen rack from the RCS deck.

CAUTION 	Damage to the instrument Make sure all required microplates, including required lids, are loaded on the RCS deck before starting a run. Missing microplates or lids will cause the robotic plate handler to crash. A crash may require the restart of the run and/or damage the RCS.
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WARNING 	Risk of inaccurate test results Make sure all microplate wells tested contain liquid. Testing an empty microplate well can clog the plate washer manifold and result in false-negative test results.
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5. Visually inspect the hybridization microplate for empty wells that should have received sample.
If sample transfer failed, manually transfer 75 µl of the specimen to the appropriate hybridization microplate well using a single-channel pipettor (20–200 µl) and extra-long pipet tips. The hybridization microplate may be removed from the RCS deck for manual transfer. If removed, make sure the hybridization microplate is returned and properly situated on the RCS deck.
6. Click **OK**.
7. Follow the script alerts and repeat steps to load the remaining specimen racks.

7.3.4 Starting the assay

1. After the last specimen rack has been transferred and at the script alert, refill all empty and partially empty disposable tip racks with full trays of tips.
2. Empty the disposable tip waste container.

Important: Follow the instructions in the script alerts before clicking **OK**. The RCS Software will control the timing of the assay once the Probe Mix is added. Any user interruptions after that point will interfere with the assay incubation times.

3. Click **OK**. The RCS will complete all subsequent steps of the test through the DR2 incubation, providing 3.5 hours of user walk-away time. Set a timer for 3 hours and 20 minutes to return to the instrument in time to measure the first capture microplate.

Recommendation: Remain within hearing distance of the instrument during the run. If an instrument error occurs, the RCS will sound an alarm, pause, and wait for user intervention. If an error occurs, immediately contact QIAGEN Technical Services for assistance.

7.4 Measuring the capture microplates and generating results

WARNING 	Risk of inaccurate test results For high-risk HPV testing, make sure only RCS-specific protocols provided by QIAGEN are used when creating plate layouts in the assay analysis software. Using the incorrect protocol could result in false-negative test results.
--	---

Things to do before starting:

- The user is required to retrieve each capture microplate from the RCS deck at the end of the DR2 incubation. Each capture microplate is then measured in the DML instrument.
- For HPV testing, verify that an RCS-specific protocol was used to create the plate layout.

1. At the script alert and audible alarm, retrieve the capture microplate from the pipetting position on the RCS deck (see “RCS deck layout,” page 47).
2. Click OK for the RCS to continue processing the remaining capture microplates, as applicable.

WARNING 	Risk of inaccurate test results Do not concurrently print a test results report while measuring a microplate. Printing test result reports while measuring a microplate can slow assay processing on the RCS and result in inaccurate test results.
---	--

3. Place the capture microplate in the DML instrument and measure. Refer to the respective software user manuals for details about measuring a capture microplate and generating test result reports.

Recommendation: Print test result reports from the current capture microplate before measuring subsequent capture microplates to avoid slowing down the operation of the RCS. Alternatively, print test result reports after the RCS run is complete and all capture microplates are measured.

4. Repeat above steps for all remaining capture microplates, as applicable.
5. Refer to the respective *digene* HC2 DNA test instructions for use for quality control, assay verification and instructions for interpretation of the results.

7.5 Understanding the limitations of the procedure

Refer to the respective *digene* HC2 DNA test instructions for use for limitations specific to the test.

7.6 Performance characteristics

Refer to the respective *digene* HC2 DNA test instructions for use for performance characteristics specific to the test.

8 Maintenance

<p>WARNING/ CAUTION</p> 	<p>Risk of personal injury and material damage</p> <p>QIAGEN Field Service employees or personnel trained by QIAGEN must perform all maintenance, unless otherwise specified in this user manual.</p>
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8.1 Routine cleaning

Perform this procedure to clean the RCS after every run.

1. Discard used microplates, microplate lids and waste according to your local safety regulations.
2. Replace the Waste Bottle and reconnect the quick-disconnect fittings, securely clicking the quick-disconnect fittings in place. Make sure the Waste Bottle is situated correctly without kinks in the lines.

Note: RCS waste has a relatively neutral pH.

3. Discard all reagent aliquots and residual reagents in reagent troughs according to local safety regulations.
4. Clean reagent troughs, in the following order:
 - Wash and rinse with deionized/distilled water.
 - Fill completely with 0.5% v/v sodium hypochlorite solution.
 - Allow the troughs to soak in the sodium hypochlorite solution overnight.
 - The next day, rinse troughs thoroughly with deionized/distilled water for at least 60 seconds.
 - Place inverted troughs on a low-lint paper towel to dry.
5. Clean reagent trough lids, in the following order:
 - Wash and rinse with deionized/distilled water.
 - Soak overnight in 0.5% v/v sodium hypochlorite solution.
 - The next day, rinse thoroughly with deionized/distilled water for at least 60 seconds.
 - Place on a new low-lint paper towel to air dry.
6. Cover the disposable tip racks containing unused disposable tips with a microplate lid to prevent dust from contaminating the tips.
7. Empty the disposable tips waste container.
8. Remove and rinse the tip eject station drip guard with deionized/distilled water. Wipe the tip eject station with a new alcohol-dampened low-lint paper towel.
9. Remove all tips from the tip eject slide. Wipe between the rails with a new alcohol-dampened low-lint paper towel to remove residual fluid.
10. Remove the tip rinse station cover, and rinse the tip rinse station cover with deionized/distilled water. Wipe the tip rinse station and the tip rinse station cover with a new alcohol-dampened low-lint paper towel.
11. Wipe all RCS deck surfaces with a new alcohol-dampened low-lint paper towel including the following:

- Shake positions and rollers (rollers should not stick in position)
- Trough rack
- Inside of Stacker A and Stacker B
- Pipetting positions

12. Clean each tip adapter with an alcohol wipe.

13. Remove the RCS washer boat, and clean the top and bottom with a new alcohol-dampened low-lint paper towel. With the RCS washer boat removed, clean the plate washer with a new alcohol dampened low-lint paper towel.

8.2 Monthly maintenance

Perform this procedure once every month to ensure optimum performance of the RCS.

1. Replace reagent troughs with new troughs. Label new reagent troughs appropriately.

Note: It is not required to replace the trough lids monthly.

2. Flush the RCS tubing lines and bottles with 0.5% v/v sodium hypochlorite solution. See “Flushing the system lines,” page 58, for additional instructions.

3. Visually check the syringes for leaks, bubbles or internal contamination. If indicated, replace the syringes. See “Cleaning and replacing syringes,” page 59, for additional instructions.

8.3 Semi-annual maintenance

QIAGEN Field Services or personnel trained by QIAGEN should perform a semi-annual maintenance on the RCS. Contact QIAGEN Technical Services for assistance.

8.4 Cleaning tubing lines and bottles

<p>WARNING/ CAUTION</p> 	<p style="text-align: center;">Risk of personal injury and material damage</p> <p>Do not reach onto the RCS deck while the instrument is running unless the system has paused and displayed a dialog box indicating a user-intervention is required.</p> <p>Reaching onto the RCS deck at any other time during a run may result in injury to the user and/or an aborted run.</p>
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<p>WARNING</p> 	<p>Risk of personal injury</p> <p>Users must wear lab coats, powder-free gloves, and safety goggles when performing the cleaning procedure.</p>
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8.4.1 Flushing the system lines

1. Verify that the instrument is ON, but not running. There should be no RCS System window open or minimized on the RCS computer screen.
2. Disconnect the quick-disconnect fitting of the System Liquid Bottle. To prevent alkaline phosphatase contamination, rest the disconnected end of the tubing on a clean Kimtowels® wiper or equivalent low-lint paper towel.
3. Remove the lid and empty the bottle into a sink.
4. Fill the bottle with 1 liter of freshly prepared 0.5% v/v sodium hypochlorite solution.
5. Replace the bottle lid. Tighten it securely.
6. Cover the air vent in the lid with a Kimtowels wiper or equivalent low-lint paper towel. Shake the bottle vigorously to make sure that the sodium hypochlorite solution rinses all inside surfaces, including the lid.
7. Restore tubing connection.
8. Using the Wash Bottle, repeat steps 2 through 7.
9. Launch the RCS System Software by double-clicking the **Rapid Capture System** desktop icon.
10. Click the **Run** icon from the RCS Tool Menu bar.
11. Select the **CLEANSYS** script and click **OK**.
12. This will flush all system liquid lines, including the syringes and plate washer cannulas, thoroughly with the sodium hypochlorite solution.

8.4.2 Rinsing the bottles off-line

1. Disconnect the quick-disconnect fittings of the System Liquid Bottle and the Wash Bottle. Rest the free ends of the tubing on clean Kimtowels wipers or equivalent low-lint paper towels to prevent alkaline phosphatase contamination.
2. Remove the lids and empty the bottles into a sink.
3. Add 1 liter of deionized or distilled water to the System Liquid Bottle and 2 liters of deionized or distilled water to the Wash Bottle.
4. Replace the lids securely.
5. For each bottle, cover the air vent in the lid with a Kimtowels wiper or equivalent low-lint paper towel, and shake vigorously to rinse all interior surfaces with the deionized or distilled water.
6. Empty each bottle and repeat the deionized or distilled water rinse once more for a total of two deionized or distilled water rinses for each bottle.

8.4.3 Rinsing and priming the RCS lines

1. Once both bottles are emptied of their second deionized or distilled water rinse, fill the System Liquid Bottle with deionized or distilled water and the Wash Bottle with prepared Wash Buffer.

Note: Refer to the *digene* HC2 DNA test instructions for use for reagent preparation.

2. Reattach the tubing from the instrument to the bottle lids. Make sure that each bottle is connected to the appropriate tubing line.

Note: The entrance port of each tubing line into the instrument is labeled.

3. Make sure the quick-disconnect fittings click securely in place.
4. Run the **CLEANSYS** script. This will replace the sodium hypochlorite solution in all lines with the deionized or distilled water or Wash Buffer, as applicable.

