



March 2023

Hybrid Capture® System Multi-Specimen Tube Vortexer 2 User Manual



IVD

REF

6000-5021 (120 V)
6000-5022 (240 V)



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1. Introduction

The Hybrid Capture System (HCS) Multi-Specimen Tube (MST) Vortexer 2 has been designed specifically for vortexing specimens secured in either a *digene*[®] Specimen Rack or a Conversion Rack.

Read this user manual before operating the HCS MST Vortexer 2.

1.1. General information

1.1.1. About this user manual

This user manual provides information about the HCS Multi Specimen Tube Vortexer in the following sections:

- Introduction
- Safety Information
- Unpacking Instructions
- General Description
- General Operation
- Maintenance
- Troubleshooting
- Technical Data
- Appendices
- Ordering Information
- Document Revision History

1.1.2. Technical assistance

For technical assistance and more information, please see our Technical Support Center at www.qiagen.com/TechSupportCenter or contact QIAGEN[®] Technical Services or a local distributor.

1.1.3. Version management

This document is *Hybrid Capture System Multi-Specimen Tube Vortexer 2 User Manual*; see the front cover of this user manual for document number and revision.

1.2. Intended use

The Hybrid Capture System (HCS) Multi-Specimen Tube (MST) Vortexer 2 is intended for use only in conjunction with *digene* Hybrid Capture 2 (HC2[®]) DNA tests. The HCS MST Vortexer 2 is used in conjunction with a Conversion Rack or a *digene* Specimen Rack in an indoor laboratory setting and is intended for professional use.

1.3. Materials required

- HCS MST Vortexer 2
- Power Cord

1.4. Materials required but not provided

- *digene* Specimen Rack and Lid (cat. no. 6000-5018)
- Conversion Rack and Lid (cat. no. 6000-5017)
- Specimen Collection Tubes (cat. no. 6000-5000)
- DuraSeal™ Sealing Film (cat. no. 6000-5003)

2. Safety Information

This manual contains information about warnings and cautions that must be followed by the user to ensure safe operation of the MST Vortexer 2 and to maintain the instrument in a safe condition.

<p>WARNING</p> 	<p>The term WARNING is used to inform you about situations that could result in personal injury to you or other persons.</p> <p>Details about these circumstances are provided to avoid personal injury to you or other persons.</p>
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<p>CAUTION</p> 	<p>The term CAUTION is used to inform you about situations that could result in damage to the instrument or other equipment.</p> <p>Details about these circumstances are provided to avoid damage to the instrument or other equipment.</p>
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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 manual carefully and to pay particular attention to any details it contains concerning hazards that may arise from the use of the instrument.

The details given in this manual are intended to supplement, not supersede, the normal safety requirements prevailing in the user's country.

2.1. Proper use

<p>WARNING/ CAUTION</p> 	<p>Risk of personal injury and material damage</p> <p>Improper use of the MST Vortexer 2 may cause personal injuries to the user or damage to the instrument. The MST Vortexer 2 must only be operated by qualified personnel who have been appropriately trained.</p>
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<p>WARNING</p> 	<p>Risk of personal injury</p> <p>The MST Vortexer 2 is a heavy instrument. After the MST Vortexer 2 is unpacked, two people must lift the instrument. Lift the MST Vortexer 2 by the handles provided.</p>
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<p>WARNING</p> 	<p>Risk of personal injury</p> <p>Always wear shatterproof eye protection.</p>
<p>WARNING</p> 	<p>Risk of personal injury</p> <p>To avoid possible pinch hazard, load and unload the specimen rack with one hand on top of the rack handle. Use the other hand to engage or disengage the MST Vortexer 2 mechanism clamp.</p>
<p>WARNING</p> 	<p>Risk of personal injury</p> <p>Do not immerse the MST Vortexer 2 in water or pour liquids over the instrument as electrical shock may occur.</p>
<p>WARNING</p> 	<p>Risk of personal injury</p> <p>Sodium hypochlorite solution is caustic; wear rubber gloves and eye protection when handling it.</p>

Take the following precautions when operating or working near the MST Vortexer 2:

- Make sure that the MST Vortexer 2 is placed on a firm surface of solid construction.
- Make sure that the platform and any hardware are secure.
- Make sure the specimen rack is secured on the platform on all 4 sides.
- Load only one specimen rack at a time.
- Do not use solvents and flammables on or near the MST Vortexer 2.
- Make sure that the rubber pads remain attached to the MST Vortexer 2 while relocating the equipment.