8.4.4 Bleaching the Waste Bottle

1. Disconnect both quick-disconnect fittings to the Waste Bottle. Make sure the disconnected ends are allowed to rest on a clean Kimtowels wiper or equivalent low-lint paper towel to prevent contamination of lab surfaces.
2. Remove the lid and empty the bottle carefully into a sink. Rinse the sink thoroughly, as this waste is a source of alkaline phosphatase.
3. Add 2 liters of 0.5% v/v freshly prepared sodium hypochlorite solution to the bottle.
4. Replace the lid securely.
5. Cover the air vent in the lid with a Kimtowels wiper or equivalent low-lint paper towel, and shake the bottle to rinse all sides with the sodium hypochlorite solution.
6. Empty the bottle and add 2 liters of deionized or distilled water.
7. Replace the lid securely.
8. Cover the air vent with a Kimtowels wiper or equivalent low-lint paper towel, and shake the bottle to rinse all sides with the deionized or distilled water.
9. Empty the bottle into the sink.
10. Replace the lid securely, and reattach both waste tubing lines to the bottle, making sure that the quick-disconnect fittings click securely in place.

The system liquid lines and bottles are now clean and ready for use. Make sure to record the date, instrument serial number, and your initials in the maintenance log.

8.5 Cleaning and replacing syringes

If the syringes need to be replaced because of leaks, bubbles or internal contamination (i.e., particles, crystals, etc.), switch off the instrument and remove the syringes from the Syringe Pump modules as described below.

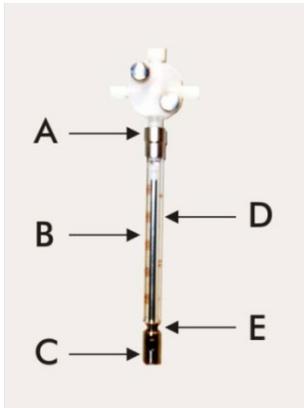
If a syringe is leaking, try to clean the syringe first. If that does not solve the problem, replace the syringe.

Make sure to have replacement syringes on hand. Contact QIAGEN Technical Services for ordering replacement syringes.

<p>CAUTION</p> 	<p>Risk of material damage Syringes are glass. Use caution when handling.</p>
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8.5.1 Removing a syringe

1. Switch OFF the instrument.



2. Unscrew the Luer-lock connector (A) of the syringe from the lower port of the valve.
3. Pull the syringe barrel (B) slowly down until it is clear of the valve.
4. Loosen the plunger retainer screw (C), and carefully pull the syringe away from the plunger drive pin (E).

8.5.2 Cleaning a syringe

1. Switch OFF the instrument.
2. Remove the plunger (D) from the syringe barrel.
3. Wash with a mild detergent.
4. Rinse with deionized or distilled water, and follow with 70% isopropanol.

8.5.3 Replacing a syringe

1. Place the bottom of the syringe plunger over the plunger drive pin (E), and tighten the screw on the underside of the plunger (C).
2. Pull the syringe barrel up until the Luer-lock connector (A) on the syringe can be inserted into the Luer-lock hub on the lower port of the valve; then carefully screw the syringe clockwise into the valve. Take care not to cross-thread.
3. Make sure that all the valve screws, the Luer-lock connection, all the syringe-tubing connections and the plunger screw are tight to prevent leakage.
4. Power ON and park the instrument. Make sure that the syringe initializes.
5. Run the FLUSH script at least twice to check for leaks. Flush the system until air bubbles in the syringe or tubing are removed.

8.6 System decontamination

After the RCS deck or any other location is flooded, the area must be cleaned and decontaminated.

1. Remove all excess liquid with absorbent, low-lint paper towels.

2. Wipe down the affected area with 0.5% v/v sodium hypochlorite solution using a low-lint paper towel.
3. Completely wipe the area with a paper towel dampened with deionized water.
4. Take extra care to clean and dry a flooded plate washer to prevent the washer boat from sticking to the platform.
5. Clean the RCS tubing lines and bottles with 0.5% v/v sodium hypochlorite solution. See “Cleaning tubing lines and bottles,” page 57, for additional instructions.

8.7 RCS contamination check

If contamination (e.g., alkaline phosphatase contamination) of the RCS is suspected, perform the following procedure for verification. This procedure initiates the 1D script, aborts the script, and then restarts the script at the appropriate line, based on the type of script being used.

Required equipment and supplies:

- 1 capture microplate frame
- 3 new capture well strips from a *digene* HC2 DNA test kit
- 9 blank microplate well strips
- 1 microplate lid
- 1 bottle DR1
- 1 bottle DR2
- Wash Buffer
- 0.5% v/v sodium hypochlorite solution

1. Perform the procedure in “Cleaning tubing lines and bottles,” page 57.
2. Place 3 capture strips onto the empty capture microplate frame.
3. Make sure to fill the remaining 9 empty columns with blank microplate well strips. The strips serve as filler microplate wells and are required for counterbalance.
4. Place the capture microplate in Pipetting Position 2 on the RCS deck.
5. Place the microplate lid face down in Pipetting Position 1 on the RCS deck.

Note: When placing the capture microplate and lid in Pipetting Position 2 and Pipetting Position 1, it is critical to properly set the items within the grooves of their respective positions.

6. Fill the respective reagent troughs with 4 ml of DR1 and DR2.
7. Place the DR1 and DR2 reagent troughs on the RCS deck in their proper location on the reagent trough rack.
8. From the **Scripts** window in the RCS Software, select **1D**.

Note: If the 1D script is not in the run list, add it using the ScriptSelect Software.

9. From the **Run List**, initiate the **1D** script.
10. Type **16** for the number of samples and **24** for the number of microplate wells.
11. Following the system flush, abort the assay by either pressing the **Esc** key on the RCS computer keyboard or by clicking **Abort** in the lower left corner of the screen.
12. On the **Abort** prompt, click the **Yes** button.

13. Initiate the **ID** script.
14. The **Continue at line** dialog box will display.
15. If a RCS Bar Code Scanner has not been installed, enter 83 in the **Continue at line** field.
If a RCS Bar Code Scanner has been installed, enter 88 in the **Continue at line** field.
16. Click the **Continue run** button.
17. The RCS performs the assay from the DR1 reagent addition through the DR2 microplate incubation.
18. Measure the microplate in the DML instrument.
Note: From the *digene* assay analysis software, perform a Raw Data measurement. Refer to the *digene* assay analysis software user manual for instructions.
19. Send the data to QIAGEN Technical Services for analysis.
20. Compare the RLU values from pre- and post-decontamination.
21. If there is a significant reduction in the RLU values following decontamination, it can be assumed the elevated values exhibited by the RCS were attributable to contamination.

9 Troubleshooting

Refer to this section for error handling and troubleshooting. If recommended steps do not resolve the problem, contact QIAGEN Technical Services for assistance.

9.1 Incorrect specimen rack usage

9.1.1 *digene* Specimen Rack (blue) used with a **C** script

When testing Specimen Transport Medium (STM) specimen types, the user must select a **D** script. The **C** script parameters are programmed to aspirate from a sample volume of 150 μ l. Therefore, the tip adapters are set to go to a lower position to aspirate the specimen. If the **C** script is selected and a *digene* Specimen Rack is used, the tip adapters may jam in to the collection device during sample transfer and generate an error message. Use the ScriptSelect Software to choose the correct script for the specific run.

9.1.2 Conversion Rack (silver) used with a **D** script

When testing converted samples in 15 ml conical tubes, the user must select an appropriate **C** script. In general, the converted sample volume is much lower than an STM specimen. The **C** script parameters are programmed to aspirate from a sample volume of 150 μ l. If a **D** script is selected for converted samples, the sample will not be transferred to the hybridization microplate because the tip adapters are set to a higher position to aspirate the sample to avoid interference with the brush. Use the ScriptSelect Software to choose the correct script for the specific run.

9.1.3 Specimen type and specimen rack

Make sure to use the correct specimen rack for the type of specimen. STM samples must be placed in the *digene* Specimen Rack (blue). Liquid cytology specimens must be placed in the Conversion Rack (silver). The rack lid for the *digene* Specimen Rack will not fit the converted samples in 15 ml conical tubes.

9.2 Incorrect reagent or specimen rack placement

9.2.1 Incorrect probe or calibrator placement

When running a script requiring more than one probe, it is imperative that the placement of probe and calibrator corresponds to the specimen rack order in accordance with the selected script. Improper placement of the probe or calibrator positioning will produce an invalid assay. For a dual assay, probe 1 must match the positive calibrator 1 (PC1) located in the D1 position and probe 2 must match the positive calibrator 2 (PC2) located in the E1 position. Use the ScriptSelect Software printout to assist with proper RCS deck setup.

9.2.2 Incorrect specimen rack order for sample transfer

Label the specimen racks to make sure that the correct samples are transferred for the probe/assay to be tested. If a specimen rack is misplaced for sample transfer, then the incorrect probe will be distributed on the hybridization microplate resulting in an

invalid assay or a valid assay with mismatched sample results. Label specimen racks and use the ScriptSelect Software printout to assist with proper RCS deck setup.

9.3 Errors during run initiation

9.3.1 Incorrect number of samples entered

The user must enter the correct number of samples if the number of samples per microplate to be run on the RCS is less than the default (a complete microplate). If the incorrect number of samples is entered in the Start run window, one of the following problems will occur:

- Samples will not be transferred.
- Samples will not receive reagents, or reagents will be delivered to too many microplate wells.

These problems will cause either a false-negative result or tip clogging, both of which can lead to erroneous results. The assay will have to be aborted and restarted after entering the correct sample number. For the proper procedure in this case, see "Restarting scripts," page 72.

9.3.2 Waste flooding

During the flush step, flooding can occur if tubing is kinked or not snapped properly into the Waste Bottle. If flooding occurs, check the tubing to make sure it is not restricted and that it is snapped firmly into the Waste Bottle. If the system is flooded, perform the decontamination procedure as part of the post-run cleanup. Contact QIAGEN Technical Services to reevaluate the tubing setup and connections if there is a problem with frequent flooding due to restricted tubing.

9.3.3 Disposable tip rack picked up

If the disposable tip rack is not snapped properly into the disposable tip rack holder, or if the tab no longer holds the tip rack securely, the tip rack can be picked up by the tip adapters and could generate an error message, which will interrupt the run.

9.3.4 Jamming of the tip adapters at the tip ejection station

Jamming at the tip eject station can occur if the disposable tip waste container is over filled or if the eject slide is blocked. This prevents the ejected tips from falling clear of the tip eject station. This could damage the tip adapter and generate an error message.

9.4 Sample transfer errors

9.4.1 Incorrect orientation of drop-on caps or no drop-on caps

Drop-on caps are only required for STM specimens. If drop-on caps are not placed on the specimen collection tubes or if they are oriented incorrectly, the caps or the collection device may interfere with the disposable tips. This will cause damage to the tip adapters and will generate an error message.

9.4.2 No hybridization microplates loaded on plate shaker

The robotic plate handler will not detect whether an object is actually picked up or not. The robotic plate handler is not equipped with a sensor that will alert the system if an object, such as a microplate or microplate lid, is not within its grasp. If hybridization microplates are not loaded on the plate shaker, the robotic plate handler will go through the motion of moving the microplate or lid and add reagents regardless of whether a microplate is present. This will cause reagents to be transferred onto the RCS deck and will require cleanup and possibly decontamination.

9.4.3 Microplates and lids not properly loaded on the plate shaker

The location settings for placement of microplates at the beginning of a run are precisely defined. Microplates not placed properly will cause an error message.

9.4.4 Liquid level detection problems

Liquid level detection is turned on for the aspiration of controls and calibrators but is turned off for sample aspiration. If the instrument fails to detect liquid in the controls and/or calibrators and gives an error message, make sure there is sufficient volume in the controls and calibrators. If there is sufficient volume, it is possible that the wrong system liquid (other than deionized or distilled water) is being used or that the fitting is not properly snapped into the System Liquid Bottle. If this is not the problem and the liquid level detector continues to generate an error message, contact QIAGEN Technical Services for assistance.

9.4.5 Samples fail to transfer or are partially transferred

If samples are not transferred to the hybridization microplate, it is possible that a **D** Script was selected when actually running a Conversion Rack requiring a **C** script. Avoid this problem by selecting the correct script.

This problem also can occur if the tubing lines are empty or contain a large amount of air bubbles. If the tubing is not snapped firmly into the System Liquid Bottle, or if the bottle is empty, air bubbles will form in the lines.

It is important to visually inspect each microplate after sample transfer as prompted by the RCS Software in order to determine if all of the samples were transferred to each microplate. A pause is provided to allow transfer of missing samples manually. Liquid detection is turned off and samples can be missed if the tubes have trapped air bubbles or if the volume of the sample is low.

9.4.6 Robotic plate handler fails to pick up microplate or microplate lids

Exact placement of microplates and lids is necessary for the instrument to properly pick up and move a microplate or lid. If a lid or microplate is improperly picked up, the robotic plate handler will not sense it, and plate handling problems can occur.

9.5 Reagent addition errors

9.5.1 Probe Mix not transferred

If Probe Mix is detected but not transferred properly, make sure there is sufficient volume and that there are minimal bubbles present. If any of the reagents are frothy, the liquid level detector may be detecting bubbles and fail to draw up reagent.

9.5.2 Reagent liquid level detection problems

If liquid is not detected and an error message is generated, check the reagent liquid level and make sure there is sufficient volume. If the reagent volume is sufficient, then there may be a problem with the liquid level detector. If so, contact QIAGEN Technical Services for assistance. If **Continue** is clicked when the error message dialog box appears, the tips will then go to a set height and transfer the reagent without using liquid level detection. If the liquid level detector is not functioning properly, it will be necessary to click **Continue** when the error dialog box appears for each draw of reagent.

9.5.3 Sample splashing while shaking

Samples may splash if the plate shaker is not functioning properly. Results are invalid if splashing occurs (indicated by drops on the lid), as contamination may have occurred. Contact QIAGEN Technical Services for assistance.

9.5.4 The 65°C incubator fails

If the 65°C incubator is not functioning properly or has failed to reach the specified temperature, an error message will appear. If the incubator is not functioning, contact QIAGEN Technical Services for assistance.

9.5.5 Robotic plate handler fails to pick up microplate or microplate lids

See "Sample transfer errors," page 64, for additional instructions.

9.6 Plate-to-plate transfer errors

9.6.1 System runs out of disposable tips

The instrument will alert and prompt you to refill the disposable tips after all sample transfer is complete. If the disposable tips are not replaced during this pause, there will not be enough tips to complete the assay. If the tips run out during the assay, the instrument will attempt to pick up tips five times, after which an error message is displayed. The instrument will not allow you to replace tips at this point, unless the run is aborted and restarted. Contact QIAGEN Technical Services for assistance.

9.6.2 Failure to load capture microplates or incorrect number of capture microplates loaded onto Stacker A

If the incorrect number of capture microplates is loaded, the robotic plate handler will fail to pick up the microplate. The robotic plate handler does not have a sensor capability and will not detect whether or not a microplate or microplate lid is being carried.

Failure to load enough capture microplates will cause the robotic plate handler to go through the motion of moving the microplate or lid and transfer sample, whether or not a microplate is present. Loading too many capture microplates will cause the run to be interrupted and generate an error message. The run must be aborted and restarted at the point of interruption. Contact QIAGEN Technical Services for assistance.

9.6.3 Waste hybridization microplates left in Stacker B from previous run

If waste microplates or lids from the previous assay are left in Stacker B, the robotic plate handler will not be able to place subsequent waste hybridization microplates in Stacker B. The run will be interrupted and an error message will be displayed.

9.6.4 No empty microplate well strips used to fill partial capture microplates

Microplate well strips are required to counterbalance partial capture microplates. Failure to place empty microplate well strips into partial capture microplates may cause the microplate to tip and the robotic plate handler to drop the microplate during transfer to the room temperature incubation chamber.

9.6.5 Microplates or lids left in incubation chambers from previous runs

Microplates or lids left in the incubation chambers will prohibit a new microplate or lid from being placed in the occupied chamber. The run will be interrupted and an error message will be displayed.

9.6.6 Robotic plate handler failure to pick up microplate or microplate lids

See "Sample transfer errors," page 64, for additional instructions.

9.7 Capture step errors

9.7.1 Plate shaker roller problems

If the plate shaker rollers are loose or broken, the robotic plate handler may not properly place the microplate onto the plate shaker. Improper placement of the microplate onto the plate shaker may result in an error message. Additionally, if the rollers are loose or broken, the plate shaker may not hold the microplate tightly, resulting in splashing. If this occurs, contact QIAGEN Technical Services for assistance. Results are invalid if splashing occurs (indicated by drops on the lid), as contamination may have occurred.

9.7.2 Sample splashing while shaking

See "Reagent addition errors," page 66, for additional instructions.

9.8 Aspiration and washing step-plate washer errors

9.8.1 Wash Bottle not filled or tubing not snapped into place

The tubing must be snapped properly into the Wash Bottle and System Liquid Bottle or the liquid will not flow properly. This will cause pipetting problems, flooding or failure to flush or wash. The RCS does not detect if the bottles have insufficient liquid or if the tubing is improperly connected. Refill the bottles with the appropriate liquid and properly attach the connection tubing. If problem persists, contact QIAGEN Technical Services for assistance.

9.8.2 Flooding of plate washer

Improper connection of the plate washer tubing can cause the plate washer to flood. Check the tubing to make sure it is not kinked and is properly snapped into the Wash Bottle. If this is not the case or if the flooding still occurs after correction, contact QIAGEN Technical Services for assistance.

9.8.3 Plate washer has residual wash buffer buildup

Previous flooding of the plate washer can cause the washer platform to stick and not move properly. This situation could go undetected because this portion of the script is not monitored by the instrument and will not cause an error code. Dried wash buffer will crystallize on the platform and potentially prevent movement of the washer platform; therefore, the wash cycle will not be performed properly. This could also cause additional flooding during the wash or aspiration steps. Cleaning and decontaminating the plate washer will resolve this situation. Contact QIAGEN Technical Services for assistance.

9.8.4 Uneven liquid aspiration

If the liquid in the microplate well strips is not aspirating evenly, the plate washer head may be clogged and may require cleaning. Contact QIAGEN Technical Services for assistance.

9.8.5 Plate washer head out of alignment

If the plate washer head is out of alignment, microplate wells may not be aspirated. The plate washer head needs to be realigned. Contact QIAGEN Technical Services for assistance.

9.9 Microplate completion errors

9.9.1 Not removing the microplate when the RCS prompts

The RCS places the microplate in Pipetting Position 1 at the completion of each plate run. The RCS will sound an alarm to notify you to remove the microplate and measure the microplate in the DML instrument. If you remove the plate but do not click **OK** to continue the run, the system remains paused in the alert status. If you click OK and do not remove the microplate from Pipetting Position 1, the instrument cannot place the consecutive microplate onto Pipetting Position 1 and will generate an error message. Note that either event results in longer incubation times for the subsequent microplates and could invalidate the assays. Reference

either “Moving the robotic plate handler,” page 69, or “Error codes, system interruptions and corrective action,” page 75, for additional information or contact QIAGEN Technical Services for assistance.

The user must read the microplate in the DML instrument within the indicated timeframe per the *digene* HC2 DNA test instructions for use for valid results.

9.10 Moving the robotic plate handler

Use this procedure to dislodge a jammed object after aborting the script from the RCS Software.

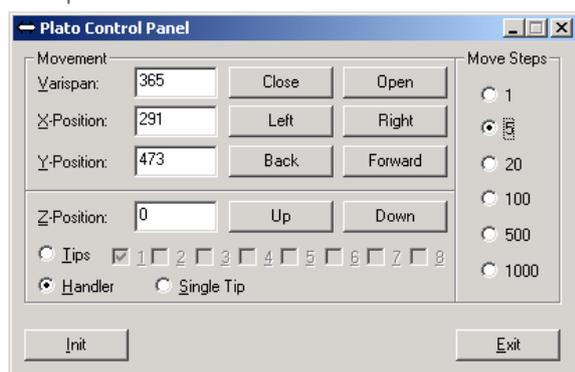
1. From the RCS main menu, select **External**.

A menu appears.

2. Select **Move Handler**.

The **Plato Control Panel** window appears:

Example:



3. Change the settings appropriately to manipulate the robotic arm and robotic plate handler. **0**.

Important: Make sure that there is nothing in the way when the user moves the robotic arm and robotic plate handler using the **Move Handler** commands.

Notes:

- The **Move Steps** selection, located on the right side of the dialog box, controls the degree to which the robotic plate handler is moved. The lower numbers move the robotic plate handler a small amount of steps and the higher numbers move the robotic plate handler more steps. The default is set on 5 to prevent the user from accidentally damaging the robotic arm, tip adapters or robotic plate handler by moving it too abruptly.
- The robotic plate handler’s VariSpan can be opened or closed.
- The X-, Y-, and Z-positions are defined relative to the “0 position” of the park position. The X-position is defined as the area from the tip eject station toward the incubation chambers (moves in the left to right directions). The Y-position is from the front of the platform to the back (moves in the forward and back directions). The Z-position moves in the up and down direction. Small step moves should be made at first to make sure the operator is moving the robotic arm in the correct direction. The robotic arm can be moved in the X- and/or Y-positions separately.
- The robotic plate handler and tip adapters can be moved in the Z-direction.