2.2. Electrical safety

Only operate the MST Vortexer 2 with the power cord provided with the instrument. For satisfactory and safe operation of the MST Vortexer 2, it is essential that the line power cord is connected to true electrical earth (ground).

2.3. Environment

Place the MST Vortexer 2 on a level, stable, firmly secured bench top near a grounded electrical outlet. Allow at least 7.5 cm (3 inches) of clearance on all sides of the instrument for proper ventilation. While operating, make sure that the Vortexer platform does not touch other objects. Locate it away from other vibration-sensitive instruments, such as an analytical balance.

Make sure that the MST Vortexer 2 is rated for the proper voltage by checking the right side panel. Record the serial number, located on the right side panel, in a secure location for future reference.

2.4. Biological safety

<p>WARNING</p> 	<p>Hazardous substances</p> <p>The products used with this instrument may contain hazardous substances. 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 PDF format at www.qiagen.com/safety where you can find, view and print the SDS for each QIAGEN kit and kit component. For further information see the instructions for use that comes with the kit.</p>
<p>WARNING</p> 	<p>Risk of exposure to hazardous material</p> <p>Shake hazardous samples only in appropriate containment vessels.</p>
<p>WARNING/ CAUTION</p> 	<p>Risk of personal injury and material damage</p> <p>Consider any laboratory equipment used for research or clinical analysis a potential biohazard that requires decontamination before reuse.</p>

To dispose of the MST Vortexer 2, follow all national, state and local health and safety regulation and laws for disposing of laboratory waste. For disposal of Waste Electrical and Electronic Equipment (WEEE compliance), see “Appendix A – Waste Electrical and Electronic Equipment (WEEE)” page 22.

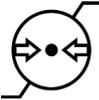
2.5. Waste disposal

Waste 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.

2.6. Symbols

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

Symbol	Location	Description
	On the instrument	Warning, dangerous voltage
	On the instrument	General warning sign
	Type plate on the instrument, instrument box label, and the front cover of this user manual	CE mark for Europe
	Type plate on the instrument, instrument box label, and the front cover of this user manual	In vitro diagnostic medical device
	Type plate on the instrument and instrument box label	RoHS mark for China (indicates the product does not have any hazardous substances in excess of the concentration limits)
	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	Manufacturer
	Instrument box label	Fragile, handle with care

Symbol	Location	Description
	Instrument box label	Consult instructions for use
	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	Authorized representative in the European Community
	Type plate on the instrument, instrument box label, and the front cover of this user manual	Catalog number
	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
	The front cover of this user manual	Material
	Type plate on the instrument and instrument box label	UL Mark in compliance with electrical safety
	Type plate on the instrument and instrument box label	RCM mark for Australia/New Zealand, former A-Tick mark (supplier identification N17965)

3. Unpacking Instructions

Before using the MST Vortexer 2 for the first time, examine the exterior carton and the equipment itself for damage. In the event of shipping damage, contact your local QIAGEN representative or QIAGEN Technical Services.

Carefully unpack the instrument and verify the contents of the package, which should contain the following components of the instrument:

- 1 MST Vortexer 2 (base with platform)
- 1 power cord

If any of these items are missing, contact your local QIAGEN representative or QIAGEN Technical Services. Save the original packaging until the instrument is operated successfully.

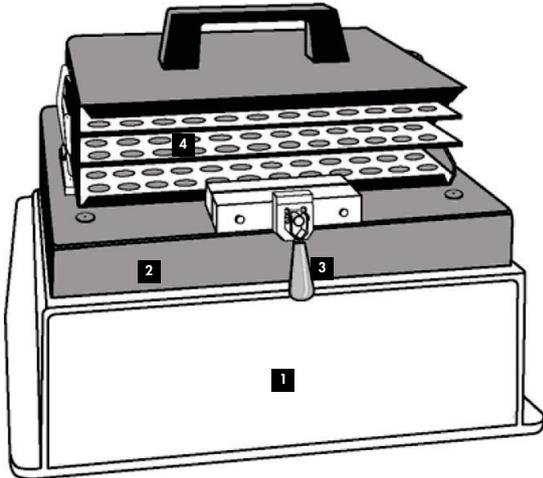
3.1. Start up

Plug the power cord into a grounded wall socket. The motor speed control electronics of the MST Vortexer 2 depend on a sinusoidal power source. Do not connect the MST Vortexer 2 to a UPS or other device that produces a stepped or square power waveform.