9.11 Powering OFF the RCS following a system interruption

When the RCS is powered OFF, the tip adapters and the plate grippers automatically descend toward the platform in the exact position they were located prior to the unit being switched off. To prevent possible damage to the tip adapters and the plate grippers, 2 people are required to power down the instrument. To perform this procedure, one person manually supports the tip adapters and the plate grippers, while another person powers down the instrument.

<p>WARNING</p> 	<p>Risk of personal injury</p> <p>Do not place any part of your hand under a disposable tip while pulling down to remove it. Placing your hand under a disposable tip while removing it may result in injury to the user.</p>
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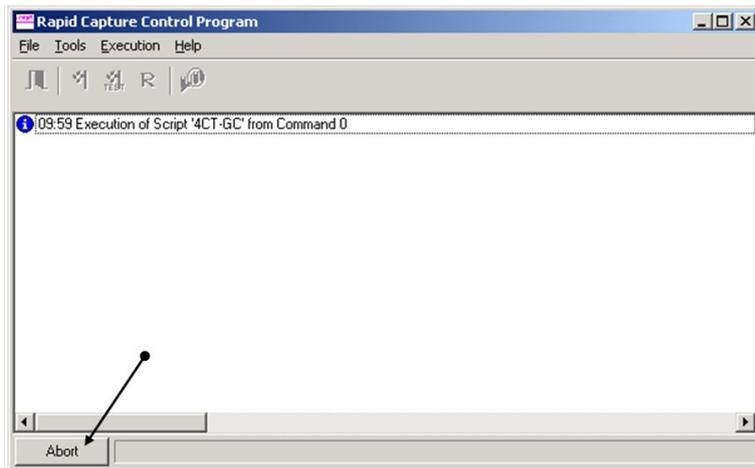
<p>WARNING</p> 	<p>Biohazardous substances</p> <p>The materials used with this instrument may contain biohazardous substances.</p> <p>When using the instrument, follow Universal Precautions regarding potentially infectious material.</p>
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1. The first person supports the tip adapters by placing one hand under the black plastic at the bottom of each vertical bar. Make sure not to push or pull on the bars horizontally as their alignment is sensitive.
2. The first person also supports the plate grippers from below with the other hand.
3. The second person powers OFF the RCS using the power switch located in the lower-left corner on the rear panel of the instrument.
4. If there is a microplate in the robotic plate handler, remove it now.
5. The first person moves the robotic arm to Pipetting Position 1 using the plate grippers and the tip adapters to pull the robotic arm into position.
6. Safely lower the tip adapters and plate grippers to the RCS deck.
7. If there are disposable tips in place, it is best to let the RCS unload them by powering ON the RCS and running the **FLUSH** script.
8. If this procedure is not possible due to a malfunction, disposable tips may be removed manually.
9. To manually remove disposable tips, pull each tip gently but firmly straight down while supporting the black plastic at the bottom of each vertical bar. It is critical that the tip adapters not be pulled horizontally.
10. If neither the tip adapters nor the plate grippers are compromised, park the system and power down the instrument.

9.12 Aborting or pausing the script

1. Click the **Abort** button. Alternatively, press the **Esc** key on the RCS computer keyboard.

Example of the **Abort** button:



A dialog box appears with the following message: **Do you want to abort the current run?**

2. Select the appropriate response: **0**.
 - Select **Yes** to abort the current run.
 - Select **No** to continue the run.
 - Select **Skip** to advance to the next step and continue the run.

9.13 Maximum allowable down time for RCS steps during assay

Depending when an assay interruption occurs, the time period allowed prior to continuation of the assay is limited. The following chart lists the time limitations for each assay step of the *digene* HC2 DNA test. Adhere to these times to make sure of valid assay results.

Step	Current time	Additional time allowed	Total assay time
Denaturation	45 minutes	45 minutes	90 minutes
Hybridization	60 minutes	60 minutes	120 minutes
Hybrid capture	60 minutes	60 minutes	120 minutes
Hybrid capture pause	N/A	60 minutes	60 minutes
Hybrid detection	45 minutes	60 minutes	105 minutes
Signal amplification	15 minutes	75 minutes	90 minutes

An RCS run experiencing a recoverable problem can be continued if the interruption is within the total permissible time described above. Results are valid if the assay verification criteria are met.

9.14 Restarting scripts

Contact QIAGEN Technical Services for assistance in determining the correct line at which to restart after aborting a script.

9.14.1 Restarting the script in the middle of an assay

A script cannot restart in the middle of any of the following steps once a script has been aborted:

- Sample transfer from the specimen rack to the hybridization microplate
- Reagent addition to the microplate wells
- Plate-to-plate sample transfer
- Aspiration step
- Wash step

For these procedures, the script must be started either at the beginning of the step or the subsequent step.

If a script is aborted during a distribute operation, such as the transfer of samples, reagent addition or plate-to-plate transfer, the script cannot continue from the last microplate wells of reagent transferred.

The script can only be started from the beginning of the distribute operation or following the completion of the distribute operation. The entire distribute operation is considered one command in the script log. The script only allows for a command to be started at the beginning.

The entire sample transfer can be started over if there is sufficient sample volume. Initiate the script at the beginning of the transfer command. Alternatively, the sample transfer can be completed by hand. Reagent addition can also be completed manually. The plate-to-plate transfer can be restarted and only a few tips will be wasted. After this, the script can be continued.

The aspiration and wash procedure cannot be restarted in the middle of the process. The steps require restarting from the beginning or manually completing the process before the script is restarted.

If the script is aborted during a plate-shaking step, the plate shaker will not automatically continue shaking. In order to restart the plate shaker, the script must be started before the line that starts the shaking incubation.

Do not manually place microplates or lids into either the 65°C incubator or the room temperature chamber. The system must place the microplate or lid in the exact position for the robotic plate handler to successfully retrieve them from the incubators. It may be necessary to abort the script and back track to the point of microplate pickup to move the microplate into the appropriate position. Alternatively, when the microplate is not at a 65°C incubation, washing, or shaking step, the microplate or lid can be moved and the microplate put back in the proper position. Accomplish this by pausing the script and initiating the script following the command in which the microplate has been moved to the appropriate position.

An error message or system interruption may require one or more microplates to be discarded. Depending on the situation, the assay interruption and damage to a particular microplate may render it impossible to produce valid results.

In order to obtain valid results from the remaining microplates in the run, the invalid microplate(s) cannot simply be removed from the run. At the beginning of a run, the user initiates the script that corresponds to the number of microplates. The script will continue to operate and function according to the original programmed microplate number; therefore, the damaged microplate cannot be removed from a run without causing another system error.

The user can also manipulate the system by utilizing a dummy microplate or continue to use the invalid microplate. The dummy microplate needs to be used to manipulate the assay so reagents are not added to an empty pipetting position or washed, which would cause the wash buffer to flood the plate washer.

Restarting the script resets the tip retrieval to the first tip rack. Therefore, it is imperative that the tip racks be refilled.

A user is not given the option to restart a script at the desired line if the following scenarios occur:

- If there has been a power failure or the power to the RCS is switched off before aborting a script properly.
- Following a power failure, the system does not store the location of the last tip obtained from the disposable tip rack. Therefore, the tip adapter will start to obtain a tip from the first rack, position one.
- If the wrong script is selected and the user wishes to continue the assay using the correct script.

After restarting an aborted script, a dialog box appears.

Example:



Note: If the instrument is powered OFF, the software will not notify the user of the line at which the last script was interrupted. The user will not see the dialog box above.

The following table describes the possible options for an aborted run.

Option	Definition
Continue run	This option continues the script run at the line after the run interruption. The software defaults to the line at which the assay was interrupted. The script will continue to the next line of the script after the line number displayed in the Continue at line dialog box. The line number displayed in the dialog box has already been performed according to the system. To determine the line number to restart, contact QIAGEN Technical Services for assistance.
Restart run	This option cancels the current script run and reverts back to the Start run window of the same script.
Cancel	This option closes the dialog box. You have the option to re-select the script from the Run List and view the same dialog box again.

9.14.2 Restarting a script after a power failure or wrong script

To start the script at a specific line after a power failure or incorrect script selection, first initiate the desired script from the **Run List**. Abort the run following the flush at the beginning of the run and restart the script a second time. The following dialog box will then appear, giving you the option to continue the script at the required line.



9.14.3 Restarting the script after entering a wrong sample number or total microplate well number

If the wrong number of samples has been selected and you want to restart the script with the correct sample number, restart and abort the script (see "Aborting or pausing the script", page 71). Restart the run using one of the following options:

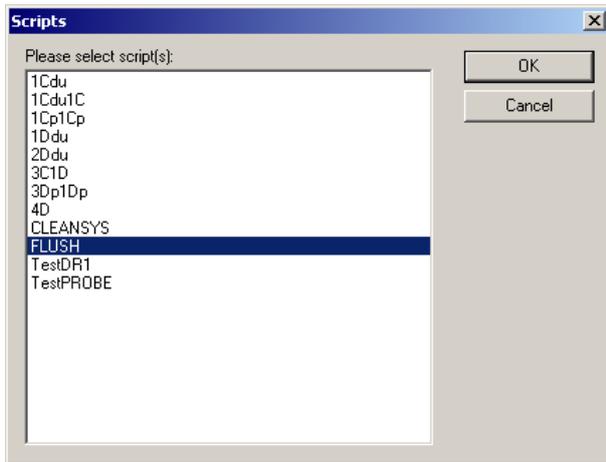
- Stop the script and restart it after entering the correct number for sample transfer and reagent distribution.
- If the assay has progressed to a point where you do not want to restart the assay from the beginning, abort the original script, then restart the script.

Following the flush step, abort the script again. This time, when the script is restarted, enter the start line number to continue the run.

9.15 Removing air in the tubing lines

Air bubbles in the RCS tubing can cause pipetting inaccuracy. The air bubbles must be removed before starting an RCS run. If air bubbles are visible in the RCS tubing, remove them by refilling the system liquid, properly connecting the tubing connector and flushing the system. A FLUSH script is required to remove air bubbles.

1. Select the **FLUSH** script in the **Scripts** window and click **OK**.



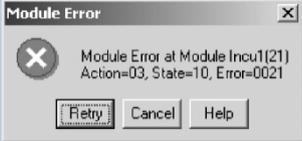
2. Repeat the **FLUSH** script until large bubbles are no longer seen in the lines or in the syringes.0.

If air bubbles continue to be observed and the above steps have been followed, contact QIAGEN Technical Services for assistance.

9.16 Error codes, system interruptions and corrective action

The intervention and corrective actions provided below do not make sure that assay results have not been compromised. Contact QIAGEN Technical Services for additional information.

For assay validation failure analysis, refer to the *digene* HC2 DNA test instructions for use or contact QIAGEN Technical Services.

Symptom	Possible problem/cause	Intervention/corrective action
<p>Incubator (65°C)</p> <p>The screen displays Module Error at Module Incu 1 (21). One or all of the incubator chambers are not initializing.</p> 	<p>There may be a problem with the motors of the incubator drawers that is not allowing initialization.</p>	<p>Click the Retry button. If initialization fails again, power OFF the RCS, power ON the RCS and click the Park icon to initialize the RCS.</p> <p>If the incubator still fails to initialize, the incubator needs repair or replacement by a service technician. Contact QIAGEN Technical Services for assistance.</p>
<p>The system is poised for Probe Mix addition. A window displays the present temperature of the incubator. The incubator has not reached the specified temperature of 65°C.</p>	<p>The incubator may not have had enough time to heat up.</p> <p>There may be a problem with the incubator's heating elements. Allow at least 20 minutes for incubators to heat.</p>	<p>Power OFF the RCS, power ON the RCS, and run the FLUSH script to initialize the RCS.</p> <p>Start the script at the desired line and allow time for the incubator to heat up.</p> <p>If after 20 minutes the incubator has not reached 65°C or the temperature is not increasing, there is a problem with the incubator's heating elements. Contact QIAGEN Technical Services for assistance.</p>
<p>Plate shaker</p> <p>The system has stopped during initialization.</p> <p>The RCS has stopped during the assay run. The robotic arm is poised over the microplate on the plate shaker. An error message is displayed.</p> <p>The screen displays Module Error at Module Shaker (22).</p>	<p>The plate shaker failed to initialize before the robotic plate handler retrieved the microplate.</p> <p>The plate shaker may not be reaching 1100 rpm.</p>	<p>Click the Retry button.</p> <p>If the error message repeats, abort the run and run the FLUSH script to initialize the RCS. If initialization proceeds, continue the script at the applicable line.</p> <p>If the error message repeats, contact QIAGEN Technical Services for assistance.</p>



<p>Liquid splashes in the microplate wells (droplets on the microplate lid). Hybridization solution appears on the plate shaker. The hybridization microplate may or may not have empty or low volume wells. No message is generated.</p>	<p>The microplate is not being held tightly by the plate shaker rollers. The microplate is misaligned. The plate shaker is out of alignment and is wobbling instead of spinning on a flat plane.</p>	<p>Check that roller arms are tight and the rollers move freely. If defective, contact QIAGEN Technical Services for assistance. Check the microplate alignment on the plate shaker. If the rollers and microplate alignment are in good working order, the plate shaker may be out of alignment. Make a note of splashing on the microplate lids. Retest the samples. Contact QIAGEN Technical Services for assistance.</p>
<p>The microplate rattles while shaking. Liquid may or may not be visible on the microplate lid or RCS deck.</p>	<p>The microplate is not held firmly on the plate shaker. The coating on the plate shaker guides has worn off. The microplate is misaligned.</p>	<p>Check the microplate alignment on the plate shaker. Check that the shaker roller arms are tight and move freely. If defective, contact QIAGEN Technical Services for assistance. A white powdery dust on the plate shaker guides indicates that the coating of the plate shaker guides is wearing off. Contact QIAGEN Technical Services for assistance.</p>

Plate washer

<p>The system freezes and the screen displays error code Error Addressing Module Washer (5).</p>	<p>The plate washer failed to initialize prior to the robotic plate handler retrieving or placing a microplate on the plate washer. The RCS washer boat is stuck.</p>	<p>Click the Retry button. If the RCS does not respond, abort the script. Power OFF the RCS, power ON the RCS, and run the FLUSH script to initialize the RCS. Remove the RCS washer boat. Clean the wheels on the RCS washer boat and the plate washer with a 0.5% v/v sodium hypochlorite solution using a low-lint paper towel. If the problem continues, contact QIAGEN Technical Services for assistance.</p>
<p>Microplate wells are full. The aspiration pump is running, and the usual noises associated with plate washing and aspiration are heard. Severe flooding may follow as buffer is being dispensed. The plate washer trough is full, and the plate washer is not aspirating from the microplate wells or the trough.</p>	<p>The quick-disconnect fitting to the Waste Bottle is not securely snapped in place. The plate washer head is not properly aligned. The plate washer head is blocked.</p>	<p>Check that the quick-disconnect fitting to the Waste Bottle is in place and properly connected. Make sure the tubing leading to the Waste Bottle is not kinked or pinched. If the plate washer head is clogged, contact QIAGEN Technical Services for assistance. If the plate washer head is misaligned, contact QIAGEN Technical Services for assistance.</p>
<p>The aspiration pump is not running, and the usual noises associated with plate aspiration are not heard. Severe flooding may follow as buffer is being dispensed by the inlet valve but no aspiration is taking place.</p>	<p>The aspiration pump is malfunctioning.</p>	<p>If the aspiration pump is not operating, contact QIAGEN Technical Services for assistance to test the aspiration pump. Remove all microplates, lids and reagents troughs from the RCS deck. Clean the plate washer to the extent possible.</p>
<p>The RCS washer boat is not moving during sample aspiration or plate washing, resulting in the plate washer head moving up and down only within the plate washer trough and not moving to the individual columns of the microplate.</p>	<p>As a result of a previous flooding, salt residue is covering the plate washer and is hindering movement. The aspiration pump is malfunctioning.</p>	<p>Clean the plate washer and click the Retry button. If the aspiration pump malfunctions, contact QIAGEN Technical Services for assistance. If the plate washer head is improperly aligned, contact QIAGEN Technical Services for assistance. Note: After extensive flooding, contact QIAGEN Technical Services to install a new plate washer and to clean the underside of the plate washer assembly and interior surfaces of the RCS deck and chassis.</p>
<p>No buffer dispenses during sample aspiration or the plate washing step and the plate washer trough is empty. The plate washer head is going through aspiration motions but no buffer dispenses. No error message is displayed.</p>	<p>The Wash Bottle is empty. The quick-disconnect fitting to the Wash Bottle is not connected or is improperly snapped in place. The tubing is not performing properly. The tubing inside the Wash Bottle is either curling above the liquid level, or liquid flow is being restricted by</p>	<p>Make sure recommended volumes are in the Wash Bottle. Make sure the quick-disconnect fitting to the Wash Bottle is in place. Make sure the tubing is performing properly and remaining in place in the Wash Buffer. Depending on which step of the assay the wash buffer is not being dispensed, and whether or not the problem has been found and solved, it may be possible to pause, abort, and continue the script to wash the microplate. Otherwise, the run must be aborted.</p>

	<p>suction against the wall of the bottle.</p> <p>The Wash Buffer dispense pump is malfunctioning.</p>	<p>Contact QIAGEN Technical Services for assistance if the pump is malfunctioning. Remove all microplates, lids and reagent troughs from the RCS deck.</p>
<p>The robotic plate handler crashed trying to retrieve a microplate from the plate washer.</p> <p>Aspiration has finished and the plate washer is buffer free.</p> <p>The robotic plate handler and microplate are slightly above the RCS washer boat and the right end of the microplate is caught under the plate washer head.</p>	<p>The plate washer head did not return to home position after the last column aspiration and stopped travel when cannulas were just above the side of the trough.</p> <p>The RCS washer boat may be resting on an unlevelled piece of metal.</p>	<p>Release the microplate from the robotic plate handler by powering OFF the system.</p> <p>Retrieve the microplate and move the robotic arm to a safe position for parking.</p> <p>Seat the microplate on the RCS washer boat.</p> <p>Power ON the RCS and park. Run the FLUSH script to initialize the syringes.</p> <p>Find the correct script line to continue the run.</p> <p>Contact QIAGEN Technical Services to adjust the magnet sensor on the RCS washer boat or to install a new plate washer.</p>
<p>Uneven distribution of Wash Buffer in one or more rows.</p>	<p>The plate washer head dispense tip corresponding to that row is blocked.</p>	<p>Contact QIAGEN Technical Services to assist with cleaning the plate washer head.</p>
<p>There is Wash Buffer on the plate washer or RCS washer boat.</p> <p>The RCS washer boat may be covered in salt residue and not moving freely.</p> <p>Leaking/dripping is occurring at the plate washer.</p>	<p>Faulty tubing connection.</p> <p>Leaking inlet or outlet tubing.</p> <p>The waste tubing may not be delivering waste to the bottle.</p> <p>The plate washer head is blocked.</p> <p>The pump head is blocked.</p> <p>A plate washer fluid valve is open.</p> <p>A twin-head vacuum pump is faulty.</p>	<p>If dripping is not severe enough to cause flooding and if the RCS washer boat is moving freely, continue with the assay.</p> <p>Check all tubing connections.</p> <p>Check the flow path of the waste tubing. Make sure the tubing is not kinked or bent.</p> <p>Empty the Waste Bottle, if full.</p> <p>Remove the RCS washer boat; clean and dry the plate washer to the extent possible.</p> <p>Contact QIAGEN Technical Services to check or replace the pump head and the valve, and to remove and clean the plate washer head, etc.</p>
<p>The pressure release opening on the bottle cover is splattering waste liquid.</p> <p>The waste container is overflowing.</p>	<p>The waste container was not emptied prior to starting the run.</p>	<p>Empty the waste container and reconnect it. Press Continue to proceed with the script. If the RCS is at a flush, aspirate or wash step, pause the script for intervention when the step is over.</p> <p>Power OFF the RCS and separate the power cord from the appliance inlet (disconnecting device), which is located in the lower left corner on the rear panel of the instrument. Clean up spilled waste, and decontaminate the area of the spill.</p>
<p>Residual Wash Buffer in one or more strips.</p> <p>One or more strips have Wash Buffer and DR2 in the individual microplate wells when the microplates are read.</p>	<p>The plate washer head is not properly aligned, and some strips were not properly aspirated at the last wash step.</p>	<p>Contact QIAGEN Technical Services to realign the plate washer head.</p> <p>Retest the affected samples.</p>
<p>No Wash Buffer is dispensed.</p>	<p>Wash Buffer quick-disconnect tubing is not connected properly to the Wash Bottle.</p> <p>Insufficient volume of Wash Buffer.</p>	<p>Refill the Wash Bottle. Run the aspirate/wash script to fill the lines in preparation for the next plate washing.</p> <p>Unless the problem is detected and corrected before the microplate proceeds to the next step, the assay is lost and the samples must be retested.</p>
<p>Syringes</p>		
<p>The syringe is leaking.</p>	<p>The syringe is worn.</p>	<p>Replace syringe(s). See "Cleaning and replacing syringes," page 59, for additional instructions.</p>
<p>The syringe constantly has air bubbles.</p>	<p>Low system liquid.</p> <p>System lines are not fully primed.</p> <p>The syringe is worn.</p>	<p>Fill the System Liquid Bottle.</p> <p>Run the FLUSH script several times until bubbles are gone.</p> <p>Replace the worn syringe. See "Cleaning and replacing syringes," page 59, for additional instructions.</p>
<p>The system stops during initialization or flushing. The screen displays an error for module diluter 1, 2, 3 or 4.</p>	<p>The syringes did not initialize during flushing.</p> <p>A dilutor module is faulty.</p>	<p>Select the Retry button. If the error still occurs, power the RCS OFF and then power the RCS ON. Run the FLUSH script and restart the script.</p> <p>If the syringes do not initialize, contact QIAGEN Technical Services for assistance.</p>