4. General Description

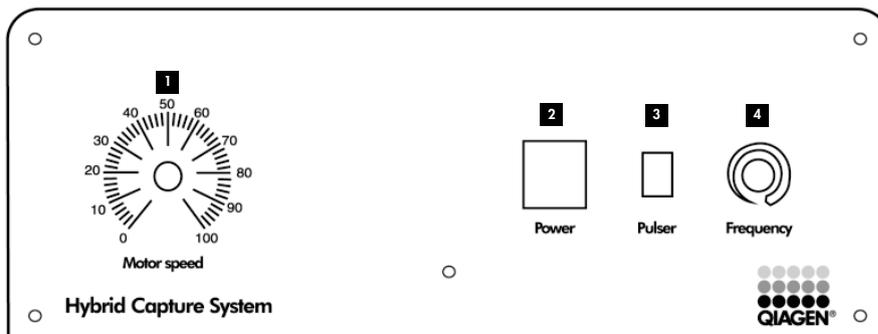
The MST Vortexer 2 is composed of a base (120V or 240V) and a vortexer platform. The MST Vortexer 2 is constructed of heavy-gauge steel that provides a stable base for steady operation, even at maximum speed. The vortexer platform can hold up to 4.5 kg (10 lbs) of weight. The MST Vortexer 2 can only be used in environments from 0–37°C.

The following figure shows the major external components of the instrument.



- | | |
|----------------------------|--------------------------|
| 1 Base | 3 Red lever |
| 2 Vortexer platform | 4 Conversion rack |

All of the operating controls for the MST Vortexer 2 are located on the front panel. The following figure shows the front panel.



- | | |
|------------------------------|-----------------------------------|
| 1 Motor speed dial | 3 Pulser toggle switch |
| 2 Power toggle switch | 4 Pulsation frequency dial |

4.1. Operational modes

The motor speed of the MST Vortexer 2 varies from 0–1600 revolutions per minute (RPM). It operates in a circular motion with an orbit of 0.51–0.71 cm (0.20–0.28 inches). The MST Vortexer 2 has two vortexing modes: continuous or pulsating.

4.2. Specimen racks

The MST Vortexer 2 has been designed to function with either a *digene* Specimen Rack or a Conversion Rack. Each specimen rack is engraved with a serial number on the rack and the lid; when using a specimen rack, the serial numbers of the rack and the lid must match. The specimen racks are color-coded for easy identification of the specimen rack type.

The *digene* Specimen Rack is blue and is used with specimens collected in approved Hybrid Capture collection kits, as specified in the associated *digene* HC2 DNA test instructions for use.

The Conversion Rack is silver and used with liquid cytology specimens collected in 15 mL conical tubes. These specimens require processing prior to testing with a *digene* HC2 DNA test. The Conversion Rack has a notched corner that orients the rack for proper placement on the MST Vortexer 2.

5. General Operation

5.1. Continuous vortexing

Note: The *digene* HC2 DNA tests only use the continuous vortexing operational mode.

1. Move the red lever to the horizontal position.
2. Position the specimen rack and lid on the vortexer platform until it fits snugly within the guides. If using a Conversion Rack, place the specimen rack with the notched corner of the specimen rack in the right-front position of the vortexer platform.
3. To lock the specimen rack in place, push the red handle all the way down to the vertical position.
4. Turn the motor speed dial clockwise to the applicable setting.
5. Make sure the pulser toggle switch is in the **OFF** position.
6. To begin operation of the MST Vortexer 2, turn the power toggle switch to the **ON** position.
The MST Vortexer 2 speed will be consistent until the power toggle switch is set to **OFF**.