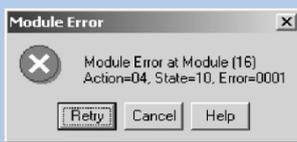
Liquid level detection

One or more tips are not detecting the liquid level.	Poor connection at the detector cable.	Contact QIAGEN Technical Services to fix the connection or replace the Z-Rack.
Reagents are not being aspirated.	Excessive bubbles on top of reagent liquid. A tubing leak. Worn syringe(s).	Remove the foam layer by aspirating bubbles manually with a pipet (without aspirating reagent). Check tubing for leaks. If there are leaks, contact QIAGEN Technical Services for assistance. Replace worn syringes. See "Cleaning and replacing syringes," page 59, for additional instructions.
Tips are crashing into the floor of the reagent trough.	Failed cable connections.	Contact QIAGEN Technical Services to replace the tubing or detector board.

Robotic plate handler

The robotic plate handler fails to pick up a microplate. The robotic plate handler fails to place a microplate. The robotic plate handler drops a microplate.	Incorrect placement of microplates and lids on the plate shaker. Microplate is misaligned. Strips are placed upside-down in the microplate. Plate grippers are bent. Plate grippers are misaligned.	Make sure that the microplate is correctly placed at set-up. Make sure covered microplates are positioned within the plate shaker guides. Make sure that microplate strips are placed in the correct orientation. Strips placed upside-down prevent the lid from lying flat on the microplate and can cause the robotic plate handler to fail to pick up the microplate. Contact QIAGEN Technical Services to replace the plate grippers.
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The robotic arm and robotic plate handler are moving backward and forward. The system is not responding. The screen displays an error at Module Y Motor (15) or X Motor (16).



The robotic arm has crashed against an obstacle and has lost its position.

Select the **Retry** or **Cancel** buttons.
Park and restart the script at the appropriate line.

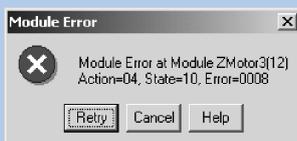
The robotic plate handler is in Stacker B. A microplate is jammed in the robotic plate handler; **Module Error at Module Handler (17)** is displayed on the screen. The robotic plate handler may be moving slowly up and down and has lost its placement.



Faulty setup. Microplates were left in Stacker B from a previous run.
The microplate already in Stacker B has been manually manipulated and moved from its original placement.

Select the **Retry** button. Release the microplate from the handler manually, or exit the script and use the **Move Handler** commands (see page 69) to release the microplate.
Correct an RCS deck setup error by removing microplates left from the previous run.
Continue the script at the appropriate script line.

Error message **Module Error at Module Z Motor 3 (12)**.

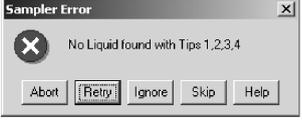


The Z-rack may be blocked by an obstacle, or the Z Motor may not be working properly.

Select the **Retry** button.
Reinitialize the RCS by selecting **Park** or by powering the RCS OFF and ON.
If the problem persists, contact QIAGEN Technical Services to fix or replace the Z Motor.

<p>The robotic plate handler fails to reach VariSpan-close setting and gives the error message Module Error at Module V Motor (14).</p>	<p>There may be a microplate in the robotic plate handler preventing the VariSpan from closing. VariSpan may need cleaning and lubricating.</p>	<p>If a microplate is held in the robotic plate handler, use the Move Handler commands to release the microplate (see page 69), park the robotic plate handler, and continue with recovery. Contact QIAGEN Technical Services to clean and lubricate the VariSpan.</p>
<p>The robotic plate handler bumps or crashes when it retrieves or positions microplates or lids.</p>	<p>Microplate or lids were not placed properly in their respective positions. The plate grippers are bent. The setting allocations are off.</p>	<p>Adjust the lid or microplates if they are misplaced and select the Retry button. If the plate grippers are bent, contact QIAGEN Technical Services to replace them. Contact QIAGEN Technical Services to readjust setting allocations.</p>
<p>The robotic plate handler crashes onto the capture microplates in Stacker A.</p>	<p>The microplates have been loaded improperly into Stacker A. Too many microplates or extra lids. The settings are off.</p>	<p>Abort the script. Use the Move Handler commands to move the robotic plate handler out of the way (see page 69), or park the handler if it is not holding a microplate. Replace the microplates correctly in Stacker A, and continue the script at the appropriate line. If this is a persistent problem, the settings need to be adjusted by a service technician. Contact QIAGEN Technical Services for assistance.</p>
<p>A microplate is found on the platform, or the robotic plate handler crashed on a microplate left at the pipetting position.</p>	<p>The robotic plate handler dropped a microplate. The robotic plate handler did not pick up a microplate from the pipetting position in the previous steps.</p>	<p>The results of the microplate will be invalid if the microplate was dropped and the samples splashed, or the microplate missed an important step. Discard the microplate. In a multi-microplate assay that is recoverable, a dummy microplate is used to hold the position and prevent reagents and wash buffer from being added to the RCS deck or the plate washer. If the microplate samples have not splashed and the microplate has not missed an assay step, the script can be continued at the appropriate line. If the problem persists, contact QIAGEN Technical Services to check alignment of the plate grippers and make the necessary adjustments.</p>
<p>A microplate lid is found on the platform. The robotic plate handler crashed on a microplate lid left at the pipetting position or ambient temperature plate stacker.</p>	<p>The robotic plate handler dropped a microplate lid. The robotic plate handler failed to pick up a microplate lid.</p>	<p>If the lid can be removed without forcing any component, then remove the lid and continue the script. If the lid is jammed, abort the script and use the Move Handler commands to disentangle the crash (see page 69). Replace all components and continue the script at the appropriate line. If the problem persists, contact QIAGEN Technical Services to check alignment of the plate grippers and make necessary adjustments.</p>
<p>Tip adapters and pipetting</p>		
<p>One tip hits the side of a microplate well. One or all tips hit the side of a microplate well. One tip hits the bottom of a microplate well. All tips hit the bottom of microplate wells.</p>	<p>Tip alignment problem. Loose tip adapter. Bent tip adapter. The Z-Rack is cracked, bent or bowed.</p>	<p>Check that the thumbscrew on the tip adaptor is tight. If not, hand-tighten it and check tip alignment. Contact QIAGEN Technical Services to replace the tip adapter. Inspect the Z-Rack for damage. Contact QIAGEN Technical Services to replace the Z-Rack. Contact QIAGEN Technical Services to adjust tip allocation.</p>
<p>A tip is leaking.</p>	<p>Air bubbles in system lines. The tip adapter is worn and does not make a tight seal with the tip. A worn syringe.</p>	<p>Check the system lines for visible bubbles. Run the FLUSH script. Contact QIAGEN Technical Services to replace the tip adapter. Contact QIAGEN Technical Services to replace worn syringes.</p>
<p>Drops form on the end of the disposable pipet tip.</p>	<p>Tip adapters have collected lint or other debris, preventing a tight fit of the tip adapter to the disposable pipet tip. Loose liquid system connection. Worn syringes.</p>	<p>Clean the tip adapter with alcohol and a low-lint paper towel. Contact QIAGEN Technical Services to tighten the liquid system connections and clean or replace syringes and plunger caps.</p>
<p>Sample is not aspirated.</p>	<p>Aspiration of an air bubble. Insufficient sample volume.</p>	<p>Check for air bubbles or low or no volume in the sample tube.</p>