5.2. Pulsating vortexing

1. Move the red lever to the horizontal position.
2. Position the specimen rack and lid on the vortexer platform until it fits snugly within the guides. If using a Conversion Rack, place the specimen rack with the notched corner of the specimen rack in the right-front position of the vortexer platform.
3. To lock the specimen rack in place, push the red handle all the way down to the vertical position.
4. Turn the motor speed dial clockwise to the applicable setting.
5. Turn the pulser toggle switch to the **ON** position.
6. Adjust the pulsation frequency dial to the applicable setting.
7. To begin operation of the MST Vortexer 2, turn the power toggle switch to the **ON** position.
The MST Vortexer 2 will pulsate until the power toggle switch is set to **OFF**.

6. Maintenance

If you have a problem with maintenance of the MST Vortexer 2, contact QIAGEN Technical Services. QIAGEN charges for repairs that are required due to incorrect maintenance.

6.1. Monthly Cleaning and decontamination

WARNING/ CAUTION 	Risk of personal injury and material damage Consider any laboratory equipment used for research or clinical analysis a potential biohazard that requires decontamination before reuse. Wear powder-free gloves when handling potentially contaminated equipment.
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Before using any cleaning or decontamination method, except those recommended in this user manual, check with your local QIAGEN representative or QIAGEN Technical Services to make sure that the proposed method will not damage the equipment.

WARNING 	Risk of personal injury Sodium hypochlorite solution is caustic; wear rubber gloves and eye protection when handling it.
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To decontaminate the MST Vortexer 2, wipe down exposed surfaces using a cleaning pad wetted with a solution of 0.5% sodium hypochlorite (NaOCl or bleach). Industrial bleach contains 10% NaOCl; household bleach contains 5% NaOCl. When using industrial bleach, prepare a 1:20 mixture of bleach to water. When using household bleach, prepare a 1:10 mixture of bleach to water.

6.2. Regular maintenance

WARNING 	Risk of personal injury Do not immerse the MST Vortexer 2 in water or pour liquids over the instrument as electrical shock may occur.
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Wipe down the MST Vortexer 2 after each use with a soft, dry cloth.

The motor and vortexing mechanism in the MST Vortexer 2 do not require routine maintenance or lubrication.

6.3. Speed calibration

Verify the RPM speed of the MST Vortexer 2 every 3 months. The recommended method of calibration verification is described below. A standard optical tachometer is required to perform this procedure.

6.3.1. Prepare the materials

1. If using a *digene* Specimen Rack, fill 92 empty Specimen Collection Tubes with 1.5 mL of water and load into a *digene* Specimen Rack.
If using a Conversion Rack, load 56 empty 15 mL conical tubes into the Conversion Rack in positions A1–A12, B2–B12, D1–D9, G1–G12, and H1–H12.
2. Apply sealing film to cover the specimen rack and latch the lid.
3. Apply a 3 x 3 cm (1 x 1 inch) strip of reflective tape to the front, top and right side of the vortexer platform.
4. Make sure that the optical tachometer is set for revolutions per minute (RPM).

6.3.2. Secure the specimen rack

1. Move the red lever to the horizontal position.
2. Position the specimen rack and lid on the vortexer platform until it fits snugly with the guides. If using a Conversion Rack, place the specimen rack with the notched corner of the specimen rack in the right-front position of the vortexer platform.
3. To lock the specimen rack in place, push the red handle all the way down to the vertical position.
4. Set the motor speed dial to **100**.
5. Turn the power toggle switch to **ON**.
6. Wait at least 60 seconds.