	<p>Tubing leak. Worn syringe.</p>	<p>Manually transfer the missing samples when the script prompts for a sample transfer check. Replace the microplate on the RCS deck and select OK to continue.</p> <p>Check tubing for leaks. Contact QIAGEN Technical Services to replace tubing, if necessary.</p> <p>Contact QIAGEN Technical Services to replace worn syringes.</p>
<p>Reagent is not aspirated.</p>	<p>The reagent level in the trough is too low. The system lines have been loaded with ionized water. A worn syringe. There is a problem with the liquid level detection mechanism.</p>	<p>Refill the reagent trough and select the Retry button.</p> <p>Make sure that the RCS lines are filled with deionized water. (Tap water or other reagents will interfere with liquid level detection.)</p> <p>There may be a problem with the liquid level detection mechanism. Contact QIAGEN Technical Services.</p> <p>See "Liquid level detection" in this table.</p> <p>Contact QIAGEN Technical Services to replace worn syringes.</p>
<p>A number of samples were not transferred to the hybridization microplate during the sample transfer step.</p>	<p>Incorrect script selected. Insufficient sample volume. Air bubbles are trapped in the tubes.</p>	<p>The C scripts require a minimum volume of 150 µl for a single transfer. The D scripts require a minimum volume of 1125 µl plus a collection device for a single transfer.</p> <p>Verify that the MST Vortexer 2 is within the calibration specifications.</p> <p>Manually transfer the samples missed by the system.</p> <p>Abort the run and run the FLUSH script.</p>
<p>Pipetting volume is uneven. Pipet tips are leaking reagent.</p>	<p>Air bubbles may be trapped in the system lines, interfering with accurate sample/reagent transfer. A tip adapter is damaged or worn.</p>	<p>Abort the run and flush the system to eliminate air bubbles in the lines.</p> <p>If the problem persists, contact QIAGEN Technical Services to replace damaged or worn tip adapters.</p>
<p>Reagents are not added to all the samples transferred.</p>	<p>The wrong number of total samples and controls for the partial plate was entered at the beginning of the script. The box same for all tests was checked when the sample number was entered.</p>	<p>If the problem is noticed at the time of Probe Mix addition, abort the script and re-enter the correct number of samples. Continue the assay at the Probe Mix addition point. See "Restarting the script after entering a wrong sample number or total microplate well number," on page 74.</p> <p>If the problem is discovered after Probe Mix addition, make a note of the untested samples and test these samples in a later run.</p>
<p>The disposable tip tray is lifted out of the tip rack and taken with the tip adapter.</p>	<p>The disposable tip tack is loose or was not firmly snapped into place. The brackets that hold the disposable tip rack in place may be loose.</p>	<p>The Z-Rack will return an error message when it initiates the VariSpan to perform the next step.</p> <p>To avert a crash, pause the script by pressing Esc on the RCS computer keyboard</p> <p>If there is a crash, disentangle the involved components without forcing. The script can be continued after setup when the tip tray is back in its proper position and adequately snapped into the tip rack. Make sure the clips of the tip rack maintain sufficient tension to hold the disposable tip tray in place.</p> <p>If the tip tray and tip adapters are jammed, abort the script. Use the Move Handler commands (see page 69) to lift and move the tip adapters and disentangle the tip tray. If the samples are not compromised by spillage or splashing,, and if the tip adapters are not bent, the script can continue.</p> <p>If the tip racks are bent or not maintaining sufficient tension to hold the disposable tip tray in place, contact QIAGEN Technical Services for assistance.</p>
<p>The disposable tips jam at the tip eject station, and the tips cannot be removed.</p>	<p>The tip waste container has not been emptied and is overflowing. The tip eject slide requires cleaning. A disposable tip is jammed on the tip eject station.</p>	<p>Pause the script, clear the tip eject station and continue.</p> <p>Empty the tip waste container.</p> <p>If a tip adapter has two tips jammed on it, use the Move Handler commands to release the tip adapters (see page 69). Alternatively, power OFF the RCS to release the jammed tip adapters.</p> <p>Select the Retry button and continue the script.</p> <p>Clean the tip eject slide with alcohol.</p>
<p>A tip adapter does not recognize that it has a tip loaded, tries to load a second tip, and crashes on the disposable tip rack.</p>	<p>The setting for loading the tip is slightly off. The tip adapter is loose.</p>	<p>Check the tip eject station runway for jamming.</p> <p>Contact QIAGEN Technical Services for assistance.</p>

<p>The tip adapters crash into the disposable tip racks.</p>	<p>The disposable tip racks are not snapped in properly to the tip holders. The setting positions are incorrect and require adjusting.</p>	<p>If the disposable tip rack is not snapped in properly, snap it in, select the Retry button and continue the assay. If the disposable tip racks are properly placed and the crashing is persistent, there is a setting problem or a bent tip adapter. Contact QIAGEN Technical Services for repairs and/or adjustments.</p>
<p>The tip adapters fail to draw up samples or reagent.</p>	<p>The quick-disconnect fitting is not snapped in properly to the System Liquid Bottle.</p>	<p>Stop the script. Make sure the tubing is connected firmly to the System Liquid Bottle. Run the FLUSH script. 0</p>
<p>The RCS has stopped, the tip adapters are over an empty tip rack, and the RCS is beeping with the dialog box reading No Tips found with Motors 1, 2, 3, 4.</p> 	<p>Disposable tips were not loaded.</p>	<p>Load tips and select the Retry button. (Elevate tip adapters if they are too low on the rack and interfering with rack loading). Proceed as instructed in "Restarting the script in the middle of an assay," page 72.</p>
<p>The RCS has stopped, the tips are over the empty reagent troughs, and the system is beeping with the dialog box reading No Liquid found with Tips 1, 2, 3, 4.</p> 	<p>Reagents have not been loaded, or reagents have been depleted.</p>	<p>Add more reagent to empty reagent troughs. Select the Retry button.</p>
<p>The tip adapter sometimes fails to pick up a disposable tip from the tip rack.</p>	<p>The tip adapter is bent. The setting is off and needs adjusting. Steps have been lost in the alignment due to a previous crash.</p>	<p>Contact QIAGEN Technical Services for assistance.</p>
<p>Liquid level detection with one tip drives the tip down below the reagent level during reagent aspiration. The tip dips below the reagent level and may or may not rise again to meet the level of the remaining tips.</p>	<p>Loose Z-Bracket screw on the tip adapter. The tip adapter is not contacting the back of the bracket in order to complete the liquid level detection circuit.</p>	<p>Contact QIAGEN Technical Services for assistance.</p>
<p>One or more of the tip adapters (1, 2, 3, 4) appears slightly out of alignment, almost touching the edge of the microplate wells.</p>	<p>A crash of the Z-Rack or other impact may have caused the adapter to misalign.</p>	<p>Continue the assay if the tips are dispensing sample/reagent into the microplate wells. Contact QIAGEN Technical Services for assistance.</p>
<p>A tip adapter crashes into the hybridization microplate and gives the error message Module Error at Module Z Motor 1 (10).</p> 	<p>A tip adapter locking screw is loose.</p>	<p>Tighten the locking screw of the tip adapter.</p>
<p>Non-module-related error</p>		
<p>Reagents or samples are pipetted onto the RCS deck.</p>	<p>Faulty RCS deck setup. The microplates are not loaded in the proper location, and the robotic plate handler failed to pick them up.</p>	<p>If this happens during sample transfer, the assay can be aborted, restarted or continued at the point of sample transfer depending on the number of microplates being tested.</p>

The setting or the plate grippers' alignment is slightly off, and the robotic plate handler failed to pick up the microplate.

If this happens at reagent addition to the assay samples, and if this is detected early, the RCS can be paused, the microplate placed manually onto the platform, and the assay continued.

If this happens in the plate-to-plate transfer and the hybridized samples are pipetted onto the platform, the samples are lost and the assay must be aborted and repeated.

If other microplates were transferred satisfactorily, the assay can be continued with a substitute microplate.

Observe correct platform setup.

A partial microplate tips and falls when placed into the ambient temperature plate stacker.

Dummy (clear) strips were not added to the partial microplate to counterbalance the weight from the removed capture strips.

The microplate is lost. If it is the only microplate being tested, the assay must be stopped and samples retested at a later time.

If it is one of multiple microplates, a mock microplate is inserted in the place of the lost microplate and used throughout the assay. Abort the assay and continue at the place where the microplate was retrieved for placement in the plate stacker.

Note: Do not manually place microplates in the ambient temperature plate stacker.

The RCS does not respond and generates a Communication Error, **Error addressing Module (10).**



The RCS is powered OFF.

If the RCS has been powered OFF, power ON the system and select the **Retry** button.

If the computer is not communicating with the RCS, check the connections, reboot the system, and try again.

If communication still fails, contact QIAGEN Technical Services for assistance.

The building has lost electric power. The UPS is beeping, indicating that the RCS is now running on the UPS power. The RCS has lost power.

The RCS is running on back-up emergency power supply. The emergency electrical power supply is exhausted.

If the outage lasts for more than 45 minutes, **Abort** the script at a convenient place to avoid crashing when the power runs out. The RCS will stop when the power supply runs out. If the RCS loses power before an assay is aborted, there will be no record of the run, and no option available for continuing with the script when power is restored. Contact QIAGEN Technical Services to restart the system.

If the power is restored within 45 minutes, continue with the script at the appropriate line (see "Restarting a script after a power failure or wrong script," page 74).

Incorrect script selection or sample error

The script calls for the wrong number of specimen racks (either too few or too many).

The incorrect script was used. The user did not use ScriptSelect Software.

Abort the run.

Use ScriptSelect Software to choose the correct script.

From the RCS Software, select the chosen script from the **Run List**.

Enter the correct number of samples.

Start the script and then abort the run.

Restart the run at the appropriate line of specimen rack transfer. Microplates already transferred should be incorporated in the restarted script. See "Restarting scripts," page 72, for additional instructions.

The last few samples are added to the blank dummy strips in a partial microplate.

The wrong number of strips was put into the strip holder. The wrong number of reagent microplate wells was entered.

The wrong number of strips on the microplate:

If this is noticed at the time of plate-to-plate transfer, the script can be paused, strips added to the microplate, and the samples transferred manually. If this is noticed after this step, the samples have been lost and must be retested.

The wrong number of reagent microplate wells entered:

If this is noticed during the plate-to-plate transfer, **Abort** the script and enter the correct number of reagent microplate wells. Continue at the appropriate line. If this is noticed at a later time when DR1 has already been mixed with remaining Probe Mix in the microplate, a heavy precipitate will occur that can potentially clog the plate washer cannulas.

If microplates do not wash properly due to clogged cannulas, retest the corresponding samples.

The RCS does not transfer all of the samples from the specimen rack to the last partial microplate.

The wrong number of samples has been entered.

If the assay is at the sample transfer step, **Abort** the script. Add the missing samples manually.

Restart the script and enter the correct number of samples. See "Restarting scripts," page 72, for additional instructions.

Retest samples not transferred.

The system is set to proceed to Probe Mix addition without transferring all of the intended specimen racks.

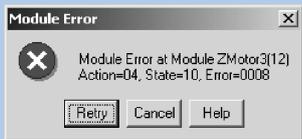
The wrong script has been selected.

Abort the script and start the script that matches the microplates being assayed. Follow the instructions outlined for starting at the correct script line. See “Restarting scripts,” page 72, for additional instructions.

The tips crash into the brush stick of the specimen tube.

The tips crash or bump into the drop-on caps.

The system gives the error message **Module Error at Module Z Motor 3 (10, 11, 12, 13)**.