6.3.3. Measure the RPM

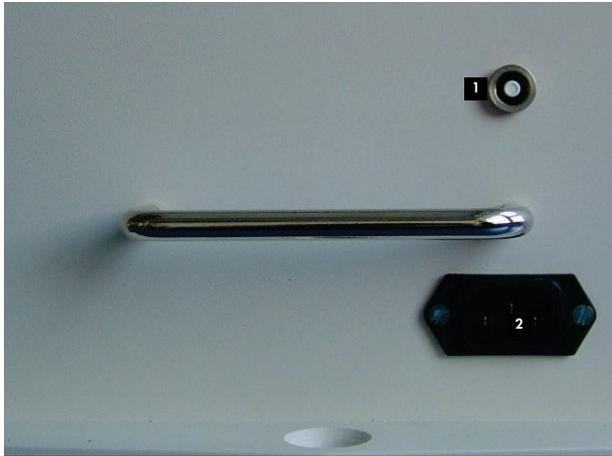
1. Press and hold the **Start Measurement** button on the tachometer.
Note: Depending on the calibration tool, the functional description of the tachometer may vary.
2. Aim the light beam onto the reflective tape so the reflective tape crosses the light beam once every revolution. Focus the light beam on the reflective tape by raising or lowering the tachometer.
3. Hold the tachometer steady for at least 5 seconds.
4. Release the **Start Measurement** button on the tachometer.
5. Turn the power toggle switch to **OFF**.
6. Press the **Memory** or **Recall** button on the tachometer to display the average RPM measurement.
7. Record the RPM average measurement.

6.3.4. Results

If the measured RPM is within 1500–1700 RPM at the **100** setting of the motor speed dial, the speed is verified and no further action is required. If the measured RPM is not within specification, contact QIAGEN Technical Services.

6.4. Resetting the circuit breaker

When the circuit breaker has been tripped, the circuit needs to be reset. The circuit breaker is located on the right side of the chassis. The following figure shows the location of the circuit breaker.



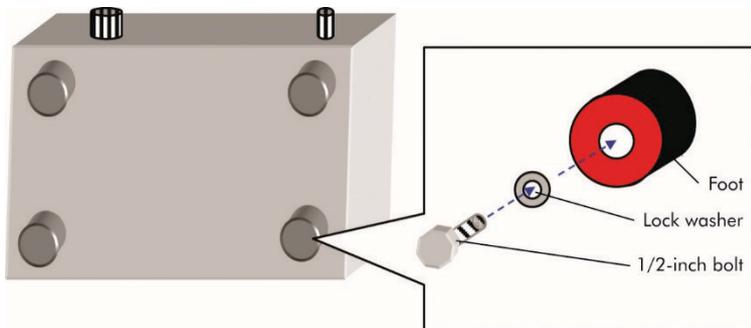
1 Circuit breaker **2** Power source

1. Unplug the power cord from the power source.
2. Press the white button of the circuit breaker.
3. If the white button does not stay pressed, contact your local QIAGEN representative or QIAGEN Technical Services.

6.5. Mounting feet replacement

1. Unplug the power cord from the power source.
2. Turn the MST Vortexer 2 on its side using the two handles (right and left) such that the bottom is visible and easily accessible.
3. Using a ratchet and $\frac{1}{2}$ inch socket, remove the center bolt from each foot.
4. Discard the feet and attaching bolts.
5. Install the new feet with the provided $\frac{1}{2}$ inch bolt and lock washers.

Diagram:



6. Tighten the feet securely with the ratchet and ½ inch socket.
7. Return the MST Vortexer 2 to the correct operational orientation.
8. Plug the power cord into the power source.

The instrument is now operational.

6.6. Servicing

Maintain your instrument in good working order. In the event that the instrument is subjected to adverse conditions, such as a fire, flood or earthquake, schedule a service inspection of the instrument to ensure safe operation.

Do not attempt to repair the instrument. Removing the case will nullify the warranty. In the event that the product is inoperable, please contact your local QIAGEN representative and provide full failure details. When making your call, please make sure that you have the serial number of the instrument.

Do not ship the instrument back for repair until advised to do so by your local representative or QIAGEN Technical Services.

In the event that you are requested to return the instrument or any part thereof, it is your legal requirement to ensure that the unit is fully decontaminated. Your local QIAGEN representative or QIAGEN Technical Services may request a certificate is included with the instrument to verify the decontamination. Failure to do this may result in the refusal to repair the unit. Contact your local QIAGEN representative or QIAGEN Technical Services for a Return Goods Authorization (RGA) number. Mark this number on the outside of the shipping box.