Drop-on caps have not been put on the specimen collection tube.

Drop-on caps are placed in the wrong orientation on the specimen collection tube.

The specimen rack is not properly placed on the platform.

The system is misaligned.

Abort the run.

Using the **Move Handler** commands (see page 69), lift the Z-Rack.

Dislodge the tip adapter from the brush stick.

Add drop-on caps and place them into the correct orientation. Make sure the brush stick is held in place.

Restart the script at the appropriate line. See “Restarting scripts,” page 72, for additional instructions.

If the problem persists after the tubes are properly placed and the drop-on caps are properly aligned, the system requires alignment adjustment. Contact QIAGEN Technical Services for assistance.

10 Glossary

Term	Description
Appliance inlet	The disconnecting device that is located in the lower left corner on the rear panel of the instrument. If a power cord is connected to the appliance inlet of the instrument and to the electrical outlet on the wall, mains power is delivered to the instrument.
CAUTION	The term used to inform you about situations that could result in damage to the instrument or other equipment.
Conversion Rack (silver)	The silver specimen rack used for converted samples.
Converted sample	A patient specimen collected in a non- <i>digene</i> collection medium that requires sample processing prior to <i>digene</i> HC2 DNA testing. Liquid cytology specimens must be converted samples.
<i>digene</i> specimen	A patient specimen collected in Specimen Transport Medium (STM).
<i>digene</i> Specimen Rack (blue)	The blue specimen rack used for specimens collected in Specimen Transport Medium (STM). This specimen rack can be used for both single- and dual-probe assays.
Disconnecting device	See Appliance inlet.
Dual assay	A test where one specimen rack of specimens is distributed to two different microplates. Each microplate is then tested with a different probe. See Table 8. Example 4 in "Examples of Script names," page 40, for further clarification.
Dual- and single-probe script	A script indicating that the RCS will perform a dual-probe assay and single-probe assay. The dual assay is always performed first and allows for one specimen rack to be tested on two microplates using probe located on the RCS deck in the Probe 1 and 2 positions. The remaining specimen racks are tested using the probe located in the RCS deck in the Probe 3 position. "Dual- and Single-Probe Script" is printed on the confirmation printout generated at the beginning of the RCS run. For more information, see the definition of dual assay and Table 6. Example 2 in "Examples of Script names," page 40.
Dual-probe script	A script indicating that one specimen rack distributed on two microplates is tested with two different probes. "Dual-Probe Script" is printed on the RCS confirmation printout generated at the beginning of the RCS run. For more information, see the definition of dual assay and Table 8. Example 4 in "Examples of Script names," page 40.
Probe 1	The probe solution that is located on the RCS deck in the Probe 1 position.
Probe 2	The probe solution that is located on the RCS deck in the Probe 2 position.
Probe 3	The probe solution that is located on the RCS deck in the Probe 3 position.
Run List	The list of scripts currently available in the RCS software. Scripts can be added or removed from the Run List using the ScriptSelect software. Only scripts present in the Run List can be used in the RCS software.
Script	The set of instructions that the RCS uses to perform an assay or a series of assays.
Single-probe script	A script indicating that all specimen racks are tested with the same probe located on the RCS deck in the Probe 1 position. "Single-Probe Script" is printed on the confirmation printout generated at the beginning of an RCS run. See Table 5. Example 1 in "Examples of Script names," page 40, for further clarification.
Two-probe script (2-probe script)	A script indicating that each specimen rack being tested generates results using a different probe. Multiple probes are used for multiple specimen racks, but each specimen rack is only tested with one probe. The terminology "Two-Probe Script" is printed on the confirmation printout generated at the beginning of the RCS run and defines the probe and script selection used in a specific RCS run. See Table 7. Example 3 in "Examples," page 40, for further clarification.
UPS	An acronym for Uninterruptible Power Supply, which is an external electrical backup power source with a rechargeable battery that acts as a temporary source of electricity during a power outage.
WARNING	The term used to inform you about situations that could result in personal injury to you or other persons.

Appendix A – Technical Data

Dimensions and weight of the instrument

Dimensions (w x d x h) (includes hose dimension)	140 x 79 x 89 cm (55 x 31 x 35 inches)
Weight	68 kg (150 lbs.)

Power requirements of the instrument

Power requirements	100–240 V AC (online frequency 50–60 Hz)
Line voltage variation	± 10% fluctuation of rated mains
Power consumption (RCS and computer)	350 Watts/4.1 A at 120 V or less
Overvoltage category	II

Operating conditions

Air temperature	15–30°C
Relative humidity	15%–75%
Pollution Level	POLLUTION DEGREE 2
Altitude	Up to 2000 meters (6500 feet)
Place of operation	For indoor use only

Note: These environmental specifications are for the RCS. Conditions for *digene* HC2 DNA tests may be more restrictive. Refer to the *digene* HC2 DNA test instructions for use for additional environmental considerations.

Storage conditions

Location	Indoors
Temperature	5-40°C in manufacturer's package
Relative humidity	15%–75%

Transport conditions

Temperature	–25 to 60°C in manufacturer's package
Maximum relative humidity	75%

Appendix B – Changing the RCS Washer Boat

Before performing this procedure, make sure that:

- The Wash Bottle is filled with prepared Wash Buffer
- The quick-disconnect fitting clicks securely in place
- The tubing from the Wash Bottle to the instrument is free of kinks and properly connected

Note especially the points where the tubing attaches to the Wash Bottle and the instrument inlet port.

A capture microplate is required for this procedure; do not use a hybridization microplate. A previously used capture microplate frame can be emptied of wells and RCS microplate well strips placed in the capture microplate frame.

Important: RCS washer boats must be installed by a QIAGEN Field Service employee and cannot be exchanged between different RCS instruments. If assistance is required, contact QIAGEN Technical Services.

1. Lift the RCS washer manifold up to the point of resistance. Slide the RCS washer boat to the left and then lift up to remove it.

Note: When lifting the RCS washer boat from the plate washer, a small amount of resistance must be overcome. A magnet on the underside of the RCS washer boat is used to position the RCS washer boat during RCS operation. Enough force to overcome the magnetic attraction is required to remove the RCS washer boat.

2. Orient the new RCS washer boat so that the plastic, white rectangular trough is to the right when placing into the plate washer.
3. Install the new RCS washer boat by lifting the RCS washer manifold and sliding the RCS washer boat into the RCS plate washer.
4. The RCS washer boat will click when oriented correctly and the magnet makes contact with the plate washer.
5. Lower the RCS washer manifold so that it rests in the plastic trough of the RCS washer boat.
6. In the RCS Software, click the **Run** icon.
7. Alternatively, select **Script/Run Script**.
8. The **Scripts** dialog box appears, listing the scripts available.
9. Highlight the **TestWash** script, and click **OK**.
10. When a dialog box appears requesting the placement of a capture microplate on the RCS plate washer, place the capture microplate in the RCS washer boat.

Important: The capture microplate must have wells in all the columns as the RCS plate washer will wash a complete microplate. Using an incomplete capture microplate may cause the RCS deck to flood.

11. Click **OK**.

The RCS will wash the capture microplate. Once complete, the main window of the RCS Software appears and testing can proceed.

If the replacement of the RCS washer boat fails, contact QIAGEN Technical Services for assistance.

Appendix C — Waste Electrical and Electronic Equipment (WEEE)

This section provides information about disposal of waste electrical and electronic equipment by users.

The crossed-out wheeled bin symbol (see below) indicates that this product must not be disposed of with other waste; it must be taken to an approved treatment facility or to a designated collection point for recycling, according to local laws and regulations.



The separate collection and recycling of waste electronic equipment at the time of disposal helps to conserve natural resources and ensures that the product is recycled in a manner that protects human health and the environment.

Recycling can be provided by QIAGEN upon request at additional cost. In the European Union, in accordance with the specific WEEE recycling requirements and where a replacement product is being supplied by QIAGEN, free recycling of its WEEE-marked electronic equipment is provided.

Appendix D — FCC Declaration

The United States Federal Communications Commission (FCC) in 47 CFR 15.105 declares that the users of this equipment must be informed of the following facts and circumstances:

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

QIAGEN is not responsible for any radio or television interference caused by unauthorized modifications of this instrument or the substitution or attachment of connection cables and equipment other than those specified by QIAGEN. The correction of interference caused by such unauthorized modification, substitution, or attachment will be the responsibility of the user.

Appendix E — Warranty Clause

QIAGEN shall be released from all obligations under its warranty in the event repairs or modifications are made by persons other than its own personnel, except in cases where the Company has given its written consent to perform such repairs or modifications.

All materials replaced under this warranty will be warranted only for the duration of the original warranty period, and in no case beyond the original expiration date of original warranty unless authorized in writing by an officer of the Company. Read-out devices, interfacing devices and associated software will be warranted only for the period offered by the original manufacturer of these products. Representations and warranties made by any person, including representatives of QIAGEN, which are inconsistent or in conflict with the conditions in this warranty shall not be binding upon the Company unless produced in writing and approved by an officer of QIAGEN.

11 Ordering Information

Product	Description	Cat. no.
Rapid Capture System	Rapid Capture System for high-volume sample throughput.	6000-3101
Related Products		
RS-232 Cable		9233583
Wash Bottle		9022179 and 9022181
System Liquid Bottle		9013248
PC System		9003090
HCS Laser Printer		9023211 (120V) and 9023212 (240V)
<i>digene</i> Specimen Rack and Lid		6000-5018
Conversion Rack and Lid		6000-5017
Specimen Collection Tubes		6000-5000
Dura Sealing Film		6000-5003
Reagent Troughs		6000-5008
Reagent Troughs Lids		6000-5010
Disposable Tips		6000-5006
Drop-on Caps		6000-5007
Extra Long Pipette Tips		5075-1011
<i>digene</i> HC2 System Software		9024225, 9024226, 9024228, and 9024230

12 Document Revision History

Date	Changes
R1, February 2023	Initial release for IVDR compliance.

Trademarks: QIAGEN®, Sample to Insight®, *digene*, Hybrid Capture®, Rapid Capture® (QIAGEN Group); DuraSeal™ (Diversified Biotech); Kimtowels® (Kimberly-Clark Corporation); Microsoft®, Windows® (Microsoft Corporation); McAfee® (Intel Corporation); Mylar® (DuPont Teijin Films). Registered names, trademarks, etc., used in this document, even when not specifically marked as such, are not to be considered unprotected by law.

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