7. Troubleshooting

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

Possible problem or cause	Corrective action
Instrument vibrates excessively	
a) The instrument is placed on an uneven surface	Relocate the unit to a flat, even surface.
b) The feet and bench top are not clean	Clean the feet and bench top with alcohol.
c) No specimen rack is secured on the MST 2 Vortexer	Do not use the MST Vortexer 2 without a specimen rack.
Power switch not lit when placed in the ON position	
a) The power cord is not plugged in properly	Make sure that the power cord is plugged into a known, working power source.
b) The power source is not functioning	Make sure the power source has power and correct as necessary.
c) The circuit breaker is tripped	Reset the circuit breaker. See "Resetting the circuit breaker," page 17.
Power switch is in the ON position but no shaking occurs	
a) The motor speed dial position is at 0	Make sure the motor speed dial position is set correctly. If problem persists, perform speed calibration. See "Speed calibration," page 15.
b) The circuit breaker is tripped	Reset the circuit breaker. See "Resetting the circuit breaker," page 17.
Shaking stops unexpectedly	
The circuit breaker is tripped	Reset the circuit breaker. See "Resetting the circuit breaker," page 17.

8. Technical Data

8.1. Operating conditions

Condition	Parameter
Dimensions (w x d x h)	254 x 305 x 470 mm (10 x 12 x 18.5 inches)
Weight	27 kg (60 lbs)
Power requirements	110–120 Volts AC 60Hz; Fuse: 180VA, 220–240 Volts AC 50Hz, Fuse: 345VA
Power consumption	50 W
Air temperature	0–37°C
Relative humidity	0–90% (noncondensing)
Maximum load	4.5 kg (10 lbs)
Place of operation	For indoor use only
Pollution level	II
Altitude	Up to 2000 meters (6500 feet)
Vortexing speed	0–1600 RPM
Vortexing motion	Clockwise orbit
Vortexing orbit diameter	0.51–0.71 cm (0.20–0.28 inches)

8.2. Transport conditions

Condition	Parameter
Air temperature	0–60°C
Relative Humidity	Up to max of 80%

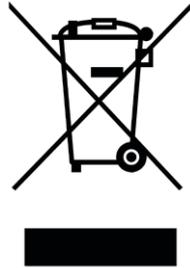
8.3. Storage conditions

Condition	Parameter
Air temperature	0–60°C
Humidity	5–80% (relative humidity); non-condensing at 30°C

Appendix A – Waste Electrical and Electronic Equipment (WEEE)

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

The following 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.



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

QIAGEN provides recycling upon request at additional cost. To recycle electronic equipment, contact your local QIAGEN sales office for the required return form. After you submit the form, QIAGEN will contact you either to request follow-up information for scheduling the collection of your electronic waste or to provide you with an individual quote.

Appendix B – Warranty

The MST Vortexer 2 is warranted against defects in materials and workmanship for a period of one year from the date it is shipped from the manufacturer. If notified of such defects during the warranty period, the manufacturer will, at its option, either repair or replace products that prove to be defective.

The warranty shall not apply to defects resulting from improper or inadequate maintenance by the customer, unauthorized modification or service, misuse, operation outside of the environmental specifications for the product or units returned with inadequate packaging.

Ordering Information

Product	Contents	Cat. no.
Hybrid Capture System Multi-Specimen Tube Vortexer 2	120 volt vortexer for use with <i>digene</i> Hybrid Capture 2 DNA tests	6000-5021
Hybrid Capture System Multi-Specimen Tube Vortexer 2	240 volt vortexer for use with <i>digene</i> Hybrid Capture 2 DNA tests	6000-5022
Related products		
<i>digene</i> Specimen Rack and Lid	1 specimen rack for use with specimens collected using Hybrid Capture collection kits	6000-5018
Conversion Rack and Lid	1 specimen rack for use with liquid cytology specimens	6000-5017
Specimen Collection Tubes	1000 empty tubes	6000-5000
DuraSeal Sealing Film	1 roll of sealing film	6000-5003

Document Revision History

Revision	Description
R1, March 2023	Initial release for IVDR compliance.

Trademarks: QIAGEN®, Sample to Insight®, *Jigene*®, HC2®, Hybrid Capture® (QIAGEN Group); DuraSeal™ (Diversified Biotech).

Mar-2023 HB-3351-001 1128782 © 2023 QIAGEN, all rights reserved

